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.

SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug and Cosmetic Act. On May 5 and 6, 1999, FDA and the Association for the Advancement of Medical Instrumentation cosponsored a conference on reuse of single-use devices to help examine policy alternatives regarding the practice of reuse. As a result of that meeting, FDA made the draft guidance entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' available on November 3, 1999. Risk categorization of SUD's was one topic of discussion at an open meeting held by FDA on December 14, 1999. This document was the basis for the discussion at that meeting and is now being made more widely available for public comment. FDA expects to issue an updated draft of this guidance shortly and will also make that draft available for public comment.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the categorization of risk for SUD's. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1156 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme'' will be available at http://www.fda.gov/cdrh/Reuse.

IV. Comments

Interested persons may, on or before May 2, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 23, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–2244 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3031–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—March 1, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations to us about clinical coverage issues. The Committee will hear reports from its subcommittee, and will discuss and consider the levels of evidence (including the types and presentation format of information) that it believes should be considered by the medical specialty panels of the MCAC at future public meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* March 1, 2000, from 8 a.m. until 4 p.m., E.D.T.

Deadline for Presentation Submissions: February 10, 2000.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must notify the Executive Secretary by February 15, 2000.

ADDRESSES: *The Meeting:* The meeting will be held at the Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244.

Presentations and Comments: Submit formal presentations and written comments to Sharon Lappalainen, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3–02–01; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Executive Secretary, (410) 786–9262.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR 44231) describing the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical coverage issues. This notice announces the following public meeting of the MCAC:

Current Members of the Panel

Harold C. Sox, MD (Chairperson); Thomas V. Holohan, MD (FACP); Leslie P. Francis, JD, PhD; John H. Ferguson, MD; Robert L. Murray, PhD; Alan M. Garber, MD, PhD; Michael D. Maves, MD, MBA; David M. Eddy, MD, PhD; Frank J. Papatheofanis, MD, PhD; Ronald M. Davis, MD; Daisy Alford-Smith, PhD; Joe W. Johnson, DC; Robert H. Brook, MD, ScD; Linda A. Bergthold, PhD; Randel E. Richner, MPH.

Topic of the Meeting

The Committee will hear reports from its subcommittee, and will discuss and consider the levels of evidence (including the types and presentation