required to bear a unique device identifier (UDI):

(1) A finished device manufactured and labeled prior to the compliance date established by FDA for §801.20 regarding the device. This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device.

(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.

(78 FR 58818, Sept. 24, 2013)

§ 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.

§ 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