§ 106.90

the vitamin D bioassay and, if required, a protein biological quality bioassay are complete, provided such bioassays have been initiated, and if another analysis for the vitamin D has been run and the protein content has been determined by a suitable method. The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis. The manufacturer shall analyze additional samples from the same batch for vitamin D, by any suitable method, and for the biological quality of the protein. The manufacturer shall perform such analyses at least annually for a period not to exceed the expected shelf life of the product.

(d) A simple adjustment in the level of an ingredient to accommodate inconsistencies in processing is considered to be neither a minor nor a major change.


§ 106.90 Coding.

The manufacturer shall code all infant formulas in conformity with the coding requirements that are applicable to thermally processed low-acid foods packaged in hermetically sealed containers as prescribed in §113.60(c).

Subpart C—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to §174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:

(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manufacturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).

(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the act and §107.100 of this chapter.

(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:

(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the act or §107.100 of this chapter and any other nutrient listed in the certificate and guarantee;

(2) The weight of each nutrient added;

(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and

(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

(e) The manufacturer shall maintain all records necessary to ensure proper nutrient quality control in the manufacture of infant formula products. Such records shall include the results of any testing conducted to verify that each nutrient required by section 412(i) of the act or §107.100 of this chapter is present in each batch of infant formula at the appropriate concentration. This requirement pertains to ingredients, in process batch and finished product from the time of manufacture through its expiration date.

(f) The manufacturer shall maintain all records necessary to ensure required nutrient content at the final product stage. Such records shall include, but are not limited to, testing results for vitamins A, B₁ (thiamine),
C, and E for each batch of infant formula. “Final product stage” means the point in the manufacturing process prior to distribution at which the infant formula is homogenous and not subject to further degradation from the manufacturing process.

(g) The manufacturer shall maintain all records pertaining to distribution of the infant formula. Such records shall include, but not be limited to, all information and data necessary to effect and monitor recalls of the manufacturer’s infant formula products in accordance with subpart E of part 107 of this chapter.

(h) The manufacturer shall maintain all records pertaining to the microbiological quality and purity of raw materials and finished powdered infant formula.

(i) [Reserved]

(j) The manufacturer shall maintain all records pertaining to regularly scheduled audits, including audit plans and procedures. Audit plans identify the specific manufacturing and quality control procedures to be reviewed. Audit procedures are the methods used to review the manufacturing and quality control procedures. Records of audits shall include the information and data necessary for a determination as to whether the manufacturer complies with the current good manufacturing practices and quality procedures identified in parts 106, 107, 109, 110, and 113 of this chapter. The records shall include written assurances from the manufacturer that regularly scheduled audits are being conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula, and that the complete audit plans and procedures for the firm have been followed. The actual written reports of the audits need not be made available.

(k) The manufacturer shall maintain procedures describing how all written and oral complaints regarding infant formula will be handled. The manufacturer shall follow these procedures and shall include in them provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health.

(1) For purposes of this section, every manufacturer shall interpret a “complaint” as any communication that contains any allegation, written or oral, expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a hazard to health and about appearance, taste, odor, and quality. Correspondence about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health shall not, for compliance purposes, be considered a complaint and therefore need not be made available to an FDA investigator.

(2) When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. Where such an investigation is conducted, the manufacturer shall include in its file on the complaint the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall include in the record the reason that an investigation was found to be unnecessary and the name of the responsible person making that determination.

(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant’s death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the agency as required in §106.120(b).

(4) The manufacturer shall maintain in designated files all records pertaining to the complaints it receives. The manufacturer shall separate the files into two classes:

(i) Those complaints that allege that the infant became ill from consuming the product or required treatment by a physician or health-care provider.

(ii) Those complaints that may involve a possible existence of a hazard to health but do not refer to an infant becoming ill or the need for treatment by physician or a health care provider.
§ 106.120 New formulations and refor- 
mulations.
(a) Information required by section 412(b)(2) and (3) of the act shall be 
submitted to Center for Food Safety and 
Applied Nutrition (HFS–830), Food and 
Drug Administration, 5100 Paint 
Branch Pkwy., College Park, MD 20740.
(b) The manufacturer shall promptly 
notify the Food and Drug Administra-
tion when the manufacturer has knowl-
edge (as defined in section 412(c)(2) of 
the act) that reasonably supports the 
conclusion that an infant formula that 
has been processed by the manufac-
turer and that has left an establish-
ment subject to the control of the man-
ufacturer may not provide the nutri-
tents required by section 412(g) of 
the act and by regulations promulgated 
under section 412(a)(2) of the act, or 
when there is an infant formula that is 
otherwise adulterated or misbranded 
and that may present risk to human 
health. This notification shall be made,