



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

November 30, 2004

Docket No. 03033542
Control No. 135254

License No. 29-30152-01

Stephen A. Spearman, Ph.D.
Executive Vice President & Chief Operating Officer
Pharmacoepia Drug Discovery, Inc.
P.O. Box 5350
Princeton, NJ 08543-5350

SUBJECT: PHARMACOPEIA DRUG DISCOVERY, INC., ISSUANCE OF LICENSE
RENEWAL, CONTROL NO. 135254

Dear Mr. Spearman:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The Monmouth Junction, New Jersey facility is still listed as an authorized use location on the enclosed renewed license. Your license amendment request (mail control number 134943) to remove this facility from your license is still being processed. When that action has been completed you will receive an amended copy of your license with the Monmouth Junction, New Jersey facility removed as an authorized use location.

Matthew Sills has been added as an authorized user for all licensed material on your license except phosphorus-32. The information you provided indicates Mr. Sills does not have experience working with energetic beta emitting radionuclides. Mr. Sills may work with phosphorus-32 under the supervision of another authorized user until such time as you deem he has sufficient training and experience working with this radionuclide. At that time you may submit a license amendment to have Mr. Sills listed as an authorized user for phosphorus-32.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing of any change in mailing address.
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
 - a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license Amendment before you:
 - a) change Radiation Safety Officers;
 - b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
 - c) add or change the areas of use, or addresses of use identified in the license application or on the license; or
 - d) change the name or ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

S. Spearman
Pharmacopeia Drug Discovery, Inc.

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Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosures:

1. Amendment No. 12
2. 10 CFR Parts 19, 20, 21, 30, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

cc:
Robert N. Swanson, Ph.D., Radiation Safety Officer

S. Spearman
Pharmacopeia Drug Discovery, Inc.

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| OFFICE | DNMS/RI | N | DNMS/RI | N | DNMS/RI | | | |
| NAME | JNicholson/JJN | | EUlrich/EXU | | | | | |
| DATE | 11/30/2004 | | 11/30/2004 | | | | | |

OFFICIAL RECORD COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

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| Licensee | In accordance with the application dated June 29, 2004, |
| 1. Pharmacopeia Drug Discovery, Inc. | 3. License number 29-30152-01 is amended in its entirety to read as follows: |
| 2. P.O. Box 5350 Princeton, New Jersey 08543-5350 | 4. Expiration date December 31, 2014 |
| | 5. Docket No. 030-33542 Reference No. |

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|---|----------------------------------|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Hydrogen 3 | A. Any | A. 150 millicuries |
| B. Carbon 14 | B. Any | B. 50 millicuries |
| C. Phosphorus 32 | C. Any | C. 50 millicuries |
| D. Phosphorus 33 | D. Any | D. 150 millicuries |
| E. Sulfur 35 | E. Any | E. 50 millicuries |
| F. Calcium 45 | F. Any | F. 1 millicurie |
| G. Iodine 125 | G. Non volatile agents | G. 50 millicuries |

9. Authorized use:

A. through G. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 3000 Eastpark Boulevard, Cranbury, New Jersey, and 2000 Cornwall Road, Monmouth Junction, New Jersey.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-30152-01Docket or Reference Number
030-33542

Amendment No. 12

11. A. Licensed material shall be used by, or under the supervision of, Kenneth C. Appell, Doug Auld, James R. Beasley, Carolyn Dilanni Carroll, Tsung Lin, Jinqi Liu, Laura Rokosz, Ilana Stroke, Robert N. Swanson, or Jiuqiao Zhao.
- B. Licensed material in items 6.A. through 6.F., may also be used by or under the supervision of David Dunn.
- C. Licensed material in items 6.A., 6.B. and 6.D. through 6.G., may also be used by or under the supervision of Matthew Sills.
12. The Radiation Safety Officer for this license is Robert N. Swanson, Ph.D.
13. The licensee shall not use licensed material in or on human beings.
14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-30152-01Docket or Reference Number
030-33542

Amendment No. 12

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated June 29, 2004
- B. Letter dated November 22, 2004



For the U.S. Nuclear Regulatory Commission

Date November 30, 2004
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By ***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406