Official Use Only - Security-Related Information



UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

DEC 0 6 2013

Mr. Clay Cramer Radiation Safety Officer Esperion Therapeutics, Inc. 46701 Commerce Center Drive Suite B Plymouth, MI 48170

SUBJECT:

APPROVAL FOR RELEASE OF ROOMS 006-1520 AND 006-1522 IN

VIVARIUM FACILITY FOR UNRESTRICTED USE

Dear Mr. Cramer:

Enclosed is Amendment No. 05 to your NRC Material License No. 21-32115-02 in accordance with your request dated October 16, 2013. Please note that the changes made to your license are printed in **bold** font.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c) (20) (iii).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

The enclosed document contains sensitive security-related information. When separated from this cover letter this letter is uncontrolled.

Official Use Only - Security Related Information

C. Cramer

-2-

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be 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.

If you have any questions, please contact me at (630) 829-9870.

Sincerely,

Peter J. Lee, Ph.D., CHP Materials Control, ISFSI, and Decommissioning Branch

License No. 21-32115-02 Docket No. 030-37940

Enclosure: Amendment No. 05