

NUCLEAR REGULATORY COMMISSION

DOCKET NO. 030-04544

**NOTICE OF AVAILABILITY OF ENVIRONMENTAL ASSESSMENT AND FINDING OF NO
SIGNIFICANT IMPACT FOR LICENSE AMENDMENT FOR
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (FDA/CDRH) IN
ROCKVILLE, MARYLAND**

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability.

FOR FURTHER INFORMATION CONTACT: Betsy Ullrich, Commercial and R&D Branch,
Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia,
Pennsylvania, 19406, telephone (610) 337-5040, fax (610) 337-5269; or by email:
exu@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (FDA/CDRH) for Materials License No. 19-07538-01, to authorize release of its facility at 12709 Twinbrook Parkway, Rockville, Maryland for unrestricted use. NRC has prepared an Environmental Assessment (EA) in

support of this proposed action 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.

II. EA Summary

The purpose of the proposed action is to authorize the release of the licensee's 12709 Twinbrook Parkway, Rockville, Maryland facility for unrestricted use. FDA/CDRH was authorized by NRC from 1965 to use radioactive materials for research and development purposes at the site. On August 23, 2005, FDA/CDRH requested that NRC release the facility for unrestricted use. FDA/CDRH has conducted surveys of the facility and provided information to the NRC to demonstrate that the site meets the license termination criteria in Subpart E of 10 CFR Part 20 for unrestricted use.

The NRC staff has prepared an EA in support of the license amendment. The facility was remediated and surveyed prior to the licensee requesting the license amendment. The NRC staff has reviewed the information and final status survey submitted by FDA/CDRH. Based on its review, the staff has determined that there are no additional remediation activities necessary to complete the proposed action. Therefore, the staff considered the impact of the residual radioactivity at the facility and concluded that since the residual radioactivity meets the requirements in Subpart E of 10 CFR Part 20, a Finding of No Significant Impact is appropriate.

III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of the license amendment to terminate the license and release the facility for unrestricted use. The NRC staff has evaluated FDA/CDRH's request and the results of the surveys and has concluded that the

completed action complies with the criteria in Subpart E of 10 CFR Part 20. The staff has found that the radiological environmental impacts from the action are bounded by the impacts evaluated by NUREG-1496, Volumes 1-3, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities" (ML042310492, ML042320379, and ML042330385). Additionally, no non-radiological or cumulative impacts were identified. On the basis of the EA, the NRC has concluded that there are no significant environmental impacts from the proposed action, and has determined not to prepare an environmental impact statement for the proposed action.

IV. Further Information

Documents related to this action, including the application for the license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this Notice are: Environmental Assessment [ML053480176] and Final Status Survey Report, Food and Drug Administration, Center for Devices and Radiological Health, 12709 Twinbrook Parkway, Rockville, Maryland, August 22, 2005, Final Report [ML052380179]. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at (800) 397-4209 or (301) 415-4737, or by email to pdr@nrc.gov.

Documents related to operations conducted under this license not specifically referenced in this Notice may not be electronically available and/or may not be publicly available. Persons who have an interest in reviewing these documents should submit a request

to NRC under the Freedom of Information Act (FOIA). Instructions for submitting a FOIA request can be found on the NRC's web Site at

<http://www.nrc.gov/reading-rm/foia/foia-privacy.html>.

Dated at King of Prussia, Pennsylvania this 14th day of December, 2005.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

John D. Kinneman, Chief
Materials Security & Industrial Branch
Division of Nuclear Materials Safety
Region I