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life sciences and healthcare lawflash
from the FDA Practice

June 15, 2013

FDA Issues New Medical Device Reporting Guidance

Device manufacturers should be aware of new issues and policy changes, which include the removal of the "two-year rule" for malfunctions.

On July 9, the U.S. Food and Drug Administration (FDA) issued a new draft guidance document, "Medical Device Reporting for Manufacturers."[1] The draft guidance, when finalized, will replace the 1997 FDA guidance document with the same title. The new draft guidance provides detailed recommendations and clarifications on manufacturers' obligations for submitting medical device reports (MDRs), maintaining MDR procedures, and related recordkeeping requirements. The draft guidance also includes sections addressing frequently asked questions and common reporting errors. Because the draft guidance is intended to update FDA's policy with respect to manufacturers' MDR reporting obligations and its interpretation of the MDR regulations, device manufacturers should carefully consider the new draft guidance and whether to submit comments for consideration by FDA before the guidance is finalized.

In particular, device manufacturers should be aware that the draft guidance document includes some new issues and changes with respect to prior FDA policy and interpretations of the MDR regulations. These include the following:

- **Removal of "Two-Year Rule" for Malfunctions:** Although FDA has always taken the position that, once a malfunction has caused or contributed to a death or serious injury, future malfunctions of the same type are presumed to be reportable, the prior 1997 guidance stated that the presumption would cease if the malfunction did not cause or contribute to any more deaths or serious injuries for a period of two years. The new draft guidance states that manufacturers that wish to stop reporting a malfunction that previously caused or contributed to a death or serious injury would need to submit a request to FDA for an exemption, which may be supported by evidence that the malfunction had not caused or contributed to any further deaths or serious injuries. Under the new draft guidance, it is not clear how much data (e.g., one year's or two years' worth) FDA would require to support such an exemption.
- **Contract Manufacturer Arrangements:** The 1997 guidance stated that, for contract manufacturer arrangements, "FDA would expect only one report from either the specifications developer or the contract manufacturer for one reportable event. Nevertheless, there must be a written agreement which identifies which party is responsible for completing Form 3500A." Although not stated in the 1997 guidance, FDA's policy in recent years has been to require an exemption when only one entity will be reporting in a contract manufacturer arrangement. The new draft guidance reflects this policy, stating that both the specifications developer and contract manufacturer must submit MDR reports unless an exemption is obtained from FDA to allow reporting by only one entity.
- **MDR Obligations After Selling a 510(k):** A new clarification provided in the draft guidance relates to the obligations of the seller when a 510(k) is sold from one manufacturer to another (with the buyer taking over the manufacture of the devices under the 510(k) after the sale). In the draft guidance, FDA states that the seller remains responsible for submitting MDRs for all of the devices that it manufactured prior to the sale, even if the agreement between the parties states that the buyer will assume this responsibility, unless an exemption is obtained from FDA.

1. View the draft guidance at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm.

- **Reporting Events Found in Literature:** The new draft guidance also discusses FDA's expectations and recommendations for investigating adverse events identified in scientific articles and other literature. The draft guidance suggests that manufacturers may need to contact the authors of these materials to obtain additional information during their investigation. The draft guidance also allows for the reporting of multiple events in one report when a manufacturer is unable to obtain sufficient information to provide a complete report for each reportable event, but FDA recommends submitting a separate report for each event type (if multiple event types are identified) and for each device (if more than one generic device type is implicated).

Comments on the new draft guidance may be submitted to FDA electronically at www.regulations.gov or in writing through October 7, 2013.

Contacts

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