

April 15, 2011

Mr. Herman Scholtz, General Manager
and Vice President
Clinical Pharmacology Services
Covance Clinical Research Unit, Inc.
Global Clinical Pharmacology
Covance – Evansville
617 Oakley Street
Evansville, IN 47710

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-33820/10-01(DNMS) –
COVANCE CLINICAL RESEARCH UNIT, INC.

Dear Mr. Scholtz:

On November 19, 2010, two U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at your Honolulu, Hawaii facility, with continued in-office review through March 29, 2011. The in-office review included, in part, receipt and review of information about when licensed material was transferred from the Honolulu facility. On March 29, 2011, a telephonic final exit meeting was held between Robert Gattone of my staff and Robert Kochan of your staff.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). Title 10 Code of Federal Regulations (CFR) Section 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of when no principal activities under the license have been conducted for a period of 24 months. Between approximately January 2006 and November 2010, a period greater than 24 months, your staff did not conduct principal activities under the license and did not provide notification to the NRC in writing within 60 days of January 2008. The cause of the violation is that your Radiation Safety Officer (RSO) was unaware of the requirement.

Your staff received and stored the licensed material without conducting principal activities until November, 2010 when your staff accessed it for disposal. As corrective action to prevent a similar violation, on March 29, 2011, your RSO committed to develop a procedure to ensure that actions are taken to comply with the requirements in 10 CFR 30.36(d) or request an extension of the notification time pursuant to 10 CFR 30.36(f).

This failure constitutes a violation of minor significance and is not subject to formal enforcement action in accordance with the NRC Enforcement Manual Section 2.10.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in this letter.

Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III. If you contest the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary, information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-33820
License No. 13-26640-01

cc: Robert Kochan, Ph.D., RSO
State of Hawaii

H. Scholtz

-2-

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Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-33820
License No. 13-26640-01

cc: Robert Kochan, Ph.D., RSO
State of Hawaii

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