

§ 821.55

FDA representative of official credentials and the issuance of Form FD 482 at the initiation of an inspection of an establishment or person under section 704 of the act, make each record and all information required to be collected and maintained under this part and all records and information related to the events and persons identified in such records available to FDA personnel.

(b) Records and information referenced in paragraph (a) of this section shall be available to FDA personnel for purposes of reviewing, copying, or any other use related to the enforcement of the act and this part. Records required to be kept by this part shall be kept in a centralized point for each manufacturer or distributor within the United States.

§ 821.55 Confidentiality.

(a) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with § 20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(b) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

§ 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use,

21 CFR Ch. I (4-1-98 Edition)

has been explanted, returned to the manufacturer, or the patient has died.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

- Sec.
- 860.1 Scope.
- 860.3 Definitions.
- 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.
- 860.7 Determination of safety and effectiveness.

Subpart B—Classification

- 860.84 Classification procedures for "old devices."
- 860.93 Classification of implants, life-supporting or life-sustaining devices.
- 860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Reclassification

- 860.120 General.
- 860.123 Reclassification petition: Content and form.
- 860.125 Consultation with panels.
- 860.130 General procedures under section 513(e) of the act.
- 860.132 Procedures when the Commissioner initiates a performance standard or pre-market approval proceeding under section 514(b) or 515(b) of the act.
- 860.134 Procedures for "new devices" under section 513(f) of the act and reclassification of certain devices.
- 860.136 Procedures for transitional products under section 520(l) of the act.

AUTHORITY: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or