

Food and Drug Administration, HHS

Pt. 7

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201-2199.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237-3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237-3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207-3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401-1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: Textron Bldg., 6600 Plaza Dr., suite 400, New Orleans, LA 70127.

Nashville Branch of NOL-DO: 297 Plus Park Blvd., Nashville, TN 37217.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmwood Rd., suite 102, Dallas, TX 75247-4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214-3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143-3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 14-T, rm. 104, Jefferson, AR 72079-9502.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502-7070.

Los Angeles District Office: 19900 Mac Arthur Blvd., suite 300, Irvine, CA 92715.

Seattle District Office: P.O. Box 3012, Bothell, WA 98021-3012.

Pacific Regional Laboratory, SW: 1521 West Pico Blvd., Los Angeles, CA 90015-2488.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021-4421.

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AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 241, 262, 263b-263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any

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food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal* means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery* means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of