Pre-Licensing Inspection for Immunization (7/7/88)

Date: 7 July 1988

From: Director, Center for Biologics Evaluation and Research

Subject: Discontinuance of Pre-Licensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines

To: All Licensed Source Plasma Manufacturers

Pre-license inspections will no longer be required prior to approval of product license amendments for Source Plasma collected from donors immunized with licensed tetanus, rabies and hepatitis B vaccines according to the approved immunization schedules provided in the manufacturer's package insert. Product license amendments must be submitted for each antigen and the following documentation should be submitted in addition to the requirements under Section Y, Immunization of Donors, Form FDA 2600:

1. Complete donor records for at least 5 donors including:

a. Records for titers at 2 months or more post initial immunization.

b. What determines whether booster immunizations are administered?

c. Volume, route and amount of antigen administered.

d. Criteria for evaluation of donor response.

e. Copy of informed consent.

2. Summary of any adverse reactions encountered during the immunization schedule to date.

In addition, we recommend keeping records in a format that permits easy retrieval and analysis of all adverse reactions related to immunization.

Immunization procedures should not begin until a reference number has been assigned. Units of Source Plasma collected from immunized donors may not be shipped until the amendment has been approved.

For further information or clarification, contact Blood Bank Practices Laboratory, Division of Blood and Blood Products, CBER at (301) 496-0952.

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