

## MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

**OFFICIAL RECORD COPY**

Licensee 1. Department of Health & Human Services-FDA Antiviral Research Laboratory (HFD-535) Division of Antiviral Drug Products (ODEII) 2. Center for Drug Evaluation and Research 5600 Fishers Lane Rockville, Maryland 20857		In accordance with the letter dated January 22, 1997, 3. License Number 19-07538-06 is amended in its entirety to read as follows: 4. Expiration Date February 28, 2002 5. Docket or Reference No. 030-32506	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Hydrogen 3 B. Carbon 14 C. Phosphorus 32 D. Sulphur 35 E. Chromium 51 F. Iodine 125 G. Iodine 131	A. Any B. Any C. Any D. Any E. Any F. Any G. Any	A. 50 millicuries B. 56 millicuries C. 50 millicuries D. 50 millicuries E. 30 millicuries F. 50 millicuries G. 25 millicuries	

## 9. Authorized use

A. through G. Research and development as defined in 10 CFR 30.4; animal studies.

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 5516 Nicholson Lane, Suite 300, Kensington, Maryland.
11. A. Licensed material shall be used by, or under the supervision of Michael A. Ussery, Ph.D., or Carl J. Nielsen.  
B. The Radiation Safety Officer for this license is Michael A. Ussery, Ph.D.
12. Licensed material shall not be used in or on human beings.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

19-07538-06

Docket or Reference Number

030-32506

Amendment No. 01

15. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
  - A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - A. Application dated August 9, 1991
  - B. Letter dated December 21, 1991
  - C. Letter dated January 22, 1997

For the U.S. Nuclear Regulatory Commission

**Original Signed By:**

**John D. Kinneman**

By

Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

Date

FEB - 7 1997

FEB - 7 1997

License No. 19-07538-06  
Docket No. 030-32506  
Control No. 124130

Michael A. Ussery, Ph.D.  
Radiation Safety officer  
Department of Health & Human Services-FDA  
Antiviral Research Laboratory HFD-535  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Ussery:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

Please note the following changes that are made to your license in accordance with the current NRC policy:

1. Old Condition 12 is replaced by two new Conditions 12 and 13.
2. New Condition 15 is the revised version of old Condition 14.

From the telephone conversation of January 28, 1997, between Dr. Carl Nielsen of your staff and Dr. Sattar Lodhi of this office, it is our understanding that you will be using TLD's for monitoring personnel exposures, and not the film badges as you stated in your letter dated January 22, 1997. Please let this office know immediately in writing if our understanding differs from yours.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

M. Ussery, Ph.D.

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Department of Health & Human Services

Thank you for your cooperation.

Sincerely,

Original Signed By:  
**John D. Kinneman**

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

License No. 19-07538-06  
Docket No. 030-32506  
Control No. 124130

Enclosure:

Amendment No. 01

DOCUMENT NAME: R:\WPS\MLTR\L1907538.06

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"/> N			
NAME	SLodhi		JKinneman				
DATE	01/28/97		01/30/97		01/ /97		01/ /97

OFFICIAL RECORD COPY

DNMS TELEPHONE CONVERSATION RECORD

Person Called: Michael Ussery, Ph.D., RSO Phone No.: (301) 827 5246  
Person Calling: Sattar Lodhi Date: 1/28/97  
Facility Name: Department of Health & HS Time: 11:15 a.m.  
Antiviral Drug Products  
Rockville, MD  
License No. 19-07538-06 Docket No. 030-32506

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Subject: Confirmation of use of TLDs

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Summary: The licensee had requested an amendment that included changing the frequency of exchange of personnel monitoring devices. They want to change from monthly exchanges to quarterly. I wanted to find out if they are going to use film badges as stated in the letter, or they plan to switch to TLDs (Pam inspected this facility recently and her recollection was that they are using TLDs.

Dr. Ussery was out of his office for the rest of the week. I talked to Dr. Nielsen, who is the other authorized user. He stated that they probably use TLDs and he will let Dr. Ussery know and if this information is incorrect, he will call me back to provide correct information.

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Action Required/Taken: Document

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Signature: 

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Mail Control No. 124130

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ML 10



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

22 January 1997

U.S. Nuclear Regulatory Commission  
Attn: Betsy Ullrich  
475 Allendale Road  
King of Prussia, PA 19406-1415

030-32506

To whom it may concern:

I would like to request that we add new areas of radioisotope use to our license 19-07538-06. These are laboratories within Suite 300 at 5516 Nicholson Lane, Kensington, MD (the area currently covered under our license) that have been remodeled to provide more suitable storage and use areas for radioactive materials. We propose adding Room 2339 for radiation storage, and dark room 2343, instrument lab 2341, and microbiology lab 2345 for radioisotope use as shown on the accompanying plans. We propose moving our scintillation and gamma counters into room 2341. Once these areas are approved for addition to the license we proposing decommissioning of rooms (2)302, (2)303, (2)307 and (2) 309 and will send in surveys to close out these use areas.

Additionally, we would propose amending our license to a quarterly frequency for exchange of film badges. Our experiments generally involve working with quantities in the microcurie range. Our history over the past three years indicates that all exposures have been minimal.

Please let me know if additional information is needed.

Sincerely yours,

Michael A. Ussery, Ph.D.  
Laboratory Director  
Radiation Safety Officer  
Antiviral Research Laboratory  
HFD-535, 5600 Fishers Lane  
Rockville, MD 20857

124130

OFFICIAL RECORD COPY

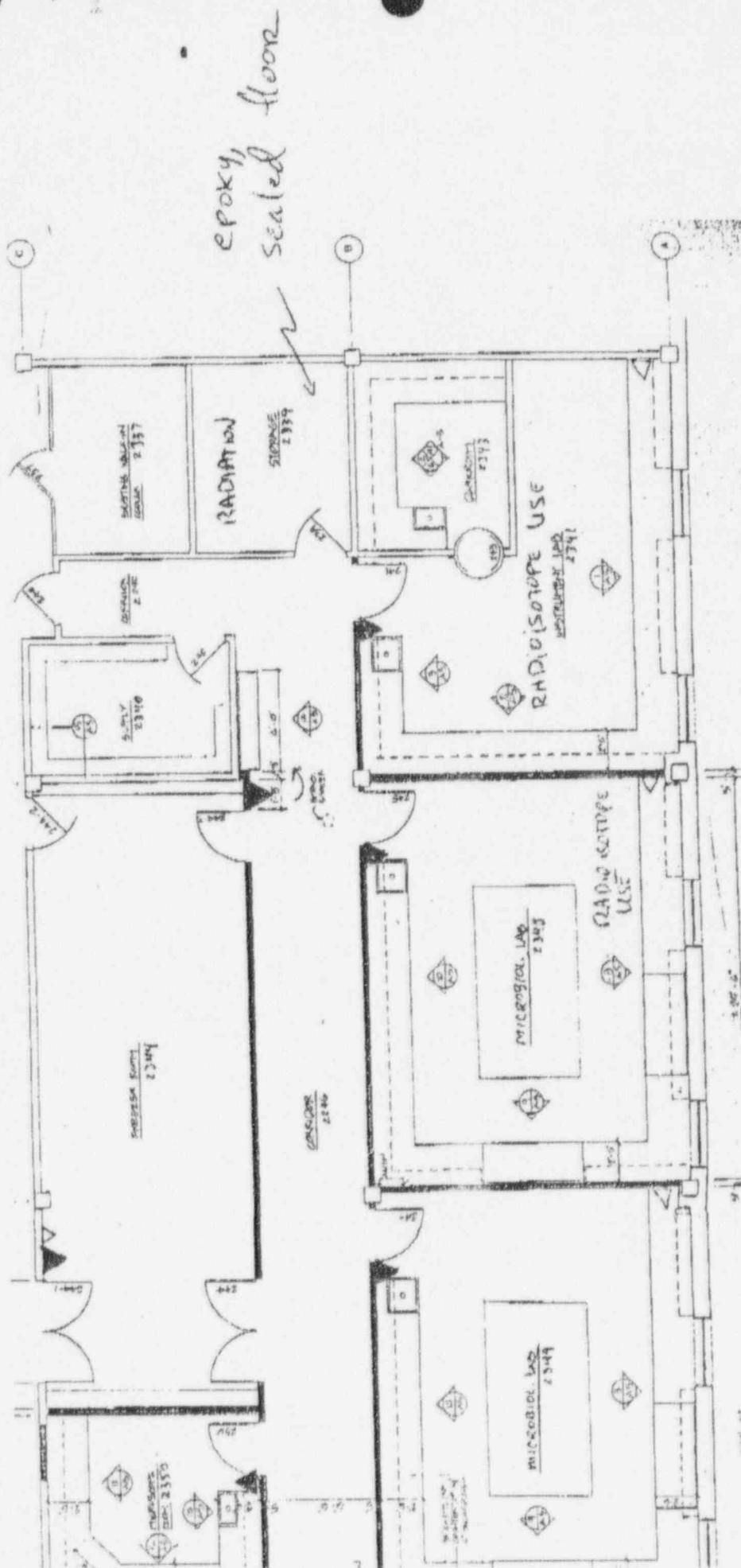
ML 10

FAX REC'D

JAN 22 1997









BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: 03620  
STATUS CODE: 0  
FEE CATEGORY: EX 3M  
EXP. DATE: 20020228  
FEE COMMENTS: 170.11(A)(5)  
DECOM FIN ASSUR REQD: N  
.....

LICENSE FEE TRANSMITTAL

4. REGION *I*

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: HEALTH & HUMAN SERVICES, DEPT. OF  
RECEIVED DATE: 970122  
DOCKET NO: 3032506  
CONTROL NO.: 124130  
LICENSE NO.: 19-07538-06  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED  
AMOUNT: -----  
CHECK NO.: -----

3. COMMENTS

SIGNED *M. A. Perkins*  
DATE *1/22/97*

8. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /\_\_/) )

1. FEE CATEGORY AND AMOUNT: -----

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:  
AMENDMENT -----  
RENEWAL -----  
LICENSE -----

3. OTHER -----  
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SIGNED -----  
DATE -----