



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

April 28, 2020

Ulrich Roth, Ph.D., Head of Development NCE  
& Sr. VP, Development  
Boehringer Ingelheim Pharmaceuticals, Inc.  
900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT 06877-0368

**SUBJECT:** TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION REGULATIONS, TITLE 10 CODE OF FEDERAL REGULATIONS AND LICENSE CONDITIONS OF NRC MATERIALS LICENSE 06-19183-01, BOEHRINGER INGELHEIM PHARMACEUTICALS, INCORPORATED MAIL CONTROL NO. 618708

Dear Dr. Roth:

By letter dated April 23, 2020 (ML20114E086) and in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2301 and 30.11(a), Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) requested temporary exemptions from regulation 10 CFR 20.1101(c) and License Condition 23 of its NRC Materials License 06-19183-01 (ML20028F329).

In its request, Boehringer stated that it is seeking these exemptions due to the COVID-19 public health emergency (PHE), Boehringer has reduced its onsite work force. Boehringer noted that because of limited onsite personnel, they would be challenged to meet the two requirements for which exemptions are being requested.

The exemption provision in 10 CFR 20.2301 states:

The Commission may, upon application by a licensee, grant exemptions from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

The NRC staff reviewed Boehringer's exemption requests and finds that the criteria in 10 CFR 20.2301 were met.

The regulation in 10 CFR 20.2301 authorizes granting of exemptions specific to Part 20. The NRC staff has determined that the granting of the requested exemptions will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemptions is authorized by law.

Boehringer requested exemption from 10 CFR 20.1101(c), which requires annual review of the radiation protection program content and implementation. The NRC determined that the 90-day exemption is relatively short compared to the annual review interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.

The licensee also requested exemption from License Condition 23 which requires in part that the licensee conduct its program in accordance with the statements, representations, and the procedures contained on certain documents submitted to the NRC, including any enclosures, which included a letter dated February 5, 2015 (ML15048A074). This letter contains the licensee's commitment to perform an inventory of all licensed material every six months. License Condition 23 was imposed upon the licensee by the NRC per 10 CFR 30.34(e), and the regulation in 10 CFR 30.34(c) requires that the licensee confine its use of the byproduct material to the locations and purposes authorized in the license. Therefore, exemptions to the requirement in 10 CFR 30.34(c) to comply with the terms of a license may be granted pursuant to 10 CFR 30.11. The NRC staff has determined that the granting of the requested exemption from this requirement in License Condition 23 will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

License Condition 23 requires the licensee to perform an inventory every six months of all licensed material. The NRC determined that the 90-day exemption is relatively short compared to the six-month inventory interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.

From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempt from the requirement in 10 CFR 20.1101(c) to perform an annual review of its radiation protection program content and its implementation. The licensee shall perform the required review within 90 days of the expiration of this exemption.

From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempt from the requirement in License Condition 23 to perform an inventory of all licensed material. The licensee shall perform the required inventory within 90 days of the expiration of this exemption.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(F) and (I). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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 <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Steve Shaffer of my staff at [Steve.Shaffer@nrc.gov](mailto:Steve.Shaffer@nrc.gov) or call 610-337-5225.

Thank you for your cooperation.

Sincerely,

Christopher G. Cahill, Chief  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Nuclear Materials Safety  
Region I

Docket No. 03017101  
License No. 06-19183-01  
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cc: Drané O'Brien, Radiation Safety Officer

TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION  
 REGULATIONS, TITLE 10 CODE OF FEDERAL REGULATIONS AND LICENSE CONDITIONS  
 OF NRC MATERIALS LICENSE 06-19183-01, BOEHRINGER INGELHEIM  
 PHARMACEUTICALS, INCORPORATED MAIL CONTROL NO. 618708 DATED  
 APRIL 28, 2020

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