

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§803.18 Files.

(a) User facilities and manufacturers shall establish and maintain MDR event files. All MDR event files shall be prominently identified as such and filed to facilitate timely access.

(b)(1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities and manufacturers. MDR event files may incorporate references to other information, e.g., medical records, patient files, engineering reports, etc., in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

(i) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity’s deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part.

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (e.g., a distributor or manufacturer).

(2) User facilities and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) User facilities shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. MDR event files must be maintained for the time periods described in this paragraph even if the device is no longer distributed.

(d) [Reserved]

(e) The manufacturer may maintain MDR event files as part of its complaint file, under §820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under

this subpart A shall not be considered to comply with this part unless the event has been evaluated in accordance with the requirements of §§820.162 and 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer’s MDR event file.

§803.19 Exemptions, variances, and alternative reporting requirements.

(a) The following persons are exempt from the reporting requirements under this part.

(1) An individual who is a licensed practitioner who prescribes or administers devices intended for use in humans and who manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a “physician-patient” relationship.

(2) An individual who manufactures devices intended for use in humans solely for such person’s use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, parts 812 and 813 of this chapter, which require reporting of all adverse device effects.

(3) Dental laboratories, or optical laboratories.

(b) Manufacturers or user facilities may request exemptions or variances from any or all of the reporting requirements in this part. The request shall be in writing and include information necessary to identify the firm and device, a complete statement of the request for exemption, variance, or alternative reporting, and an explanation why the request is justified.

(c) FDA may grant in writing, to a manufacturer or user facility, an exemption, variance or alternative from, or to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. These modifications may be initiated by a request as specified in this section, or at the discretion of FDA. When granting

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