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 anticompetitive 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;

(2) The information concerns a device that is neither manufactured in the United States nor in interstate commerce in the United States,

(3) The information concerns a product that FDA determines is not a device or a combination product that includes a device constituent part,

(4) The information concerns a device or a combination product that requires, but does not have, FDA premarket approval, licensure, or clearance;

(5) A device that FDA has banned under section 516 of the Federal Food, Drug, and Cosmetic Act; or

(6) FDA has suspended the accreditation of the issuing agency that operates the system used by the labeler.

§ 830.310 Information required for unique device identification.

The contact for device identification designated under § 830.320(a) shall provide FDA with the following information concerning each version or model

of a device required to bear a unique device identifier (UDI) on its label:

(a) *Concerning the labeler:*

(1) The name of the labeler;

(2) A telephone number or email address that will allow FDA to communicate with the contact for device identification designated under § 830.320(a); and

(3) The name of each issuing agency whose system is used by the labeler to assign UDIs used by the labeler.

(b) *Concerning each version or model of a device with a UDI on its label:*

(1) The device identifier portion of the UDI assigned to the version or model;

(2) When reporting a substitution of a new device identifier that will be used in lieu of a previously reported identifier, the device identifier that was previously assigned to the version or model;

(3) If § 801.45 of this chapter requires the device to bear a UDI as a permanent marking on the device itself, either:

(i) A statement that the device identifier that appears as a permanent marking on the device is identical to that reported under paragraph (b)(1) of this section, or

(ii) The device identifier portion of the UDI that appears as a permanent marking on the device;

(4) The proprietary, trade, or brand name of the device as it appears on the label of the device;

(5) Any version or model number or similar reference that appears on the label of the device;

(6) If the device is labeled as sterile, a statement to that effect;

(7) If the device is labeled as containing natural rubber latex that contacts humans, or is labeled as having packaging containing natural rubber latex that contacts humans, as described by §§ 801.437(b)(1), 801.437(b)(3), and 801.437(f) of this chapter, a statement to that effect;

(8) Whether a patient may be safely exposed to magnetic resonance imaging, nuclear magnetic resonance imaging, or magnetic resonance tomography while using the device, or while the device is implanted in patient.

(9) If the device is available in more than one size, the size of the particular version or model, together with the unit of measure, as it appears on the label of the device;

(10) The type of production identifiers that appear on the label of the device;

(11) The FDA premarket submission number of a cleared or approved device, or a statement that FDA has by regulation exempted the device from premarket notification;

(12) The FDA listing number assigned to the device;

(13) The Global Medical Device Nomenclature (GMDN) term or code for the device;

(14) The total number of individual devices contained in the device package.

§ 830.320 Submission of unique device identification information.

(a) *Designation of contact for device identification.* Each labeler must designate an individual to serve as the point of contact with FDA on matters relating to the identification of medical devices marketed by the labeler. The contact for device information is responsible for ensuring FDA is provided with all information required by this part. The contact for device information may authorize an issuing agency or any other person to provide information to FDA on behalf of the labeler.

(b) *Information shall be submitted via electronic means.* All information required by this subpart shall be submitted electronically to FDA's Global Unique Device Identification Database (GUDID) in a format that we can process, review, and archive, unless the labeler has obtained a waiver from electronic submission of unique device identifier (UDI) data.

(c) *Waiver from electronic submission.* (1) A labeler may request a waiver from electronic submission of UDI data by submitting a letter addressed to the appropriate Center Director explaining why electronic submission is not technologically feasible; send the request 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.