U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

General Controls for Medical Devices

Introduction

General Controls are the basic provisions (authorities) of the May 28, 1976 Medical Device Amendments (hereafter referred to as the Amendments) to the Food, Drug and Cosmetic Act, that provide the FDA with the means of regulating devices to ensure their safety and effectiveness. The General Controls in the Amendments apply to all medical devices. They include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices.

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Application of The Provisions of General Controls

Devices are classified according to the degree of difficulty in assuring their safety and effectiveness. Class I, which is synonymous with General Controls, is the least stringent of the three device classes provided in the Amendments. Before placing a device in Class I, the FDA must first determine that there is sufficient information available to support such a classification decision. Second, the FDA must decide that the General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness. Class I devices are not subject to the restrictions of Class II - Special Controls or Class III - Premarket Approval. In addition, Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury

Unless otherwise exempted, the General Controls provisions of the Amendments are applicable to all devices regardless of their classification status.

KEY POINTS

- General Controls are the basic authorities of the Medical Device Amendments that provide the FDA with the means of regulating devices to ensure their safety and effectiveness.
- General Controls apply to all three classes of medical devices; however, they are the only level of controls that apply to Class I devices.
- Class I devices are not intended to be:
    1. For use in supporting or sustaining life;
    2. Of importance in preventing impairment to human life; and may not
    3. Present a potential unreasonable risk of illness or injury
- General Controls include the provisions of the Act pertaining to:
    1. Adulteration;
    2. Misbranding;
    3. Device registration and listing;
    4. Premarket notification;
    5. Banned devices;
    6. Notification and repair, replacement, and refund;

7. Records and reports;
8. Restricted devices; and
9. Good Manufacturing Practices.

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Adulteration

Medical devices are subject to the adulteration provisions of the FD&C Act under Section 501. The first two provisions of Section 501 define adulteration for most cases. A device is held to be adulterated if it includes any filthy, putrid, or decomposed substance, or if it is prepared, packed, or held under unsanitary conditions. The FD&C Act further states that a device is held to be adulterated if:

- Its container is composed, in whole or part, of any poisonous or deleterious substance;
- It contains, for the purposes of coloring only, an unsafe color additive; and
- Its strength differs from, or its purity or quality falls below, that which it claims to represent.

When the Medical Device Amendments were added to the FD&C Act, certain conforming laws, applying specifically to medical devices, were added to Section 501. These provisions relate directly to other portions of the Amendments, granting the FDA authority to control performance standards; compliance with premarket approval applications and product development protocol requirements; banning; good manufacturing practices; and investigational device exemptions. These sections state that a device will also be considered adulterated if:

- It is subject to a performance standard and does not comply with all the requirements of the standard;
- It is a Class III device and fails to conform to the requirements for an approved premarket approval application or a notice of completion of a product development protocol;
- It is a banned device;
- It is in violation of good manufacturing practice requirements; or
- It fails to comply with an Investigational Device Exemption (IDE).

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Misbranding

The misbranding provisions of the FD&C Act in Section 502 cover various aspects of drug and device labeling requirements. Many of the provisions apply to drugs and devices both; however, there are also specific misbranding provisions that apply to only drugs or only devices. The misbranding provisions that apply to both drugs and devices are listed in the following:

Drugs and Device Misbranding Provisions

A drug or device is deemed to be misbranded if:

- Its labeling is false and misleading.
- Its packaging does not bear a label containing:
    1. the name of the place of business of the manufacturer, packer, or distributor, and
    2. an accurate statement of the quantity of contents in terms of weight, measure, or numerical count.

  Reasonable variations and exemptions for small packages may be permitted.
- Any word, statement, or other required information is not prominently placed on the labeling or not clearly stated so as to be read and understood by the ordinary individual under customary conditions of purchase and use.
- It is for use by man and contains any quantity of a narcotic or habit forming substance, unless its label bears the name and quantity or proportion of the substance or derivative and the statement "Warning - may be habit forming."
- Its label does not bear adequate directions for use. The label must include warnings against use in certain pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application. Adequate directions and warnings must be present when it is necessary to protect the health of the user. Exemptions to this provision may be obtained. The phrase "adequate directions for use" pertains to over-the-counter drugs and device.
- It is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling.
- It does not comply with the color additive provisions listed under Section 706 of the FD&C Act.

Device Misbranding Provisions Added by the Amendments

The Amendments added new authority relating to the misbranding of medical devices. These new provisions state that a device is misbranded if:

- The device's established name (if it has one) or its name in an official compendium, or any common or usual name, is not prominently printed in type at least half as large as that used for any proprietary name or designation. Exemptions from this provision may be granted.
- A restricted device offered for sale in any State uses false or misleading advertising, or is sold, distributed, or used in violation of restricted device regulations under Section 820(e) of the FD&C Act.
- A restricted device manufacturer, packer, or distributor fails to include in all advertisements or other descriptive materials:
    1. a true statement of the device's established name, prominently printed, and
    2. a brief statement of the intended uses of the devices and relevant warnings, precautions, side effects, and contradictions.
- The device commercially distributed without FDA concurrence on a Section 510(k) submission.
- The device is subject to a performance standard and it does not bear the labeling prescribed in that standard.
- There is a failure or refusal to comply with any requirement prescribed under section 518 (Notification and Other Remedies); to furnish any material or information required by or under Section 518; or to furnish any material or information requested by or under Section 519 (Records and Reports on Devices).

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False or Misleading Labeling

The FD&C Act states that a drug or device is misbranded "if its labeling is false or misleading in any particular." "Labeling" includes the label and any other written, printed, or graphic material that accompanies a device and any of its wrappers or containers. Operating and servicing instructions are also regarded as part of the labeling. The labeling must bear adequate directions for use and any warnings needed to ensure the safe and effectiveness use of the device

Medical Device Labeling Information (/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm)

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