**DATES:** Written comments on the draft guidance may be submitted by May 26, 1999. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'', or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or FAX 301–594–3215.

**FOR FURTHER INFORMATION CONTACT:**

Regarding prescription human drugs: Tracy L. Acker, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831, or via Internet at ackert@cder.fda.gov.

Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at stifano@cber.fda.gov.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval Products: Submission of Promotional Materials.'' This draft guidance is intended to assist sponsors of drug and biological products who are submitting promotional materials as part of the accelerated approval process.

In the **Federal Register** of December 11, 1992 (57 FR 58942), FDA published final regulations under which the agency would accelerate the approval of certain new drugs and biological products for serious or life-threatening illnesses. In November 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105–115). Section 112 of the Modernization Act, in part, essentially codified in statute the accelerated approval regulations in an amendment to the Federal Food, Drug, and Cosmetic Act (section 506 of the act (21 U.S.C. 356) entitled ''Fast Track Products''). On November 12, 1998, FDA published a draft guidance for industry on its policies and procedures regarding fast track drug development programs. The draft guidance that is the subject of this notice would apply to all products approved under § 314.500 (21 CFR 314.500), including those designated as fast track development programs.

Among other things, the accelerated approval regulations (§§ 314.550 and 601.45 (21 U.S.C. 314.550 and 601.45)) require that applicants, unless otherwise informed by the agency, submit to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication during the 120 days following marketing approval. The accelerated approval regulations also require that promotional materials intended for use following the 120-day postapproval period must be submitted to FDA for review at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement, unless otherwise informed by the agency.

During the past several years, representatives of the pharmaceutical industry have requested guidance from FDA on the procedures for submitting promotional materials under §§ 314.550 and 601.45. The draft guidance is intended to assist applicants submitting promotional materials under these regulations.

This draft guidance document represents the agency's current thinking on the process for submitting promotional materials for accelerated approval 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 requirement of the applicable statute, regulations, or both.

Interested persons may, on or before May 26, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments or requests for copies are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 19, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99–7516 Filed 3–25–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Number 99D–0392]**

### Seafood HACCP Transition Guidance; Request for Comment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for comment draft guidance setting forth circumstances under which the agency may consider refraining from regulatory action under the seafood Hazard Analysis Critical Control Point (HACCP) regulation and the Federal Food, Drug, and Cosmetic Act (the act) pending completion of studies to resolve scientific issues relating to whether the agency should revise or amend its policies concerning particular hazard analyses or controls.

**DATES:** Submit written comments by May 26, 1999.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should contain the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**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:** On December 18, 1995 (60 FR 65096), FDA published final regulations (21 CFR part 123) that require processors of fish and fishery products to develop and implement HACCP systems for their operations. Those regulations became effective on December 18, 1997. As a companion to the regulation, FDA also issued a 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. In the period since the publication of the final regulations, FDA has produced two editions of the Guide. The agency intends to publish

new editions of the Guide as knowledge and technology advance about fish and fishery products hazards and controls.

Under the act and its implementing regulations, processors are responsible for ensuring that their HACCP systems are adequate. If processors need help in developing a HACCP system, the Guide provides them with information that can help them put in place a HACCP system that should generally satisfy a processor's obligations under the seafood HACCP regulation. However, as the Guide itself makes clear, the materials contained in the Guide consist of recommendations, and not binding requirements. Processors may control hazards in other ways so long as they can demonstrate that their approaches are scientifically defensible. Processors may also rely on hazard analyses that differ from those in the Guide so long as they can demonstrate that their own analyses are valid for their particular circumstances.

As a general matter, processors should establish the adequacy of a hazard analysis or control before implementing it. FDA can envision circumstances, however, where the industry could make a strong threshold case for the validity of a particular hazard analysis or system of controls even though complete confirmation of its validity was not yet available from scientific studies.

FDA believes that a mandatory HACCP program should serve as a catalyst for research and science-based resolution of food safety questions. Thus, where the consuming public would not be placed at risk, FDA believes it is appropriate to use a mechanism that encourages the resolution of legitimate scientific questions before they become legal controversies.

The purpose of this notice is to propose and obtain comment on guidance on the submission of citizen's petitions under § 10.30 (21 CFR 10.30), whereby any member of the public may request that FDA consider exercising enforcement discretion on certain matters under the seafood HACCP regulations pending their scientific resolution. This proposed guidance applies to issues involving matters of scientific fact related to whether a hazard is reasonably likely to occur or whether a control is sufficient, the resolution of which is likely only after the completion of a scientific study or a search of existing scientific literature. Other issues that relate to broader policy, such as circumstances where regulations specify hazards that are reasonably likely to occur in certain situations or enumerate performance standards or the actual critical limits that must be met, may also be addressed by filing a citizen's petition, or by discussing the issue directly with the agency in a less formal manner, but are not within the scope of this proposed guidance.

FDA anticipates that matters for which limited enforcement discretion will be considered will be narrow. In determining whether to exercise enforcement discretion, the agency may consider, among other things, whether the position presented by the petitioner has sufficient scientific merit and whether the petitioner's proposal is appropriate and adequate to answer the necessary scientific questions (e.g., whether the study and/or literature search that will be undertaken will, in the agency's judgment, provide the information needed to support the requested change; whether the identification of the time necessary to complete the study and any data analysis is reasonable; whether the petitioner commits to keeping FDA apprised of the progress being made on the study plan over the course of the study; and whether the petitioner agrees to provide FDA with all data from the study in order to advance the public state of knowledge, regardless of the outcome of the study).

FDA recommends that such petitions be submitted as requests to revise or amend the Guide. If a party believes that the Guide should be revised based on scientific data to be provided at a later date, the party should submit a petition under § 10.30 to the Dockets Management Branch (address above). Petitions must comply with the requirements of § 10.30. In addition, interested persons are encouraged to discuss the contents of an intended petition in advance of submission with representatives of FDA's Office of Seafood either in person or by telephone (202–418–3133). Such communication may minimize misunderstandings and time-consuming written communication during the consideration process.

If FDA determines, after reviewing a request, that it is appropriate for the agency to exercise enforcement discretion, the agency will advise the requester in writing that the agency does not anticipate enforcement action for the practice at issue and will post the letter on its Internet website at ''http://www.fda.gov''. FDA will also advise the requester of the time period that the agency believes is reasonable for the study and data analysis. If, at the end of this timeframe, the agency concludes that the data from the study are inadequate, or if no data are submitted, FDA will proceed with its regulatory options. The agency may also reconsider the use of enforcement discretion before the end of the timeframe if circumstances change or otherwise warrant reconsideration. If such reconsideration takes place, FDA will notify the original requester and make its reconsideration public.

In considering the information submitted, FDA will evaluate, as appropriate: (1) The methodology of the scientific study; (2) the scientific merit of the conclusions; and (3) the consistency of the recommended action with agency policy. Any changes in agency position will be posted on FDA's Internet website at ''http://www.fda.gov'' and then reflected in the next edition of the Guide.

The public is reminded that it is welcome to discuss with the agency at any time, including before finalization of this guidance, issues relating to seafood hazards and controls and how these issues may be resolved through research.

The guidance provided in this notice 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.

FDA tentatively concludes that this guidance would not impose any paperwork burden that has not already been approved by OMB under OMB No. 0910–0183 ''Citizen Petition—21 CFR 10.30.'' These guidelines simply provide information to the public to assist them in submitting citizen petitions to obtain changes in the Guide under certain circumstances.

Dated: March 17, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99–7363 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should