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

harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health; Committee on Veterinary Medicinal Products, FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/ New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Carcinogenicity Testing

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28) should be made available for public comment. This guidance is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food (''VICH Guidance on General Testing Approach'') will be made available at a later time.

VICH developed this draft guidance after consideration of the existing ICH guidances for pharmaceuticals for human use entitled ''Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals'' and ''Testing for Carcinogenicity of Pharmaceuticals,'' which published in the **Federal Register** of March 1, 1996 (61 FR 8153), and February 23, 1998 (63 FR 8983), respectively. The draft guidance has been adapted for veterinary use by the VICH from the aforementioned guidances regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidances and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance. (Information collection is covered under OMB No. 0910–0117. Information collection also could be covered by OMB No. 0910–0032.)

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will '' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

The draft guidance represents the agency's current thinking on carcinogenicity testing for veterinary drug residues in human food. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document. Written or electronic comments should be submitted to the Dockets Management Branch (address above). Submit written or electronic comments by September 28, 2001, to ensure adequate consideration in preparation of the final guidance. 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select ''01D–0357 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (VICH GL28)'' and follow the directions.

Copies of the draft guidance entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: August 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21664 Filed 8–27–01; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comments.

SUMMARY: The collection of information listed below has been submitted to the Office of Management and Budget (OMB) for renewal under the provisions of the Paperwork Reduction Act. Copies of the specific information collection requirements, related forms, and explanatory material may be obtained by contacting the Service Information