

February 3, 1997

Docket No. 030-32506

License No. 19-07538-06

Michael A. Ussery, Ph.D.
Radiation Safety Officer
Antiviral Research Laboratory
Division of Antiviral Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-530
Rockville, MD 20857

SUBJECT: INSPECTION NO. 030-32506/97-001

Dear Dr. Ussery:

On January 22, 1997, Pamela J. Henderson of this office conducted a safety inspection, at 5516 Nicholson Lane, Kensington Maryland, of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Susan Papermaster and you, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed and categorizes each violation by severity level, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the

RETURN ORIGINAL TO
REGION I

9702100001 970203
PDR ADDCK 03032506
C PDR

1/1
12/97

M. A. Ussery, Ph.D.
Antiviral Research Laboratory

-2-

information from the public. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

ORIGINAL SIGNED BY:

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Docket No.: 030-32506
License No.: 19-07538-06

Enclosure:
Notice of Violation

cc w/enclosure:
Susan Papermaster, Safety Manager
State of Maryland

M. A. Ussery, Ph.D.
Antiviral Research Laboratory

-3-

Distribution: w/encl

PUBLIC

Nuclear Safety Information Center (NSIC)

Region I Docket Room (w/concurrences)

D. J. Holody, RI

DOCUMENT NAME: R:\WPS\MLDL\1907538.06

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/>	N	DNMS/RI	<input checked="" type="checkbox"/>			
NAME	PHenderson			JHenneman				
DATE	01/28/97			01/30/97		01/ /97		01/ /97