Food and Drug Administration, HHS

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in §5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.
(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
(3) Evaluation of the risk associated with the deficiency or possible deficiency.
(4) Total amount of such products produced and/or the timespan of the production.
(5) Total amount of such products estimated to be in distribution channels.
(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
(7) A copy of the firm’s recall communication if any has issued, or a proposed communication if none has issued.
(8) Proposed strategy for conducting the recall.