document should be sent by mail or facsimile to: Nancy Tips, NCEH/CDC, Mailstop F42, 4770 Buford Highway, N.E., Atlanta, GA, 30341–3724, facsimile (770) 488–7335.

SUPPLEMENTARY INFORMATION: Childhood lead poisoning is a major preventable environmental health problem in the United States. Since 1975, when CDC issued its first comprehensive guidelines for preventing lead poisoning in children, ''Increased Lead Absorption and Lead Poisoning in Young Children,'' CDC has worked with public health agencies, child health-care providers, and various concerned groups to prevent lead poisoning in young children. Other editions of the guidelines have been published in 1975, 1978, 1985, and 1991. Each revision has incorporated new scientific and practical information on how best to reduce the adverse effects of lead on the health of young children. This draft guidance is narrower in scope than the 1991 edition of ''Preventing Lead Poisoning in Young Children.'' It does not modify CDC's position on adverse health effects caused by lead. Instead, it makes recommendations to improve the use of screening to prevent lead poisoning among young children. These recommendations are needed because data indicate that many children, especially those living in older housing, continue to be heavily exposed to lead, whereas the average exposure of children in the United States has substantially declined. To address this situation, the recommendations in this guidance are intended to increase the screening and follow-up care of children who most need these services and to ensure that prevention approaches are appropriate to local conditions. The audience for this guidance includes State and local public health officials, who will make screening recommendations for their jurisdictions, and pediatricians and other child health-care providers, public health agencies, and health care organizations, including managed care organizations.

Dated: February 14, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–4281 Filed 2–20–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 97N–0025]

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 March 24, 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: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

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:

Medical Devices Standards Activities Report (OMB Control Number 0910–0219—Extension)

FDA is collecting information necessary to update a comprehensive listing of current national and international standards activities in the field of medical devices. The collection of this information is authorized by section 514(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(4)(B)), which requires FDA to consult with other nationally or internationally recognized standard-setting entities, including other Federal agencies concerned with standard-setting, in carrying out its responsibility to establish special controls for medical devices. This report is used by approximately 39 standards-developing organizations to coordinate their standards activities. This coordination prevents duplication of effort and insures efficient and expeditious management of standards development. Over 700 copies of this report are used by government, hospitals, libraries, industry, private citizens, and State and local government agencies, including FDA, to keep abreast of standards development activities and current technology concerning the safety of medical devices. Without the report, there would be duplication of standards efforts by voluntary standards organizations because there is no other publication that can be easily referenced to ascertain if a certain medical device standard is being or has been developed.

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

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
39	0.5	19.5	3	58.5

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

This collection occurs biennially and is voluntary. There are 39 national and international organizations with one report each reporting period.

Dated: February 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4227 Filed 2–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0283]

Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.