

(2) *Unlicensed in vitro diagnostic biological products.* Blood, plasma, or serum that is reactive when tested for hepatitis B surface antigen or that was collected from a donor known to be reactive for hepatitis B surface antigen may be used in manufacturing unlicensed in vitro diagnostic biological products including clinical chemistry control reagents if all of the following conditions are met:

(i) The final product cannot be prepared from blood, plasma, or serum that is nonreactive when tested for hepatitis B surface antigen, due either to the nature or to the scarcity of the final product.

(ii) The label of the source blood, plasma, or serum states conspicuously that either it is reactive when tested for hepatitis B surface antigen and it may transmit viral hepatitis; or that the source blood, plasma, or serum was collected from a donor known to be reactive for hepatitis B surface antigen and it may transmit viral hepatitis, although confirmatory hepatitis testing has not been done.

(iii) The manufacturer of the source blood, plasma, or serum obtains written assurance from the manufacturer(s) of the final unlicensed product that package labels of all unlicensed products will conspicuously state, as required by §809.10(a)(4) of this chapter, that the product was prepared from blood, plasma, or serum that was reactive when tested for hepatitis B surface antigen and it may transmit viral hepatitis; or that the source material was collected from a donor known to be reactive for hepatitis B surface antigen and it may transmit viral hepatitis, although confirmatory hepatitis testing has not been done.

(iv) At the time of shipment, the Director, Center for Biologics Evaluation and Research (HFB-1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, is notified in writing of each shipment of source blood, plasma, or serum signifying the kind and the amount of source material shipped, the name and address of the consignee, the date of shipment, and the manner in which such source material was labeled. Such shipments shall not be subject to the requirements of paragraph (b)(3) of this section.

(e) *Manufacturing responsibility.* When the radioimmunoassay method for hepatitis B surface antigen testing is performed by personnel other than those of the facility collecting the blood, plasma, or serum, as provided in paragraph (b) of this section, it shall not be considered as divided manufacturing as described in §610.63, provided the following conditions are met:

(1) The collecting facility has obtained a written agreement that the testing laboratory will permit authorized representatives of the Food and Drug Administration to inspect its testing procedures and facilities during reasonable business hours.

(2) The testing laboratory will participate in any proficiency testing programs undertaken by the Center for Biologics Evaluation and Research, Food and Drug Administration.

(f) The information collection requirements in paragraph (d) of this section were approved by the Office of Management and Budget and assigned OMB control number 0910-0136.

(Information collection requirements contained in paragraph (b)(4) were approved by the Office of Management and Budget under control number 0910-0168)

[40 FR 29710, July 15, 1975, as amended at 48 FR 23181, May 24, 1983; 49 FR 23834, June 8, 1984; 49 FR 26718, June 29, 1984; 51 FR 15607, Apr. 25, 1986; 55 FR 11013 and 11014, Mar. 26, 1990]

#### **§610.41 History of hepatitis B surface antigen.**

A person known to have previously tested positive for hepatitis B surface antigen, testing positive, or both, may not serve as a donor of human blood, plasma, or serum, except that under §640.120 of this chapter, such a donor may serve as a source of hepatitis B surface antigen for the manufacture of hepatitis B vaccine or the preparation of a diagnostic product for laboratory tests, or a person known to have previously tested positive for hepatitis B surface antigen may serve as a source of antibody to hepatitis B surface antigen for the preparation of a biological product or a diagnostic product for laboratory tests.

[48 FR 23182, May 24, 1983, as amended at 57 FR 10814, Mar. 31, 1992]