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:

(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.


§ 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.


PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

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108.25 Acidified foods.
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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