March 9, 1981

## OFFICE OF INSPECTION AND ENFORCEMENT NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

EN-81-08 PDR

Licensee: Pharmatopes, Incorporated, Oak Park, Michigan Subject: PROPOSED IMPOSITION OF CIVIL PENALTIES - \$1,500

This is to inform the Commission that a Notice of Violation and a Notice of Proposed Imposition of Civil Penalties in the amount of One Thousand Five Hundred Dollars will be issued on or about March 9, 1981 to Pharmatopes. Incorporated. This action is based on alleged items of noncompliance relating to transportation of radioactive materials and to the radiation protection program at the licensee's Oak Park, Michigan radiopharmaceutical facility. The items of noncompliance involved a loss of radioactive material during transport resulting in minor contamination to a member of the general public; failure to use certified packaging for radiopharmaceuticals during transport; failure to use a proper sealing device for transport packages; failure to properly calibrate a radiation dose calitrator; failure to calibrate radiation survey instruments at the required intervals, failure to follow bioassay procedures; and failure to leak test a sealed radiation source at the required intervals. A news release has been prepared and will be issued about the time the licensee receives the Notices. The State of Michigan will be informed.

It should be noted that the licensee has not been specifically informed of the enforcement action. The schedule of issuance and notification is:

Action Signed 3/9/81 Mailing of Notices 3/9/81 Telephone Notification of Licensee 3/9/81 Telephone Notification of State 3/9/81 NRC News Release to be made Following Licensee Notification

The licensee has 25 days from the date of the Notices in which to respond: Following NRC staff evaluation of the response, the civil penalties may in be remitted, mitigated or imposed by Order.

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Contact: J. Metzger, IE 28188	D. Thompson, IE 28487	Commission rom
Distribution: Chairman Hendrie Commissioner Gilinsky Commissioner Ahearne	Transmitted H St: 9.58 Commissioner Bradford S. J. Chilk, SECY ACRS	C. C. Kauneker, CA E. J. Hanrahan, PE (For Distribution)
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