



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

February 25, 2008

Docket No. 03036603
Control No. 140582

License No. 37-30924-01

Mark McKinlay, Ph.D.
Chief Scientific Officer
TetraLogic Pharmaceuticals
343 Phoenixville Pike
Malvern, PA 19355

SUBJECT: TETRALOGIC PHARMACEUTICALS, LICENSE AMENDMENT, CONTROL NO.
140582

Dear Dr. McKinlay:

This refers to your license amendment request. Enclosed with this letter is the amended license. The facility at 365 Phoenixville Pike, Malvern, PA may be released for unrestricted use.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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 Notice of Availability of Environmental Assessment and Finding of No Significant Impact for this action was published on February 21, 2008 in the Federal Register, Volume 73, Number 35. A copy of the Federal Register Notice is enclosed for your information.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Farrah C. Gaskins

Farrah C. Gaskins
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

M. McKinlay
TetraLogic Pharmaceuticals

2

Enclosure:

1. Amendment No. 4
2. Copy of FRN

cc:

Srinivas Chunduru, Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML080650291.wpd

SUNSI Review Complete: FGaskins

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

| | | | | | | | | |
|--------|----------------|---|---------|--|---------|--|--|--|
| OFFICE | DNMS/RI | N | DNMS/RI | | DNMS/RI | | | |
| NAME | FGaskins /FCG/ | | | | | | | |
| DATE | 2/25/08 | | | | | | | |

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.

| | |
|--|--|
| <p style="text-align: center;">Licensee</p> <p>1. TetraLogic Pharmaceuticals</p> <p>2. 343 Phoenixville Pike Malvern, Pennsylvania 19355</p> | <p>In accordance with the letter dated March 27, 2007,</p> <p>3. License No. 37-30924-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date: September 30, 2014</p> <hr/> <p>5. Docket No. 030-36603</p> |
|--|--|

- | | | |
|---|---|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Phosphorus 33</p> <p>E. Sulfur 35</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries</p> <p>B. 10 millicuries</p> <p>C. 60 millicuries</p> <p>D. 25 millicuries</p> <p>E. 200 millicuries</p> |
|---|---|--|

9. Authorized use:
- A. through E. 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 343 Phoenixville Pike, Malvern, Pennsylvania.
11. A. Licensed material shall be used by, or under the supervision of, Srinivas K. Chunduru, Ph.D., Mark A. McKinlay, Ph.D., and Christopher Benetatos, B.S.
- B. The Radiation Safety Officer (RSO) for this license is Srinivas K. Chunduru, Ph.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
37-30924-01Docket No.
03036603

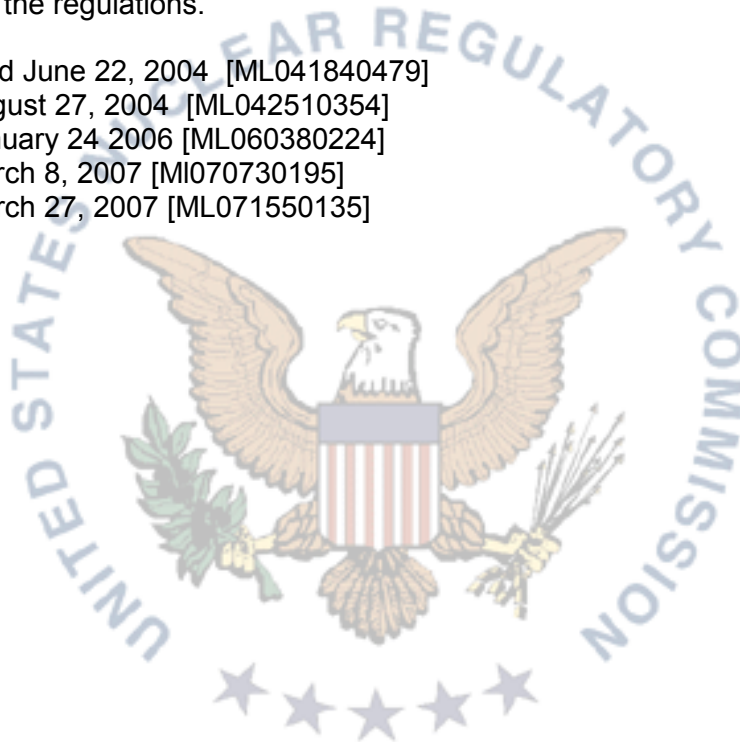
Amendment No. 4

12. The licensee shall not use licensed material in or on human beings.
13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. Notwithstanding the requirements of Condition 17, the licensee is authorized to make changes to the licensee's emergency procedures which were specifically identified in Item 10 E. of the licensee's application dated June 22, 2004, without prior Commission approval as long as:
 - A. The proposed revision is documented, reviewed, and approved by the licensee's management and the RSO in accordance with established procedures prior to implementation.
 - B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
 - C. The licensee's staff is trained in the revised procedures prior to implementation.
 - D. The licensee's audit program evaluates the effectiveness of the change and its implementation.
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 without regard to its radioactivity if it:
 - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes and obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed material for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level 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 No.
37-30924-01Docket No.
03036603

Amendment No. 4

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 22, 2004 [ML041840479]
 - B. Letter dated August 27, 2004 [ML042510354]
 - C. Letter dated January 24 2006 [ML060380224]
 - D. Letter dated March 8, 2007 [MI070730195]
 - E. Letter dated March 27, 2007 [ML071550135]



For the U. S. Nuclear Regulatory Commission

Date February 25, 2008

By *Original signed by Farrah C. Gaskins*
Farrah C. Gaskins
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406