

(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to part 803 of this chapter, any data generated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement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

sold exceeds 4,000 per year, an explanation and estimate of the number of devices used per patient shall be included. Similarly, 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.) The holder of the HDE shall also report information regarding retrieval or disabling of unused devices, a summary of results and conclusions with regard to clinical use of the device, and a summary of the medical device reports submitted under part 803 of this chapter. The report shall also contain a summary and bibliography of published and unpublished data, reports, and studies involving the device that are known to or that reasonably should be known to the applicant and were not previously submitted to FDA. If, after reviewing the summary and bibliography, FDA concludes that FDA needs a copy of the unpublished or published information, FDA will notify the applicant that copies shall be submitted.

(2) *Other.* An HDE holder shall, for the duration of the period that a HUD is approved for marketing, maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information requested by a reviewing IRB or FDA.

## PART 820—QUALITY SYSTEM REGULATION

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### Subpart E—Purchasing Controls

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### Subpart F—Identification and Traceability

- 820.60 Identification.
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- 820.250 Statistical techniques.

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