Health Department Charge; a review of the Top Five Priority Issues of the HDS and how to proceed on the next top priority issues; a discussion on the formulation of recommendations on the Environmental Health Workforce; a discussion on issues the BSC would like addressed; and a discussion to establish the regularity and timing of the HDS face-to-face and teleconference meetings.

Items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This teleconference meeting is scheduled to begin at 1 p.m. e.s.t. To participate during the Public Comment period (2–2:10 p.m.), dial (877) 315–6535, conference code 383520.

FOR FURTHER INFORMATION CONTACT: Individuals interested in attending the meeting, contact Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, M/S E–28, Atlanta, Georgia 30333; telephone 404/498–0003, fax 404/498–0059; e-mail: *smalcom@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

Dated: December 27, 2005.

Alvin Hall,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. E5–7868 Filed 12–23–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by January 26, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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

Reclassification Petitions for Medical Devices—(OMB Control Number 0910–0138)—Extension

FDA has the responsibility under sections 513(e), 513(f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), 360c(f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes (I, II, and III) to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

Respondents are device manufacturers seeking reclassification.

In the **Federal Register** of September 14, 2005 (70 FR 54392), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current trends and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7804 Filed 12–23–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0481]

Draft Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy; Draft Supporting Document: Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy.'' This draft guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the recommended maximum level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. The agency is also announcing the availability of a draft supporting document entitled ''Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children.'' These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practicably can be obtained.

DATES: Submit written or electronic comments on the draft guidance by March 13, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance and/or draft supporting document to the Division of Plant Product Safety (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance and/or draft supporting document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance and draft supporting documents.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy.'' This draft guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the recommended maximum level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. FDA notes that the recommended level is not for enforcement purposes. In addition, FDA is rescinding previous guidance provided in a 1995 letter to the industry regarding an enforcement level. Finally, this draft guidance reiterates FDA's enforcement policy toward the use of lead based ink on candy wrappers as stated in the 1995 letter to the industry.

FDA also is announcing the availability of a draft document entitled ''Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children.'' The draft supporting document provides additional background and rationale for the recommended maximum level. These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practically can be obtained.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance is being issued as a level 1 draft guidance consistent with GGPs. The draft guidance represents the agency's current thinking on lead levels in candy that are achievable with the use of good manufacturing practices in the production of candy and candy ingredients and that also provides for the protection of human health. 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 an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance and draft supporting document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and draft supporting document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: December 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24494 Filed 12–22–05; 8:45 am]

BILLING CODE 4160–01–S