

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER CBER / FDA 301 295-9049 1401 Rockville Pike Rockville MD 20852-1448	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Dr. Robert Meyer Myers		PERIOD OF INSPECTION MAY 4 to May 7 1993	C. F. NUMBER
TITLE OF INDIVIDUAL Responsible Head		TYPE ESTABLISHMENT INSPECTED Biologic	
FIRM NAME Michigan Department of Public Health		NAME OF FIRM, BRANCH OR UNIT INSPECTED ← Same	
STREET ADDRESS 3500 North 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. In bldg - , room . . . , the -30°C freezer contained several totes that were not secured with plastic cable locks e.g.,			
2. Reaction tank in room in the fractionation area had an undated record of cleaning tag affixed.			
3. In bldg in room ; the buffer, lot prepared on 4/22/93 did not bear an expiration date.			
4. The -30°C cold storage area in room contained a quarantined cage that was not secured.			
5. In bldg in room several tanks (e.g., had no cleaning tags affixed.			
6. part # with a test date of 3/9/93 did not bear an expiration date.			
7. In bldg room the animal area for mice, the last calibration for the chart recorder was 7/90.			
8. GMP. was labeled 7-27-93 as an expiration date, but the date in the log book record for GMP testing gave the expiration date as 7-28-93.			
9. In bldg in the hallway outside of room where cryoprecipitate is stored, the chart recorder was past due date for calibration.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel C. Lewis Eleanor Koo Bobby Mason	EMPLOYEE(S) NAME AND TITLE (Print or Type) Daniel C. Lewis, CSO ELEANOR Koo, Biologist Bobby Mason, HSO	DATE ISSUED 5/7/93

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
<p>10. In bldg in room instruments lacked calibration stickers, maintenance SOPs, or validation data, e.g.,</p> <p>11. The sterility suite in bldg is inadequate for proper sterility testing, i.e., there is no separate sample staging area, no gowning area, and the area is not restricted to unwanted traffic.</p> <p>12. In room the aseptic filling suite, there is no volumetric sampling for vials (airborne bacteria).</p> <p>13. There is no SOP for conducting a recall.</p> <p>14. There are no time limits for production processes, e.g., the filtration step for albumin.</p> <p>15. There is no validation of electronic calculations used <sup>SK 5-6-93</sup> performed by scales used in the formulation of product e.g., the scale in room used for weighing powder.</p> <p>16. There is no annual review of production batch records.</p> <p>17. There are insufficient personnel to assure compliance with current GMP regulations, e.g., failure to report changes in manufacturing, failure to maintain calibration records adequately, failure to adequately validate equipment used in the formulation or testing of product.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Daniel C. Kearns</i> <i>Eleanor Kov</i> <i>Bobby Mason</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) DANIEL KEARNS, CSO ELEANOR Kov, Biologist BOBBY MASON, HSO	DATE ISSUED 5/7/93

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