

such modifications, FDA may impose other reporting requirements to ensure the protection of public health.

(d) FDA may revoke or modify in writing an exemption, variance, or alternative reporting requirements if FDA determines that protection of the public health justifies the modification or a return to the requirements as stated in this part.

(e) Firms granted a reporting modification by FDA shall provide any reports or information required by that approval. The conditions of the approval will replace and supersede the reporting requirement specified in this part until such time that FDA revokes or modifies the alternative reporting requirements in accordance with paragraph (d) of this section.

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

[60 FR 63597, Dec. 11, 1995, as amended at 61 FR 44615, Aug. 28, 1996]

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports by user facilities and manufacturers of FDA-regulated products. The form has sections that must be completed by all reporters and other sections that must be completed only by the user facility or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device and “initial reporter” (i.e., the first person or entity that submitted the information to the user facility, manufacturer, or distributor).

(2) The back part of the form contains sections to be completed by user facilities and manufacturers. User facilities must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter’s 3500A form, it should attach a copy of that form to the manufacturer’s report form. If the information from the other reporter’s 3500A form is complete and correct, the manufacturer can fill in the remaining information on the same form.

(b) *Reporting standards.* (1) User facilities are required to submit MDR reports to:

(i) The device manufacturer and to FDA within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. Such reports shall be submitted to FDA if the device manufacturer is not known.

(2) [Reserved]

(3) Manufacturers are required to submit MDR reports to FDA:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) Within 30 days of becoming aware of information that reasonably suggests a device has malfunctioned and that device or a similar device marketed by the manufacturer would be likely to cause a death or serious injury if the malfunction were to recur; or

(iii) Within 5 days if required by §803.53.

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

(2) Entities required to report under this part do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to determine that a device-related event is or is not reportable must be contained in the MDR event files, as described in §803.18.

§803.21 Reporting codes.

(a) FDA has developed a MEDWATCH Mandatory Reporting Form Coding Manual for use with medical device reports. This manual contains codes for hundreds of adverse events for use with FDA Form 3500A. The coding manual is available from the Division of Small Manufacturer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX 301-443-8818.

(b) FDA may use additional coding of information on the reporting forms or modify the existing codes on an ad hoc or generic basis. In such cases, FDA will ensure that the new coding information is available to all reporters.

§803.22 When not to file.

(a) Only one medical device report from the user facility or manufacturer is required under this part if the re-

porting entity becomes aware of information from multiple sources regarding the same patient and same event.

(b) A medical device report that would otherwise be required under this section is not required if:

(1) The user facility or manufacturer determines that the information received is erroneous in that a device-related adverse event did not occur. Documentation of such reports shall be retained in MDR files for time periods specified in §803.18.

(2) The manufacturer determines that the device was manufactured by another manufacturer. Any reportable event information that is erroneously sent to a manufacturer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured by that firm.

Subpart C—User Facility Reporting Requirements

§803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by §803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under §803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by §803.32, on FDA Form 3500A or electronic equivalent, as approved under §803.14, to the