Criteria for Exemption of Lot Release (8/26/88)

Date: August 26, 1988

From: Director, Center for Biologics Evaluation and Research

Subject: Criteria for Exemption of Lot Release

To: Licensed Manufacturers of Blood Grouping Reagents

This is to notify you that effective immediately, the Center for Biologics Evaluation and Research (CBER) will consider requests for exemption from official product lot release of Blood Grouping Reagent specificities: Anti-A; Anti-B; and Anti-D (slide and modified tube high protein) produced from human blood.

The following information must be provided for each specificity for which the exemption is requested:

1. A summary of all lots manufactured for each specificity identifying the total number of lots processed and the number of lots prepared initially for licensure but not submitted for release.

2. A summary of the disposition of those lots manufactured and not submitted for release.

3. A detailed summary of all valid complaints to include labeling errors, presence of contaminating antibodies, decreased potency and presence of particulate matter; and the actions taken by the manufacturer for each product not identified.

4. Annual summary report of all lots manufactured, released, and distributed.

The above documentation should cover a period of three years of manufacturing prior to the date of the request.

Subsequent to an acceptance of an exemption, each manufacturer will be required to submit one lot of each specificity annually for surveillance purposes.

Additionally, there must be a history of satisfactory establishment inspection by the FDA during the immediate proceeding three years.

Acceptance of this exemption does not exempt the manufacturer from appropriate ongoing in-house stability studies of representative lots of each specificity for review at periodic inspections. (21 CFR 660.21)

Paul D. Parkman, M.D.