§ 822.38

§ 822.38 What reports must I submit to you?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

PART 830—UNIQUE DEVICE IDENTIFICATION

Subpart A—General Provisions

830.3 Definitions.

Subpart B—Requirements for a Unique Device Identifier

Sec.
830.10 Incorporation by reference.
830.20 Requirements for a unique device identifier.
830.40 Use and discontinuation of a device identifier.
830.50 Changes that require use of a new device identifier.
830.60 Relabeling of a device that is required to bear a unique device identifier.

Subpart C—FDA Accreditation of an Issuing Agency

830.100 FDA accreditation of an issuing agency.
830.110 Application for accreditation as an issuing agency.
830.120 Responsibilities of an FDA-accredited issuing agency.
830.130 Suspension or revocation of the accreditation of an issuing agency.

Subpart D—FDA as an Issuing Agency

830.200 When FDA will act as an issuing agency.
830.210 Eligibility for use of FDA as an issuing agency.
830.220 Termination of FDA service as an issuing agency.

Subpart E—Global Unique Device Identification Database

830.300 Devices subject to device identification data submission requirements.
830.310 Information required for unique device identification.
830.320 Submission of unique device identification information.