Event Reporting for User facilities

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Accountable Care Exposition, August 1, 2012

Introduction

- My name is Judy Burton and I am a regulatory affairs consultant specializing in medical device establishment registration, device listings and 510(k) submissions.

  I have over 10 years experience processing documents and registrations for FDA regulated industries including devices, dietary supplements, drugs and food. Additionally, I have actively participated in internal and external facility inspections to ensure both FDA and ISO 13485 compliance to good manufacturing processes.

- Today we will take a brief look at the definition of a medical device and FDA User Facility requirements for reporting adverse events involving medical devices.

http://www.fda.gov

Definition of a Medical Device

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

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Definition of a Medical Device

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

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User Facility Reporting Requirements

- Under the Safe Medical Devices Act of 1990 (SMDA), device user facilities must report device-related deaths to the FDA and the manufacturer, if known.

- Device user facilities must also report device-related serious injuries to the manufacturer, or to the FDA if the manufacturer is not known.

- In addition, SMDA also required that device user facilities submit to FDA, on an annual basis, a summary of all reports submitted during that time period. The device user facility reporting section of SMDA became effective on November 28, 1991, and amendments became effective on February 19, 1998.

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Failure to Report

- If FDA inspects your facility and finds inadequate/missing procedures for reporting adverse events your firm will receive a 483 observation report and possibly a warning letter:

  - "Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, the investigator asked the medical director and refractory consultants if the facility had written MDR procedures and they confirmed that they did not and did not know what events would be considered serious injuries and reportable to manufacturers. The investigator reviewed some of the adverse events identified in the assignment guidance with them and they confirmed that these types of events have occurred at their facility. They explained that they inform their patients through the consenting process that they may have vision-threatening complications following the surgery.

http://www.fda.gov

How and Where to Report

- Health professionals and consumers may submit reports of device adverse events or product problems to FDA via the MedWatch program on FDA Form 3500 in one of the following ways:

- online at: https://www.accessdata.fda.gov/scripts/medwatch/

- by telephone at 1-800-FDA-1088

- by fax at 1-800-FDA-0178

- by mail to:
  - MedWatch
    The FDA Safety Information and Adverse Event Reporting Program
    Food and Drug Administration
    5600 Fishers Lane
    Rockville, MD 20852-9787

Optional Reporting

- In 2010, FDA launched an initiative to seek help from User Facilities/Health Practitioners to report additional violations such as:
  - Promotion of off-label use
  - Advertising the device as "FDA Approved" or "Registered with FDA" (21 CFR Part 807.97 "Misbranding by reference to premarket notification")
  - Sales and marketing of devices not registered/cleared with FDA http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Contact the Office of Compliance Division of Enforcement to report suspicious activities at: 301-796-5770 or 301-796-5540

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