

Wyeth

Wyeth Research
500 Arcola Rd.
Mail Stop COL RS 1149
Collegeville, PA 19426

Robert C. Wickline
Radiation Safety Officer
484-865-5546 tel
wicklir@wyeth.com

November 13, 2007

Licensing Assistance Team
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

NMSB 2

RECEIVED
REGION 1
2007 NOV 15 PM 12:22

Subject: Amendment to license #37-00401-03,

Dear Sir/Madame,

030 05990

Enclosed is an application for an amendment to the license referenced above, issued to the Wyeth Research facility in Collegeville, Pa. The amendment modifies the license as follows:

- Remove from item #5 in the application, line K relating to ¹³⁷Cs Sealed Sources,
- Remove Appendix A - "Radiation Protection Program for Gamma-Cell 40 Research Irradiator.
- Update item #7, the Organizational Chart of Radiation Safety Senior Management; this includes the addition of the position of Manager – R&D Radiation Safety.

The changes will affect the materials license issued by the US Nuclear Regulatory Commission by removing line 6K, 7K and 8K relating to the possession limit, and line 19 restricting the licensee actions relating to repair, removal, replacement, and alteration of irradiator mechanisms.

Please do not hesitate to contact me for all concerns.

Sincerely,



Robert C. Wickline, RSO

Encl.

141328

NMSS/RGN1 MATERIALS-002

NRC FORM 313
(4-2004)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

03005990

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 37-00401-03
☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Wyeth Pharmaceuticals dba Wyeth Research
500 Arcola Rd.
Collegeville, PA 19426

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

500 Arcola Rd.
Collegeville, PA 19426

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Robert C. Wickline

TELEPHONE NUMBER

(484) 865-5546

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3L AMOUNT ENCLOSED \$ 0.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Dr. Richard Ciccarelli, Vice President Research Administration

SIGNATURE

Richard Ciccarelli

DATE

Nov 9, 2007

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

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Items 1-4: Applicant Information

1. This is an application for:	Amendment to materials license no. 37-00401-03
2. Name of applicant	Wyeth Pharmaceuticals, Inc. DBA Wyeth Research 500 Arcola Road Collegeville, PA 19426
3. Address where licensed material will be used or possessed	500 Arcola Rd. Collegeville, PA 19426
4. Name of person to be contacted about this application	Robert C. Wickline Address above Mail Stop S1153 Ph# 484-865-5546
5. Radioactive material	Element, mass number, chemical and physical form, and maximum amount allowed are listed on a separate sheet.
6. Purposes for which licensed material will be used	A through J: – Research and development as defined in 10 CFR 30.4
7. Individuals responsible for the radiation safety program and their training and experience	unchanged
8. Training for individuals working in or frequenting restricted areas	unchanged
9. Facilities and equipment	unchanged

Item 5: Radioactive Materials

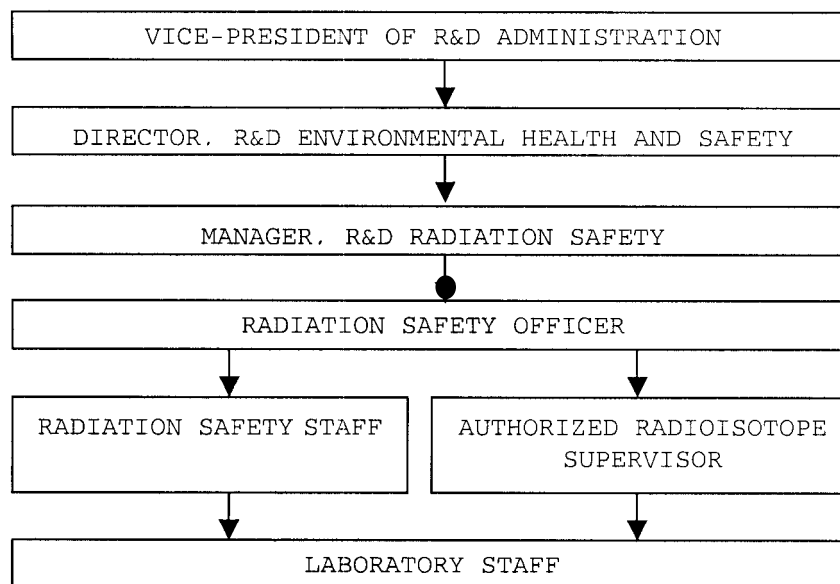
A. Radioactive Materials, Chemical and Physical Forms, Possession Limits Requested.

Byproduct, source, or special nuclear material	Chemical and/or physical form	Maximum amount which will be possessed at any one time
A. Byproduct Material as specified in Section 33.100, Schedule A, of 10 CFR 33 (Type B Broad Scope License) with half-lives of less than 120 days	ANY	As specified in Section 33.11(b) of 10 CFR 33 (Type B Broad Scope License)
B. Hydrogen 3	ANY	2 curies
C. Carbon 14	ANY	2 curies
D. Calcium 45	ANY	100 millicuries
E. Manganese 54	ANY	10 millicuries
F. Iron 55	ANY	100 millicuries
G. Nickel 63	ANY	150 millicuries
H. Zinc 65	ANY	100 millicuries
I. Iodine 129	Solid calibration source	0.01 millicuries
J. Cesium 137	ANY	1 millicurie

Item 7: Individuals Responsible for the Radiation Safety Program

A. Senior Management

Senior management is responsible for ensuring that the radiation safety program is conducted according to NRC regulations and company policies. Senior management approves standard operating procedures, reviews radiation safety program audits conducted by third parties, and approves the response to audit findings.



This is to acknowledge the receipt of your letter/application dated

11/13/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 3700401-03
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141328.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.