§ 660.36  Samples and protocols.

(a) The following shall be submitted to the Center for Biologics Evaluation and Research Sample Custodian (ATTN: HFM–672) (see mailing addresses in § 600.2 of this chapter), within 30 days after each routine establishment inspection by FDA.

(i) From a lot of final product, samples from a cell panel intended for identification of unexpected antibodies. The sample shall be packaged as for distribution and shall have at least 14 days remaining in the dating period when shipped to the Center for Biologics Evaluation and Research.

(ii) A protocol which shall include the following:

(1) Complete test records of at least two donors of the samples submitted, including original and confirmation phenotyping records.

(2) Bleeding records or receipt records which indicate collection date, volume, and HBsAg test results.

§ 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.