

4/4/97
Bf**WARNING LETTER**Food and Drug Administration
Rockville MD 20857
APR - 2 1997**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED**Ref. No.: 97-HED-340-0301**

Dr. John B. Sapp, Jr.
Dean, College of Arts and Sciences
Texas Southern University
3100 Cleburne Avenue
Houston, Texas 77004

Dear Dr. Sapp:

During March 1997, Mr. Joel Martinez, Investigator, from the Food and Drug Administration (FDA), inspected the nonclinical laboratory of Sunday O. Fadulu, Ph.D., located in the Department of Biology. His purpose was to assess compliance with the Good Laboratory Practice (GLP) regulations; Title 21, Code of Federal Regulations, Part 58. At the same time, Mr. Martinez reviewed the records for two studies, six week and six month toxicity safety studies in rats.

During the inspection, Mr. Martinez found numerous serious deviations from the GLP regulations. His observations were listed on a form FDA 483 (copy enclosed), which was presented to, and discussed with Dr. Fadulu at the conclusion of the inspection.

The most significant deviations involved a failure to provide:

1. Raw data records regarding dosing and observations of the test system (21 CFR 58.190a).
2. Raw data records regarding test article characterization and stability (21 CFR 58.105a; 58.105b).
3. Analyses of the test article carrier mixture for determination of uniformity and stability (21 CFR 58.113a1; 58.113a2).
4. A functional Quality Assurance Unit (21 CFR 58.35).
5. An approved written protocol (21 CFR 58.120).

Because of the nature and severity of the deviations, we must recommend to the appropriate FDA new drug evaluation staffs that studies conducted in Dr. Fadulu's laboratory should not be used to support applications for research permits or marketing approvals, such as Investigational New Drug Applications (INDs) or New Drug Applications (NDAs).

The above description of our findings is not intended to be an all inclusive list of violations and

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deficiencies. This letter is notification that the GLP deficiencies observed during this inspection must be corrected before new nonclinical safety studies intended for submission to FDA are planned or begun. Prior to initiation of any further new studies, Dr. Fadulu should request from this office that his laboratory be reinspected.

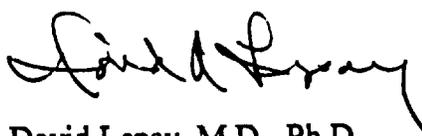
Please notify this office in writing within fifteen (15) days of receipt of this letter and indicate your intentions to immediately correct the GLP violations and/or assure the agency that there will be no further studies conducted which are subject to the GLP regulations until corrections are made and verified.

We consider this a serious matter and are interested in your response. Failure to respond may result in further agency action.

If you have any questions concerning these matters, or the Good Laboratory Practice regulations, please contact:

C. T. Viswanathan, Ph.D.
Associate Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
7520 Standish Place, Room 102
Rockville, Maryland 20855
Telephone: (301) 594-1023

Sincerely yours,



David Lepay, M.D., Ph.D.
Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

Enclosure: FDA 483

cc:
Sunday O. Fadulu, Ph.D.
Texas Southern University
Department of Biology
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