



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

MAY 04 2018

Timothy J. Fedewa, CSP  
Radiation Safety Officer  
Pharmacia & Upjohn Company LLC  
7000 Portage Road  
PORT-41-016  
Kalamazoo, MI 49001

Dear Mr. Fedewa:

Enclosed is Amendment No. 2 to your NRC Material License No. 21-32848-04 in accordance with your request. Please note that the format of your license has been changed due to our new licensing process.

Items 6-9 on your license have been updated in accordance with your request and the applicable Sealed Sources and Devices Registries; note that device manufacturer names have been updated to the current company names registered with the NRC or Agreement States.

Additionally, the following License Conditions have been updated in accordance with our licensing policy: Condition 12 regarding training requirements for users, Condition 13 regarding the leak test requirements for sealed sources, Condition 15 regarding the biannual inventory requirement, and Condition 16.B. regarding records of periodic on-off mechanism (shutter) and indicator test results. Lastly, License Condition 24, as described on License Amendment No. 1, has been deleted as these requirements are already specified in the regulations in 10 CFR Part 71.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>.

Sincerely,

*Laura B. Cender*

Laura B. Cender  
Health Physicist  
Materials Licensing Branch

License No. 21-32848-04  
Docket No. 030-38566

Enclosure: Amendment No. 2