U.S. FOOD & DRUG ADMINISTRATION

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Custom Device Exemption Annual Report

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Overview of Today's Webinar

- Review information required for the Custom Device Annual Report
  - Section 520(b) of the Food, Drug and Cosmetic Act (FD&C Act) and the amendment effective July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144)
- Share current observations for Custom Device Annual Reports
- Discuss ways to improve annual reports submitted to the FDA

Annual Reports

- The Food and Drug Administration Safety and Innovation Act amended the FD&C Act to include a new reporting requirement for the Custom Device Exemption.
- The manufacturer of a custom device must report to the FDA annually on the custom devices it supplied.
- Annual Reports should cover an entire calendar year and be submitted to the FDA within the first quarter of the following calendar year – no later than March 31.

What to Include in the Annual Report Cover Letter

- Cover Letter
  - Reference line - “Custom Device Annual Report”
  - Contact Information
  - Custom Devices Manufactured and Distributed
  - Reporting Period
- Truthful and Accurate Statement
  - I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the custom device annual report are truthful and accurate and that no material fact has been omitted.

What to Include in an Annual Report

- Information to include in the Annual Report:
  - The number of all custom devices distributed;
  - An account of custom devices that were returned or destroyed;
  - The number of patients who received a device or revisions of a previous custom device and;
  - If multiple custom devices were used in one patient, each custom device used must be accounted for in the Annual Report.

What Justification to Include in Annual Reports

- The Annual Report for patient-centric custom devices should include a justification for how or why the device manufactured to treat an individual patient meets the following conditions contained in the FD&C Act:
  - 520(b)(1)(B) & 520(b)(2)(A) – why the device necessarily deviates from the premarket requirements including treating a sufficiently rare condition such that conducting clinical investigations are impractical.

Information Required for Annual Reports

- 520(b)(1)(A) – indicate whether the device is a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician.
- 520(b)(1)(C) – attest that the device is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer or distributor for commercial distribution.

Information Required for Annual Reports

- 520(b)(1)(D) & 520(b)(2)(B) – provide a complete description of the device including device type and the patient's unique pathology of physiological condition.
- 520(b)(1)(D) – provide a statement that no other device is domestically available to treat the patient's unique pathology or physiological condition.
- 520(b)(1)(E)ii – provide a unique patient identifier for the individual patient in the physician's order.

Information Required for Annual Reports

- 520(b)(1)(F) – state whether the device is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals.
- 520(b)(1)(G) – explain whether the device or device components have common, standardized design characteristics, chemical and material compositions and the same manufacturing processes as commercially distributed devices.

Annual Report Submission Observations

- FDA has recently found inconsistencies within Annual Reports filed in 2017 for the following topics. Some reports included this information while others did not:
  - Name of device
  - Indication for use/intended use
  - Lack of names of rare conditions
  - Special needs of the health care professional who ordered the device
  - Establishment registration number
  - Facility establishment identifier
  - Labeling
  - Supporting documentation

Ensuring Annual Reports are High-Quality and Comprehensive

- Documentation should be provided to support statements made in annual report
- Suggested forms of documentation include, but are not limited to:
  - published studies,
  - web based searches,
  - professional society pages, etc.

How does the FDA use the Information in Annual Reports?

- Annual Report information helps the FDA understand how industry is interpreting and applying the custom device exemption.
- Annual Reports allow the FDA to ensure compliance with the custom device requirements.
- FDA uses the information to track the number and type of custom devices to respond to inquiries from stakeholders, such as Congress.

Questions?

Contact:

Customdevices@fda.hhs.gov

For General Questions: Division of Industry and Consumer Education:
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Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading: Specialty Technical Topics;

Subheading: Custom Devices

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