

SANDOZ RESEARCH INSTITUTE

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October 11, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

SUBJECT: REPLY TO A NOTICE OF VIOLATION
Re: License No. 29-08978-02 & 29-08978-04
Docket No. 030-05357 & 030-31037

Following an NRC inspection of Sandoz Pharmaceuticals Corp. conducted on September 1-2, 1994, we have received your Notice of Violation, dated September 20, 1994, describing a Severity Level IV violation. This violation specifically describes an error in administrative procedure in which the Radiation Protection Officer and the Radiation Safety Committee Chairman reviewed and approved all proposals for use of radionuclides. After internal review of this issue, we agree with the NRC conclusion that the Sandoz Radiation Protection Guide [Section II, A.4a] requires that such approval should be the responsibility and function of the full Radiation Safety Committee.

Discussions with Elizabeth Ullrich of your NRC Region 1 office have been most helpful in determining the corrective steps that we are now taking to establish appropriate review of all proposals for radionuclide use at Sandoz Pharmaceuticals Corp. These steps can be described as follows:

1. An agenda item for review of applications for approval of uses of radionuclides will be added to the list of topics for discussion at each Radiation Safety Committee meeting.
2. The full Radiation Safety Committee will be responsible for review of all major changes in protocol or quantity of radionuclides used by currently experienced and approved radionuclide users at Sandoz Pharmaceuticals Corp. The Committee will also be responsible for approval of all new Authorized and Qualified Users as defined in the Radiation Protection Guide. The Chairman of the Radiation Safety Committee and the Radiation Protection Officer will continue to review all proposals for radionuclide use and bring to the full Committee for review those that involve major changes in protocol and/or quantity of radionuclides.

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3. A retroactive review of the experience and expertise of all currently approved radionuclide users will begin at the next meeting of the Radiation Safety Committee that will be held before the end of October 1994. At that meeting, changes in procedure for approval of radionuclide users will also be reviewed and formally adopted. The Committee review of all current Authorized and Qualified Users will be completed by the end of 1994.

4. The Radiation Protection Guide will be amended to reflect the above changes in procedure. These changes will be incorporated into the Protection Guide during the annual year-end review of the Guide by members of the Radiation Safety Committee.

The Radiation Safety Committee believes that the steps delineated above will assure complete compliance with NARC requirements.

Sincerely,



Allen S. Ginsberg, Ph.D.
Vice President
Research Operations & Planning

cc: John R. McGrath, NARC Regional Administrator,
Region 1
Carmine Sodano, Radiation Safety Officer