§ 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.