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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

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March 31, 1971

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Harold L. Atkins, M.D.
Medical Department
Brookhaven National Laboratory
Upton, L. I., New York 11973

Dear Dr. Atkins:

As I indicated by phone on March 31, 1971 your letter to Commissioner Charles C. Edwards was referred to this division for reply. We wish to assure you that your letter to the Hearing Clerk was not lost but the time for receiving comments was extended thirty days. Customarily such letters are not answered directly, but are noted in a subsequent Federal Register statement.

As we discussed, it is the mission of the FDA to assure that safe and effective drugs are made available to the American public and medical profession as expeditiously as possible by regulating the activity of pharmaceutical manufacturers who introduce, or deliver for introduction, drugs into interstate commerce. This is accomplished under section 505 of the Federal Food, Drug, and Cosmetic Act, as amended, through the new drug application (NDA) procedure. A manufacturer must have an approved NDA before he can sell a new drug commercially in interstate commerce.

An NDA must provide full information relative to the manufacture of the product, the data upon which a determination of the safety and efficacy of the drug can be made, and the labeling which gives full disclosure regarding the use of the drug. In order to obtain the necessary clinical data, an exemption to an approved NDA is permitted under section 505(i) of the Act for qualified experts to use investigational drugs provided a "Notice of Claimed Investigational Exemption for a New Drug" (IND) is submitted to the FDA. An IND provides for the orderly progression of scientific research in drug development in all fields of medicine including nuclear medicine.

In 1962 an agreement was made between the FDA and AEC to exempt temporarily the reactor-produced radionuclides from the investigational new drug requirements of the New Drug Regulations, Section 130.3, Title 21, Code of Federal Regulations, as long as such products were shipped in conformance with AEC regulations. Investigational studies were and

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are done by special AEC licensed investigators (broad license). Accelerator-produced and naturally occurring radioactive materials were not included in the exemption and have been under FDA regulatory authority.

Radiopharmaceutical manufacturers have not been exempt from the responsibility of developing and submitting the necessary data through the new drug application procedures and obtaining formal approval for commercialization of radiopharmaceuticals.

The FDA considers those radionuclides and procedures which appear on the AEC "well-established" list to have sufficient investigational studies completed to establish the safety and effectiveness of the drug, in the chemical form and for the indications stated, in order to permit their marketing under approved new drug applications. Manufacturers or distributors must have approved NDAs if they wish to continue to ship such products in interstate commerce. For products for which adequate data are not available, interested manufacturers can ship them for investigational use under an IND to seek the necessary data. Thus, removal of the exemption for reactor-produced isotopes should not interfere with the practice of nuclear medicine, nor impede or restrict orderly scientific and research development.

We would call to your attention that there are approved NDAs which include ^{57}Co, ^{60}Co, ^{32}P, ^{51}Cr, ^{198}Au, ^{131}I and several in process for other isotopes. Not included in the above are those products licensed by Division of Biologics Standards of National Institutes of Health.

Removal of the exemption will insure that all manufacturers of the radiopharmaceuticals published in the Federal Register on January 27, 1971, will be under the regulatory control of FDA and that proper labeling for safe and effective use will be available to practitioners of nuclear medicine, as distinct from researchers.

For your information a pamphlet about NDA and IND procedure is enclosed.

Sincerely yours,

Bryant L. Jones, M.D.

Bryant L. Jones, M.D.
Acting Director
Division of Oncology and
Radiopharmaceutical Drug Products
Office of Scientific Evaluation
Bureau of Drugs

Enclosure

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