AMERSHAM RECEIVES "APPROVABLE LETTER" FROM FDA FOR INDIUM-111 OXYQUINOLINE

The US Food and Drug Administration (FDA) sent an "approvable letter" on October 17 to the Amersham Corp., based in Arlington Heights, IL, for indium-111 oxyquinoline.

Commonly known as indium-111 oxine, the radiopharmaceutical is involved in over 700 of the approximately 1,600 investigational new drug (IND) applications now on file with the FDA, said Neil M. Abel, a reviewing pharmacist in the agency's Center for Drugs and Biologics.

The approvable letter from the FDA indicates to the manufacturer that the new drug will receive approval if certain minor stipulations outlined in the letter are met and final printed labeling (FPL) is submitted. Mr. Abel said that he foresees no obstacles within the FDA to granting approval of indium-111 oxyquinoline no later than the end of this year, but "the ball is now in Amersham's court."

"I feel that this is a giant step forward for the practice of nuclear medicine," said Mr. Abel, adding that it will relieve the FDA staff of its responsibility for monitoring hundreds of INDs for indium-111 oxyquinoline and allow the staff to concentrate more on reviewing other items. Because of the drug's importance to the nuclear medicine community, "the FDA will utilize all efforts to get an approval as quickly as possible," he added.

William Ehmig, manager of sales and marketing for Amersham's Nuclear Medicine Products Division, said that the company will concentrate on an educational marketing approach. "The Society of Nuclear Medicine (SNM) has produced impressive and well-balanced educational tools, such as audiovisuals on leukocyte labeling and a section in the SNM Central Chapter's monograph of Clinical Nuclear Medicine Updates, which we will recommend to users," he said.

"Not a panacea"

The new drug is "not a panacea," noted Mr. Ehmig, "but it has a definite place in the nuclear medicine physician's armamentarium."

According to the draft package insert attached to the approvable letter, the approved indication for indium-111 oxyquinoline is radiolabeling of autologous leukocytes. "It is intended for use as an adjunct in the detection of inflammatory processes to which leukocytes migrate," said Donald E. Baker, Amersham's manager of medical regulatory affairs.

The FDA's Radiopharmaceutical Drugs Advisory Committee reviewed the package insert as it was developed, and the FDA incorporated some of the committee's comments into the final version (see *Newsline*, June 1985, p. 555).

"Our company was very pleased to have the advisory committee participate," said Mr. Ehmig, noting that the FDA's use of the committee's expertise is a positive addition to the approval process. The advisory committee also reviewed data pertaining to the possible risk of lymphocytic leukemia from blood labeling with indium-111 oxyquinoline, and found the risk to be "remote" and acceptable (see *Newsline*, Feb. 1985, p. 122).

When the drug receives FDA approval, added Mr. Baker, letters will be sent to all IND-holders informing them of the new status for indium-111 oxyquinoline. The company submitted its new drug application (NDA) to the agency on September 12, 1983, said Mr. Ehmig.

In response to the usual criticism that the procedure for leukocyte labeling with indium-111 oxyquinoline is too complicated, Mr. Ehmig said that "the procedure is not that daunting," although it requires careful attention to detail. "It's certainly not like making up a technetium kit, but the technique is not outside the bounds of most nuclear medicine departments," he added.

In many medical institutions, the labeling is not done in nuclear medicine departments, he explained, but rather in institutional or regional nuclear pharmacies. "These nuclear pharmacies are providing a valuable service, and will probably continue to do so when nuclear medicine departments, for whatever reason, do not do their own labeling," he added.

[The SNM audiovisual, "Clinical Applications of Labeled Leukocytes" (CEL 13), includes 79 slides in a 40-minute program created in 1983 by R. Edward Coleman, MD. The SNM Technologist Section audiovisual programs include: "Clinical Uses of Indium-111 Labeled Blood Products" (SNM 234, 1985) by Robert W. Burt, MD; "Practical Aspects of Indium-111 Labeled Blood Cellular Products" (SNM 235, 1985) by Bruce H. Mock, PhD; and "Theoretical Aspects of the Use of Indium-111 Labeled Blood Products" (SNM 236, 1985) by Donald S. Schauwecker, MD, PhD. The SNM Central Chapter published its clinical nuclear medicine update, "Indium-111 Leukocytes for Abscess Detection," by George H. Hinkle, PhD, last March.]