

## § 801.35

## 21 CFR Ch. I (4–1–23 Edition)

(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for record-keeping under §§ 820.180 and 820.198.

(3) Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution. This exception is not available for any implantable device. The device package containing these individual devices is not excepted from the requirement of § 801.20, and must bear a UDI.

(4) A device used solely for research, teaching, or chemical analysis, and not intended for any clinical use.

(5) A custom device within the meaning of § 812.3(b) of this chapter.

(6) An investigational device within the meaning of part 812 of this chapter.

(7) A veterinary medical device not intended for use in the diagnosis of disease or other conditions in man, in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man.

(8) A device intended for export from the United States.

(9) A device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2).

(10) A device for which FDA has established a performance standard under section 514(b) of the Federal Food, Drug, and Cosmetic Act and has provided therein an exception from the requirement of § 801.20, or for which FDA has recognized all or part of a performance standard under section 514(c) of the Federal Food, Drug, and Cosmetic Act and has included an exception from the requirement of § 801.20 within the scope of that recognition.

(11) A device packaged within the immediate container of a combination product or convenience kit, *provided that* the label of the combination product or convenience kit bears a UDI.

(b) *National Drug Code (NDC) Numbers.* If a combination product properly bears an NDC number on its label—

(1) The combination product is not subject to the requirements of § 801.20.

(2) A device constituent of such a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) of this chapter is not subject to the requirements of § 801.20.

(3) Each device constituent of such a combination product, other than one described by § 3.2(e)(1) of this chapter, must bear a UDI on its label unless paragraph (a)(11) of this section applies.

(c) *Exception for shipping containers.* This rule does not require a UDI to be placed on any shipping container.

(d) The UDI of a class I device is not required to include a production identifier.

[78 FR 58818, Sept. 24, 2013]

### § 801.35 Voluntary labeling of a device with a unique device identifier.

(a) The labeler of a device that is not required to bear a unique device identifier (UDI) may voluntarily comply with § 801.20. If a labeler voluntarily includes a UDI for a device, the labeler may voluntarily provide information concerning the device under subpart E of part 830 of this chapter.

(b) A device may bear both a Universal Product Code (UPC) and a UDI on its label and packages.

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### § 801.40 Form of a unique device identifier.

(a) Every unique device identifier (UDI) must meet the technical requirements of § 830.20 of this chapter. The UDI must be presented in two forms:

(1) Easily readable plain-text, and  
(2) Automatic identification and data capture (AIDC) technology.

(b) The UDI must include a device identifier segment. Whenever a device label includes a lot or batch number, a serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by § 1271.290(c) of this chapter, the UDI must include a production identifier segment that conveys such information.

(c) If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must disclose the presence of AIDC technology.

(d) A class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to meet all requirements of subpart B of this part. The UPC will serve as the unique device identifier required by § 801.20.

[78 FR 58818, Sept. 24, 2013]

**§ 801.45 Devices that must be directly marked with a unique device identifier.**

(a) *In general.* A device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

(b) *UDI for direct marking.* The UDI provided through a direct marking on a device may be:

(1) Identical to the UDI that appears on the label of the device, or

(2) A different UDI used to distinguish the unpackaged device from any device package containing the device.

(c) *Form of a UDI when provided as a direct marking.* When a device must bear a UDI as a direct marking, the UDI may be provided through either or both of the following:

(1) Easily readable plain-text;

(2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand.

(d) *Exceptions.* The requirement of paragraph (a) of this section shall not apply to any device that meets any of the following criteria:

(1) Any type of direct marking would interfere with the safety or effectiveness of the device;

(2) The device cannot be directly marked because it is not technologically feasible;

(3) The device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use.

(4) The device has been previously marked under paragraph (a) of this section.

(e) *Exception to be noted in design history file.* A labeler that decides to make use of an exception under paragraph (d) of this section) must document the basis of that decision in the design history file required by § 820.30(j) of this chapter.

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**§ 801.50 Labeling requirements for stand-alone software.**

(a) Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet the UDI labeling requirements of this subpart if it complies with the requirements of paragraph (b) of this section and conveys the version number in its production identifier.

(b) Regardless of whether it is or is not distributed in packaged form, stand-alone software regulated as a medical device must provide its unique device identifier through either or both of the following:

(1) An easily readable plain-text statement displayed whenever the software is started;

(2) An easily readable plain-text statement displayed through a menu command (e.g., an “About \* \* \*” command).

(c) Stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier.

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**§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.**

(a) A labeler may submit a request for an exception from or alternative to the requirement of § 801.20 or any other requirement of this subpart for a specified device or a specified type of device. A written request for an exception or alternative must:

(1) Identify the device or devices that would be subject to the exception or alternative;

(2) Identify the provisions of this subpart that are the subject of the request for an exception or alternative;