ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the presiding officer summary decisions, presiding officer reports, and the Commissioner of Food and Drugs (the Commissioner) decisions that are issued concerning a regulatory hearing on the proposed disqualification of a clinical investigator from eligibility to continue to receive investigational products for use in clinical investigations. These reports and decisions and an index are available at the FDA Internet site.

ADDRESSES: Copies of an index to presiding officer summary decisions, presiding officer reports, and Commissioner decisions, as well as the reports and decisions themselves, may be obtained from the Freedom of Information Office home page at http://www.fda.gov/foi/clinicaldis.

Copies of the index and reports and decisions are also available at the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of the Ombudsman (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

SUPPLEMENTARY INFORMATION: FDA regulates scientific studies, known as clinical investigations, designed to test the safety and effectiveness of investigational human and animal drugs, biological products, and medical devices. The data from these clinical investigations may be used as the basis of applications to FDA for approval to market the investigational products. The clinical investigators who conduct clinical trials must comply with FDA's regulations that govern clinical investigations. FDA may seek to disqualify a clinical investigator if the agency has information indicating that the investigator has repeatedly or deliberately failed to comply with the requirements of the regulations for conducting clinical investigations, or repeatedly or deliberately submitted false data to the FDA or the study's sponsor. If the Commissioner makes this determination, the Commissioner will notify the investigator and the sponsor of any investigation, in which the investigator has been named as a participant, that the investigator is not entitled to receive investigational drugs.

The criteria for disqualification are set forth in FDA's regulations. For clinical investigations involving human drugs and biologic products, the applicable regulation is found at 21 CFR 312.70. For clinical investigations involving medical devices, the applicable regulation is found at 21 CFR 812.119. For clinical investigations involving investigational animal drugs, the applicable regulation is found at 21 CFR 511.1.

The disqualification process is initiated when FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, or Center for Veterinary Medicine sends the investigator a written notice of the matter complained of, and offers the investigator an opportunity to explain in writing or, at the option of the investigator, at an informal conference. If the Center does not find the investigator's explanation to be acceptable, the agency will send the investigator a notice of opportunity for a hearing. If a regulatory hearing is held, it will be conducted under part 16 (21 CFR part 16). Under part 16, if a clinical investigator requests a hearing, a presiding officer is appointed to hear the case. A request for a hearing may be denied if the Commissioner or his or her delegate determines that there is no genuine and substantial issue of fact to justify a hearing. A written notice of this determination will be given to the parties. In addition, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines that there is no genuine and substantial issue of fact respecting that issue.

After a hearing is conducted, the presiding officer, under § 16.60, prepares a written report of the hearing, including a recommended decision with a statement of the reasons, on the proposed disqualification. The written report will include a recommended decision with a statement of reasons, unless the Commissioner directs otherwise. The presiding officer's report is one component of the administrative record of the hearing. Based on the administrative record, the Commissioner issues a written decision on the question of whether the investigator is entitled to receive investigational products. If the Commissioner finds that the clinical investigator repeatedly or deliberately failed to comply with agency regulations, or repeatedly or deliberately submitted false information to FDA or the sponsor, the investigator may be disqualified from receiving investigational products.

Disqualification hearings are informal, and presiding officer summary decisions, presiding officer reports, and Commissioner decisions are not published in the **Federal Register**; they have been made publicly available to parties that request regulatory hearings on clinical investigator disqualifications. They are also publicly available under the Freedom of Information Act. The purpose of this notice is to announce that an index to, and copies of, presiding officer summary decisions, presiding officer reports, and Commissioner decisions on clinical investigator disqualification matters are now available on FDA's Internet site. These records are also available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21663 Filed 8–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0195]

Guidance for Industry: Fish and Fishery Products Hazards and Controls Guidance, Third Edition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance for industry (third edition) entitled ''Fish and Fishery Products Hazards and Controls Guidance'' (the guidance). The guidance supports and complements FDA regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point (HACCP) methods. The guidance represents the agency's current views on potential hazards in seafood products and how to control them, and it is designed to assist seafood processors in the development of HACCP plans. The guidance is revised about every 2 years to address comments and to reflect our current understanding of seafood hazards and control methods.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of the guidance to the Office of Seafood (HFS–415), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington DC 20204. Send one-self adhesive address label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150.

SUPPLEMENTARY INFORMATION:

I. Background

We (FDA) are announcing the availability of the third edition of the ''Fish and Fishery Products Hazards and Controls Guidance'' (the guidance). A summary of the changes incorporated in the third edition are listed in the introduction of the guidance.

Under our HACCP regulations at parts 123 and 1240 (21 CFR parts 123 and 1240) processors and importers of fish and fishery products are required to operate preventive control systems that incorporate the principles of HACCP. Under § 123.6(g), fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) if a processor or importer fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the guidance is to help processors and importers of seafood products identify the likelihood that a food safety hazard may occur in their product, and to guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur.

We published the first edition of the guidance in September 1996, about 1 year before the seafood HACCP regulations became effective, and issued the second edition in January 1998. The guidance describes current information relating to: (1) Potential hazards associated with the known commercial species of vertebrate and invertebrate seafood; (2) potential hazards associated with certain processing operations; (3) HACCP strategies that may be used to control the potential hazards; and (4) other information related to food safety.

FDA is not seeking public comment before implementing this edition of the guidance because we have determined that it is not feasible or appropriate in accordance with 21 CFR 10.115(g)(2). We revise this guidance relatively frequently to keep it up-to-date. When revising each edition, we consider both any formal comments received on the previous edition and informal feedback obtained from our HACCP inspections. Thus, each edition is effectively a ''draft'' for the next edition and each new addition has the benefit of significant up-to-date public comment.

The guidance represents the agency's current thinking on the potential hazards that are associated with various seafood species and certain processing operations, and how their occurrence can be avoided with HACCP controls when they are reasonably likely to occur, as required under parts 123 and 1240 (pertaining to the safe and sanitary processing of fish and fishery products). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

II. Electronic Access

Copies of this guidance for industry are available on the Internet at http://vm.cfsan.fda.gov/~dms/guidance.html.

Dated: August 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21624 Filed 8–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0357]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#141) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28). This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). The objective of this draft VICH guidance document, when final, will be to help ensure that the assessment of carcinogenic potential is appropriate to human exposure through residues of veterinary drugs in food in the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on the draft guidance by September 28, 2001, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of