

CFR - Code of Federal Regulations Title 21

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES
PART 200 -- QUALITY SYSTEM REGULATION

Subpart M - Records

Sec. 200.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

- (1) All complaints are processed in a uniform and timely manner;
- (2) Oral complaints are documented upon receipt; and
- (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 200.198(e), records of investigation under this paragraph shall include a determination of:

- (1) Whether the device failed to meet specifications;
- (2) Whether the device was being used for treatment or diagnosis; and
- (3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

- (1) The name of the device;
- (2) The date the complaint was received;
- (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
- (4) The name, address, and phone number of the complainant;
- (5) The nature and details of the complaint;

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positive law the underlying statutes are repealed and the title then becomes legal evidence of the law Currently 26 of the 51 titles in the Code have been so enacted These are identified in the table of titles near the beginning of each volume The Law Revision Counsel of the House of Representatives continues to prepare legislation pursuant to 2 U S C 285b to enact the remainder of the Code on a title by title basis into positive law The 2012 edition of the Code was prepared and published under the supervision of Ralph V Seep Law Revision Counsel Grateful acknowledgment is made of the contributions by all who helped in this work particularly the staffs of the Office of the Law Revision Counsel and the Government Printing Office

Preface *United States Code, 2006, Supplement 3, V. 4* ,2011 The United States Code 2006 Edition contains the General and Permanent Laws of the United States Enacted Through the 109th Congress Ending January 3 2007 the Last Law of Which was Signed on January 15 2007 *Federal Program Evaluations* ,1982 Contains an inventory of evaluation reports produced by and for selected Federal agencies including GAO evaluation reports that relate to the programs of those agencies *1996 Annual Report on Alaska's Mineral Resources* ,1997 **The Code of Federal Regulations of the United States of America** ,1994 The Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government *Monthly Catalog of United States Government Publications* ,2004 *Federal Register* ,2013 **Hydrogeology and Steady-state Simulation of Ground-water Flow in the San Juan Basin, New Mexico, Colorado, Arizona, and Utah** John Michael Kernodle,1996 **Water-resources Investigations Report** ,1996

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