Food and Drug Administration, HHS

§ 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 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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SOURCE: 61 FR 58018, 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.