agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.35(c)(1)	5	1	5	2614 (avg.)	13,070

There are no capital costs or operating and maintenance costs associated with this collection.

This estimate is based on the number of GRAS affirmation petitions received in 1995. Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work and analysis of appropriate toxicological studies, as well as the work of drafting the petition itself.

Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21
CFR part 186—Indirect Food Substances Affirmed As Generally Recognized As Safe. Section 184.1(a) (21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184—Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

Dated: December 13, 1996.

William K. Hubbard.

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32551 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0467]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 23, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Geraldine M. Hogan, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1481.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Gender Differences in Perception of Risks Communicated by Prescription and Over-the-Counter (OTC) Drug Labels

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The Marketing Practices and Communications Branch of FDA's Division of Drug Marketing, Advertising, and Communications is studying the effectiveness of various formats for the presentation of risk and benefit information for OTC and prescription drugs to male and female patients through patient labeling. To gain information about the value and utility of benefit and risk information presented in several formats, three studies will be undertaken. In each study subjects will examine materials varied by one or more risk formatting variables for one prescription and one OTC drug. Subjects will be recruited at large shopping malls. They will be brought to a private interview room where they will examine the materials, and a structured interview will be conducted. Equal numbers of subjects of each gender will be included in each study. In addition, there will be a control group for each study that receives ''no-risk'' information labels for the drugs. The original study design was to use male-oriented and female-oriented drugs with 2,700 respondents. Based on focus group responses, the design was refined. It was determined that more accurate information would be obtained by assessing males' and females' responses to gender-neutral drugs. Accordingly, the sample size has been reduced to 960. The annual estimated hour burden for respondents is 480 hours.

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
960	1	1	0.5	480

There are no capital costs or operating and maintenance costs associated with this collection.

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