



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 20, 2005

Docket No. 03030473

License No. 29-28169-01

Kathleen Moore
Vice President of Operations
Synaptic Pharmaceutical Corporation
215 College Road
Paramus, NJ 07652-1431

SUBJECT: INSPECTION 03030473/2005001, SYNAPTIC PHARMACEUTICAL CORPORATION, PARAMUS, NEW JERSEY SITE AND THE RAMSEY, NEW JERSEY SITE, AND NOTICE OF VIOLATION

Dear Ms. Moore:

On May 11, 2005, Steven Courtemanche of this office conducted a safety inspection at the above address and at 170 Williams Drive, Ramsey, New Jersey of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

K. Moore
Synaptic Pharmaceutical Corporation

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Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Halim A. Hasan, Radiation Safety Officer
State of New Jersey

K. Moore
Synaptic Pharmaceutical Corporation

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NAME	SCourtemanche/src	JDwyer						
DATE	05/17/2005	6/20/05						

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NOTICE OF VIOLATION

Synaptic Pharmaceutical Corporation
Paramus, NJ

Docket No. 03030473
License No. 29-28169-01

During an NRC inspection conducted on May 11, 2005, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, on May 9, 2005, the licensee disposed of licensed radioactive material by release to the non-radioactive trash, a method not authorized by §20.2001. Specifically, on May 11, 2005, the inspector identified radioactively contaminated waste in a non-radioactive waste container and, if not for identification by the inspector, the radioactive waste would have been collected and disposed of as non-radioactive trash.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Synaptic Pharmaceutical Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site.

Current NRC regulations and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement>. Or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to

9:00 p.m. EST, Monday through Friday (except Federal holidays). To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 20th day of June 2005