

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 21-00182-03 , Zoetis P&U, LLC**

DATE: 03/18/2015

DOCKET NO.: 030-04781

LICENSE NO.: 21-00182-03

LICENSEE: Zoetis P&U, LLC

**333 Portage Street
Kalamazoo, Michigan 49007**

TECHNICAL REVIEWER: William P. Reichhold

SUMMARY AND CONCLUSIONS

Zoetis P&U, LLC is authorized by NRC License 21-00182-03 for the possession and use of byproduct material for purposes of pharmaceutical research and development including animal studies. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by Zoetis P&U, LLC that will result from an internal reorganization so its manufacturing, research and development operations and the NRC license will be transferred to Zoetis, LLC. Zoetis, Inc. remains the parent company. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML15035A642.

The request for consent was reviewed by NRC staff for a direct change in control of a 10CFR Part 30 license using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000. The NRC staff finds that the information submitted by Zoetis P&U, LLC sufficiently describes and documents the transaction and commitments made by Zoetis, LLC and Zoetis P&U, LLC.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds that the proposed change in control is in accordance with the Act. The staff finds that, after completion of the change in control, Zoetis, LLC will be the licensee and will be qualified to use byproduct material for the purpose requested, and will continue to have the equipment, facilities, and procedures needed to protect public health and safety, and promotes the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from NRC's Web-Based Licensing (WBL), Zoetis P&U, LLC (formerly known as Pharmacia & Upjohn Company, LLC) has been an NRC licensee since April 24, 1958. The NRC conducted a main office inspection of Zoetis P&U, LLC (formerly known as Pharmacia & Upjohn Company, LLC) on August 21, 2012, and no violations were identified during this inspection. The commitments made by Zoetis, LLC and Zoetis P&U, LLC state that Zoetis P&U, LLC License No. 21-00182-03:

- A. will not change the radiation safety officer listed in the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license; and
- E. will keep regulatory required surveillance records and decommissioning records.

This is an internal corporate restructuring action where Zoetis, P&U, LLC will transfer its manufacturing, research and development operations and the NRC license to Zoetis, LLC. Zoetis Inc. remains the parent company. Therefore, for security purposes, Zoetis, LLC is considered a known entity following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "Checklist to Provide a Basis for Confidence that Radioactive Materials will be Used as Specified on the License", September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use.

Zoetis P&U, LLC is required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 21-00182-03. Zoetis, LLC committed to assuming the responsibility, coverage, and liability of the NRC license.

REGULATORY FRAMEWORK

Zoetis P&U, LLC License No. 21-00182-03, was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the change of control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15. As discussed in NUREG-1556, Volume 15, NRC is generally using the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. Zoetis P&U, LLC request for consent describes a direct change of control resulting from an internal reorganization so its manufacturing, research and development operations and the NRC license will be transferred to Zoetis, LLC, and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML15035A642. After completion of the internal reorganization, Zoetis, LLC will be the licensee and be in control of all licensed activities under Materials License No. 21-00182-03. Zoetis, Inc. will remain the parent company. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction, and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15.

TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Zoetis P&U, LLC sufficiently describes and documents the commitments made by Zoetis, LLC and Zoetis P&U, LLC, and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 21-00182-03 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the license and commitments; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; And, in the future, will abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15.

Therefore, the staff concludes that the proposed change in control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be harmful to the common defense and security, or to the health and safety of the public.