

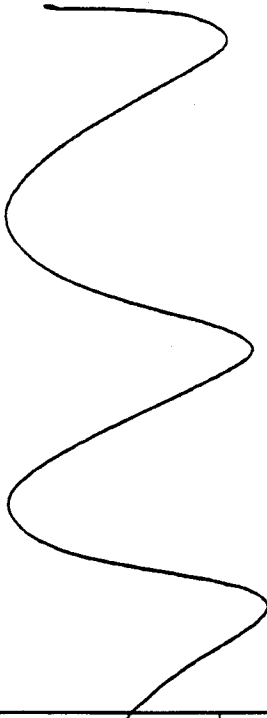
DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER CBER HFM-655 1401 Rockville Pike Rockville MD 20852-1448	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Dr Robert Myers		PERIOD OF INSPECTION May 31 - June 3 1994	C. F. NUMBER
TITLE OF INDIVIDUAL Responsible Head		TYPE ESTABLISHMENT INSPECTED Biologics	
FIRM NAME Michigan Dept. of Public Health		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
STREET ADDRESS 3500 Logan street		STREET ADDRESS OF PREMISES INSPECTED	
CITY AND STATE (Zip Code) Lansing MI 48914		CITY AND STATE (Zip Code)	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
<p>1. There are insufficient personnel to assure compliance with current GMP regulations, e.g., failure to maintain calibration records adequately, failure to maintain environmental controls adequately in that production area temperatures were above 80°F, and failure to submit changes to CBER.</p> <p>2. MDPH has not given the responsible head adequate authority relating to matters involved in the manufacture of licensed biologics in that: He has no direct authority over building engineers and he has been unable to fill open personnel positions.</p> <p>3. There is no annual review of production batch records.</p> <p>4. There are no established time limits or records concerning room temperature exposure of final containers during labeling operations.</p> <p>5. There is no validation data supporting the expiration dating of media used in the manufacture of Pertussis vaccine.</p> <p>6. Raw materials stored in an unapproved warehouse, building i.e., no LLA supplement has been submitted for this area.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel Kearns Debra L Jansen	EMPLOYEE(S) NAME AND TITLE (Print or Type) DANIEL KEARNS CSO DEBRA L JANSEN Biologist	DATE ISSUED 6-3-94

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER CBER HFM-655 301 594-2049 1401 ROCKVILLE PIKE ROCKVILLE MD 2085-1448	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: ROBERT MYERS DVM		PERIOD OF INSPECTION 5-31-94/6-3-94	C. F. NUMBER
TITLE OF INDIVIDUAL MICHIGAN DEPT. OF PUBLIC HEALTH		TYPE ESTABLISHMENT INSPECTED	
FIRM NAME		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
STREET ADDRESS		STREET ADDRESS OF PREMISES INSPECTED	
CITY AND STATE (Zip Code)		CITY AND STATE (Zip Code)	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
7. IN PROCESS MATERIALS IN ROOM BLDG WERE NOT LABELLED. INCUBATOR			
8. <del>THERE IS NO CLEANING VALIDATION DATA FOR PRODUCT</del> CS 6-3-94 PRODUCT CONTACT EQUIPMENT USED TO FILL MULTIPLE FINAL PRODUCTS DOES NOT HAVE VALIDATED CLEANING DATA DEMONSTRATING REMOVAL OF CLEANING AGENT OR PREVIOUSLY FILLED FINAL PRODUCTS.			
9. THERE WAS NO MONITORING OF TEMPERATURE OF A REFRIGERATOR IN ROOM BLDG USED TO STORE PERTUSSIS SEED CULTURES AND IN-PROCESS MATERIALS.			
10. SOP'S ARE NOT ALWAYS AVAILABLE IN AREAS WHERE UTILIZED: EG. NO SILKONIZATION SOP IN ROOM BLDG NO GOWNING SOP'S IN ROOM BLDG ROOM BLDG OR TETANUS FACILITY, BLD			
11. BATCH RECORD REVIEW FOR DTP LOT PERTUSSIS POTENCY TESTING RECORD FOR TEST REVEALS AN INCONSISTENCY BETWEEN DILUTION SCHEME AND THE DOSE PER MOUSE. THIS INDICATES THAT WHAT IS RECORDED IS NOT NECESSARILY WHAT IS PERFORMED.			
12. THE PERTUSSIS POTENCY TEST SOP HAS NO SURVIVAL LIMITS SET FOR THE CHALLENGE DOSE CONTROL MICE			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel Kearns DEBRAH L. JANSEN	EMPLOYEE(S) NAME AND TITLE (Print or Type) DANIEL KEARNS CSO DEBRAH L. JANSEN BIOLOGIST	DATE ISSUED 6-3-94

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER CBER HFM-655 301-594-3049 1401 ROCKVILLE PIKE ROCKVILLE, MD 20852	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: ROBERT MYERS, DVM		PERIOD OF INSPECTION 5-31-94/6-3-94	C. F. NUMBER
TITLE OF INDIVIDUAL MICHIGAN DEPT. OF PUBLIC HEALTH		TYPE ESTABLISHMENT INSPECTED	
FIRM NAME		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
STREET ADDRESS		STREET ADDRESS OF PREMISES INSPECTED	
CITY AND STATE (Zip Code)		CITY AND STATE (Zip Code)	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

13. THERE WERE RAW MATERIALS IN RELEASE AREA OF BLDG  
 EXPIRED  
 IE. LOT EXPIRED 4-14-93
  
14. MATERIALS STORED IN ROOM BLDG ROOM BLDG  
 AND ROOM BLDG WERE NOT SEGREGATED APPROPRIATELY  
 IE ROOM BLDG - CONTAINED SALINE LOT SHELVED IN  
 SPACE LABELLED FOR DIPHTHERIA PURIFIED TOXIN.
  
15. CORNING TISSUE CULTURE FLASKS, USED TO INITIATE VACCINE  
 CULTURES. STORED IN BLDG, ARE NOT HANDLED AS G.M.P  
 MATERIAL AND NOT SUBJECT TO RELEASE TESTING.



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel Kearns Deborah L. Jensen	EMPLOYEE(S) NAME AND TITLE (Print or Type) DANIEL KEARNS CSO DEBORAH L. JENSEN RIDGESS	DATE ISSUED 6-3-94
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# ADDENDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER 301 CBER HFM-655 594-2049 1401 ROCKVILLE PIKE ROCKVILLE, MD 20852-1448	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Dr Robert Myers		PERIOD OF INSPECTION May 31 - June 3 1994	C. F. NUMBER
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CITY AND STATE (Zip Code) Lansing MI		CITY AND STATE (Zip Code)	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
<ol style="list-style-type: none"> <li>1. Filling of Botulinum Toxin occurs in room building without an approved establishment license supplement.</li> <li>2. There is no use log for the filling line in room building</li> <li>3. There is no cleaning/use log for the filling machine in room, building</li> <li>4. There is no validation data for the vision inspection system on the labelling machine, MDPH ID number in room, building</li> </ol>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel Kearns Deborah L. Jansen	EMPLOYEE(S) NAME AND TITLE Daniel Kearns Deborah L. Jansen Biologist	DATE ISSUED 6-20-94