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oped benign testicular lesions, compared to only one mouse out of 115 in a control group.

Another snag is the discovery of unique radiolytic products (URPs). They are unusual molecules, altered forms of amino and fatty acids, for example, that are never found in unexposed food. Although they are not necessarily harmful, scientists have not yet identified all URPs or shown that they cause no ill effects.

Since the U.S. Environmental Protection Agency banned ethylene dibromide last September, though, irradiation is a more viable alternative.

Misleading labeling?

Officials cannot agree on a labeling requirement. The FDA has dropped its labeling proposal for retail packages because irradiated foods "have already been shown to be safe."

A label connotes a warning, some regulators say, which is misleading—especially when food treated with potentially more harmful pesticides does not require a label.

Although the public is wary of radiation, other officials feel that the technology is doomed unless consumers are fully informed.

The Netherlands requires a "RADURA" symbol, composed of a stylized flower in a solar disc, on all packages. In South Africa, foods are labeled with this emblem on the wholesale level, and retail labels are optional

A poll conducted for the Canadian Dept. of Fisheries and Oceans indicated that labels are necessary. Test-marketed consumers preferred "freshness extended by irradiation" and "ionized fresh" over "irradiated" and "treated with ionizing radiation."

Although the process has gained acceptance in some regions, many consumers have yet to learn that irradiated food is not radioactive.

—Linda E. Ketchum

FDA Revamps Drug and Antibiotic Regulations

The U.S. Food and Drug Administration (FDA) has announced its new drug and antibiotic regulations (*Federal Register*, Feb. 22, 1985, pp. 7452–7519).

"The improvements will help applicants prepare and submit higher quality applications, and permit the FDA to review them more efficiently and with fewer delays," according to the agency.

The final regulations take effect on May 23, 1985, although the agency will accept applications under the old regulations until February 24, 1986. The reform effort began in October of 1979, and was accelerated at the request of the President's Task Force on Regulatory Relief.

About 120 comments were reviewed, with input ranging from pharmaceutical manufacturers, trade associations, and consumer groups to health professionals, including some members of The Society of Nuclear Medicine.

"It's a very good start toward improving the review process and making it more efficient," said Capt. William H. Briner, chairman of the Society's Government Relations Committee.

One major change in the regulations, approval of applications based solely on foreign data, may be of particular interest to radiopharmaceutical manufacturers. The agency has increasingly relied upon foreign data in its decisions, and has decided that its "foremost consideration would be the quality of the data submitted, regardless of the country of origin."

To meet various concerns raised about this change, such as medical, genetic, and cultural differences between countries, lack of the FDA's knowledge of foreign investigators and facilities, and the FDA's inability to conduct onsite verification of many foreign studies, the agency specified three criteria to be met in these applications: (a) foreign data must be applicable to the U.S. population and medical practice, (b) clinical investigators must be of recognized competence, and (c) the FDA must be able to validate data through onsite inspection if necessary.

The FDA also recognized, but did not change, the role of outside experts, such as the Radiopharmaceutical Drugs Advisory Committee. The agency denied requests to formally establish a role for these committees in the routine review of applications, and does not permit applicants to utilize advisory committees on demand for review or to resolve scientific disputes.

The agency also did not agree with suggestions to place stricter controls on conflict of interest problems with outside experts. The current guidelines stipulate that advisors will not be barred from serving on a committee where such a problem may arise, but will be excluded from participating in specific matters in which a real or potential conflict of interest exists.

Several Society members participate in the Radiopharmaceutical Drugs Advisory Committee. Under the chairmanship of Barry A. Siegel, MD, director of nuclear medicine at Washington University School of Medicine, this committee has worked constructively with the FDA to gain approval of new indications for widely-used radiopharmaceuticals (see *Newsline*, Mar. 1985, p. 218). ■