meet the criteria in §1271.10(a) and that is also regulated as a device.

Issuing agency means an organization accredited by FDA to operate a system for the issuance of unique device identifiers.

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 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, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Shipping container means a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another.

Small business means a medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees.

Specification means any requirement with which a device must conform.

Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of §830.20. A UDI is composed of:

(1) A device identifier—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A production identifier—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

Universal product code (UPC) means the product identifier used to identify an item sold at retail in the United States.

Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler.

Subpart B—Requirements for a Unique Device Identifier

§ 830.10 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Food and Drug Administration must publish notice of change in the FEDERAL REGISTER and the material must be available to the public.

All approved material is available for inspection at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from the source listed in paragraph (b) of this section. Copies are also available for purchase from the American National Standards Institute (ANSI), mailing address: ANSI, Attn: Customer Service Department, 25 West 43rd St., 4th floor, New York, NY 10036, phone: 212–642–4980, and may be ordered online at http://webstore.ansi.org/. The material is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to http://www.archives.gov/federal_register/
§ 830.20 Requirements for a unique device identifier.

A unique device identifier (UDI) must:

(a) Be issued under a system operated by FDA or an FDA-accredited issuing agency;
(b) Conform to each of the following international standards:
   (1) ISO/IEC 15459–2, which is incorporated by reference at § 830.10; and
   (2) ISO/IEC 15459–4, which is incorporated by reference at § 830.10.
   (3) ISO/IEC 15459–6, which is incorporated by reference at § 830.10.
(c) Use only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

§ 830.40 Use and discontinuation of a device identifier.

(a) Only one device identifier from any particular system for the issuance of unique device identifiers (UDIs) may be used to identify a particular version or model of a device. A particular version or model may be identified by UDIs from two or more systems for the issuance of UDIs.
(b) A device identifier shall be used to identify only one version or model.
(c) In the event that a version or model of a device is discontinued, its device identifier may not be reassigned to another device. If a discontinued version or model is re-introduced and no changes have been made that would require the use of a new device identifier, the device identifier that was previously in use may be used to identify the device.
(d) In the event that an issuing agency relinquishes or does not renew its accreditation, you may continue to use a previously issued UDI until such time as § 830.50 requires you to assign a new device identifier.

§ 830.50 Changes that require use of a new device identifier.

(a) Whenever you make a change to a device that is required to bear a unique device identifier (UDI) on its label, and the change results in a new version or model, you must assign a new device identifier to the new version or model.
(b) Whenever you create a new device package, you must assign a new device identifier to the new device package.

§ 830.60 Relabeling of a device that is required to bear a unique device identifier.

If you relabel a device that is required to bear a unique device identifier (UDI), you must:

(a) Assign a new device identifier to the device, and
(b) Keep a record showing the relationship of the prior device identifier to your new device identifier.

Subpart C—FDA Accreditation of an Issuing Agency

§ 830.100 FDA accreditation of an issuing agency.

(a) Eligibility. A private organization may apply for accreditation as an issuing agency.