

§810.13

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cease distribution and notification strategy, and shall address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order, including an appropriate recall strategy.

(c) The agency official who issued the cease distribution and notification order shall provide the requestor written notification of the agency's decision to affirm, modify, or vacate the order or amend the order to require a recall of the device within 15 working days of receipt of the written request. The agency official shall include in this written notification:

(1) A statement of the grounds for the decision to affirm, modify, vacate, or amend the order; and

(2) The requirements of any modified or amended order.

§810.13 Mandatory recall order.

(a) If the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or, if the Commissioner of Food and Drugs or the presiding officer denies a request for a hearing, or, if after conducting a regulatory hearing under §810.11 or completing agency review of a cease distribution and notification order under §810.12, FDA determines that the order should be amended to require a recall of the device with respect to which the order was issued, FDA shall amend the order to require such a recall. FDA shall amend the order to require such a recall within 15 working days of issuance of a cease distribution and notification order if a regulatory hearing or agency review of the order is not requested, or within 15 working days of denying a request for a hearing, or within 15 working days of completing a regulatory hearing under §810.11, or within 15 working days of receipt of a written request for review of a cease distribution and notification order under §810.12.

(b) In a mandatory recall order, FDA may:

(1) Specify that the recall is to extend to the wholesale, retail, or user level;

(2) Specify a timetable in accordance with which the recall is to begin and be completed;

(3) Require the person named in the order to submit to the agency a proposed recall strategy, as described in §810.14, and periodic reports describing the progress of the mandatory recall, as described in §810.16; and

(4) Provide the person named in the order with a model recall notification letter that includes the key elements of information that FDA has determined are necessary to inform health professionals and device user facilities.

(c) FDA will not include in a mandatory recall order a requirement for:

(1) Recall of a device from individuals; or

(2) Recall of a device from device user facilities, if FDA determines that the risk of recalling the device from the facilities presents a greater health risk than the health risk of not recalling the device from use, unless the device can be replaced immediately with an equivalent device.

(d) FDA will include in a mandatory recall order provisions for notification to individuals subject to the risks associated with use of the device. If a significant number of such individuals cannot be identified, FDA may notify such individuals under section 705(b) of the act.

§810.14 Cease distribution and notification or mandatory recall strategy.

(a) *General.* The person named in a cease distribution and notification order issued under §810.10 shall comply with the order, which FDA will fashion as appropriate for the individual circumstances of the case. The person named in a cease distribution and notification order modified under §810.11(e) or §810.12(c) or a mandatory recall order issued under §810.13 shall develop a strategy for complying with the order that is appropriate for the individual circumstances and that takes into account the following factors:

(1) The nature of the serious, adverse health consequences related to the device;

(2) The ease of identifying the device;

(3) The extent to which the risk presented by the device is obvious to a