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Drug information by name - Merck Manuals Professional Edition

The IOM is the primary operational guide for FDA employees who perform field investigational activities in support of the agency's public health mission. Investigations Operations Manual | FDA ...

Chapter 9 Import Operations And Actions - fda.gov

A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures.

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Investigations Operations Manual | FDA

Coverage Gap Discount Program. An applicable drug is a Part D drug that is approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a biologics license application under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such Act).

[CFR - Code of Federal Regulations Title 21](#)

The Cancer Drug Manual® provides concise, evaluative information on drugs used in oncology. Inclusion in this index is not an indication of the funding status of a drug through BC Cancer. To determine drug coverage, see Benefit Drug List.

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The Food and Drug Administration (FDA or Agency) has determined that it is necessary for manufacturers of certain reusable medical devices to include in their premarket notifications (510(k)s) instructions for use which have been validated and validation data regarding cleaning, disinfection, and...

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A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay. (b) Classification. Class I (general controls).

Regulatory Procedures Manual | FDA

(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part. (b) Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety ...

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* Drugs@FDA includes information about drugs, including biological products, approved for human use in the United States (see FAQ), but does not include information about FDA-approved products regulated by the Center for Biologics Evaluation and Research (for example, vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products).

Compliance Program Guidance Manual (CPGM) | FDA

FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws ...

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