

**Subpart H—Humanitarian Use Devices**

SOURCE: 61 FR 33244, June 26, 1996, unless otherwise noted.

**§ 814.100 Purpose and scope.**

(a) This subpart H implements section 520(m) of the act. The purpose of section 520(m) is, to the extent consistent with the protection of the public health and safety and with ethical standards, to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year. This subpart provides procedures for obtaining:

- (1) HUD designation of a medical device; and
- (2) Marketing approval for the HUD notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the act.

(b) Although a HUD may also have uses that differ from the humanitarian use, applicants seeking approval of any non-HUD use shall submit a PMA as required under § 814.20, or a premarket notification as required under part 807 of this chapter.

(c) Obtaining marketing approval for a HUD involves two steps:

- (1) Obtaining designation of the device as a HUD from FDA’s Office of Orphan Products Development, and
- (2) Submitting an HDE to the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), or the Center for Drug Evaluation and Research (CDER), as applicable.

(d) A person granted an exemption under section 520(m) of the act shall submit periodic reports as described in § 814.126(b).

(e) FDA may suspend or withdraw approval of an HDE after providing notice and an opportunity for an informal hearing.

[61 FR 33244, June 26, 1996, as amended at 63 FR 59220, Nov. 3, 1998; 73 FR 49942, Aug. 25, 2008]

EFFECTIVE DATE NOTE: At 75 FR 16351, Apr. 1, 2010, § 814.100 was amended by redesignating paragraphs (b) through (e) as paragraphs (d) through (g) respectively; redesignating paragraph (a) as paragraph (b), removing the first sentence of the newly redesignated paragraph (b); and adding new paragraphs (a) and (c), effective Aug. 16, 2010. For the convenience of the user, the added text is set forth as follows:

**§ 814.100 Purpose and scope.**

(a) This subpart H implements sections 515A and 520(m) of the act.

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(c) Section 515A of the act is intended to ensure the submission of readily available information concerning actual and potential pediatric uses of medical devices.

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**§ 814.102 Designation of HUD status.**

(a) *Request for designation.* Prior to submitting an HDE application, the applicant shall submit a request for HUD designation to FDA’s Office of Orphan Products Development. The request shall contain the following:

- (1) A statement that the applicant requests HUD designation for a rare disease or condition or a valid subset of a disease or condition which shall be identified with specificity;
- (2) The name and address of the applicant, the name of the applicant’s primary contact person and/or resident agent, including title, address, and telephone number;
- (3) A description of the rare disease or condition for which the device is to be used, the proposed indication or indications for use of the device, and the reasons why such therapy is needed. If the device is proposed for an indication that represents a subset of a common disease or condition, a demonstration that the subset is medically plausible should be included;
- (4) A description of the device and a discussion of the scientific rationale for the use of the device for the rare disease or condition; and
- (5) Documentation, with appended authoritative references, to demonstrate that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 people in the United States