M E M O R A N D U M DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE : April 6, 2000

FROM : Joseph P. Salewski, Bioresearch Monitoring, HFM-650
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 301-827-6221 FAX: 301-827-6748

CP: 7348.811
PAC: 41811G
Priority: TOP-ORA concurrence #2000040501
Due Date: 60 days from April 17, 2000

PLEASE NOTE: A conference call to discuss this set of inspections will be held on April 13, 2000, at 1:00pm EDT. Reading materials relevant to the inspections will be transmitted separately by ORA/ORA/DEIO prior to the Districts call and are to be reviewed prior to the conference call.

TO: Director, Investigations Branch:

Atlanta District Office, HFR-SE150
Baltimore District Office, HFR-CE250
Chicago District Office, HFR-CE650
Cincinnati District Office, HFR-CE450
Dallas District Office, HFR-SW150
Denver District Office, HFR-SW240
Detroit District Office, HFR-CE750
Florida District Office, HFR-SE250
Kansas City District Office, HFR-SW350
Los Angeles District Office, HFR-PA250
Minneapolis District Office, HFR-CE850
New Orleans District Office, HFR-SE450
New England District Office, HFR-NE250
New York District Office, HFR-NE150
Philadelphia District Office, HFR-CE150
San Francisco District Office, HFR-PA150
Seattle District Office, HFR-PA350

General Instructions

We request that an inspection of the following clinical investigators (see attached) be performed in accordance with CP 7348.811 using the attached list of questions. Periodic status updates on the progress towards completion of the assignment are to be submitted by the Districts to DEIO.

Background

Gene therapy studies in the United States have come under close scrutiny in recent months. The Center for Biologics Research and Review (CBER) has determined that the status of biological gene therapy trials should be reviewed. Currently, there are no licensed gene therapy products and the majority of ongoing gene therapy IND clinical trials are at the Phase 1 or Phase 2 stage. Therefore, a sampling of all studies submitted to CBER will be inspected to determine their level of compliance with current regulations. This survey is a random sampling of all studies submitted under active INDs.

Please note that a description of the vector and its use are provided in the protocol, sent to the Districts under express delivery service.

Special Request

Please conduct a clinical investigator inspection following the compliance program. In addition to the attached questionnaire, please provide answers to the following questions:

1. Where was the vector produced?
2. How many vectors are used at this site?
3. How many subjects have been treated with each vector?
4. Was anyone denied treatment and why?
5. Who monitored the study and how often was it monitored?
6. Obtain a list of all other gene therapy protocols that the CI is conducting.
7. How were subjects recruited for the study (advertisement, personal patient, or referral)?
8. Did the principal investigator receive monetary compensation for each subject recruited?
9. Did the investigator receive advisories regarding adverse events occurring at other locations from the sponsor?

Please contact Dr. Maritza McIntyre at 301-827-0620 if you have any technical questions regarding gene therapy. For questions about the assignment, I can be reached at 301-827-6350.

Reporting

If the District has more than one inspection assigned, submit the information on an as-completed basis. Do not hold the reports until all investigations have been completed. Upon completion of the inspection, FAX the 483 and summary questionnaire to HFM-650 at 301-827-6748.

On/about the 15th and 30th of each month, please notify DEIO/Michael Rogers via e-mail of the number of inspections completed to date and the anticipated date of submission of the final ERI for the District's portion of the assignment.

Please send the establishment inspection report by first class U.S. mail or overnight carrier to:

Joseph P. Salewski, HFM-650
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Joseph P. Salewski

Attachments:

List of clinical investigators
Questionnaire
Protocol
Informed Consent Form

CC:

HF-1	Henney
HFM-1	Zoon
HFM-650	Access/Chron
HFM-650	Cole
HFM-500	Siegel
HFM-515	Noguchi
HFC-230	McCormack
HFC-102	Lynch
HFC-130	Pierce
HFM-99	IND 6869, 7290, 4647, 6446, 5963, 7658, 6743, 6260, 8528, 8267, 6585, 6970, 7135, 6237, 8599, 7111, 6100, 6946, 5512, 7792, 6658, 4697, 6625, 7565, 6602, 8293, 7328, 8559, 4272, 5370

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