NOV 29 2001 WARNING LETTER

Food and Drug Administration
Rockville MD 20857

Certified Mail
Return Receipt Requested

Reference No: 01-HFD-45-1101

Wha Suk Eum
President
American Histolabs, Inc.
7605-F Airpark Road
Gaithersburg, MD 20879

Dear Mrs. Eum:

In September 2000, investigators from FDA's Baltimore District Office conducted an inspection at your facility to assess adherence to the Good Laboratory Practice (GLP) regulations, Title 21, Code of Federal Regulations (CFR), Part 58. The inspection covered your firm's activities as a histologic slide preparation service.

During the inspection, the FDA investigators found several departures from the GLP regulations. These findings were listed on an Inspectional Observations Form FDA-483 which was issued to you at the conclusion of the inspection. We have evaluated the report of this inspection and your response to FDA's request on February 6, 2001 for additional information and conclude that your firm failed to adhere to the GLP regulations. We emphasize that:

1. You failed to assure that there was a quality assurance unit (QAU) as described in § 58.35 [21 CFR 58.31 c)].

We found that since you terminated your private QAU contract in September of 1998 you failed to assure QAU oversight during the preparation of histology slides for GLP studies. We acknowledge your comment that [ ] audits your facility every 1-2 months. Although a sponsor may perform QAU audits of their own studies, the general process audits performed by [ ] do not fulfill the requirement for an in-process QAU inspection of each [ ] GLP study that you conduct [21 CFR 58.35(b 3]. Furthermore, QAU audits performed by [ ] of their own studies do not provide QAU oversight for studies by sponsors other than [ ] Your February 23, 2001 response indicating that personnel follow all applicable standard operating procedures does not relieve you of

the requirement to assure in-process QAU inspection of each GLP study that you conduct.

(2) You failed to maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility that contained all the elements required by the GLP regulations [21 CFR 58.35(b)(1)].

Specifically, the revised master schedule submitted to FDA on February 23, 2001 fails to list the current status of the studies.

The above discussion of violations is not intended to be an all-inclusive list of deficiencies at your facility. Failure to correct these violations may result in regulatory action without further notice. You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps that you have taken to correct these violations for your future studies.

If you have any questions concerning these matters, please contact:

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Sincerely,

Joanne L. Rhoads

Joanne L. Rhoads, M.D., M.P.H.
Acting Director
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research