

HDE, subject to the institutional review board regulations in part 56 of this chapter or the informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected;

(8) The applicant does not permit an authorized FDA employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and controls, and to have access to and to copy and verify all records pertinent to the application; and

(9) The device's HUD designation should be revoked in accordance with § 814.102(c).

(b) If FDA issues an order denying approval of an application, the agency will comply with the same notice and disclosure provisions required for PMA's under § 814.45(b) and (d), as applicable.

(c) FDA will issue an order denying approval of an HDE after an approvable or not approvable letter has been sent and the applicant:

(1) Submits a requested amendment but any ground for denying approval of the application under § 814.118(a) still applies;

(2) Notifies FDA in writing that the requested amendment will not be submitted; or

(3) Petitions for review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33 of this chapter.

(d) Before issuing an order withdrawing approval of an HDE, FDA will provide the applicant with notice and an opportunity for a hearing as required for PMA's under § 814.46(c) and (d), and will provide the public with notice in accordance with § 814.46(e), as applicable.

(e) Unless FDA otherwise determines that continued marketing under the HDE is inconsistent with the intent of section 520(m) of the act, FDA will not withdraw approval of an HDE solely because it is subsequently determined that the disease or condition for which the HUD is intended affects or is manifested in more than 4,000 people in the United States per year. However, this fact may serve as a basis for disapproving an extension request.

§ 814.120 Requests for extension.

(a) *Eligibility.* In response to a request by the holder of an HDE, FDA may extend the HDE for an additional 18-month term. An exemption may be extended more than once, and may be extended after the expiration of the 5-year period that began on October 24, 1996, as provided by section 520(m)(5) of the act. If the approval term for an HDE has lapsed, the HDE is ineligible for extension under this section and the applicant must cease marketing the device until a new HDE has been submitted and approved in accordance with this part.

(b) *Submission.* In order to avoid the risk of a lapse in marketing approval, the holder of an HDE wishing to obtain an extension shall submit such a request to FDA at least 90 days prior to the expiration of the HDE. A request for extension must be submitted in writing, together with a new, separately bound, request for HUD designation. The request for extension and the request for HUD designation shall be submitted to the Office of Device Evaluation, CDRH at the address specified for the submission of original HDE's (§ 814.104(e)), and the outside envelope should be plainly marked: "Request for Extension of HDE Approval." The submission shall state the applicant's name and address, the HDE number, and shall include the following information based upon the first 12 months of experience with the device following the most recent HDE approval or extension:

(1) An update of the information required under § 814.102(a) in a separately bound volume;

(2) An update of the information required under §§ 814.104(c)(2), (c)(3), and (c)(5);

(3) The number of devices that have been shipped or sold since initial marketing approval under this subpart and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(4) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This shall include safety information that is known or reasonably should be known to the applicant, medical device reports made pursuant to part 803 of this chapter, any data generated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device labeling; and

(5) A summary of any changes made to the device in accordance with supplements submitted under § 814.108.

(c) *Action.* Within 90 days of receipt of a request for an extension of an HDE that is submitted in accordance with this section, FDA will send the applicant either an approval order, approvable letter, a not approvable letter, or an order denying approval, applying the same criteria under this subpart as are applicable to the original HUD designation and HDE application. The effective date of an extension shall be the day the extension was granted or the day following the last effective day of the original HDE approval or the most recent extension, whichever is later. An extension request not acted upon by FDA within 90 days shall be deemed approved.

(d) *Waiver of final report.* An HDE holder seeking a request for extension under this section is exempt from the requirement of submitting a final report under § 814.126(b).

§ 814.122 Confidentiality of data and information.

(a) *Requirement for disclosure.* The "HDE file" includes all data and information submitted with or referenced in the HDE, any IDE incorporated into the HDE, any HDE amendment or supplement, any report submitted under § 814.126, any master file, or any other related submission. Any record in the HDE file will be available for public disclosure in accordance with the provisions of this section and part 20 of this chapter.

(b) *Extent of disclosure.* Disclosure by FDA of the existence and contents of an HDE file shall be subject to the same rules that pertain to PMA's under § 814.9(b) through (h), as applicable.

§ 814.124 Institutional Review Board requirements.

(a) *IRB approval.* The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use and to which the local IRB has deferred in a letter to the HDE holder, signed by the IRB chair or an authorized designee.

(b) *Withdrawal of IRB approval.* A holder of an approved HDE shall notify FDA of any withdrawal of approval for the use of a HUD by a reviewing IRB within 5 working days after being notified of the withdrawal of approval.

§ 814.126 Postapproval requirements and reports.

(a) An HDE approved under this subpart H shall be subject to the postapproval requirements and reports set forth under subpart E of this part, as applicable. In addition, medical device reports submitted to FDA in compliance with the requirements of part 803 of this chapter shall also be submitted to the IRB of record.

(b) In addition to the reports required under subpart E of this part, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

(1) *Final report.* Unless a request for extension is submitted in accordance with § 814.120, a final report shall be submitted no later than 90 days following the expiration of the period of marketing approval. The final report shall include: An estimate of the number of patients who were treated or diagnosed with the device and the number of devices shipped or sold since initial marketing approval under this subpart H. (If the number of devices shipped or