

April 22, 2003

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
HFA-305
Rockville, MD 20852

2311 :03 APR 30 P2 :03

Re: Docket no. 75N-0069, from FR 68(77):19766-19770, 22 Apr. 2003

Dear Sir or Madam:

The California Chapter of the American College of Nuclear Physicians notes with interest the announcement by FDA to retract the portion of Docket no. 75N-0069 that deals with Proposed Regulations and/or the intention to create regulations. This document, "Radioactive Drugs, Including Biological Products", was the original announcement by FDA of the lifting of the exemptions for radioactive drugs (FR 40[144]:31298-31314, 25 July 1975). The exemption was lifted at the request of the Atomic Energy Commission, which no longer wished to be involved with radiopharmaceutical approvals or research.

Which portion(s) of this document is(are) being retracted? It appears that the last section of this document, "Notice to Nuclear Pharmacies Regarding the Development of Proposed Regulations and Interim Enforcement Policy" may be the portion you have in mind. If so, what does this mean? That you are no longer contemplating an effort to create regulations for nuclear pharmacies, and are leaving them where they belong, under State Boards of Pharmacy? After 28 contentious years, we feel that this would be a very good thing indeed. On the other hand, it could be much more ominous. FDA could be contemplating a declaration that nuclear pharmacies will be regulated as manufacturers, and needs to get rid of a 1975 announcement recognizing nuclear pharmacies as pharmacies.

Therefore, we request a clear written description of (1) which sections of this docket are being retracted, and (2) exactly what each retraction means and what FDA intends as a result.

Thank you for your attention and consideration.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
President, ACNP-CA

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ACNP



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