

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 25 1984

Our Reference No. HJ-367

Michael D. Rosell, Ph.D.
Armour Pharmaceutical Co.
303 South Broadway
Tarrytown, NY 10591

Dear Dr. Rosell:

The amendment to your product license application for Antibovine Bacter (human) to include an optional heat treatment step has been approved.

The dating period for the product shall be two years when stored at 2-8°C. Within this period, the product may be stored for up to six months at room temperature not to exceed 30°C.

The first production lot should be placed on stability for the entire dating period. Results of this study as well as the results of ongoing stability studies should be submitted to the Office of Biologics Research and Review at the appropriate intervals.

Please submit three copies of final printed labeling at the time of use and include part II of the transmittal form with completed implementation information. In addition, we request that advertising and promotional labeling be submitted for review at the time of initial publication of any advertisement and at the time of initial dissemination of promotional labeling.

Sincerely yours,

William C. Weber, M.D.
Acting Director
Office of Biologics Research and Review
National Center for Human Blood and Biologics

cc: C. Books, HJ-830

PREPARED BY: HJ-830/12-10-83
REVISOR BY: HJ-830/12-10-83
Director
National Center for Human Blood and Biologics

FILE
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DATE	REMARKS	DATE	REMARKS	DATE	REMARKS	DATE	REMARKS
1/25/84	GRO-C	1/25/84	GRO-C	1/25/84	GRO-C	1/25/84	GRO-C
1/25/84	GRO-C	1/25/84	GRO-C	1/25/84	GRO-C	1/25/84	GRO-C
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CONFIDENTIAL
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METHODS OF VIRAL INACTIVATION CURRENTLY UNDER STUDY

1. WET HEAT 60°C, 10 HOURS
2. DRY HEAT 68°C, 72 HOURS
3. COPPER PHENANTHROLINE
4. LIPID EXTRACTANTS
 - a. CHLOROFORM, MeCl_2 , EtOAc, Hexane, AmOAc
 - b. SURFACTANTS e.g., TWEENS, DEOXYCHOLATE
 - c. ETHER
 - d. TRI N-BUTYL PHOSPHATE
 - e. SUPERCRITICAL GASES

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METHODS OF VIRAL INACTIVATION CURRENTLY UNDER STUDY

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EXPERIMENTAL PROTOCOL

All quantitations of the SAIDS agent will be performed in tissue culture.

- A) Spike human plasma with concentrated SAIDS agent. Determine its distribution during cryoprecipitate collection (precipitate and effluent).
- B) Spike dissolved human cryoprecipitate with concentrated SAIDS agent. Determine its distribution during isolation/purification of AHF concentrate. The concentrate product is used for in vivo transmission experiments.
- C) Spike AHF concentrate with concentrated SAIDS agent. During inactivation procedure (heat, e.g.) follow the inactivation kinetics. The final treated product is used for in vivo transmission experiments.

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MILESTONES

EVENTS	DATE
HBV CHIMP INACTIVATION STUDY - BEGIN	Q1 1984
COMPLETION OF ABOVE	Q1 1985
INITIATE PREPARATION OF PR LOTS	Q3 1984
COMPLETE ASSESSMENT OF CuPh INDUCED PROTEIN CHANGES	Q3 1984
FILE PLA AMENDMENT	Q3 1985
FEASIBILITY STUDIES WITH INACTIVATION STUDIES.....	Q3 1984
CHIMP STUDIES WITH PREFERRED METHOD	Q4 1984

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