

MAY 16 1994

Docket No. 030-33140

License No. 20-30035-01

Myco Pharmaceuticals, Inc.
ATTN: Barry Berkowitz
President and Chief Executive Officer
One Kendall Square, Building 300
Cambridge, MA 02139-1562

Dear Mr. Berkowitz:

SUBJECT: ROUTINE INSPECTION NO. 030-33140/94-001

On April 11, 1994, Kathleen Dolce of this office conducted a routine safety inspection at the above address 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. The findings of the inspection were discussed with Dr. William E. Timberlake, Dr. Vance Morgan and Dr. Chris Bulawa at the conclusion of the inspection. This also refers to the telephone conversation on April 25, 1994 between you and Kathleen Dolce.

Based on the results of this inspection, it appears that many of your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

The NRC is concerned about the apparent lack of the Radiation Safety Officer's (RSO) attention to the program and the numerous violations identified during the inspection. In your response to the identified violations you should pay particular attention to the root cause(s) for these violations and your actions to improve management oversight of your radiation safety program. In particular, you should address the apparent lack of effectiveness of the RSO in overseeing the program and ensuring compliance with the NRC regulatory requirements.

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REGION I

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The NRC has amended its inspection schedule for your facility to provide for more frequent inspections. Further violations of NRC requirements or repeated or uncorrected violations may lead to further enforcement actions that may involve monetary civil penalties, suspension or revocation of your NRC license.

During the inspection we noted an error in Item No. 6.G. on your license that authorizes you to possess up to 10 millicuries of iodine-133 instead of the correct isotope iodine-131. We corrected this error. A copy of the corrected license will be mailed to you in the near future.

At the conclusion of the inspection, you informed the inspector that you changed your mailing address from that which is listed on your license application that was submitted to the NRC with a letter dated April 6, 1993 and incorporated into Item No. 2 of your license. We understand that you will submit the required license amendment request to change your mailing address on the license.

Please use the enclosed self-addressed green envelope when you submit your copy to the Regional Administrator, Region I. This will 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. 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:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix A, Notice of Violation

Myco Pharmaceuticals, Inc.

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cc:

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Chris Bulawa
Commonwealth of Massachusetts

bcc:

Region I Docket Room (w/concurrences)
D. J. Holody, RI

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