



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

August 16, 2013

Docket No. 03017101
Control No. 581419

License No. 06-19183-01

James G. Baxter, Ph.D.
Sr. Vice President, Development
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

SUBJECT: BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; LICENSE
AMENDMENT; CONTROL NO. 581419

Dear Dr. Baxter:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

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

J. Baxter

2

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.

Thank you for your cooperation.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 25

cc:
William L. Galdenzi, Radiation Safety Officer
Mark Castles, Vice President, Drug Metabolism and Pharmacokinetics

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SUNSI Review Complete: DLawyer

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