

be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.

(h)(1) When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.

(2) When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the Commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.

(3) When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.

(4) When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

[44 FR 12168, Mar. 6, 1979]

§ 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

(a) Records related to a section 305 opportunity for presentation of views constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memorandums.

(1) Notwithstanding the rule established in § 20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure

until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with § 20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and § 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305

presentation of views before public disclosure only under §20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

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AUTHORITY: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase *to publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 69 FR 17290, Apr. 2, 2004]

§ 10.3 Definitions.

(a) The following definitions apply in this part and parts 12, 13, 14, 15, 16, and 19:

Act means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

Administrative action includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal