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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, DC 20555

DOCKETING & SERVICE
BRANCH

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing nuclear pharmacist at Syncor International Corporation in Metairie, LA. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high quality Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

For example, the regulations do not allow medical use licensees to modify methods of reconstituting reagent kits outside of package insert recommendations. Past experience and published data indicate that package insert recommendations regarding expiration times and maximum added activity may be overly conservative for certain products. It is the physcian's and pharmacist's responsibility and obligation to know the quality of all drugs administered. Forced compliance with package inserts does not guarantee the highest quality product.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs (see enclosure). The package insert was never intended to prohibit physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnosic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely

Tim Quinton

Tim Quinton, R.Ph.
Syncor
2603 L&A Road
Metairie, LA 70001

DS10

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date December 7, 1988

From Robert L. West

Subject Use of Microlite to label WBCs

To Tim Quinton, PharmD
Syncor Nuclear Pharmacy

I have attached a copy of the April 1982 FDA Drug Bulletin which discusses FDA's position relative to the use of approved drugs (Microlite®) for unlabeled indications (labeling of WBCs). Such use is permissible under acceptable medical practice. In addition, such use is exempted from the need for submitting an IND application under 21 CFR 312.2 (b).

Robert L. West

United States Food and Drug Administration
Center for Drugs and Biologics
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Senior Pharmacists
U.S. Public Health Service

FDA Drug Bulletin

Information of Importance To Physicians and Other Health Professionals

April 1982

Volume 12 Number 1

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.