§ 5.1110 FDA public information offices.

(a) Division of Dockets Management. The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301–827–6860.

(b) Division of Freedom of Information. The Division of Freedom of Information public room is located in rm. 1050, Element Bldg., 12420 Parklawn Dr., Rockville, MD 20857, Telephone: 301–796–3900.

(c) Press Relations Staff. Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301–436–2335.

PART 7—ENFORCEMENT POLICY

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.


§ 7.3 Definitions.

(a) Agency means the Food and Drug Administration.

(b) Citation or cite means a document and any attachments thereto that provides 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 food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for...