VOID SHEET

TO: License Fee Management Branch

FROM: RIII - James R. Mullauer

SUBJECT: VOIDED APPLICATION

Control Number: 303605

Applicant: Pharmacia & Upjohn Company

License Number: 21-00182-03

Docket Number: 030-04781

Date Voided: 3/3/98

Reason for Void: The licensee's situation has changed and will resubmit a new license amendment under control No. 303605. The way the current amendment request is written, the amendment would not be approved so the cleanest way to clarify the licensee's needs is to resubmit in its entirety.

James Mullauer 3/3/98
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

___ Refund Authorized and processed

__✓__ No Refund Due

___ Fee Exempt or Fee Not Required

Comments: _____ Log completed ✓

_____ Processed by: SAC 3/12/98

ML 30 0/1 BT

9803170029 980303
PDR ADOCK 03004781
C PDR

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03211
Status Code: 0
Fee Category: 7B 3E
Exp. Date: 20050131
Fee Comments: 3E ADDED 2/29/88
Decom Fin Assur Reqd: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: PHARMACIA & UPJOHN COMPANY
   Received Date: 980213
   Docket No: 3004781
   Control No.: 303605
   License No.: 21-00182-03
   Action Type: Amendment

R4

2. FEE ATTACHED
   Amount: 740
   Check No.: 3778093

3. COMMENTS

Signed D. Hersey
Date 2-17-98

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /✓/)

1. Fee Category and Amount: (7B) 3E $740

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 2/18/98

Log Feb 7 III
Remitter
Check No. 3778093
Amount $740
Fee Category 7B 3E
Type of Fee NRSD
Date Check Rec'd 2/
Date Completed 2/18/98
By: SC

98 FEB 18 PM 3:06

PHARMACIA & UPJOHN

301 Henrietta Street
Kalamazoo, MI 49007
NRC Lic. 21-00182-03

Research & Development
Clark W. Smith, Ph.D.
Director, Protein Science
7240-209-638
Telephone No. (616) 833-0924
Fax No. (616) 833-2500

February 4, 1998

Mr. James Mullauer
Nuclear Materials Licensing Section
Nuclear Regulatory Commission , Region III
801 Warrenville Road
Lisle, IL 60532-4351

re: Request for Amendment to NRC Byproduct Material License Number 21-00182-03

Dear Mr. Mullauer,

Pharmacia & Upjohn is requesting an amendment to our byproduct material license number 21-00182-03 to allow for the redistribution of prepackaged in vitro diagnostic kits to specifically licensed facilities or as generally licensed kits. Attachment 1 contains a list of the specific changes that are being requested.

A check for the license amendment fee of $ 740.00 is enclosed.

Please contact Mr. Timothy Popp at (616) 833-9364 if you have any questions concerning these requested changes.

Sincerely,
PHARMACIA & UPJOHN

Clark W. Smith,
Chairman, Radiation Safety Committee

RECEIVED
FEB 1 3 1998
REGION III
303605
FEB 1 3 1998

pm: 2-10-98

Attachment 1

Pharmacia & Upjohn is requesting an amendment to our NRC Materials License and conditions to allow for the redistribution of prepackaged units for in vitro tests containing I-125. This redistribution program is currently being conducted at a Pharmacia & Upjohn facility in Clayton, North Carolina. However, Pharmacia & Upjohn has decided to divest itself of this facility and perform this redistribution activity at its Kalamazoo, Michigan facility. Termination and decommissioning of the licensed activities at the Clayton, North Carolina facility will be handled through the State of North Carolina, an NRC Agreement State.

The following is a list of the requested changes to the NRC Material License and/or to any of the requirements in the documents listed in Condition 20 of the NRC Materials License 21-00182-03. The date in parentheses after each item reflects the date of the letter(s) that last amended the effected section.

1. Refer to Condition 10 of the Materials License and
   Item 3 of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, September 22, 1995, September 25, 1996, and May 13, 1997)

   Prepackaged in vitro diagnostic kits will be received, stored, and redistributed from Pharmacia & Upjohn's warehouse located at 701 East Milham Road, Kalamazoo, Michigan. This location is not currently listed as an authorized facility. Condition 10 of the NRC material license should be revised to include this facility.

   Item 3.C of Pharmacia & Upjohn's NRC License Requirements should be created as follows:

   Licensed material identified in Item 5.G shall be used only at the following Pharmacia & Upjohn facilities (refer to Attachment 3-B for current facility layouts):

   1. *Building 212 in the "Portage North" complex; location address: 701 East Milham Road, Kalamazoo, MI.*

   This facility location is already included in Attachment 3-B as revised in the letter dated April 7, 1995, therefore, the attachment requires no further revision.

2. Refer to Condition 6, 7, 8, and 9 of the Materials License and
   Items 5 and 6 of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, November 3, 1995 and October 23, 1997)

   Item 5 of Pharmacia & Upjohn's NRC License Requirements should be revised to include a letter G. For ease of review, a copy of this entire table is included in Enclosure 1. The italics indicate the added text. Conditions 6, 7, and 8 of the Materials License should be revised accordingly.

A letter G. should be added to Item 6 of Pharmacia & Upjohn's NRC License Requirements and read as follows:

To be used for redistribution of prepackaged in vitro test kits to general licensees or specific licensees.

Condition 9 of the Materials License should be revised accordingly.

3. Refer to Item 12 of Pharmacia & Upjohn's NRC License Requirements (newly created section)

Item 12 of Pharmacia & Upjohn's NRC License Requirements is a new section added to describe the specific Training, Facilities and Equipment, Radiation Safety Program, and Waste Management required to conduct the requested redistribution of prepackaged units for in vitro tests. Pharmacia & Upjohn has adopted the guidance provided in Draft Regulatory Guide DG-0006, "Guide for the Preparation of Applications for Commercial Nuclear Pharmacy Licenses," section 4.4, "Redistribution of Prepackaged Units for In Vitro Kits." The language for this new Item 12 of Pharmacia & Upjohn's NRC License Requirements is included as Enclosure 2. References to existing, previously approved, Pharmacia & Upjohn's NRC License Requirements are made throughout this new section. For the ease of review, the referenced items are listed below along with the date of the letter(s) that last amended the effected section.

Item 12.2.B refers to Item 9.7 of Pharmacia & Upjohn's NRC License Requirements (letter dated April 7, 1995)

Item 12.3.D refers to Item 10.1.C of Pharmacia & Upjohn's NRC License Requirements (letter dated April 7, 1995)

Item 12.3.E.2 refers to Item 10.1.F of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, October 23, 1997)

Item 12.3.E.3 refers to Item 10.5.A.1.b.(1), (2), and (3) of Pharmacia & Upjohn's NRC License Requirements (letters dated September 6, 1994, April 7, 1995)

Item 12.3.F.1 refers to Item 10.5.C of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, August 17, 1995, May 13, 1997)

Item 12.3.F.2 refers to Item 10.5.D.6 and Attachment 10-C of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, October 23, 1997)

Item 12.3.G refers to Item 10.3 and Item 10.3.A of Pharmacia & Upjohn's NRC License Requirements (letters dated April 7, 1995, May 13, 1997, October 23, 1997, December 1, 1997)

Item 12.4 refers to Item 11 of Pharmacia & Upjohn's NRC License Requirements (letters dated September 6, 1994, April 7, 1995, May 13, 1997, June 2, 1997, October 23, 1997)

4. Upon approval of this requested license amendment, Pharmacia & Upjohn, Clayton, North Carolina will transfer any remaining inventory of prepackaged in vitro units to Pharmacia & Upjohn, Kalamazoo, Michigan. . Pharmacia & Upjohn, Clayton, North Carolina currently has approximately 0.2 mCi (not decay corrected) of inventory on hand.

   Pharmacia & Upjohn's Clayton, North Carolina facility also currently has approximately 6 mCi (not decay corrected) of rejected or expired inventory on hand. Pharmacia & Upjohn's Clayton, North Carolina facility is authorized by the State of North Carolina to decay in storage for ten half-lives any rejected or expired inventory. To expedite the license termination and decommissioning of the Clayton, North Carolina facility, Pharmacia & Upjohn, Kalamazoo, Michigan requests authorization to receive this licensed material for disposal in accordance with Item 12.4. Transfer of this rejected or expired inventory to Kalamazoo, Michigan will be contingent upon the State of North Carolina approving Pharmacia & Upjohn's, Clayton, North Carolina facility request to transfer the material to Kalamazoo, Michigan.

ENCLOSURE 1

RADIOACTIVE MATERIAL

Licensed Material	Chemical and/or Physical Form	Possession Limit
A. Any byproduct material with Atomic Nos. 1-83, inclusive	Any	Not to exceed one curie of each isotope; 10 curies total
B. Any byproduct material with Atomic Nos. 1-83, inclusive	Any Hydrogen-3 Carbon-14 Iodine-125	Not to exceed one curie of each isotope; 25 curies total, except as noted: 150 curies 20 curies 3 curies
C. Americium-241	Sealed sources (any evaluated source which has been registered with the NRC or an Agreement State in accordance with 10 CFR 32.210)	Not to exceed 150 millicuries per source & not exceed one curie total
D. Nickel-63	Plated or foil sources (any source which has been registered with the NRC or an Agreement State in accordance with 10 CFR 32.210)	No single source to exceed 25 millicuries & not to exceed 5 curies total
E. Cesium-137	Sealed sources (any source which has been evaluated by the NRC or an Agreement State in accordance with 10 CFR 32.210)	No single source to exceed 100 millicuries; not to exceed 2 curies total
F. Cesium-137	Sealed sources (AECL Model C-161 Type 8) in Gammacell 40 [Model G.C. 40 Type B (U)] Irradiator	Two sources not to exceed 4200 curies total
G. Iodine-125	*Prepackaged units for in vitro tests*	*200 millicuries total, no kit to exceed 10 microcuries*

ENCLOSURE 2

REDISTRIBUTION OF PREPACKAGED UNITS FOR IN VITRO TESTS

The information delineated in this section constitutes the specific Training, Facilities and Equipment, Radiation Safety Program, and Waste Management required to conduct the authorized use of radioactive material for the purpose of redistribution of prepackaged units for in vitro tests to general licensees or specific licensees as described in Item 6.G. Pharmacia & Upjohn may make changes to specific elements of the program described herein without amending the license, as long as the changes do not change the intent of the program as described and do not compromise health and safety.

12.1. Training for Individuals Handling In Vitro Test Kits

The following training will be provided by Pharmacia & Upjohn to meet the requirements of 10CFR19.12, "Instructions to Workers".

A. Redistribution of Prepackaged Units for In Vitro Tests Training

Personnel whose job function requires the receiving, storing, or redistribution of prepackaged units for in vitro tests (Item 6.G) shall complete Pharmacia & Upjohn's Redistribution of Prepackaged Units for In Vitro Tests Training Course (refer to Attachment 12-A, "Training Course Outlines"). Documentation of course attendance shall be maintained.

B. Training Records

The training records for personnel involved with the Redistribution of Prepackaged Units for In Vitro Tests include the following:

- Approximate time spent on each topic
- Name of instructor and students
- Dates of training
- Written assessment or test for each student documenting satisfactory completion of the training

12.2. Facilities and Equipment

A. Prepackaged units for in vitro tests containing licensed material will be stored in a refrigerator or cold room within the facility described in Item 3.C. Access to the building is controlled by the use of security "check points", picture-I.D. cards, and keys or electronic key cards. The refrigerator or a designated caged enclosure area inside the cold room, where these radioactive materials will be stored, will be kept locked at all times, except when kits are either being received or removed for shipment. Only personnel that have been trained in the redistribution of these products (Item 12.1) shall have access to this caged

area.

B. Radiation detection instrumentation necessary for surveys to demonstrate compliance with the requirements of 10CFR20, based on the radionuclide being used (e.g. end-window GM meter and pancake probe, NaI(Tl) probe, liquid scintillation counter) are available. These instruments are maintained and calibrated as described in Item 9.7.

12.3. Radiation Safety Program

A. Procurement, Receipt and Inventory Control of Prepackaged Units for In Vitro Tests for the Purpose of Redistribution

1. Prepackaged units for in vitro tests to be redistributed to general licensees will be obtained from a manufacturer authorized to distribute the prepackaged units for in vitro tests in accordance with a specific license issued pursuant to 10CFR32.71 or under an equivalent license of an Agreement State.

2. Pharmacia & Upjohn will obtain prepackaged units for in vitro tests (10CFR31.11(a)) for redistribution to specific licensees.

3. Packages containing prepackaged units for in vitro tests containing radioactive materials for the purpose of redistribution (Item 6.G) will only be received at the location specified in Item 3.C by personnel trained in accordance with Item 12.1. Packages will be checked for any external signs of damage, leakage, or loss of container integrity.

4. Receipt surveys required by 10CFR20.1906 are performed by Laboratory Radiation Support staff or personnel trained in accordance with Item 12.1 not later than three hours after receipt of the package, if it is received during normal working hours, or not later than three hours from the beginning of the next working day if it is received after normal working hours. If removable radioactive surface contamination levels or external radiation levels are found to exceed the limits specified in 10CFR20.1906, the RSO (or designee) will immediately contact the final delivery carrier and the Administrator of the Nuclear Regulatory Commission, Region III.

5. After completion of receipt surveys and inspections, the prepackaged units for in vitro tests will be logged into a computerized inventory data base system. This system will track all incoming and outgoing shipments of prepackaged units for in vitro tests. It will be possible to report maximum total radioactivity on hand by entering appropriate

product codes.

B. Area Designation, Posting, and Labeling Requirements

1. Building 212 is designated a restricted area. Measures to control access to the area are described in Item 12.2 All radiation areas, high radiation areas and areas or rooms in which licensed material is stored are posted in accordance with 10CFR20.1902

2. The manufacturer's packaging and labeling of the prepackaged units for in vitro tests destined for redistribution to general licensees will not be altered in any way.

3. Each prepackaged unit for in vitro tests destined for redistribution to general licensees will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

4. Labels, package insert, leaflet, brochure, or other documents accompanying prepackaged units for in vitro tests destined to be redistributed to specific licensees will be verified to not reference general licenses, exempt quantities, or NRC's regulations that authorize a general license.

5. Labeling on prepackaged units for in vitro tests destined for redistribution to specific licensees will conform to the requirements of 10CFR20.1901 and 20.1904.

C. Shipping of Radioactive Materials

Prepackaged units for in vitro tests containing licensed material will be transported in accordance with 10CFR71.

D. Emergencies

Emergencies involving spills, personnel injuries, unplanned releases, fires, or accidents of licensed materials in Building 212 will be handled as described in Item 10.1.C. Sufficient decontamination materials are maintained in the area to handle small spills. Personnel in this area, trained in accordance with Item 12.1, are capable of handling small spills without outside assistance.

E. Radiation and Contamination Surveys

1. No contamination is expected from the redistribution of prepackaged in vitro units and field monitoring dosimetry badges placed near the

storage area in Clayton, North Carolina indicate minimal radiation exposures. However, Laboratory Radiation Support staff, or assigned personnel trained in the redistribution of prepackaged in vitro kits (Item 12.1), shall perform and document a semiannual radiation and contamination survey of the areas within Building 212 where licensed materials are received, stored, or shipped.

2. Contamination surveys shall consist of a survey for fixed contamination using a GM pancake probe and a survey for removable contamination using a wipe test method and liquid scintillation counter. Surface contamination controls as described in Items 10.1.F will be followed.

3. Radiation surveys shall consist of a survey as described in Item 10.5.A.1.b.(1), (2), and (3).

F. Individual Monitoring of External and Internal Occupational Exposure

1. Based on the assessment of external doses of personnel conducting this same activity (redistribution of prepackaged in vitro kits) at Pharmacia & Upjohn's North Carolina facility, personnel external monitoring of occupational exposure is not required as indicated in 10CFR20.1502(a). However, surveillance monitoring, as described in Item 10.5.C, will be provided.

2. Prepackaged in vitro kits will only be received, stored and redistributed from this facility. No open manipulation of licensed material will occur. Therefore, personnel internal monitoring of occupational exposure is not required as indicated in 10CFR20.1502(b). The thyroid bioassay programs, as described in Item 10.5.D.6, will be utilized to investigate any potential internal exposures in the event of an accident involving the release or open manipulation of material in excess of the activity and form described in Attachment 10-C, "Action Levels Requiring Thyroid Uptake Bioassay."

G. Periodic Review of the Radiation Safety Program; Audits and Appraisals

Periodic review of the Radiation Safety Program will be conducted as described in Item 10.3. Independent audits (Item 10.3.A) of the program involving the redistribution of prepackaged units for in vitro tests will be conducted annually.

12.4. Waste Management

Radioactive wastes resulting from the redistribution of prepackaged in vitro test kits

(expired product, contaminated shipping material or other related contaminated waste as a result of this operation) will be managed as described in Item 11.

TRAINING COURSE OUTLINES

Redistribution of Prepackaged Units for In Vitro Tests Training Course Outline

1. Introduction to Radiation and Radioactive Materials
2. Biological Effects and Risks of Radiation and Radioactive/Radiotoxic Materials
3. Federal Regulations - NRC and DOT
4. Pharmacia & Upjohn's Radiation Safety Policies and Procedures
5. Work Practices - ALARA and Safety Practices, Contamination Controls and Emergency Response
6. Employee's Rights and Responsibilities
7. Review

Examination of Content

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

February 17, 1998

Lawrence J. Kenaga
Radiation Safety Officer
Pharmacia & UpJohn Company
7000 Portage Road
Kalamazoo, MI 49001

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 02/04/98)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License _X_ Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 303605
License No. 21-00182-03