

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

(30) Investigational device exemptions in § 813.38 of this chapter.

(31) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

(32) Data and information submitted in offers to develop a proposed performance standard for medical devices, in § 861.26 of this chapter.

(33) Investigational device exemptions in § 812.38 of this chapter.

(34) Health claims petitions, in § 101.70 of this chapter.

(35) Premarket approval application, in § 814.9 of this chapter.

(36) Report of certain adverse experiences with a medical device, in § 803.9 of this chapter.

(37) Disqualification determination of an institutional review board, in § 56.122 of this chapter.

(38) Disqualification determination of a nonclinical laboratory, in § 58.213 of this chapter.

(39) Minutes or records regarding a public advisory committee, in § 14.65(c) of this chapter.

(40) Data submitted regarding persons receiving an implanted pacemaker device or lead, in § 805.25 of this chapter.

(41) Humanitarian device exemption application, in § 814.122 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 42 FR 19989, Apr. 15, 1977; 42 FR 42526, Aug. 28, 1977; 42 FR 58889, Nov. 11, 1977; 43 FR 32993, July 28, 1978; 51 FR 22475, June 19, 1986; 54 FR 9038, Mar. 3, 1989; 58 FR 2533, Jan. 6, 1993; 59 FR 536, Jan. 5, 1994; 61 FR 33244, June 26, 1996; 62 FR 40592, July 29, 1997; 64 FR 56448, Oct. 20, 1999]

#### § 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory

inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD-483 and FD-2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 20.64. For example, an establishment inspection report is an investigatory record and thus subject to § 20.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 20.82.

#### § 20.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public