

OCT 16 1996

Docket No. 030-04605

License No. 20-01489-01

Steven M. Neimi, DVM  
Vice President, U.S. Operations  
Genzyme Transgenics Corporation  
25 Birch Street  
Milford, MA 01757

SUBJECT: INSPECTION NO. 030-04605/96-001

Dear Dr. Neimi:

On September 24, 1996, James M. Bondick of this office conducted a safety inspection at the facility located at 57 Union Street, Worcester, Massachusetts of activities authorized by the above listed 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 selective examination of representative records. In addition, our inspection examined the activities covered in your correspondence dated September 30, 1996 and October 2, 1996. The findings of the inspection were discussed with Mr. R. Jeffrey Grant, 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 and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. 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.

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S. M. Neimi, DVM  
Genzyme Transgenics Corporation

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Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response. In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR 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. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

**ORIGINAL SIGNED BY:**

John D. Kinneman, Chief  
Nuclear Material Safety Branch 2  
Division of Nuclear Materials Safety

Docket No.: 030-04605  
License No.: 20-01489-01

Enclosure:  
Notice of Violation

cc w/enclosure:  
R. Jeffrey Grant, Radiation Safety Officer  
Commonwealth of Massachusetts

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S. M. Neimi, DVM  
Genzyme Transgenics Corporation

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