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Editorial

News Highlights

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New Shellfish Sanitation Rules Proposed

Commissioner of Food and Drugs Alexander M. Schmidt has signed a proposal to strengthen the National Shellfish Sanitation Program (NSSP) under which the Federal Government, the States, and industry agree to cooperate to ensure safe and wholesome shellfish.

The proposed regulations, which were published June 19 in the *Federal Register* for public comment, would for the first time establish nationally uniform administrative procedures for ensuring sanitary practices in the harvesting and processing of shellfish such as clams, oysters, and mussels. The regulations would define the scope, requirements, and responsibilities of the State and Federal Government agencies involved.

In most instances the voluntary Federal-State-industry program has worked well, FDA said. Recent surveys by FDA and the U.S. General Accounting Office, however, have found shortcomings that include, for example, inconsistent procedures for dealing with violative producers and products in interstate commerce. The proposed regulations were developed to overcome these shortcomings and to make other improvements to assure the safety of shellfish marketed in the United States. In addition to improving the domestic shellfish safety program, the new regulations also impose equivalent requirements on imported fresh and frozen shellfish.

In proposing the new regulations FDA said it recognizes that without the cooperation and participation of the States an effective shellfish safety program would be vastly more difficult and expensive to achieve. The proposed regulations, therefore, provide for continued State inspections and for continued reliance on NSSP standards of sanitation.

An important goal of the new proposal is to achieve better consumer understanding of the system under which the Government seeks to assure the safety and wholesomeness of shellfish.

All affected parties, including consumers, will have 120 days to present their views on the proposed regulations. These comments will be analyzed to determine any necessary and appropriate revisions in the proposal before a final regulation is published.

Contact Lenses Seized at FDA's Request

The entire inventory of a new and different type of contact lens, together with instructions for its use, has been seized from the Rynco Scientific Corp. of Floral Park, New York, by U.S. marshals at the request of the Food and Drug Administration.

About 7,000 Rynco RX-56 lenses, materials for several thousand more, and all accompanying literature were seized on court order after the firm had been told by FDA to stop the manufacture and sale of the lenses because they were made from a type of plastic that has not been shown to be safe and effective.

FDA policy is that only hard contact lenses made from one type of plastic, polymethylmethacrylate (PMMA), are generally regarded as safe and effective for correcting vision. Contact lenses made from any other plastic must be approved by FDA before they can be sold.

FDA charged that Rynco's claims that the lenses meet current Federal regulations and that valid scientific studies exist to demonstrate their safety and effectiveness constitute false and misleading labeling.

When FDA became aware in 1974 that Rynco was marketing a non-PMMA, gas-permeable contact lens it issued a regulatory letter to the firm declaring the lens to be a "new drug" requiring premarketing approval by FDA. Subsequent meetings between Rynco and FDA resulted in additional regulatory letters reiterating that FDA considered the lens a "new drug," and that production and marketing should be discontinued and stocks recalled from opticians, physicians, and optometrists. FDA recommended seizure because the firm chose to disregard these letters and continued to market the product. The firm disputes FDA's position that the lenses require FDA approval before marketing.

FDA Lists Approved LSD Research Projects

Because of recent news reports and public concern that has followed about past testing LSD in human subjects, possibly without their informed consent, FDA has issued an informational statement about the currently permitted use of this drug for research purposes only. LSD is classified as having no currently accepted therapeutic use, but FDA permits specified research with this drug on human subjects under carefully controlled conditions.

At the present time five medical institutions are authorized by FDA to conduct research programs involving the use of LSD with human subjects. These programs are being conducted under FDA's procedures for investigational new drugs, the conditions of which provide a safeguard for the protection of the human subjects. FDA records indicate there have been about

170 legitimate research projects with LSD over the past 10 years, but most are no longer active.

The institutions currently authorized to conduct research programs with LSD and the nature of the research program are: alcoholism and psychotherapy, Veterans Administration Hospital, Topeka, Kansas; alcoholism, Vista Hill Psychiatric Foundation, San Francisco, California; psychosis (patients with special problems), Medical College of Birmingham, Birmingham, Alabama; psychotherapy in chronic LSD users, Langley Porter Neuropsychiatric Institute, San Francisco, California; evaluation of LSD in narcotics users and LSD training experience program for mental health-related professionals (total of two programs), Maryland Psychiatric Institute, Baltimore, Maryland.

All programs proposing to use LSD in humans must be reviewed, before FDA action, by an outside advisory committee operating under joint sponsorship of FDA and the National Institute of Drug Abuse. The committee is made up of recognized experts from major medical research institutions. FDA in most cases agrees with the committee's findings in approving or disapproving an application. The sponsors of the proposed test are investigated beforehand by the Department of Justice's Drug Enforcement Administration. All such programs must provide for protection of patients, followup care, and informed consent by the patient or responsible guardian. Each investigating institution must maintain a review panel to evaluate the usefulness of the proposed study and assure protection of patients.

Drug investigations conducted by the military arms of the Federal Government are exempted from FDA procedures for investigational new drugs under a 1974 memorandum of understanding between FDA and the Department of Defense that permits the military to classify such investigational programs for purposes of national security. The memorandum provided exemptions based on experience between 1964 and 1974 which indicated that military researchers have adhered to FDA standards, adequately protected human subjects, did not compromise the intent of the Food, Drug, and Cosmetic Act's protection requirements, and that certain conditions required before 1974 were no longer necessary.

Dalkon IUD Won't Be Returned to Market

The A.H. Robins Co., Richmond, Virginia, has announced that its Dalkon Shield intrauterine (IUD) contraceptive device will not be returned to the market. As reasons, the firm cited FDA's delay in establishing a patient registry system to gather data on IUD's, adverse publicity which has eroded confidence in the Shield, and the year that it has already been off the market.

The Dalkon Shield first came to public attention in May 1974, when seven deaths from septic abortions were reported among women using the device. Since then, FDA has received reports of another nine deaths and of 245 nonfatal septic abortions related to the Dalkon Shield. A total of 43 deaths and 313 nonfatal septic abortions has been reported for all IUD's.

FDA, over the past year, has stressed that IUD's are safe and effective, comparing favorably with other forms of contraception. But the Agency has cautioned that any woman using an IUD who suspects she is pregnant should see her physician as soon as possible. If pregnancy is confirmed, the IUD should be removed.

The major problems associated with the Dalkon Shield and other IUD's have occurred when the IUD is left in place during pregnancy. Most of the septic abortions associated with IUD's have developed in the second trimester (4th, 5th, and 6th months) of pregnancy.

Women who are presently using the Dalkon Shield successfully need not have it removed as a result of Robins' action.

FDA is continuing to develop plans for a voluntary registry system for some women who use IUD's. Since most IUD's are classified as medical devices rather than drugs, they do not require approval by FDA as to their safety and effectiveness before they can be marketed. Because of this, there has been no central point for gathering data on the use of these devices and adverse reactions to them. The registry system now being discussed would be designed to compile information on normal usage time and such reactions as pregnancy rates, pelvic inflammatory disease (PID), perforation of the uterus, septic abortion, and expulsion. Although there have been numerous studies of IUD's, each clinical investigator has reported differing rates for these reactions.

Changes Proposed in X-ray Standards

FDA has proposed a group of 11 general amendments to the Federal performance standard for diagnostic x-ray systems and their major components. The notice of proposed rulemaking was published June 11 in the *Federal Register*.

The proposed amendments include revisions of the list of major components to which the standard applies; addition of alternate certification and labeling procedures for products marketed as a combination of two or more major components; strengthening of the requirements for fluoroscopic x-ray field limitation and high-level controls; and revision of the wording of several definitions, performance requirements, and methods for determining compliance.

Those amendments which reflect current interpretations rather than substantive changes would become effective 60 days after a final regulation is published in the *Federal Register*. The remaining amendments would become effective 1 year after the date of final publication.