



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

July 30, 2007

Docket No. 03005990

License No. 37-00401-03

Mary Dorman  
Manager, Radiation Safety  
Wyeth Pharmaceuticals, Inc.  
500 Arcola Road  
Collegeville, PA 19342

SUBJECT: INSPECTION 03005990/2007001, WYETH PHARMACEUTICALS, INC.,  
COLLEGEVILLE, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Ms. Dorman:

On July 30, 2007, Michelle Beardsley of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of the circumstances surrounding the improper transfer of a generally licensed fluid chromatography device. The findings of the inspection were discussed with you (by telephone) and Robert Wickline 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. The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in your letter dated June 29, 2007. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement**; then **Enforcement Policy**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

M. Dorman  
Wyeth Pharmaceuticals, Inc.

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Please contact Michelle Beardsley at 610-337-6942 if you have any questions regarding this matter.

Sincerely,

***Original signed by Elizabeth Ullrich***

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

Enclosure:  
Notice of Violation

cc:  
Robert Wickline, Radiation Safety Officer  
Commonwealth of Pennsylvania

M. Dorman  
Wyeth Pharmaceuticals, Inc.

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Please contact Michelle Beardsley at 610-337-6942 if you have any questions regarding this matter.

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Notice of Violation

cc:  
Robert Wickline, Radiation Safety Officer  
Commonwealth of Pennsylvania

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**SUNSI Review Complete: MBeardsley**

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NAME	Mbeardsley/mrb		Jdwyer/exu f/				
DATE	07/30/07		08/02/07				

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## **NOTICE OF VIOLATION**

Wyeth Pharmaceuticals, Inc.  
Collegeville, PA

Docket No. 03005990  
License No. 37-00401-03

During an NRC inspection conducted on July 30, 2007, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 31.5 (c)(8)(i) states, in part, that the licensee shall transfer a device containing byproduct material only by transfer to another general or specific licensee.

Contrary to the above, on May 17, 2007, the licensee transferred a generally licensed device containing a 14 mCi source of Ni-63 to an entity not possessing a general or specific license.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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. 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 30 day of July 2007