

Food and Drug Administration, HHS

§ 814.1

5 working days of receipt of notice of such use.

(9) *Significant risk device determinations.* If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.

(10) *Other.* A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

[45 FR 3751, Jan. 18, 1980, as amended at 45 FR 58843, Sept. 5, 1980; 48 FR 15622, Apr. 12, 1983; 62 FR 48948, Sept. 18, 1997]

PART 813 [RESERVED]

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart A—General

Sec.

- 814.1 Scope.
- 814.2 Purpose.
- 814.3 Definitions.
- 814.9 Confidentiality of data and information in a premarket approval application (PMA) file.
- 814.15 Research conducted outside the United States.
- 814.17 Service of orders.
- 814.19 Product development protocol (PDP).

Subpart B—Premarket Approval Application (PMA)

- 814.20 Application.
- 814.37 PMA amendments and resubmitted PMA's.
- 814.39 PMA supplements.

Subpart C—FDA Action on a PMA

- 814.40 Time frames for reviewing a PMA.
- 814.42 Filing a PMA.
- 814.44 Procedures for review of a PMA.
- 814.45 Denial of approval of a PMA.
- 814.46 Withdrawal of approval of a PMA.
- 814.47 Temporary suspension of approval of a PMA.

Subpart D—Administrative Review [Reserved]

Subpart E—Postapproval Requirements

- 814.80 General.
- 814.82 Postapproval requirements.
- 814.84 Reports.

Subparts F-G [Reserved]

Subpart H—Humanitarian Use Devices

- 814.100 Purpose and scope.
- 814.102 Designation of HUD status.
- 814.104 Original applications.
- 814.106 HDE amendments and resubmitted HDE's.
- 814.108 Supplemental applications.
- 814.110 New indications for use.
- 814.112 Filing an HDE.
- 814.114 Timeframes for reviewing an HDE.
- 814.116 Procedures for review of an HDE.
- 814.118 Denial of approval or withdrawal of approval of an HDE.
- 814.120 Requests for extension.
- 814.122 Confidentiality of data and information.
- 814.124 Institutional Review Board requirements.
- 814.126 Postapproval requirements and reports.

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Subpart A—General

§ 814.1 Scope.

(a) This part implements section 515 of the act by providing procedures for the premarket approval of medical devices intended for human use.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:

- (1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or

(2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or

(3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

(d) This part amends the conditions to approval for any PMA approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

§ 814.2 Purpose.

The purpose of this part is to establish an efficient and thorough device review process—

(a) To facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and

(b) To ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. This part shall be construed in light of these objectives.

§ 814.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (sections 201–902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–392)).

(b) *FDA* means the Food and Drug Administration.

(c) *IDE* means an approved or considered approved investigational device exemption under section 520(g) of the act and parts 812 and 813.

(d) *Master file* means a reference source that a person submits to FDA. A master file may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device.

(e) *PMA* means any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein. “PMA” includes a new

drug application for a device under section 520(1) of the act.

(f) *PMA amendment* means information an applicant submits to FDA to modify a pending PMA or a pending PMA supplement.

(g) *PMA supplement* means a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

(h) *Person* includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

(i) *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(j) *30-day PMA supplement* means a supplemental application to an approved PMA in accordance with § 814.39(e).

(k) *Reasonable probability* means that it is more likely than not that an event will occur.

(l) *Serious, adverse health consequences* means any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

(m) *HDE* means a premarket approval application submitted pursuant to this subpart seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the act as authorized by section 520(m)(2) of the act.

(n) *HUD (humanitarian use device)* means a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than