



331 Treble Cove Road North Billerica, MA 01862
www.bmsmi.com 800.362.2668

December 27, 2004

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King Of Prussia, PA 19406-1415

ATTN: John D. Kinneman, Chief
Nuclear Materials Safety Branch 2

03034187

Reference: Materials License 52-25361-01MD

Dear Mr. Kinneman:

This is written to request a license amendment to the above referenced license to authorize the following change to our license:

- Increase Iodine-131 maximum amount that licensee may possess at any one time under this license from 33.3 GBq (900 mCi) to 111 GBq (3 Ci). Reference Materials License Condition 8.D.


Our Radiopharmacy operation anticipates an increase in Iodine-131 demand as a result of recent changes in the commercial availability of this radiopharmaceutical in Puerto Rico. The increase in possession limit to our Materials License will enable our business to continue to provide this important therapeutic radiopharmaceutical to authorized physicians on the island.

To further maintain radiation exposures to our employees ALARA we will be upgrading our Iodine-131 dispensing operations with the acquisition of a new Iodine-131 dispensing station. In addition, the existing procedure of requiring bioassays (i.e. thyroid monitoring) at least once per week of every employee who compounds the I-131 will continue.

All other licensed conditions and radiation program requirements will remain the same.

We request the priority processing of this license amendment to help meet the anticipated demand in I-131 therapy capsules. Please contact me if you require additional information on this license amendment application.

Best regards,


Rolando Garcia, RPh, BCNP
Radiation Safety Officer
Bristol Myers Squibb Radiopharmaceuticals, Inc.
Medical Imaging Division.
San Juan, Puerto Rico



A Bristol-Myers Squibb Company

136210
NRC/RONI MATERIALS-002

REC'D IN LAT

DEC 28 2004

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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

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.

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

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 52-25361-01 MD
☐ C. RENEWAL OF LICENSE NUMBER _____

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

Rolando Garcia, RPh, BCNP
Bristol-Myers Squibb Radiopharmaceuticals, INC.
1500 Marg. Bori
Urb. Antonsanti
San Juan PR 00927

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Bristol-Myers Squibb Radiopharmaceuticals, INC.
1500 Marg. Bori
Urb. Antonsanti
San Juan PR 00927

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Rolando Garcia, RPh, BCNP

TELEPHONE NUMBER

(787) 765-1571

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 AMOUNT ENCLOSED \$

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

Rolando Garcia, RPh, BCNP

SIGNATURE

DATE

12/27/2004

FOR NRC USE ONLY

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

136210

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

12/27/2004, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND 52-25361-01MD
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 136210.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 02500
: Status Code: 0
: Fee Category: 3C 3P
: Exp. Date: 20120630
: Fee Comments: 3P OK SEE CONDT 14G & 19
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION

I

1. APPLICATION ATTACHED

Applicant/Licensee: BRISTOL-MYERS SQUIBB RADIOPHARM, INC
Received Date: 20041228
Docket No: 3034187
Control No.: 136210
License No.: 52-25361-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed
Date

M. A. Perkins
12/28/2004

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

