§ 640.120 Alternative procedures

(a) The Director, Center for Biologics Evaluation and Research, may approve an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products. Requests for such exceptions or alternatives shall ordinarily be in writing. Licensed establishments shall submit such requests in accordance with § 601.12 of this chapter. However, in limited circumstances, such requests may be made orally and permission may be given orally by the Director. Oral requests and approvals must be promptly followed by written requests and written approvals.

(b) FDA will publish a list of approved alternative procedures and exceptions periodically in the FEDERAL REGISTER.


PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

Subpart A—Antibody to Hepatitis B Surface Antigen

Sec. 660.1 Antibody to Hepatitis B Surface Antigen.
660.2 General requirements.
660.3 Reference panel.
660.4 Potency test.
660.5 Specificity.
660.6 Samples; protocols; official release.

Subpart B [Reserved]

Subpart C—Blood Grouping Reagent

660.20 Blood Grouping Reagent.
660.22 Potency requirements with reference preparations.
660.25 Potency tests without reference preparations.
660.26 Specificity tests and avidity tests.
660.28 Labeling.

Subpart D—Reagent Red Blood Cells

660.30 Reagent Red Blood Cells.
660.31 Suitability of the donor.