

METRIC

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SUPERSEDING

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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
		202
		203
		204
		Tear notch or serrations missing.
		Tear notch or serrations not located as specified.
		Depth of tear notch or serrations not as specified.
		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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