

Reagent. Except as a component of the approved/cleared test (name of approved/cleared test), analytical and performance characteristics are not established"; and

(4) Shall not make any statement regarding analytical or clinical performance.

(e) The laboratory that develops an in-house test using the ASR shall inform the ordering person of the test result by appending to the test report the statement: "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." This statement would not be applicable or required when test results are generated using the test that was cleared or approved in conjunction with review of the class II or III ASR.

(f) Ordering in-house tests that are developed using analyte specific reagents is limited under section 520(e) of the act to physicians and other persons authorized by applicable State law to order such tests.

(g) The restrictions in paragraphs (c) through (f) of this section do not apply when reagents that otherwise meet the analyte specific reagent definition are sold to:

- (1) In vitro diagnostic manufacturers; or
- (2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

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PART 810—MEDICAL DEVICE RECALL AUTHORITY

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AUTHORITY: 21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 360h, 371, 374, 375.

SOURCE: 61 FR 59018, Nov. 20, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 810.1 Scope.

Part 810 describes the procedures that the Food and Drug Administration will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act.

§ 810.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Cease distribution and notification strategy* or *mandatory recall strategy* means a planned, specific course of action to be taken by the person named in a cease distribution and notification order or in a mandatory recall order, which addresses the extent of the notification or recall, the need for public warnings, and the extent of effectiveness checks to be conducted.

(d) *Consignee* means any person or firm that has received, purchased, or used a device that is subject to a cease distribution and notification order or a mandatory recall order. Consignee does not mean lay individuals or patients, i.e., nonhealth professionals.

(e) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient

monitoring) of a device, without its physical removal from its point of use to some other location.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office.

(g) *Health professionals* means practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use.

(h) *Reasonable probability* means that it is more likely than not that an event will occur.

(i) *Serious, adverse health consequence* means any significant adverse experience, including those that may be either life-threatening or involve permanent or long-term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

(j) *Recall* means the correction or removal of a device for human use where FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(k) *Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

§ 810.3 Computation of time.

In computing any period of time prescribed or allowed by this part, the day of the act or event from which the designated period of time begins to run shall not be included. The computation of time is based only on working days.

§ 810.4 Service of orders.

Orders issued under this part will be served in person by a designated employee of FDA, or by certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt, to the named person or designated agent at the named person's or designated agent's last known address in FDA's records.

Subpart B—Mandatory Medical Device Recall Procedures

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