UNITED STATES
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD PANEL
WASHINGTON, D.C. 20555

November 14, 1990

Mr. C. A. Catizone, M.S., R.Ph., Executive Director
National Association of Boards of Pharmacy
O'Hare Corporate Center
1300 Higgins Road, Suite 103
Park Ridge, IL 60068

Dear Mr. Catizone:

Thank you for your letter of November 8 commenting on a recent Commission action. In my present position I have no role in that particular rulemaking, and, indeed, I think it unlikely that the Commission will opt to involve the Licensing Board Panel in the development of a rule concerning pharmaceuticals (although that course of action would probably be open to the Commission if it so chose). Accordingly, I have treated your letter as a comment in response to the Federal Register Notice of August 23, 1990 (55 Fed. Reg. 34513), and forwarded it to the Secretary of the Commission, Mr. Samuel Chilk.

The Federal Register Notice responded to two of many points made in a Petition for Rulemaking submitted by the American College of Nuclear Physicians and the Society of Nuclear Medicine in June of 1989. The notice announced an "interim final rule" ("interim" in that it is effective for a limited period, "final" in that it is effective from the date of publication). Of the matters mentioned in your letter, the rule focusses chiefly on permission to depart from the manufacturer's package insert in accord with a valid prescription. Other aspects of the petition concerning compounding and dispensing are still pending, I understand.

I have been in contact with our Dr. Anthony Tse, whom I believe you know, and he tells me that progress is being made on the other aspects of the ACNP/SNM petition, and that further responses to the matters contained in that petition should be forthcoming shortly.

Yours truly,

Frederick J. Shon

cc: A. Tse
S. Chilk