



DEPARTMENT OF VETERANS AFFAIRS  
Office of General Counsel  
Post Office Box 76  
Hines IL 60141

February 3, 1993

In Reply Refer To: 025

Dear Radiopharmacy Operator:

On November 4, 1992, the Veterans Health Care Act of 1992 (the "Act"), Public Law 102-585, was signed into law. Section 603 of the Act adds a new Section 8126 to Title 38 U.S.C.

The Department of Veterans Affairs ("VA") has determined that In Vivo Diagnostics are "covered drugs" for purposes of the new Statute, since they clearly fall within the definitions of innovator "multiple source" drug and "single source" drug, as these terms are defined in the Social Security Act. The definition of "Manufacturer" contained in Section (h)(4)(A) of our Statute reads as follows:

"The term 'Manufacturer' means any entity which is engaged in A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."

We understand that radiopharmacies prepare patient doses of In Vivo Diagnostics by mixing portions of these products with radioactive technetium. We believe that this action by the radiopharmacy changes the nature of the product supplied by the original manufacturer so as to result in a different product being sold to the Government. We would like to consider your comments on this issue prior to requiring all radiopharmacies to sign Master Agreements and Pharmaceutical Pricing Agreements. In order to consider all aspects of this industry, VA is sponsoring a conference on February 17, 1993, at 10:00 a.m. (C.S.T.), at VA Hines Hospital in Hines, Illinois. VA is inviting all radiopharmacies. We hope that you will attend and invite you to bring any written information which might bear on VA's decisions. We anticipate this forum to be an informal exchange of information between VA and manufacturers.

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Dear Radiopharmacy Operator:

Enclosed you will find a map and directions to the conference room. For further information, please call Albert A. Patterson, RPh, Chief, Drug & Pharmaceutical Product Management, at (708) 216-1944.

Sincerely Yours,

William E. Thomas, Jr.  
Assistant General Counsel

Enclosures