

distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the agency terminates the order in accordance with §810.17.

§810.17 Termination of a cease distribution and notification or mandatory recall order.

(a) The person named in a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 may request termination of the order by submitting a written request to FDA. The person submitting a request shall certify that he or she has complied in full with all of the requirements of the order and shall include a copy of the most current status report submitted to the agency under §810.16. A request for termination of a recall order shall include a description of the disposition of the recalled device.

(b) FDA may terminate a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under §810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

Subpart A—General Provisions

- Sec.
- 812.1 Scope.
 - 812.2 Applicability.
 - 812.3 Definitions.
 - 812.5 Labeling of investigational devices.
 - 812.7 Prohibition of promotion and other practices.
 - 812.10 Waivers.
 - 812.18 Import and export requirements.
 - 812.19 Address for IDE correspondence.

Subpart B—Application and Administrative Action

- 812.20 Application.
- 812.25 Investigational plan.
- 812.27 Report of prior investigations.
- 812.30 FDA action on applications.
- 812.35 Supplemental applications.
- 812.36 Treatment use of an investigational device.
- 812.38 Confidentiality of data and information.

Subpart C—Responsibilities of Sponsors

- 812.40 General responsibilities of sponsors.
- 812.42 FDA and IRB approval.
- 812.43 Selecting investigators and monitors.
- 812.45 Informing investigators.
- 812.46 Monitoring investigations.
- 812.47 Emergency research under §50.24 of this chapter.

Subpart D—IRB Review and Approval

- 812.60 IRB composition, duties, and functions.
- 812.62 IRB approval.
- 812.64 IRB's continuing review.
- 812.65 [Reserved]
- 812.66 Significant risk device determinations.