

## UNITED STATES NUCLEAR REGULATORY COMMISSION

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

## MAY 0 9 2007

Douglas Decker Radiation Safety Officer Pharmoptima 6 710 Quality Way Portage, MI 49002

Dear Mr. Decker:

Enclosed is your NRC Material License No. 21-32649-01 in accordance with your request.

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.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

- 1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- 2. Notify NRC, in writing, within 30 days:
  - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the mailing address listed on the license changes.
- 3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
- 4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;

- d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
- e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
- f. Change ownership of your organization.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

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.

In accordance with 10 CFR 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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <u>http://www.nrc.gov/reading-rm/adams.html</u> (the Public Electronic Reading Room).

Sincerely,

James R. Multauer Health Physicist

Health Physicist Materials Licensing Branch

License No. 21-32649-01 Docket No. 030-37444

Enclosures: 1. License No. 21-32649-01 2. New R & D License Package