Food and Drug Administration, HHS

§ 660.46 Samples; protocols; official release.

(a) Samples. (1) For the purposes of this section, a sample of product not iodinated with $^{125}$I means a sample from each filling of each lot packaged as for distribution, including all ancillary reagents and materials; and a sample of product iodinated with $^{125}$I or unlyophilized HBsAg-coated red blood cells means a sample from each lot of diagnostic test kits in a finished package, including all ancillary reagents and materials.

(2) Unless the Director, Center for Biologics Evaluation and Research, determines that the reliability and consistency of the finished product can be assured with a smaller quantity of sample or no sample and specifically reduces or eliminates the required quantity of sample, each manufacturer shall submit the following samples to the Director, Center for Biologics Evaluation and Research (see mailing addresses in §600.2 of this chapter), within 5 working days after the manufacturer has satisfactorily completed all tests on the samples:

(1) A sample of product not iodinated with $^{125}$I shall be tested against the Reference Hepatitis B Antiserum Panel and shall be sufficiently potent to detect the antibody in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.

(2) A sample of product iodinated with $^{125}$I or unlyophilized HBsAg-coated red blood cells shall be tested for incorporation of radioactivity.

(3) A sample of product iodinated with $^{125}$I shall be tested for radioactivity and labeled with $^{125}$I.

(4) A sample of product unlyophilized HBsAg-coated red blood cells shall be tested for viability of red blood cells.

(b) Protocols. (1) Each manufacturer shall conduct each test as described in the package insert and in §660.44 of this part.

(2) Each manufacturer shall submit the results of each test to the Director, Center for Biologics Evaluation and Research, within 5 working days after the test is completed.

(3) Each manufacturer shall conduct each test at least twice and shall provide the Director, Center for Biologics Evaluation and Research, with the results of each test.

(c) Official release. (1) Each manufacturer shall submit a copy of each test report to the Director, Center for Biologics Evaluation and Research, within 5 working days after the test is completed.

(2) Each manufacturer shall provide the Director, Center for Biologics Evaluation and Research, with a copy of each test report within 5 working days after the test is completed.

(3) Each manufacturer shall provide the Director, Center for Biologics Evaluation and Research, with a copy of each test report within 5 working days after the test is completed.

(4) Each manufacturer shall provide the Director, Center for Biologics Evaluation and Research, with a copy of each test report within 5 working days after the test is completed.

§ 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 detect the antibody in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.

§ 660.44 Specificity.

Each filling of the product shall be specific for Hepatitis B Surface Antigen as determined by specificity tests found acceptable to the Director, Center for Biologics Evaluation and Research.

§ 660.45 Labeling.

In addition to the requirements of §§610.60, 610.61, and 809.10 of this chapter, the labeling shall bear the following:

(a) The “d and y” antigen subtype and the source of the product to follow immediately the proper name on both the final container label and the package label. If the product is intended to identify antibodies to the “r and w” antigen subtype, the antigen subtype designation shall include the “r and w” antigen subtype.

(b) The name of the test method(s) recommended for use of the product on the package label and on the final container label, when capable of bearing a full label (see §610.60(a) of this chapter).

(c) A warning on the package label and on the final container label stating that the product is capable of transmitting hepatitis and should be handled accordingly.

(d) The package shall include a package insert providing (1) detailed instructions for use, (2) an adequate description of all recommended test methods, and (3) warnings as to possible hazards, including hepatitis transmitted in handling the product and any ancillary reagents and materials accompanying the product.
§ 660.50 Anti-Human Globulin

(a) Proper name and definition. The proper name of this product shall be Anti-Human Globulin which shall consist of one or more antiglobulin antibodies identified in §660.55(d).

(b) Source. The source of this product shall be either serum from animals immunized with one or more human serum globulins or protein-rich fluids derived from stable immunoglobulin-secreting cell lines maintained either in tissue cultures or in secondary hosts.

§ 660.51 Processing.

(a) Processing method. (1) The processing method shall be one that has been shown to yield consistently a specific, potent final product, free of properties that would adversely affect the product for its intended use throughout its dating period.

(2) Anti-IgG, –C3d (polyspecific) reagents and anti-IgG products may be colored green.

(3) Only that material which has been fully processed, thoroughly mixed in a single vessel, and filtered shall constitute a lot. Each lot shall be identified by a lot number.

(4) A lot may be subdivided into sublots which shall be identified by the lot number to which has been added a distinctive prefix or suffix. If lots are to be subdivided, the manufacturer...