KENYA MEDICAL SUPPLIES AUTHORITY YOUR PARTNER IN HEALTHCARE

**Open International Tender (OIT)**

Government of Kenya,
Ministry of Health
Nairobi/Kenya

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**Tender Document**

**For the**

**Supply & Delivery of Nutritional Supplements**

**IFT N°.: GF ATM TB NFM -17/18-OIT-001**

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**Tender Closing Date: 6th June, 2017**

**Time: 10.00 a.m. (Nairobi Local Time)**

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**INVITATION TO TENDER (ITT)**

**Open International Tender (OIT)**

**GLOBAL FUND TB PROGRAM, GRANT: KEN-T-TNT**

**IFT N$^{o}$.: GF ATM TB NFM -17/18-OIT-001**

**Supply and Delivery of Nutritional Supplements**

**Date: 25th April, 2017**

1. The Government of Kenya has received a grant from the **Global Fund** to fight **AIDS, Tuberculosis** and **Malaria under New Funding Model (NFM)** which it intends to use part of the proceeds to fund payments under the contract (s) for the **Supply and Delivery of Nutritional Supplements.**
2. The **Kenya Medical Supplies Authority (KEMSA),** on behalf of the Government of Kenya, Ministry of Health, and Global Fund herewith invites sealed tender (s) for:

**Supply and Delivery of Nutritional Supplements**

3. This Tender will be conducted through the **Open International Tender (OIT**) procedure specified in the Government of Kenya (GOK), The Public Procurement and Asset Disposals Act, 2015 and the Global Fund's Policies on Procurement and Supply Management, June 2012.

4. Interested eligible bidders may obtain further information from KEMSA office and inspect the bidding documents at the address given below, **Mondays to Fridays between 0900hrs to 1600hrs** except on public Holidays **or** download at the **IFMIS Supplier portal** http://supplier.treasury.go.ke. Documents downloaded are free of charge and bidders are advised to register their bid documents at the procurement office or via email at procurement.programs@kemsa.co.ke (**Refer to registration form in the tender document**).

5. A complete set of bidding documents in English (hardcopy) may be purchased by eligible bidders on the submission of **a written application** to the address below and upon payment of a non-refundable/non-transferable **fee of 13 US Dollars or 1,000 Kenya Shillings**. The method of payment will be by Cash, Bankers cheque or direct deposit to the specified **account no 01141217405100 for KES or 02120217405100 for USD to Co-operative Bank, Enterprise Road Branch, Nairobi, Kenya, Swift: KCOOKENA**.

6. Completed serialized bidding documents **one original and a copy** in plain sealed envelopes clearly marked on top with the Tender Number and description must be accompanied by a tender security of **USD 10,000.00 or KES 1,000,000.00** or equivalent in a freely convertible currency and must be delivered to the address below on or **before 10:00 AM on 6th June, 2017** and Tenders must be deposited at **KEMSA Tender Box 2** for **Global Fund Tenders** at **KEMSA, Main Reception**. Bulky tenders can be handed over to KEMSA Procurement Director's Office for registration and safe keeping till the tender opening date. Tenders will be opened promptly in public and in the presence of the Tenderers' representatives who choose to attend.

7. Late bids, portion of bids, electronic bids, bids not received, bids not opened and not readout in public at bid opening ceremony shall not be accepted for evaluation irrespective of circumstances.

**Address for information on/collection of the Tender Document and Tender Opening venue.**

Kenya Medical Supplies Authority (KEMSA) 13 Commercial Street, Industrial Area
P. O. Box 47715-00100 Nairobi, Kenya; Tel: (+254) 20-392 20 00
E-mail: **procurement.programs@kemsa.co.ke**

**Kenya Medical Supplies Authority reserves the right to accept or reject any or all bids without incurring liability to the affected tenderers.**

**REGISTRATION FORM FOR ONLINE TENDERES/BIDDERS/SUPPLIERS**

**IFT N°.: GF ATM TB NFM -17/18-OIT-001 FOR SUPPLY AND DELIVERY OF NUTRITIONAL SUPPLEMENTS**

**NOTE:** Please provide your details below for purposes of communication in case you download this tender document from IFMIS or KEMSA website.

Name of the firm:……..

Postal Address:……..

Telephone Contacts:……..……

Company email address:……..

Contact Person:……

Once completed please submit this form to the email below;

**procurement.programs@kemsa.co.ke**

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# Section I. Instructions to Tenderers

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**Instructions to Tenderers**

## A. INTRODUCTION

**1. Scope of Tender**

1.1 The Procuring entity, as specified in the Tender Data Sheet (TDS) and in the Special Conditions of Contract (SCC), invites tenders for the supply of Health Sector Goods as specified in the TDS and described in the Schedule of Requirements. The name and identification number of the Contract is provided in the TDS and in the SCC.

1.2 Throughout these tender documents, the terms "in writing" means communicated in written form (e.g. by mail, e-mail fax or telex) with proof of receipt and "day" means calendar day. Singular also means plural.

**2. Source of Funds**

2. The Beneficiary named in the **TDS** has received funding as identified in the **TDS** to the amount indicated in the **TDS** toward the cost of the project named in the **TDS**. The Purchaser intends to apply a part of the proceeds of this fund to eligible payments for which these tender documents are issued.

**3. Fraud and Corruption**

3.1 It is the Purchaser's policy to require that the purchaser's employees/ Tenderers / Suppliers /Contractors under the Purchaser's financed contracts, observe the highest standard of ethics during the procurement and execution of such. In pursuance of this policy, the Government of Kenya defines, for the purposes of this provision, the terms set forth below as follows:

(a) (i) "corrupt practice" means the offering, giving, receiving, or soliciting of anything or any advantage of value to influence the action of a public official in the procurement process or in execution; and

(a) (ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a tender to the detriment of the Beneficiary it includes collusive practices among Tenderers (prior to or after tender submission) designed to establish tender prices at artificial, noncompetitive levels and to deprive the Beneficiary of the benefits of free and open competition and that the

(b) Purchaser will reject a proposal for the award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the tender in question.

(c) purchaser will declare a firm ineligible, for a stated period of time, to be awarded a Purchaser's financed contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Purchaser's financed

contract.

3.2 Furthermore, Tenderers shall be aware of the provision stated in sub-clause 23.1 (d) of the GCC.

3.3 In pursuance of the policy defined in ITT sub-clause 3.1, the Purchaser will cancel the portion of the fund allocated to a contract for Goods or Works if he at any time determines that corrupt or fraudulent practices were engaged in by the representatives of the Tenderer during the procurement or the execution of that contract, without the Tenderer having taken timely and appropriate action satisfactory to the Purchaser to remedy the situation.

**4. Eligibility**

4.1 Except as provided in ITT sub-clauses 4.2 and 4.3, this tender process is

a) Open to qualified eligible tenderers (pre – qualified or not) as described in the **TDS**.

b) Candidates as defined in the Public Procurement and Asset Disposal Act 2015.

4.2 Firms may be excluded from tendering if:

(a) a firm has been engaged by

i) the Purchaser or

ii) a Purchasing Agent that has been duly authorized to act on behalf of the Purchaser to provide consulting services for the preparation of the design, specifications and other documents to be used for the procurement of the goods described in these tender documents.

4.3 A firm declared ineligible in accordance with ITT sub-clause 3.1 (c) shall be ineligible to tender for a contract awarded by the Purchaser during the period of time determined by the Purchaser.

4.4 Pursuant to ITT sub-clause 14.1, the Tenderer shall furnish, as part of its tender, documents establishing, to the Purchaser's satisfaction, the Tenderer's eligibility to tender.

4.5 Tenderers shall provide such evidence of their continued eligibility satisfactory to the Purchaser as the Purchaser shall reasonably request.

**5. Eligible Goods and Services**

5.1 All goods to be supplied under the contract shall have their origin in eligible source countries.

5.2 For purposes of this clause, "origin" means the place where the goods are mined, grown, or produced. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized product results that is substantially different in basic characteristics or in purpose

or utility from its components

5.3 The origin of goods is distinct from the nationality of the tenderer.

**6. Documents Establishing Eligibility of Goods and Services and Conformity to Tender Documents**

6.1 Pursuant to ITT Clause 14, the Tenderer shall furnish, as part of its tender, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and services to be supplied under the contract.

6.2 The documentary evidence of the eligibility of the Goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered that shall be confirmed by a Certificate of Origin, issued shortly before the time of shipment.

6.3 The documentary evidence of conformity of the Goods and services to the Tender Documents may be in the form of literature, drawings, and data and shall consist of:

(a) a detailed description of the essential technical and performance characteristics of the goods;

(a) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the goods and services to those specifications, or a statement of (even allegedly minor) deviations and exceptions to the provisions of the Technical Specifications;

(b) Any other procurement-specific documentation requirement as stated in the **TDS**.

6.4 Unless the **TDS** stipulates otherwise, the Goods to be supplied under the contract shall be registered with the relevant authority in the Purchaser's country. A Tenderer who has already registered its goods by the time of tendering shall submit a copy of the Registration Certificate with its tender.

6.5 For purposes of the commentary to be furnished pursuant to ITT clause 6.3 (b) above, the Tenderer shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Tenderer may substitute alternative standards, brand names, and/or catalogue numbers in its tender, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

**7. Qualifications of the Tenderer**

7.1 The Tenderer shall provide documentary evidence to establish to the Purchaser's satisfaction that:

(a) The Tenderer has the financial and technical capability necessary to perform the contract, meets the qualification

criteria specified in the **TDS**, and has a successful performance history in accordance with criteria specified in the **TDS**. If a prequalification process has been undertaken for the contract, the Tenderer shall, as part of its tender, update any information submitted with its application for prequalification.

(b) in the case of a Tenderer offering to supply Health Sector Goods identified in the **TDS**, that the Tenderer did not manufacture or otherwise produce, the Tenderer has been duly authorized by the manufacturer or producer of such goods to supply the Goods in the Purchaser's country;

(c) in the case of a Tenderer who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Tenderer is or will be (if awarded the contract) represented by a local service/maintenance provider in the Purchaser's country, equipped and able to carry out the Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications.

**8. One Tender per Tenderer**

8.1 A firm shall submit only one tender either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITT clause 20). A firm that submits either individually or, as a member of a joint venture, more than one tender will cause all the proposals with the firm's participation to be disqualified.

**9. Cost of Tendering**

9.1 The Tenderer shall bear all costs associated with the preparation and submission of its tender, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the tendering process.

## B. THE TENDER DOCUMENTS

**10. Content of Tender Documents**

10.1 The Tender Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITT clause 12.

| | |
|---|---|
| Section I. | Invitation For Tender (IFT) |
| Section II. | Instructions to Tenderers (ITT) |
| Section III. | Tender Data Sheet (**TDS**) |
| Section IV. | General Conditions of Contract (GCC) |
| Section V. | Special Conditions of Contract (**SCC**) |
| Section VI. | Schedule of Requirements (**SOR**) |
| Section VII. | Technical Specifications (TS) |
| Section VIII. | Sample Forms (including Contract Agreement) |

10.2 The Tenderer is expected to examine all instructions, forms, terms, and specifications in the tender documents. Failure to

furnish all information required by the tender documents or to submit a tender not substantially responsive to the tender documents in every respect will be at the tenderers risk and may result in the rejection of its tender.

**11. Clarification of Tender Documents**

11.1 A prospective Tenderer requiring any clarification of the Tender Documents shall contact the Purchaser in writing (for these ITT, the term "in writing" means communicated in written form (e.g. email, fax, telex) with proof of receipt at the entity's address as indicated in the **TDS**. The Purchaser will respond in writing to any request for clarification received no later than Seven (7) calendar days prior to the deadline of submission of tenders. The content of the Purchaser's response shall be sent to all prospective Tenderers including a description of the inquiry but without identifying the source of the inquiry.

11.2 The Procuring Entity shall reply to any clarifications sought by the tenderer within three (3) days of receiving the request to enable the timely submission of the tender.

**12. Amendment of Tender Documents**

12.1 At any time prior to the deadline for submission of tenders, the Purchaser may amend the Tender Documents by issuing addenda/amendments.

12.2 Any addendum/amendment thus issued shall be part of the Tender Document pursuant to ITT sub-clause 10.1 and shall be communicated in writing to all purchasers of the Tender Documents and will be binding on them. Tenderers are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the addendum/amendment will have been taken into account by the Tenderer in its tender.

12.3 To give prospective Tenderers reasonable time in which to take addenda/amendments into account in preparing their tenders, the Purchaser may extend, at its discretion, the deadline for submission of tenders, in which case, the Purchaser will notify all Tenderers in writing of the extended deadline

## C. PREPARATION OF TENDERS

**13. Language of Tender**

13.1 The tender, as well as all correspondence and documents relating to the tender exchanged by the Tenderer and the Purchaser, shall be written in the language specified in the **TDS.** Supporting documents and printed literature furnished by the Tenderer may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **TDS,** in which case, for purposes of interpretation of the Tender, the translation shall govern.

**14. Documents**

14.1 The tender submitted by the Tenderer shall comprise the

**Constituting the Tender**

following:

(a) duly filled-in and signed Tender Form and Price Schedule, in accordance with the forms indicated in Section VII;

(b) original form of tender security in accordance with the provisions of ITT sub-clause 19 (Tender Security);

(c) written power of attorney, authorizing the named signatory of the tender to commit the Tenderer and showing the authorizing as well as the authorized person's function in the firm, name and signature;

(d) in the absence of prequalification, documentary evidence in accordance with ITT sub-clause 4.4 establishing to the Purchaser's satisfaction the Tenderer's eligibility to tender including but not limited to documentary evidence that the Tenderer is legally incorporated as defined under ITT clause 4;

(e) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITT clause 6 that the goods and ancillary services to be supplied by the Tenderer are eligible goods and services, pursuant to ITT clause 5, and that they conform to the Tender Documents;

(f) Documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITT clause 7 that the Tenderer is qualified to perform the contract if its tender is accepted. In the case where prequalification of Tenderers has been undertaken, and pursuant to ITT clause 7.1 (a) the Tenderer must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;

(g) Any other documentation as requested in the **TDS**.

**15. Tender Form**

15.1 The Tenderer shall complete the Tender Form and the Price Schedule furnished in the Tender Documents, indicating the goods to be supplied, a brief description of the goods, their country of origin, quantity, and prices.

**16. Tender Prices**

16.1 The Tenderer shall indicate in the Price Schedule, as applicable, the unit prices of each item, total prices of each item and lot, and the total tender price of the goods it proposes to supply under the contract.

16.2 The trade terms EXW and DAP shall be governed by the rules prescribed in the current edition at the time of tender submission of the *Incoterms* published by the International Chamber of Commerce, Paris, added by any deviation if so specified in the **TDS**.

16.3 Unless otherwise specified in the **TDS**, prices quoted by the Tenderer shall be fixed during the Tenderer's performance of the contract and not subject to variation on any account. A tender submitted with an adjustable price quotation will be treated as non-responsive and will be rejected, pursuant to ITT clause 29.

16.4 Pursuant to sub-clause 16.1 above, and if so indicated in the **TDS**, tenders are being invited for all items. Each item offered must comprise the full quantity required under each item.

**17. Currencies of Tender**

17.1 The Tenderer may express the tender price of the Health Sector Goods to be supplied entirely in any freely convertible currency. If the Tenderer wishes to be paid in a combination of different currencies, it must quote its prices accordingly, but no more than three foreign currencies may be used. Tenderers expressing their foreign currency requirements in any of the national currencies should do so in accordance with the provisions of the **TDS**.

**18. Period of Validity of Tenders**

18.1 Tenders shall remain valid for the period stipulated in the **TDS** after the date of tender submission specified in ITT clause 23. A tender valid for a shorter period shall be rejected by the Purchaser as non-responsive.

18.2 In exceptional circumstances, prior to expiry of the original tender validity period, the Purchaser may request that the Tenderers extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. Except as provided in ITT clause 18.3, a Tenderer agreeing to the request will not be required or permitted to modify its tender, but will be required to extend the validity of its tender security for the period of the extension.

**19. Tender Security**

19.1 Unless otherwise specified in the **TDS**, the Tenderer shall furnish, as part of its tender, a tender security in the amount stipulated in the **TDS** in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

19.2 The tender security shall remain valid for a period of thirty (30) days beyond the validity period for the tender i.e. 120 days from the date of tender opening.

19.3 The tender security shall be denominated in Kenya shillings or in a freely convertible currency and shall be, at the Tenderer's option, in one of the following forms:

(a) a cashier's or certified cheque;

(b) a letter of credit issued by a reputable Bank located in any eligible country;

(c) Unconditional Bank Guarantee issued by a reputable Bank selected by the Tenderer, located in any eligible

country and valid for one hundred and twenty (120) days from the date of tender opening The format of the Bank Guarantee shall be in accordance with the form of tender security included in Section VII. (***Tender Securities from Insurance Companies shall not be acceptable*****).**

19.4 Any tender not accompanied by an acceptable tender security shall be rejected by the Purchaser as nonresponsive. The tender security of a joint venture must be in the name of the joint venture submitting the tender.

19.5 The tender securities of unsuccessful Tenderers will be returned as promptly as possible, but not later than 30 days after the expiration of the period of tender validity.

19.6 The tender security of the successful Tenderer will be returned when the Tenderer has signed the Agreement and furnished the required performance security.

19.7 The tender security may be forfeited

(a) if the Tenderer withdraws its tender after the deadline for submitting tenders but before the expiry of the period during which tenders shall remain valid; or

(b) If the Tenderer, refuses to enter into a written contract as required under section 136 of the act or fails to furnish any required performance security.

**20. Alternative Proposals by Tenderers**

20.1 Unless specified in the **TDS**, alternative tenders shall not be accepted under any circumstance.

**21. Format and Signing of Tender**

21.1 The Tenderer shall prepare an original and the number of copies/sets of the tender indicated in the **TDS**, clearly marking each one as **"ORIGINAL TENDER"** and **"COPY OF TENDER,"** as appropriate. In the event of any discrepancy between them, the original shall govern.

21.2 The original and all copies of the tender, each consisting of the documents listed in ITT sub-clause 14.1, shall be typed or written in indelible ink and shall be signed by the Tenderer or a person or persons duly authorized to bind the Tenderer to the Contract. The authorization shall be indicated by written power of attorney, which pursuant to ITT sub-clause 14.1 (d) shall accompany the tender.

21.3 Any interlineations, erasure, or overwriting to correct errors made by the Tenderer shall be initialed by the person or persons signing the tender.

## D. SUBMISSION OF TENDERS

**22. Sealing and Marking of Tenders**

22.1 The Tenderer shall enclose the original and each copy of the tender in accordance with ITT clause 20, in separate sealed envelopes, duly marking the envelopes as **"ORIGINAL"** and **"COPY."** The envelopes containing the original and copies shall then be enclosed in one outer envelope.

The Tenderer shall seal and mark the original and copy of the tender in separate envelopes, duly marking the envelopes as **"ORIGINAL OF TENDER"** and **"COPY OF TENDER".** The Original and Copy must be properly bound for ease of handling.

22.2 The inner and outer envelopes shall:

(a) be addressed to the Procuring entity at the address given in the Invitation to Tender:

(b) Bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the **TDS** relating to ITT sub-clause 23.1.

(c) The inner envelopes shall also indicate the name and address of the tenderer to enable the tender to be returned unopened in case it is declared "late".

22.3 If the outer envelope is not sealed and marked as required by ITT sub-clause 22.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the tender.

**23. Deadline for Submission of Tenders**

23.1 Tenders must be received by the Purchaser at the address specified in the **TDS** relating to ITT sub-clause 22.2 (b) no later than the time and date specified in the **TDS**.

23.2 The Purchaser may, at its discretion, extend the deadline for the submission of tenders by amending the Tender Documents in accordance with ITT sub-clause 12.3, in which case all rights and obligations of the Purchaser and Tenderers previously subject to the deadline will thereafter be subject to the deadline as extended.

**24. Late Tenders**

24.1 Any tender received by the Purchaser after the deadline for submission of tenders prescribed by the Purchaser in the **TDS** pursuant to ITT clause 23 will be rejected and returned unopened to the Tenderer.

**25. Modification and Withdrawal of Tenders**

25.1 The Tenderer may modify or withdraw its tender after submission, provided that written notice of the modification, or withdrawal of the tenders duly signed by an authorized representative, is received by the Purchaser prior to the deadline prescribed for submission of tenders.

25.2 The Tenderer's modification shall be prepared, sealed,

marked, and dispatched as follows:

(a) The Tenderer shall provide an original and the number of copies specified in the **TDS** of any modifications to its tender, clearly identified as such, in two inner envelopes duly marked "TENDER MODIFICATION-ORIGINAL" and "TENDER MODIFICATION-COPIES." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "TENDER MODIFICATION."

(b) Other provisions concerning the marking and dispatch of tender modifications shall be in accordance with ITT sub-clauses 22.2 and 22.3.

25.3 A Tenderer wishing to withdraw its tender shall notify the Purchaser in writing prior to the deadline prescribed for tender submission. A withdrawal notice shall be received prior to the deadline for submission of tenders. The notice of withdrawal shall:

(a) be addressed to the Purchaser at the address named in the **TDS**,

(b) bear the specific identification of the Tender process (Contract name), the IFT title and IFT number, and the words "TENDER WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the tender.

25.4 Tenders requested to be withdrawn in accordance with ITT sub-clause 25.3, shall be returned unopened to the Tenderers.

25.5 No tender may be withdrawn in the interval between the tender submission deadline and the expiration of the tender validity period specified in ITT clause 18. Withdrawal of a tender during this interval may result in the forfeiture of the Tenderer's tender security, pursuant to ITT sub-clause 19.7.

## E. Opening and Evaluation of Tenders

**26. Tender Opening**

26.1 The Purchaser will open all tenders, including withdrawal notices and modifications, in public, in the presence of Tenderers and/or representatives who choose to attend, at the time, on the date and at the place specified in the **TDS**. Tenderers and/or representatives shall sign a register as proof of their attendance.

26.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding tender shall not be opened but returned to the Tenderer. No tender withdrawal

shall be permitted unless the corresponding withdrawal notice is read out at tender opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding tender.

26.3 Tenders shall be opened one at a time, reading out the name of the Tenderer and whether there is a modification; the tender price of each item, the presence or absence of a tender security; and any other such details as the Purchaser may consider appropriate. No tender shall be rejected at tender opening except for late tenders pursuant to sub-clause 24.1.

26.4 Tenders (and modifications sent pursuant to ITT sub-clause 25.2) that are not opened or read out at tender opening shall not be considered further for evaluation, irrespective of the circumstances.

26.5 The Purchaser will prepare minutes of the tender opening at the end of the opening session, including, as a minimum: the name of the Tenderer and whether there was a withdrawal or modification; the tender price; the presence or absence of a tender security;. The Tenderers and/or representatives who are present shall be requested to sign the minutes. The omission of a Tenderer's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Tenderers who request them.

**27. Clarification of Tenders**

27.1 During evaluation of the tenders, the Purchaser may, at its discretion, ask the Tenderer for a clarification of its tender. The request for clarification and the response shall be in writing, and no change in the prices or substance of the tender shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the tenders, in accordance with ITT Sub-Clause 30.1.

**28. Confidentiality**

28.1 Information relating to the examination, clarification, evaluation, and comparison of tenders, and recommendations for the award of a Contract shall not be disclosed to Tenderers or any other persons not officially concerned with such process until the Notification of Contract award is made to all Tenderers.

28.2 Any effort by a Tenderer to influence the Purchaser in the Purchaser's tender evaluation, tender comparison, or contract award decisions may result in the rejection of the Tenderer's tender.

28.3 From the time of tender opening to the time of Contract award, if any Tenderer wishes to contact the Purchaser on any matter related to its tender, it should do so in writing.

**29. Examination of Tenders and Determination of Responsiveness**

29.1 The Purchaser will examine the tenders to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the tenders are generally in order. In the case where a prequalification process has been undertaken for the Contract(s) for which these tender documents have been issued, the Purchaser will ensure that each tender is from a prequalified Tenderer.

29.2 The Purchaser may waive any minor informality, nonconformity, or irregularity in a tender that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Tenderer.

29.3 Prior to the detailed evaluation, pursuant to ITT Clause 32, the Purchaser will determine whether each tender is of acceptable quality, is complete, and is substantially responsive to the tender documents. For purposes of this determination, a substantially responsive tender is one that conforms to all the terms, conditions, and specifications of the Tender Documents without material deviations, exceptions, objections, conditionality's or reservations. A material deviation, exception, objection, conditionality or reservation is one:

(i) that limits in any substantial way the scope, quality, or performance of the goods and/or related services;

(ii) that limits, in any substantial way that is inconsistent with the tender documents, the Purchaser's rights or the successful Tenderer's obligations under the Contract;

and

(iii) The acceptance of which would unfairly affect the competitive position of other Tenderers who have submitted substantially responsive tenders.

29.4 If a tender is not substantially responsive, it will be rejected by the Purchaser and cannot subsequently be made responsive by the Tenderer by correction of the nonconformity. The Purchaser's determination of a tender's responsiveness is to be based on the contents of the tender itself, and any written clarification submitted by the Tenderer in accordance with ITT sub-clause 27.1.

**30. Correction of Errors**

30.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and the quantity, the unit price shall prevail. If there is a discrepancy between the unit price and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Tenderer does not accept the correction of errors, its tender will be rejected and its tender security shall be forfeited.

**31. Conversion to Single Currency**

31.1 To facilitate evaluation and comparison, the Purchaser will convert all tender prices expressed in the various currencies in which they are payable to either:

(a) the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the Purchaser's country.

31.2 The currency selected for converting tender prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the **TDS**.

**32. Evaluation and Comparison of Tenders**

32.1 The Purchaser will evaluate and compare the tenders that have been determined to be substantially responsive, pursuant to ITT clause 29.

32.2 The comparison shall be between the EXW (ex-factory/ex-warehouse/off-the-shelf) price of the Goods offered from within the Purchaser's country plus local transportation, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the Goods, and the DAP named place of destination price of the Goods offered from outside the Purchaser's country, plus local transportation.

32.4 The Purchaser's evaluation of a tender will take into account one or more of the following factors as specified in the **TDS**, and quantified in ITT sub-clause 32.5*:*

(i) Delivery schedule offered in the tender;

(ii) deviations in payment schedule from that specified in the **SCC**;

(iii) Other specific criteria indicated in the **TDS** and/or in the Technical Specifications.

32.5 For factors retained in the **TDS** pursuant to ITT sub-clause 32.3, one or more of the following quantification methods will be applied, as detailed in the **TDS**:

(a) Delivery schedule.

(i) The Purchaser requires that the Health Sector Goods under these Tender Documents shall be delivered (shipped) at the time specified in the Schedule of Requirements.

**or**

(ii) The Health Sector Goods covered under these Tender Documents are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirements. No credit will be given to earlier deliveries, and tenderers offering delivery beyond this range may

be treated as non-responsive.

**or**

(iii) The Health Sector Goods covered under this invitation are required to be delivered (shipped) in partial shipments, as specified in the Schedule of Requirements.

(b) Deviation in payment schedule.

(i) The **SCC** stipulates the payment schedule offered by the Purchaser.

(c) Past performance:

Tenderers need a satisfactory record of performance:

(i) Those who have previously been awarded contracts to supply similar commodities and failed to deliver as per the contract terms or delivered and commodities recalled for quality issues and failed to replace the same shall be disqualified if designated for an award.

(ii) Those who are or have been seriously deficient in current or recent contract performance when the number of contracts and the extent of deficiencies each are considered (in the absence of evidence to the contrary or circumstances properly beyond their control) shall be presumed to be unable to meet this requirement and shall be disqualified if designated for a contract award.

(d) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the **TDS** and/or in the Technical Specifications.

32.6 Contacting the purchaser

(a) Subject to paragraph 28, no tenderer shall contact the purchaser on any matter relating to its tender from the time of tender opening to the time of contract award.

(b) Any effort by a tenderer to influence the purchaser in its decision on tender evaluation, tender comparison, or contract award shall result in the rejection of the tenderer 's tender

**33. Preference** 33.1 Preference not applicable for this funding.

## F. AWARD OF CONTRACT

**34. Post qualification** 34.1 In the absence of prequalification, the Purchaser will determine to its satisfaction whether the Tenderer that is

selected as having submitted the lowest evaluated responsive tender is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITT sub-clause 7.1 and any additional post qualification criteria stated in the **TDS**. If a prequalification process was undertaken for the Contract(s) for which these tender documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the prequalification that negatively affect the ability of the Tenderer that has submitted the lowest evaluated tender to perform the Contract.

34.2 The determination will evaluate the Tenderer's financial, technical, production capabilities and tenderer's past performance. It will be based on an examination of the documentary evidence of the Tenderer's qualifications submitted by the Tenderer, pursuant to ITT sub-clause 7.1, as well as other information the Purchaser deems necessary and appropriate.

34.3 An affirmative post qualification determination will be a prerequisite for award of the contract to the lowest evaluated Tenderer. A negative determination will result in rejection of the Tenderer's tender, in which event the Purchaser will proceed to the next-lowest evaluated tender to make a similar determination of that Tenderer's capabilities to perform satisfactorily.

**35. Award Criteria**

35.1 Pursuant to ITT clauses 32, 34 and 39, the Purchaser will award the Contract to the Tenderer whose tender has been determined to be substantially responsive and has been determined to be the lowest evaluated tender, provided further that the Tenderer is determined to be qualified to perform the Contract satisfactorily, pursuant to ITT clause 35.

**36. Purchaser's Right to Accept Any Tender and to Reject Any or All Tenders**

36.1 The Purchaser reserves the right to accept or reject any tender, or to annul the Tender process and reject all tenders at any time prior to contract award, without thereby incurring any liability to the affected Tenderer(s).

**37. Purchaser's Right to Vary Quantities at Time of Award**

37.1 The Purchaser reserves the right at the time of contract award or during the life of the contract to increase or decrease, by the percentage indicated in the **TDS**, the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions, except the delivery schedule.

**38. Notification of Award**

38.1 Prior to the expiration of the period of tender validity, the Purchaser will notify the successful Tenderer in writing that its tender has been accepted, the receipt of which must be confirmed in writing.

38.2 At the same time as the successful tenderer is notified of the award, the unsuccessful tenderer(s) shall be notified that

their tender(s) were unsuccessful.

38.3 A written contract will constitute the formation of the Contract, *subject to "no appeal"* from unsuccessful tenderers' within the period of fourteen (14) days from the date of Notification of Award.

38.4 Upon the successful Tenderer's furnishing of the signed Contract Form and performance security pursuant to ITT clause 39, the Purchaser will promptly release the tender security of each unsuccessful Tenderer(s), pursuant to ITT clause 19.

**39. Signing of Contract**

39.1 Promptly after the Purchaser notifies the successful Tenderer that its tender has been accepted, the Purchaser will; after fourteen days (14 days) but within twenty one days (21 days) invite the successful tenderer after complying with ITT clause 40.1 to sign a contract.

39.2 Within seven (7) days of the invitation to sign the contract, the successful Tenderer shall send authorized signatories to sign the contract.

**40. Performance Security**

40.1 Within twenty-one (21) days of the receipt of Notification of Award from the Purchaser, the successful Tenderer shall furnish the Performance Security in accordance with the Conditions of Contract, using the Performance Security Form provided in the Tender Documents or in another form acceptable to the Purchaser.

40.2 Failure of the successful Tenderer to comply with the requirement of ITT clause 38 or ITT sub-clause 39.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the tender security, in which event the Purchaser may make the award to the next-lowest evaluated tenderer or call for new tenders.

# Section II. Tender Data Sheet (TDS)

## Tender Data Sheet (TDS)

The following specific data for the goods to be procured shall complement, supplement or amend the provisions in the Instructions to Tenderers (ITT). Whenever there is a conflict, the provisions in the Tender Data Sheet (**TDS**) shall prevail over those in the ITT and MUST be substantiated at the time of Bid submission.

### A. GENERAL

| | |
|---|---|
| ITT 1.1 | Name of Purchaser:<br>**Kenya Medical Supplies Authority acting for and on behalf of Government of Kenya, Ministry of Health,**<br>**The Global Fund, Kenya Program**<br>Name of authorized Purchasing Agent:<br>**Kenya Medical Supplies Authority,**<br>Type of goods: **Health Sector Goods**<br>Name and identification number of the Contract:<br>**IFT N$^{o}$.: GF ATM TB NFM -17/18-OIT-001 for Supply and delivery of Nutritional Supplements** |
| ITT 2.1 | Name of the Beneficiary: **Government of Kenya, Ministry of Health**<br>Procurement Budget: Approx**. US$ 2 Million**<br>Name of Project: Global Fund to Fight AIDS, TB and Malaria (GFATM) |
| ITT 4.1 & 5.1 | Applicable Guidelines: Government of Kenya (GOK), The Public Procurement and Asset Disposal Act 2015.The Global Fund's Policies on Procurement and Supply Management, June 2012, The Global Fund Quality Assurance Policy effective from March, 1st 2011 and revised in February 2014.<br>**Note:** In the event of a conflict between the Public Procurement and Asset Disposal Act and the Global Fund's PSM Policies, the Global Fund's PSM Policies shall prevail. |
| ITT 6.3 (c) | Documentation and sample requirements for eligibility of the offered Goods.<br>In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following shall be included with the Tender:<br>(a) Documentary evidence demonstrating that the goods meet the requirements of manufacturing legislation and regulation of Health products in the country of origin.<br>(b) The Tenderer is requested to provide, in support of their technical offer, **a sample** for tests for each of the items offered under separate cover at or before the tender closing date and time. The sample is to be clearly labeled with the tenderer's name, tender reference and identification of the product. The sample requested is to be submitted as per technical specification offered by the Tenderer and shall |

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| | represent exactly the product that is intended to be supplied in case of contract award.<br><br>(c) If, for reasons other than the tender specific labeling requirements, the sample is not consistent with the required technical specifications then the offer for the particular item shall be rejected.<br><br>(d) For quality assurance reasons, for each sample provided, a protocol (**certificate of analysis**) of a product test conducted by the laboratory of the manufacturer has to be provided from the same batch of production in case of award of contract (where applicable). |
| ITT 6.4 | (a) Approved as safe for human consumption by Kenya Bureau of Standards (KEBS).<br>(b) The product should conform to ISO 22000 - Food Safety Management System Standards.<br>(c) Manufacturer must be ISO/KEBS certified or equivalent. |

## B. THE TENDER DOCUMENTS

| | |
|---|---|
| ITT 11.1 | Tenderer's requesting for clarifications shall do it in writing to the purchaser seven (7) days before tender submission date to below address;<br><br>**Office Address:**<br>Kenya Medical Supplies Authority (KEMSA)<br>13 Commercial Street, Industrial Area<br>P.O. Box: 47715-00100 Nairobi/Kenya<br>Tel: (+254-0)20-3922000 + 0719033000<br>Fax: (+254-0)20-558100<br>E-Mail: **procurement.programs@kemsa.co.ke**<br><br>**Attn: John Kabuchi (Procurement Manager)** |
| **ITT 11.2** | The Purchaser will respond in writing to any request for clarification of the tender documents within three (3) days of receipt of such clarification requests. |

## C. PREPARATION OF TENDERS

| | |
|---|---|
| ITT 13.1 | The language of all correspondence and documents related to the tender is English. Moreover, the key passages of all accompanying printed literature in any other language must be translated into English. |
| ITT 16.2 | The trade term DAP shall be added by the stipulation that the Seller shall be responsible and shall bear the costs for the customs clearance procedure |
| ITT 16.3 | Prices are fixed |
| ITT 16.4 | Tenders are being invited for individual contracts (one or more items/lots). Tenderers shall quote 100% of the entire quantity for each item quoted, as per Purchaser's Price Schedule. |

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| ITT 18.1 | The tender validity period shall be 90 days after the deadline for tender submission, as specified below in reference to ITT clause 23. |
| ITT 19.1 | The amount of tender security required **USD 10,000.00 or KES 1,000,000.00** or equivalent in a freely convertible currency. |
| ITT 19.2 | Tender security must be valid thirty (30) days after the end of the tender validity period. I.e. one twenty (120) days from the date of tender opening. |
| ITT 19.3 | Form of Tender Security:<br>a) Cash<br>b) Bank Guarantee<br>c) Letter of Credit<br>d) Guarantee by a deposit taking Micro Finance Institution (SACCO society, Youth Enterprise Development Fund or Women Enterprise Fund<br>**Note:** (***Tender Securities from Insurance Companies shall not be acceptable*****).** |
| ITT 20.1 | Alternative offers not allowed |
| ITT 21.1 | Required number of copies of the tender: **1 original and 1 copy of the tender shall be submitted.** |

## D. SUBMISSION OF TENDERS

| | |
|---|---|
| ITT 22.2 (b) | The address for tender submission is:<br>Kenya Medical Supplies Authority<br>Office address:<br>Chief Executive Officer<br>Kenya Medical Supplies Authority (KEMSA)<br>Commercial Street, Industrial Area<br>Nairobi/Kenya<br>Postal address:<br>P. O. Box 47715<br>00100 Nairobi/Kenya |
| ITT 22.2 (c) & (d) | See the above data for ITT 1.1 for the name of the Contract.<br>The Invitation to Tenders number and title are:<br>**IFT N$^{o}$ GF ATM TB NFM -17/18-OIT-001 for Supply and delivery of Nutritional Supplements**<br>See the below data for ITT sub-clause 23.1 for the deadline for tender submission. |
| ITT 23.1 | See the above data for ITT sub-clause 22.2 (b) for the address and deadline for tender submission.<br>Deadline for tender submission is: |

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| | **6th June, 2017, at 10:00 AM (Nairobi local time)** |
| ITT 24.1 | See the above data for ITT sub-clause 23.1 for the deadline for tender submission. |
| ITT 25.2 (a) | The required number of copies of tender modifications is the same as the number of copies of the original tender specified above in the data for ITT sub-clause 21.1. |
| ITT 25.3 (a) | See the above data for ITT Paragraph 22.2 (b) for the address to use for submission of a tender withdrawal notice. |

**E. TENDER OPENING AND EVALUATION**

| | |
|---|---|
| ITT 26.1 | Time, date, and place for tender opening are:<br><br>**6th June, 2017, at 10:00 AM (Nairobi local time)**<br><br>At : Kenya Medical Supplies Authority (KEMSA)<br>13 Commercial Street, Industrial Area<br>Nairobi/Kenya |
| ITT 31.2 | The currency chosen for the purpose of converting to a common currency is Kenya Shillings (KES)<br><br>The source of exchange rate is the Central Bank of Kenya, Nairobi<br>The date of exchange rate determination is **the selling rate on the day of tender opening.** |
| ITT 32.3 | The evaluation will take into account:<br><br>a) For Goods offered from within the Purchaser's country, the cost for inland transportation, insurance, and other incidental costs for delivery of the goods to the final destination, as indicated in ITT 16.2 has to be indicated separately for each item in the Price Schedule for Goods offered from within the Country. The above cost is added to the price EXW to the total unit price for bid evaluation.<br><br>b) For Goods offered from outside the Purchaser's country, the cost for inland transportation, insurance, and any other incidental costs for handling and delivery of the goods to the final destination, as indicated in the Tender Data Sheet has to be indicated separately for each item in the relevant Price Schedule. The above cost is included in the price for DAP KEMSA warehouse, Commercial Street, Industrial Area, Nairobi, total unit price for bid evaluation. |
| ITT 32.5 (b) (ii) | The Purchaser will not accept deviations from the payment schedule as stipulated in the **SCC**. |
| ITT 32.5 (d) | Evaluation criteria for items<br><br>Tenderers shall bid for one or more items in the Price Schedule. Bids will be evaluated item by item:<br><br>(a) Tenderers shall quote for one, more or all items and the entire quantity for each item quoted, as per Purchaser's Price Schedule;<br><br>and<br><br>(b) The items offered as per Purchaser's Price Schedule must |

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| | be responsive to the Tender Document.<br><br>Tendered items not complying with (a) and (b) above shall be treated as non-responsive.<br><br>Tender evaluation and award will be made on individual item basis. Each bidder will be given one contract irrespective of the number of items awarded. |
| ITT 33 | Not applicable |

## F. AWARD OF CONTRACT

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|---|---|
| ITT 37.1 | Percentage for increase or decrease of quantity of goods and services should not exceed 15% during the life of the contract as stipulated under ITT 39.3. |
| ITT 39.1 | Prior to the expiration of the period of tender validity, the Purchaser will notify the successful Tenderer in writing. The tenderer will be required to confirm in writing the acceptance of the offer within seven (7) days. |
| ITT 39.2 | Within seven (7) days of the invitation to sign and date the contract, the successful Tenderer shall send an authorized signatory to sign the Contract at the purchaser's premises. |
| ITT 39.3 | The contract period shall be twelve (12) months after effective contract date within which period the purchaser would have made all the calls. |
| ITT 40.1 | Performance Security from a Bank shall be 10% of the initial contract sum and valid for one year renewable. |

# Section III. General Conditions of Contract

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## General Conditions of Contract

**1. Definitions** 1.1 In this Contract, the following terms shall be interpreted as indicated:

(a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.

(e) "End User" means the organization(s) where the goods will be used, as named in the **SCC**.

(f) "GCC" means the General Conditions of Contract contained in this section.

(g) "The Goods" means all of the medical supplies that the Supplier is required to supply to the Purchaser under the Contract.

(h) "The Purchaser" or the procuring entity means the organization that is purchasing the Goods, as named in the **SCC**.

(i) "The Purchaser's country" is the country named in the **SCC**.

(j) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the applicable law.

(k) "**SCC**" means the Special Conditions of Contract.

(l) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

(m) "The Site," where applicable, means the place or places named in the **SCC**.

(n) "The Supplier / tenderer mean the individual or firm supplying the Goods and Services under this Contract, as named in the **SCC**.

**2. Application**

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

**3. Country of Origin**

3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules of the Government of Kenya, or as further elaborated in the **SCC**.

3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

**4. Standards**

4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

**5. Use of Contract Documents and Information;**

5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

**6.Certification of Goods in Accordance with Laws of the Purchaser's Country**

6.1 If required under the applicable law, Goods supplied under the Contract shall be registered for use in the Purchaser's country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's country.

6.2 Unless otherwise specified in the **SCC**, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the Goods have been registered for use in the Purchaser's country.

6.3 If thirty (30) days, or such longer period specified in the **SCC**, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

**7. Patent Rights**

7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Purchaser's country.

**8. Performance Security**

8.1 Within twenty one (21) days of receipt of the notification of Contract award, the successful Tenderer shall furnish to the Purchaser the performance security in the amount specified in the **SCC**.

8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

8.3 The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Tender Documents or another format acceptable to the Purchaser;

Or

(b) a cashier's or certified cheque.

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise in the **SCC**.

**9. Inspections and Tests**

9.1 a) The Supplier shall demonstrate conformity to Kenya Standards or approved equivalents by evidence of Test

report or Certificate from ISO/IEC 17025 accredited laboratory, recognized by the International Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA) prior to shipment. Cost shall be borne by the supplier.

b) Upon receipt of the pre-delivery samples or the consignment at the place of final destination, the Purchaser's representative shall inspect the samples or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

c) The inspections and tests may be conducted on the premises of the tenderer or its subcontractor(s), at point of delivery, and/or at the Medical commodities' final destination. If conducted on the premises of the tenderer or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be provided to the inspectors at no charge to the Procuring entity.

d) Should any inspected or tested Medical commodities fail to conform to the Specifications, the Procuring entity may reject the Medical commodities, and the tenderer shall either replace the rejected Medical commodities or make alterations necessary to meet specification requirements free of cost to the Procuring entity.

e) The Procuring entity's right to inspect, test and, where necessary, reject the Medical commodities after the Medical commodities' arrival shall in no way be limited or waived by reason of the Medical commodities having previously been inspected, tested, and passed by the Procuring entity or its representative prior to the Medical commodities' delivery.

9.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent Agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

**10. Packing**

10.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of appropriate handling facilities at all points in transit.

10.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in the **SCC** or Technical Specifications, and in any subsequent instructions ordered by the Purchaser.

**11. Delivery and Documents**

11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in the **SCC.**

11.2 For purposes of the Contract, **"EXW", "DAP"** and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.

11.3 Documents to be submitted by the Supplier are specified in the **SCC.** *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

**12. Insurance**

12.1 The Goods supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery in the manner specified in the **SCC.**

**13. Transportation**

13.1 Where the Supplier is required under Contract to deliver the Goods FOB, transport of the Goods, up to and including the point of putting the Goods on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the Goods FCA, transport of the Goods and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.2 Where the Supplier is required under Contract to deliver the Goods CIF or CIP, customs clearance and transport of the Goods to the port of destination or such other named place of destination in the Purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the

Contract Price.

13.3 Where the Supplier is required under the Contact to transport the Goods to a specified place of destination within the Purchaser's country, defined as the Site, transport to such place of destination in the Purchaser's country, including customs clearance, insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13.4 Where the Supplier is required under Contract to deliver the Goods CIF or DAP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract (a) to deliver the Goods FOB or FCA, and (b) to arrange on behalf and at the expense of the Purchaser for international transportation on specified carriers or on national flag carriers of the Purchaser's country, the Supplier may arrange for such transportation on alternative carriers if the specified or national flag carriers are not available to transport the Goods within the period(s) specified in the Contract.

**14. Incidental Services**

14.1 The Supplier shall provide such incidental services, if any, as are specified in the **SCC.**

14.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

**15. Warranty**

15.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise specified in the **SCC;** have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier shall remove, at his own risk and cost, the defective Goods WITHIN fourteen (14) Days of the advise by the purchaser,

failure to which storage charges will accrue at the prevailing market rates to be determined by the purchaser. The replacement of the Goods must be done within the time stipulated in the SCC.

15.3 In the event of a dispute by the Supplier, a counter-analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter-analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period specified in the **SCC,** the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this contract.

15.5 Recalls. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

**16. Payment**

16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in the **SCC.**

16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be specified in the **SCC** subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's tender.

16.5 All payments shall be made in the currency or currencies specified in the **SCC** pursuant to GCC 16.4.

**17. Prices**

17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its tender, with the exception of any price adjustments authorized in the **SCC** or in the Purchaser's request for tender validity extension, as the case may be.

**18. Change Orders**

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

(a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

**19. Contract Amendments**

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

**20. Assignment**

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.

**21. Delays in the Supplier's Performance**

21.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by

amendment of Contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of liquidated damages.

**22. Liquidated Damages**

22.1 Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in the **SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in the **SCC.** Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 23.

**23. Termination for Default**

23.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 21; or

(b) if the Goods do not meet the Technical Specifications stated in the Contract; or

(c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the **SCC**.

(d) if the Supplier, in the judgment of the Purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

"corrupt practice" means the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official in the procurement process or in Contract execution.

"fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a Contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after tender submission) designed to establish tender prices at artificial noncompetitive levels and to deprive the Purchaser of

the benefits of free and open competition.

(e) if the Supplier fails to perform any other obligation(s) under the Contract.

23.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 23.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

**24. Force Majeure**

24.1 Notwithstanding the provisions of GCC Clauses 21, 22, and 23, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

24.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

24.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

**25. Termination for Insolvency**

25.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

**26. Termination for Convenience**

26.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

26.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the

Purchaser may elect:

(a) to have any portion completed and delivered at the Contract terms and prices; and/or

(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

**27. Settlement of Disputes**

27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

27.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure specified in the **SCC.**

27.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

**28. Limitation of Liability**

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and

(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or

replacing defective equipment.

**29. Governing Language**

29.1 The Contract shall be written in the language specified in the **SCC.** Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

**30. Applicable Law**

30.1 The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise specified in the **SCC.**

**31. Notices**

31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address specified in the **SCC.**

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

**32. Taxes and Duties**

32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country. Commodities being procured under this GFATM grant are free of local taxes and duties. The Purchaser will facilitate the tax exemptions upon receipt of the required documentation from the supplier.

32.2 A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser. The charge of VAT is not applicable for commodities being procured with this GFATM grant. The Purchaser will facilitate VAT exemption upon receipt of the required documentation from the supplier.

# Section IV. Special Conditions of Contract

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## Special Conditions of Contract (SCC)

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| The following Special Conditions of Contract (**SCC**) shall supplement the General Conditions of Contract (GCC). Whenever there is a conflict, the provisions herein shall prevail over those in the GCC. The corresponding clause number of the GCC is indicated in parentheses | |
| **1. Definitions (GCC Clause 1)** | |
| GCC 1.1 (f) | The end user is: **Ministry of Health** |
| GCC 1.1 (i) | The Purchaser is: **Kenya Medical Supplies Authority (KEMSA) acting for and on behalf of the Government of Kenya, Ministry of Health, The Global Fund, Kenya Program, Nairobi** |
| GCC 1.1 (j) | The Purchaser's country is: **Kenya** |
| GCC 1.1 (n) | The Site is: **KEMSA, 13 Commercial Street, Industrial Area, Nairobi** |
| GCC 1.1 (o) | The Supplier is: xxxxxx |
| **4. Standards (GCC Clause 4)** | |
| GCC 4 | The Tenderer warrants that all goods supplied under this Contract shall fully conform in all respects with the technical specifications and with the conditions laid down in the Contract. |
| | **Tenderers Eligibility (ITT Clause 4.1)** |
| ITT 4.1 | The documentary evidence of the Bidders eligibility to tender shall include proof of registration/incorporation and tax compliance from the relevant authorities. |
| **6. Certification of Goods in Accordance with Laws of the Purchaser's Country (GCC Clause 6)** | |
| GCC 6.1 | Goods supplied under this Contract shall be evaluated and registered for use in the Purchaser's country by relevant authorities. |
| GCC 6.4 | In line with the Global Fund Quality Assurance Policy for single-and limited source contracts, any contract on category ERP Recommended supplier is subject to approval from the Global Fund. the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the Purchaser that any contract on category ERP Recommended supplier has been approved by the Global Fund. |
| **8. Performance Security (GCC Clause 8)** | |

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| GCC 8.1 | The amount of the Performance security shall be 10% of the contract amount and must be from Bank in the form of a **banker's Cheque, bank guarantee, irrevocable letter of credit** issued by a reputable bank. |
| **9. Inspections and Tests (GCC Clause 9)** | |
| GCC 9.1 | a) Imports of Goods to Kenya are subject to Pre-shipment verification of conformity (PVoC).<br><br>b) The supplier is requested to provide for batch by batch Certificates of Compliance by ISO/IEC 17025/ EN 45002 accredited test laboratories to prove the conformity to the technical specifications and applicable quality standards. The cost of such inspection shall be to the supplier's account.<br><br>c) Prior to shipments for contracts on category ERP Recommended supplier's with prior approval from the Global Fund, the Global Fund shall conduct random quality analysis<br><br>d) The Goods shall not be shipped unless a copy of satisfactory documentary proof of conformity has been submitted to the Purchaser.<br><br>e) The Purchaser shall analyze all new brands of products, and products that have previously failed quality analysis tests, before confirming an order. The cost of analysis shall be borne by the Tenderer and shall be paid in full prior to analysis. |
| **10. Packing (GCC Clause 10)** | |
| GCC 10.2 | Additional requirements for packing and transport are indicated in<br><br>(a) Section VI, Technical Specifications<br><br>and<br><br>(b) General Packing Instructions |
| **11. Delivery and Documents (GCC Clause 11)** | |
| GCC 11.1 & 11.3 | **For goods supplied from abroad under Incoterms DAP, KEMSA**<br><br>Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. Under all transport modes, the Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company: |

(i) three originals and two copies of the Supplier's invoice, showing Purchaser as Consignee*;* the Contract number, grant no., goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;

(ii) one original and two copies of the negotiable, clean, on-board through MT Document marked "freight prepaid" and showing Purchaser as Consignee and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multi-modal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;

(iii) four copies of the packing list identifying contents of each package;

(iv) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;

(v) one original of the manufacturer's or supplier's Warranty Certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original and six copies of the Certificate of Compliance/Test Report furnished to the supplier by ISO/IEC 17025 accredited test laboratories;

(viii) any other procurement-specific documents required for delivery/payment purposes;

(ix) one original and one copy of the certificate of quality control test results per batch, in conformity with the World Health Organization "Certification Scheme on the Quality of Non Pharmaceutical Products Moving in International Trade" These tests shall be conducted by respective laboratories that

(a) are accredited in accordance with ISO/IEC 17025 or EN 45002

or

(c) have been accepted by a recognized authority

(x) one original of the certificate of weight issued by the port authority/licensed authority and six copies.

At arrival of the goods at port of clearance, the Supplier or its Shipping agent shall provide the Purchaser with:

1) Arrival notice

and

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| | 2) Delivery note.<br><br>The above documents 1) and 2) shall be received by the Purchaser immediately after arrival of the Goods at port of clearance and, if not received, the Supplier will be responsible for any consequent expenses.<br>**Note:** In the event that the documents presented by the Supplier are not in accordance with the Contract, payment will be made against issue of the Acceptance Certificate, to be issued in accordance with **SCC** 9 (GCC 9) above. |
| | **For goods supplied from within the Purchaser's country under Incoterms EXW, delivered to named place of destination:**<br><br>The Supplier shall notify the Purchaser at least forty-eight (48) hours ahead of delivery of the goods in writing and deliver the following documents to the Purchaser:<br><br>(i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, grant number, goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;<br><br>(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as consignee and delivery through to final destination as stated in the Contract;<br><br>(iii) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;<br><br>(iv) four copies of the packing list identifying contents of each package;<br><br>(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;<br><br>(vi) one original of the Supplier's Certificate of Origin covering all items supplied;<br><br>(vii) one original and six copies of a protocol (certificate of analysis) of a product test per batch conducted by the laboratory of the manufacturer .<br><br>(viii) other procurement-specific documents required for delivery/payment purposes<br><br>(ix) One original and one copy of the certificate of quality control test results per batch, in conformity with the World Health Organization "Certification Scheme on the Quality of Non Pharmaceutical Products Moving in International Trade". These tests shall be conducted by respective laboratories that<br><br>(a) are accredited in accordance with ISO/IEC 17025 or EN 45002. |

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| **12. Insurance (GCC Clause 12)** | |
| GCC 12.1 | The Insurance shall be in an amount equal to 110 percent of the DAP value of the goods from "warehouse" to "warehouse" on "All Risks" basis, including War Risks and Strikes, and must be valid for 120 days following the date of delivery to the place of destination mentioned in the **TDS** |

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| **14. Incidental Services (GCC Clause 14)** | |
| GCC 14.1 | Incidental services to be provided:<br><br>The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser's country that may be required for the Goods. The cost shall be deemed included in the Contract Price. |
| **15. Warranty (GCC Clause 15)** | |
| GCC 15.4 | (i) The period for the replacement of defective goods is twelve (12) Weeks |
| **16. Payment (GCC Clause 16)** | |
| GCC 16.1 & 16.4 | The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:<br><br>(i) Payment shall be made after transfer of ownership of the medical commodities.<br><br>(ii) Ownership will be transferred after acceptance of quality of medical commodities.<br><br>(iii) The Procuring entity accepts medical commodities subject to checks on quality. Invoices and delivery notes shall be stamped, "received but not checked" at the time of delivery. The Procuring entity will check deliveries as quickly as possible and notify the Tenderer of any defective Medical commodities or of short/excess deliveries.<br><br>(iv) Payment shall be made by the Procuring Entity within ninety (90) days after submission of an invoice or claim by the Tenderer.<br><br>(v) The currencies in which payments shall be made to the Supplier under this Contract shall be those in which the bid prices were expressed in the Supplier's tender, subject to compliance with all aspects of the contract agreement, especially the delivery schedule. |
| **17 Prices (GCC Clause 17.1)** | |

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| GCC 17.1 | (i) Prices quoted should include all costs of shipment and handling until the medical commodities are received at KEMSA.<br><br>(ii) To facilitate evaluation and comparison, the Procuring entity will convert all bid prices expressed in the amounts in the various currencies in which bid price is payable, to the Kenya shillings using the Central Bank of Kenya (CBK) Rate on the day the bids are opened.<br><br>(iii) The Procuring entity reserves the right to award the contract in whole or in part without any change in the Unit price or other terms and conditions. |
| **21 Delays in supplier performance (GCC Clause 21.1)** | |
| GCC 21.1 | Further to the penalties described under GC 21.1 the Purchaser will initiate debarment proceedings against suppliers who fail to comply with the contract conditions as specified under the General Conditions of Contract, Special Conditions and Technical Specifications |
| **22. Liquidated Damages (GCC Clause 22)** | |
| GCC 22.1 | The applicable rate is one-half (0.5) percent per week, the maximum rate is ten (10) percent of the Contract Price and this shall be deducted from the payment due to the supplier. |
| **23. Termination for default (GCC Clause 23)** | |
| GCC 23 | Eligibility for commodity call downs in the second year will be subject to performance of the initial contract. |
| **27. Settlement of Disputes (GCC Clause 27)** | |
| GCC 27.2.2 | Clause 27.2.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 27.2.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country. The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows:<br><br>*(i)* ***Contracts with foreign Supplier:***<br><br>GCC 27.2.2 (a) –All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules.<br><br>(ii) ***Contracts with Supplier national of the Purchaser's country:***<br><br>In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country. |

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| **29. Governing Language (GCC Clause 29)** | |
| GCC 29.1 | English language |
| **30. Applicable Law (GCC Clause 30)** | |
| GCC 30.1 | The Contract shall be interpreted in accordance with the laws of the Republic of Kenya |
| **31. Notices (GCC Clause 31)** | |
| GCC 31.1 | **Procuring Entity's address**<br><br>**Kenya Medical Supplies Authority (KEMSA)**<br><br>Office address:<br>Chief Executive Officer<br>Kenya Medical Supplies Authority (KEMSA)<br>13 Commercial Street, Industrial Area<br>Nairobi/Kenya<br><br>Postal address:<br>P. O. Box: 47715<br>00100 Nairobi/Kenya<br><br>Tel: (+254-0)20-3922000<br>Fax: (+254-0)20-3922400<br>E-Mail: **procurement.programs@kemsa.co.ke**<br><br>***Supplier's address:*** |

# Section V. Schedule of Requirements

1. **Price Schedules for Goods Offered**

2. **Schedule of Requirements** ***(Refer to attached price schedule)***

# Price Schedule for Goods Offered Within The Country

IFB Number: GF ATM TB NFM -17/18-OIT-001

**SUPPLY & DELIVERY OF NUTRITIONAL SUPPLEMENTS**

| | 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Unit Price | | | | | | | |
| No. | Product Description | UOM | Quantity Offered | (a) Unit Price Port of Entry | (b) Inland transport, insurance and other local costs incidental to delivery | (c) Other incidental cost as defined in the SCC | TOTAL UNIT PRICE (4a+b+c+d) | TOTAL PRICE (3x5) | Manufacturer | Delivery Period | Delivery Period offered by Bidder |
| 1 | FORTIFIED BLENDED FOOD (FBF) FLOUR, 420-480KCAL/100G [FOR C | pack of 2kg | 693,642 | | | | | | | 8 to 12 Weeks | |
| 2 | READY TO USE THERAPEUTIC FOOD (RUTF) 500 KCAL/92G | SATCHET | 2,222,250 | | | | | | | 8 to 12 Weeks | |

| Currency | TOTAL PRICE (Sum of Column 6) | In Figures | |
|---|---|---|---|
| | | In Words | |

DAP,Named Final Destination, KEMSA Commercial Sreet, Industrial Area - Nairobi

Procurement Financed under the GF NFM shall be free from any Customs duties, VAT, IDF Fees, RDL and any other similar levies imposed under Laws in effect in Kenya

Note. Incase of descripancy between the unit price and total, the unit price shall prevail.

| Currency | Grand TOTAL BID PRICE (Sum of Lots) | In Figures | |
|---|---|---|---|
| | | In Words | |

| Bidder's Name and Address | Date | Signature and Stamp |
|---|---|---|
| | | |

Remarks

# Price Schedule for Goods Offered From Abroad

**SUPPLY & DELIVERY OF NUTRITIONAL SUPPLEMENTS**

IFB Number: GF ATM TB NFM -17/18-OIT-001

| | 1 | 2 | 3 | 4 | | | | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Unit Price | | | | | | | | | |
| No. | Product Description | UOM | Quantity Offered | (a) Unit Price FOB Port of Loading | (b) Unit Price named place of destination | (c) Inland transport, insurance and other local | (d) Other incidental cost as defined in the SCC | TOTAL UNIT PRICE (4a+b+c+d) | TOTAL PRICE (3x5) | Manufacturer | Country of Origin | Delivery Period | Delivery Period offered by Bidder |
| 1 | FORTIFIED BLENDED FOOD (FBF) FLOUR, 420-480KCAL/100G [FOR C | pack of 2kg | 693,642 | | | | | | | | | 8 to 12 Weeks | |
| 2 | READY TO USE THERAPEUTIC FOOD (RUTF) 500 KCAL/92G | SATCHET | 2,222,250 | | | | | | | | | 8 to 12 Weeks | |

* Note. Incase of descripancy between the unit price and total, the unit price shall prevail.

DAP,Named Final Destination,
KEMSA Commercial Sreet,
Industrial Area - Nairobi

Grand TOTAL BID PRICE (Sum of Lots)

| Currency | In Figures | |
|---|---|---|
| | In Words | |

Procurement Financed under the GF NFM shall be free from any Customs duties, VAT, IDF Fees, RDL and any other similar levies imposed under Laws in effect in Kenya

| Bidder's Name and Address | Date | Signature and Stamp |
|---|---|---|
| | | |

# Section VI. Technical Specifications

1) **Technical Specifications**

2) **General Technical Specifications**

3) **General Packing Instructions**

**Technical Specifications**

## Item 1

## Fortified Blended Flour - Extruded FBF children 6-59 months –Package 6 x 2kgs packs ( qty 115,607 packs) - 693,642 packets of 2kgs

# TECHNICAL SPECIFICATIONS

## 1.0 Scope

This technical specification covers Fortified Blended food (FBF) for children aged 6 months to 59 months, packaged in flexible packaging, suitable for use by Government, humanitarian agencies, and non- governmental organizations for the treatment and prevention of moderate acute malnutrition (MAM) in any cultural setting. The FBF – Children is expected to be used as part of a Nutrition Assessment Counselling and Support (NACS) intervention program for targeted children between the 6 to 59 monthsdiagnosed with MAM in accordance with Integrated Management of Acute Malnutrition guidelines for the management of MAM The FBF Children may be used as the sole source of food, except water and breast milk, during the period of use and to provide adequate energy, protein, fat, vitamins, and minerals to effectively resolveMAM and meets the specifications of the WHO. *Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*. Geneva, 2012.

### 2.0 Background

Malnutrition in infants and young children typically develops during the period between the first 6 and 18 months of age (*5*), and is often associated with intake of low nutrient and energy density diets, consisting predominantly of starch-rich staples that are provided in addition to breast milk. Linear growth and brain development are especially rapid during the first 2 years of life and young children are particularly susceptible to growth failure and developmental delays if they are not breastfed and are fed complementary foods with low nutrient and energy density and poor bioavailability of vitamins and minerals (*6*). Furthermore, preparation of complementary foods in conditions of poor hygiene and sanitation can lead to dietary contamination and frequent infections, which further impairs children's nutritional status.

Children with moderate acute malnutrition have nutritional requirements that differ from non-malnourished and severely malnourished children, that is, they require increased intake of energy and essential nutrients over and above those required by non-malnourished children and, when necessary, treatment for any associated medical conditions.

The dietary management of moderate acute malnutrition should normally be based on the optimal use of locally available nutrient-dense foods to improve the nutritional status of children and prevent them from becoming severely acutely malnourished or failing to thrive (*7*). Intake of nutrients present in inadequate amounts in the habitual diet can be increased through a number of approaches, including dietary diversification and fortification of certain staple foods with vitamins and minerals.

In situations of food shortage, or where some nutrients are not sufficiently available through local foods, caregivers may not be able to provide infants and young children recovering from moderate acute malnutrition with a diet that meets their nutritional needs. This risk of nutrition insecurity may be aggravated in emergencies, droughts and/or displacement situations. In such conditions, specially formulated supplementary foods are usually required to supplement the regular diet and contribute to an improved intake of the required nutrients (*8*). Supplementary foods with varying nutrient compositions have been used to facilitate the recovery of children with moderate acute malnutrition but their efficacy and effectiveness have been suboptimal.

## 3.0 Classification

Moderate acute malnutrition in children is defined as weight-for-height between –3 and –2 Z-scores of the median of the WHO child growth standards without oedema (*1*).
**Supplementary foods** are specially formulated foods, in ready-to-eat or in milled form, which are modified in their energy density, protein, fat or micronutrient composition to help meet the nutritional requirements of specific populations. Supplementary foods are not intended to be the only source of nutrients and are different from complementary foods, in that the latter are intended for progressive adaptation of infants 6 months of age and older to the food of the family. They are also different from food supplements, which refer to vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders or solutions, where national jurisdictions regulate these products as food.
Supplementary foods have been used to rehabilitate moderately malnourished persons or to prevent a deterioration of nutritional status of those most at risk by meeting their additional needs, focusing particularly on children 6–59 months of age, pregnant women and lactating mothers. Examples of supplementary foods include fortified blended foods, which can be used to prepare smooth, ready-to-eat porridges, and lipid-based nutrient supplements.

The FBF Children shall conform to the following list which shall be specified in the contract, or purchase order. The FBF – Children will be used by multiple ethnic and cultural groups. No alcohol, animal products other than dairy products, nor any known allergens except, soy, and dairy products shall be used in the manufacture of these items. According to guidance from WHO the FBF Children"*These foods are usually solid or semi-solid foods with low water content, which can be cooked every day athome in the form of porridge or soups for children.*"

## 4.0 Types:

*Extrusion cooking process is a high temperature and short time process in which moist food material is fed into the extruder where the desired temperature and pressure are obtained over the required period of residence time.*

- Type 1: Extruded FBF Children

This is a precooked product that could be reconstituted at 60°C to a porridge or gruel eliminating the need for prolonged cooking.

- Type II : Ready to eat FBF Children

This is a product that is reconstituted without the need for cooking. The raw materials are preconditioned to specified moisture content and the barrel temperatures during extrusion monitored and controlled to achieve physical and organoleptic properties of ready to eat foods.

**NB**: *This technical specifications unless otherwise stated refer the type I Extruded FBF Children*

## 5.0 MANUFACTURER'S NOTES

**Manufacturer's products *shall meet* the requirements of the:**

- Salient characteristics (Sec. 5.0).
- Analytical requirements: as specified by the purchaser (Sec. 6.0).
- Sachet requirements and examinations (Sec. 7.0).
- Packaging and Labelling specifications (Sec.8.0)
- Manufacturer's product assurance (Sec. 9.0).
- Regulatory requirements (Sec. 10.0).
- Quality assurance provisions: as specified by the purchaser (Sec. 10.1).

### *5.0 Salient characteristics*

#### 5.1.1 Processing

- The FBF Children must be processed in accordance with applicable Codex Alimentarius guidelines i.e. General Principles of food hygiene (CAC/RCP 1-1969)and Code of Hygienic practice for powdered formulae for infants and young children (CAC/RCP 66 – 2008)
- The FBF Children may be processed under HACCP (Hazard Analysis of Critical Control Points), International Organization for Standardization (ISO) Standard 22000, or other standards that assure the safety and quality of the product.
- The dry ingredients shall be Food Chemicals Codex (FCC) purity or U.S. Pharmacopeia (USP) - National Formulary quality, as appropriate, and free from foreign materials.
- Additives shall not exceed levels allowable by the Codex Alimentarius.

#### 5.1.2 Ingredients

- The ingredients for the FBF Children shall comply with the requirements cited below. Any stabilizers or emulsifiers used must be specifically identified, and the product **will contain no animal products** other than dairy products. .
- An energy intake of 25 kcal/kg/day in addition to the requirements of non-malnourished children is likely to support a weight gain of 5 g/kg/day, based on average tissue composition.
- The suggested concentrations for nutrients in the FBF Children are calculated as an example when supplementary foods provide 70% of energy. This does not constitute a recommendation that supplementary foods should provide 70% of the energy intake of moderately malnourished children. The formulation is such that it would be safe and effective if the quantity taken by moderately malnourished children represented 100% of the energy needs and that it would also provide benefit, although of a lesser order of magnitude, if taken in lower quantities. There is no evidence to determine maximum levels for some nutrients. (WHO, 2012)
- The Type I, Extruded FBF children shall have an energy content of 420 to 480 kilocalories (kcal) per 100 grams;
- The energy density of FBF children when they are ready to be consumed should be not less than 0.8 kcal/g.

- The Type I, *Extruded* FBF Children shall have a protein content of between 10.0 to 12.0 percent of kcal and shall have a Protein digestibility-corrected amino acid score >70%. Corresponds to cereal/legume mixtures, milk and animal proteins. The sources of protein may be dairy, protein concentrates, vegetable proteins or protein isolates.
- The Type I, Extruded FBF Children shall have a lipid content between 8 and 9 percent of the kcal. The only added oils allowed will be canola oil or soybean oil. Partially hydrogenated (Trans) fatty acids shall not be used in Extruded FBF Children (CODEX STAN 074-1981, Revised 1-2006).
- The FBF Children shall include omega-6 fattyacid series and should comprise at least 4.5% of energy(5 g/1,000 kcal), the omega-3 fatty acid series should comprise at least 0.5% of energy (0.85 g/1,000 kcal),and the total fat content of the diet used to treat moderately malnourished children should provide 35% to45% of the dietary energy.
- When dairy ingredients are used, at least 8 percent of the protein shall be derived from milk products; such as, but not limited to whole whey protein, dry whole milk, whole fat milk, or non-fat dry milk.
- The FBF Children shall not contain artificial antioxidants and artificial flavorings

### 5.1.3 Water Activity

The Aw of the packaged product shall not be more than 0.60

### 5.1.4 Grains, and legume ingredients

- When grain and/or legume products, are used as an ingredient, the manufacturer shall provide a Certificate of Analysis (COA) as verification of aflatoxin testing.
- Permitted cereal flours are wheat, oats, rice, millet, barley, and sorghum; and manufacturers shall present a COA as verification of applicable mycotoxin testing.

### 5.1.5 Dairy ingredients

The inclusion of dairy ingredients is <u>not mandatory</u> for FBF Children, however, it should be noted that the inclusion of milk powder as an ingredient improves the amino acid profile (has a high Protein Digestibility Corrected Amino Acid Score) and it is a good contributor of bioavailable calcium and potassium. In addition, it has a specific stimulating effect on linear growth and insulin growth factor 1 (IGF-1) levels in the child and does not contain anti-nutrients. (WHO, 2012)

The dairy ingredients shall be derived from milk products such as, but not limited to:

- Whole whey protein;
- Dry whole milk (Codex Standard for Milk Powders and Cream Powder [CODEX STAN 207-1999] 8, non-fat dry milk (Codex Standard for Milk Powders and Cream Powder, [CODEX STAN 207-1999];
- The dry whey and dry whole milk ingredients shall be no more than 9 months old at the time of FBF Children production.
- Dairy ingredient manufacturers must certify that the dairy ingredients provided are melamine free and the manufacturer shall provide a COA to the purchaser.

### 5.1.6 Sweeteners

The Type I – Extruded FBF Children may contain natural sweeteners, except honey.
**Honey is not permitted due to potential toxicity from** *Clostridium botulinum***.**

### 5.1.7 Stability

The Type I, Extruded, shall be stable at temperatures ranging from -15 to 49°C. There shall be no more than slight oil separation throughout the shelf life of the product.

### 5.1.8 Fortification.

- The FBF Children shall be fortified with a vitamin and mineral premix, meeting the requirements in Table I, which is in accordance WHO. *Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*.
- Unless otherwise required in the solicitation, contract, or purchase order, the manufacturer will provide a COA stating that the vitamin and mineral premix meets the requirement listed in Table I.

**Table 1 Nutrient requirements of FBF Children premix**

| Nutrient per 1000 kcal | Unit | Minimum | Maximum |
|---|---|---|---|
| Protein[c] | g | 20 | 43 |
| Fat | g | 25 | 65 |
| **Minerals** | | | |
| Sodium (Na) | mg | — | 500 |
| Potassium (K) | mg | 1500 | 2200 |
| Magnesium (Mg) | mg | 280 | 420 |
| Phosphorus (P)[d] | mg | 850 | 1400 |
| Zinc (Zn) | mg | 20 | 35 |
| Calcium (Ca) | mg | 1000 | 1400 |
| Copper (Cu) | mg | 1 | 3.5 |
| Iron (Fe)[e] | mg | 18 | 30 |
| Iodine (I) | µg | 150 | 350 |
| Selenium (Se)[f] | µg | 35 | 90 |
| Manganese (Mn) | mg | 1 | 2g |
| **Vitamins, water soluble** | | | |
| Thiamin (B1) | mg | > 1 | — |
| Riboflavin (B2) | mg | > 4 | — |
| Pyridoxine (B6) | mg | > 2 | — |
| Cobalamine (B12) | µg | > 5 | — |
| Folate (dietary folate equivalent) | µg | > 400h | — |
| Niacin | mg | > 25 | — |
| Ascorbate (vitamin C) | mg | > 150 | — |
| Pantothenic acid | mg | > 5 | — |
| Biotin | µg | > 20 | — |
| **Vitamins, fat soluble** | | | |
| Retinol (vitamin A) | µg | 2000 | 3000 |
| Cholecalciferol (vitamin D) | µg | 20 | 60 |
| Vitamin E (dl-α tocopherol acetate) | mg | >30 | — |
| Phytomenadione (vitamin K) | µg | >50 | — |
| **Fatty acids** | | | |
| ω-6 fatty acid | % energy | >4.5 | <10 |

| | | | |
|---|---|---|---|
| ω-3 fatty acid | % energy | >0.5 | <3 |
| Trans-fatty acids | % total fat | | 3 |
| **Ratios of nutrients (based on weight)** | | | |
| Ca/P ratio | | 1.0 | 1.5 |
| Zn/Cu ratio | | 5 | 20 |
| Zn/Fe ratio | | 0.8 | 3.5 |
| Vitamin C/Fe | | 3 | 16 |

Table 2 Mineral and vitamin compounds currently used in supplementary foods available on the market for the dietary management of moderate acute malnutrition in children

| **Minerals** | **Chemical form** | **Lipid-based nutrient supplements** | **Fortified blended foods** |
|---|---|---|---|
| Iron | Ferrous sulfate | x | – |
| | Ferrous fumarate[b] | x | x |
| | Coated ferrous fumarate | x | x |
| | Coated ferrous sulfate | x | x |
| | Ferrous gluconate | x | x |
| | NaFeEDTA[a] | x | x |
| Zinc | Zinc sulfate[b] | x | x |
| | Zinc oxide | (x) | (x) |
| Copper[c] | Copper sulfate[d] | x | — |
| | Encapsulated copper sulfate[e] | — | (x) |
| | Copper gluconate[e] | — | (x) |
| Iodine | Potassium iodide[f] | x | x |
| Potassium | Potassium chloride[g] | x | x |
| Magnesium | Magnesium sulfate | x | x |
| | Magnesium oxide[b] | — | x |
| | Magnesium citrate | x | x |
| | Magnesium gluconate | x | x |
| Calcium and phosphate[h] | Dicalcium phosphate | x | x |
| | Tricalcium phosphate | x | x |
| Selenium[i] | Sodium selenite | x | x |
| | Sodium selenate | x | x |
| Manganese | Manganese sulfate | x | x |
| | Manganese gluconate | x | x |

a. The intake of ethylene diamine tetra acetic acid (EDTA) (including other dietary sources) should not exceed 1.9 mg EDTA/kg of body weight/day (15, 16).
b. Bioavailability with low stomach acidity is questioned.
c. Addition of copper is recommended, unless it negatively affects product stability, such as in blended flours. The total amount of zinc in the product should respect the limits of the Zn/Cu ratio and thus depends on whether copper is added to the product.
d. Most soluble form.
e. Stability of fortified blended foods when adding copper needs to be tested.
f. A formulation is needed that avoids caking/lumping.
g. The amount needs to be limited because of taste impact and formulation with anti-caking compound is needed.
h. Best calcium/phosphate ratio.
i. Ensure homogeneity in food because of the low toxicity limit for selenium

| Vitamins | Chemical form | Lipid-based nutrient | Fortified blended |
|---|---|---|---|
| Vitamin A | Dry vitamin A acetate | x | – |
| | Dry vitamin A palmitate | x | – |
| | Dry vitamin A palmitate beadlet | – | x |
| | Dry vitamin A palmitate spray dried | – | x |
| Vitamin D | Dry vitamin $D_3$ spray dried | x | x |
| | Dry vitamin $D_3$ beadlet | – | x |
| | Dry vitamin E acetate 50% | x | x |
| Vitamin K | Dry vitamin K 5% | x | x |
| Vitamin $B_1$[j] | Thiamine hydrochloride | x | — |
| | Thiamine mononitrate | x | x |
| Vitamin $B_2$[k] | Riboflavin | x | — |
| | Riboflavin fine powder | — | x |
| Vitamin $B_6$ | Pyridoxine hydrochloride | x | x |
| Niacin | Niacin amide | x | x |
| Folic acid | Folic acid | x | x |
| Vitamin $B_{12}$ | Vitamin $B_{12}$ 0.1% spray dried or 1% spray dried | x | x |
| Vitamin C | Ascorbic acid[m] | x | x |
| | Ascorbic acid fine powder[n] | x | x |
| | Sodium ascorbate[o] | x | x |
| | Sodium selenate | x | x |
| Pantothenic | Calcium p-panthothenate | x | x |
| Biotin | Biotin 1% | x | x |

j. Cannot be used in flour because of ability to absorb water.
k. Shows as yellow spots, but not visible in lipid-based nutrient supplements
l. Fine powder does not show as yellow spots.
m. Sour taste, disappears after cooking.
n. Less acid taste.
o. Less acid taste, but more costly

### 5.2 Finished product.

#### 5.2.1 Appearance and texture
The Type I, FBF Children shall be free flowing and homogeneous when reconstituted and cooked into porridge; shall be free of lumps; the porridge shall not separate and be free of a gritty, grainy, and sandy texture.

#### 5.2.2 Flavour and odour.
The Type I, FBF Children shall be free from foreign odours and flavours such as, but not limited to burnt, scorched, rancid, malted, sour, or stale. The FBF CHILDREN **shall not** contain any artificial flavouring.

#### 5.2.3 Colour
The Type I, FBF Children shall have a cream to light brown colour. The Type I, FBF Children shall not have a dull, greytinge, or other abnormal cast. The FBF children shall show no evidence of over cooking during extrusion (materially darkened or scorched).

### 5.3 Foreign material.
The FBF Children shall be clean, sound, wholesome, and free from evidence of rodent or insect infestation.

### 5.4 Age requirement (Shelf Life)
- Unless otherwise specified in the solicitation, contract, or purchase order the **FBF Children shall not be more than 90 days old** when it leaves the manufacturer's plant for delivery to purchaser.
- The FBF Children shall have a shelf life of at least 12 months when stored at 25°C.

### 5.5 Product standard
- Unless otherwise specified in the solicitation, contract, or purchase order, a sample of the FBF Children shall be subjected to product demonstration model (PDM) inspection as applicable, in accordance with the requirements of this technical specifications
- The approved sample shall serve as the product standard when evaluating each production lot
- Any failure to conform to the finished product requirements or any appearance or palatability failure shall be cause for rejection of the lot
- Should the manufacturer at any time plan to, or actually produce the product using different formulation or process methodologies from the approved product standard, which result in a product non comparable to the product standard, the manufacturer shall arrange for a replacement PDM approval
- In any event, all product produced must meet all requirements of this technical specifications including product standard comparability.

## 6.0 ANALYTICALREQUIREMENTS.

### 6.1 Proximate and microbiological testing requirements.

Unless otherwise specified in the solicitation, contract, or purchase order the proximate and microbiological testing requirements for the FBF CHILDREN shall be as follows:

| Test | Tolerance |
|---|---|
| Energy | 420 - 480kcal/100g |
| Protein | 10-12 percent of kcal |
| Total Fat | 9 – 10 percent of kcal |
| Water Activity($A_w$) | Less than 0.60 |
| Crude fibre | 3.0% |
| Standard plate count | Not more than 10,000 Colony Forming Units(CFU)/g |
| Aflatoxin | Less than 5 parts per billion (ppb) total Alfatoxin |
| Melamine/ Cyanuric acid | Less than 25 ppb |
| Coliform | Less than 10 CFU/g or less than 3 Most Probable Number (MPN)/g |
| Yeast | Not more than 10 in 1g |
| Mould | Not more than 50 in 1g |
| *Clostridium perfrigens* | Negative |
| *Salmonella* | Negative |
| *E.coli* | Negative |
| *Listeria monocytogenes* | Negative |
| *Staphylococcus aureus* | Negative(coagulase positive) |
| *Cronobacter sakazakii* | Negative in 10g |
| Vitamin A | 0.8 - 1.1 mg/100 g |
| Vitamin B1 | Minimum 0.5 mg/100 g |
| Vitamin C | Minimum 50 mg/100 g |
| Iron | 10 - 14 mg/100 g |

### 6.2 Product verification

When verification of the proximate, chemical, and microbiological testing requirements is specified in the solicitation, contract, or purchase order, analytical testing shall be performed on composite samples.

- For proximate tests the composite sample shall be 500 g (0.5kg).
- For the Aflatoxin test a single composite sample shall be produced from 60 randomly drawn sachets
- For microbiological tests five homogenized composite samples shall be produced from a total of 60 randomly drawn sachets (12 per composite) per production lot / batch

### 6.3 Test portion size for microbiological tests.

The test portions for microbiological tests shall be derived from each of the five composite samples specified in Sec. 5.1.

- The test portion size for testing aerobic plate count, coliform, and yeast and mould shall be 25 g (0.025kg);
- *Salmonella* shall be 125 g (0.125kg);
- *Staphylococcus aureus* (coagulase positive), *Clostridium perfringens*, *E.coli*, and *Listeria monocytogenes* shall be 25 g (0.025kg) each.
- *Cronobacter sakazakii* shall be10 g (0.01kg) each.

## 6.4 Proximate and microbiological testing

When specified in the solicitation, contract, or purchase order, the analysis shall be performed in accordance with the following methods from the AOAC International Official Methods of Analysis (OMA), the FDA Bacteriological Analytical Manual (BAM), or as specified below:

| **Test** | **Method** |
|---|---|
| Protein | 988.05, 992.15 |
| Total Fat | 991.36, 2007.04, 2008.06 |
| Water Activity($A_w$) | 978.18 |
| Standard plate count | 966.23, 990.12, 2008.10, or BAM, Ch 3 |
| Aflatoxin | 990.33, 991.31, 998.03, or 999.07 |
| Melamine/ Cyanuric acid | FDA LIB 4421, FDA LIB 4422, FDA LIB 4423 |
| Coliform | 966.24, 986.33, 989.19, 991.14, 2000.15, 2008.10, or BAM, Ch. 4 |
| Yeast | 997.02, 995.21 |
| Mould | 997.02, 995.21 |
| *Clostridium perfrigens* | 976.30 or BAM, Ch. 16 |
| *Salmonella* | 2004.03, 2003.09, 2011.03, or BAM, Ch. 5 |
| *E.coli* | 966.24, 986.33, 989.19, 991.14, 2000.15, 2009.02, or BAM, Ch.4 |
| *Listeria monocytogenes* | 992.18, 2003.12, 2004.02, or 2010.02 |
| *Staphylococcus aureus* | 2003.07, 2003.08, or 2003.11 |
| *Cronobacter sakazakii* | ISO 22964 or BAM ucm289378 |
| Vitamin A | 2001.13, 2011.11, or 2011.13 |
| Vitamin B1 | 986.27, 957.17 |
| Vitamin C | 967.21, 985.33, or 985.33 |
| Iron | 985.35, 984.27, or 999.10 |

### 6.5 Test results

- The test results for protein shall be reported to the nearest 0.1 percent.
- The test results for aflatoxin shall be reported as negative when the results are not greater than 5 ppb.
- The test results for melamine/cyanuric acid shall be reported as negative when the results are not greater than 25 ppb.
- The test results for Aw shall be reported to the nearest 0.01 value. No individual sample shall have an Aw value exceeding 0.60.
- The test results for standard plate count and yeast and mould shall be reported to the nearest 10 CFU per g.
- The test results for coliform and E. coli shall be reported to the nearest 10 CFU per g or to the nearest MPN per g.
- The test results for *Clostridium perfringens*, *Salmonella, Listeria monocytogenes, Staphylococcus aureus* (coagulase positive), and *Cronobacter sakazakii* shall be reported as negative or positive.
- Test results for Vitamin A, Vitamin B1 (Thiamin), Vitamin C, iron, and fat shall be reported with units and precision as specified or as described in the test method.
- Any result not conforming to the analytical testing shall be cause for rejection of the lot/batch

## 7.0 PACKAGING REQUIREMENTS AND EXAMINATIONS.

### *7.1 Sachet requirements*

#### 7.1.1 Sachet material

- The sachet material shall be capable of being fabricated into sachets.
- The material used for the sachet shall be generally recognized as safe (GRAS) for use with food in accordance with accepted standards and regulations.
- Recycled, recovered, or environmentally preferable materials should be used to the maximum extent possible, provided that the material meets or exceed the material requirements cited herein.
- The size of the sachet shall be 185mm in length and 150mm in width

#### 7.1.2 Oxygen transmission rate

- The oxygen transmission rate ($O_2$TR) of the material shall not exceed 0.06 cc/m2/24 hrs/atm.The $O_2$TR of the material shall be determined in accordance with ASTM D 3985, at 23°C and 50 percent relative humidity (RH).
- Any $O_2$TR exceeding 0.06 cc/m2/24 hrs/atm shall be considered a test failure and shall be cause for rejection of the lot.
- Compliance to the $O_2$TR requirement may be verified by COA from the packaging manufacturer.

#### 7.1.3 Water vapour transmission rate.

- The water vapor transmission rate (WVTR) of the material shall not exceed 0.01 gm/m2/24 hrs.

- The WVTR of the material shall be determined in accordance with ASTM F 372, at 38°C and 90 percent RH.
- Any WVTR exceeding 0.01 gm/m2/24 hrs shall be considered a test failure and shall be cause for rejection of the lot.
- Compliance to the WVTR requirement may be verified by COA from the packaging manufacturer.

**7.1.4 Filled and sealed sachets.**

- Filled and sealed sachets shall be free of damage (such as, but not limited to: tears, cuts, holes, or if a multi-layer laminate is used, abrasions through one or more layers in the sachet material, or leakage through any seal).
- The sachet material shall not transfer any foreign flavour or odour to the product being packaged.

*7.1.4.1 Closure seal*

- The closure seal width shall be a minimum 2.5 mm.
- The closure seal shall be free of impression or design on the seal surface that would conceal or impair visual detection of seal defects.
- The closure seal shall be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease that reduces the closure seal width to less than 1.6 mm at any location along its continuous path.

*7.1.4.2 Internal pressure*

The sachets shall be filled and hermetically sealed such that they shall withstand the applicable pressure for 30 seconds.

**7.2 Filled and sealed sachet examination**

The filled and sealed sachets shall be examined for the defects listed in Table 3 utilizing ANSI/ASQC Z1.4, Sampling Procedures and Tables for Inspection by Attributes, in effect on the date of the solicitation. The lot size shall be expressed in sachets. The sample unit shall be one filled and sealed sachet. The inspection level shall be 1 and the acceptable quality level (AQL), expressed in terms of defects per hundred units shall be1.5 for major defects and 4.0 for minor defects. A minimum of 200 samples shall be examined for critical defects. The finding of any critical defect shall be cause for rejection of the lot

*Notes*

- Any evidence of insect or rodent infestation shall be cause for rejection of the lot.
- A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using the item.
- A major defect is a defect, other than critical, that is likely to result in failure, or to reduce materially the usability of the unit of product for its intended purpose.
- A minor defect is a defect that is not likely to reduce materially the usability of the unit of product for its intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the unit.
- Aberrations in sachet material or heat seals include:
    - Major fold-over wrinkles or severe wrinkles, that extend into heat seal area and reduce effective seal width to less than1.6 mm or
    - Severe wrinkles in the body of the sachet along the inside edges of the heat seals.

- Sachets exhibiting one or more of these aberrations shall be tested in accordance with internal pressure testing procedures

Table 3 Filled and Sealed sachets defects

| Category | | | Defect |
|---|---|---|---|
| **Critical** | **Major** | **Minor** | **Both sachets** |
| 1 | | | Tear, hole, or open seal |
| 2 | | | Aberrations in sachet material or heat seals resulting from heat sealing, sachet fabrication, hot filling or heat processing that reduce the effective closure seal width to less than 1.6 mm (1/16 in) |
| | 101 | | Seal width not as specified |
| | 102 | | Not heat sealed as specified |
| | 103 | | Inside sachet dimensions not as specified |
| | 104 | | Closure seal not located as specified |
| | 105 | | Closure or top seal extends into or below tear notch location |
| | 106 | | Not clean |
| | 107 | | Required labeling or marking missing, incorrect, illegibleor that smudges |
| | 108 | | Embossed code marking not located as specified |
| | 109 | | Distance between inside edge of tear notch or serrationsand inside edge of seal is less than 4.7625 mm (3/16 in) |
| | 110 | | Presence of entrapped matter (for example, productresidue) that reduces the effective closure seal to less than1.6 mm (1/16 in) wide |
| | | 201 | Tear notch or serrations missing |
| | | 202 | Tear notch or serrations not located as specified |
| | | 203 | Depth of tear notch or serrations not as specified |
| | | 204 | Excess sachet material at edges exceeds 4.7625 mm (3/16in) |
| 3 | | | Swollen sachet |
| | 111 | | Sachet has foreign odour |
| | 112 | | Evidence of loss of vacuum |

### 7.3 Sachet leakage and delamination examination

- All exterior surfaces and edges of the filled and sealed sachet shall be examined visually for product leakage while applying a manual kneading action which forces the product against the interior sachet surface in the area being observed.
- After leakage testing, the sachet shall be examined for evidence of delamination.
- Any product leakage from the sachet or evidence of delamination of the sachet shall be classified as a major defect, except delamination of outer ply when located in the seal area 1.6 mm or further from the food product edge of seal.
- Sachets exhibiting this type of delamination shall be tested by manually flexing the delaminated area 10 times. The area of delamination shall be held between the thumb and forefinger of each hand with both thumbs and forefingers touching each other.
- The delamination area shall then be rapidly flexed by rotating both hands in alternating clockwise - counter clockwise directions.
- Care shall be exercised when flexing delaminated area near the tear notches to avoid tearing the sachet material. After flexing, the separated outer ply shall be grasped

between the thumb and forefinger and gently lifted toward the food product edge of the seal.

- If the separated area is too small to be held between thumb and forefinger, a number two stylus shall be inserted into the delaminated area and a gentle lifting force applied against the outer ply.
- If separation of the outer ply can be made to extend to less than 1.6 mm (1/16 in) from the product edge of the seal with no discernible resistance to the gentle lifting, the sachet shall be rejected.
- The lot size shall be expressed in sachets.
- The sample unit shall be one filled and sealed sachet.
- The inspection level shall be 1 and the AQL, expressed in terms of defects per hundred units, shall be 0.65 for major defects

**7.4 Internal pressure test**

- Internal pressure resistance shall be determined by pressurizing the sachets while they are restrained between two rigid plates.
- The plates shall be 12.7 + 1.6 mm (1/2 + 1/16 in) apart or 25.4 + 1.6 mm (1 + 1/16 in) apart. If a three-seal tester (one thatpressurizes the sachet through an open end) is used, the closure seal shall be cut off for testing the side and bottom seals of the sachet; for testing of the closure seal, the bottom seal shall be cut off.
- The sachets shall be emptied prior to testing. If a four-seal tester (designed to pressurize filled sachets by use of a hypodermic needle through the sachet wall) is used, all four seals can be tested simultaneously.
- Pressure shall be applied gradually until 17 psig pressure is reached. The17 psig pressure shall be held constant for 30 seconds and then released.
- The sachets shall then be examined for separation or yield of the seals.
- Any rupture of the sachet or evidence of seal separation greater than 1.6 mm in the sachet manufacturer's seal shall be considered a test failure.
- Any seal separation that reduces the effective closure seal width to less than 1.6 mm shall be considered a test failure and shall be cause for rejection of the lot.

**7.5 Net weight examination**

- The net weight of the filled and sealed sachets shall be determined by weighing each sample unit on a suitable scale tared with a representative empty sachet.
- Any individual net weight of less than 200g shall be classified as a minordefect.
- The lot size shall be expressed in sachets. The sample unit shall be one filled and sealed sachet
- The inspection level shall be S-3 and the AQL, expressed in terms of defects per hundred units, shall be 2.5
- The results shall be reported to the nearest 0.1 g. In addition, thelot shall be rejected if the sample average net weight is less than 200 g.

**8.0 Packaging and Labelling specifications**

### 8.1 General Requirements

- The material used for packaging shall be generally recognized as safe (GRAS) for use with food in accordance in accordance with good manufacturing practices (see attached)or other standards and regulationswith accepted standards and regulations.
- Recycled, recovered, or environmentally preferable materials should be used to the maximum extent possible, provided that the material meets or exceed the material requirements cited herein
- All labelling, package inserts and specifications shall be in English
- Each Secondary package should have a Product information insert in English containing:
    - Product Name (both International Non-proprietary Name)
    - Nutritional information
    - Composition / ingredients
    - Indications
    - Dosage and administration
    - Contraindications
    - Precautions
    - Adverse effects
- All branding and marking for the primary secondary and tertiary packages shall comply to the Ministry of Health Branding and Marking plan requirements

### 8.2 Primary package labelling requirements

The primary package is a sachet of 200g ; 185mm length by 150mm width

- Product Name (International Non-proprietary Name)
- Nutritional information
- Composition / ingredients
- Batch number
- Manufacturing date
- Best before date
- Directions for use: Should indicate “For single use only”
- Dosage
- Should have a label “**GOK - Not for sale**” clearly labelled in a place where it is visible.

### 8.3 Secondary package requirements and labelling

- The secondary package for FBF Children is a transparent low density polyethylene (LDPE) bag300mm length x 480 mm width)
- The LDPE bag contain 15 sachets of200g each of FBF Children and each bag shall meet the following labelling requirements
    - minimum gross weight of a bag should be 3000g or 3 kg
    - Product Name (International Non-proprietary Name)
    - Batch number
    - Manufacturing date
    - Best before date
    - Storage instructions

    - Manufacturers contact information and physical address
    - Should have a label “GOK - Not for sale” clearly labelled in a place where it is visible
- Corrugated Fibreboard Shipping boxes (Shipping Container) – Shall contain 5bags of 3kg of FBF Children. The shipping container will be a regular slotted container constructed of a minimum 450lb (204kg) burst test, corrugated fibreboard.
- The outside dimensions of each shipping container will be no less than 280mm in height, and cases should be designed to the optimal dimensions to fill at least 80% of the cubic capacity of a 20 foot intermodal when stacked two pallets high.
- Cases of dimensions shall be no less280mm. height x 460mm. length x 275 mm. width and will have been found to comply with this requirement (when stacked 6 cases per layer and five tiers high on a standard pallet).
- Other case dimensions will be considered providing the height of the case does not exceed 300mm and the pallets, when double stacked, can fill at least 80% of the cubic capacity of a 20 foot intermodal
- The corrugated fibreboard will meet the following labelling specifications:
    - Product Name (both International Non-proprietary Name)
    - Batch number
    - Manufacturing date
    - Best before date
    - Quantity of the tertiary package will be determined by weight and should contain 5bags of 3kg each of FBF Children, the carton should have a minimum gross weight of 15kg
    - Storage instructions
    - Manufacturers contact information and physical address
    - Should have a label “GOK - Not for sale” clearly labelled in a place where it is visible.

## 9.0 MANUFACTURER’S PRODUCT ASSURANCE

- The manufacturer shall certify that the FBF Children provided, meets the requirements of this technical specifications
- The purchaser or procuring entity shall require proof of conformance

## 10.0 REGULATORY REQUIREMENTS

- The delivered FBF Children shall comply with all applicable Government , County, and local by-laws and regulations relating to the manufacturing, storage, and distribution of packaged foods for human consumption, including all applicable provisions of Food, Drugs and Chemical Substances Act Chapter 254 (2012), Public Health Act Cap 242 (2012) and regulations promulgated thereunder
- All certificates of analysis for both raw materials and delivered FBF Children will be from a Kenya National Accreditation Services (KENAS) accredited laboratories or from labs with valid ISO 17025:2005 certification.

## 10.1 QUALITY ASSURANCE PROVISIONS

The product manufacturer shall be required to provide evidence, by certificate, that the manufacturing plant has undertaken one of the following quality assurance measures within 12 months prior to providing a bid, or no later than 10 business days from the date of awarding of the contract.
Failure to provide this documentation within the proper time frame may result in the contract being terminated for cause

## 10.2 ISO 22000 Assessment

- A supplier quality assessment (SQA) verifies the manufacturer's capability to produce products in a clean sanitary environment in accordance with ISO 22002-1:2009 – *Prerequisite programmes on food safety part 1 : Food Manufacturing* and verifies that the manufacturer has in place an internal quality assurance and food safety program
- A supplier quality audit (SQA) based on ISO 22000:2005 by a third party auditing service is required within 12 months prior to the date of the awarding of the contract.
- The food manufacturer must have attained an SQA score of 75% or above
- The food manufacturer must be ISO 22000 certified
- The relevant certificate/letter bearing the name of any of the above bodies must be submitted for scrutiny

## 10.3 Kenya Bureau of Standards (KEBS) certification

- KEBS is the standards authority in Kenya and therefore all food must be approved as safe for human consumption
- The locally produced FBF Children must have the Standardization mark as this is a mandatory product certification scheme for locally manufactured products provided for under section 10 of the Standards Act Cap 496, Laws of Kenya

## Item 2.

## Ready to Use Therapeutic Food (RUTF spread) - sachets 92gms (150 sachets/carton) - qty 14,815 cartons (sachets 2,222,250)

### 1.0 Scope

This technical specification covers ready-to-use therapeutic foods (RUTF), packaged in flexible packaging, suitable for use by Government, humanitarian agencies, and non- governmental organizations for the treatment of severe acute malnutrition (SAM) in any cultural setting. The RUTF is expected to be used in the Integrated Management of Acute Malnutrition Program, including children and adults with SAM who are free from complications and who have appetite, in accordance with Integrated Management of Acute Malnutrition guidelines for the outpatient care and management of SAM. The RUTF may be used in climatic extremes from the arctic to tropical zones and may be the sole source of food, except water and breast milk, during the period of use and to provide adequate energy, protein, fat, vitamins, and minerals to effectively treat SAM and meets the specifications of the United Nations Children's Fund (UNICEF) Supply Catalogue: https://supply.unicef.org/.

### 2.0 Classification

The RUTF shall conform to the following list which shall be specified in the solicitation, contract, or purchase order. The RUTF will be used by multiple ethnic and cultural groups. No alcohol, animal products other than dairy products, nor any known allergens except peanuts, soy, tree nuts, and dairy products shall be used in the manufacture of these items. According to UN guidance the RUTF "*should be soft or crushable and should be easy for young children to eat without any preparation*."

### 3.0 Types:

- Type 1 : RUTF Spread
- Type II : RUTF Bar

**NB:** ***This technical specifications unless otherwise stated refer the type I RUTF spread***

# Manufacturer's notes

**Manufacturer's products *shall meet* the requirements of the:**

- Salient characteristics (Sec. 4.1).
- Analytical requirements: as specified by the purchaser (Sec. 5.0).
- Sachet requirements and examinations (Sec. 6.1).
- Manufacturer's product assurance (Sec. 8).
- Regulatory requirements (Sec. 9).
- Quality assurance provisions: as specified by the purchaser (Sec. 10).

### 4.1 Salient characteristics

#### 4.1.1 Processing

- The RUTF must be processed in accordance with applicable Codex Alimentarius guidelines ie General Principles of food hygiene (CAC/RCP 1-1969)and Code of Hygienic practice for powdered formulae for infants and young children (CAC/RCP 66 – 2008)
- The RUTF may be processed under HACCP (Hazard Analysis of Critical Control Points), International Organization for Standardization (ISO) Standard 22000, or other standards that assure the safety and quality of the product.
- The dry ingredients shall be Food Chemicals Codex (FCC) purity or U.S. Pharmacopeia (USP) - National Formulary quality, as appropriate, and free from foreign materials.
- Additives shall not exceed levels allowable by the Codex Alimentarius.

#### 4.1.2 Ingredients

The ingredients for the RUTF shall comply with the requirements cited below. Any stabilizers or emulsifiers used must be specifically identified, and the product **will contain no animal products** other than dairy products.

- The Type I, RUTF spread shall have an energy content of 520 to 550 kilocalories (kcal) per 100 grams.
- The Type I, RUTF spread formula shall have a protein content of 10.0 to 12.0 percent of kcal and shall have a protein digestibility corrected amino acid score (PDCAAS) of 1.0. The sources of protein may be dairy, protein concentrates, vegetable proteins or protein isolates.
- The Type I, RUTF spread shall have a lipid content between 45.0 and 60.0 percent of the kcal. The only added oils allowed will be canola oil or soybean oil. Partially hydrogenated (Trans) fatty acids shall not be used in RUTF spreads (CODEX STAN 074-1981, Revised 1-2006).
- At least 50 percent of the protein shall be derived from milk products; such as, but not limited to whole whey protein, dry whole milk, whole fat milk, or non-fat dry milk.
- The RUTF shall not contain artificial antioxidants and artificial flavourings

#### 4.1.3 Water Activity

The Aw of the packaged product shall not be more than 0.60

#### 4.1.4 Nuts, grains, and legume ingredients

- When nut, grain and/or legume products, are used as an ingredient, the manufacturer shall provide a Certificate of Analysis (COA) as verification of aflatoxin testing.

- Permitted cereal flours are wheat, oats, rice, millet, barley, and sorghum; and manufacturers shall present a COA as verification of applicable mycotoxin testing.

#### 4.1.5 Dairy ingredients

The dairy ingredients shall be derived from milk products such as, but not limited to:

- Whole whey protein (FDA's Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS) for Whey Protein Concentrate [21 CFR § 184.1979(c)], U.S. Standards for Dry Whey, and USDA Specifications for Dry Whey Protein Concentrate);
- Drywhole milk (Codex Standard for Milk Powders and Cream Powder [CODEX STAN 207-1999] 8, FDA's Standard of Identity for Dry Whole Milk [21 CFR §131.147], and the U.S. Standards for Dry Whole Milk); whole fat milk ( FDA's Standard of Identity for Milk [21 CFR § 131.110]; non-fat dry milk (Codex Standard for Milk Powders and Cream Powder, [CODEX STAN 207-1999];
- FDA's Standard of Identity for Non-fat Dry Milk [21 CFR § 131.125] and FDA's Standards of Identity for Non-fat Dry Milk fortified with vitamins A and D [21 CFR § 131.127]).
- The dry whey and dry whole milk ingredients shall meet the U.S. Standard for Extra Grade as defined in the appropriate U.S. Standards for Grade and shall be no more than 9 months old at the time of RUTF production.
- Dairy ingredient manufacturers must certify that the dairy ingredients provided are melamine free and the manufacturer shall provide a COA to the purchaser.

#### 4.1.6 Sweeteners

The RUTF may contain natural sweeteners, except honey.
**Honey is not permitted due to potential toxicity from** *Clostridium botulinum***.**

#### 4.1.7 Stability

The Type I, RUTF spread, shall be stable at temperatures ranging from -15 to 49°C. There shall be no more than slight oil separation throughout the shelf life of the product.

### 4.1.8 Fortification.

- The RUTF shall be fortified with a vitamin and mineral premix, meeting the requirements in Table I, which is in accordance with the UNICEF requirements for RUTF.
- The vitamins and minerals used in the premix shall be USP-FCC compliant unless otherwise specified and specific vitamins shall be encapsulated as necessary to provide the required product shelf life and to avoid objectionable odours and flavours.
- Unless otherwise required in the solicitation, contract, or purchase order, the manufacturer will provide a COA stating that the vitamin and mineral premix meets the requirement listed in Table I.

Table 4 Nutrient requirements of RUTF premix

| **Nutrient** | **min/100 g** | **Max/100g** |
|---|---|---|
| Vitamin A | 0.8 mg | 1.1 mg |
| Vitamin $B_1$ | 0.5 mg | – |
| Vitamin $B_2$ | 1.6 mg | – |
| Niacin | 5.0 mg | – |
| Vitamin $B_6$ | 0.6 mg | – |
| Vitamin $B_{12}$ | 1.6 µg | – |
| Biotin | 60 µg | – |
| Folic Acid | 200 µg | – |
| Pantothenic Acid | 3.0 mg | – |
| Vitamin C | 50 mg | – |
| Vitamin D3 | 15 µg | 20 µg |
| Vitamin E | 20 mg | – |
| Vitamin K1 | 15 µg | 30 µg |
| Calcium | 300 mg | 600 mg |
| Copper | 1.4 mg | 1.8 mg |
| Iodine | 70 µg | 140 µg |
| Iron (as encapsulated ferrous | 10 mg | 14 mg |
| Magnesium | 80 mg | 140 mg |
| Phosphorus (excluding phytate) | 300 mg | 600 mg |
| Potassium | 1,100 mg | 1,400 mg |
| Selenium | 20 µg | 40 µg |
| Sodium | | 290 mg |
| Zinc | 11 mg | 14 mg |

Table 5 Chemical forms of nutrients

| Nutrient | Possible chemical forms | Preferred chemical form |
|---|---|---|
| Vitamin A | Retinyl acetate or palmitate or beta-carotene | Retinyl acetate |
| Vitamin $B_1$ | | Thiamin hydrochloride (paste) or thiamin mononitrate (bars) |
| Vitamin $B_2$ | | Riboflavin |
| Niacin | | Niacinamide |
| Vitamin $B_6$ | --- | Pyridoxine HCl |
| Vitamin $B_{12}$ | Cyanocobalamin (diluted form[0.1% or 1%] with 100% active particles spray dried form) | Cyanocobalamin (0.1%) |
| Nutrient | Possible chemical forms | Preferred chemical form |
| Biotin | | --- |
| Folic Acid | | Ptroylmonoglutamic acid |
| Vitamin C | | L-ascorbic acid |
| Vitamin $D_3$ | | Cholecalciferol (D3) |
| Vitamin E | | DL-alpha-tocopherol acetate |
| Vitamin K1 | --- | Phylloquinon 5% |
| Calcium | Ca phosphate, Ca carbonate (Calcium salts containing well absorbed anions such as chloride should be avoided as they may induce acidosis) | Tricalcium Phosphate |
| Copper | Copper sulfate, copper gluconate | Encapsulated copper sulfate |
| Iodine | --- | Potassium Iodide |
| Iron (paste) | Encapsulated ferrous sulfate, encapsulated ferrous fumarate | Encapsulated ferrous sulfate |
| Iron (bars) | Na Fe EDTA (subject to Codex limits) | Na Fe EDTA |
| Magnesium | | Magnesium sulfate |
| Phosphorus | | Dipotassium Phosphate, Tricalcium Phosphate |
| Potassium | | Potassium chloride |
| Selenium | Sodium selenite | Sodium selenite (1.5%) |
| Sodium | | |
| Zinc | Zinc sulfate, zinc gluconate, zinc oxide | Zinc sulfate |

### 4.2 Finished product.

#### 4.2.1 Appearance and texture
The Type I, RUTF spread shall have a smooth homogeneous finish and shall be free of lumps; the oil shall not separate and be free of a gritty, grainy, and sandy texture.

#### 4.2.2 Flavour and odour.
The Type I, RUTF spread shall be free from foreign odours and flavours such as, but not limited to burnt, scorched, rancid, malted, sour, or stale. The RUTF **shall not** contain any artificial flavouring.

#### 4.2.3 Colour
The Type I, RUTF spread shall have a cream to light brown colour. The Type I, RUTF spread shall not have a dull, greytinge, or other abnormal cast. The RUTFs shall show no evidence of excessive heating (materially darkened or scorched).

### 4.3 Foreign material.
The RUTF shall be clean, sound, wholesome, and free from evidence of rodent or insect infestation.

4.4 Age requirement (Shelf Life)

- Unless otherwise specified in the solicitation, contract, or purchase order the **RUTF shall not be more than 90 days old** when it leaves the manufacturer's plant for delivery to purchaser.
- The RUTF spread shall have a shelf life of at least 24 months when stored at 25°C.

### 4.5 Product standard

- Unless otherwise specified in the solicitation, contract, or purchase order, a sample of the RUTF shall be subjected to product demonstration model (PDM) inspection as applicable, in accordance with the requirements of thistechnical specifications
- The approved sample shall serve as the product standard when evaluating each production lot
- Any failure to conform to the finished product requirements or any appearance or palatability failure shall be cause for rejection of the lot
- Should the manufacturer at any time plan to, or actually produce the product using different formulation or process methodologies from the approved product standard, which result in a product non comparable to the product standard, the manufacturer shall arrange for a replacement PDM approval
- In any event, all product produced must meet all requirements of this technical specifications including product standard comparability.

## 5.0 ANALYTICALREQUIREMENTS.

### 5.1 Proximate and microbiological testing requirements.

Unless otherwise specified in the solicitation, contract, or purchase order the proximate and microbiological testing requirements for the RUTF shall be as follows:

| Test | Tolerance |
|---|---|
| Energy | 520 - 550kcal/100g |
| Protein | 10-12 percent of kcal |
| Total Fat | 45-60 percent of kcal |
| Water Activity($A_w$) | Less than 0.60 |
| Standard plate count | Not more than 10,000 Colony Forming Units(CFU)/g |
| Aflatoxin | Less than 5 parts per billion (ppb) total Alfatoxin |
| Melamine/ Cyanuric acid | Less than 25 ppb |
| Coliform | Less than 10 CFU/g or less than 3 Most Probable Number (MPN)/g |
| Yeast | Not more than 10 in 1g |
| Mould | Not more than 50 in 1g |
| *Clostridium perfrigens* | Negative |
| *Salmonella* | Negative |
| *E.coli* | Negative |
| *Listeria monocytogenes* | Negative |
| *Staphylococcus aureus* | Negative(coagulase positive) |
| *Cronobacter sakazakii* | Negative in 10g |
| Vitamin A | 0.8 - 1.1 mg/100 g |
| Vitamin B1 | Minimum 0.5 mg/100 g |
| Vitamin C | Minimum 50 mg/100 g |
| Iron | 10 - 14 mg/100 g |

### 5.2 Product verification

When verification of the proximate, chemical, and microbiological testing requirements is specified in the solicitation, contract, or purchase order, analytical testing shall be performed on composite samples.

- For proximate tests the composite sample shall be 454 g (1 lb).
- For the Aflatoxin test a single composite sample shall be produced from 60 randomly drawn sachets
- For microbiological tests five homogenized composite samples shall be produced from a total of 60 randomly drawn sachets (12 per composite) per production lot / batch

### 5.3 Test portion size for microbiological tests.

The test portions for microbiological tests shall be derived from each of the five composite samples specified in Sec. 5.1.

- The test portion size for testing aerobic plate count, coliform, and yeast and mould shall be 25 g (0.88 oz);
- *Salmonella* shall be 125 g (4.4 oz);
- *Staphylococcus aureus* (coagulase positive), *Clostridium perfringens*, *E.coli*, and *Listeria monocytogenes* shall be 25 g (0.88 oz) each.
- *Cronobacter sakazakii* shall be10 g (0.32 oz) each.

### 5.4 Proximate and microbiological testing

When specified in the solicitation, contract, or purchase order, the analysis shall be performed in accordance with the following methods from the AOAC International Official Methods of Analysis (OMA), the FDA Bacteriological Analytical Manual (BAM), or as specified below:

| **Test** | **Method** |
|---|---|
| Protein | 988.05, 992.15 |
| Total Fat | 991.36, 2007.04, 2008.06 |
| Water Activity($A_w$) | 978.18 |
| Standard plate count | 966.23, 990.12, 2008.10, or BAM, Ch 3 |
| Aflatoxin | 990.33, 991.31, 998.03, or 999.07 |
| Melamine/ Cyanuric acid | FDA LIB 4421, FDA LIB 4422, FDA LIB 4423 |
| Coliform | 966.24, 986.33, 989.19, 991.14, 2000.15, 2008.10, or BAM, Ch. 4 |
| Yeast | 997.02, 995.21 |
| Mould | 997.02, 995.21 |
| *Clostridium perfrigens* | 976.30 or BAM, Ch. 16 |
| *Salmonella* | 2004.03, 2003.09, 2011.03, or BAM, Ch. 5 |
| *E.coli* | 966.24, 986.33, 989.19, 991.14, 2000.15, 2009.02, or BAM, Ch.4 |
| *Listeria monocytogenes* | 992.18, 2003.12, 2004.02, or 2010.02 |
| *Staphylococcus aureus* | 2003.07, 2003.08, or 2003.11 |
| *Cronobacter sakazakii* | ISO 22964 or BAM ucm289378 |
| Vitamin A | 2001.13, 2011.11, or 2011.13 |
| Vitamin B1 | 986.27, 957.17 |
| Vitamin C | 967.21, 985.33, or 985.33 |
| Iron | 985.35, 984.27, or 999.10 |

### 5.5 Test results

- The test results for protein shall be reported to the nearest 0.1 percent.
- The test results for aflatoxin shall be reported as negative when the results are not greater than 5 ppb.
- The test results for melamine/cyanuric acid shall be reported as negative when the results are not greater than 25 ppb.
- The test results for Aw shall be reported to the nearest 0.01 value. No individual sample shall have an Aw value exceeding 0.60.
- The test results for standard plate count and yeast and mould shall be reported to the nearest 10 CFU per g.
- The test results for coliform and E. coli shall be reported to the nearest 10 CFU per g or to the nearest MPN per g.
- The test results for *Clostridium perfringens*, *Salmonella, Listeria monocytogenes, Staphylococcus aureus* (coagulase positive), and *Cronobacter sakazakii* shall be reported as negative or positive.
- Test results for Vitamin A, Vitamin B1 (Thiamin), Vitamin C, iron, and fat shall be reported with units and precision as specified or as described in the test method.
- Any result not conforming to the analytical testing shall be cause for rejection of the lot/batch

## 6.0 PACKAGING REQUIREMENTS AND EXAMINATIONS.

### 6.1 Sachet requirements

#### 6.1.1 Sachet material

- The sachet material shall be capable of being fabricated into sachets.
- The material used for the sachet shall be generally recognized as safe (GRAS) for use with food in accordance in accordancewith 21 CFR Parts 170-199 (see attached)or other standards and regulationswith accepted standards and regulations.
- Recycled, recovered, or environmentally preferable materials should be used to the maximum extent possible, provided that the material meets or exceed the material requirements cited herein.

#### 6.1.2 Oxygen transmission rate

- The oxygen transmission rate ($O_2$TR) of the material shall not exceed 0.06 cc/m2/24 hrs/atm.The $O_2$TR of the material shall be determined in accordance with ASTM D 3985, at 23°C (73°F) and 50 percent relative humidity (RH).
- Any $O_2$TR exceeding 0.06 cc/m2/24 hrs/atm shall be considered a test failure and shall be cause for rejection of the lot.
- Compliance to the $O_2$TR requirement may be verified by COA from the packaging manufacturer.

#### 6.1.3 Water vapour transmission rate.

- The water vapor transmission rate (WVTR) of the material shall not exceed 0.01 gm/m2/24 hrs.
- The WVTR of the material shall be determined in accordance with ASTM F 372, at 38°C (100°F) and 90 percent RH.
- Any WVTR exceeding 0.01 gm/m2/24 hrs shall be considered a test failure and shall be cause for rejection of the lot.

- Compliance to the WVTR requirement may be verified by COA from the packaging manufacturer.

**6.1.4 Filled and sealed sachets.**

- Filled and sealed sachets shall be free of damage (such as, but not limited to: tears, cuts, holes, or if a multi-layer laminate is used, abrasions through one or more layers in the sachet material, or leakage through any seal).
- The sachet material shall not transfer any foreign flavour or odour to the product being packaged.

**6.1.4.1 Closure seal**

- The closure seal width shall be a minimum 2.5 mm (0.10 in).
- The closure seal shall be free of impression or design on the seal surface that would conceal or impair visual detection of seal defects.
- The closure seal shall be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease that reduces the closure seal width to less than 1.6 mm (1/16 in) at any location along its continuous path.

**6.1.4.2 Internal pressure**

The sachets shall be filled and hermetically sealed such that they shall withstand the applicable pressure for 30 seconds.

**6.2 Filled and sealed sachet examination**

The filled and sealed sachets shall be examined for the defects listed in Table 3 utilizing ANSI/ASQC Z1.4, Sampling Procedures and Tables for Inspection by Attributes, in effect on the date of the solicitation. The lot size shall be expressed in sachets. The sample unit shall be one filled and sealed sachet. The inspection level shall be 1 and the acceptable quality level (AQL), expressed in terms of defects per hundred units shall be1.5 for major defects and 4.0 for minor defects. A minimum of 200 samples shall be examined for critical defects. The finding of any critical defect shall be cause for rejection of the lot

**Notes**

- Any evidence of insect or rodent infestation shall be cause for rejection of the lot.
- A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using the item.
- A major defect is a defect, other than critical, that is likely to result in failure, or to reduce materially the usability of the unit of product for its intended purpose.
- A minor defect is a defect that is not likely to reduce materially the usability of the unit of product for its intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the unit.
- Aberrations in sachet material or heat seals include:
    - Major fold-over wrinkles or severe wrinkles, that extend into heat seal area and reduce effective seal width to less than1.6 mm (1/16 in); or
    - Severe wrinkles in the body of the sachet along the inside edges of the heat seals.
    - Sachets exhibiting one or more of these aberrations shall be tested in accordance with internal pressure testing procedures

Table 6 Filled and Sealed sachets defects

| Category | | | Defect |
|---|---|---|---|
| **Critical** | **Major** | **Minor** | **Both sachets** |
| 1 | | | Tear, hole, or open seal |
| 2 | | | Aberrations in sachet material or heat seals resulting from heat sealing, sachet fabrication, hot filling or heat processing that reduce the effective closure seal width to less than 1.6 mm (1/16 in) |
| | 101 | | Seal width not as specified |
| | 102 | | Not heat sealed as specified |
| | 103 | | Inside sachet dimensions not as specified |
| | 104 | | Closure seal not located as specified |
| | 105 | | Closure or top seal extends into or below tear notch location |
| | 106 | | Not clean |
| | 107 | | Required labeling or marking missing, incorrect, illegibleor that smudges |
| | 108 | | Embossed code marking not located as specified |
| | 109 | | Distance between inside edge of tear notch or serrationsand inside edge of seal is less than 4.7625 mm (3/16 in) |
| | 110 | | Presence of entrapped matter (for example, productresidue) that reduces the effective closure seal to less than1.6 mm (1/16 in) wide |
| | | 201 | Tear notch or serrations missing |
| | | 202 | Tear notch or serrations not located as specified |
| | | 203 | Depth of tear notch or serrations not as specified |
| | | 204 | Excess sachet material at edges exceeds 4.7625 mm (3/16in) |
| 3 | | | Swollen sachet |
| | 111 | | Sachet has foreign odour |
| | 112 | | Evidence of loss of vacuum |

### 6.3 Sachet leakage and delamination examination

- All exterior surfaces and edges of the filled and sealed sachet shall be examined visually for product leakage while applying a manual kneading action which forces the product against the interior sachet surface in the area being observed.
- After leakage testing, the sachet shall be examined for evidence of delamination.
- Any product leakage from the sachet or evidence of delamination of the sachet shall be classified as a major defect, except delamination of outer ply when located in the seal area 1.6 mm (1/16 in) or further from the food product edge of seal.
- Sachets exhibiting this type of delamination shall be tested by manually flexing the delaminated area 10 times. The area of delamination shall be held between the thumb and forefinger of each hand with both thumbs and forefingers touching each other.
- The delamination area shall then be rapidly flexed by rotating both hands in alternating clockwise - counter clockwise directions.
- Care shall be exercised when flexing delaminated area near the tear notches to avoid tearing the sachet material. After flexing, the separated outer ply shall be grasped between the thumb and forefinger and gently lifted toward the food product edge of the seal.
- If the separated area is too small to be held between thumb and forefinger, a number two stylus shall be inserted into the delaminated area and a gentle lifting force applied against the outer ply.

- If separation of the outer ply can be made to extend to less than 1.6 mm (1/16 in) from the product edge of the seal with no discernible resistance to the gentle lifting, the sachet shall be rejected.
- The lot size shall be expressed in sachets.
- The sample unit shall be one filled and sealed sachet.
- The inspection level shall be 1 and the AQL, expressed in terms of defects per hundred units, shall be 0.65 for major defects

**6.4 Internal pressure test**

- Internal pressure resistance shall be determined by pressurizing the sachets while they are restrained between two rigid plates.
- The plates shall be 12.7 + 1.6 mm (1/2 + 1/16 in) apart or 25.4 + 1.6 mm (1 + 1/16 in) apart. If a three-seal tester (one thatpressurizes the sachet through an open end) is used, the closure seal shall be cut off for testing the side and bottom seals of the sachet; for testing of the closure seal, the bottom seal shall be cut off.
- The sachets shall be emptied prior to testing. If a four-seal tester (designed to pressurize filled sachets by use of a hypodermic needle through the sachet wall) is used, all four seals can be tested simultaneously.
- Pressure shall be applied gradually until 17 psig pressure is reached. The17 psig pressure shall be held constant for 30 seconds and then released.
- The sachets shall then be examined for separation or yield of the seals.
- Any rupture of the sachet or evidence of seal separation greater than 1.6 mm (1/16 in) in the sachet manufacturer's seal shall be considered a test failure.
- Any seal separation that reduces the effective closure seal width to less than 1.6 mm (1/16 in) (see Table 3) shall be considered a test failure and shall be cause for rejection of the lot.

**6.5 Net weight examination**

- The net weight of the filled and sealed sachets shall be determined by weighing each sample unit on a suitable scale tared with a representative empty sachet.
- Any individual net weight of less than 92 g (3.246 oz) shall be classified as a minordefect.
- The lot size shall be expressed in sachets. The sample unit shall be one filled and sealed sachet
- The inspection level shall be S-3 and the AQL, expressed in terms of defects per hundred units, shall be 2.5
- The results shall be reported to the nearest 0.1 g (0.003 oz). In addition, thelot shall be rejected if the sample average net weight is less than 92 g (3.246 oz).

**7.0 Packaging and Labelling specifications**

**7.1 General Requirements**

- The material used for packaging shall be generally recognized as safe (GRAS) for use with food in accordance in accordance with good manufacturing practices (see attached)or other standards and regulationswith accepted standards and regulations.
- Recycled, recovered, or environmentally preferable materials should be used to the maximum extent possible, provided that the material meets or exceed the material requirements cited herein
- All labelling, package inserts and specifications shall be in English
- Each Secondary package should have a Product information insert in English containing:

- Product Name (both International Non-proprietary Name)
- Nutritional information
- Composition / ingredients
- Indications
- Dosage and administration
- Contraindications
- Precautions
- Adverse effects

### 7.2 Primary package labelling requirements

- Product Name (International Non-proprietary Name)
- Nutritional information
- Composition / ingredients
- Batch number
- Manufacturing date
- Best before date
- Directions for use: Should indicate “For single use only”
- Dosage
- Should have a label “**GOK - Not for sale**” clearly labelled in a place where it is visible.

### 7.3 Secondary package requirements and labelling

- The secondary package for RUTF is a transparent low density polyethylene (LDPE) pouch 11in. length x 9 in. width)
- The LDPE pouch contain 7 sachets of 92g each of RUTF and each pouch meet the following labelling requirements
  - minimum gross weight of a pouch should be 644g
  - Product Name (International Non-proprietary Name)
  - Batch number
  - Manufacturing date
  - Best before date
  - Storage instructions
  - Manufacturers contact information and physical address
  - Should have a label “GOK - Not for sale” clearly labelled in a place where it is visible.

### 7.4 Tertiary package requirements and labelling

- Corrugated Fibreboard Shipping boxes (Shipping Container) – Shall contain 21 pouches of 644g of RUTF. The shipping container will be a regular slotted container constructed of a minimum 450lb (204kg) burst test, corrugated fibreboard.
- The outside dimensions of each shipping container will be no less than 8 inches in height, and cases should be designed to the optimal dimensions to fill at least 80% of the cubic capacity of a 20 foot intermodal when stacked two pallets high.
- Cases of dimensions shall be no less 8 in. height x 16 in. length x 13.25 in. width and will have been found to comply with this requirement (when stacked nine cases per layer and five tiers high on a standard pallet).
- Other case dimensions will be considered providing the height of the case does not exceed 12 inches and the pallets, when double stacked, can fill at least 80% of the cubic capacity of a 20 foot intermodal

- The corrugated fibreboard will meet the following labelling specifications:
    - Product Name (both International Non-proprietary Name)
    - Batch number
    - Manufacturing date
    - Best before date
    - Quantity of the tertiary package will be determined by weight and should contain 21 pouches of 7 sachets each of RUTF, the carton should have a minimum gross weight of 13.5kg
    - Storage instructions
    - Manufacturers contact information and physical address
    - Should have a label “GOK - Not for sale” clearly labelled in a place where it is visible.

## 8.0 MANUFACTURER’S PRODUCT ASSURANCE

- The manufacturer shall certify that the RUTF provided, meets the requirements of this technical specifications
- The purchaser or procuring entity shall require proof of conformance

## 9.0 REGULATORY REQUIREMENTS

- The delivered RUTF shall comply with all applicable Government , County, and local by-laws and regulations relating to the manufacturing, storage, and distribution of packaged foods for human consumption, including all applicable provisions of Food, Drugs and Chemical Substances Act Chapter 254 (2012), Public Health Act Cap 242 (2012) and regulations promulgated thereunder
- Allcertificates of analysisfor both raw materials and delivered RUTF will be from Kenya National Accreditation Services (KENAS) accredited laboratories or from labs with valid ISO 17025:2005 certification.

## 10.0 QUALITY ASSURANCE PROVISIONS

The product manufacturer shall be required to provide evidence, by certificate, that the manufacturing plant has undertaken one of the following quality assurance measures within 12 months prior to providing a bid, or no later than 10 business days from the date of awarding of the contract.
Failure to provide this documentation within the proper time frame may result in the contract being terminated for cause

### 10.1 ISO 22000 Assessment

- A supplier quality assessment (SQA) verifies the manufacturer's capability to produce products in a clean sanitary environment in accordance with ISO 22002-1:2009 –*Prerequisite programmes on food safety part 1 : Food Manufacturing* and verifies that the manufacturer has in place an internal quality assurance and food safety program
- A supplier quality audit (SQA) based on ISO 22000:2005 by a third party auditing service is required within 12 months prior to the date of the awarding of the contract.
- The food manufacturer must have attained an SQA score of 75% or above
- The food manufacturer must be ISO 22000 certified
- The relevant certificate/letter bearing the name of any of the above bodies must be submitted for scrutiny

### 10.2 Kenya Bureau of Standards (KEBS) certification

- KEBS is the standards authority in Kenya and therefore all food must be approved as safe for human consumption
- The locally produced RUTF must have the Standardization mark as this is a mandatory product certification scheme for locally manufactured products provided for under section 10 of the Standards Act Cap 496, Laws of Kenya

## General Technical Specifications

These specifications describe the basic requirements for the items. Bidders are requested to submit with their offers the detailed specifications and **samples** for the products they intend to supply.

The Bidders are requested to present information along with their offers indicating the shortest possible delivery period of each product.

## Particulars

1. **Qualifications of Manufacturers**.

The Tenderer shall provide copies of all certificates and documents issued by the proper National Authorities, that the Manufacturer of the supplies proposed is authorised to manufacture and sell these products.

**2. Appraisal**

A manufacturer, who has not dealt with the Procuring entity in the past must provide evidence of certification by a recognized authority (e.g. ISO, KEBS) or be subject, at the Manufacturer's expense, to inspection by a competent authority designated by the Procuring entity in conjunction with the national regulatory authority.

**3. Documentary Evidence**

3.1 Bidders must provide the following documentary evidence of the Tenderer's qualifications to perform the Contract in support of their bid;

(i) That in the case of a bidder offering to supply Medical commodities under the Contract that the Tenderer manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:

(a) Is incorporated in the country of manufacture of the Medical commodities

(b) Has received satisfactory quality inspection certificate in line with the WHO certification scheme on Non pharmaceuticals moving in International Commerce.

(c) For Disinfectants, Topical Preparations and Antiseptics, bidders must submit valid certificates of quality issued by recognized authorities.

(d) Has manufactured and marketed specific goods for at least two (2) years and similar goods for at least five (5) years.

(ii) That, in the case of a Tenderer offering to supply Medical commodities under the Contract that the Tenderer does not manufacture or otherwise produce,

(a) That the Tenderer has been duly authorized by a manufacturer of the Medical commodities that meets the Criteria under (i) above to supply the Medical commodities in Kenya, and

(b) That the Tenderer has been duly authorized by a manufacturer of the Medical commodities that meets the Criteria under C above

**4. Certificates**

4.1 All certificates granted to distributors and or manufacturers from the country of origin or/and recognized regulatory authorities should be valid and clear.

4.2.1 The certificate of quality should indicate

a) That the manufacturing plant in which the products are produced is subject to inspection at regular intervals

b) That the manufacture conforms to requirements of good manufacturing and quality control as recommended by WHO in respect of products to be sold or distributed in the country of origin or to be exported.

c) The date the certificate is issued and the period of its validity.

4.3 All certificates indicated above and all other technical documents required to qualify for the tender participation should be submitted together with the bid on or before the closing date. Any bid not accompanied by the certificates shall be rejected as non-responsive

**5. Standards of Quality Assurance for Supply.**

5.1 All products must:

a) Meet the requirements of manufacturing legislation and regulation of Non-pharmaceutical and medical products in the country of Origin;

b) Be certified by a competent authority in the manufacturer's country according to World Health Organization "Certification Scheme on the Quality of Non-Pharmaceutical Products Moving in International Commerce"[1].

c) Conform to all the specifications contained herein; and

5.2 In case of new bidders to the procuring entity who succeed to win an item or more in price and other preliminary evaluation parameters, the procuring entity reserves the right to send samples to the National Quality Control laboratory or other competent laboratory for quality control test. In such cases, the bidder shall cover the expense up on request by the procuring entity.

5.3 The successful Bidder will be required to provide to the Procuring entity:

a) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

b) Ensure that Medical commodities arrive at the port of entry or ex-factory (for local purchases) with a remaining shelf life of at least five sixths (5/6ths) of the total stipulated shelf life for medical commodities with a shelf life of more than two years and three-fourths (3/4) of the total stipulated shelf life for medical commodities with a shelf life of two years or less.

5.4 The successful Bidder will also be required to provide the Procuring entity with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods and in-process tests.

## 6. Packaging Specifications:

### 6.1 General

6.1.1 The successful bidder shall provide such packing of the Medical commodities as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Medical commodities' final destination and the absence of heavy handling facilities at all points in transit.

## 7. Tertiary Packing

1.1 Tertiary packing shall be undertaken in Heavy Duty five-ply cartons, **(175K/B/175K/C/175K)** duly labeled and marked. The shapes of the cartons must be consistent and complementary to allow stacking.

1.2 The cartons must have consistent dimensions of length, width and height. The cartons must contain polyethylene sheets inside to ensure that water does not seep through.

1.3 The size of the carton should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transport.

1.4 All carton flaps must be properly secured and sealed with special repackers gum paper tapes. Two strong plastic strappings should be tied around the carton properly bound by a machine and stapled tightly.

1.5 To facilitate manual loading and off-loading, the dimensions of each carton should not exceed 610mm x 460mm x 355 mm. The Gross weight of each parked carton should not exceed 35kg.

## 8. Labeling Instructions.

8.1 The Label for each Non pharmaceutical products shall include:

a) The Procuring entity's logo and code number if required in the special conditions of these Specifications.
b) Content per pack
c) Instructions for use
d) Special storage requirements
e) Batch number
f) Date of manufacture and date of expiry (in clear language, not code)
g) Name and address of manufacturer
h) Any cautionary statement

8.2 All labeling and packaging inserts shall be in English.

8.3 All outer cartons should be labeled as follows:

**"GoK-MoH-Not for Sale"**
**"Funded by the Global Fund GF ATM TB NFM"**

**KENYA MEDICAL SUPPLIES AUTHORITY**

**13 COMMERCIAL STREET, INDUSTRIAL AREA**
**P. O. BOX 47715-00100, NAIROBI**

8.4 The outer case or carton should also display the above information.

**9. Case Identification.**

9.1 All cases should prominently indicate the following:

a) Procuring entity's Name and Address
b) Date of manufacture and expiry
c) Batch number
d) Quantity per case
e) Package Number
f) Special instructions for storage;
g) Name and address of manufacture;
h) Gross weight and net weight in kilograms.
i) The legends: " Top, do not turn over " Handle with Care" …etc
j) Any additional cautionary statements.

**10. Unique Identifiers**

**10.1** The word **"GoK-MoH-Not for Sale" shall be extensively and conspicuously imprinted on the primary, secondary and tertiary packaging of products to be supplied to the procuring entity.**

**11 Bar coding Requirements For All KEMSA Medical Supplies**
**(Application of International Barcoding Standards**)

**Section A**

**Primary packaging (Item level and Mono carton level)**

a) GS1 Linear-'barcode Symbology,(EAN-13/UPC-A/EAN-8)'to encode GTIN (Global Trade Identification Number) within the barcode,

or

b) GS1 Data Matrix symbology to encode 14 digits product code (GTIN-14) within the Barcode and using (01) Application Identifier (To be used where printing space is extremely limited)

**Examples of the same are reproduced at Annexure "A"**

*All other human readable Information on product packaging shall be as required under Existing Regulatory labeling & marking requirements*

**Section B.**

**Secondary Level Packaging**

1. Product Identification Code (GTIN-14 of secondary pack) using Application Identifier (01)
2. Expiry date in YYMMDD format using Application Identifier (17)
3. Batch/Lot Number using Application Identifier (10)

GS1-128 barcode symbology to be used to generate the barcode, Examples of the same are reproduced at Annexure “B”

*All other human readable Information on product packaging shall be as required under existing Regulatory labeling & marking requirements.*

**Section C**

**Tertiary level packaging (Pallet level packaging)**

At Shipper/Pallet level packaging, a single label containing two barcodes needs to be generated and stickered. The barcode will encode the following information;

**The first barcode will contain the 'following information.**

1. Product Identification Code (GTIN-14 or shipper level pack) using Application Identifier (01)
2. Expiry Date in YYMMDD format using Application Identifier (17)
3. Batch/Lot Number using Application Identifier (10)

**The second barcode will contain the following information;**

1. SSCC (Serial Shipping Container Code) using Application Identifier (00)

Examples of the same are reproduced at annexure “C”.

*All other human readable Information on product packaging shall be as required under existing Regulatory labelling & marking requirements,*

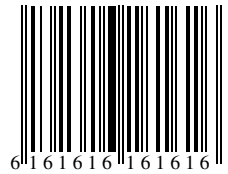
## ANNEXURE "A"

**Example of Primary Level Packaging**

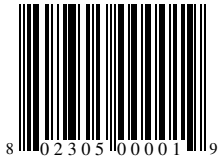
For generation of GS1 barcode at primary level packaging either of the mentioned symbologies can be used, following GS1 General Specifications

The following GS1 barcode symbologies are available as options:

1. The bar code sample of EAN-13 bar code symbology encoding GTIN -13



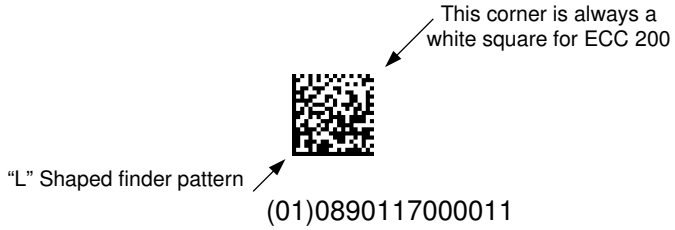

2. The bar code sample UPC – A bar code symbology encoding GTIN – 12




Note: Both GTIN-13 and GTIN – 12 are in extensive use worldwide.

3. The bar code sample for EAN – 8 bar code symbology encoding GTIN – 8 ( Used where printing space is a constraint)


4. The bar code sample for GS1 Data Matrix barcode symbology encoding GTIN – 14 (used where printing space is extremely limited)

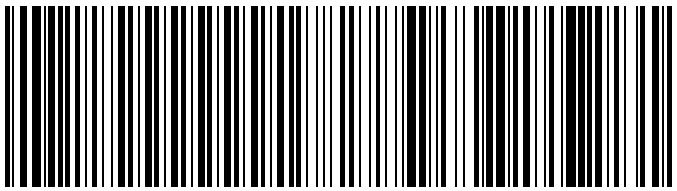


**Annexure "B"**

**Example of Secondary Level Packaging**

The bar code will encode:

1) Product identification (GTIN-14 of secondary pack) using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)



**Annexure "C"**

**Example of Tertiary Level Packaging (Shipper Level Packaging)**

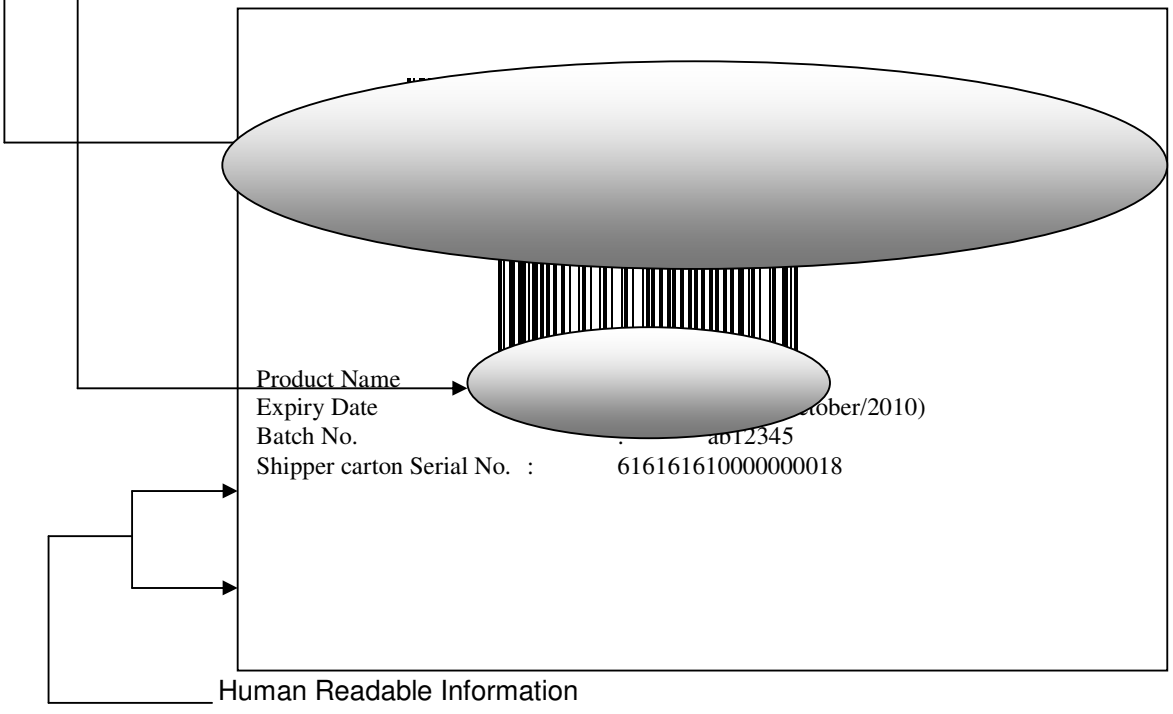
The first bar code will encode the following:

1) Product identification (GTIN – 14 of Shipper Pack) using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)

The second bar code will encode the following:

SSCC (Serial Shipping Container Code)

**(Single Label for each Shipper Level Packaging)**




Human Readable Information

*Complete details on GS1 standards along with technical guidelines are available at* www.gs1kenya.org or www.gs1.org

## 12 Sample

12.1 A Properly labeled non-returnable sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing of the tender. The sample must be of the required pack size as indicated in the schedule of requirements.

12.2 The sample including literature should be submitted in their normal or usual commercial packing and should be labeled in English. The sample must be a true representative of the product tendered for.

12.3 Bidders who submit two different samples for any given item will have their samples disqualified.

## 13 Product Specifications

All specifications stated in the tender and confirmed in the contract must be adhered to, i.e. stated strength, pack size, manufacturer, labeling and markings, etc. The Procuring entity **will not** approve change of manufacturer of the items to be supplied.

## Section VII. Sample Forms


| | | |
|---|---|---|
| 1. | Form of Tender | 98 |
| 2. | Tender Security Form | 99 |
| 3. | Form of Contract Agreement | 100 |
| 4. | Performance Security Bank Guarantee (unconditional) | 102 |
| 5. | Manufacturer's Authorization Form | 103 |
| 6. | Declaration of Undertaking (Integrity Statement) | 104 |
| 7. | Supplier Data Record | 106 |

## 1. Form of Tender

**IFT N°.: GF ATM TB NFM-17/18-OIT-001**

**Supply and delivery of Nutritional Supplements**

**To: Kenya Medical Supplies Authority (KEMSA)**
**13 Commercial Street, Industrial Area**
**P.O. Box 47715-00100**
**Nairobi, Kenya;**

Dear Sir or Madam,

1. Having examined the tender documents including **Addenda Nos……[Insert numbers]** the receipt of which is hereby duly acknowledged, we, the undersigned, offer to **Supply and deliver Nutritional Supplements** in conformity with the said tender documents for the sum of [**Insert: Total tender amount in words and figures**] ……
   ……..
2. or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this Tender.

3. We undertake, if our Tender is accepted, to deliver the goods in accordance with the delivery schedule specified in the Schedule of Requirements.

4. If our Tender is accepted, we will obtain the guarantee of a bank in a sum equivalent to **10% Percent of the Contract Price** for the due performance of the Contract, in the form prescribed by **Kenya Medical Supplies Authority (KEMSA).**

5. We agree to abide by this Tender for a period of **90 days** from the date fixed for tender opening of the Instructions to Bidders, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

6. Until a formal Contract is prepared and executed, this Tender, together with your written acceptance thereof and your notification of award, shall constitute a binding Contract between us.

6. We understand that you are not bound to accept the lowest or any tender you may receive.

Dated this …… day of …… 20……

Signed…….

In the capacity of [***insert: title or position***]……..

Duly authorized to sign tender for and on behalf of *[**insert: name of tenderer**]*

**2. Tender Security Form**

**IFT N°.: GF ATM TB NFM-17/18-OIT-001**

**Supply and delivery of Nutritional Supplements**

**To: Kenya Medical Supplies Authority (KEMSA)**
**13 Commercial Street, Industrial Area**
**P.O. Box 47715-00100**
**Nairobi, Kenya;**

WHEREAS *[insert: **name of Tenderer**]* (hereinafter called "the Tenderer") has submitted its tender dated *[insert: **date of tender**]* for the performance of the above-named Contract (hereinafter called "the Tender")

KNOW ALL PERSONS by these present that WE *[insert: **name of bank**]* of *[insert: **address of bank** ]* (hereinafter called "the Bank") are bound unto *[ insert: **name of Purchaser** ]* (hereinafter called "the Purchaser") in the sum of: *[ insert: **amount** ]*, for which payment well and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents.

Sealed with the Common Seal of the said Guarantor this *[insert: **number**]* day of *[insert: **month**], [insert: **year**]*.

THE CONDITIONS of this obligation are:

1. If after tender opening the tenderer withdraws his tender during the period of tender validity specified in the instructions to tenderers or

2. If the tenderer rejects the correction of an error upon prompt notice by the procuring entity and

3. If the tenderer, having been notified of the acceptance of his tender by the employer during the period of tender validity:

    a) Fails or refuses to execute the form of agreement in accordance with the instructions to tenderers if required or

    b) Fails or refuses to furnish the Performance Security, in accordance with instructions to tenderers

We undertake to pay to the Procuring Entity up to the above amount upon receipt of its first written demand, without the Procuring Entity having to substantiate its demand, provided that in its demand the Procuring Entity will note that the amount claimed by it is due to it, owing to the occurrence of one or both of the two conditions specifying the occurred condition or conditions.

This guarantee will remain in full force up to and including **thirty (30) days** after the period of tender validity and any demand in respect thereof should reach the Guarantor not later than the above date.

**Signature of the Guarantor…….. Date:……**

**(Witness) …….. Date:……**

***Common Seal of the Bank***

## 3. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the *[ insert: **number** ]* day of *[ insert: **month** ]*, *[ insert: **year** ]*.

BETWEEN

1 THIS AGREEMENT made the _____ day of _____ 20_____ between…….*[name of Procurement entity)* of……*[country of Procurement entity]* (hereinafter called "the Procuring entity") of the one part and *[ insert: **name of Tenderer**]*, a corporation incorporated under the laws of *[ insert: **country of Tenderer** ]* and having its principal place of business at *[ insert: **address of Tenderer** ]* (hereinafter called "the Supplier").

2 WHEREAS the Procuring entity invited tenders for certain goods and ancillary services, viz., *[insert: **brief description of goods and services**]* and has accepted a tender by the tenderer for the supply of those goods and services in the sum of *[insert: **contract price in words and figures]*** (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

2.4.1 In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2.4.2 The following documents shall constitute the Contract between the Purchaser and the Tenderer, and each shall be read and construed as an integral part of the Contract:

(a) This Contract Agreement

(b) Special Conditions of Contract

(c) General Conditions of Contract

(d) Technical Requirements (including Functional Requirements and Implementation Schedule)

(e) The Supplier's tender and original Price Schedules

(f) The Purchaser's Notification of Award

(g) The Supplier's Acceptance letter

(h) *[Add here: **any other documents**]*

3. In consideration of the payments to be made by the Procuring Entity to the Tenderer as hereinafter mentioned, the Tenderer hereby covenants with the Procuring Entity to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

The Procuring Entity hereby covenants to pay the Tenderer in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Procuring Entity

Signed: _____

in the capacity of *[ insert:* ***title or other appropriate designation*** *]*

in the presence of _____

For and on behalf of the Tenderer

Signed: _____
in the capacity of *[ insert:* ***title or other appropriate designation*** *]*

in the presence of _____

CONTRACT AGREEMENT
dated the *[ insert:* ***number*** *]* day of *[ insert:* ***month*** *]*, *[ insert:* ***year*** *]*

BETWEEN

*[ insert:* ***name of Procuring Entity*** *],* "the Purchaser"

and

*[ insert:* ***name of Tenderer*** *],* "the Supplier"

**4. Performance Security Bank Guarantee (unconditional)**

**IFT N°.: GF ATM TB NFM-17/18-OIT-001**

**Supply and delivery of Nutritional Supplements**

**To: Kenya Medical Supplies Authority (KEMSA)**
**13 Commercial Street, Industrial Area**
**P.O. Box 47715-00100**
**Nairobi, Kenya;**

We refer to the Contract Agreement ("the Contract") signed on *[ insert: **date** ]* between you and *[ insert: **name of Tenderer** ]* ("the Supplier") concerning the supply and delivery of *[ insert: **a brief description of the Goods**]*. By this letter we, the undersigned, *[insert: **name of bank**]*, a bank (or company) organized under the laws of *[insert: **country of bank**]* and having its registered/principal office at *[ insert: **address of bank** ]*, (hereinafter, "the Bank") do hereby jointly and severally with the Tenderer irrevocably guarantee payment owed to you by the Tenderer, pursuant to the Contract, up to the sum of *[ insert: **amount in numbers and words** ]*. This guarantee shall be reduced or expire as provided for by GCC Sub-Clause 8.4.

We undertake to make payment under this Letter of Guarantee upon receipt by us of your first written demand signed by your duly authorized officer declaring the Tenderer to be in default under the Contract and without cavil or argument any sum or sums within the above-named limits, without your need to prove or show grounds or reasons for your demand and without the right of the Tenderer to dispute or question such demand. Our liability under this Letter of Guarantee shall be to pay to you whichever is the lesser of the sum so requested or the amount then guaranteed under this Letter in respect of any demand duly made under this Letter prior to expiry of this Letter of Guarantee, without being entitled to inquire whether or not this payment is lawfully demanded.

This Letter of Guarantee shall be valid from the date of issue until the date of expiration of the guarantee, as governed by the Contract. Except for the documents herein specified, no other documents or other action shall be required, notwithstanding any applicable law or regulation. Our liability under this Letter of Guarantee shall become null and void immediately upon its expiry, whether it is returned or not, and no claim may be made under this Letter after such expiry or after the aggregate of the sums paid by us to you shall equal the sums guaranteed under this Letter, whichever is the earlier. All notices to be given under this Letter shall be given by registered (airmail) post to the addressee at the address herein set out or as otherwise advised by and between the parties hereto.

We hereby agree that any part of the Contract may be amended, renewed, extended, modified, compromised, released, or discharged by mutual agreement between you and the Tenderer, and this security may be exchanged or surrendered without in any way impairing or affecting our liabilities hereunder without notice to us and without the necessity for any additional endorsement, consent, or guarantee by us, provided, however, that the sum guaranteed shall not be increased or decreased.

No action, event, or condition that by any applicable law should operate to discharge us from liability hereunder shall have any effect, and we hereby waive any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and, except as stated herein, unconditional in all respects.

For and on behalf of the Bank

**Signature of the Guarantor…….. Date:……**

**(Witness) ……Date:…… *Common Seal of the Bank***

## 5. Manufacturer's Authorization Form

***(Must be on Manufacturer's or Producer's letterhead)***

**To. Kenya Medical Supplies Authority**
**13 Commercial Street, Industrial Area**
**P.O Box 47715-00100**
**Nairobi, Kenya**

Dear Sirs,

WHEREAS *[ insert: **name of the manufacturer or producer** ]* (hereinafter, "we" or "us") who are established and reputable manufacturers or producers of *[ insert: **name and/or description of the Goods requiring this authorization** ]* (hereinafter, "Goods") having production facilities at *[ insert: **address of factory** ]* do hereby authorize *[ insert: **name and address of Tenderer** ]* (hereinafter, the "Tenderer") to submit a tender, and subsequently negotiate and sign the Contract with you against **IFT N$^{o}$.: GF ATM TB NFM-17/18-OIT-001 for Supply and Delivery of Nutritional Supplements** including the above Goods produced by us.
We hereby extend our full guarantee and warranty for the above specified Goods against these tender documents.

For and on behalf of the Manufacturer or Producer

Signed: _____

Date: _____

In the capacity of *[insert: **title, position, or other appropriate designation**]* and duly authorize to sign this Authorization on behalf of *[insert: **name of manufacturer or producer**]*

**NOTE: Manufacturer's Authorization must be ON LETTER HEAD and addressed to KEMSA and must be tender and item specific and signed by an authorized signatory. - MANDATORY**

## 6. Declaration of Undertaking (Integrity Statement)

***Ethics and Anti – Corruption Policy in the Procurement Process***

**Undertaking by Bidder on Anti – Corruption Policy / Code of Conduct and Compliance Programme**

The governments of Kenya is committed to fighting corruption in all its forms and in all its institutions to ensure that all the government earned revenues are utilized prudently and for the purpose intended with a view to promoting economic development as the country work towards actualizing Vision 2030.

Here at KEMSA and also being one of the government entities mandated under the government Legal Notice number 466 of 2004 to procure, warehouse and distribute Essential Medicines and Medical Supplies to all the public health facilities in Kenya, on behalf of the government, we are highly committed to fighting any form of corruption in our organization to ensure that all the monies that the government entrust with us, is optimally and prudently utilized for the benefits of all the people we serve.

**The following is a requirement that every Bidder wishing to do business with KEMSA must comply with:**

(1) Each bidder must submit a statement, as part of the tender documents, in the format given and which must be signed personally by the Chief Executive Officer or other appropriate senior corporate officer of the bidding company and, where relevant, of its subsidiary in Kenya. If a tender is submitted by a subsidiary, a statement to this effect will also be required of the parent company, signed by its Chief Executive Officer or other appropriate senior corporate officer.

(2) Bidders will also be required to submit similar No-bribery commitments from their subcontractors and consortium partners; the bidder may cover the subcontractors and consortium partners in its own statement, provided the bidder assumes full responsibility.

(3) a) Payment to agents and other third parties shall be limited to appropriate compensation for legitimate services.

b) Each bidder will make full disclosure in the tender documentation of the beneficiaries and amounts of all payments made, or intended to be made, to agents or other third parties (including political parties or electoral candidates) relating to the tender and, if successful, the implementation of the contract.

c) The successful bidder will also make full disclosure [quarterly or semi- annually] of all payments to agents and other third parties during the execution of the contract.

d) Within six months of the completion of the performance of the contract, the successful bidder will formally certify that no bribes or other illicit commissions have been paid. The final accounting shall include brief details of the goods and services provided that are sufficient to establish the legitimacy of the payments made.

e) Statements required according to subparagraphs (b) and (d) of this paragraph will have to be certified by the company's Chief Executive Officer, or other appropriate senior corporate officer.

(4) Tenders which do not conform to these requirements shall not be considered.

(5) If the successful bidder fails to comply with its No-bribery commitment, significant sanctions will apply. The sanctions may include all or any of the following:

a) Cancellation of the contract;

b) Liability for damages to the public authority and/or the unsuccessful competitors in the bidding possibly in the form of a lump sum representing a pre-set percentage of the contract value (liquidated).

(6) Bidders shall make available, as part of their tender, copies of their anti-Bribery Policy/Code of Conduct, if any, and of their-general or project - specific - Compliance Program.

(7) The Government of Kenya through Ethics and Anti-Corruption Commission has made special arrangements for adequate oversight of the procurement process and the execution of the contract. Those charged with the oversight responsibility will have full access if need be to all documentation submitted by Bidders for this contract, and to which in turn all Bidders and other parties involved or affected by the project shall have full access (provided, however, that no proprietary information concerning a bidder may be disclosed to another bidder or to the public).

## 1. MEMORANDUM ( FORMAT )

**(Clause 41, 62 and 66 of Kenya Public Procurement and Asset Disposal Act 2015)**

This company _____*(name of company)* has issued, for the purposes of this tender, a Compliance Program copy attached -which includes all reasonable steps necessary to assure that the No-bribery commitment given in this statement will be complied with by its managers and employees, as well as by all third parties working with this company on the public sector projects or contract including agents, consultants, consortium partners, subcontractors and suppliers')"

Authorized Signature:_____

Name and Title of Signatory: _____

Name of Bidder: _____

Address: _____

**7. Supplier Data Record**

| **SUPPLIER BUSINESS DETAILS (fill in Block letters)** | | |
|---|---|---|
| Company name | | |
| Company Post Office Address: | | |
| Telephone Nos:<br>Office No. ----------<br><br>Mobile No. ----------<br><br>_____ | Fax No.<br>(with entering your fax no. here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken):<br>_____<br>_____ | e-Mail Address<br>(with entering your e-Mail address here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken):<br><br>_____ |

Company Registration Number:

1. Location of business premises ----------
2. Building name and number ----------
3. Floor Number ----------
4. Room number ----------
5. Plot Number ----------
6. VAT Certificate Number ----------
7. Local Authority License Number ---------- Expiry Date ----------
8. PIN certificate Number ----------
9. Website if any ----------

**when submitting your bid, please ensure that you submit copies of the following documents;**

1. **Copy of Certificate of incorporation**
2. **Copy of current Tax Compliance Certificate**

| Contact Name | Job Title |
|---|---|

| | | |
|---|---|---|
| Telephone No.<br><br>_____ | Fax No.<br>(with entering your fax no. here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken):<br><br>_____ | e-Mail Address<br>(with entering your e-Mail address here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken):<br><br>_____ |
| Main business activity | | |
| <u>Please NOTE giving false information in this section will lead to outright Disqualification from tendering process</u>**.** | | |
| Type of organization (please tick as necessary)<br>1. Partnership<br>2. Co-operative<br>3. Private Ltd.<br>4. Public Company<br>5. Other. | | |
| Type of premises (tick as necessary)<br>1. factory,<br>2. warehouse<br>3. Other. | Freehold<br><br>Leasehold | |
| | | |
| Names of executives<br>Chairman ---------- ---------Nationality ---------- Shares held --------<br>Managing Director ----------Nationality ---------- Shares held -------<br>Company Secretary ----------Nationality ---------- Shares held -------<br>Name of Directors<br>1. ---------- ---------- Nationality ---------- Shares held -------<br>2. ---------- --------Nationality ---------- Shares held --------<br>3. ----------Nationality ---------- Shares held -------<br>4. ----------Nationality ---------- Shares held ------<br>5. ---------- ------Nationality ---------- Shares held ------ | | |

| | |
|---|---|
| Name and address of ultimate holding company and any subsidiary companies | |
| Total no. of employees in group | No. of locations/premises in group |
| Member of a Trade Association?<br><br>**Details of any Certification e.g. ISO 9000 (attach copies of valid certificates)** | |
| **Name product(s) for which you act as an Authorized Dealer / Distributor and attach copies of valid certificates of authority**.<br><br>1. 5.<br><br>2. 6.<br><br>3. 7.<br><br>4. 8. | |
| Bidders should only provide documentation for products they are offering to supply in the tender | |

| **Bank References and other details** | |
|---|---|
| **A) Primary Bank (The Main Bank)** | |
| 1) Name: ----------<br>2) Postal Address: ----------<br>3) Telephone Land line number;----------<br>4) Fax Number: ----------<br>5) Email Address: ---------- | |
| Name of the account: ---------- | |
| | |

| | |
|---|---|
| Account number: ---------- | Number of years operated: ---------- |

**SECONDARY BANKERS (if applicable)**

Bank name and address: ----------

Name of the account: ----------

| | |
|---|---|
| Account number: ---------- | Years of operation ---------- |

**Commercial References**

Provide names and contact details of four customers that have done business with you in the last three years.

**A) Trade References - customer 1**

| | |
|---|---|
| Activity: ---------- | Period of relationship: (Year) ---------- |
| Contact name: ---------- ---------- | Fax no. ---------- Email address: ---------- |

Value of contract orders in USD----------

Telephone No. ----------

Physical address; ----------

**B) Trade References - customer 2**

| | |
|---|---|
| Activity: ---------- | Period of relationship: (Year) ---------- |

| | |
|---|---|
| Contact name: ----------<br>---------- | Fax no. ----------<br>Email address: ---------- |
| Value of contract orders in USD---------- | |
| Telephone No. ----------<br>Physical address; ---------- | |
| | |
| **Trade References - customer 3** | |
| Business Activity: ----------<br>---------- | Period of relationship (year) ---------- |
| Contact name: ----------<br>---------- | Fax no.----------<br>Email address: ---------- |
| Value of contract orders in Kenya Shillings KSHS ---------- | |
| Telephone No. Mobile ----------<br>Telephone Number Land line ----------<br>Physical address: ---------- | |
| | |
| **Trade References - customer 4** | |
| Business Activity: ----------<br>---------- | Period of relationship (year) ---------- |

| | |
|---|---|
| Contact name: ----------<br>---------- | Fax no.----------<br>Email address: ---------- |
| Value of contract orders in Kenya Shillings KSHS ---------- | |
| Telephone No. Mobile ----------<br>Telephone Number Land line ----------<br>Physical address: ---------- | |

| **SUPPORT SERVICES AVAILABLE** |
|---|
| What after sales / warranty / spare parts / support services / local agent / repair are available?<br>(Please feel free to attach any further supporting information with this form) |

| **DECLARATION BY THE APPLICANT** | |
|---|---|
| Full names: ----------<br>Telephone Number mobile ----------<br>Telephone No. Land Line ---------- | Job title of signatory:---------- |
| Signature of the applicant…… | Date of application: ---------- |

**Please affix company rubber stamp or seal**

## Section VIII: Evaluation Criteria

**A –Preliminary Examination_____**

**A –Preliminary Examination_____**

**B –Technical Evaluation_____**

i) **Documentary Compliance**

ii) **Product Evaluation**

**C – Financial Evaluation_____**

## A) PRELIMINARY EXAMINATION

**Required documents;**

1. Must paginate and serialize all the pages of the bid documents, failure to which shall lead to disqualification **(MANDATORY).**
2. Copy of Certificate of incorporation **(MANDATORY).**
3. Copy of current Tax Compliance Certificate (For local bidders only) **(MANDATORY).**
4. Tender form **duly completed and signed** by the tenderer or his authorized agent **(MANDATORY).**
5. Original Bid Bond provided and valid for 120 days from date of tender opening. Value of bid bond should be **USD 10,000.00 or KES 1,000,000.00**or equivalent in a freely convertible currency **(MANDATORY).**
6. Declaration of Undertaking (Integrity Statement) **must be signed (MANDATORY).**

**NOTE:** Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

## B) TECHNICAL EVALUATION

### 1) Documentary Compliance

i) Duly signed Manufacturer's Authorization letter (if Tenderer is not a Manufacturer) **(MANDATORY).**

ii) Current Certificate of Quality for products offered issued by a recognized independent body **(MANDATORY).**

**NOTE:** Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

### 2) Product Evaluation for the sample submitted by the tenderer

The technical evaluation will involve the product evaluation, packaging evaluation and labeling evaluation. The evaluation will be based on product type, product form i.e. the physical configuration and shape, product ingredients i.e. content, components and composition, measurements i.e. dimension and weight, elasticity where applicable, absorbency where applicable, texture where applicable and the packaging criteria will be based on securely wrapped, quality of packaging material, unit package, individual package, presence of peel off sign and peel ability (ease of opening the package), presence of tamper-proof seal , while the labeling criteria will be drawn from the technical specifications spelt out in the tender document.

The evaluation will be on a **"Yes/No"** basis.

**NOTE:** Only bidders who are successful at this stage will proceed to the next stage of evaluation.

## C) FINANCIAL EVALUATION

Bidders who are successful at preceding stages of evaluation and offer acceptable delivery schedules will have their prices compared and award recommended to the lowest evaluated responsive bid.