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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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Use of Reclaimed Water and Sludge in Food Crop Production National Research Council, Division on Earth and Life Studies, Commission on Geosciences, Environment and Resources, Committee on the Use of Treated Municipal Wastewater Effluents and Sludge in the Production of Crops for Human Consumption, 1996-03-26 This book reviews the practice of reclaiming treated municipal wastewater for agricultural irrigation and using sewage sludge as a soil amendment and fertilizer in the United States It describes and evaluates treatment technologies and practices effects on soils crop production and ground water public health concerns from pathogens and toxic chemicals existing regulations and guidelines and some of the economic liability and institutional issues The recommendations and findings are aimed at authorities at the federal state and local levels public utilities and the food processing industry **2018 CFR Annual Digital e-Book Edition, 40 Protection of Environment - Part 52 (52.01 to 52.1018** Office of The Federal Register, 2018-07-01 Part 52 52 01 to 52 1018 Volume 3 *Code of Federal Regulations, Cfr Index and Finding AIDS, Revised as of January 1, 2016* ,2016-05-06

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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

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web 1 appreciation for the female worldview lots of guys just don t know what goes into making a woman look good there s the outfit color coordination the makeup the

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web in 1990 allen published transformations crossdressers and those who love them a photography book documenting her decade of travels within this community and the

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