Medical file cy

SEP 28 1988

John F. Schlegel, Pharm.D.
President
American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, D.C. 20037

Dear Dr. Schlegel:

Your letter of September 13, 1988, to Lando W. Zech, Chairman of the U.S. Nuclear Regulatory Commission (NRC), concerning requirements for the medical use of byproduct material radiopharmaceuticals has been referred to me for response.

Our regulations in 10 CFR 35.100, 35.200, and 35.300 allow authorized user physicians to administer only radiopharmaceuticals for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA). As you correctly concluded, the purpose of these requirements is to protect the public health and safety by authorizing only FDA-approved radiopharmaceuticals for medical use. The NRC relies on FDA's programs to evaluate new radiopharmaceuticals for safety and effectiveness under its IND and NDA regulations, to monitor the administration of radiopharmaceuticals in medical research under the IND regulations, and to monitor the manufacture and product quality of NDA radiopharmaceuticals during its "good manufacturing practice" (GMP) inspections.

We are currently unaware of state boards of pharmacy that duplicate FDA's evaluation, monitoring, and inspection functions in a similar manner to the Agreement States' duplication of the NRC's regulatory activities in their States.

We would welcome specific information on the training of nuclear pharmacists, requirements for certification by the Board of Pharmaceutical Specialties, the extent of state boards of pharmacy regulatory programs, and other areas that you believe should be considered regarding this issue. The NRC Medical and Academic Section staff is prepared to meet with you to discuss your concerns and explore whether there are ways of resolving those concerns compatible with our mandate to protect the public health and safety. Please call Donna-Beth Howe, Ph.D., of the Medical and Academic Section at 492-0636 for further coordination.

Thank you for your interest in our regulatory program.

Sincerely,

/s/

Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety
and Safeguards

cc: Dr. Alfred E. Jones, FDA

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

**ACTION**

EDO Principal Correspondence Control

FROM: JOHN F. SCHLEGEL, PRESIDENT
AMERICAN PHARMACEUTICAL ASSOC.

DUE: 09/30/88

EDO CONTROL: 0003958
DOC DT: 09/13/88
FINAL REPLY:

TO:
CHAIRMAN ZECH

FOR SIGNATURE OF: ** GRN **

CRC NO: 88-0834

THOMPSON

DESC:
CONCERNS THAT NUCLEAR PHARMACISTS ARE FACI[illegible]
DUE TO REGULATION OF 10 CFR PART 35

ROUT[illegible]

DATE: 09/16/88

ASSIGNED TO: NMSS
CONTACT: THOMPSON

SPECIAL INSTRUCTIONS OR REMARKS:

IMNS Action
Due to NMSS Director's Office
By 9/27/88
rec'd 9/16/88

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

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|---|---|
| PER NUMBER: | CRC-88-0634 LOGGING DATE: Sep 15 88 |
| ACTION OFFICE: | EDO |
| AUTHOR: | J.F. Schlegel |
| AFFILIATION: | DC (DISTRICT OF COLUMBIA) |
| LETTER DATE: | Sep 13 88 FILE CODE: ID&R-14 Pt 35 |
| SUBJECT: | NRC regulation 10 CFR 35.100, 35.2000, and 35.3000 pertaining to nuclear pharmacists |
| ACTION: | Direct Reply |
| DISTRIBUTION: | |
| SPECIAL HANDLING: | None |
| NOTES: | |
| DATE DUE: | Sep 23 88 |
| SIGNATURE: | DATE SIGNED: |
| AFFILIATION: | |

Rec'd Off. EDO
Date 9-16-88
Time 1:30p

EDO---003956