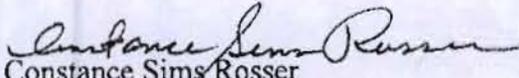


TO: Mr. Thomas K. Thompson, Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Q-5

FAX: 610-337-5269

FROM: 
Constance Sims Rosser
Radiation Safety Officer
Center for Food Safety and Applied Nutrition
301-436-2105

03036120

SUBJECT: NRC Form 483, Registration Certificate—*In Vitro* Testing with Byproduct
Material Under General License for NRC License No. 19-30771-01; Docket No.
03036120; Control No. 136722

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
College Park, MD 20740

Mr. Thomas K. Thompson, Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

NRC License No. 19-30771-01
Docket No. 03036120
Control No. 136722

RE: NRC Form 483, Registration Certificate—*In Vitro* Testing with Byproduct Material
Under General License

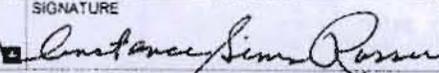
This letter is to request authorization to purchase reagents kits containing Iodine-125 and a Mock Iodine-125 reference or calibration sources as generally licensed. These items would be possessed, used, stored and disposed of in accordance with Title 10 Code of Federal Regulation, Part 31.11(b)(1). Appropriate precautions and good laboratory practices shall be used in the storage, handling, and disposal of this material. Please find a completed NRC Form 483 attached for your review and approval.

Questions regarding this request should be directed to Mr. Peter Doob at 301-436-2178.

Sincerely,

Constance Sims Rosser
Radiation Safety Officer
Center for Food Safety and
Applied Nutrition

Enclosure

NRC FORM 483 (8-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0038 EXPIRES: 1/31/2012 <small>Estimated burden per response to comply with this mandatory collection request: 8 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to: Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE-OB-10202, (3150-0038), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>
REGISTRATION CERTIFICATE -- <i>in vitro</i> TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE		
<small>Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for <i>in vitro</i> clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.</small>		
1. NAME AND ADDRESS OF APPLICANT (See instruction 3 B. below) Department of Health & Human Services Center for Food Safety and Applied Nutrition Harvey W. Wiley Building 5100 Paint Branch Parkway, HFS-650 College Park, MD 20740	2. APPLICATION (Check one box only) I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for: <ul style="list-style-type: none"> <input type="checkbox"/> Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine. <input checked="" type="checkbox"/> The above-named clinical laboratory. <input type="checkbox"/> The above named hospital. <input type="checkbox"/> Veterinarian in the practice of veterinary medicine. 	
TELEPHONE NUMBER (Include Area Code): (301) 436-2500	4. REGISTRATION REGISTRATION NUMBER:	
INSTRUCTIONS A. Submit this form to: Division of Materials Safety & State Agreements (T-8 E24) Office of Federal and State Materials and Environmental Management Programs U.S. Nuclear Regulatory Commission Washington, DC 20555-0001 (At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.) B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.	 (If this an initial registration, leave this space blank – number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)	
5. If place of use is different from address listed above, give complete address. Muirkirk Road Complex -Module One Facility (MOD I), 8301 Muirkirk Road, Laurel, Maryland 20708		
6. CERTIFICATION I hereby certify that: <ul style="list-style-type: none"> A. All information in this registration certificate is true and complete. B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials. C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director, Office of Federal and State Materials and Environmental Management Programs within 30 days from the effective date of such change. D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission. 		
PRINTED OR TYPED NAME AND TITLE OF APPLICANT Constance Sims Rosser, CFSAN Radiation Safety Officer	SIGNATURE 	DATE 11/09/2009
WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 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.		

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§31.11 General license for use of byproduct materials for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen 3 (Tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron 59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt 57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate - In vitro Testing with Byproduct Material Under General License," with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in §30.6(a), and has received from the Commission a validated copy of NRC Form 483 with registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

(c) A person who receives, acquires, possesses or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (Tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

DiaSozin and ALPCO
(NAME OF MANUFACTURER)

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License," Form NRC-483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

NOTES

¹ A State to which certain regulatory authority over radioactive material has been transferred by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

² Labels authorized by the regulations in effect on September 26, 1979 may be used until one year from September 27, 1979.

³ A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NRC Form 313, "Application for Byproduct Material License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

This is to acknowledge the receipt of your letter/application dated 11/16/09 ^{received} and to inform you that the initial processing which includes an administrative review has been performed.

Notification (19-30771-01)
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** 144296.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.