DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 27 2003

Carol S. Marcus, MD, PhD
Professor, Radiation Oncology
UCLA Medical Center
1877 Comstock Avenue
Los Angeles, CA 90025-5014

Re: Docket Nos. 02N-0434, 75N-0069

Dear Dr. Marcus:

This is in response to your letter dated May 23, 2003, written on behalf of the American College of Nuclear Physicians, California Chapter, concerning the proposed withdrawal by the Food and Drug Administration (FDA) of the notice in Docket No. 75N-0069 published in the July 25, 1975, issue of the *Federal Register* (40 FR 31314). Your inquiry to Mark McClellan, MD, PhD, Commissioner of the U.S. Food and Drug Administration (FDA), was referred to the Center for Drug Evaluation and Research (CDER) for response. FDA published notice of its intent to withdraw that notice, along with 83 other proposed actions, in the April 22, 2003, issue of the *Federal Register* (68 FR 19766). FDA proposes to withdraw these proposed documents because they are no longer considered viable candidates for final action at this time.

Your letter states that under the above-named 1975 notice, FDA removed the exemption from FDA registration for radiopharmaceuticals and announced its intent to begin regulation of this group of drugs. You speculated that FDA probably did not intend to withdraw the entire notice because that would indicate that the Agency was no longer regulating radiopharmaceuticals. So that you could comment on the proposed withdrawal, you requested that FDA publish in the *Federal Register* a clarification as to what part or parts of Docket No. 75N-0069 are to be withdrawn, the reasons for the withdrawal, and what the consequences will be. You also requested that we extend the comment period by 90 days after the date of publication of the clarification.

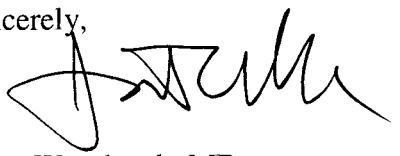
Mr. Brian Pendleton of the Center for Drug Evaluation and Research's Office of Regulatory Policy discussed this matter with you in a telephone conversation on June 19, 2003. As Mr. Pendleton stated, the document that FDA proposes to withdraw is not the document that you described in your letter. The document that the Agency intends to withdraw is the "Notice to Nuclear Pharmacies Regarding the Development of Proposed Regulations and Interim Enforcement Policy" (40 FR 31314, July 25, 1975). This notice, in Docket No. 75N-0069, stated that FDA would not take regulatory action for the failure of a nuclear pharmacy to comply with the requirements of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act except where necessary to safeguard the

public health. FDA is proposing to withdraw this notice because the Agency announced in May 1984 that it could fulfill its regulatory responsibilities in the area of registration of nuclear pharmacies by issuing a guideline on the subject, entitled "Nuclear Pharmacy Guideline: Criteria for Determining When to Register as a Drug Establishment."

The July 25, 1975, notice in Docket No. 75N-0069 refers to a final rule in Docket No. 75N-0067, published in the same issue of the *Federal Register* (40 FR 31298), that terminated the exemption from new drug requirements for radioactive drugs, including radioactive biological products. This final rule, entitled "Termination of Exemptions," is the document that you thought FDA was proposing to withdraw. The Agency is *not* proposing to withdraw that final rule.

I hope that this clarifies FDA's proposal and adequately addresses your concerns. Thank you for your inquiry on this matter.

Sincerely,



Janet Woodcock, MD
Director
Center for Drug Evaluation and Research