§ 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),