ALQUEST

Clinical • Regulatory • Compliance

Medical Device Labeling

HealthPack 2004 Program

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Overview

- Regulatory Agencies and Pathways
- Labeling Regulations
- General Medical Device Labeling Requirements
- Electronic Labeling
- FDA's Current View on International Symbols
- Questions

Regulatory Agencies and Pathways

- Three branches of Government
  - **Legislative** – creates laws or statutes
  - **Executive** – carries out the laws
  - **Judicial** – courts that create case law or common law

  Agencies – create regulations or administrative law (FDA)

Regulatory Agencies and Pathways

- The Food and Drug Administration (FDA) and Federal Trade Commission (FTC) are consumer protection agencies
  - **FDA**
    - **Center for Devices and Radiological Health (CDRH)**
      - **Medical Devices and In-Vitro Diagnostics**
    - Center of Biologics Evaluation and Research (CBER)
    - Center for Drug Evaluation and Research (CDER)
    - Center for Food Safety and Applied Nutrition (CFSAN)
    - Center for Veterinary Medicine (CVM)

Regulatory Agencies and Pathways

- Office of Regulatory Affairs (ORA) is the lead office for all FDA field activities
  - Office of Regional Operations
  - **Office of Enforcement –**
    - Monitors compliance activities
  - Office of Regulatory Resource Management
  - Office of Criminal Investigations
  - **Environmental Protection Agency (EPA)**

  There are also regional and **district** offices

Regulatory Agencies and Pathways

- FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, **repackage, relabel**, and/or import medical devices sold in the United States.

- Medical devices are classified into Class I, II, and III.
  - Device classification defines regulatory requirements for the general device type.

Regulatory Agencies and Pathways

- Class I – devices are exempt from Premarket Notification 510(k)
- Class II – most devices require 510(k) submission
- Class III – devices require Premarket Approval

Labeling Regulations

- Labeling regulations pertaining to medical devices are found in the following parts of Title 21 of the Code of Federal Regulations (CFR)

General Device Labeling –	21 CFR Part 801
In-Vitro Diagnostics –	21 CFR Part 809
Investigational Device Exemptions -	21 CFR Part 812
Good Manufacturing Practices –	21 CFR Part 820
General Electronic Products -	21 CFR Part 1010

Labeling Regulations

- 21 CFR Part 801
  - Labeling includes labels on the device as well as descriptive and information literature that accompanies the device.

Label vs. Labeling

- The federal Food, Drug and Cosmetic Act (FFDCA) is the law under which the FDA takes action against regulated products.

- Section 201(k) defines “label” as a:
  - “display of written, printed, or graphic matter upon the immediate container of any article…”

Label vs. Labeling

- Section 201 (m) defines “labeling” as:
  - “all labels and other written, printed, or graphic matter
    - (1) Upon any article or any of its containers or wrappers, or
    - (2) Accompanying such article” at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.

U.S. Minimal Labeling Requirements

- Must be included on the package label
  - Name and place of manufacturer, packer **or** distributor
    - Including the street address, city, state and zip code
  - Adequate directions for use under which the layman can use a device safely for intended purposes

U.S. Minimal Labeling Requirements

- A prescription device is exempt form "adequate directions for use", provided:
  - Device is in possession of a licensed practitioner
  - Labeling has a Rx statement
  - Labeling includes information for use
  - All labeling other than labels and cartons includes the date of issuance or date of the latest revision
  - Common use is known to the ordinary individual

U.S. Minimal Labeling Requirements

- Required information must be displayed prominently on the device label
- Exemptions to prominence may be granted if device labeling lacks sufficient space
- Labeling must be in English
- More specific labeling requirements for specific devices 21 CFR 801.403

U.S. Minimal Labeling Requirements

- IDE (investigational device exemption) devices
  - Name and place of firm
  - Quantity
  - “CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use.”
  - Contraindications, hazards adverse effects, interfering substances or devices, warnings and precautions.

U.S. Minimal Labeling Requirements

- Sterile Devices Require:
  - What is actually sterile and what is not
  - Lot, batch or other control numbers are required for critical devices

  Requirements for labeling of in-process sterile goods in transit to a contract sterilizer are addressed in 801.150.

In-Vitro Diagnostic Medical Device Labeling Requirements

- FDA –
  - In Vitro Diagnostic Products For Human Use- 21 CFR Part 809
- International:
  - In-Vitro Diagnostic Directive (IVDD), October 27, 1998
  - EN 591:2001 – Instructions for Use In-Vitro Diagnostics, Instructions for Professional Use
  - EN 592:2002 – Instructions for Use In-Vitro Diagnostics, Instruments for Self-Testing

Misbranding

- Section 502 of the Federal Food, Drug and Cosmetic Act
- Includes:
  - Violation or absence of the previously stated labeling requirements.
  - Contains false or Misleading information

Misbranding

- FDA Enforcement Options
  - Inspections
  - Lists of inspectional observations (FDA Form 483)
  - Warning letters
  - Adverse publicity
  - Voluntary or FDA-initiated recalls
  - Delay and suspension or withdrawal of product approvals
    - Fines
    - Prosecution

Quality System Regulation

- The QA program must be adequate to ensure that labeling meets the GMP device master record requirements with respect to legibility, adhesion, etc.
  - Label Integrity
  - Receipt and Inspection
  - Area Separation and Inspection
  - Storage
  - Label Check and Record
  - Changes
  - Relabeling and Over-labeling
  - Control Number

Electronic Labeling

- Section 206 of Medical Device User Fee and Modernization Act (MDUFMA)
  - Prescription devices used within the confines of a health care facility may provide labeling for those devices solely in electronic form
  - Paper form must be provided upon request of the user without additional cost

FDA's Current View on International Symbols

- Draft Guidance for Industry and FDA Staff – Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
  - October 23, 2003

International Labeling

- CE Marking: The CE Mark must appear in a visible, legible and indelible form on the device or its sterile pack and on the instructions for use.
- As far as practical and appropriate, information needed to use the device safely must be on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging (MDD).
- Instructions for use must be included in the packaging for every device.
- Where appropriate, the information should take the form of symbols.

Websites

- www.fda.gov
- QSIT - To know it is to love it
- http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF
- Small Entity Guidance
- http://www.fda.gov/cdrh/dsma/gmpman.hmtl
- Process Validation & “Computerized”
- http://www.fda.gov/cdrh/ode/425.pdf
- http://www.fda.gov/cdrh/qsr/appdx2.pdf
- Quality Systems & Premarket Submissions
- http://www.fda.gov/cdrh/comp/guidance/1140.pdf

Websites

- Device Advice Overview
- http://www.fda.gov/cdrh/devadvice/51.html
- Part 7 Enforcement Polices & FDA Manuals
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CRFSearch.cfm?CFRPart=7
- http://www.fda.gov/ora/compliance_ref/rpm_new2/ch7.html
- Part 810 Medical Device Recall Authority
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=810
- Part 806 Reports and Records
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806

Websites

- Talk to THE DISTRICT
- http://www.fda.gov/ora/inspect_ref/iom/IOMORDIR_3.html#mindo
- http://www.fda.gov/cdrh/ode/225.pdf
- Searching for FDA recognized Standards
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- Searching for FDA guidances*
- http://www.fda.gov/opacom/morechoices/industry/guidedc.htm
- Standards Organizations & Resources
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