


SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS				1. REQUISITION NUMBER REQ-FFP-15-000XXX		PAGE 1 OF	
Offeror to complete blocks 12, 17, 23, 24, & 30							
2. CONTRACT NO. AID-OAA-E-15-00XXX-00		3. AWARD/EFFECTIVE DATE		4. ORDER NUMBER		6. SOLICITATION ISSUE DATE 03/26/2015	
7. FOR SOLICITATION INFORMATION CALL:		A. NAME Prince Boateng		B. TELEPHONE NUMBER (No Collect Calls) 202-567-4104		8. OFFER DUE DATE/local time 04/08/15 @ 01200 hours	
9. ISSUED BY CODE				10. THIS ACQUISITION IS X UNRESTRICTED <input type="checkbox"/> SET-ASIDE 100 % FOR <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> HUBZONE SM. BUSINESS BUSINESS <input type="checkbox"/> 8(A) NAICS: 423450 SIZE STANDARD:		11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED XX SEE SCHEDULE <input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) 13b. RATING 14. METHOD OF SOLICITATION RFQ IFB XRFP	
15. DELIVER TO CODE F. o. b. Origin (FAR 52.247-29)				16. ADMINISTERED BY CODE Same as Block 9			
17a. CONTRACTOR/OFFEROR CODE FACILITY CODE				18a. PAYMENT WILL BE MADE BY CODE United States Agency for International Development (USAID) Office for Food for Peace Ronald Reagan Building, Room 8.07-069 1300 Pennsylvania Avenue, N.W. Washington, D.C. 20523 Facsimile: (202) 216-3399 Email: EI@USAID.GOV			
TELEPHONE NO. <input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED: <input type="checkbox"/> SEE ADDENDUM			
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY		22. UNIT	
						23. UNIT PRICE	
						24. AMOUNT	

Blanket Purchase Agreement for Ready To Use Therapeutic Food (RUTF) and Ready To Use Supplementary Food (RUSF). Up to 500 nmt will be placed in storage at the contractor's facility, and shall be ready for purchase and for immediate delivery to USAID. The remaining shelf life of commodity shall be at least 20 months from the date of delivery. See the attached BPA agreement schedule for details of this agreement, including commodity prices for the base period and the option periods. See the attached Commercial Item Description and USDA Commodity Requirement

Agreement Base Period of Performance: April 15, 2015 to October 14, 2016 (Actual dates to be negotiated).

Four each 6 months option periods are available to the government.

This Blanket Purchase Agreement does not obligate any funds. The government will fund individual contracts and orders for the delivery of RUTF/RUSF. The government may award more than one BPA under this solicitation.

25. ACCOUNTING AND APPROPRIATION DATA REQ-FFP-15-000XXX Contract Number AID-OAA-E-15-00XXX-00				26. TOTAL AWARD AMOUNT (For Govt. Use Only)			
X 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-3. FAR 52.212-4 AND 52.212-5 ARE NOT ATTACHED.				ADDENDA ARE X ARE NOT ATTACHED			
27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 ARE NOT ATTACHED.				ADDENDA ARE X ARE NOT ATTACHED.			
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.				29. AWARD OF CONTRACT: REFERENCE OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: <input type="checkbox"/>			
30a. SIGNATURE OF OFFEROR/CONTRACTOR				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) 			
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)		30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT)		31c. DATE SIGNED	
				Prince Boateng, M/OAA/T		03 /26/15	

The United States Agency for International Development, Office of Food For Peace is seeking to establish a Blanket Purchase Agreement (BPA) with one or more firms that will allow USAID to contract simply and quickly with these firms for immediate delivery of Ready To Use Therapeutic Food (RUTF) and Ready To Use Supplementary Food (RUSF). This competition for the BPA allows offerors to submit their proposals to USAID describing how their firm is capable and qualified to provide the commodities and services outlined in this BPA. The winning firm(s) would then have a signed agreement with USAID (which includes a minimum order guarantee of **zero nmt**), through which future contracts and delivery orders could easily be issued. The selected BPA holders must be able to perform all activities specified in the scope of work in support of USAID programs including storage of the RUTF/RUSF units so that they will be available for immediate delivery upon issuance of a written contract or order.

1. **Background**

RUTFs and RUSFs are high-energy fortified foods to be used by United States Agency for International Development for the treatment of Severe Acute Malnutrition (SAM) and Moderate Acute Malnutrition (MAM) in any cultural setting in accordance with guidelines for the outpatient care and management of Severe Acute Malnutrition and Moderate Acute Malnutrition. The RUTF/RUSF may be used in a wide variation of climatic zones and may be the sole source of food, in addition to and breast milk, during the period of use.

2. **Description:** This **Blanket Purchase Agreement** is issued to establish arrangements for ordering, storage, delivery, replenishment and billing to cover RUTF/RUSF during the agreement period of performance. The essence of this agreement is to have a contractor / vendor assemble, store, deliver and replenish the RUTF/RUSF for the United States Agency for International Development, Office of Food For Peace. RUTF/RUSF delivered under this BPA shall conform to the latest Commercial Item Description (CID) and USDA Commodity Requirement. RUTF/RUSF shall be stored at the contractor/vendor's facility until the government issues a contract or a purchase order for immediate release. As the RUTF/RUSF are standard configuration commodities, which are purchased by other governmental and non-governmental entities, any balance of RUTF/RUSF remaining in storage at the end of this agreement shall be retained by the contractor, without obligation by USAID, at the end of the BPA agreement period of performance. RUTF/RUSF may not be sold to other organization with USAID logo on them without specific written approval from the USAID Contracting Officer.

3. **AUTHORIZED GEOGRAPHIC CODE:** The authorized geographic code for procurement of goods and services under this BPA is Code 935.

4. The Government will evaluate proposal(s) submitted in response to this RFP and issue a Master BPA to those contractors determined to be responsible and acceptable by the government. As a result, the master BPAs will be sent to the contractor(s) for their acceptance. No agreement will exist until both the government and contractor sign the agreement. Master BPAs are not contracts and are not funded. Under the BPA, contracts or orders will be issued to order items under the Blanket Purchase Agreement.

5. **EXTENT OF OBLIGATION:** The agreement will not obligate the Government to order, or the contractor to furnish, any articles in any quantity except to the extent agreed upon in individual written contracts or orders. Individual orders maybe up to 1800 nmt. The government intends to purchase commodities and ship directly from manufacture warehouse and deliver to program location. This BPA is not a contract, but orders placed against it become contractual upon acceptance by the contractor. Generally 500 nmt will be held in storage by the contractor in preparation for order by the government. From time to time the government will order the contractor to deliver a quantity of RUTF/RUSF for transportation. Once RUTF/RUSFs are removed from storage, the contractor shall undertake action to replace those RUTF/RUSF with new RUTF/RUSF, so that

generally 500 nmt are in storage and available for delivery or release at any time. Replenishment or replacement RUTF/RUSF shall be placed in storage within one month of the delivery of commodity.

6. This agreement is made in accordance with negotiation authority of the U.S. Federal Acquisition Regulation 13.303 - Blanket Purchase Agreements.

7. **PRICING:** The prices to the U.S. government shall be as low as, or lower than, those charged the supplier's most favored customer for comparable quantities under similar terms and conditions, and shall include any discounts for prompt payment.

Notwithstanding any agreed discounts, the Contractor guarantees that the prices specified in this BPA, are the maximum prices that shall remain firm and shall not be increased during the entire term of the base period, provided however that in the event that the Contractor is able to offer the Government a discounted price, the unit prices shall be reduced for specific Purchase Orders.

RUTF/RUSF pricing shall be on the basis of FOB Origin (see U.S. Federal Acquisition Regulation clause 52.247-29).

8. The minimum purchase order quantity for items awarded under this entire agreement (base agreement period plus all option periods) is 0 nmt RUTF/RUSF. This is not a requirements contract, and the government may purchase RUTF/RUSF from other vendors as necessary.

9. No single purchase under this agreement shall exceed 1800 nmt.

10. The USAID Contracting Officer for FFP (for transportation or commodities) shall be the individual authorized to purchase commodities (RUTF/RUSF) under this BPA.

11. RUTF/RUSF shall be ready for purchase, delivery, pick-up and transport within 10 day of acceptance of written order placed by the government. The remaining shelf life of any delivered RUTF/RUSF shall be at least 20 months from the date of delivery.

12. RUTF/RUSF shall be packaged and boxed in such a manner to preclude damage to the RUTF/RUSF contents during international air or ocean transport.

13. The contractor shall prepare or make available standard shipping documents (packing lists, certificates of origin, etc. to permit the government or its agent or transport company to export and transport the RUTF/RUSF from the country of origin.

14. As specified in individual transactions, items are to be made available FOB Origin, unless otherwise agreed in writing between the parties.

15. All orders and deliveries and documents under this agreement shall be accompanied by written contract orders that contain the following information:

- (i) Standard Form 1449 with the BPA number.
- (ii) Name of supplier.
- (iii) Date of purchase.
- (iv) Purchase or Contract number.
- (v) Itemized list of supplies or services to be furnished.
- (vi) Quantity
- (vii) Date of delivery and delivery point.
- (viii) Funding and Accounting Information

- (ix) All purchase orders, which may be issued under this Blanket Purchase Agreement will be subject to and include the terms and conditions contained herein.

16. **TERM AND OPTION OF BPA:** The initial BPA is for a period of 6 months

17. **OPTION TO EXTEND THE TERM OF THE AGREEMENT:** The term of this agreement may be extended by mutual agreement of the parties, provided:

- a. Contractor may be contacted prior to the expiration of the current agreement if the government intends to extend the BPA (this notice **shall not** be deemed to commit the Government to an extension).
- b. The extension shall be a period of no more than 6 months. **BPA contract pricing shall be as stated in the attached contract schedule.**

18. **CONTRACT TYPE AND SERVICES :** The contract anticipated from this solicitation is a Blanket Purchase Agreement (BPA) utilizing individual task orders to provide technical services. Task Orders issued under this award will be Firm Fixed Price (FFP). The contractor must perform the services set forth in task orders at prices consistent with the simplified acquisition threshold (i.e. \$6,500,000 for commercial item)

19. **CONTRACTING OFFICER TECHNICAL REPRESENTATIVE:** The Contracting Officer's Technical Representative (COTR) will be designated by the Contracting Officer and is authorized to act within the limitations specified herein and written restrictions specifically imposed under the terms of the BPA award and under each Task Order, and by the Contracting Officer. This authority shall extend to the following: assisting with negotiating/ordering, inspection, acceptance, or rejection of work.

This designation does not include authority to direct changes in scope, price, terms or conditions of the contract or order. The authority herein also does not include authority to execute modifications to the contract or order, which require the signature of the Contracting Officer, or to bind the Government by contract in terms of a proposed contract change

- BPA COTR to be specified after signature of the award;
- Task Order COTR to be specified after signature of each Task Order.

20. **TASK ORDERS**

a. **Order Management Requirements:** Delivery of services shall be implemented only if directed by a Request from the Contracting Officer.

b. **Order Procedures:** Each Request will contain a statement describing the program to be performed, a description of the task, the deliverables, an anticipated starting and completion date, and the name of the COTR.

c. The Contracting Officer will issue Firm Fixed Price (FFP) Task/Delivery Order upon completion of negotiations

d. The BPA holder will respond to the Contracting Officer with a countersigned SF1449 if in agreement with the terms of the Contract within 3 working days.

21. INVOICES. The BPA holder will prepare and submit invoices to USAID. All invoices submitted for payment shall clearly identify:

- a. Task Order number;
- b. Period of performance

The BPA holder will submit one proper invoice, on a SF-1034 to USAID/W, Financial Management Office and one copy the COTR. Invoices can be submitted either electronically or in paper copy; however electronic submission to ei@usaid.gov is preferred. The financial Management Office will proceed to payment of each order upon receipt of the invoice approved by the COTR and accompanied by a receiving report. Under no circumstances will any invoice exceed the dollar amount (ceiling price) for any funded task order without prior Contracting Officer Approval. For more detailed information about invoices and payment, see the FAR clause 52.212-4, paragraph (g), "Invoice."

22. INSPECTION AND ACCEPTANCE: For all services/commodities furnished under any Task/Delivery Order, USAID will designate a COTR as the point of final inspection and acceptance. Deliverables will be submitted in accordance with terms stated in an individual Task/Delivery Order.

In general inspection and acceptance will be conducted at the contractor's FOB origin delivery point. Inspection and acceptance shall be conducted in accordance with the U. S. Federal Acquisition Regulations clause FAR 52.246-2 Inspection of Supplies – Fixed price.

The Contractor shall permit USAID, or any other representative as may be designated by USAID, to have access to the manufacturing facilities of the Goods, at all reasonable times to inspect the manufacturing site and processes for the production, quality control, quality assurance and packing of the Goods. The Contractor shall provide reasonable assistance to the representative for such appraisal, including copies of any documentation as may be necessary. USAID reserves the right to reject any Goods that do not conform to the required specifications.

The Contractor should conduct a periodic self-assessment of their operations and Quality System. The contractor shall provide USAID with results upon request.

The Contractor shall inform USAID whenever there is a significant change on their main processes / change of manufacturing site that could affect the quality of the product.

23. QUALITY ASSURANCE. Contract from this BPA shall provide the government quality assurance at source. The Government, through the USDA Agricultural and Service Marketing shall weigh, audit, inspect, and test the product offered in performance of the contract. In addition to internal quality assurance systems as indicated below, the contractor will submit samples to USDA/AMS laboratories for both nutritional and microbiological compliance as established below.

- a. Inspections and audits. Prior to any award, suppliers should have demonstrated sound quality and food safety programs, through written quality programs and a letter expressing their commitment to the highest quality and food safety standards through the provision of appropriate supplier's Certificate of Analysis (CoAs). USG usually carries out comprehensive audits annually, as well as unannounced routine inspections. Suppliers are expected to have and use a system for ensuring release and delivery of conforming product.
- b. Sampling and testing. Comprehensive testing including all the parameters in commodity specification shall be carried out during start up and annually thereafter. For ongoing monitoring testing, on a daily basis and reported in a per lot basis, the following parameters will be monitored for nutritional compliance:

No.	Parameter	Units	Min Qty	Max Qty
Main Composition				
1	Protein	g	13	16
2	Fat (total)	g	28	36
3	Water activity	aw	0.2	0.5
Vitamins and Minerals (expressed in a per 535 kcal/100 grams of product)				
4	Vitamin A (retinol isomers)	mcg	1100	1600
5	Vitamin C	mg	60	120
6	Iron	mg	10	14

For microbiological parameters shall be monitored daily, in a per lot basis:

Microbiological Test	IC/SU	n	c	m	M	Report Unit
<i>Enterobacteriaceae</i>	I/10	5	2	10	100	/g
<i>Salmonella</i>	C/25	10	0	0	0	/250g
<i>Aflatoxin B1, B2, G1 and G2. (ppb)</i>	C/25	10	0	5	5	/250g

24. **SHELF LIFE.** Unless specifically authorized in writing by USAID Contracting Officer, products must be of fresh production e.g., less than 4 months old at the time of delivery.

25. **CLOSEOUT PROCEDURE:** To facilitate closeout of individual Task/Delivery Order placed under this BPA, within thirty (30) days of completion of any individual task order, the BPA holder shall present the final invoice to Financial Management, and a copy to the Contracting Officer.

26. **LIQUIDATED DAMAGES.** USAID may claim liquidated damages from the Contractor on contracts under this BPA as following. Charges may be applied if the Contractor does not meet the individual purchase order delivery date.

a. If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the Government liquidated damages of \$1000 per calendar day of delay.

b. If the Government terminates this contract in whole or in part under the Default—Fixed-Price Supply and Service clause, the Contractor is liable for liquidated damages accruing until the Government reasonably obtains delivery or performance of similar supplies or services. These liquidated damages are in addition to excess costs of repurchase under the Termination clause.

c. The Contractor will not be charged with liquidated damages when the delay in delivery or performance is beyond the control and without the fault or negligence of the Contractor as defined in the Default—Fixed-Price Supply and Service clause in this contract.

27. By signing below you are certifying that the products offered the government under this BPA, and to be delivered, meet all the requirements of the item purchase description. Failure to meet these requirements may result in your bearing the cost of:

- a. Replacing items.
- b. Transportation Expenses

c. Government administrative re-procurement expenses.

Offeror's Name and Signature

Date

Company Name:

Address:

Email Address:

Phone Number:

28. This BPA may be cancelled for default if the contractor is noncompliant with terms and conditions of this agreement.

29. OFFEROR'S CONTACT INFORMATION:

NAME: _____

DUNS #: _____ EIN/TIN: _____

ADDRESS: _____

CITY: _____ STATE: ____ ZIP CODE: _____

TELEPHONE: _____ FAX: _____

EMAIL Address: _____

30. NOTICE OF INDIVIDUAL AUTHORIZED TO PURCHASE UNDER THE BPA: USAID Contracting Officers located at:

USAID/Washington, D.C.
Office of Acquisition and Assistance
Transportation Contracting Officer for DCHA/FFP
DCHA/FFP Commodity Contracting Officer

31. EVALUATION of PROPOSALS:

See Federal Acquisition Regulation clause 52.212-2 "Evaluation – Commercial Items." The following factors shall be used to evaluate offers:

Technical responsiveness of the items offered; technical capability of the offering manufacturer/supplier; ability to complete the RUTF/RUSF with perishable or temperature controlled items or supplies upon issuance of a written order; ability to quickly replenish purchased/delivered items and place them in storage for available delivery; price for RUTF/RUSF per ton; past performance information. **Technical and past performance criteria are slightly less important than price in determining the best value to the government.** Any resulting agreement will be based on a best value determination by the U.S. government. Consideration shall be given to the vendor price, delivery schedule, replacement or replenishment time, transportation costs from the contractor's point of origin and past performance. For proposal instructions, see the United States Federal Acquisition Regulation

FAR 52.212-1 INSTRUCTIONS TO OFFERORS COMMERCIAL ITEMS

Past Performance - "CONTRACTOR PERFORMANCE INFORMATION"

(a) The offeror (including all partners of a joint venture) must provide past performance information for itself in accordance with the following:

1. Your technical proposal shall include up to 3 of the most recent and relevant contracts for efforts similar to the work in this BPA. The most relevant indicators of performance are contracts of similar contract type, type of work, scope of work, complexity/diversity of tasks, skills and expertise required.
2. Provide for each of the contracts listed above a list of contact names, job titles, mailing addresses, phone numbers, e-mail addresses, and a description of the performance to include:
 - Scope of work or complexity/diversity of tasks,
 - Point of contact information
 - Term of performance,
 - Commodities required,
 - Dollar value, and
 - Contract type, i.e. fixed-price, cost reimbursement, etc.

(USAID recommends that you alert the contacts that their names and contact information have been submitted and that they are authorized to provide performance information concerning the listed contracts if and when USAID requests it).

If extraordinary problems impacted any of the referenced contracts, provide a short explanation and the corrective action taken.

Describe any quality awards or certifications that indicate exceptional capacity to provide the commodities and service or product described in the statement of work.

32. APPLICABLE UNITED STATES FEDERAL ACQUISITION REGULATION CLAUSES:

All contract orders placed against this BPA are subject to the terms and conditions of these clauses and provisions:

- | | |
|---------------|---|
| FAR 52.211-11 | LIQUIDATED DAMAGES |
| FAR 52.212-1 | INSTRUCTIONS TO OFFERORS COMMERCIAL ITEMS |
| FAR 52.212-2 | EVALUATION – COMMERCIAL ITEMS |
| FAR 52.212-3 | OFFERORS REPRESENTATIONS AND CERTIFICATIONS
COMMERCIAL ITEMS |
| FAR 52.212-4 | CONTRACT TERMS AND CONDITIONS -COMMERCIAL ITEMS |

- | | |
|--------------|--|
| FAR 52.212-5 | Contract Terms and Conditions Required to Implement Statutes or Executive
Orders – Commercial Items, Including Alternate 1.
The following clauses are “checked” and incorporated by reference:52,203-13;
52.222-26; 52.222-35; 52.225-50. |
|--------------|--|

- | | |
|---------------|---|
| FAR 52.216-24 | LIMITATION OF GOVERNMENT LIABILITY |
| FAR 52.216-18 | ORDERING |
| FAR 52.217-9 | OPTION TO EXTEND THE TERM OF THE CONTRACT |
| FAR 52.225-13 | RESTRICTIONS ON CERTAIN FOREIGN PURCHASES |

- FAR 52.232-33 PAYMENT BY ELECTRONIC FUNDS TRANSFER – CENTRAL CONTRACTOR REGISTRATION.
- FAR 52.232-38 SUBMISSION OF ELECTRONIC FUNDS TRANSFER INFORMATION WITH OFFER
- FAR 52.246-2 INSPECTION OF SUPPLIES -FIXED PRICE
- FAR 52.222-50 COMBATING TRAFFICKING IN PERSON (FEB 2009)
- FAR 52.249-1 TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED PRICE) (SHORT FORM)
- FAR 52.249-8 TERMINATION FOR Default (Fixed-Price Supply and Service).

The Contractor is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor/recipient to ensure compliance with these Executive Orders and laws. This provision must be included in all subcontracts/sub-awards issued under this contract/agreement.

The above clauses are available on the internet at <https://www.acquisition.gov/>
Copies of the clauses are also available from this office.

Submit clean (all-inclusive) written proposal(s) for the above requirement to USAID by Thursday, April 9, 2015 at 1200 hours (Washington, D.C. local time). Only EMAIL transmission is acceptable and must be sent to all: Pboateng@usaid.gov Pvicinanza@usaid.gov rohick@usaid.gov and OAA.DRTransport@USAID.GOV. Any questions about this solicitation should be addressed to the USAID contracting officer.

Late proposals will not be considered except in accordance with FAR and agency provisions.

BPA Price Schedule

The below prices shall include all expenses incident to the services to be performed and materials to be delivered. Payments shall be limited to actual commodities purchased. No claim for any additional compensation shall be considered unless it has been authorized by the Contracting Officer in writing in advance. The Government shall not be responsible for any work performed that is not specifically provided for under the terms of this Agreement or authorized by the Government in writing in advance.

Item Purchase Description (IPD)

Agreement Base Period

LINE ITEM	Commodity	Unit of Issue	Size	EST. ANNUAL QTY.	Shipping Location	FOB ORIGIN UNIT PRICE
CLIN 001	RUTF/RUSF – 500 nmt in storage and available for immediate delivery within 10 days of acceptance of a written purchase order	Each		8,000-10000	Contractor's Origin	\$ _____

Agreement Option Period 1

LINE ITEM	Commodity	Unit of Issue	Size	EST. ANNUAL QTY.	Shipping Location	FOB ORIGIN UNIT PRICE
CLIN 001	RUTF/RUSF – 500 nmt in storage and available for immediate delivery within 10 days of acceptance of a written purchase order	Each		8,000-10000	Contractor's Origin	\$ _____

Agreement Option Period 2

LINE ITEM	Commodity	Unit of Issue	Size	EST. ANNUAL QTY.	Shipping Location	FOB ORIGIN UNIT PRICE
CLIN 001	RUTF/RUSF – 500 nmt in storage and available for immediate delivery within 10 days of acceptance of a written purchase order	Each		8,000-10000	Contractor's Origin	\$ _____

Agreement Option Period 3

LINE ITEM	Commodity	Unit of Issue	Size	EST. ANNUAL QTY.	Shipping Location	FOB ORIGIN UNIT PRICE
CLIN 001	RUTF/RUSF – 500 nmt in storage and available for immediate delivery within 10 days of acceptance of a written purchase order	Each		8,000-10000	Contractor's Origin	\$ _____

Agreement Option Period 4

LINE ITEM	Commodity	Unit of Issue	Size	EST. ANNUAL QTY.	Shipping Location	FOB ORIGIN UNIT PRICE
CLIN 001	RUTF/RUSF – 500 nmt in storage and available for immediate delivery within 10 days of acceptance of a written purchase order	Each		8,000-10000	Contractor's Origin	\$ _____

FAR 52.204-7 CENTRAL CONTRACTOR REGISTRATION (APR 2008)

(a) Definitions. As used in this clause—

“Central Contractor Registration (CCR) database” means the primary Government repository for Contractor information required for the conduct of business with the Government.

“Data Universal Numbering System (DUNS) number” means the 9-digit number assigned by Dun and Bradstreet, Inc. (D&B) to identify unique business entities.

“Data Universal Numbering System +4 (DUNS+4) number” means the DUNS number assigned by D&B plus a 4-character suffix that may be assigned by a business concern. (D&B has no affiliation with this 4-character suffix.) This 4-character suffix may be assigned at the discretion of the business concern to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see the FAR at [Subpart 32.11](#)) for the same concern.

“Registered in the CCR database” means that—

(1) The Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the CCR database; and

(2) The Government has validated all mandatory data fields, to include validation of the Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS), and has marked the record “Active”. The Contractor will be required to provide consent for TIN validation to the Government as a part of the CCR registration process.

(b)(1) By submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the CCR database prior to award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.

(2) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation “DUNS” or “DUNS +4” followed by the DUNS or DUNS +4 number that identifies the offeror’s name and address exactly as stated in the offer. The DUNS number will be used by the Contracting Officer to verify that the offeror is registered in the CCR database.

(c) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.

(1) An offeror may obtain a DUNS number—

(i) Via the Internet at <http://fedgov.dnb.com/webform> or if the offeror does not have internet access, it may call Dun and Bradstreet at 1-866-705-5711 if located within the United States; or

(ii) If located outside the United States, by contacting the local Dun and Bradstreet office. The offeror should indicate that it is an offeror for a U.S. Government contract when contacting the local Dun and Bradstreet office.

(2) The offeror should be prepared to provide the following information:

(i) Company legal business.

(ii) Trade style, doing business, or other name by which your entity is commonly recognized.

(iii) Company Physical Street Address, City, State, and ZIP Code.

(iv) Company Mailing Address, City, State and ZIP Code (if separate from physical).

(v) Company Telephone Number.

(vi) Date the company was started.

(vii) Number of employees at your location.

(viii) Chief executive officer/key manager.

(ix) Line of business (industry).

(x) Company Headquarters name and address (reporting relationship within your entity).

(d) If the Offeror does not become registered in the CCR database in the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror.

(e) Processing time, which normally takes 48 hours, should be taken into consideration when registering. Offerors who are not registered should consider applying for registration immediately upon receipt of this solicitation.

(f) The Contractor is responsible for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(g)

(1)

(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in [Subpart 42.12](#), the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of [Subpart 42.12](#) of the FAR; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (g)(1)(i) of this clause, or fails to perform the agreement at paragraph (g)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see FAR [Subpart 32.8](#), Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(h) Offerors and Contractors may obtain information on registration and annual confirmation requirements via the internet at <http://www.ccr.gov> or by calling 1-888-227-2423, or 269-961-5757.

USDA COMMODITY REQUIREMENTS

**RUTF2
READY-TO-USE THERAPEUTIC FOOD FOR USE IN EXPORT
PROGRAMS**

READY-TO-USE THERAPEUTIC FOOD (RUTF)

Effective Date: May 22, 2012

**USDA COMMODITY REQUIREMENTS
RUTF2
READY-TO-USE THERAPEUTIC FOOD
FOR USE IN EXPORT PROGRAMS**

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Part 1 Commodity Specifications

Section 1.1 Ready-to-Use Therapeutic Food Product Requirements

- A. Quality of Ready-to-Use Therapeutic Food (RUTF)
The RUTF shall meet the requirements as specified in the Commercial Item Description (CID) for Ready-to-Use Therapeutic Food (RUTF), A-A-20363A, dated May 17, 2012, which is available at:
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5091746>
- B. Fortification
The RUTF shall be fortified with a vitamin and mineral premix, meeting requirements in the CID.

Section 1.2 Quality Assurance

- A. The Dairy component manufacturer will be required to have their facility inspected by the Dairy Grading Branch (DGB), Dairy Program (DP), Agricultural Marketing Service (AMS), USDA to meet requirements contained in Title 7 Code of Federal Regulations, Part 110. DGB shall certify and document with official DGB certificates that the dairy components meet the requirements as stated in Section 10.2 of the CID. For DGB certification contacts refer to the CID, Section 14.

In addition to any testing that the Government may perform under the Inspection clause of the contract, the contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results of the contractor's testing shall be evidenced by a Certificate of Analysis (COA). The COA shall provide the results of all tests specified. In addition, the contractor shall provide a Certificate of Conformance (COC) certifying that the product meets all the specifications of the contract. Copies of both the original COA and COC must be submitted as part of the invoice package.

- B. The manufacturer will be required to provide evidence that the manufacturing plant has undertaken quality assurance measures within the 12 months prior to the date of contract award in accordance with CID, Quality Assurance provisions, Section 11.2.

Part 2 Container and Packaging Requirements

Section 2.1 General

This part provides the container specifications and requirements for packaging materials. "Pouch," as used in this Part, means the primary packaging for the RUTF as defined in Section 7 of the CID.

Section 2.2 Containers and Materials

- A. All containers and packaging shall be constructed to meet the requirements of the Food and Drug Administration (FDA) for safe contact with the packaged product. The contractor shall obtain and maintain documentation from the container or packaging material manufacturer to verify that the containers and packaging materials used in this contract were in compliance with the Government's regulatory requirements for safe contact with food products as required in the Master Solicitation, Part 3, Section A, Number 3.
- B. Questions concerning the containers and materials should be directed to:
USDA/FSA/DACO
Room 5755 – South Bldg, STOP 0553
1400 Independence Avenue SW
Washington, DC 20250-0551
ATTN: Packaging
- C. If the contractor purchases packaging and container ingredients from a foreign country and/or the package and container is manufactured in a foreign country, the package and container SHALL NOT display country of origin labeling. Phrases including, but not limited to, "Made in [Name of Foreign Country]" or "Product of [Name of Foreign Country]" are strictly prohibited.

Section 2.3 Primary Pouch Requirements and Examinations for RUTF

- A. The primary pouch requirements and examinations are specified in Section 7 of the CID.
- B. For labeling of primary pouch package – See Exhibit A
- C. Primary packaging shall have a code to indicate production lot.

Section 2.4 Section 2.4 Secondary Packaging (Corrugated Fiberboard Shipping Containers) for RUTF

- A. Corrugated Fiberboard Shipping Containers (Shipping Container) – Shall contain 150 pouches of RUTF. The shipping container will be a regular slotted container constructed of a minimum 450 lb. burst test, corrugated fiberboard. The outside dimensions of each shipping container will be no higher 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 approximately 8 in. height x 16 in. length x 13.25 in. width, 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 8 inches and the pallets, when double stacked, can fill at least 80% of the cubic capacity of a 20 foot intermodal

container. No liners shall be used inside the shipping containers. 150 pouches shall be placed directly into the fiberboard shipping container.

- B. The shipping container will be of a sturdy export quality, of virgin base materials and constructed and closed to provide adequate protection of the goods for transportation by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity.
- C. The shipping containers may be pre-printed, printed on line, or a pre-printed label may be affixed to the box.
- D. Shipping container labeling – See Exhibit B. The outer shipping container shall include the statement, “This Product is not to be Sold or Exchanged.” Weight must be stated in Kilograms and Lbs.
- E. The shipping container shall comply with the following unitization requirements:
 - (1) All shipments of packaged products shall be unitized (palletized and stretch wrapped).
 - (2) Pallets shall be:
 - a. Constructed to facilitate the safe handling and transportation of the packaged product, as a unit, without loss or damage.
 - b. Pallets will be 1200 x 1000 x 144 mm, 4-way or partial 4-way entry with reversible or nonreversible flush stringer, wooden pallets suitable for international shipment. Pallets manufactured from other materials than solid wood are NOT acceptable (such as wood chip, plastic, MDF board, ply wood or carton). Pallets must have three (3) longitudinal bottom deck lead boards, feet are NOT acceptable.
 - c. All wood packaging, including pallets and boxes, utilized in any shipment, must have undergone the treatment, marking and documentation required to meet the specifications described in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at www.ippc.int

(3) Plastic stretch wrap shall be:

- a. Constructed of a plastic film which is to be stretched a minimum of 50 percent beyond its original length when stretched around the pallet load.
- b. Applied as tightly as possible around all tiers of the palletized shipping containers. The shipping containers shall be held firmly in place by the stretch wrap.

(4) Pallet loads shall be:

- a. Stacked in such a way as to minimize the amount that shipping containers overhang the edges of pallets.
- b. Blocked and braced or otherwise loaded into the conveyance in a manner that prevents shifting during transit.

- F. The packaging unit will be strong enough to be stacked to a height of 2 pallets during storage and transport without damage to the product, and will be resistant to puncturing. Shipping containers shall be marked to show the maximum safe stacking height. This should be expressed as follows: "Do not stack above ___ tiers per pallet, ___ pallets high." It is the responsibility of the contractor in cooperation with the container manufacturer to determine the safe stacking height.

Part 3 Marking Requirements

Following are the marking exhibits for the RUTF Paste. All packaging shall meet the USAID Branding/Markings requirements described in the USAID Graphic Standards Manual on USAID's website at: <http://www.usaid.gov/branding/gsm.html>. Markings for the pouches are to be printed entirely in red Pantone Matching System (PMS) 200.

Section 3.1 Lot Codes

Lot codes unique to each lot offered for inspection shall be legibly marked on each individual primary container and shipping container. Commodity suppliers may use any type of lot coding system provided a unique code is used to identify each lot offered for inspection under contract. Commodity suppliers shall provide the contracting officer with an explanation of the lot coding system used.

Section 3.2 Containers with Incorrect Markings

- A. Any labels, bags, cans, can lids, cases, or any other type of packaging (hereinafter referred to as "containers") displaying incorrect markings may be used under a Government contract provided that the incorrect markings are obliterated and correct markings are applied in a permanent manner with approval of the contracting officer.
- B. The appearance of containers in commercial or other channels either filled or unfilled bearing markings identifying the containers as part of a Government

contract may cause the Government expense in determining whether commodities have been diverted from authorized use and in answering inquiries. The contractor shall take all necessary action to prevent the appearance in commercial or other channels of containers and container materials bearing any markings required under a Government contract, including those held by the contractor or others; e.g., overruns, misprints, etc. The contractor shall ensure that any container from a Government contract that appears in commercial or other channels shall have all markings required under this contract permanently obliterated.

Exhibit A RUTF Paste Primary Container Markings

Offerors may find more detailed renderings of the markings at the following web link: <http://www.fsa.usda.gov/FSA/webapp?area=home&subject=coop&topic=pas-ex-cr>.

Contract Number:
Date of Manufacture:
Best used by date:
Lot no.:

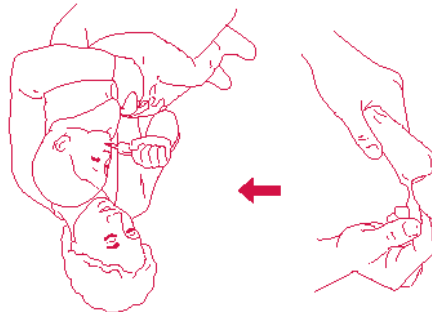


N° Contrat:
Date de fabrication:
À consommer de
préférence avant:
N° lot:

USAID
FROM THE AMERICAN PEOPLE

RUTF

Ready-to-Use Therapeutic Food
for children with Severe Acute Malnutrition (SAM)



» Tear off tab of package and squeeze
bite size contents into mouth.
» Once package is opened, consume in
one day.
» Not suitable for children less than 6
months of age.

Net Weight: 92 grams
50kcal
Ingredients:

Exhibit B RUTF Paste Secondary Container Markings

Offerors may find more detailed renderings of the markings at the following web link:
<http://www.fsa.usda.gov/FSA/webapp?area=home&subject=coop&topic=pas-ex-cr>.

Contains 150 – 92 gram pouches
Total Weight: (XX) Kilograms, (XX) Lbs.
Net Weight: (XX) Kilograms, (XX) Lbs.



Vendor Contract Number:
Date of Manufacture:
Best If Used By Date:
Lot Number:

USAID
FROM THE AMERICAN PEOPLE

RUTF

**Ready-to-Use Therapeutic Food
for children with Severe Acute Malnutrition (SAM)**

This Product is Not to be Sold or Exchanged

METRIC

A-A-20363B

November 21, 2012

SUPERSEDING

A-A-20363A

May 17, 2012

COMMERCIAL ITEM DESCRIPTION

READY-TO-USE THERAPEUTIC FOOD (RUTF)

The U.S. Department of Agriculture (USDA) has authorized the use of this Commercial Item Description (CID).

1. SCOPE. This CID covers ready-to-use therapeutic foods (RUTF), packaged in flexible packaging, suitable for use by the Federal 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 as part of a medical malnutrition intervention program for targeted populations, including children 6 months to 5 years of age with SAM who are free from severe medical complications and who have appetite, in accordance with United Nations (UN) guidelines for the outpatient care and management of SAM¹ and in accordance with national guidelines for the management of SAM, Valid International 2006 Community-based Therapeutic Care (CTC) A field manual.² 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 Catalog: <https://supply.unicef.org/>.

2. PURCHASER NOTES.

2.1 Purchasers *shall* specify the following:

- Type(s) of RUTF required (Sec. 3).
- When the RUTF fortification (vitamin and mineral premix used in RUTF) is different than specified (Sec. 5).
- When product standard is not required (Sec. 5.7).

¹ "Community-Based Management of Severe Acute Malnutrition." A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition, and the United Nations Children's Fund. 2007. Website: http://www.who.int/nutrition/topics/Statement_community_based_man_sev_acute_mal_eng.pdf. Date accessed November 16, 2012.

² "Community-based Therapeutic Care (CTC) A Field Manual." Valid International. 2006. Website: <http://www.fantaproject.org/ctc/manual2006.shtml>. Date accessed November 15, 2012.

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- When proximate and microbiological testing requirements are different than specified (Sec. 6.1).
- When proximate and microbiological testing requirements does not need to be verified (Sec. 6.1).
- When proximate and microbiological testing requirements need to be verified by USDA (Sec. 6.2).
- When packaging examinations do not need to be verified by USDA (Sec. 7).
- Manufacturer's certification (Sec. 11.3) or USDA certification (Sec. 11.4).
- When finished product examination does not need to be conducted (Sec. 11.5).

2.2 Purchasers *may* specify the following:

- When the dairy components for the RUTF are to be graded or inspected by the Dairy Grading Branch (DGB), Dairy Programs (DP), Agricultural Marketing Service (AMS), USDA (Sec. 10).
- Food Defense System Survey (FDSS) (Sec. 11.1 with 11.2.1) or (Sec. 11.1 with 11.2.2).
- Manufacturer's quality assurance (Sec. 11.2 with 11.2.1) or (Sec. 11.2 with 11.2.2).
- Packaging requirements other than specified (Sec. 7.2.1 and Sec. 12).

3. 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.”

Types.

Type I - RUTF Spread

Type II - RUTF Bar

4. MANUFACTURER'S NOTES. Manufacturer's products *shall meet* the requirements of the:

- Salient characteristics (Sec. 5).
- Analytical requirements: *as specified by the purchaser* (Sec. 6).
- Pouch requirements and examinations (Sec. 7).
- Manufacturer's product assurance (Sec. 8).
- Regulatory requirements (Sec. 9).
- Quality assurance provisions for the dairy components: *as specified by the purchaser* (Sec. 10).

- Quality assurance provisions: *as specified by the purchaser* (Sec. 11).
- Packaging requirements other than specified (Sec. 12).

5. SALIENT CHARACTERISTICS.

5.1 Processing. The RUTF must be processed in accordance with applicable Codex Alimentarius Standards and Guidelines^{3, 4, 5, 6, 7} and the Food and Drug Administration's (FDA's) Current Good Manufacturing Practices (Code of Federal Regulations (CFR) 21 Part 110). In addition, 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.

5.2 Food Security. The RUTF shall be processed and transported in accordance to the FDA's *Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance*.

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm>. This guidance identifies the kinds of preventive measures food manufacturers, processors, or handlers may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. The implementation of enhanced food security preventive measures provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials, other ingredients and postproduction finished product.

³ "Recommended International Code of Practice General Principles of Food Hygiene." CAC/RCP 1-1969, revised 4-2003. Website: www.codexalimentarius.org/input/download/standards/23/CXP_001e.pdf. Date accessed November 15, 2012.

⁴ "Code of Hygienic Practice for Powdered Formulae for Infants and Young Children." CAC/RCP 66-2008. Website: http://www.codexalimentarius.org/download/standards/11026/CXP_066e.pdf. Accessed November 15, 2012.

⁵ "Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria Monocytogenes in Foods." CAC/GL 61-2007. Website: http://www.codexalimentarius.net/download/standards/10740/CXG_061e.pdf. Accessed November 16, 2012.

⁶ "Codex Standard for Processed Cereal-Based Foods for Infants and Young Children." CODEX STAN 074-1981. Revised 1-2006. Website: http://www.codexalimentarius.net/download/standards/290/cxs_074e.pdf. Accessed November 16, 2012.

⁷ "Guidelines on Formulated Supplementary Foods for Older Infants and Young Children." CAC/GL 08-1991. Website: http://www.codexalimentarius.net/download/standards/298/CXG_008e.pdf. Accessed November 16, 2012.

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5.3 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.

5.3.1 Type I, spread. 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 nonfat dry milk. The RUTF shall not contain artificial antioxidants and artificial flavorings.

5.3.2 Type II, bars. The Type II, RUTF bars shall have an energy content of 520 to 550 kcal per 100 grams. The Type II RUTF bars are compressed bars, manufactured from a pre-cooked grain-based cereal and dairy mix. The Type II, RUTF bar formula shall have a protein content of 10.0 to 12.0 percent of kcal and the protein component shall have a PDCAAS of 1.0. The sources of protein may be grains, dairy, legumes, and protein isolates. The Type II, RUTF bar shall have a lipid content between 45.0 and 60.0 percent of the kcal. The Type II, RUTF bar shall have approximately 10.0 percent kcal from saturated fat, and the only added oils allowed will be canola oil or soybean oil. Partially hydrogenated (Trans) fatty acids shall not be used in RUTF bars (CODEX STAN 074-1981, Revised 1-2006). The Type II, RUTF bar may contain a grain-based cereal, pre-cooked cereal, vitamin and mineral pre-mix, protein source, oil, sweeteners and antioxidants (ascorbyl Palmitate, BHA, and mixed tocopherols). At least 50 percent of the protein content shall be derived from milk products such as, but not limited to: whole whey protein, whey protein concentrate 80 percent, dry whole milk, whole fat milk, or nonfat dry milk. The undigestible fiber content should be less than 5g/100g. The RUTF shall not contain artificial flavoring or coloring.

5.3.3 Water Activity (A_w). The A_w of the packaged product shall not be more than 0.60.

5.3.4 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.

5.3.5 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); dry

whole 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]; nonfat dry milk (Codex Standard for Milk Powders and Cream Powder, [CODEX STAN 207-1999]; FDA's Standard of Identity for Nonfat Dry Milk [21 CFR § 131.125] and FDA's Standards of Identity for Nonfat 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.

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

5.3.7 Stability. The Type I, RUTF spread, shall be stable at temperatures ranging from -15 to 49°C (5 to 120°F). There shall be no more than slight oil separation throughout the shelf life of the product (see paragraph 5.6).

5.3.8 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 odors and flavors. 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 I. Nutrient requirements of RUTF premix

	Spread/100 g	Bars/100 g
Vitamin A	0.8 - 1.1 mg	0.8 - 1.1 mg
Vitamin B ₁	0.5 mg min ⁹	0.5 mg
Vitamin B ₂	1.6 mg min	1.6 mg
Niacin	5.0 mg min	5.0 mg min
Vitamin B ₆	0.6 mg min	0.6 mg min
Vitamin B ₁₂	1.6 µg min	1.6 µg min
Biotin	60 µg min	60 µg min

⁸ "Codex Standard for Milk Powders and Cream Powder." CODEX STAN 207-1999. Website: http://www.codexalimentarius.net/download/standards/333/CXS_207e.pdf. Accessed November 16, 2012.

⁹ Minimum

TABLE I. Nutrient requirements of RUTF premix (continued)

	Spread/100 g	Bars/100 g
Folic Acid	200 µg min	200 µg min
Pantothenic Acid	3.0 mg min	3.0 mg min
Vitamin C	50 mg min	50 mg min
Vitamin D ₃	15 - 20 µg	15 - 20 µg
Vitamin E	20 mg min	20 mg min
Vitamin K ₁	15 - 30 µg	15 - 30 µg
Calcium	300 - 600 mg	300 - 600 mg
Copper	1.4 - 1.8 mg	1.4 - 1.8 mg
Iodine	70 - 140 µg	70 - 140 µg
Iron (as encapsulated ferrous sulfate)	10 - 14 mg max ¹⁰	7 - 11 mg max
Iron (as Na Fe EDTA) [Bars]	---	2.5 mg ¹¹
Magnesium	80 - 140 mg	80 - 140 mg
Phosphorus (excluding phytate)	300 - 600 mg	300 - 600 mg
Potassium	1,100 - 1,400 mg	1,100 - 1,400 mg
Selenium	20 - 40 µg	20 - 40 µg
Sodium	290 mg max	290 mg max
Zinc	11 - 14 mg	11 - 14 mg

TABLE II. 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%)

¹⁰ Maximum

¹¹ For bars, the iron fortificant will be in the form of Na Fe EDTA up to the maximum allowable regulatory limit, with the remainder provided in the form of Ferrous Fumarate in order to get to a minimum of 10 - 14 mg iron per 100 gm.

TABLE II. Chemical forms of nutrients (continued)

Nutrient	Possible chemical forms	Preferred chemical form
Biotin	---	---
Folic Acid	---	Ptroylmonoglutamic acid
Vitamin C	---	L-ascorbic acid
Vitamin D ₃	---	Cholecalciferol (D ₃)
Vitamin E	---	DL-alpha-tocopherol acetate
Vitamin K ₁	---	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

5.4 **Finished product.**

5.4.1 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. The Type II, RUTF bars shall be compressed into a rectangular shape approximately 50 g in weight. The Type II, RUTF bars shall have a smooth exterior that easily crumbles with gentle finger pressure and the interior particle size is uniform.

5.4.2 Flavor and odor. The Type I, RUTF spread shall be free from foreign odors and flavors such as, but not limited to burnt, scorched, rancid, malted, sour, or stale. The Type II, RUTF bars shall have a slightly sweet grain odor (appropriate for the grain used) with a blended cereal flavor

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of the pre-cooked cereal mix. The Type II, RUTF bars shall not possess distinct flavor notes attributable to the protein sources or the vitamins and minerals. The RUTF shall not contain any artificial flavoring.

5.4.3 Color. The Type I, RUTF spread shall have a cream to light brown color. The Type I, RUTF spread shall not have a dull, gray tinge, or other abnormal cast. The Type II, RUTF bars shall have a light tan to dark tan color. The RUTFs shall show no evidence of excessive heating (materially darkened or scorched).

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

5.6 Age requirement. 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 26.7°C (80°F) and the RUTF bar shall have a shelf life of at least 24 months when stored at 26.7°C (80°F).

5.7 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 this CID (Sec. 11.6). 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 CID including product standard comparability.

6. ANALYTICAL REQUIREMENTS.

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 RUTF shall be as follows:

<u>Test</u>	<u>Tolerance</u>
Energy	520-550 kcal/100 g for Type I, RUTF spread 520-550 kcal/100 g for Type II, RUTF bars
Protein	10-12 percent of kcal
Total Fat	45-60 percent of kcal

<u>Test</u>	<u>Tolerance</u>
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 Aflatoxin
Melamine/Cyanuric acid	Less than 25 ppb
Coliform	Less than 10 CFU/g or less than 3 Most Probable Number (MPN)/g ¹²
Yeast	Not more than 10 in 1 g
Mold	Not more than 50 in 1 g
<i>Clostridium perfringens</i>	Negative
<i>Salmonella</i>	Negative
<i>E. coli</i>	Negative
<i>Listeria monocytogenes</i>	Negative
<i>Staphylococcus aureus</i> (coagulase positive)	Negative
<i>Cronobacter sakazakii</i>	Negative in 10 g
Vitamin A	0.8 - 1.1 mg/100 g
Vitamin B ₁	Minimum 0.5 mg/100 g
Vitamin C	Minimum 50 mg/100 g
Iron	10 - 14 mg/100 g

6.2 Product verification. When USDA 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). The number of subsamples drawn to make the proximate composite shall be based on USDA procedures. For the Aflatoxin test a single composite sample shall be produced from 60 randomly drawn pouches. For microbiological tests five homogenized composite samples shall be produced from a total of 60 randomly drawn pouches (12 per composite) per production lot.

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. 6.2. The test portion size for testing aerobic plate count, coliform, and yeast and mold 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 be 10 g (0.32 oz) each.

¹² Findings indicate zero colonies (CFU) per plate or zero tubes producing gas for MPN.

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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.

<u>Test</u>	<u>Method</u>
Protein	988.05, 992.15
Fat	991.36, 2007.04, 2008.06
A _w	978.18
Aflatoxin	990.33, 991.31, 998.03, or 999.07
Melamine/Cyanuric acid	FDA LIB 4421, FDA LIB 4422, FDA LIB 4423
Standard plate count	966.23, 990.12, 2008.10, or BAM, Ch 3 ¹³
Coliform	966.24, 986.33, 989.19, 991.14, 2000.15, 2008.10, or BAM, Ch. 4 ¹³
Yeast and Mold	997.02, 995.21
<i>Clostridium perfringens</i>	976.30 or BAM, Ch. 16 ¹³
<i>Salmonella</i>	2004.03, 2003.09, 2011.03, or BAM, Ch. 5 ¹³
<i>E. coli</i>	966.24, 986.33, 989.19, 991.14, 2000.15, 2009.02, or BAM, Ch.4 ¹³
<i>Listeria monocytogenes</i>	992.18, 2003.12, 2004.02, or 2010.02
<i>Staphylococcus aureus</i> (coagulase positive)	2003.07, 2003.08, or 2003.11
<i>Cronobacter sakazakii</i>	ISO 22964 or BAM ucm289378 ¹⁴
Vitamin A	2001.13, 2011.11, or 2011.13
Vitamin B ₁	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 A_w shall be reported to the nearest 0.01 value. No individual sample shall have an A_w value exceeding 0.60. The test results for standard plate count and yeast and mold 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*,

¹³ 8th Edition, FDA BAM or the FDA BAM Online.

¹⁴ The FDA's update methodology for testing *C. sakazakii* is available at: <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm289378.htm>. Date accessed November 16, 2012.

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.

7. PACKAGING REQUIREMENTS AND EXAMINATIONS.

7.1 Pouch requirements.

7.1.1 Pouch material. The pouch material shall be capable of being fabricated into pouches. The material used for the pouch shall be generally recognized as safe (GRAS) for use with food in accordance with 21 CFR Parts 170-199 or other 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.

7.1.2 Oxygen transmission rate. The oxygen transmission rate (O₂TR) of the material shall not exceed 0.06 cc/m²/24 hrs/atm. The O₂TR of the material shall be determined in accordance with ASTM D 3985, at 23°C (73°F) and 50 percent relative humidity (RH). Any O₂TR 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 O₂TR requirement may be verified by COA from the packaging manufacturer.

7.1.3 Water vapor 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.

7.1.4 Filled and sealed pouches. Filled and sealed pouches 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 pouch material, or leakage through any seal). The pouch material shall not transfer any foreign flavor or odor to the product being packaged.

7.1.4.1 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.

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

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7.2 Filled and sealed pouch examination. The filled and sealed pouches shall be examined for the defects listed in Table III 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 pouches. The sample unit shall be one filled and sealed pouch. The inspection level shall be I and the acceptable quality level (AQL), expressed in terms of defects per hundred units shall be 1.5 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.

TABLE III. Filled and sealed pouch defects¹⁵

Category	Defect
<u>Critical</u> ¹⁶ <u>Major</u> ¹⁷ <u>Minor</u> ¹⁸	
	<u>Both Pouches</u>
1	Tear, hole, or open seal.
2	Aberrations in pouch material or heat seals resulting from heat sealing, pouch fabrication, hot filling or heat processing that reduce the effective closure seal width to less than 1.6 mm (1/16 in). ¹⁹
101	Seal width not as specified.
102	Not heat sealed as specified.
103	Inside pouch dimensions not as specified.
104	Closure seal not located as specified.
105	Closure or top seal extends into or below tear notch location.

¹⁵ Any evidence of insect or rodent infestation shall be cause for rejection of the lot.

¹⁶ A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using the item.

¹⁷ 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.

¹⁸ 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.

¹⁹ Aberrations in pouch material or heat seals include:
a. Major fold-over wrinkles or severe wrinkles, that extend into heat seal area and reduce effective seal width to less than 1.6 mm (1/16 in); or
b. Severe wrinkles in the body of the pouch along the inside edges of the heat seals. Pouches exhibiting one or more of these aberrations shall be tested in accordance with Sec. 7.4.

TABLE III. Filled and sealed pouch defects (continued)¹⁵

Category			Defect
Critical ¹⁶	Major ¹⁷	Minor ¹⁸	
	106		Not clean. ²⁰
	107		Required labeling or marking missing, incorrect, illegible, or that smudges.
	108		Embossed code marking not located as specified.
	109		Distance between inside edge of tear notch or serrations and inside edge of seal is less than 4.7625 mm (3/16 in).
	110		Presence of entrapped matter (for example, product residue) that reduces the effective closure seal to less than 1.6 mm (1/16 in) wide. ²¹
		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 pouch material at edges exceeds 4.7625 mm (3/16 in).
			<u>Flat Pouches</u>
	3		Swollen pouch.
			<u>Brick Style Pouches</u>
	111		Pouch has foreign odor.
	112		Any evidence of loss of vacuum. ²²

²⁰ Outer packaging shall be free from foreign matter, which is unwholesome, has the potential to cause pouch damage (for example, glass, metal fillings, etc.) or generally detracts from the clean appearance of the pouch. The following examples shall not be scored as defects for unclean:

- Foreign matter which presents no health hazard or potential pouch damage and which can be readily removed by gently shaking the pouch or by gently brushing the pouch with a clean dry cloth.
- Dried product, which affects less than 1/8 of the total surface area of one pouch face (localized and aggregate).
- Water spots.
- Very thin film of grease, oil, or product residue, which is discernible to touch, but is not readily discernible by visual examination.

²¹ The effective closure seal is defined as any uncontaminated, fusion bonded, continuous path, minimum 1.6 mm (1/16 in) wide from side seal to side seal that produces a hermetically sealed pouch.

²² The filled brick style pouches shall be sealed under a minimum vacuum level of 23 inches of mercury and shall be visually examined for conformance to the vacuum requirement not less than 96 hours after filling and sealing. The sealed pouch shall

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7.3 Pouch leakage and delamination examination. All exterior surfaces and edges of the filled and sealed pouch shall be examined visually for product leakage while applying a manual kneading action which forces the product against the interior pouch surface in the area being observed. After leakage testing, the pouch shall be examined for evidence of delamination. Any product leakage from the pouch or evidence of delamination of the pouch 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. Pouches 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 - counterclockwise directions. Care shall be exercised when flexing delaminated area near the tear notches to avoid tearing the pouch 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 pouch shall be rejected. The lot size shall be expressed in pouches. The sample unit shall be one filled and sealed pouch. The inspection level shall be I 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 pouches while they are restrained between two rigid plates. The plates shall be 12.7 ± 1.6 mm ($1/2 \pm 1/16$ in) apart or 25.4 ± 1.6 mm ($1 \pm 1/16$ in) apart. If a three-seal tester (one that pressurizes the pouch through an open end) is used, the closure seal shall be cut off for testing the side and bottom seals of the pouch; for testing of the closure seal, the bottom seal shall be cut off. The pouches shall be emptied prior to testing. If a four-seal tester (designed to pressurize filled pouches by use of a hypodermic needle through the pouch wall) is used, all four seals can be tested simultaneously. Pressure shall be applied gradually until 17 psig pressure is reached. The 17 psig pressure shall be held constant for 30 seconds and then released. The pouches shall then be examined for separation or yield of the seals. Any rupture of the pouch or evidence of seal separation greater than 1.6 mm (1/16 in) in the pouch 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 III) 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 pouches shall be determined by weighing each sample unit on a suitable scale tared with a representative empty pouch. Any individual net weight of less than 92 g (3.246 oz) shall be classified as a minor

continue to exhibit tight adherence to the surface contours of the contents when a pulling force is applied at the top and bottom seal. This force shall be applied by holding the top and bottom seal between the thumb and forefinger of each hand, while simultaneously exerting a slight pull with both hands. Any evidence of loss of vacuum shall be classified as a major defect.

defect. The lot size shall be expressed in pouches. The sample unit shall be one filled and sealed pouch. 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, the lot shall be rejected if the sample average net weight is less than 92 g (3.246 oz).

8. MANUFACTURER'S PRODUCT ASSURANCE. The manufacturer shall certify that the RUTF provided, meets the requirements of this CID. The purchaser shall require proof of conformance.

9. REGULATORY REQUIREMENTS. The delivered RUTF shall comply with all applicable Federal, State, and local laws and regulations relating to the manufacturing, storage, and distribution of packaged foods for human consumption, including all applicable provisions of the Federal Food, Drug, and Cosmetic Act, and regulations promulgated thereunder.

10. QUALITY ASSURANCE PROVISIONS FOR THE DAIRY COMPONENTS. Purchaser shall specify in the solicitation, contract, or purchase order when the following provisions shall be met.

10.1 Manufacturer's quality assurance. When required in the solicitation, contract, or purchase order, the dairy component manufacturer shall be required to have their facilities inspected by the DGB, DP, AMS, USDA, and be eligible for listing in Section I of the AMS publication "Dairy Plants Surveyed and Approved for USDA Grading Service." (An AMS, DP plant survey verifies that, at the time of the survey, the manufacturer produces products in a clean sanitary environment and satisfactorily meet the requirements contained in *7 CFR Part 58 Subpart B - General Specification for Dairy Plants Approved for USDA Inspection and Grading Service and 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.*)

10.2 USDA, DP certification. When required in the solicitation, contract, or purchase order, the DGB, DP, AMS, USDA, shall certify that the dairy components used for the manufacturing of RUTF meets or exceeds the requirements (FDA's Direct Food Substances Affirmed as GRAS for Whey Protein Concentrate [21 CFR § 184.1979(c)]; U.S. Standards for Dry Whey, and USDA Specifications for Dry Whey Protein Concentrate); dry whole milk (Codex Standard for Milk Powders and Cream Powder [CODEX STAN 207-1999], 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]; nonfat dry milk (Codex Standard for Milk Powders and Cream Powder, [CODEX STAN 207-1999]; FDA's Standard of Identity for Nonfat Dry Milk [21 CFR § 131.125] and FDA's Standards of Identity for Nonfat Dry Milk fortified with vitamins A and D [21 CFR § 131.127]). The DGB inspectors shall certify the dairy components in accordance with DGB procedures which include random sampling of the dairy components; evaluating the samples for conformance with the appropriate

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U.S. Standards for Grade, USDA Specifications, and/or Codex Standard; and documenting the requirements on official DGB certificates.

11. QUALITY ASSURANCE PROVISIONS. *Purchaser shall specify 11.3 11.4, or 11.5; purchaser may specify 11.1 with 11.1.1, 11.1 with 11.2.1, 11.1 with 11.2.2, 11.2 with 11.2.1, or 11.2 with 11.2.2.*

11.1 Food Defense. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, AMS, Specialty Crops Inspection Division (SCI). Food Defense requirements include a documented and operational food defense plan that provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials and other ingredients and postproduction finished product. The plan shall address the following areas: (1) food security plan management; (2) outside and inside security of the production and storage facilities; (3) slaughter, when applicable, and processing, including all raw material sources; (4) shipping and receiving; (5) storage; (6) water and ice supply; (7) mail handling; (8) personnel security; and (9) transportation, shipping, and receiving.

11.1.1 FDSS. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, AMS, SCI. The FDSS verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. *(An AMS, FDSS verifies the participating company's adherence to the FDA's "Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.") For further information, see section 14.1.1 and 14.3.2.*

11.1.2 Food Defense Addendum to Plant Systems Audit (PSA). When required in the solicitation, contract, or purchase order, a Food Defense addendum shall be conducted by USDA, AMS, SCI auditors. This verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. *(An AMS, FDSS verifies the participating company's adherence to the FDA's "Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.") For further information, see section 14.1.1 and 14.3.2.*

11.2 Manufacturer's quality assurance. When required in the solicitation, contract, or purchase order, 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.

11.2.1 PSA. A PSA conducted by USDA, AMS, or other audit performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. *(An AMS PSA verifies the manufacturer's capability to produce products in a clean sanitary*

environment in accordance with 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and verifies that the manufacturer has in place an internal quality assurance program.) (Perform with Food Defense addendum when required.)

11.2.2 Plant survey. A plant survey conducted by USDA, AMS, or other survey performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. *(An AMS plant survey audit verifies that, at the time of the survey, the manufacturer produces products in a clean sanitary environment in accordance with 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.)*

11.3 Manufacturer's certification. When required in the solicitation, contract, or purchase order, the manufacturer shall certify that the finished RUTF distributed meets or exceeds the requirements of this CID.

11.4 USDA certification. When required in the solicitation, contract, or purchase order that product quality, acceptability, or both be determined, the SCI, Fruit and Vegetable Program (FV), AMS, USDA, shall be the certifying agency. SCI inspectors shall certify the quality and acceptability of the RUTF in accordance with SCI procedures which include: selecting random samples of the packaged RUTF, evaluating the samples for conformance with the salient characteristics of this CID and other contractual requirements, and documenting the findings on official SCI score sheets and/or certificates. In addition, when required in the solicitation, contract, or purchase order, SCI inspectors will examine the RUTF for conformance to the U.S. Standards for Condition of Food Containers (7 CFR Part 42) in effect on the date of the solicitation.

11.5 Finished Product Examination. The finished product shall be examined for compliance with the product requirements specified in Sec. 5.4, utilizing the double sampling plans indicated in ANSI/ASQC Z1.4 in effect on the date of the solicitation. The lot size shall be expressed in pouches. The sample unit shall be the contents of one pouch. The inspection level shall be S-3 and the AQL, expressed in terms of defects per hundred units, shall be 1.5 for major defects and 4.0 for minor defects. Defects and defect classifications are listed in Table IV.

The pouches of RUTF shall be kneaded prior to conducting any portion of the product examination.

TABLE IV. Product defects^{23, 24}

Category		Defect
<u>Major</u>	<u>Minor</u>	
<u>Appearance and texture</u>		
101		Product not fortified, Type I, RUTF paste, or Type II, RUTF bar.
102		Type I, RUTF spread, not a smooth, homogeneous finish and not free of lumps.
103		Type I, RUTF spread, shows separation of oil.
104		Type I, RUTF spread, not free of gritty, grainy, and sandy texture.
105		Type I, RUTF spread or Type II, RUTF bar, shows evidence of excessive heating (material darkened or scorched).
106		Type II, RUTF, bars, not a compressed rectangular shape with a dimension of 63.5 mm long by 44.4 mm wide by 14.7 to 16.0 mm thick (2-1/2 in long by 1-3/4 in wide by 0.58 to 0.63 in thick). ²⁵
107		Type II, RUTF bars, do not have a smooth exterior and an interior particle size which is uniform; and do not easily crumble with gentle finger pressure.
<u>Flavor and Odor</u>		
108		Type I, RUTF spread, does not have a pleasing sweet, clean dairy flavor and odor.
109		Type II, RUTF bars, does not have a slightly sweet grain odor (appropriate for the style) with a blended cereal flavor.
110		Type I, RUTF spread, does not have a pleasing sweet, clean flavor and odor associated with the major ingredients.
	201	Type I, RUTF spread, not cream to light brown color or has a dull gray or other abnormal cast.
	202	Type II, RUTF bars, not a medium tan to dark tan color, shows evidence of excessive heating (materially darkened or scorched).

²³ Presence of any foreign materials such as, but not limited to: dirt, insect parts, hair, wood, glass, metal, or any foreign odors or flavors such as, but not limited to: burnt, scorched, rancid, malted, sour, or stale shall be cause for rejection of the lot.

²⁴ Finished product not equal to or better than the approved product standard in palatability and overall appearance shall be cause for rejection of the lot.

²⁵ The length and width measurements for the Type II, RUTF bars have an allowable tolerance of ± 3.2 mm (1/8 in).

TABLE IV. Product defects (continued)^{23, 24}

Category		Defect
<u>Major</u>	<u>Minor</u>	
		<u>Color</u>
	201	Type I, RUTF spread, not cream to light brown color or has a dull gray or other abnormal cast.
	202	Type II, RUTF bars, not a medium tan to dark tan color, shows evidence of excessive heating (materially darkened or scorched).

TABLE V. Filled and sealed pouch defects

Category		Defect
<u>Major</u>		<u>Packing</u>
	111	Type II, RUTF bars, not individually shrink-wrapped in a thin monolayer wrap of polyolefin.
	112	Type II bars, not nine bars packed into a vacuum packed brick style pouch. ²⁶

11.6 Product standard inspection. The RUTF PDM shall be inspected in accordance with the provisions of this CID and evaluated for overall appearance and palatability. Any failure to conform to the CID requirements or any appearance or palatability failure shall be cause for rejection of the lot. The approved PDM shall be used as the product standard for periodic review evaluation and inspection activities. All food components that are inspected by USDA shall be subject to periodic review sampling and evaluation. The USDA shall select sample units during production of the contract and submit them to USDA Headquarters and the purchasers' designee, as specified in the solicitation, contract, or purchase order. One lot shall be randomly selected during each calendar month of production. Twelve (12) sample units of RUTF shall be randomly selected from that one production lot. The 12 sample units shall be shipped to USDA headquarters and the purchasers' designee within five working days from the end of the production month and upon completion of all USDA inspection requirements. The sample units shall be evaluated for the salient characteristics including appearance, odor, flavor, texture, and overall quality.

²⁶ Each sample bar examined for Table IV defects shall be drawn from a separate 9-bar brick pack pouch. Inspection of the 9-bar brick pack pouch for Defect 112 shall be performed prior to obtaining the sample Type II, RUTF bar from the 9-bar pack.

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12. PACKAGING. The packing, labeling, and case marking shall be specified in the commodity requirement document (CRD), solicitation, contract, or purchase order.

13. USDA INSPECTION NOTES. When Sections 11.4 and 11.5 are specified in the CDR, solicitation, contract, or purchase order, USDA certification shall include evaluation of the quality and condition of samples of RUTF and compliance with requirements in the following areas:

- Salient characteristics (Sec. 5).
- Product standard evaluation of the PDM (Sec. 5.7 and 11.6).
- Analytical requirements *when specified in the CDR, solicitation, contract, or purchase order* (Sec. 6.2). When USDA analytical testing is specified, SCI inspection personnel shall select samples and submit them to the USDA, Science and Technology Programs (S&TP) laboratory for analysis.
- Packaging requirements (Sec. 7 and 12 or as specified in the CRD, solicitation, contract, or purchase order).

14. REFERENCE NOTES.

14.1 USDA certification contacts.

14.1.1 USDA certification, FDSS, Plant Survey, and PSA contact. For a USDA certification, FDSS, Plant Survey, and PSA, contact the **Chief, Inspection Branch, SCI, FV, AMS, USDA, STOP 0240, 1400 Independence Avenue, SW, Washington, DC 20250-0240** telephone (202) 720-2482, Fax (202) 720-0393, or via E-mail: nathaniel.taylor@ams.usda.gov.

14.1.2 DGB certification contact. For dairy product certification, contact the **Branch Chief, DGB, DP, AMS, USDA, STOP 0230, 1400 Independence Avenue, SW, Washington, DC 20250-0230**, telephone (202) 720-3171, Fax (202) 720-2643, or via E-mail: Ken.Vorget@ams.usda.gov.

14.2 Analytical testing and technical information contact. For USDA technical information on analytical testing, contact the **Director, USDA, AMS, S&TP, Laboratory Division, 801 Summit Crossing Place, Suite B, Gastonia, NC 28054**, telephone (704) 867-3873, Fax (704) 853-2800, or via E-mail: AMSLaboratoryDivision@ams.usda.gov.

14.3 Sources of documents.

14.3.1 Sources of information for nongovernmental documents are as follows:

Copies of the AOAC International OMA may be obtained from: **AOAC International, 481 North Fredrick Avenue, Suite 500, Gaithersburg, MD 20877-2417**, telephone (301) 924-

7077. Internet address: <http://www.aoac.org> for non-members and <http://www.eoma.aoac.org> for members and AOAC OMA subscribers.

Copies of the Food Chemicals Codex and U.S. Pharmacopeia may be purchased from: **United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852-1790, telephone (800) 227-8772 or (301) 881-0666, Fax (301) 816-8148. Internet address:** www.usp.org.

Copies of latest edition of ANSI/ASQC Z1.4 may be purchased from: **ANSI, ATTN: Customer Service Department, 25 W 43rd Street, 4th Floor, New York, NY 10036, telephone (212) 642-4900, (212) 642-4980, Fax (212) 302-1286. Internet address:** <http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI/ASQC%20Q9000-1-1994>.

Copies of the: Recommended International Code of Practice, General Principles of Food Hygiene CAC/RCP 1-1969, Revision 4-2003; Report of the 28th session of the Codex committee on nutrition and foods for special dietary uses, Chiang Mai, Thailand, 30 October – 3 November 2006 (Alinorm 07/30/26); Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, CAC/RCP 66 - 2008; Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children of the Codex Alimentarius Standard (CAC/GL 10 - 1979); all standards linked to specific products for ingredients/raw materials and final products (ex.: aflatoxin levels in peanuts, peroxide levels in vegetable oils, radioactive elements in milks, etc.); and the concept of “fit for human consumption” must comply with Codex Alimentarius raw material specification sheets for STAN 207 - 1999 for milk, STAN 212 - 1999 for sugar, STAN 200 for peanuts, and STAN 210 for vegetable oil may be downloaded free from: **Codex Alimentarius, via the Internet. Internet address:** http://www.codexalimentarius.net/web/index_en.jsp.

Copies of ASTM D 3985 Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor are available from: **ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, telephone (610) 832-9585. Internet address:** www.astm.org/Standard/index.shtml.

Copies of ISO Standard 22000 are available from: **International Organization for Standardization, 1 ch. de la Voie-Cruse, Case Postale 56, CH-1211 Geneva 20, Switzerland, telephone 41-22-749-01-11, Fax 41-22-749-09-47, E-mail: sales@iso.org. Internet address:** www.iso.org.

Copies of the United Nations Children’s Fund (UNICEF) specifications for Ready-To-Use Therapeutic Foods (RUTF) are available from: **UNICEF Supply Catalogue. Internet address:** <https://supply.unicef.org/>.

Additional information on Nutrition, therapeutic 0000240 Therapeutic spread, sachet 92g/CAR-150 may be obtained by writing to: **Jan Komrska, MPH, MSc, Contracts Specialist, Essential**

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Medicines and Nutrition, Medicines and Nutrition Center, UNICEF Supply Division, Freeport, 2100 Copenhagen, telephone: +45 35 27 30 40, or via E-mail: jkomrska@unicef.org.

Copies of the *Community-based Therapeutic Care (CTC) A Field Manual*, 2006 are available from: **Valid International, Unit 14, Standingford House, 27 Cave Street, Oxford OX4 1BA, U.K., telephone: +44 1865 722180, or via E-mail: office@validinternational.org. Internet address: www.validinternational.org.**

14.3.2 Sources of information for governmental documents are as follows:

Applicable provisions of the U.S. Standards for Condition of Food Containers are contained in 7 CFR Part 42, the Fair Packaging and Labeling Act are contained in 16 CFR, Parts 500 to 503 and the Federal Food, Drug, and Cosmetic Act are contained in 21 CFR Parts 1 to 199. These documents may be purchased from: **Superintendent of Documents, New Orders, P.O. Box 979050, St. Louis, MO 63197-9000. Credit card (Visa, MasterCard, Discover/NOVUS, and American Express) purchases may be made by calling the Superintendent of Documents on (866) 512-1800, (202) 512-1800. These documents may also be obtained free of charge on the Internet at:**

<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>.

Copies of the Bacteriological Analytical Manual (BAM) are available from: **FDA, Center of Food Safety and Applied Nutrition (CFSAN) on the Internet at:**

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm>.

Copies of the Analytical Methods for Melamine and Triazine Analogs are available from: **FDA, CFSAN on the Internet at:**

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/ucm135002.htm>.

Copies of Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance are available online from: **FDA, CFSAN on the Internet at:**

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm>.

Copies of the U.S. Standards of Grade are available from: **Standardization Branch, DP, AMS, USDA, STOP 0230, 1400 Independence Avenue, S.W., Washington, DC 20250-0230, telephone (202) 720-7473, Fax (202) 720-2643, or on the Internet at:**

<http://www.ams.usda.gov/dairy/grade.htm>.

Copies of Dairy Plants Surveyed and Approved for USDA Grading Service are available from: **Branch Chief, DGB, DP, AMS, USDA, STOP 0230, 1400 Independence Avenue, SW,**

Washington, DC 20250-0230, telephone (202) 720-3171 or on the Internet at:
www.ams.usda.gov/dairygrading.

Copies of this CID, the U.S. Standards for Condition of Food Containers (7 CFR Part 42), and beneficial comments, recommendations, additions, deletions, clarifications, etc., and any data which may improve this CID are available from and/or provided to: **Chief, Standardization Branch, SCI, FV, AMS, USDA, STOP 0240, 1400 Independence Avenue, SW, Washington, DC 20250-0240, telephone (202) 720-5021, Fax (202) 690-1527, or via E-mail: robin.chilton@ams.usda.gov.**

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