§ 809.20  General requirements for manufacturers and producers of in vitro diagnostic products.

(a) [Reserved]

(b) Compliance with good manufacturing practices. In vitro diagnostic products shall be manufactured in accordance with the good manufacturing practices requirements found in part 820 of this chapter and, if applicable, with §610.44 of this chapter.

§ 809.30  Restrictions on the sale, distribution and use of analyte specific reagents.

(a) Analyte specific reagents (ASR’s) (§ 864.4020 of this chapter) are restricted devices under section 520(e) of the Federal Food, Drugs, and Cosmetic Act (the act) subject to the restrictions set forth in this section.

(b) ASR’s may only be sold to:

(1) In vitro diagnostic manufacturers;

(2) Clinical laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as qualified to perform high complexity testing under 42 CFR part 493 or clinical laboratories regulated under VHA Directive 1106 (available from Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420); and

(3) 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.

(c) ASR’s must be labeled in accordance with §809.10(e).

(d) Advertising and promotional materials for ASR’s:

(1) Shall include the identity and purity (including source and method of acquisition) of the analyte specific reagent and the identity of the analyte;

(2) Shall include the statement for class I exempt ASR’s: “Analyte Specific Reagent. Analytical and performance characteristics are not established”;

(3) Shall include the statement for class II or III ASR’s: “Analyte Specific Reagent. Except as a component of the approved/cleared test (name of approved/cleared test), analytical and performance characteristics are not established”;

and