

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 21-32190-01MD, PHARMALOGIC MICHIGAN. LLC**

DATE: MAR 25 2015
DOCKET NO.: 030-35125
LICENSE NO.: 21-32190-01MD
LICENSEE: PharmaLogic Michigan, LLC
TECHNICAL REVIEWER: Toye L. Simmons

SUMMARY AND CONCLUSIONS

PharmaLogic Michigan, LLC is authorized by NRC License 21-32190-01MD for the possession and use of byproduct material for purposes of providing radiopharmaceuticals and radiation sources and devices to medical facilities for human use. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license change of control submitted by PharmaLogic Holding Corp. that will result from a merger between PL Holding Merger Sub, Inc. and PharmaLogic Holdings Corp. In a merger agreement PL Holding Merger Sub, Inc., a Delaware corporation (Merger Sub) which is wholly-owned by PL Holding, Inc. a Delaware corporation (Purchaser) merged with and into PharmaLogic Holdings Corp. PharmaLogic Holdings Corp. will be the surviving corporation and will retain its corporate name and its federal employer identification number. PharmaLogic Holdings Corp. will continue to operate its business and own its subsidiaries, including PharmaLogic Ltd. Further, PharmaLogic Holdings Corp. reports to PL Holding, Inc. who reports to PL Holding, LLC. (See revised organizational charts with letter dated March 24, 2015). The indirect change of control is described in Agency Documents Access and Management System (ADAMS) accession number ML15029A059.

The request for consent was reviewed by NRC staff for an indirect change in control of a 10 CFR 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 PharmaLogic Holdings Corp. sufficiently describes and documents the transaction and commitments made by PharmaLogic Holdings Corp and PharmaLogic Michigan, L.L.C.

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 the change of control, PharmaLogic Michigan, L.L.C. will remain 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 the NRC's Agencywide Documents Access and Management System, PharmaLogic Michigan, L.L.C. has been an NRC licensee since September 1, 1999. The NRC conducted a main office inspection on November 6, 2012, and no violations were identified. The commitments made by PharmaLogic Holdings Corp and PharmaLogic Michigan, L.L.C. state that PharmaLogic Michigan, L.L.C. (License No. 21-32190-01MD):

- 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;
- E. will not change the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

PharmaLogic Holdings Corp is a known entity in that it has maintained oversight of PharmaLogic Michigan, L.L.C. for at least the past 10 years. Therefore, for security purposes, PharmaLogic Holdings Corp 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.

PharmaLogic Michigan, L.L.C. is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 21-32190-01MD.

REGULATORY FRAMEWORK

PharmaLogic Michigan, L.L.C.'s License No. 21-32190-01MD, 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. PharmaLogic Michigan, L.L.C.'s request for consent describes an indirect change of control resulting from a planned merger between PL Holding Merger Sub, Inc. Delaware and PharmaLogic Holdings Corp in which PharmaLogic Holding Corp retains its corporate name and its federal employer identification number and will continue to operation its businesses and own its subsidiaries including the NRC licensee PharmaLogic Michigan LLC and, as such, the change of control requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML15029A059. After completion of the merger, PharmaLogic Michigan, L.L.C. will continue as the licensee and remain in control of all licensed activities under Materials License No. 21-32190-01MD. 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 sufficiently describes and documents the commitments made by PharmaLogic Holdings Group and PharmaLogic Michigan, L.L.C., 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) (14) (xi).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to an indirect change of control of byproduct materials license No. 21-32190-01MD 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 inimical to the common defense and security, or to the health and safety of the public.