§ 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 696-1991(E), Information technology—ISO 7-bit coded character set for information interchange (third edition; December 15, 1991), into §§ 830.20(c) and 830.100(b);
   (2) ISO/IEC 15459–2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition; March 1, 2006), into §§ 830.20(b) and 830.100(b);
   (3) ISO/IEC 15459–4:2008(E), Information technology—Unique identifiers—Part 4: Individual items (second edition; July 15, 2008), into §§ 830.20(b) and 830.100(b);
   (4) ISO/IEC 15459–6:2007(E), Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition; June 15, 2007), into §§ 830.20(b) and 830.100(b).

§ 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 reintroduced 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.

[78 FR 58825, Sept. 24, 2013]

§ 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.

[78 FR 58825, Sept. 24, 2013]

§ 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.

[78 FR 58825, Sept. 24, 2013]

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.
§ 830.110 Application for accreditation as an issuing agency.

(a) Application for initial accreditation. (1) An applicant seeking initial FDA accreditation as an issuing agency shall notify FDA of its desire to be accredited by sending a notification by email to udi@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(2) FDA will provide the applicant with additional information to aid in submission of an application for approval as an issuing agency, together with an email address for submission of an application.

(3) The applicant shall furnish to FDA, via email to the email address provided in paragraph (a)(1) of this section, an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant;
(ii) Detailed descriptions of any standards or criteria the applicant will apply to participating labelers;
(iii) A detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device;
(iv) A detailed description of the review and decisionmaking process the applicant will apply when determining whether a particular labeler may use the applicant’s UDI system, including:
   (A) Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant’s unique device identification system;
   (B) Policies and procedures for notifying a labeler of deficiencies in its use of UDIs;
   (C) Procedures for monitoring a labeler’s correction of deficiencies in its use of UDIs;
   (D) Policies and procedures for suspending or revoking a labeler’s use of the applicant’s UDI system, including any appeals process.
   (v) Description of the applicant’s electronic data management system with respect to its review and decision processes and the applicant’s ability to provide electronic data in a format compatible with FDA data systems;
   (vi) Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available;
   (vii) Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies); and
   (viii) Other information required by FDA to clarify the application for accreditation.

(b) Application for renewal of accreditation. An accredited issuing agency that intends to continue to serve as an issuing agency beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of its accreditation, an issuing agency shall inform FDA, at the address given in paragraph (a)(1) of
this section, of its intent to seek renewal.

(2) FDA will notify the issuing agency of the relevant information, materials, and supporting documentation that we will require the issuing agency to submit as part of the renewal procedure. We will tailor these requirements to reflect our experience with the issuing agency during the current and any prior period of accreditation. We will limit our request to the types of the information required by paragraph (a)(3) of this section, and we will require less information if experience shows that we need only a subset of that information.

(3) At least 6 months before the date of expiration of its accreditation, an issuing agency shall furnish to FDA, at the email address we provide, a copy of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with paragraph (b)(2) of this section.

(4) Any issuing agency that does not plan to renew its accreditation shall so notify FDA at the address given in paragraph (a)(1) of this section at least 9 months before the expiration of the issuing agency’s term of accreditation and shall include a description of its plans for allowing continued use of UDIs issued prior to the expiration of the current term of accreditation.

(c) FDA action on an application for initial or renewal accreditation. (1) FDA will conduct a review and evaluation to determine whether the applicant meets the requirements of this subpart and whether the UDI system proposed by the applicant will meet the requirements of this subpart.

(2) Within 60 days of receipt of an application for accreditation, FDA will notify the applicant of any deficiencies in its application and will request correction of those deficiencies within 60 days. The applicant may request an extension if it needs additional time to correct deficiencies in its application. If the deficiencies are not resolved to FDA’s satisfaction within the specified time period, the application for accreditation as an issuing agency may be denied.

(3) FDA shall notify the applicant whether the application for accreditation has been granted or denied. That notification shall list any conditions of approval or state the reasons for denial.

(4) If FDA denies an application, we will advise the applicant of the circumstances under which a denied application may be resubmitted.

(5) If FDA does not reach a final decision on a renewal application before the expiration of an issuing agency’s current accreditation, the approval will be deemed extended until FDA reaches a final decision on the application.

(d) Relinquishment of accreditation. If an issuing agency decides to relinquish its accreditation before expiration of the current term of accreditation, it shall submit a letter of such intent to FDA, at the address provided in paragraph (a)(1) of this section, at least 9 months before relinquishing its accreditation.

(e) Notice of termination of accreditation. An issuing agency that does not apply for renewal of its accreditation, is denied renewal of accreditation by FDA, or relinquishes its accreditation and duties before expiration of the current term of accreditation, shall notify all labelers that are using the issuing agency’s UDI system, in a manner and time period approved by FDA, of the date that the issuing agency will cease to serve as an FDA-accredited issuing agency.

(f) Term of accreditation. The initial term of accreditation for an issuing agency shall be for a period of 3 years. An issuing agency’s term of accreditation may be periodically renewed for a period of 7 years.

§ 830.120 Responsibilities of an FDA-accredited issuing agency.

To maintain its accreditation, an issuing agency must:

(a) Operate a system for assignment of unique device identifiers (UDIs) that meets the requirements of §830.20;

(b) Make available information concerning its system for the assignment of UDIs;

(c) Maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list in electronic form by December 31 of each year;
(d) Upon request, provide FDA with information concerning a labeler that is employing the issuing agency’s system for assignment of UDIs; and
(e) Remain in compliance with the eligibility and accreditation criteria set forth in §830.100.

§ 830.130 Suspension or revocation of the accreditation of an issuing agency.

FDA may suspend or revoke the accreditation of an issuing agency if FDA finds, after providing the issuing agency with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the issuing agency or any officer, employee, or other agent of the issuing agency:
(a) Has been guilty of misrepresentation or failure to disclose required information in obtaining accreditation;
(b) Has failed to fulfill the responsibilities outlined in §830.120;
(c) Has failed to protect against conflicts of interest that may impede the issuing agency’s ability to independently operate a fair and neutral identifier system;
(d) In the operation of the issuing agency, has engaged in any anti-competitive activity to restrain trade;
or
(e) Has violated or aided and abetted in the violation of any regulation issued under section 510(e) or section 519(f) of the Federal Food, Drug, and Cosmetic Act.

Subpart D—FDA as an Issuing Agency

Source: 78 FR 58826, Sept. 24, 2013, unless otherwise noted.

§ 830.200 When FDA will act as an issuing agency.

(a) During any period where there is no accredited issuing agency, FDA will act as an issuing agency.
(b) If FDA determines that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies, FDA will act as an issuing agency.
(c) FDA may, in its discretion, act as an issuing agency if we determine it is necessary for us to do so to ensure the continuity or the effectiveness of the system for the identification of medical devices.
(d) FDA may, in its discretion, act as an issuing agency if we determine it is appropriate for us to do so in order to facilitate or implement an alternative granted under §801.55 of this chapter.

§ 830.210 Eligibility for use of FDA as an issuing agency.

When FDA acts as an issuing agency, any labeler will be permitted to use FDA’s unique device identification system, regardless of whether the labeler is considered a small business.

§ 830.220 Termination of FDA service as an issuing agency.

(a) FDA may end our services as an issuing agency if we determine that the conditions that prompted us to act no longer exist and that ending our services would not be likely to lead to a return of the conditions that prompted us to act.
(b) If FDA has ended our services as an issuing agency, a labeler may continue to use a device identifier assigned under FDA’s unique device identification system until such time as §830.50 requires the use of a new device identifier.

Subpart E—Global Unique Device Identification Database

Source: 78 FR 58826, Sept. 24, 2013, unless otherwise noted.

§ 830.300 Devices subject to device identification data submission requirements.

(a) In general. The labeler of a device must provide the information required by this subpart for each version or model required to bear a unique device identifier (UDI).
(b) Voluntary submission of information. If a labeler voluntarily includes a UDI on the label of a device under §801.40, the labeler may also voluntarily submit information concerning that device under this part.
(c) Exclusions. FDA may reject or remove any device identification data where:
(1) The device identifier submitted does not conform to §830.20.