However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 3, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 31, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–2243 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0392]

Seafood HACCP Transition Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Seafood HACCP Transition Guidance.'' This guidance sets forth the policies and procedures under which the agency may consider refraining from regulatory action under the seafood Hazard Analysis Critical Control Point (HACCP) regulations and the Federal Food, Drug, and Cosmetic Act (the act). This guidance provides for the submission to FDA of citizen petitions that describe scientific studies that petitioners are proposing to resolve issues relating to particular hazard analyses or controls for particular food safety hazards.

DATES: This notice is effective February 2, 2000.

FOR FURTHER INFORMATION CONTACT: Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 26, 1999 (64 FR 14736), FDA published for comment a notice containing a draft guidance setting forth policies and procedures under which the agency may take into account a planned or ongoing scientific study when deciding whether to pursue regulatory action under the seafood HACCP regulations and the act. Specifically, the draft guidance indicated that FDA might consider refraining from regulatory action against a seafood processor or processors to allow the conduct of a scientific study to resolve a dispute between FDA and the processor(s) over questions of fact. These questions would either relate to whether certain food safety hazards are reasonably likely to occur in specific situations or to the effectiveness or need for certain controls for those hazards. FDA would only consider refraining from regulatory action if the public would not be jeopardized by doing so.

The draft guidance requested that individuals desiring to propose a scientific study under these circumstances submit a petition to the agency in accordance with FDA's regulations for citizen's petitions at 21 CFR 10.30. The petition would describe the study and request that FDA consider exercising enforcement discretion on certain matters under the seafood HACCP regulations and the act pending their scientific resolution.

FDA further recommended that the petition be submitted as a request to revise or amend the agency's guidance document entitled ''The Fish and Fishery Products Hazards and Controls Guide (the Guide).'' The Guide contains FDA's compilation of what the agency believes to be the latest, science-based knowledge about when food safety hazards are reasonably likely to occur and what controls are appropriate for those hazards.

II. The Comments

Three comments were received on the draft of the Seafood HACCP Transition Guidance. Two of the comments were from trade associations, and one was from a professional association. All comments supported the general approach proposed by the agency to rely on scientific studies under circumstances described in the draft, but asked for specific modifications in order to expedite or otherwise improve the process.

1. One comment suggested that the petition process would be time consuming and would inhibit the agency's ability to respond quickly to requests for discretionary enforcement, especially considering that the agency allows itself up to 180 days to respond on petitions.

As noted by the comment, the 180-day period is the maximum permitted tentative response time. However, given the significance of the food safety issues that are likely to be submitted for review under the guidance and the desire of the agency to obtain new scientific information on issues having bearing on scientific questions related to HACCP implementation, FDA believes that it would be mutually advantageous for the agency to respond to the petitioner as expeditiously as possible. For this reason, the agency continues to encourage potential petitioners to engage in presubmission consultations with FDA on the merits. Familiarity with the issues presented in a petition would greatly facilitate the agency's ability to respond quickly. The agency anticipates that review of the scientific merits of any proposal will be a more likely cause of delay, than the mechanics of the petition process. Consequently, FDA does not agree that the citizen's petition process will cause the agency to significantly delay its response.

A related comment stated that the citizen's petition is a cumbersome mechanism, which could be overwhelming for those unaccustomed to FDA's administrative procedures. This comment recommended that the guidance policy clarify the applicability of certain provisions in part 10 (21 CFR part 10), particularly as they relate to the need for environmental and economic impact statements.

FDA does not anticipate that the contents of a citizen's petition would be notably different than the contents of a request to the agency under another format. The contents need only include information that enables FDA to make an informed decision on a petitioner's request. In that regard, the agency does not expect that either an environmental or economic impact statement will be relevant, especially since the research to be conducted is at the petitioner's initiative and would not ordinarily be

the subject of an extramural contract, grant, or other research agreement with the government.

2. One comment expressed concern for the need for confidentiality to protect proprietary information, in that the citizen petition process could result in the disclosure of trade secrets to competitors.

FDA's regulations (21 CFR 10.30 and 21 CFR 10.20(j)) provide that citizen petitions and supporting information are to go on public display (i.e., be made public). Under 21 CFR 10.20(j)(2), the only exception is for petitions that contain information the disclosure of which would be a clearly unwarranted invasion of personal privacy. Thus, FDA is not in a position to protect other information in a citizen petition from disclosure. If a person believes they have a situation that CFSAN should consider under this guidance, but would need to rely on trade secret on confidential commercial information to make their case, they should raise the matter with CFSAN to see if other approaches are appropriate

3. Two comments stated that FDA should consider other options to further advance the science needed to support HACCP implementation. One of these comments suggested that the agency should consider establishing an external scientific review process to evaluate the scientific merit of the research proposed in a citizen petition. The comment stated that an outside review would provide a wider range of scientific input and discussion than otherwise occur and may yield a stronger consensus among FDA, industry, and academia.

FDA agrees there may be cases when the agency will need the assistance of an expert review panel, particularly when there is a diversity of scientific opinion within the agency. However, two advisory committees, the National Food Advisory Committee and the National Advisory Committee on Microbiological Criteria for Foods, already exist for this purpose. FDA anticipates that the benefits of consulting with a panel of outside experts will be considered on a case-by-case basis.

4. One comment requested that the HACCP transition guidance outline the agency's expectation of the level of detail expected in studies, and the amount of time allowed for completion of scientific studies or literature searches, and that these factors should be influenced by the nature of the specific issue being addressed. The comment stated that, in many cases, the scientific detail need not be exhaustive, especially where the issue applies to a product that has been marketed safely for some time, or where the data supporting FDA's current policy are not exhaustive.

FDA intends to assess the adequacy of scientific detail on a case-by-case basis. The factors that the agency will generally take into consideration when determining the adequacy of a scientific study may include the severity of the hazard at issue in the petition and the extent and credibility of existing data.

5. One comment expressed the need for caution should the agency announce that it intends to exercise enforcement discretion, because State agencies may have compliance actions occurring on their own. To avoid inconsistent regulatory policies between FDA and the States, it was suggested that FDA establish an information sharing mechanism with the States on this subject.

FDA agrees with this concern and intends to take steps to prevent conflict between Federal and State actions. FDA expects to advise the public about petitions on its website. In addition, the agency intends to take appropriate steps to ensure that states are adequately apprised. These steps may include advising the Association of Food and Drug Officials (AFDO), a professional association of State, Federal, and local regulatory officials (with industry representatives participating as associate members) on the status of petitions and posting petition information in the State Action Information Letter (SAIL) at http://www.fda.gov/ora/fed_state/sail.htm.

III. Availability

This Seafood HACCP Transition Guidance is now available on the home page for FDA's Center for Food Safety and Applied Nutrition (CFSAN) at http:/vm.cfsan.fda.gov/dms/guidance.html. It may also be obtained through the Activities Staff, Office of Constituent Operations, CFSAN, phone 202–205–5251.

IV. Status of This Guidance

This guidance represents the agency's current thinking on the subject and does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

V. Paperwork Reduction Act

FDA concludes that this guidance would not impose a paperwork burden that has not already been estimated and approved by OMB under OMB Control No. 0910–0183 ''Citizen Petition—21 CFR 10.30.'' This guidance provides information to the public to assist them in submitting petitions to obtain changes in the Guide under certain circumstances.

Dated: January 21, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–2147 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0053]

Draft Guidance on Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme.'' This draft guidance is not final nor is it in effect at this time. This document is intended to provide draft guidance for categorizing the risks posed by single-use devices (SUD's) that are reprocessed and/or reused. FDA may use this scheme to set enforcement priorities for regulation of reprocessed and/or reused SUD's.

DATES: Submit written comments concerning this draft guidance by March 3, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this draft guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.