

Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

1000 U.S. Highway 202, P.O. Box 300
Raritan NJ 08869

March 27, 2009

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RECEIVED
REGION 1
MAR 30 AM 10:34

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Sir or Madam:

03010814

This is a request by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. in Raritan, NJ to amend its NRC Material License number **29-02608-03** to reflect changes in the locations where licensed materials will be used or possessed.

Please remove the following locations from line item **#10** on NRC Material License number **29-02608-03**:

- Sterilization Sciences and Technology (SST), U.S. Route 1 North and Commerce Boulevard, North Brunswick, New Jersey
 - The North Brunswick facility has closed down and the Johnson & Johnson Sterilization facility has relocated to Raritan, NJ. Comprehensive surveys were completed to ensure the facility was free of radioactive contamination and it has been released for general use.
- Ortho Clinical Diagnostics, Inc., 1001 U.S. Route #202 North, Raritan, New Jersey
 - Johnson & Johnson Pharmaceutical Research & Development, L.L.C. is no longer using radioactive materials at the Ortho Clinical Diagnostics facility. All radioactive material, equipment and waste have been disposed of according to the disposal policies and procedures required by the NRC and License **29-02608-03**. In addition, comprehensive surveys have been completed to ensure all laboratories formerly occupied by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. are free of radioactive contamination. The laboratories have been released back to Ortho Clinical Diagnostics.
- Ethicon, U.S. Route 22 West, Somerville, New Jersey
 - Radioactive byproduct materials have never been used at this location under NRC Material License number **29-02608-03**.

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NMSS/RGN1 MATERIALS-002

As a result of a company name change for Sterilization Sciences and Technology and a relocation of the facility, please add an additional location for licensed material to be used or stored for NRC Material License number **29-02608-03**:

- Johnson & Johnson, Sterile Process Technology, Building **930** East, U.S. Route **202** and Ortho Drive, Raritan, NJ **08869**

Each facility approved to utilize radioactive materials under this license is a subsidiary **and/or** division of Johnson & Johnson. A completed NRC Form **313** and its attachment fully describe the facility and their anticipated use of byproduct material.

If there are any questions regarding this information, please contact the Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Radiation Safety Officer, James Kwiatkowski at **(908) 704-4930**.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Evans", written in a cursive style.

David Evans
Vice President, Global Head BA/DMPK
Johnson & Johnson Pharmaceutical
Research & Development, L.L.C.

Estimated burden per response to comply with this mandatory collection request is 4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate facilities exist to protect the public health and safety. Send comment regarding burden estimates to the Office of Management and Budget, Paperwork Reduction Project (3150-0120), Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the information collection is not approved by the Office of Management and Budget, and a person is not required to respond to the information collection.

APPLICATION FOR MATERIALS 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:

IF YOU ARE LOCATED IN:

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

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, 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:

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

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

03010814

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 **29-02608-03**
- C. RENEWAL OF LICENSE NUMBER _____

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

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
1000 Route 202
Raritan, NJ 08869

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

See attachment.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James Kwiatkowski

TELEPHONE NUMBER

(908) 704-4930

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 **N/A** 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, NA CONFIRMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

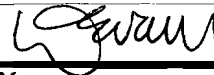
IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND

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

David Evans - Vice President, Global Head BA/DMPK

SIGNATURE



DATE

27 MAR 2009

FOR NRC USE ONLY

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

APPROVED BY

DATE

ITEM NO. 3: ADDRESS WHERE CENSEE ERI ILL BE USED OR POSSESSED

Johnson & Johnson, Sterile Process Technology
Building 930 East
U.S. Route 202 and Ortho Drive
Raritan, NJ 08869

ITEM NO. 5: RADIOACTIVE MATERIAL

There is no request to change the current possession limit!;

ITEM NO. 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Johnson & Johnson Sterile Process Technology (SPT) shall utilize radioactive materials approved by the NRC of License 29-02608-03. Johnson & Johnson SPT shall receive radiolabeled research materials/products for sterilization purposes only. SPT shall sterilize research materials/products, then transfer the materials/products to a facility that is appropriately licensed to receive the materials to be used for non-human research and development. SPT anticipates performing this sterilization process at a frequency not to exceed once per year.

ITEM NO. 7: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

The Radiation Safety Officer (RSO) for this license shall (continue to be James Kwiatkowski.

ITEM NO. 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

SPT employees shall follow all training requirements currently approved by the NRC and required of License 29-02608-03.

ITEM NO. 9: FACILITIES AND EQUIPMENT

The SPT site is a typical industrial facility that has receiving, administrative, research & development and operations-type areas. All areas assigned for sterilization, research or storage of radioactive materials shall be approved by the RSO and the Radiation Safety Committee prior to the initiation of any work with radioactive materials.

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

3/27/2009, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND, 29-02602-03
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** 143601.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.