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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER Food and Drug Administration 850 Third Avenue Brooklyn, NY 11232-1593 Tel. (718) 965-5300	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Dr. Arnold E. Eggers		PERIOD OF INSPECTION 4/10-19/95	C. F. NUMBER None
TITLE OF INDIVIDUAL Sponsor/Clinical Investigator		TYPE ESTABLISHMENT INSPECTED Clinical Study	
FIRM NAME SUNY Health Sciences Center		NAME OF FIRM, BRANCH OR UNIT INSPECTED Dept. of Neurology	
STREET ADDRESS 450 Clarkson Ave		STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Brooklyn, New York 11203		CITY AND STATE (Zip Code) Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:
IND [REDACTED] " [REDACTED] " (also entitled Experimental [REDACTED] of [REDACTED]) was reviewed for all eight patients.

- The investigation was not conducted according to the protocol, which required the subcutaneous (SC) injection of [REDACTED]. The eight (8) patients that were entered into this study received intralymphatic (IL) injections. One patient (FS) also received intravenous (IV) and intrasplenic (IS) injections. Another patient (LK) also received an intravenous (IV) injection.
- The investigator's raw data did not always correlate to information contained in submissions that were sent to FDA.

PT.	Route Administration & # injections (per raw data)	Submission Dates with discrepant data
FC	IL - 5 SC - 2	1/26/95 IL - 3 SC - 0
LK	IL - 8 IV - 1	7/26/94 IL - 6 IV - 0 1/26/95 IV - 0
FS	IL - 7 IS - 9 IV - 5	7/26/94 IL - 5 IV - 4 10/13/94 IL - 5
FV	IL - 6 SC - 1	1/26/95 IL - 6 SC - 0

PT.	[REDACTED] used (per raw data)	reported in submissions
FC	[REDACTED] and [REDACTED]	8/30/94 & 1/26/95 [REDACTED] only
BS	[REDACTED] and [REDACTED] [REDACTED] injections # 1, 2 & 3 weekly 4th injection one month later	8/30/94 & 1/26/95 [REDACTED] only 8/30/94 18.6 million 1/26/95 qw x 4 (every week)
LK	[REDACTED] and [REDACTED] [REDACTED]	8/30/94 [REDACTED] 1/26/95 [REDACTED] and [REDACTED] [REDACTED]
FV	[REDACTED] and [REDACTED] [REDACTED]	8/30/94 [REDACTED] and [REDACTED] [REDACTED]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>James A. Liubicich</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) James A. Liubicich, CSO	DATE ISSUED 4/19/95
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Dept. of Neurology

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Brooklyn, New York 11203

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DURING AN INSPECTION OF YOUR FIRM (I) ~~WAS~~ OBSERVED:

3. Exclusion criteria for this study includes allergies to beef products, penicillin and streptomycin. This was not documented for any of the 8 patients.
4. The treatment plan requires that CBCs and chemistry profiles be ordered as indicated clinically, but not less than every 3 months. There is no documentation of these for any of the 8 patients.
5. The informed patient consent forms lacked the following:
 - a. disclosure about the expected duration of subject's participation
 - b. a statement about providing a contact for answers to questions about the research, research subject's rights and research-related injury to the subject
 - c. one of the procedures to be used, CT scan, is not mentioned
 - d. that injections could be intralymphatic or intravenous besides the stated "under the skin" (PT. FC)
6. The informed patient consent form for patient FC is not dated.
7. The test article administered to subjects has not been tested for sterility or endotoxins.
8. Records for the manufacturing of the test article does not indicate each processing step. The time, temperature and pH for the manufacturing processes are not documented.
9. The spacer used in the manufacture of the [REDACTED] is between 10 - 12 years old. The stability of this product has not been determined.
10. The amount of [REDACTED] (the [REDACTED] used in the manufacturing process) that is [REDACTED] to the patient [REDACTED] has not been quantified.
11. The storage temperature for [REDACTED] was -70°C according to the protocol. The investigator found that this temperature inactivated the [REDACTED]. Four (4) patients were treated with the inactivated [REDACTED].

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OF THIS PAGE

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James A. Liubicich

EMPLOYEE(S) NAME AND TITLE (Print or
Type)

James A. Liubicich, CSO

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