



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

July 14, 2020

VIA E-MAIL

Ashley M. Cockerham  
Mercurie Consulting LLC  
Ashley@mercurieconsulting.com

SUBJECT: NRC APPROVAL OF BAYER HEALTHCARE LLC REQUEST FOR  
WITHHOLDING INFORMATION FROM PUBLIC DISCLOSURE RELATED TO  
PATIENT ACCESS BARRIERS FOR RADIONUCLIDE THERAPY (SECY-20-0005)

Dear Ms. Cockerham:

By letter dated July 7, 2020, Mercurie Consulting LLC, on behalf of Bayer Healthcare LLC (Bayer), submitted an affidavit dated May 21, 2020, executed by Shaemus Gleason of Bayer, requesting that the information contained in the following document be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 2, Section 2.390: "Confidential Commercial Presentation." A non-proprietary copy of this document has been placed in the Nuclear Regulatory Commission's (NRC's) Public Document Room and added to the Agencywide Documents Access and Management System Public Electronic Reading Room under Accession No. ML20196L965.

The affidavit stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

- a. The information is and has been held in confidence by Bayer.
- b. The information is of a type that is customarily held in confidence by Bayer.
- c. There is a rational basis for withholding because this information, if released, might result in the loss of an existing or potential competitive advantage as follows:
  - i. The information, if used by a competitor, is likely to reduce the competitor's expenditure of resources or improve their advantage in the research, production, and licensing of similar targeted radionuclide therapies.
  - ii. The information reveals distinguishing aspects of Bayer's business model, operations, and future business endeavors in connection with targeted radionuclide therapies.
  - iii. The information reveals practice dynamics of the use of targeted radionuclide therapies.
- d. The information is being transmitted to the Commission voluntarily and in confidence.
- e. The information is not available in public sources or available information has not been previously employed in the same original manner or method to the best of my knowledge.
- f. Public disclosure of this information is likely to cause substantial harm to the competitive position of Bayer as it would enhance the ability of a competitor to understand Bayer's business and targeted radionuclide therapies, including licensing

and other confidential commercial and financial information without commensurate time, research and expense.

We have reviewed your request and the information in accordance with the requirements of 10 CFR 2.390 and, on the basis of Bayer's statements, have determined that the submitted information sought to be withheld contains proprietary commercial information and should be withheld from public disclosure. We have also determined that Bayer's demonstrated concern for protection of a competitive position does not interfere with the public's right to be fully apprised of the bases for and effects of any future Commission decision on SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)". Therefore, the version of the submitted information marked as proprietary will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5).

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. The NRC may have cause to review this determination in the future, for example, if the information has been requested in a Freedom of Information Act (FOIA) request. If the NRC determines that the information should be disclosed in response to a FOIA request, you will be notified of this determination and given the opportunity to object, in accordance with 10 CFR 9.28.

If you have any questions regarding this matter, I may be reached at 301-415-5422.

Sincerely,

Christian Einberg, Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

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**\*via email**

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