Medical Device Labeling

FDA Small Business
Regulatory Education for Industry (REdI)

Silver Spring, Maryland
September 29, 2015

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Learning Objectives

- Learn how FDA defines terms such as “Label,” “Labeling,” and “Advertising”
- Understand the requirements for medical device labeling
- Review some key labeling provisions for different types of medical device submissions
- Learn how to avoid misbranding of your medical device

Medical Device Labeling

The authority to regulate medical device labeling is provided for in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations found in 21 CFR Parts 801, 809, 812, and 820.

What is a "Label"?

- A display of written, printed, or graphic matter upon the immediate container of any article
- Any word, statement, or other information that appears on the label shall also appear on the outside container or wrapper of the retail package or is easily legible through the outside container or wrapper

Section 201(k) of FD&C Act

What is “Labeling”?

- All labels and other written, printed, or graphic matter
  - upon any article or any of its containers or wrappers
  - or accompanying such article

Section 201(m) of FD&C Act

What is Advertising?

Generally defined as promotional materials found in newspapers, journals, magazines, radio, and television (pay for placement)

Regulation of Labeling and Advertising

- **Food and Drug Administration (FDA)** has the statutory authority to regulate labeling of all medical devices.
- **Federal Trade Commission (FTC)** has the authority to regulate all medical device advertising, except restricted device advertising.
- **FDA** regulates advertising of restricted devices (per Sections 502(q) and 502(r) of FD&C Act).

Restricted Devices

- The Secretary may, by regulation, require that a device be restricted to sale, distribution, or use:
  - By written or oral authorization of a practitioner licensed to administer or use such device
  - Other conditions as the Secretary may prescribe in such regulation
- The label of a restricted device shall bear appropriate statements of the restriction as required by regulation.

Section 520(e) of FD&C Act

Restricted Devices

- 514 & 515 of FD&C Act provides for restriction of Class III devices.
- 520(e) of FD&C Act establishes a category called restricted devices. Examples of restricted devices include:
  - Analyte-Specific Reagents
  - Hearing Aids
  - over-the-counter (OTC) test sample collection systems for drugs of abuse testing
- Most restricted devices are prescription devices; but most prescription devices are not restricted devices

Misbranded Devices

- Its labeling is false or misleading in any particular manner.
- It is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
- Any required wording is not prominently displayed on the label or labeling as compared with other wording on the device, or is not clearly stated.
- Its label does not bear adequate directions for use.

21 U.S. Code §352

Exemptions from Adequate Directions for Use

Prescription Devices

(1) The statement **"Caution: Federal law restricts this device to sale by or on the order of a ____",** the blank to be filled with the word **"physician", "dentist", "veterinarian"**, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

21 CFR 801.109

General Labeling Requirements

The label shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor

21 CFR 801.1

Labeling Requirements: for types of submissions

- 510(k)
- IDE
- PMA
- *In Vitro* Diagnostics

510(k) Labeling

Submission should include the proposed labels, labeling, and advertisements sufficient to describe:

- the device;
- its intended use; and
- the directions for its use

Where applicable, photographs or engineering drawings should be supplied.

21 CFR 807.87(e)

510(k) Labeling

Labeling information to be included in a 510(k) submission may include:

- Special handling or storage instructions
- Instruction manuals
- Service manuals
- Promotional literature such as advertisements, publications, and website copy

IDE Labeling

- Required labeling specified in the IDE study protocol
- General Labeling Requirements
- This statement:

  "CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use."
- A description of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions.

21 CFR 812.5

IDE Labeling

- Absence of any statements that are false or misleading, or that represent the device as safe and effective for its investigational purpose.

- If a device is shipped solely for use on laboratory animals, this labeling statement is required:

  "CAUTION-Device for investigational use in laboratory animals or other tests that do not involve human subjects."

21 CFR 812.5

PMA Labeling

Submissions should include copies of all proposed labeling for the device.

Such labeling may include:

- Instructions for installation
- Any information, literature, or advertising that constitutes labeling under section 201(m) of FD&C Act.

21 CFR 814.20(b)(10)

In Vitro Diagnostic Labeling

Requirements for the label and the labeling (the package insert) are found in 21 CFR 809.10

Labeling Summary

- Requirements for the label and the labeling are found in 21 CFR Parts 801, 809, 812, and 820.
- All devices have some of the same general requirements.
- Additional labeling requirements depend on the submission type.
- To avoid misbranding of a device, it is important to understand the requirements described under 21 U.S. Code §352.

Industry Education Resources

Three Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   http://www.fda.gov/Training/CDRHLearn

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D1S6