

- (i) Report number;
 - (ii) Name and address of the device manufacturer;
 - (iii) Device brand name and common name;
 - (iv) Product model, catalog, serial, and lot number and unique device identifier (UDI) that appears on the device label or on the device package;
 - (v) A brief description of the event reported to the manufacturer and/or us; and
 - (vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.
- (c) In lieu of submitting the information in paragraph (b)(7) of this section, you may submit a copy of each medical device report that you submitted to the manufacturers and/or to us during the reporting period.
- (d) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015; 85 FR 18442, Apr. 2, 2020]

Subpart D—Importer Reporting Requirements

§ 803.40 If I am an importer, what reporting requirements apply to me?

(a) *Reports of deaths or serious injuries.* You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable, but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. You must submit the information required by § 803.42. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(a).

(b) *Reports of malfunctions.* You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through

your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. You must submit the information required by § 803.42. Reports to manufacturers may be made in accordance with § 803.11(b).

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if the information is known or should be known to you, as described in § 803.40. These types of information correspond generally to the format of Form FDA 3500A:

(a) Patient information (Form FDA 3500A, Block A). You must submit the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:

- (i) A life-threatening injury or illness;
- (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

- (3) Date of event;
- (4) Date of this report;

(5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;