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| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION | | DISTRICT ADDRESS AND PHONE NUMBER CBER 8800 ROCKVILLE PIKE BETHESDA MD 20892 | |
| NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: ROBERT MYERS, D.V.M. | | PERIOD OF INSPECTION July 29-31, 1992 | C. F. NUMBER |
| TITLE OF INDIVIDUAL CHIEF DIVISION OF BIOLOGIC PRODUCTS | | TYPE ESTABLISHMENT INSPECTED BIOLOGICAL MANUFACTURER | |
| FIRM NAME MICHIGAN DEPARTMENT OF PUBLIC HEALTH | | NAME OF FIRM, BRANCH OR UNIT INSPECTED SAME | |
| STREET ADDRESS 3500 N. LOGAN | | STREET ADDRESS OF PREMISES INSPECTED SAME | |
| CITY AND STATE (Zip Code) LANSING MI 48909 | | CITY AND STATE (Zip Code) SAME | |
| DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED: | | | |
| 1. Changes in the manufacturing methods for albumin were not submitted as amendments to the product license application for prior to releasing the material for distribution by the American Red Cross. | | | |
| 2. Package labels for AHF does not contain "Caution: New Drug Limited by Federal Law to Investigational Use" warning. | | | |
| 3. Formulation and aseptic filtration of final bulk product is not performed in a controlled environment. | | | |
| 4. Cleaning and sanitizing agents are not tested and released by the QC department. | | | |
| 5. The sterile bulk product tanks are not pressurized during storage and time limits are not established for the period between sterile filtration and filling. | | | |
| 6. Temperature sensitive materials are stored in a warehouse where temperature is neither controlled nor monitored. | | | |
| 7. The following SOPs were not available in the area where procedures are performed: <ul style="list-style-type: none"> a. Pyrogen testing b. Receiving and Checking-In Plasma c. Autoclave loading patterns and operation in Bldg. filling area. | | | |
| 8. Records observed were incomplete or inaccurate in that: <ul style="list-style-type: none"> a. Operators do not initial entries of guinea pig weights. b. Changes to the records were not always initialed. c. Temperature record for the 5/12/92 shipment of fresh frozen plasma from the American Red Cross Blood Services S. E. Michigan Region contained two temperatures at receipt, one of which was above specifications. d. Cleaning records for reaction tank were not verified by the shift supervisor on 7/27/92. | | | |
| 9. There is no program to provide training in current good manufacturing practices. | | | |
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE John A. Etter, Jr. | EMPLOYEE(S) NAME AND TITLE (Print or Type) Glen D. Jones, Staff Follow JOHN A. CECIMAN, Jr. Chief Div. Dir. | DATE ISSUED 7-31-92 |

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| CITY AND STATE (Zip Code) LANSING, MI 48909 | | CITY AND STATE (Zip Code) SAME | |
| DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED: | | | |
| 10. There are no established limits as to the number of times albumin can be reprocessed. | | | |
| 11. Several tanks and centrifuges do not have permanent identification numbers. | | | |
| 12. Calibration and equipment maintenance was not always current in that: | | | |
| a. Chart recorder for freezer had no calibration sticker. | | | |
| b. Chart recorder for refrigerator had a calibration sticker with a due date of Sept. 1991. | | | |
| c. There were no calibration stickers for the temperature controllers and monitors. | | | |
| d. A pH meter and balance in room had no current calibration sticker. | | | |
| 13. No SOP exists to describe procedures for handling potentially infectious material, therefore: | | | |
| a. Workers are not required to wear gloves, face masks, or other protective clothing when handling units of plasma. | | | |
| b. Broken bags of plasma are poured down a sink. | | | |
| c. Knife blades used to open plasma bags are disposed of in a container that is not identified as biohazardous waste. | | | |
| d. Boxes containing spilled plasma are bundled with other boxes and placed outside for pickup. | | | |
| 14. Rejected process materials are neither clearly identified or quarantined in freezer | | | |
| 15. Sampling plan for raw materials does not provide for a representative sample of a lot, and some CMP materials are always released without any sampling or testing. | | | |
| 16. Plant steam is used in the autoclave and lyophilizer in Bldg. | | | |
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Glen D. Jones John A. Elter | EMPLOYEE(S) NAME AND TITLE (Print or Type) Glen D. Jones, Staff Fellow John A. Elter, Chief, Division of Biologics | DATE ISSUED 7-31-92 |