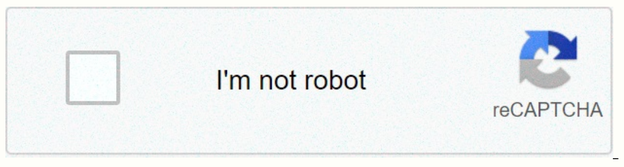

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Fda guidelines for post marketing surveillance

In this section: Search guidelines FDA Docket No. applicants and other responsible parties in meeting the postmarketing fda safety reporting requirements = existing for human marketing of drugs and biological products at 21 CFR 310305 , 314.8 , 314.98, 600.80 and 600.81.2 According to these regulations, the following safety reports must be submitted to the Agency for the following: 1. Experience serious and unexpected disadvantages from all sources (at home and abroad) 2. Naturally report the detrimental experiences occurring in the country and that is: • Serious and expected • Nonserious and unexpected You can post comments online or in writing on any tutorial at any time (see 21 CFR 10115(g)(5)) If you are unable to submit comments online, please submit written comments to : Dockets Food Management and Pharmacy Administration 5630 Fishers Lane, Rm 1061 Rockville, MD 20852 All written opinions should be identified with this document docket number: FDA-2001-D-0506. Question? Looking for FDA Guidelines Back to the Top Despite CDER's pre-market caution assessment, positive post-marketing monitoring of the drug's side effects is also essential. Because all possible side effects of a drug cannot be predicted based on pre-approved studies involving only a few hundred to several thousand patients, the FDA maintains a postmarketing monitoring system and risk assessment programs to identify side effects that do not appear during drug approval. The FDA tracks side effects such as detrimental reactions and poisoning. The agency uses this information to update drug labeling, and, on rare occasions, to reeade approval or marketing decisions. This page describes how CDER works to ensure the ongoing safety and effectiveness of medicinal products currently marketed in the United States. The FDA's Event Reporting System (FAERS) is a computer-based information database designed to support the FDA's post-marketing safety monitoring program for all approved therapeutic and medicinal biological products. Faers' ultimate goal is to improve public health by providing the best tools available for storing and analyzing safety reports. Reports in FAERS are evaluated by a multidisciplinary safety assessor, epidemiologist and other scientists in the Drug Evaluation and Research Center's Office of Monitoring and Epidemiology (CDER) to detect drug safety signals and safety monitoring. As a result, the FDA may take legal action to improve product safety and protect public health, such as updating product labeling information, mailing Dear Health Care Professional, or re-evaluating approval decisions. MedWatch program for health professionals and the public to voluntarily report serious reactions and problems with medical products, such as and medical devices. It also ensures that new safety information is communicated quickly to the medical community thereby improving patient care. All data contained on the MedWatch form will be entered into the AERS database. The MedWatch page includes sections on how to report a disadvantage event, safety information, and publication. For more information on how to report a disadvantage event, see Report a problem to the FDA. The Marketing, Advertising and Drug Communications page also contains other useful drug advertising and monitoring information. After a drug is approved and marketed, the FDA uses various mechanisms to ensure that 1) companies comply with the approved terms and conditions described in the application and 2) that the drug is manufactured consistently and controlledly. This is done by periodically checking, not notifying drug production and control facilities of FDA investigators and field analysts. Manufacturers of prescription medical products are required by prescription to submit reports of events that are detrimental to the FDA. The MedWatch website provides information about mandatory reporting by manufacturers. In addition, drug manufacturers must submit error and accident reports or drug quality reports when deviations occur compared to current good manufacturing practice regulations. The FDA receives drug bug reports on the human drug market (including prescription drugs, generic drugs, and over-the-counter drugs) and nonvaccine biological products and devices. The National Coordinating Council for Drug Error Reporting and Prevention defines drug errors as any preventable event that may cause or result in inappropriate or harmful use of the drug while the drug is under the control of a healthcare professional , patient or consumer. Such events may involve professional practice, health care products, procedures and systems, including regulation; order communications; labeling products, packaging and nosimal; compounding; dispensing; distribution; governance; education; supervise; and use. CDER Drug Error Program employees review drug error reports sent to the USP-ISMP Drug Error Reporting Program and MedWatch, evaluate cause and effect, and analyze data to provide feedback to others at the FDA. Drug shortages. It is fda policy to try to prevent or alleviate a shortage of medically necessary products. Drug shortages can arise from various causes, such as unavailable raw materials or packaging ingredients, marketing decisions, and enforcement issues. See MaPP on drug shortage management (PDF - 78KB) for an overview of CDER's drug shortage management responsibilities and how to handle drug shortage reports. Report treatment inequivalence. Over the past 10 years, the FDA's Center for Drug Evaluation and Research has received an increase of reports on drug products that do not work in patients because of products simply have no effect or are toxic. These issues often attributed to the conversion of drug brands. As a result, On September 14, 1988, the FDA created in the CDER Inequivalence Treatment Commission (TIACC) to identify and evaluate reports of treatment failures and toxicity may indicates that a product does not equates to another similar product Related to ResourcesForYou TITLE 21--FOOD AND DRUGSCHAPTER I-DEPARTMENT OF MEDICINE AND HUMAN SERVICES SUBCHAPTER H - MEDICAL EQUIPMENT SECTION 822POSTMARKET MONITORING Subpart A - General Regulations § 822.1 - What does this section include? § 822.2 - What is the purpose of this section? § 822.3 - How do you define the terms used in this section? § 822.4 - Does this section apply to me? Part B - Notice § 822.5 - How will I know if I have to conduct postmarket monitoring? § 822.6 - When will you notify me that I am required to conduct after-sales supervision? § 822.7 - What should I do if I disagree that after-sales monitoring is appropriate? Part C - After-sales monitoring plan § 822.8 - When, where and how do I submit my post-market monitoring plan? § 822.9 - What should I include in my submission? § 822.10 - What should I include in my monitoring plan? § 822.11 - What should I consider when designing my plan to conduct after-sales monitoring? § 822.12 - Do you have any information that will help me prepare my submissions or design my after-sales monitoring plan? § 822.13 - [Reserved] § 822.14 - Can I refer to previously submitted information instead of ressying it? § 822.15 - How long do I have to monitor my equipment? Part D - FDA Review and Action § 822.16 - What would you consider in reviewing my submission? § 822.17 - How long will it take to review my submission? § 822.18 - How will I be informed of your decision? § 822.19 - What decisions can you make? § 822.20 - What are the consequences if I do not submit a post-market monitoring plan, my plan is rejected and I do not submit a new plan or I do not conduct supervision according to my approved plan? § 822.21 - What do I do if I want to change my after-sales monitoring plan after you have approved it? § 822.22 - What do I claim if I disagree with your decision? § 822.23 - Is the information in my submission considered confidential? Part E - Manufacturers' Responsibilities § 822.24 - What are my responsibilities when I am informed that I am required to conduct post-market supervision? § 822.25 - What are my responsibilities after my after-sales monitoring plan has been approved? § 822.26 - If my company changes ownership, what do I do? § 822.27 - If I go out of business, what do I do? § 822.28 - If I stop marketing after-sales monitoring equipment, what do I do? Part F - Exemption § 822.29 - Can I request a waiver of a specific requirement of this section? § 822.30 - I can request postmarket monitoring? Subs section G - Records and Reports § 822.31 - What records do I need to keep? § 822.32 - What records do investigators in my monitoring plan need to keep? § 822.33 - How long do we have to keep records? § 822.34 - What do I do with the record if the program's sponsor or investigator in the program changes? § 822.35 - Can you check my production site or other sites related to my postmarket monitoring plan? § 822.36 - Can you check and copy records related to my after-sales monitoring plan? § 822.37 - Under what circumstances will you check the record of identifying the subject? § 822.38 - What report do I have to submit to you? You?