Subpart E—Hepatitis B Surface Antigen

§ 660.40 Hepatitis B Surface Antigen.

(a) Proper name and definition. The proper name of this product shall be Hepatitis B Surface Antigen (HBsAg), which shall consist of a serum or tissue preparation containing one or more subtypes of the Hepatitis B Surface Antigen.

(b) Source. The source of the product shall be blood, plasma, serum, or tissue, obtained aseptically from nonhuman primates that have met the applicable requirements of §600.11 of this chapter, or from human donors whose blood is positive for the Hepatitis B Surface Antigen.

§ 660.41 Processing.

(a) Method. The processing method shall be one that has been shown to yield consistently a specific and potent final product, free of properties which would adversely affect the test results when the product is tested by the methods recommended by the manufacturer in the package insert. The product and all ancillary reagents and materials supplied in the package with the product shall be manufactured in a manner that will reduce the risk of transmitting type B viral hepatitis.

(b) Ancillary reagents and materials. All ancillary reagents and materials supplied in the package with the product shall meet generally accepted standards of purity and quality and shall be effectively segregated and otherwise manufactured in a manner that will reduce the risk of contaminating the product and other biological products. Ancillary reagents and materials accompanying the product, which are used in the performance of the test as described by the manufacturer’s recommended test procedures, shall have been shown not to affect adversely the product within the prescribed dating period.

(c) Final container. A final container shall be sufficiently transparent to permit visual inspection of the contents for presence of particulate matter and increased turbidity. The effectiveness of the contents of a final container shall be maintained throughout its dating period.

(d) Date of manufacture. The date of manufacture of Hepatitis B Surface Antigen that has been iodinated with radioactive iodine (125I) shall be the day of labeling the antibody with the radionuclide.

§ 660.43 Potency test.

To be satisfactory for release, each filling of Hepatitis B Surface Antigen shall be tested against the Reference Hepatitis B Antiserum Panel and shall be sufficiently potent to be able to detect the antibody in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.