

**July 21, 2006**

**NUCLEAR REGULATORY COMMISSION**

**DOCKET NUMBER 030-34810**

**ENVIRONMENTAL ASSESSMENT RELATED TO ISSUANCE OF A LICENSE**

**TERMINATION TO BYPRODUCT MATERIAL LICENSE NO. 21-32115-01**

**FOR THE ESPERION THERAPEUTICS, INC., ANN ARBOR, MICHIGAN**

Introduction

The U.S. Nuclear Regulatory Commission (NRC) staff has prepared this environmental assessment (EA) to support Esperion Therapeutics Inc.'s (the licensee) May 17, 2006 request to terminate its license and release its Ann Arbor, Michigan facility for unrestricted use. On September 24, 1998, the NRC authorized the licensee to use labeled compounds such as hydrogen-3, carbon-14, phosphorus-32, phosphorus-33, sulfur-35, etc. for research and development. The EA has been developed in accordance with the requirements of 10 CFR Part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate for the proposed licensing action.

Proposed Action

The proposed action is to terminate Byproduct Material License No. 21-32115-01 issued to Esperion Therapeutics Inc., and release its Ann Arbor, Michigan facility for unrestricted use. The licensee provided survey results which demonstrated that the facility was in compliance with 10 CFR 20.1402, "Radiological Criteria for Unrestricted Use." No radiological remediation activities are required to complete the proposed action.

Need for the Proposed Action

Esperion Therapeutics Inc. is requesting this license termination because it no longer plans to conduct NRC-licensed activities at the Ann Arbor, Michigan facility. The NRC is

fulfilling its responsibilities under the Atomic Energy Act to make a decision on the proposed license amendment for decommissioning that ensures that residual radioactivity is reduced to a level that is protective of the public health and safety and the environment, and allows the Ann Arbor, Michigan facility to be released for unrestricted use.

#### Environmental Impacts of the Proposed Action

The NRC staff has reviewed the surveys performed by Esperion Therapeutics Inc., which the licensee provided to demonstrate compliance with the license termination criteria in 10 CFR Part 20.1402 for unrestricted release. Based on its review, the staff has determined there were no radiological or non-radiological environmental impacts associated with the action since no radiological remediation activities were required to complete the proposed action. The staff has, therefore, concluded that the release of the Ann Arbor, Michigan facility for unrestricted use is bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG-1496). No outdoor areas were affected by the use of licensed materials.

#### Alternatives to the Proposed Action

The only alternative to the proposed action of allowing decommissioning of the site is no action. Under the no-action alternative, the Ann Arbor, Michigan facility would remain under an NRC license and would not be released for unrestricted use. Denial of the license amendment request would result in no change to current conditions at the facility. The no-action alternative is not acceptable because it would result in violation of NRC's Timeliness Rule (10 CFR Part 30.36), which requires licensees to decommission their facilities when licensed activities cease. This alternative would also impose an unnecessary regulatory burden and limit potential benefits from future uses of the licensee's facility.

### Agencies and Persons Consulted

This EA was prepared by Peter J. Lee, Ph.D., CHP, Health Physicist, Decommissioning Branch, Division of Nuclear Materials Safety, Region III. The NRC staff have determined that Section 7 consultation under the Endangered Species Act is not required as the proposed action does not have the potential to affect the physical environment and, therefore, will not affect listed or proposed endangered species. Additionally, the proposed action is not the type of activity that has the potential to affect historic properties; therefore, no additional consultation under Section 106 of the National Historic Preservation Act is required.

The NRC provided a draft of its Environmental Assessment (EA) to Mr. Bob Skowronek, Chief, Radioactive Material and Medical Waste Unit, State of Michigan, for review on June 23, 2006. On June 23, 2006, Mr. Skowronek responded by phone and stated that the State had no objections to the proposed action.

### Conclusion and Finding of No Significant Impact

The NRC staff concluded that the proposed action complies with the license termination criteria in Subpart E of 10 CFR Part 20 for unrestricted release. Based on its review, the staff has determined there are no environmental impacts associated with the unrestricted release of the Ann Arbor, Michigan facility, and the proposed licensing action is bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," (NUREG-1496). Additionally, no non-radiological or cumulative impacts were identified. Therefore, the NRC has concluded that the proposed action will not have a significant effect on the quality of the human environment and has determined that an environmental impact statement for the proposed action is not necessary.

### Further Information

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," documents related to this action, including the application for amendment and supporting documentation, will be available electronically for public inspection and copying from the Publicly Available Records (PARS) of NRC's document system (ADAMS), accessible from the NRC's web site at <http://www.nrc.gov/reading-rm/adams.html>. The following references are available:

- Letter dated May 17, 2006, with enclosures, from Esperion Therapeutics Inc., to NRC (ADAMS Accession No. ML061390181).
- NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs"
- NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities."

These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by email to [pdrc@nrc.gov](mailto:pdrc@nrc.gov).

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