CHAPTER 21 – FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS

SUBJECT:	**IMPLEMENTATION DATE**
INFANT FORMULA PROGRAM – IMPORT AND DOMESTIC (FY 06/07/08) ***NOTE: This program has completed a Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in July 2006.***	July 31, 2006 **COMPLETION DATE** September 30, 2008

DATA REPORTING

PRODUCT CODES		PROGRAM/ASSIGNMENT CODES
40C[][]01	(milk base)	21006
40C[][]20	(meat base)	
40C[][]25	(soy base)	
40C[][]30	(wheat base)	
40C[][]35	(whey base)	
40C[][]99	(other infant formula products, NEC)	

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

NOTE: The work to be accomplished under this compliance program has been identified as high priority by CFSAN. The firms to be inspected and the products to be collected are considered high risk because of the susceptible population for which the products are intended. Districts are required to complete 100% of the operations planned in the ORA Field Workplan for this program.

FIELD REPORTING REQUIREMENTS

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1. Inspectional

All hardcopy reports to headquarters are to be sent to the following address and the appropriate office identified below:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

a) Forward a copy of the Summary of Findings for each inspection to the Infant Formula Program Contact (HFS-636), Rm. 3C007, within 30 days after completion of the inspection. If CFSAN has requested that specific information be collected and documented during the inspection, that information must also be submitted along with the Summary of Findings, this includes Attachment B (Infant Formula Nutrient Information Reporting Form).

b) Complete EIRs for foreign inspections must be sent to Chief, Imports Branch (HFS-606) upon completion with a copy also forwarded to: Rebecca Hackett, ORA/ORO/Division of Field Investigations (HFC-130).

c) Collect and submit product labels, promotional literature and brochures **that are new or revised since the last inspection** conducted at the firm to CFSAN/ONPLDS/Food Labeling and Standards Staff (HFS-812)within 30 days after completion of the inspection.

d) Attachment A must be completed and sent electronically to Sue Anderson at sue.anderson@cfsan.fda.gov upon completion of the inspection if information obtained during the inspection indicates changes in processing or formulation have occurred (see Part III, Page 2 for more specific information).

NOTE: CFSAN will no longer review domestic EIRs and analytical results prior to district Compliance Branch's submission of recommendations. SRL will use the criteria contained in Part IV of this program to determine when to forward the analytical results to the district Compliance Branch.

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2. Analytical

a) *Forward a copy of the complete analytical worksheet for all samples classified as lab class "2" or "3" to the Compliance Branch of the home district (and notify the collecting district if they are not identical) for regulatory follow-up immediately upon completion.*

b) Report results of all analyses into the Field Accomplishment and Compliance Tracking System using the following Problem Area Flags (PAF):

Nutrient Analysis	= PAF "NIF"
Microbiological Analysis	= PAF "MIC" (APC, Coliform, *B. cereus*, *Listeria, Salmonella*, *S. aureus*, Staphyloccoccal Toxin, *E. Coli*, ETEC & EHEC)
If appropriate	= PAF "SAL" (*Salmonella* serotyping)
	= PAF "ABR" (*Salmonella* antibiotic resistance)
	= PAF "GSA" (PFGE *Salmonella*)
	= PAF "GEC" (PFGE; *E. coli* 0157:H7)
Label Reviews	= PAF "FDF" Results Flag "FDL"

PART I – BACKGROUND

*The term “infant formula” is defined in the Federal Food, Drug, and Cosmetic Act (the Act) in section 201(z). The term “infant formula” means a food which purports to be or is represented for special dietary use solely as food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk. While there is no statutory definition of “infant” the customary definition used by the agency is a child under 1 year of age.

An “exempt infant formula” is any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight, or who otherwise has an unusual medical or dietary problem.

The term “exempt” in the term “exempt infant formula” refers to those infant formulas that are exempt under section 412(h) of the Act from certain aspects of the infant formula requirements. Attachment E is the current list of exempt infant formula products and manufacturers currently available in the U.S. marketplace. To ensure the adequacy of the composition of infant formulas, Section 412 of the Act provides for, among other items:*

a) A definition of an "adulterated" infant formula product;

b) Notification to the Secretary of Health and Human Services, of changes in the formulation or processing procedures of infant formula products;

c) Recall procedures;

d) Minimum nutrient levels, and in some cases maximum nutrient levels, that infant formula products shall contain;

e) Specific nutrient testing requirements to ensure appropriate nutrient levels;

f) Access to and the right to copy and verify records of all nutrient and microbiological product testing;

g) Access to records assuring that regularly scheduled audits are being conducted, although the actual written report of such audit need not be made available;

h) Access to complaints and complaint files; and

i) *Certain exemptions from the nutrient requirements, quality control procedure requirements and labeling requirements for infant formulas that are represented for use by an infant who has an inborn error of metabolism or low birth weight or who otherwise has an unusual medical or dietary problem.*

The Act applies equally to infant formulas produced in this country and infant formulas produced in other countries and imported into this country for commercial distribution. Because of the susceptible population for which infant formulas are intended, the Agency is committed to assuring their continued safety and integrity through annual inspections of all infant formula manufacturers in the U.S. and elsewhere. Refusal of access to or copy of records as required by section 412 is a prohibited act under 301(e) of the Act.

Prior to the start of each fiscal year, CFSAN/Office of Compliance/Division of Field Programs (DFP)(HFS-636) will provide the Office of Regulatory Affairs, Division of Field Investigations (DFI) a list of all foreign firms that have filed notice of their intent to manufacture infant formula. ORA/DFI will work with individual districts to schedule an annual inspection at each of these firms.

21 CFR Part 106 sets forth the regulations establishing quality control procedures for the manufacture of infant formulas. These regulations are designed to assure that infant formulas contain the necessary nutrients, at the levels specified, in the Act. The 1986 Amendments to the Act require additional quality control and GMP procedures. FDA published a proposal to implement the 1986 Amendments on July 9, 1996 (FR Vol. 61, No. 132, pg. 36154). These regulations have not yet been finalized.

21 CFR Part 106 requires each manufacturer to adopt a quality control system that is best suited to its needs. It permits manufacturers to analyze nutrients either during processing or after processing, but before the finished product is released for distribution by the manufacturer.

The revised infant formula nutrient requirements (21 CFR 107, Subpart D) of the Act became effective January 14, 1986 for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after that date (FR, Vol. 50, No. 210, Oct. 30, 1985, pgs. 45106-45108).

The infant formula labeling requirements (21 CFR 107, Subpart B) became effective January 14, 1986 for all affected products (FR, Vol. 50, No. 9, Jan. 14, 1985, pgs. 1833-1841).

Final rule 21 CFR 107, Subpart C, "Exempt Infant Formulas" became effective February 20, 1986 and established the terms and conditions under which those specialty infant formulas, intended for use by infants with special medical and dietary needs, will continue to be exempt from some requirements of the Infant Formula Act of 1980 (FR, Vol. 50, No. 226, Nov. 23, 1985, pgs. 48183-48188).

Final rule 21 CFR 107, Subpart E, "Infant Formula Recalls" became effective March 28, 1989 with requirements that (1) specify mandatory recall procedures to be used by manufacturers in removing from the marketplace an adulterated or misbranded infant formula that the Agency has determined may present a risk to human health; (2) require a manufacturer recalling an infant formula that represents a risk to human health to request each retail establishment at which such infant formula is sold or available for sale to post a notice of such recall; and (3) establish requirements for retention of infant formula distribution records (FR, Vol.54, No. 17, Jan. 27, 1989, pgs. 4006-4009).

21 CFR Part 106, Subpart C, Infant Formula Record and Record Retention Requirements, became effective April 22, 1992. These regulations establish requirements for records concerning: (1) food packaging materials; (2) nutrient premixes; (3) verification of nutrient levels present through the expiration date on product; (4) quality control procedures; (5) nutrient levels and testing results at the final product stage; (6) microbiological and purity testing of raw materials and finished product; (7)distribution of infant formula; (8) manufacturer's audits; and (9) complaints. The regulations define administrative requirements as to where, how, and for how long the records are to be maintained. In particular, the section pertaining to consumer complaints provides the Agency the authority to review the complaints received by manufacturers in a comprehensive manner, and requires that manufacturers maintain procedures describing how all written and oral complaints will be handled.

PART II - IMPLEMENTATION

1. Objectives

a) To conduct an annual inspection at each domestic and foreign establishment manufacturing infant formulas to ascertain the firm's compliance with all of the requirements of Section 412 of the Federal Food, Drug, and Cosmetic Act (the Act).

b) To collect samples of infant formulas during each domestic and foreign inspection for nutrient and/or microbiological analyses.

c) *To ensure that imported infant formula manufactured by firms that have not filed the required notifications under the Act are investigated as instructed in Part III of this program.*

d) *To ensure that infant formulas that are offered for import as American Goods Returned are investigated as instructed in Part III of this program.*

2. Planning Management Instructions

Domestic

CFSAN/Office of Compliance/Division of Field Programs will provide the inspection schedule that identifies the domestic firms to be inspected in a separate memorandum prior to the start of each fiscal year. # Domestic inspections and sample collections are also entered into FACTS. In order for the Southeast Regional Laboratory to receive a steady flow of samples, it is imperative that this schedule be followed. Contact the Infant Formula Program Manager if difficulties in implementation are encountered.

When CFSAN is notified of a new infant formula manufacturer or a new or reformulated infant formula product, the appropriate district may be contacted to conduct an unplanned inspection and/or collect samples. Attachment D is the current list of infant formulas manufactured in the US that have undergone the required notification procedure.

Imports

Imported infant formulas are not exempt from the notification requirements of Section 412 of the Act. Therefore, foreign manufacturers of infant formula offered for entry into the U.S. must notify the Agency of their intent to market such formulas in the U.S. Attachment C is the current list of infant formulas manufactured outside the U.S. that have undergone the required notification procedure.

ORA/DFI will be contacting individual districts during the fiscal year to arrange for an annual inspection to be conducted at each foreign firm listed on Attachment C. The inspection will include collection of appropriate samples for nutrient and/or microbiological analysis. Only products intended for exportation into the U.S. are to be sampled. Documentation of product exportation to the U.S. must be collected and included as part of each EIR. If the firm is no longer manufacturing infant formulas, or no longer manufacturing infant formula that is distributed in the U.S. market, this information must be documented and reported in the EIR. The firm will be removed from the inventory and annual inspection schedule.

Note: Import Alert #40-04 "Detention without Physical Examination of Infant Formulas that have not Been Through the Required Notification Process" has been canceled. Districts should examine all infant formula imports offered for entry into US distribution. Import entries must be examined as described in Part III – Import Investigations.

3. Program Interaction

During operations conducted under other FDA compliance programs, District personnel should be alert for products which may be represented as infant formulas, but that do not meet the requirements of Section 412 of the FD&C Act. Such products have, in the past, been produced/promoted by firms who have not complied with the registration requirements of the Act. Report such surveillance coverage under this program (PAC 21006).

The following inspections may be conducted concurrently during an infant formula inspection. Time expended under the following (or other) compliance programs should be reported under the specific Program/Assignment Code(s) for those programs:

a) Domestic Acidified and Low-Acid Canned Foods Program, C.P. 7303.803A;
b) Import Acidified and Low-Acid Canned Foods Program, C.P. 7303.003;
c) Medical Foods - Import and Domestic Program, C.P. 7321.002; and
d) Domestic Food Safety, C.P. 7303.803.

PART III - INSPECTIONAL

1. Inspection

If problems are encountered with the inspection schedule discussed in Part II, Page 1, notify the Infant Formula Program Manager at *(301) 436-2065*. The inspection schedule lists the week of inspection and sample collection. This scheduling is necessary to ensure an even sample flow to the laboratory.

See the Guide to Inspections of Manufacturers of Miscellaneous Food Products at http://www.ora.fda.gov/ora/inspect_ref/igs/foodsp2.html for guidance in conducting inspections. When deemed appropriate, chemists and/or microbiologists should accompany the investigator.

When conducting inspections, investigations, recall effectiveness checks, or other operations directed by FDA compliance programs or assignments, be alert for products promoted as infant formulas but that may not meet the requirements of Section 412 of the FD&C Act. Such products have in the past, been found most frequently in health food or natural food stores. Some of these products have been soy-based beverages, but they may come in other forms too.

When inspecting firms that produce “exempt infant formulas”, e.g., products indicated for treatment of infant health conditions, such as inborn errors of metabolism and low birth weight, investigators must follow-up and document any observation that indicate that the formula may contain nutrient(s) that it is specifically formulated not to contain.

When inspecting firms that pasteurize, condense or dry infant formula ingredients, or dry blend infant formula ingredients, ensure that manufacturing procedures preclude microbial contamination.

***Note Regarding Premix Inspections:** Infant formula premix manufacturers are covered under this program and will be inspected on an annual basis. However, because premixes are not “finished” infant formulas, firms that produce them are not subject to comprehensive infant formula inspections as outlined below. Section 412(b)(4)(A)(iii) of the Act and Section 106.100(d) of the Code of Federal Regulations (CFR) require that premix manufacturers retain all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis. Those records include, but are not limited to: the results of tests conducted to determine the purity of each ingredient; the weight of each ingredient added; the results of any quantitative tests conducted to identify the nutrient levels present when the premix reaches its expiration or shelf life date. Inspections of premix manufacturers should be focused on these requirements and the general Good Manufacturing Practice (GMP) regulations described in 21 CFR Part 110.*

Note Regarding Foreign Inspections: The following information must be obtained during foreign inspections in order to facilitate detention of future entries, should inspectional or analytical results warrant such action:

a) The exact products/brands being exported to the U.S.;
b) The size and frequency of the shipments;
c) How the products are shipped;
d) The importer of record for the shipments;
e) The U.S. ports where the products are offered for entry; and if possible,
f) A list of the U.S. distributors.

At the beginning of each inspection, obtain information regarding changes in processing or formulation and complete Attachment A. *The types of changes that should be reported on Attachment A include, but are not limited to:

a) Manufacture of a new infant formula;

b) Any infant formula powder processed and introduced for commercial or charitable distribution by a manufacturer who previously only produced liquids (or vice versa);

c) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), for which the manufacturer has not had previous experience;

d) Any infant formula manufactured on a new processing line or in a new plant;

e) Any infant formula manufactured containing a new constituent not listed in 412(i) of the FD&C Act and added for its potential nutrient contribution, such as taurine or L-carnitine;

f) Any processing of infant formula on new equipment that utilizes a new technology or principle (e.g., a change from terminal sterilization to aseptic processing;

g) A fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

Attachment A must be completed and sent electronically to Sue Anderson at sue.anderson@cfsan.fda.gov upon completion of the inspection. In advance of each inspection, CFSAN will notify the districts of new infant formulas, changes in formulation, processing or packaging that the firm has filed under the notification requirements of the Act. **Do not** rely solely on CFSAN notification; the investigator must also ascertain this information from the firm.*

The following items pertain specifically to these notifications and should be submitted with the EIR to determine the significance of the change, whether or not the firm has previously reported the change to the Agency because many firms report insufficient data for the Agency.

a) Results of analyses demonstrating compliance with 21 CFR 106.30(b)(3)

(shelf-life stability) must be obtained for all new infant formulas or infant formulas that have undergone a change in formulation, processing, or packaging since the last inspection;

b) Information on homogeneity must be collected when changes in processing occur that could affect the homogeneity of the formula, e.g., change in blending operations, change in point where nutrient is added, etc;

c) Compare the list of processing changes that CFSAN has provided with the list of processing changes the firm provides or that are observed during the inspection. Any differences or deviations must be documented in the EIR; and

d) Refer to 3. Sample Collection for instructions on collecting samples.

Determine if the firm has any related plants which spray dry, manufacture, or repack infant formula. For manufacturers of finished product infant formulas, determine whether or not nutrient premixes are supplied by outside firms. Report the names and physical locations of all related plants and firms in the EIR.

Consumer complaint files should be reviewed according to the following procedures at those firms identified in the inspection schedule with "(COMPLAINTS)" after the firm name. This information review should cover the time period since the last infant formula inspection.

a) Review the complaint histories for all new or reformulated products. For reformulated products or products that have undergone a processing or packaging change, compare the complaint history for product before vs. after the reformulation, process, or packaging change.

b) For each formula and type (ready to serve, concentrate, powder) determine the number of complaints and the total number classified as possibly involving a health hazard.

c) Determine the basis used to determine whether or not a potential health hazard existed.

d) For those complaints found to involve a potential health hazard, report how the firm followed up.

Determine which three batches of infant formula had the largest number of complaints involving a health hazard potential. Obtain a listing of those complaints with sufficient information to assess for trends.

This information should be included in the EIR. Additional information about manufacturers' responsibilities concerning handling of complaints can be found in 21 CFR 106.100(k).

The investigator should cover the entire Quality Control Procedures System established by the firm to ensure compliance with 21 CFR 106. Review approximately 7 days of production records for one infant formula or nutrient premix. *The record review should include all records from raw material receipt to finished product analysis, including nutrient analysis and any additional analyses performed by the firm.*

a) Frequently, records of analyses required by the Infant Formula Quality Control Procedures are not available at the plant being inspected, but are located in a centralized facility doing the quality control analyses. If analytical records are not available at the plant being inspected, request that the firm obtain the records from the centralized facility for inclusion with the inspection report. If the firm is uncooperative in making this request, report this in the EIR, and submit a request for these records to the district where the centralized facility is located.

b) Verify that testing for each nutrient in every batch occurs prior to product entering interstate commerce. *Document the firm's nutrient testing procedures for the product(s) covered during the inspection on Attachment B.* Obtain any data the firm has on stability testing of their infant formulas. Include this information with the EIR submitted to HFS-636.

c) Evaluate compliance with the requirements of 21 CFR 106.90 (code dating information). Ascertain if coding information is used by the firm to control the finished product in the marketplace, and how the firm has outdated product removed from the marketing channels (manufacturing representative visit, retail store management, etc.). Determine disposition of outdated product and amount disposed of in the last year.

d) Review QC procedures used by manufacturers of exempt infant formula and determine: 1) if they are following these procedures and 2) whether or not they comply with 21 CFR 106. Report those procedures that do not comply with the regulation in the EIR.

Collect one original of product labels, promotional literature, brochures or physician letters **that are new or revised since the last inspection**. Be aware that each product may be produced at different caloric levels. Each of these labels should be considered a different product for the purpose of this program. *Submit to HFS-812 as instructed on Page 2 of this program. Part of the review conducted on these labels will be the verification that any translation from English to Spanish language labeling is accurate.*

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2. Import Investigations

*Occasionally shipments of infant formula are offered for entry by a firm that is not one of the manufacturers listed in Attachment C or D. These shipments could be "American Goods Returned" or new infant formulas.

When a shipment of infant formula is one of the formulas listed in Attachment D, and is being offered for import entry, the shipment may be "American Goods Returned". Districts should examine the entry and attempt to determine why the product is being returned to the U.S. The information below may help to make this determination:

a) obtain any documents accompanying the entry, which may help identify whether the product was originally manufactured, distributed or packed by one of the US or foreign manufacturers listed in Attachment C or D. (Such information includes but is not limited to can codes, lot numbers and product labels.)
b) determine whether the shipment is intended for either commercial or charitable distribution in the US,
c) determine that the entry contains the products indicated in the entry documents,
d) obtain distribution information from the importer, if possible.

Obtain manufacturer information for any entry of an infant formula offered for distribution in the U.S. that is not one of the formulas listed in Attachment C or D.

All labels are required to bear the name and place of business of the manufacturer, packer, or distributor. If a firm other than the manufacturer is declared on the label, the district should attempt to locate the manufacturer through the company listed on the label or the documents obtained for the shipment. Any information obtained on the manufacturer of the new infant formula must be forwarded to the Infant Formula Program Manager so that a follow-up inspection can be scheduled to determine whether the manufacturer is in compliance with section 412 of the Act.

When a field examination determines that an entry does not contain the product that is noted in the entry documentation (see c) above)), the entry should be held pending further discussion with your supervisor and/or U.S. Customs.*

3. *Sample Collection*

General Guidance

In general, the samples collected under this program are surveillance samples collected in accordance with the separate schedule issued by the Infant Formula Program Manager, CFSAN/OC/HFS-636. However, additional compliance samples should be collected as warranted by violative inspectional findings.

In general, attempt to collect different products from those collected in recent inspections. # *If inspectional evidence indicates that an exempt infant formula may contain a nutrient(s) that it is specifically formulated to not contain, document the evidence and collect an official sample for laboratory confirmation.*

If only bulk product is manufactured by the firm being inspected, submit a request for sample collection to the district where the finished product is packaged.

Attempt collection from the most recent production date of a lot released by the firm's quality control unit. Note the production date on Collection Reports.

If surveillance activities disclose products which are promoted as infant formulas and which do not appear to meet the requirements of Section 412 of the FD&C Act, collect one sample for nutrient analysis.

If a new or reformulated infant formula product is encountered or the firm has introduced changes in its processing, determine if a premarket notification for this product was submitted to CFSAN, and whether or not a sample was collected at that time. If a sample was not collected, collect a sample of each new or reformulated product, or product manufactured with revised processing procedures. *If more than 1 or 2 new or reformulated products are encountered, contact the Infant Formula Program Manager at 301-436-2065 or Sue Anderson, CFSAN/ONPLDS at 301-436-1453 for assistance in prioritizing the sample collections. Follow the sampling guidance below and sample each new or reformulated infant formula for nutrient analysis and, in the case of powders, microbiological analysis. When collecting samples of new or reformulated infant formula or products manufactured with revised processing procedures, make certain to flag the collection report as such.*

Do not commingle lots.

Because samples collected under this program are collected at the owner named on the label or his agent, a 702(b) portion will not be collected (see IOM *4.3.3.2*). Firms should be encouraged to collect their own portion for analysis. If necessary consult with your supervisor and/or the program monitor for further instructions.

Domestic

After the inspection has been initiated, but prior to collecting samples, determine the firm's policy with respect to FDA standard sampling procedures and solicit the firm's cooperation. If firms do not permit backfilling, determine sample cost and obtain approval of the district office prior to sampling.

The inspection schedule provided in a separate memorandum # has additional guidance for sample collection.

Foreign Inspection Samples

Infant formulas produced by foreign manufacturers that have filed the appropriate notifications under the Act are listed on Attachment C. These infant formulas will be sampled during the annual inspection conducted at each foreign manufacturer. The general guidance provided for above applies equally to import samples. Sample only those formulas and lots intended for exportation to the United States. Verify the U.S. exportation by reviewing the firm's records and/or by discussions with firm management. Obtain the additional information on product exportation listed under 1. Inspectional.

To lessen the burden on investigators conducting foreign inspections and sample collections, the following method is to be used for sampling these products: 1) investigator selects the formula to be sampled, using the criteria above; 2) investigator seals the number of units required for analysis as discussed below; 3) investigator provides a pre-addressed international mailing label(s) for the firm to use to mail the sample to the district investigator's U.S. address.

*The investigator must mark the mailing label(s) as follows: **"U.S. FOOD AND DRUG ADMINISTRATION OFFICIAL SAMPLE—DO NOT REMOVE OR OTHERWISE TAMPER WITH THIS LABEL OR SHIPPING CONTAINER. U.S. CUSTOMS CONTACT INSERT INVESTIGATOR'S SUPERVISOR NAME AND PHONE NUMBER UPON RECEIPT OF THIS SHIPMENT".***

The sampling district should notify ORA/DFI if any product sampled in the foreign firm is not received in the district within a reasonable time. Upon the investigator's return to the U.S., a collection report must be prepared and the sample immediately forwarded to the analyzing laboratory upon its receipt.

***Imports**

All shipments of infant formula determined to be "American Goods Returned" and all shipments of new infant formulas should be sampled and analyzed for nutrients, microbiological contamination, and labeling in accordance with the guidance contained in this program to determine compliance with the Act.*

Samples for Nutrient Analysis

For domestic samples, follow the schedule issued by CFSAN to determine the number and types of formulas to be sampled.

Do not collect nutrient premixes during inspections of premix manufacturers. Samples of the finished product will be collected at the manufacturing plant.

Each sample designated for nutrient analysis by Atlanta Center for Nutrient Analysis (ACNA) is to consist of the following:

a) For one (1) pound powders and eight (8) oz. liquids, collect one **(1) sub** from each of twelve (12) randomly selected shipping cases.

b) For four (4) oz. units, such as Nursettes, collect two **(2) subs** from each of twelve (12) randomly selected shipping cases.

c) For larger (2.5/5 lbs.) powders and thirty-two (32) oz. liquids, collect one **(1) sub** from each of twelve (12) randomly selected shipping cases.

d) When more than one sub is collected per case, add a letter designation to the sub number (i.e., a, b, c, or d). This will ensure that the portion of the sample analyzed includes product from each case sampled.

Samples for microbiological analysis by SRL, Microbiology Branch

a) All **finished product** and **raw material** infant formula samples designated for microbiological analysis should consist of **thirty (30) subsamples of eight ounces each (or larger)**. Number subsamples 1-30 to facilitate analysis.

b) For products that are dried, collect ***1*** sample of **finished product** **NOTE:** Do not submit commercially sterilized products, such as low acid canned foods, for microbiological analysis unless processing records or the appearance of the product containers indicate the product may be microbiologically contaminated.

c) For dry blended products, collect ***1*** sample of **finished product** and ***1*** sample of a principal **raw material ingredient** used in that finished product. When possible, collect an ingredient from the same lot used in the manufacture of the sampled finished product. *Sample from bulk containers of raw material ingredient using aseptic technique in accordance with IOM Section *4.3.6*. For more guidance on aseptic technique, investigators may consult the course Food Microbiological Control 10: Aseptic Sampling, which is available to FDA employees through the ORAU intranet site.* Examples of ingredients to be collected include soy powder, nonfat dry milk, dried whey, delactosed whey, demineralized whey, whey protein concentrate, caseinates.

4. Sample Shipment

Samples for nutrient analysis and/or microbiological analysis

Send samples to:

DHHS/Food and Drug Administration
Southeast Regional Laboratory
60 Eight Street, NE
Atlanta, Georgia 30309

Note on the C/R and FDA-525 whether the sample is to be analyzed by the Atlanta Center for Nutrient Analysis (ACNA), HFR-SE680,(404-253-1181) or the Microbiology Branch HFR-SE670, (404-253-1179).

Contact the appropriate SRL unit in advance of shipment to provide the shipping details.

Samples collected for routine surveillance purposes do not need to be accompanied by EIRs when forwarded to SRL/ACNA (HFR-SE680) or SRL/Microbiology Branch (HFR-SE670). However, compliance samples should have a copy of the EIR submitted to the laboratory as soon after sample submission as possible to assist the laboratory in analyzing the sample.

5. Hardcopy Reporting

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All hardcopy reports to headquarters are to be sent to the following address and the appropriate office identified below:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

a) Forward a copy of the Summary of Findings for each inspection to the Infant Formula Program Contact(HFS-636), within 30 days after completion of the inspection. If CFSAN has requested that specific information be collected and documented during the inspection, that information must also be submitted along with the Summary of Findings, this includes Attachment B (Infant Formula Nutrient Information Reporting Form).

b) Complete EIRs for foreign inspection must be sent to CFSAN, Division of Enforcement, Chief, Imports Branch (HFS-606), upon completion with a copy also forwarded to ORA/ORO/Division of Field Investigations.

c) Collect and submit product labels, promotional literature and brochures **that are new or revised since the last inspection** conducted at the firm to CFSAN/ONPLDS/Food Labeling and Standards Staff (HFS-812), within 30 days after completion of the inspection.

d) Attachment A must be completed and sent electronically to Sue Anderson at sue.anderson@cfsan.fda.gov upon completion of the inspection when information obtained during the inspection indicates changes in processing or formulation have occurred.

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PART IV - ANALYTICAL

1. Analyzing Laboratory

For nutrient analysis and label review:

SRL/Atlanta Center for Nutrient Analysis (ACNA), HFR-SE680

For microbiological analysis:

SRL/Microbiology Branch, HFR-SE670

2. Label Reviews

SRL (ACNA and/or Microbiology Branch) will review the labels of all samples using 21 CFR Part 101, 107, and 21 CFR Part 105.65(a) and (b).

3. Nutrient Analyses

NOTE:ACNA MUST USE THE METHODS LISTED BELOW OR METHODS AGREED TO IN ADVANCE BY THE CFSAN METHODS CONTACTS FOR ALL NUTRIENT ANALYSES.

Prepare a composite using the AOAC, Current Edition, Method 985.30.

Assay finished product infant formulas for all nutrients listed in 21 CFR 107 Subpart D except for choline, iodine and inositol.

Products that have a source of selenium (i.e., sodium selenite) identified in their ingredient statement should be assayed for selenium using the method referenced in the current Total Diet Study Compliance Program.

Use factor 6.25 to convert nitrogen content to protein.

NOTE: There may be occasions where a more specific factor could be used. If there are any questions, contact Dr. Jeanne Rader (HFS-840) at(301) 436-1786.

Calculate carbohydrate by difference and kilocalories per unit weight or volume as appropriate. Use the determined kilocalories to calculate nutrient content per 100 kilocalories.

Exempt infant formulas and other specially formulated formulas must be analyzed for all nutrients listed as absent for medical reasons (e.g., "lactose free", analyze for lactose).

Analyze the composite by the following methods:

Official Methods of Analyses (AOAC) International
Current Edition

1.	Sampling	Method 985.30
2.	Proximates	Method 986.25
3.	Vitamin C	Method 985.33
4.	Thiamine	Method 986.27
5.	Riboflavin	Method 970.65
6.	Vitamin B_6	Method 985.32 (see note below)
7.	Vitamin B_{12}	Method 986.23
8.	Niacin	Method 985.34
9.	Chloride	Method 986.26
10.	Phosphorus	Method 986.24 or 984.27
11.	Vitamin A	Method 992.06/992.04
12.	Vitamin D	*Method 992.26 or 995.05*
13.	Vitamin E	Method 992.03
14.	Vitamin K	*Method 992.27 or 999.15*
15.	Folic Acid	Method 992.05
16.	Pantothenic Acid	Method 992.07
17.	Calcium, Copper Iron, Magnesium, Manganese, Potassium, Sodium, and Zinc	Method 985.35 or 984.27
18.	Fat	Method 996.01
19.	EFA (Linoleic acid)	Method 996.01 or 992.25

Note: Do not use 996.01 to measure cis- or Trans-fatty acids

FDA-IFC Collaborative Study Methods

20.	Biotin	Proc. Soc, Explt, Biol. Med. 56:95, 1944 c (modified) - Extraction - IN H_2SO_4

Note Regarding Vitamin B_6 Analysis: CFSAN has approved the use of the newly developed LC method for the original analysis.

Calculate levels detected as follows:

a) Convert amount of nutrient found by analysis to units per 100 kcal as listed in Section 412 of the Act (i.e., calculate to respective nutrient units)

b) Convert amount of nutrient found by analysis to the respective nutrient units declared on the label

4. Microbiological Analyses

SRL must refer to the guidance contained in the ORA/DFS Standard Operating Procedure dated August 6, 2001 for routine subtyping of all isolates positive for *Salmonella* spp., *Listeria monocytogenes,* and *E. coli* 0157:H7. Do not delay the sample classification or pursuit of additional regulatory action and/or follow-up pending the results of these additional tests.

All references to the BAM refer to the Bacteriological Analytical Manual (BAM) Current Edition which can be accessed online at http://www.cfsan.fda.gov/~ebam/bam-toc.html (referred to as e-BAM).

Perform the following analyses on each sample of soy or milk based finished products and soy or milk based ingredients.

NOTE: Before proceeding with the following bacteriological analyses, prepare **four** composites from the 30 subsamples for Salmonella analysis.

Each composite must be prepared as follows:

a) Using subs 1-15 remove 25 ml or g from each of 15 subsamples for a total of 375 mL or g for composite 1. Repeat using the same subs 1-15 for preparation composite 2; then

b) Using subs 16-30 remove 25 ml or g from each of 15 subsamples for a total of 375 mL or g for composite 3. Repeat using the same subs 16-30 for preparation of composite 4.

c) Analyze each of the four 375 mL or g composites using the instructions below.

Next, randomly select 20 of the 30 subsamples for preparation of four composites for Listeria analysis as follows:

d) Remove 50 mL or g from each of 5 subsamples for a total 250 mL or g for composite 1; then

e) Repeat the above procedure using different subsamples (5 subsamples) to prepare a total of 4 composites each consisting of 250 mL or g.

f) Remove 25 mL or g from each of these four composites for Listeria analysis as instructed below.

All remaining bacteriological analyses are to be done on an individual subsample basis.

Listeria monocytogenes

Refer to the July 9, 1998 supplement to the "Guidance for the Use of Rapid Methods for Food Microbiology" issued April 24, 1998.

Analyze according to the e-BAM, Chapter 10 and 11. For products subject to this compliance program, analyze four composites per sample.

> **SAFETY PRECAUTIONS:** Media Preparation for *L. monocytogenes* directs the use of cycloheximide which is an **extremely toxic** chemical and acriflavine which is a powerful mutagen **(use caution)**.

Since the *L. monocytogenes* method gives the option of using a - naphthol, **DO NOT** use a - Naphthylamine. All analysts should take **extreme safety precautions** when handling these chemicals; e.g., weigh in a containment hood free of drafts; wear gloves and face mask. Those laboratories with pesticide capabilities should take additional precautions against possible contamination as cycloheximide is a fungicide.

Enumeration

If the "processed finished product" was found to be positive for *L. monocytogenes* and growth was observed at 24 *and/or 48 hrs of the enrichment, then enumerate using the MPN method, e-BAM, Chapter 10, *L. monocytogenes.* Contact Anthony.Hitchins@CFSAN.FDA.GOV for information about the use of one of the new chromogenic agars in place of Oxford agar or if there are any other questions.*

Salmonella

Refer to the “Guidance for the Use of Rapid Methods for Food Microbiology issued April 24, 1998”.

NOTE: The serovar of *Salmonella* that has been identified in the contamination of some dried infant formula samples is *S. tennessee,* a member of *Salmonella* Group C_1. Recent isolates of this serovar from dried products have been **lactose-positive**.

Preparation of composites - BAM, Chapter 1. The minimum number of sample composites to be analyzed is four.

Isolation and Identification - BAM, Chapter 5.

Speciation - prepare slants, and provide hardcopy information requested under BAM, Chapter 5, Section E.11., for shipment to:

Food and Drug Administration
Arkansas Regional Laboratory (HFR-SW500)
3900 NCTR Road
Jefferson, AR 72079-9502
870-543-4071
Attn: Doris Farmer

Contact the laboratory in advance of shipment to provide the shipping details.

For the following analyses, analyze individual subsamples (no compositing) as directed in the referenced chapters of the e-BAM.

Staphylococcus sp.

Direct microscopic examination, e-BAM, Chapter 2.

Identification, enumeration, coagulase, ancillary tests, and viable count (MPN) will be performed using e-BAM, Current Edition, Chapter 12. Analyze 5 subsamples per sample.

*

Staphyloccoccal Enterotoxin Determination

If viable *Staphylococcus sp.* colonies are observed by either:

- most probable number (MPN) result is >11,000; or
- direct plate count indicates a level of 10,000

then determine the enterotoxigenicity of isolates as per the most current version e-BAM, Chapter 13.

Follow the methodology outlined in Chapter 13. The laboratory will individually test each sub-sample using the TECRA™ ELISA kit with proper procedures followed accordingly.

NOTE: Under no circumstances should positive TECRA™ ELISA results be conveyed to a regulated firm or consumer without confirmation. The TECRA™ ELISA kit is intended as a screening technique only.

When the TECRA™ ELISA kit is used and renders a:

- Negative result – the laboratory need not conduct further analysis for enterotoxin. The sample is considered "negative" and no other regulatory or follow-up action is warranted.

- Positive result – the labotatory must analyze the original sample using the Chapter 13, "Microslide Gel Double Diffusion and perform the ELISA-based Method (VIDAS) for confirmation.

NOTE: If the District or Regional laboratory cannot perform the VIDAS, then contact Reginald Bennett at (301) 436-2009 to arrange for shipment of portions of the actual subsamples to CFSAN for confirmation.

If the TECRA™ ELISA kit **and** the VIDAS test are **positive**, the District may proceed with regulatory consideration. However, the results must be re-confirmed by CFSAN.

NOTE: Send the extract used for the TECRA™ ELISA kit and the reserve portion of all the original sub-samples to:

Mr. Reginald Bennett (HFS-516)
CFSAN/Microbiology Methods Research Branch
5100 Paint Branch Parkway, Rm. 3E019
College Park, MD 20740
Phone: 301-436-2009
Contact Mr. Bennett prior to shipment

If the result of the TECRA™ ELISA kit is positive and the VIDAS test is negative then the sample must be confirmed positive or negative by CFSAN. Send the extract used for the TECRA™ ELISA kit and the reserve portion for all of the original subsamples to Mr. Bennett at the above address as expeditiously as possible.
*

Bacillus cereus

BAM, Chapter 14. Analyze 10 subsamples per sample. If a sample is found to be positive for **B. cereus**, send isolate slants together with the reserve portion of each of the ten subsamples representing the sample to Mr. Bennett, CFSAN/Microbiology Methods Research Branch at the above address for enterotoxigenicity testing.

Include a copy of the collection report and the analyst worksheet and ship according to the Federal Standards for Etiological Agents.

Aerobic Plate Count: Chapter 3. Analyze 5 subsamples per sample.

*

Coliform and *Escherichia coli*: See Chapter 4 e-BAM—Enumeration of *Escherichia coli* and the Coliform Bacteria. Section I.C. MPN – presumptive test coliforms, fecal coliforms and *E. coli*.

Analyze 5 subsamples per sample.

If any of the LST tubes are gas positive, subculture a loopful to BGLB to obtain confirmed results for coliforms and another loopful to EC broth for fecal coliform and *E. coli* determination.

If *E. coli* are isolated, **perform serological testing for 0157 and H7** as described in Chapter 4a. Diarrheagenic *E. coli*, e-BAM, Section Q. If less than 10 colonies of *E. coli* are found, test all isolates. If more than 10 colonies are found, randomly test 10 isolates.

If *E. coli* are present at levels of 10^4/g or higher, **perform ETEC analysis** using the DNA probe for ST and LT described in e-BAM Chapter 24.

Consult Dr. Peter Feng (HFS-516) at 301-436-1650 if needed, for final identification.
*

5. Reporting of Results to CFSAN and the Home District

*
ACNA should use the following criteria to determine when analytical results should be forwarded to the Compliance Branch of the home district for further evaluation:

- The actual caloric content and either added or naturally-occurring fat or sodium exceed 20% of the value declared on the label;

- Added vitamins, minerals, protein, linoleic acid or potassium are not at least equal to the value declared on the label; or

- Any of the following naturally occurring nutrients are present in the infant formula at less than 80% of the value declared on the label:

  -vitamins -total carbohydrate
  -minerals -protein -potassium

- The amount of any nutrient in the product is less than or greater than the nutrient specifications for infant formulas in Section 412(i) of the Act and 21 CFR 107.100.

- An exempt infant formula that is found to contain a nutrient(s) which it is specifically formulated to not contain.

*

The Southeast Regional Laboratory will immediately contact the CFSAN Regulatory/Compliance Contact and the CFSAN Regulatory/Policy Contact as well as the home district when:

a) Nutrient levels are found below the minimum or above the maximum permitted by the Infant Formula Act.

b) Selenium levels are found below 1.35 mcg/100 kcal or above 8 mcg/100 kcal.

c) Sample results with the following microbiological values are found:

Salmonella: presence

Listeria monocytogenes: presence

Escherichia coli 0157:H7: presence

**Staphylococcal enterotoxin:* presence*

Bacillus cereus: If any subsample exceeds 1000 organisms/gram.

Aerobic Plate Count: If any subsample exceeds 10,000 organisms/gram, or if three or more subsamples exceed 1,000 organisms/gram.

Coliforms: If any subsample exceeds 3 organisms/gram.

6. Hardcopy Reporting

For any sample given a lab class of "2" or "3" express mail a copy of the complete analytical worksheet immediately upon completion to the Compliance Branch of the home district (and notify the collecting district if not identical) for regulatory consideration.

7. Data Reporting

Report results of all analyses into the Field Accomplishment and Compliance Tracking System using the following Problem Area Flags (PAF):

Nutrient Analysis	= PAF "NIF"	
Microbiological Analysis	= PAF "MIC"	APC, Coliform, *B. cereus*, *Listeria, Salmonella*, *S. aureus*, Staphyloccoccal Toxin, *E. Coli*, ETEC & EHEC)
If appropriate	= PAF "SAL"	(*Salmonella* serotyping)
	= PAF "ABR"	(*Salmonella* antibiotic resistance)
	= PAF "GSA"	(PFGE *Salmonella*)
	= PAF "GEC"	(PFGE; *E. coli* 0157:H7)
Label Reviews	= PAF "FDF"	Results Flag "FDL"

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

*

1. Import Entries

Occasionally shipments of infant formula are offered for entry by a firm that is not one of the manufacturers listed in Attachment C or D. These shipments could be "American Goods Returned" or new infant formulas.

When a shipment of infant formula is one of the formulas listed in Attachment D, and being offered for import entry, the shipment may be **"American Goods Returned"**. Districts should examine the entry and attempt to determine why the product is being returned to the U.S. The information below may help to make this determination:

a) obtain any documents accompanying the entry, which may help identify whether the product was originally manufactured, distributed or packed by one of the US or foreign manufacturers listed in Attachment C or D. (Such information includes but is not limited to can codes, lot numbers and product labels.)
b) determine whether the shipment is intended for either commercial or charitable distribution in the US,
c) determine that the entry contains the products indicated in the entry documents,
d) obtain distribution information from the importer, if possible.

Obtain manufacturer information for any entry of an infant formula offered for distribution in the U.S. that is not one of the formulas listed in Attachment C and D.

All labels are required to bear the name and place of business of the manufacturer, packer, or distributor. If a firm other than the manufacturer is declared on the label, the district should attempt to locate the manufacturer through the company listed on the label or the documents obtained for the shipment. Any information obtained on the manufacturer of the new infant formula must be forwarded to the Infant Formula Program Manager so that a follow-up inspection can be scheduled to determine whether the manufacturer is in compliance with section 412 of the Act.

When a field examination determines that an entry does not contain the product that is noted in the entry documentation (see c) above)), the entry should be held pending further discussion with your supervisor and/or U.S. Customs.

All shipments of infant formula determined to be American Goods Returned (see above discussion) and all shipments of infant formulas not listed on Attachment C should be sampled and analyzed for nutrients, microbiological contamination, and labeling in accordance with the guidance contained in this program to determine compliance with the Act.

2. Situations Presenting a Health Hazard

If a situation poses a health hazard, whether it pertains to conditions at a firm or analytical findings, the District should contact CFSAN immediately. If inspectional or analytical findings are particularly egregious, CFSAN may support proceeding directly to seizure or injunction. In either case, districts should contact the CFSAN Regulatory/Contacts listed in Part VI to discuss the facts involved.

3. Foreign Inspections and Import Sample Collections

CFSAN will review establishment inspection reports and analytical worksheets resulting from foreign inspections for compliance with the Food, Drug, and Cosmetic Act (the Act). Warning Letters will be prepared by CFSAN when conditions observed during the inspection warrant regulatory follow-up. The Agency established Supplemental "Procedures for Clearing FDA Warning Letters," dated March 5, 2002, which is available on ORA's Intranet Website at:http://web.ora.fda.gov/oe/warningleters/TRKLET116.htm.

4. Domestic Inspections and Sample Collections

The District should submit Warning Letter recommendations to CFSAN/Office of Compliance/Division of Enforcement (HFS-607) for:

a) All domestic inspections classified as Official Action Indicated (OAI), including those during which no samples were collected; and

b) Firms whose sample(s) yield the following analytical results.

- The actual caloric content and either added or naturally-occurring fat or sodium exceed 20% of the value declared on the label;
- Added vitamins, minerals, protein, linoleic acid or potassium are not at least equal to the value declared on the label; or
- Any of the following naturally occurring nutrients are present in the infant formula at less than 80% of the value declared on the label:

  -vitamins -total carbohydrate
  -minerals -protein -potassium

- The amount of any nutrient in the product is less than or greater than the nutrient specifications for infant formulas in Section 412(i) of the Act and 21 CFR 107.100; or
- An Exempt infant formula determined by analysis to contain a nutrient(s) that it is specifically formulated to not contain.

Violations other than those relating to the Infant Formula Regulations will be handled under the Domestic Acidified and Low-Acid Canned Foods Program (CP 7303.803A).

Until such time as guidance for interpreting analytical results and label declarations is developed, the Compliance Branches should contact the CFSAN Regulatory/Compliance Contacts listed in Part VI of this program prior to preparing recommendations for regulatory follow-up.

5. Refusals

See the Regulatory Procedures Manual, Chapter 6, Inspection Warrant Policies/Procedures. Districts will evaluate inspectional refusals including refusal of the firm to permit review of Q.C. and distribution records, and consider obtaining an inspectional warrant *in consultation with ORA, Office of Enforcement, Division of Compliance Management and Operations (HFC-210) and CFSAN, Office of Compliance, Division of Enforcement (HFS-607),* consistent with the IOM and Agency policy.

*

PART VI - REFERENCES, ATTACHMENTS, AND CONTACTS

1. References

Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II, Section 4.
(http://www.ora.fda.gov/ora/inspect_ref/igs/foodsp2.html)

Code of Federal Regulations, Title 21, Part 105.65, Subpart B, "Foods for Special Dietary Use, Label Statements, Infant Foods."
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr105_01.html

Code of Federal Regulations, Title 21, Part 106, "Infant Formula Quality Control Procedures."
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr106_01.html

Code of Federal Regulations, Title 21, Part 107, "Infant Formula" (including Subpart E - Infant Formula Recalls).
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr107_01.html

FDA "Guidelines Concerning Notification and Testing of Infant Formulas" (mailed to the Infant Formula Council under a cover letter dated 8/01/86).

2. Attachments

Attachment A - Reporting Changes in Processing and Reformulation for Infant Formulas
Attachment B – Infant Formula Nutrient Information Reporting Form
Attachment C - Foreign Infant Formula Manufacturers and Products
Attachment D – Domestic Infant Formula Manufacturers and Products
Attachment E – Exempt Infant Formula – Reason for Exemption

3. Contacts

General Program Guidance - Brenda Aloi, CFSAN/OC/DFP/Compliance Programs Branch *(301) 436-2065, FAX (301) 436-2657*

Regulatory/Compliance Domestic Contacts—CFSAN/OC/DOE/Domestic Branch/Nutritional Products, Labeling and Dietary Supplements Team; Team Leader Jennifer Thomas (301) 436-2094

Regulatory/Compliance Import Contact—CFSAN/OC/DOE/Import Branch; (301) 436-1742

Regulatory/Policy Domestic and Import Contact - CFSAN/ONPLDS/Food Labeling and Standards Staff (301) 436-2371

Inspectional Inquiries - Barbara Marcelletti, ORA/Division of Field Investigations at (301) 827-5635

Import Operations - Ted Poplawski ORA/Division of Import Operations & Policy (301) 594-3849

CFSAN Methods Contacts

For methodology other than metals/minerals:

Dr. Jeanne Radar (HFS-840) *(301) 436-1786*

For methodology involving metals/minerals:

Primary contact - William Mindak (HFS-338) *301-436-2005*
Backup - Stephen Capar (HFS-338) *301-436-2003*

ORA Methods Contacts

Marsha Hayden (microbiology) ORA/DFS, (HFC-140), (301) 827-1039

George Salem (nutrients) ORA/DFS (HFC-140), (301) 827-1031

PART VII - CENTER RESPONSIBILITIES

The Director, Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), is responsible for submitting an annual evaluation of this program. The evaluation should be submitted to the Director, Division of Field Programs by April 1 for the previous fiscal year. The Division of Field Programs will provide accomplishment data to the Director, ONPLDS, when requested to aid in the program evaluation.

REPORTING CHANGES IN PROCESSING AND FORMULATION
FOR INFANT FORMULAS

Complete this form and send electronically to sue.anderson@cfsan.fda.gov upon completion of the inspection. The information should be submitted whether or not the firm has previously reported the change to the Agency because many firms report insufficient data for the Agency to determine the significance of the change.

FIRM NAME _____

FIRM ADDRESS _____

1. Nature of the change: Processing_____ Formulation_____

2. Has the company reported the change to FDA in accordance with 21 CFR 106.120(a) and the FDA "Guidelines Concerning Notification and Testing of Infant Formulas" document? Yes____ No ____. If yes, report the date the company reported the change:

3. Name of the infant formula and forms (i.e. liquid, powder, concentrate) involved in the change:

4. Describe the change in detail:

5. Describe purpose(s) or reason(s) for the change:

6. List nutrients changed (if any) and the target levels in the final product before and after reformulation:

7. Describe equipment changes (if any) and their purpose:

8. Describe all testing completed or underway (chemical and biological) to assure compliance with nutrient requirements of Section 412(g) of the FD&C Act and nutrient availability in the final product:

9. Attach new labels if change resulted in any label changes. (attach additional sheet(s) if necessary)

INFANT FORMULA NUTRIENT INFORMATION REPORTING FORM

This form is to be completed during each inspection of a finished product manufacturing process. It is intended to show the source of nutrients, at what stage of the manufacturing process they are analyzed, and the analytical methods used. Indicate the source of the nutrient using the abbreviations at the end of the form, on page 2, of this Attachment. Indicate the stage of the process by placing an "X" in the appropriate box. Indicate the method reference by giving specific number (eg. AOAC #), or by general description (ICP, GC, etc.). *Send the completed form along with the Summary of Findings to HFS-636 as instructed on Page 1 of this program.*

PRODUCT:_____

FIRM NAME:_____

FIRM ADDRESS:_____

FEI:_____

FORM OF PRODUCT (READY TO USE, POWDER, CONCENTRATE):_____

DATE:_____

Nutrient	Source*	Raw Material	In Process	Finished Product	Method Reference
Protein					
Linoleic Acid					
Fat					
Carbohydrate					
Vitamin A					
Vitamin B_1					
Vitamin B_2					
Vitamin B_3					
Vitamin B_6					
Vitamin B_{12}					
Folic Acid					
Pantothenic Acid					

Nutrient	Source*	Raw Material	In Process	Finished Product	Method Reference
Biotin					
Vitamin C					
Vitamin D					
Vitamin E					
Vitamin K					
Choline					
Inositol					
Calcium					
Phosphorus					
Magnesium					
Iron					
Iodine					
Zinc					
Copper					
Manganese					
Sodium					
Potassium					
Chloride					
Other					

*FSPM - Fat Soluble Premix WSPM - Water Soluble Premix
MPM - Mineral Premix IA - Independent Addition FB - Formula Base

%

%

*

%