



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

June 9, 2005

Docket No. 03035435
Control No. 136946

License No. 07-30584-01

Eric Solon, Ph.D.
Radiation Safety Officer
Quest Pharmaceutical Services, L.L.C.
Delaware Technology Park
3 Innovation Way, Suite 240
Newark, DE 19711

SUBJECT: QUEST PHARMACEUTICAL SERVICES, L.L.C., LICENSE AMENDMENT,
CONTROL NO. 136946

Dear Dr. Solon:

This refers to your license amendment request. Enclosed with this letter is the amended license which adds several places of use under Condition 10.

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.

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

Current NRC regulations and guidance are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by David B. Everhart

David B. Everhart
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 3

E. Solon
Quest Pharmaceutical Services, L.L.C.

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	DEverhart/DBE							
DATE	6/9/2005							

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.

Licensee	
1. Quest Pharmaceutical Services, L.L.C.	April 25, 2005, 3. License number 07-30584-01
2. Delaware Technology Park 3 Innovation Way, Suite 240 Newark, Delaware 19711	4. Expiration date October 31, 2010 5. Docket No. 03035435 Reference No.

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. 75 millicuries
B. Carbon 14	B. Any	B. 50 millicuries
C. Phosphorus 32	C. Any	C. 5 millicurie
D. Phosphorus 33	D. Any	D. 5 millicurie
E. Sulfur 35	E. Any	E. 5 millicurie
F. Calcium 45	F. Any	F. 4 millicuries
G. Chromium 51	G. Any	G. 5 millicuries
H. Yttrium 90	H. Any	H. 10 millicuries
I. Technetium 99m	I. Any	I. 10 millicuries
J. Iodine 125	J. Non-volatile compounds	J. 15 millicuries
K. Rhenium 188	K. Any	K. 5 millicuries

9. Authorized use:

A. through K. Research and development as defined in 10 CFR 30.4; animal studies.

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CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at: Delaware Technology Park, 3 Innovation Way, Suites 211, 225 & 240, and 1 Innovation Way, Suite 200, Newark, Delaware; and Pencader Corporate Center, 110 Executive Drive, Suite 7, Newark, Delaware.
11.
 - A. Licensed material shall be used by, or under the supervision of, Yuan-Shek Chen, Lawrence Duan, Alfred Lordi, Kumar Ramu, Helen Shen, or Eric Solon.
 - B. The Radiation Safety Officer for this license is Eric Solon, Ph.D.
12. Licensed material shall not be used in or on human beings.
13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
14. The licensee shall not use licensed material in field applications where activity 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 ten 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 three 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."

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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 July 11, 2000
- B. Letter dated September 26, 2000
- C. Letter dated March 28, 2002
- D. Letter dated April 30, 2002
- E. Letter dated May 17, 2004
- F. Letter dated April 25, 2005, with amendments received June 7, 2005

For the U.S. Nuclear Regulatory Commission

Original signed by David B. Everhart

Date June 9, 2005

David B. Everhart
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406