Dated: December 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32684 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0427]

Compliance Policy Guide; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of Compliance Policy Guide (CPG) Section 540.400, ''Shrimp—Fresh or Frozen, Raw, Headless, Peeled or Breaded—Adulteration Involving Decomposition (CPG 7108.11),'' because it no longer reflects agency policy. This action is being taken to ensure that FDA's CPG's accurately reflect agency policy and to limit misinterpretation and confusion.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION: FDA is revoking CPG Section 540.400, ''Shrimp—Fresh or Frozen, Raw, Headless, Peeled or Breaded—Adulteration Involving Decomposition (CPG 7108.11),'' because it no longer reflects agency policy. This CPG provides regulatory guidance on when shrimp is determined to be decomposed. Section 540.400 sets out criteria for deciding whether to initiate regulatory action based on the results of organoleptic and indole analyses of shrimp.

FDA's experience with this CPG as guidance has shown that the CPG is subject to misinterpretation by those within and outside the agency. To correct this problem, FDA has decided to revoke this CPG. Until such time as the agency develops appropriate new guidance, it intends to use any appropriate method of analysis for examining shrimp and to review recommendations for regulatory action against decomposed shrimp on a case-by-case basis.

FDA publishes its CPG's to present the agency's current thinking on issues that are before the agency. CPG's do not create or confer any rights for, or on, any person and do not operate to bind FDA or the public.

Dated: December 13,1996.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 96–32548 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0368]

Guidance for the Content of Premarket Submissions for Medical Devices Containing Software; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software.'' The draft guidance is not final nor is it in effect at this time. This guidance is available for comment and will eventually replace the ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review'' that was issued in 1991 (the 1991 draft guidance). This new draft guidance discusses the key elements reviewers look for in premarket medical device software submissions and provides a common baseline from which both manufacturers and scientific reviewers can operate. The new draft guidance is intended to provide applicants specific additional directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical device software.

DATES: Submit written comments by January 23, 1997.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0806 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the Internet may obtain the new draft guidance via the World Wide Web at http://www.fda.gov/cdrh/ode/dtswguid.html. The new draft guidance may also be obtained by calling the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a fax machine with a touch-tone telephone attached or built in. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and enter Shelf__ 616 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. Submit written comments on ''ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of ''ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software'' and 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: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: The final version of this guidance will provide guidance concerning regulatory review of premarket medical device software submissions under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) (the act). The new draft guidance has been developed to clarify the existing guidance. Through using the 1991 draft guidance for the last 4 years, FDA has gained experience in applying guidance to 510(k) submissions for medical devices using software. Comments were received from both manufacturers and scientific reviewers and have been incorporated into the new draft guidance. By clarifying the guidance, the agency hopes to receive a larger percentage of complete premarket submissions upon submittal. This will avoid the need for additional information requests which are time consuming for both FDA and manufacturers. In addition, the guidance has been updated to be consistent with emerging international consensus standards such as IEC 601–1–4 and ISO 9000.

The process for determining the level of concern (i.e., the severity of risk that a device could permit or inflict on a patient or operator as a result of latent failures, design flaws, or using the device) for medical device software, as discussed in the 1991 draft guidance, caused confusion for both FDA scientific reviewers and the medical device industry. Section 3 of the new draft guidance updates this process. However, the agency realizes that other

options exist; these options are identified in Attachment 2 of a letter included with the new draft guidance. Comments on the new draft guidance should indicate and explain the option(s) preferred.

On May 17, 1995, the new draft guidance was presented at the Indiana Medical Device Manufacturers Council seminar. This seminar focused on the development of medical device software in a regulated environment. The new draft guidance was again presented on September 21, 1995, at the 19th Annual Regulatory Affairs Professional Society Exhibition and Conference.

The intent of the final version of this guidance will be to provide applicants specific additional directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical device software.

This guidance, when finalized, will apply to all software, which includes embedded software, operator assisted software, and software accessories to medical devices. The new draft guidance excludes pure hospital information systems and manufacturing process control software.

Although this guidance does not create or confer any rights on or for any person and does not operate to bind the agency in any way, it does represent FDA's current thinking on the content of premarket submissions for medical devices containing software.

Interested persons may, on or before January 23, 1997, submit to the Dockets Management Branch (address above) written comments on the ''ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software.'' Comments should: (1) Refer to specific line numbers, sections, and page numbers in the document; (2) discuss the issue; and (3) propose a recommended change. 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 new draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revisions to the draft guidance are warranted.

Dated: December 13, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–32683 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92–463, the Annual Report for the following Health Resources and Services Administration's Federal Advisory Committee has been filed with the Library of Congress:

National Advisory Council on Nurse Education and Practice Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, S.E., Washington, D.C. Copies may be obtained from: Melaine Timberlake, Executive Secretary, National Advisory Council on Nurse Education and Practice, Room 9–36, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–5786.

Dated: December 19, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96–32685 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–15–P

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

The National Health Service Corps (NHSC) Application Process (OMB No. 0915–0146); Revision and Extension

The National Health Service Corps (NHSC) Scholarship Program was established to help alleviate the geographical and specialty maldistribution of physicians and other health practitioners in the United States. Under this program, health professions students are offered scholarships in return for service in a federally-designated Health Professional Shortage Area (HPSA).

In an effort to improve the procedures for selecting NHSC scholars, a revised application process was pilot tested in the spring of 1996. The revised application process is designed to broaden the scope of the information available on applicants in order to improve the Agency's ability to identify those applicants with the greatest potential to fulfill the objectives of the Scholarship Program. OMB approval is now being requested for full-scale implementation of the revised application process.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	3000	1	1.0	3000
Interview	900	1	1.67	1500

Estimated Total Annual Burden: 4500 hours. The interview burden includes 1 hour for travel time to the interview site.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 18, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–32686 Filed 12–23–96; 8:45 am]

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