

Food and Drug Administration, HHS

§ 7.59

Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted

and the quantity of products accounted for.

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

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

Subpart D [Reserved]

Subpart E—Criminal Violations

§ 7.84 Opportunity for presentation of views before report of criminal violation.

(a)(1) Except as provided in paragraph (a) (2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

(2) Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.

(3) Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.

(b) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the Commissioner's discretion, provide notice and an opportunity to present views.

(c) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.

(d) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct al-

leged to violate the law. The notice shall—

(1) Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;

(2) Specify the time and place where those named may present their views;

(3) Summarize the violations that constitute the basis of the contemplated prosecution;

(4) Describe the purpose and procedure of the presentation; and

(5) Furnish a form on which the legal status of any person named in the notice may be designated.

(e) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.

(f) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.

(g) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first