

Pt. 801

and sent to the CDRH Ombudsman at CDRHombudsman@fda.hhs.gov.

[84 FR 31477, July 2, 2019]

PART 801—LABELING

Subpart A—General Labeling Provisions

Sec.

- 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.
- 801.3 Definitions.
- 801.4 Meaning of intended uses.
- 801.5 Medical devices; adequate directions for use.
- 801.6 Medical devices; misleading statements.
- 801.15 Medical devices; prominence of required label statements.
- 801.16 Medical devices; Spanish-language version of certain required statements.
- 801.18 Format of dates provided on a medical device label.

Subpart B—Labeling Requirements for Unique Device Identification

- 801.20 Label to bear a unique device identifier.
- 801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.
- 801.35 Voluntary labeling of a device with a unique device identifier.
- 801.40 Form of a unique device identifier.
- 801.45 Devices that must be directly marked with a unique device identifier.
- 801.50 Labeling requirements for stand-alone software.
- 801.55 Request for an exception from or alternative to a unique device identifier requirement.
- 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

Subpart C—Labeling Requirements for Over-the-Counter Devices

- 801.60 Principal display panel.
- 801.61 Statement of identity.
- 801.62 Declaration of net quantity of contents.
- 801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances.

Subpart D—Exemptions From Adequate Directions for Use

- 801.109 Prescription devices.
- 801.110 Retail exemption for prescription devices.
- 801.116 Medical devices having commonly known directions.

21 CFR Ch. I (4–1–23 Edition)

- 801.119 In vitro diagnostic products.
- 801.122 Medical devices for processing, repackaging, or manufacturing.
- 801.125 Medical devices for use in teaching, law enforcement, research, and analysis.
- 801.127 Medical devices; expiration of exemptions.
- 801.128 Exceptions or alternatives to labeling requirements for medical devices held by the Strategic National Stockpile.

Subpart E—Other Exemptions

- 801.150 Medical devices; processing, labeling, or repackaging.

Subparts F–G [Reserved]

Subpart H—Special Requirements for Specific Devices

- 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.
- 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.
- 801.415 Maximum acceptable level of ozone.
- 800.417 Chlorofluorocarbon propellants.
- 801.422 Prescription hearing aid labeling.
- 801.430 User labeling for menstrual tampons.
- 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.
- 801.435 User labeling for latex condoms.
- 801.437 User labeling for devices that contain natural rubber.

AUTHORITY: 21 U.S.C. 321, 331–334, 351, 352, 360d, 360i, 360j, 371, 374.

SOURCE: 41 FR 6896, Feb. 13, 1976, unless otherwise noted.

Subpart A—General Labeling Provisions

§ 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

(a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for “Company,” “Incorporated,” etc., may

be used and “The” may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, “Manufactured for _____”, “Distributed by _____”, or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice).

(e) If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 801.3 Definitions.

As used in this part:

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Center Director means the Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Convenience kit means two or more different medical devices packaged together for the convenience of the user.

Device package means a package that contains a fixed quantity of a particular version or model of a device.

Expiration date means the date by which the label of a device states the device must or should be used.

FDA, we, or us means the Food and Drug Administration.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning.

Global Unique Device Identification Database (GUDID) means the database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use.

Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

Implantable device means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an *implantable device* for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health.

Label has the meaning set forth in section 201(k) of the Federal Food, Drug, and Cosmetic Act.

Labeler means:

(1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and

(2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.

Lot or batch means one *finished device* or more that consist of a single type,