

§ 809.40

(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.

[62 FR 62259, Nov. 21, 1997]

§ 809.40 Restrictions on the sale, distribution, and use of OTC test sample collection systems for drugs of abuse testing.

(a) Over-the-counter (OTC) test sample collection systems for drugs of abuse testing (§ 864.3260 of this chapter) are restricted devices under section 520(e) of the Act subject to the restrictions set forth in this section.

(b) Sample testing shall be performed in a laboratory using screening tests that have been approved, cleared, or otherwise recognized by the Food and Drug Administration as accurate and reliable for the testing of such specimens for identifying drugs of abuse or their metabolites.

(c) The laboratory performing the test(s) shall have, and shall be recognized as having, adequate capability to

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reliably perform the necessary screening and confirmatory tests, including adequate capability to perform integrity checks of the biological specimens for possible adulteration.

(d) All OTC test sample collection systems for drugs of abuse testing shall be labeled in accordance with § 809.10(f) and shall provide an adequate system to communicate the proper interpretation of test results from the laboratory to the lay purchaser.

[65 FR 18234, Apr. 7, 2000]

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.