

§107.240 Notification requirements.

(a) *Notification of a violative infant formula.* A manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act)) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the act and by regulations promulgated under section 412(i)(2) of the act; or

(2) May be otherwise adulterated or misbranded.

(b) *Method of notification.* The notification made pursuant to §107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in §5.215 of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 301-443-1240, shall be used. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office specified in §5.215 of this chapter.

(c) *Reports about an infant formula recall*—(1) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in §5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(2) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(i) Number of consignees notified of the recall, and date and method of notification, including, for a recall pursuant to §107.200 information about the

notice provided for retail display and the request for its display.

(ii) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(iii) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(iv) Number and results of effectiveness checks that were made.

(v) Estimated timeframes for completion of the recall.

(3) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001]

§107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in §5.215 of this chapter for transmittal to the Center for Food Safety and Applied Nutrition (HFS-605), for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Center for Food Safety and Applied Nutrition (HFS-605), of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such a notification unless it has information, from FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

Food and Drug Administration, HHS

§ 108.3

(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or

(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001]

§ 107.260 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

(a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.

(b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.

(c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information demonstrate that the original notifications were not received, or were disregarded in a significant number of cases.

§ 107.270 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonable calculated to meet the obligations set forth in this Subpart E. The recall guidance in subpart C of part 7 of this chapter specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

[54 FR 4008, Jan. 27, 1989, as amended at 65 FR 56479, Sept. 19, 2000]

§ 107.280 Records retention.

Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such

manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

[54 FR 4008, Jan. 27, 1989, as amended at 67 FR 9585, Mar. 4, 2002]

PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

Sec.

108.3 Definitions.

108.5 Determination of the need for a permit.

108.6 Revocation of determination of need for permit.

108.7 Issuance or denial of permit.

108.10 Suspension and reinstatement of permit.

108.12 Manufacturing, processing, or packing without a permit, or in violation of a permit.

108.19 Establishment of requirements for exemption from section 404 of the act.

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

108.25 Acidified foods.

108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

AUTHORITY: 21 U.S.C. 342, 344, 371.

SOURCE: 42 FR 14334, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 108.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

(b) *Commissioner* means the Commissioner of Food and Drugs.

(c) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended.

(d) *Permit* means an emergency permit issued by the Commissioner pursuant to section 404 of the act for such temporary period of time as may be necessary to protect the public health.

(e) *Manufacture, processing, or packing of food in any locality* means activities