

Law Offices

105 College Road East
P.O. Box 627
Princeton, NJ
08542-0627

609-716-6500 phone
609-799-7000 fax
www.drinkerbiddle.com

A Delaware Limited
Liability Partnership

CALIFORNIA
DELAWARE
ILLINOIS
NEW JERSEY
NEW YORK
PENNSYLVANIA
WASHINGTON DC
WISCONSIN

October 12, 2016

VIA OVERNIGHT MAIL

James Dwyer
Chief, Medical Branch
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, Pennsylvania 19406-2713

**Re: Request to Terminate Standby Trust Agreement
Ortho-Clinical Diagnostics, Inc.
130 Indigo Creek Drive
Rochester, New York 14626
NYS DOH Radioactive Materials License No. C2815
DH Nos. 15-286, 16-219 & 16-308**

REC-61 10 13 16 AM 07:47

Dear Mr Dwyer:

Thank you for speaking with me yesterday regarding the above-referenced facility, which was formerly owned by Johnson & Johnson Corporation ("J&J").

As discussed, J&J is requesting the U.S. Nuclear Regulatory Commission's ("NRC") approval to terminate the Standby Trust Agreement that J&J made with the Bank of New York Mellon to provide Financial Assurance for Decommissioning of the above-referenced facility (the "OCD Rochester STA"). The OCD Rochester STA erroneously named the NRC as the beneficiary. J&J did not hold an NRC license for the above-referenced facility, and J&J is no longer the owner of the above-referenced facility; therefore, J&J was/is not required to maintain the OCD Rochester STA for the benefit of the NRC. Further, the enclosed correspondence from the New York State Department of Health states that "new [possession] limits put[] [the above-referenced facility] under the threshold at which Financial Assurance is required."

By its terms, the OCD-Rochester STA may not be terminated without the written consent of the beneficiary (*i.e.*, the NRC). Accordingly, we ask that you please provide the NRC's written consent to terminate the OCD-Rochester STA by signing the attached statement and returning it to me in the enclosed postage paid envelope. The timely return of the NRC's written consent to terminate the OCD-Rochester STA is greatly appreciated, as it will enable J&J to stop paying annual trust administration fees for an instrument that J&J is not required to maintain.

Jonathan I. Epstein,
Partner responsible for
Princeton Office

NUCLEAR MATERIALS-002

DrinkerBiddle&Reath
LLP

James Dwyer

October 12, 2016

Page 2

Thank you for your assistance and cooperation with this matter. Should you have any questions or need for additional information, please feel free to call me at (609) 716-6607.

Very truly yours,



Mark G. Maser

MGM/mm

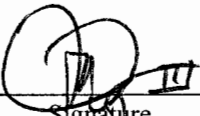
Enclosures

cc: Vincent Mignone, Manager EHS&S, J&J Consumer, Inc. (w/o encl.)
Roger Bills, Radiation Safety Officer, Ortho-Clinical Diagnostics, Inc. (w/o encl.)

CONSENT TO TERMINATE STANDBY TRUST AGREEMENT

The U.S. Nuclear Regulatory Commission ("NRC") hereby grants consent for Johnson & Johnson ("J&J") and the Bank of New York Mellon ("BNY Mellon") to terminate all Standby Trust Agreements, and amendments or restatements thereof, that were made between J&J (Grantor) and BNY Mellon (Trustee) for the benefit of the NRC (Beneficiary) in the event that Financial Assurance for Decommissioning is/was required for the Ortho-Clinical Diagnostics Inc. facilities in Rochester, New York (NYS DOH Radioactive Materials License No. C2815).

For the U.S. Nuclear Regulatory Commission:



Signature

James P. Dwyer III

Print Name

Chief, Medical Branch

Title

October 13, 2016

Date



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

JUL 22 2016

Ortho-Clinical Diagnostics, Inc.
130 Indigo Creek Drive
Rochester, New York 14626

Attention: Roger A. Bills
Radiation Safety Officer

RE: NYS Dept. of Health Radioactive
Materials License No. C2815
DH Nos. 15-286, 16-219 & 16-308

Dear Licensee:

Enclosed is a renewal of New York State Department of Health Radioactive Materials License No. C2815, which supersedes the original license and authorizes the use of the materials listed in the license subject to the conditions therein and to the applicable regulations of Part 16 of the New York State Sanitary Code and/or Industrial Code Rule 38. You should become familiar with the conditions of your license and the provisions of Part 16 and/or Industrial Code Rule 38 as they relate to your facility.

This renewal includes the following changes to the license:

- It lists the change in possession limits for Hydrogen 3 and Americium 241, as requested in the letter dated April 29, 2016, signed by Roger Bills. The new limits puts you under the threshold at which Financial Assurance is required.
- Condition 9 has been updated so you are no longer authorized to manufacture and distribute Iodine-125 Labeled *T.cruzi* Antigen to Quest Diagnostics.

Please note that in your license application you agreed to adhere to certain criteria and procedures established in Radiation Guide 1.2. Therefore, you should make copies of those procedures for reference and keep them on file with the license, as they are part of the licensing document. You are also bound by statements and representations in documents listed in Condition No. 11 of the license. These are also a part of the licensing document and must be maintained with it. If you have employed the services of a consultant for assistance in the preparation of any portion of the application or subsequent supporting information, ensure that you have a copy of all correspondence and submissions.

One of our Radiological Health Specialists or Radiophysicists will periodically inspect your installation and respond to any radiation incidents.

Any questions concerning the license or your radiation program should be directed to this office at 518/402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
ESP, Corning Tower – Room 1245
Albany, New York 12237

Sincerely,

A handwritten signature in black ink, appearing to read "Dan J. Samson", with a long horizontal flourish extending to the right.

Daniel J. Samson, CHP, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

DJS/AC/DCG:ks

Enclosures: Renewal/Amendment No. 11
Notice to Employees
Security Awareness Notice