and has caused at least one outbreak in Australia. Pink salmon, redfish, yellotail, marlin, and amberjack have also been implicated in scombroid poisoning outbreaks that have occurred in the United States. Outside the United States, pilchards, herring, anchovies, bluefish, and sardines have been involved in a number of cases. Sardines and pilchards have become a major source of histamine poisoning in Great Britain, Japan had an outbreak associated with black marlin, and anchovies have been implicated in single incidents in Japan, the United States, and Great Britain (Ref. 9).

From 1977 to 1981 there were 68 outbreaks of scombroid poisoning involving 461 illnesses (Ref. 10). In March 1980, the Centers for Disease Control and Prevention reported that mahi-mahi accounted for 40 percent of the scombroid poisoning outbreaks reported in the United States. Since 1980, FDA has placed most shipments of mahi-mahi offered for entry into the United States on automatic detention because of the frequent occurrence of histamine levels exceeding 500 ppm (Ref. 11).

Histamine is a poisonous or deleterious substance under section 402(a)(1) of the act because, when ingested at sufficiently high levels, it is known to cause scombroid poisoning (Ref. 12). In the September 14, 1982, notice, the agency established, on an interim basis, an AL of 500 ppm histamine in canned tuna (47 FR 40487). At this level, the agency considers histamine to present a hazard to public health. The agency is not changing the 500 ppm AL at this time because the threshold toxic dose of histamine is not known. However, the action level for canned tuna of 500 ppm will also apply to other species of raw, frozen, and canned fish, such as mahi-mahi, bluefish, amberjack, and mackerel, all fish that have been implicated in histamine poisoning outbreaks. Furthermore, the presence of other amine decomposition products in fish may have a synergistic effect on histamine toxicity. This synergism may dramatically lower the threshold toxic dose (Refs. 9 and 10).

Therefore, FDA is revising its histamine policy and announcing the availability of revised CPG 7108.24 “Decomposition and Histamine in Canned Albacore, Skipjack, and Yellowfin Tuna” has been changed to “Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species” to more accurately describe the contents of the revised CPG.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

3. Memorandum from Division of Science and Applied Technology (HFS-425) to Division of Programs and Enforcement Policy (HFS-415), CFSAN, FDA, dated August 6, 1992.

Interested persons may, on or before September 5, 1995, submit to the Dockets Management Branch (address above) written comments on the revised CPG 7108.24. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG 7108.24 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1995.

Gary Dykstra,
Acting Associate Commissioner for Regulatory Affairs.

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BILLING CODE 4160–01–F

[Docket No. 95N–0238]

Drug Export; Benoquin (Monobenzone U.S.P) Cream 20%

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that ICN Pharmaceuticals, Inc., has filed an application requesting approval for the export of the human drug Benoquin (Monobenzone U.S.P) Cream 20% to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug
SUMMARY: The Food and Drug Administration (FDA) is making generally available a policy statement issued on February 23, 1994, directly to manufacturers, distributors, and importers of condom-like products, regarding the marketing of condom-like products. The policy statement is intended to inform manufacturers, distributors, and importers of condoms and condom-like products, including those products labeled or packaged as novelty items, that such products are subject to all the regulatory requirements for medical devices. This policy statement revises and supercedes the 1989 policy statement regarding the labeling of condoms. FDA is making the policy statement generally available at this time to help ensure that the policy is known and understood by the regulated industry and the public.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the policy statement to the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (1–800–638–2041 outside MD). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the policy statement to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the policy statement and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.


SUPPLEMENTARY INFORMATION: On February 13, 1989, FDA issued a statement of policy regarding the marketing of condoms. This policy statement was forwarded via certified mail—return receipt requested—to all manufacturers, importers, and repackers of condoms for contraception or sexually transmitted disease prevention. Subsequently, FDA discovered that some marketers of functional condom-like products may have misinterpreted the 1989 policy statement, and were marketing functional condoms as novelty items without complying with condom leak testing requirements, current good manufacturing practice (CGMP) regulations, and promotional notification and clearance requirements. Such marketing is in violation of the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations. Therefore, to clarify that such products may only be legally marketed in compliance with these requirements, FDA issued a new policy statement on February 23, 1994.

Products that are capable of covering the penis with a closely fitting membrane and otherwise have the appearance of a condom are considered to be medical devices, regardless of their packaging or labeling. As such, these products must comply with all the above-referenced requirements.

However, when condom-like products cannot be used as condoms, they need not meet the above requirements. For example, a product that resembles a condom but which has the closed end removed, the sides shredded, or the roll permanently sealed so that it is incapable of being unrolled would not be subject to the requirements of the act and the regulations. FDA emphasizes that merely labeling the products as a novelty does not remove it from the scope of the act or in any way exempt it from the requirements applicable to condoms.

Copies of this final policy statement, along with previous policy statements, are available for public examination in the Dockets Management Branch (address above). Interested persons may, at any time, submit written comments on the final policy statement to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current policy statement. Two copies of any comments are to be