



National Institutes of Health  
Bethesda, Maryland 20892  
Building : 21  
Room : 233  
(301) 486-2254  
June 29, 1989

U.S. Nuclear Regulatory Commission  
Division of Radiation Safety and Safeguards  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

Reference: License 19-00296-10

Dear Sir or Ms.:

An amendment is requested to License 19-00296-10 to permit the use of byproduct material in a laboratory facility leased by the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration, located at 5516 Nicholson Lane, Rockville, MD. The building is located approximately 3 miles from the main NIH campus and is very close to the new NRC headquarters building in Rockville. This building also contains laboratories for biomedical research operated by Litton Bionetics, Inc. and Hazelton Laboratories. CBER has leased 3500 square feet on the ground floor and is renovating this space to include a general research laboratory, histology laboratory and electron microscope laboratory.

CBER/FDA is provided support services from the NIH via an interagency memorandum of understanding. This support includes radiation safety support from the Radiation Safety Branch, NIH for the two buildings occupied by CBER on the NIH Bethesda campus. CBER requires interim leased space for research and support laboratories while a third building is being constructed for their use on the grounds of the NIH main campus (scheduled completion is 1993). Since the NIH Broad Scope License and Radiation Safety Program already cover the activities of CBER/FDA, the Division of Safety, NIH has elected to extend this support to the interim leased facility.

The NIH Radiation Safety Branch will provide complete support services to this facility related to byproduct materials use. Such support includes materials receiving, log-in and delivery for use to the laboratory, radioactive waste pickup and processing, personnel training and monitoring, and surveillance, investigation and consultation by RSB professional health physicists commensurate with the levels of activity employed therein. Thus, the radiation safety coverage will equal that

**FEE EXEMPT**

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REG1 LIC30  
19-00296-10 PDR

**110991**

OFFICIAL RECORD COPY ML10

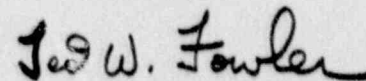
JUL 07 1989

provided to any building on the main campus at the NIH and will be the same as that performed at the other three laboratory facilities operated under NIH control in the Rockville, MD area. Security for the FDA occupied portion of the building will be provided by FDA and will be substantial due to the necessity to protect the confidentiality of documents relating to drugs and biologics that are licensed and regulated by the agency.

The target date for full operational occupancy of the space is September 1, 1989. Hence, we are requesting your assistance in expediting the approval of this amendment. Also, please consider this submittal as an amendment to our renewal application for License 19-00296-10 to ensure that, when the license is renewed, authorizations that have been granted to the NIH subsequent to our initial application of July 28, 1986 are included.

Should you have any questions regarding this matter please contact me or Mr. Robert Zoon, Acting Chief, Radiation Safety Branch at 301-496-5774.

Sincerely,



Ted W. Fowler  
Acting Radiation Safety  
Officer, NIH

cc: Dr. Jacob Robbins, Chairman, NIH Radiation Safety Committee  
Dr. Joseph E. Rall, Deputy Director for Intramural Research  
Mr. Norman Mansfield, Associate Director for Research  
Services  
Dr. Robert McKinney, Director, Division of Safety  
Mr. Richard Albrecht, Deputy Director, OM, CBER/FDA

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: 02110  
STATUS CODE: 2  
FEE CATEGORY: EX 7B  
EXP. DATE: 19860831  
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: HEALTH & HUMAN SERVICES, DEPT. OF  
RECEIVED DATE: 890707  
DOCKET NO: 3001786  
CONTROL NO.: 110991  
LICENSE NO.: 19-00296-10  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: -----  
CHECK NO.: -----

3. COMMENTS

SIGNED \_\_\_\_\_  
DATE 7/11/89

B. 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 -----

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: FEE COMMENTS: .....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: HEALTH & HUMAN SERVICES, DEPT. OF  
RECEIVED DATE: 891010  
DOCKET NO: 3001786  
CONTROL NO.: 111455  
LICENSE NO.: 19-00296-10  
ACTION TYPE: AMENDMENT



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

3. COMMENTS

SIGNED -----  
DATE -----

B. 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 -----  
-----

SIGNED -----  
DATE -----

VOID SHEET

TO: License Fee Management Branch  
FROM: Region I  
SUBJECT: VOIDED APPLICATION

Control Number: 111455  
Applicant: Health & Human Services, Dept of  
Date Voided: 25 October 1989  
Reason for Void: Combined with Control Number 110991.  
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\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Egmw  
Signature

10-25-89  
Date

Attachment:  
Official Record Copy of  
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:  
Refund Authorized and processed  
No Refund Due  
Fee Exempt or Fee Not Required

Comments: \_\_\_\_\_  
\_\_\_\_\_  
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Log completed  
Processed by: \_\_\_\_\_