Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–4005 Filed 2–20–97; 8:45 am]

BILLING CODE 4163–18–P

National Institute for Occupational Safety and Health; Request for Comments on the Toxicity of Carbonless Copy Paper

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Request for comments.

SUMMARY: NIOSH is requesting comments from all interested parties concerning possible adverse health effects among workers who have used carbonless copy paper. Interested parties may submit medical case reports, experimental data, or other information relating to the effects caused by such exposures. This information will be used by NIOSH to evaluate whether exposure to the chemical substances in carbonless copy paper poses health risks, and to determine the need for preventive health measures or additional research.

DATES: Written comments to this notice should be submitted to Diane Manning, NIOSH Docket Office, 4676 Columbia Parkway, M/S C–34, Cincinnati, Ohio 45226 on or before April 22, 1997. Comments may also be faxed to Diane Manning at (513) 533–8285 or submitted by email to: dmm2@cdc.gov as WordPerfect 5.0, 5.1/5.2, 6.0/6.1, or ASCII files.

FOR FURTHER INFORMATION CONTACT: Technical information may be obtained from Dr. Paul A. Schulte, NIOSH, CDC, 4676 Columbia Parkway, Mailstop C–14, Cincinnati, Ohio 45226, telephone (513) 533–8303.

SUPPLEMENTARY INFORMATION: Pursuant to sections 20 and 22 of the Occupational Safety and Health Act of 1970 [29 U.S.C. 669 and 671], NIOSH is authorized to gather information in order to develop recommendations for improving occupational safety and health. NIOSH has been concerned about reported undesirable health effects in workers occupationally exposed to chemicals contained in or released from carbonless copy paper. On June 12, 1987, NIOSH published a Federal Register Notice (52 FR 22534) requesting comments and secondary data on the toxicity of carbonless copy paper. At that time it was determined, based on the submitted information, that insufficient data were available to conclude that the relationship between exposure to carbonless copy paper and the suggested health effects was a causal one.

Carbonless copy paper is used to simultaneously make multiple paper copies of an original document. This system eliminates the need for carbon paper by using paper with a microencapsulated undercoating containing dyes and solvents. Writing, typing, or printing on the top sheet breaks the microcapsules immediately underneath, releasing the dyes and solvents to form the image on the paper surface below. Some substances used in carbonless copy paper include aliphatic compounds (C_{10}–C_{14}), aromatic compounds such as alkyl substituted biphenyls (polychlorinated biphenyls have not been used in carbonless copy paper in the United States since the early 1970's), phenyl methyl benzenes and hydrogenated terphenyls, diaryl ethanes, alkyl benzenes, benzyl xylene, isoparaffins, diisopropyl naththalenes, dibutyl phthalate, glutaraldehyde, formaldehyde, organic dyes, phenol-formaldehyde resin, kaolin, starch, styrene, butadiene-latex, hydrogenated aluminum silicate, mineral oil, and sanatasol oil.

Carbonless copy paper chemicals can be absorbed dermally or by inhalation. Several factors such as chemical composition and volume of the paper used, ambient temperature and ventilation rates in work or storage areas, and work practices may affect the extent of exposure. Adverse health effects in exposed workers were first reported in the scientific literature in the late 1960's. The signs and symptoms attributed to dermal exposure have included dryness, redness, irritation, eczema, tingle, and itchiness of the skin. The signs and symptoms attributed to inhalation exposures have included nasal congestion, drainage, bleeding, and irritation; upper respiratory tract irritation; asthma; throat tickle and hoarseness; and joint pain, fatigue, and headache.

In order to update the information on carbonless copy paper, NIOSH is interested in obtaining existing and available information published or developed since 1987, including reports and research findings, to evaluate whether recommendations for health protection or further research on carbonless copy paper chemicals are needed. Examples of requested information include, but may not be limited to, the following:

1. Adverse health signs or symptoms associated with occupational exposure to carbonless copy paper or its components.

2. Epidemiology data assessing the incidence of health effects associated with occupational exposure to carbonless copy paper.

3. Medical case reports and studies of adverse health effects associated with occupational exposure to carbonless copy paper. These medical case reports and studies should be submitted without personal identifiers.

4. Industrial hygiene data and reports from work places where carbonless copy paper is used or handled.

5. *In Vivo* or *In Vitro* toxicity data and studies on the components of carbonless copy paper.

All information received in response to this notice, except that designated as trade secret and protected by section 15 of the Occupational Safety and Health Act, will be available for public examination and copying at the above address.

Dated: February 12, 1997.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–4280 Filed 2–20–97; 8:45 am]

BILLING CODE 4163–19–P

Availability of Draft Guidance on Childhood Lead Screening

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice of availability and request for comments.

SUMMARY: This notice announces the availability for review and comment of a draft document entitled, ''Screening Young Children for Lead Poisoning.'' The document was prepared by CDC staff with advice from CDC's Advisory Committee on Childhood Lead Poisoning Prevention, a group of non-Federal experts on childhood lead poisoning prevention. The document also reflects the comments of many other persons involved in scientific and programmatic aspects of childhood lead poisoning prevention and child health.

DATES: To ensure consideration, written or verbal comments on this draft document must be received by April 7, 1997.

ADDRESSES: Requests for copies of the draft document must be made by calling the toll free telephone number: (888) 232–6789. Verbal comments on the draft document may be made by calling the same toll free telephone number. Written comments on the draft

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.