2-22-94

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 22 1994

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Steven K. Teplick, M.D.
c/o Saul H. Krenzel, Esq.
, Suite
Street
Philadelphia, PA 19107

Dear Dr. Teplick:

I have reviewed the record of the regulatory hearing conducted by Freddie Ann Hoffman, M.D., Presiding Officer, on December 12-13, 1991, concerning your eligibility to receive investigational new drugs. The report of the Presiding Officer which was sent to you on July 12, 1993, provided a 30-day period within which you could submit any comments you had on the report. This 30-day time period has passed and the Presiding Officer has not received any comments from you or your counsel. Thus, you had a full opportunity to comment on that report and chose not to do so.

Therefore, I am affirming and adopting the June 1993 Report of the Presiding Officer and have determined that you have repeatedly and deliberately failed to comply with the regulatory requirements regarding investigational new drugs. Specifically:

1. You violated 21 C.F.R. § 312.64(b) by failing to report the alarming adverse effects immediately to the sponsor.

2. You violated 21 C.F.R. § 312.64(b) by failing to report promptly to the sponsor adverse effects that may reasonably be regarded as caused by, or probably caused by, the investigational drug.

3. You violated § 312.66 by failing to report promptly to the IRB all unanticipated problems involving risk to human subjects.

4. You violated § 312.66 by failing to obtain IRB approval before making changes in research.

5. You violated § 312.60 by failing to conduct the investigation in accordance with the Investigator Statement.

6. You violated § 312.60 by failing to follow the investigational plan.

7. You violated § 312.62(b) by failing to prepare and maintain adequate and accurate records of all observations and other data pertinent to the investigation on each individual treated with the investigational drug.

8. You violated § 312.62(a) by failing to maintain adequate records of the disposition of the investigational drug.

9. You violated § 50.27 by failing to document informed consent.

10. You violated § 50.25 by failing to satisfy all of the requirements of informed consent.

In accordance with 21 C.F.R. § 312.70(b), you are hereby advised that you are no longer eligible to receive investigational new drugs. All such drugs in your possession should be promptly returned to their supplier.

Sincerely,

David A. Kessler, M.D.
Commissioner of Food and Drugs

cc: James S. Cohen, Esq.
Associate Chief Counsel for Enforcement
Food and Drug Administration
Office of the General Counsel
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR - 8 1994

REGISTERED MAIL
RETURN RECEIPT REQUESTED
RESENT TO CORRECTED ADDRESS

Steven K. Teplick, M.D.
c/o Saul H. Krenzel, Esq.
Saul Krenzel and Associates
1600 Lewis Tower Building 225
South 15th Street
Philadelphia, PA 19102

Dear Dr. Teplick:

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