

responses received on the alternatives and potential impacts, as a result of this NOI, will be considered for the environmental document. The public is encouraged to provide additional comments once the Draft EIS is released. The General Services Administration anticipates that release date to be January 1998.

The proposed consolidated Patent and Trademark Office (PTO) will include approximately 2 million square feet in up to eight buildings and will require between 3,500 to 7,000 parking spaces. It is proposed to be located in northern Virginia in either Arlington County or the City of Alexandria and is scheduled to be gully occupied by the year 2004. The EIS will analyze the environmental impacts and mitigation options associated with five alternatives for the construction and operation of the proposed PTO. At present those alternatives may include: (1) construction of the PTO in Arlington at Crystal City between the George Washington Memorial Parkway and Route 1 with 20th Street as the northern boundary and the overpass connecting Route 1 to National Airport as the southern boundary; (2) construction of the PTO in Alexandria in the Potomac Yards/Potomac Greens between the George Washington Memorial Parkway and U.S. Route 1 south of Four Mile Run and north of the Monroe Avenue Bridge; (3) construction of the PTO at the Carlyle site in Alexandria at Dulaney Street and Eisenhower Avenue between Elizabeth Lane and Carlyle Street; (4) construction of the PTO in Alexandria at 2111 Eisenhower Avenue at the Eisenhower Avenue Metro station; and, (5) a No Action Alternative which would not result in a consolidated Patent and Trademark Office in northern Virginia. Topics for environmental analysis will include the short-term impacts of construction; the long-term impacts of site operations and maintenance on land use, historic resources, visual resources, physical-biological resources, public transportation, traffic and parking, public services and utilities, and socioeconomic conditions within the project areas; and, the cumulative impacts associated with this and other projects in the future.

SUPPLEMENTARY INFORMATION: The public meetings will be held:

Wednesday, June 4, 1997, 7:00 p.m.

Aurora Hills Recreation Center, 735
18th Street, Arlington, Virginia,

Thursday, June 5, 1997, 7:30 p.m.

Alexandria City Hall, 301 King Street,
Room 2000, Alexandria, Virginia

Public meetings will be advertised in local and regional newspapers. Adequate signs will be posted to direct meeting participants. A short formal presentation will precede the request for public comments. General Services Administration and the Patent and Trademark Office representatives will be available at this meeting to receive comments from the public regarding issues of concern. It is important that Federal, regional, and local agencies, and interested individuals and groups take this opportunity to identify environmental concerns that should be addressed during the preparation of the Draft EIS. In the interest of available time, each speaker will be asked to limit oral comments to ten (10) minutes. A document summarizing the written and oral comments received will be prepared.

An Informational Packet will be available for review at the public meetings or upon request to the GSA contact identified below. Agencies and the general public are invited and are encouraged to provide written comments on the scoping issues in addition to, or in lieu of oral comments at the public meeting. To the most helpful, environmental review/scoping comments would clearly describe specific issues or topics which the community believes the EIS should address.

DATES: All written statements regarding environmental review of the proposed Patent and Trademark Office must be postmarked no later than May 19, 1997 to the following address: General Services Administration, Attn: Carl W. Winters, Property Acquisition and Realty Services (WPEMC), 7th and D Streets, S.W., Washington, D.C. 20407.

FOR FURTHER INFORMATION PLEASE

CONTACT: Carl W. Winters, General Services Administration, (202) 401-1025. E-mail carl.winters@gsa.gov

Dated: April 14, 1997.

Douglas G. Benton,

Director, Property Acquisition and Realty Services Division, National Capital Region.

[FR Doc. 97-10244 Filed 4-18-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Request for Comments on the Toxicity of Carbonless Copy Paper; Amendment To Extend Comment Period

A notice requesting comments from all interested parties concerning possible adverse health effects among workers who have used carbonless copy paper was published in the **Federal Register** on February 21, 1997 (62 FR 8023).

The notice is amended as follows: On page 8023, first column, under the heading **DATES**, line five, the date for submission of written comments to this notice has been extended from April 22, 1997, to "on or before June 20, 1997."

All other information and requirements of the February 21, 1997, **Federal Register** notice remain the same.

Dated: April 15, 1997.

William E. Halperin,

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

[FR Doc. 97-10205 Filed 4-18-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0129]

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 (the PRA).

DATES: Submit written comments on the collection of information by May 21, 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 PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of FDA Safety Alert/Public Health Advisory

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH)

communicates these risks to user communities through two publications: The "FDA Safety Alert" and the "FDA Public Health Advisory." Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of recent alerts include spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1702(a)(4) of the Public Health Services Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to

be completed and returned to FDA. The information to be collected will address how clearly the problem discussed in the alert or advisory is identified, how easily the problem is understood, how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

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
308	3	924	.17	157

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

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time was estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey, in addition to discussions with contacts in trade associations.

Dated: April 9, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-10253 Filed 4-18-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0047]

Determination of Regulatory Review Period for Purposes of Patent Extension; MENTAX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined

the regulatory review period for MENTAX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's

regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MENTAX (buteinafine hydrochloride). MENTAX is indicated for the topical treatment of interdigital tinea pedis (athlete's foot)