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

November 15, 2006

Docket No. 03014680 License No. 29-00117-06
Control No. 139603

Gregory R. Reinhard, DVM
Executive Director
Merck & Co., Inc.
RY80HP
P.O. Box 2000
Rahway, NJ 07065

SUBJECT: MERCK & CO., INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 139603

Dear Dr. Reinhard:

This is in reference to your letter dated October 9, 2006 requesting to amend Nuclear Regulatory Commission License No. 29-00117-06. The guidance for a broad scope license to manufacture and distribute radio labeled drugs to medical use licensees for research is contained in Appendix U of NUREG-1556 Volume 12, "Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution." The below questions are based upon the guidance in this document. In order to continue our review, we need the following additional information:

1. In order to add byproduct material to compounds for which the Food and Drug Administration has accepted a Notice of Claimed Investigational Exemption for a New Drug (IND) and distribute these materials to authorized recipients for human use research, a new 10 CFR Part 32 authorization normally is needed on your license. If your request involves only hydrogen-3 and carbon-14 an exemption from 10 CFR 32.72(a)(2) may be requested.

2. With regard to an exemption from 10 CFR 32.72(a)(2) please provide the following items:

   a. Confirm that only radioactive drugs for which the FDA has accepted an IND application containing microcurie quantities of hydrogen-3 or carbon-14 will be prepared and distributed.

   b. Confirm that you are not registered with the State or the FDA as a drug manufacturer. (The FDA, in 21 CFR 207.10(d), exempts classes of persons who manufacture or process drugs not for sale, but solely for use in research, teaching, and chemical analysis, from registering with the FDA as a drug manufacturer.)

c. Confirm that you are not licensed as a pharmacy (in order to operate as such you would need to employ an Authorized Nuclear Pharmacist (ANP)).

d. Confirm that you are neither a nuclear pharmacy nor located within a Federal institution.

e. Confirm that you will meet all other applicable sections of 10 CFR 32.72.

3. Complete the other applicable sections of an application as written in section 2 of Appendix U to NUREG-1556, Volume 12.

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 **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 139603. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Vincent Williams, Radiation Safety Officer

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SUNSI Review Complete: DLawyer
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