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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 810 -- MEDICAL DEVICE RECALL AUTHORITY

Contents

Subpart B - Mandatory Medical Device Recall Procedures 1
Sec. 810.10 Cease distribution and notification order. 1
Additional Information and Updates 2
About Us 2

Subpart B - Mandatory Medical Device Recall Procedures

Sec. 810.10 Cease distribution and notification order.

(a) If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order requiring the person named in the order to immediately:

(1) Cease distribution of the device;

(2) Notify health professionals and device user facilities of the order; and

(3) Instruct these professionals and device user facilities to cease use of the device.

(b) FDA will include the following information in the order:

(1) The requirements of the order relating to cessation of distribution and notification of health professionals and device user facilities;

(2) Pertinent descriptive information to enable accurate and immediate identification of the device subject to the order, including, where known:

(i) The brand name of the device;

(ii) The common name, classification name, or usual name of the device;

(iii) The model, catalog, or product code numbers of the device;

(iv) The manufacturing lot numbers or serial numbers of the device or other identification numbers; and

(v) The unique device identifier (UDI) that appears on the device label or on the device package; and

(3) A statement of the grounds for FDA's finding that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(c) FDA may also include in the order a model letter for notifying health professionals and device user facilities of the order and a requirement that notification of health professionals and

device user facilities be completed within a specified timeframe. The model letter will include the key elements of information that the agency in its discretion has determined, based on the circumstances surrounding the issuance of each order, are necessary to inform health professionals and device user facilities about the order.

(d) FDA may also require that the person named in the cease distribution and notification order submit any or all of the following information to the agency by a time specified in the order:

(1) The total number of units of the device produced and the timespan of the production;

(2) The total number of units of the device estimated to be in distribution channels;

(3) The total number of units of the device estimated to be distributed to health professionals and device user facilities;

(4) The total number of units of the device estimated to be in the hands of home users;

(5) Distribution information, including the names and addresses of all consignees;

(6) A copy of any written communication used by the person named in the order to notify health professionals and device user facilities;

(7) A proposed strategy for complying with the cease distribution and notification order;

(8) Progress reports to be made at specified intervals, showing the names and addresses of health professionals and device user facilities that have been notified, names of specific individuals contacted within device user facilities, and the dates of such contacts; and

(9) The name, address, and telephone number of the person who should be contacted concerning implementation of the order.

(e) FDA will provide the person named in a cease distribution and notification order with an opportunity for a regulatory hearing on the actions required by the cease distribution and notification order and on whether the order should be modified, or vacated, or amended to require a mandatory recall of the device.

(f) FDA will also provide the person named in the cease distribution and notification order with an opportunity, in lieu of a regulatory hearing, to submit a written request to FDA asking that the order be modified, or vacated, or amended.

(g) FDA will include in the cease distribution and notification order the name, address, and telephone number of an agency employee to whom any request for a regulatory hearing or agency review is to be addressed.

Additional Information and Updates
Always ensure that you are using the most current version:
eCFR :: Title 21 of the CFR (2022-02-13) -- Food and Drugs

A summary of changes can be found here:
eCFR :: Recent Changes

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About Us
Quality Systems Compliance LLC primarily works with companies in the FDA regulated industries (medical devices, human tissue, animal tissue, cosmetics, and pharmaceuticals) focusing on quality management system implementation, integration, updates, and training.

Additionally, Quality Systems Compliance LLC assists companies by providing internal and external (supplier and due diligence) audit support as well as FDA 483 and Warning Letter response and remediation services.