Food and Drug Administration, HHS

§ 830.120 Access to the master list.

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 E—Global Unique Device Identification Database

§ 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;