

ACTION: Notice of request for comments and information relevant to occupational exposure to toluene.

SUMMARY: NIOSH is reviewing the recommendations in its document "Criteria for a Recommended Standard: Occupational Exposure to Toluene" [NIOSH 1973] (<http://www.cdc.gov/niosh/73-11023.html>). A review of recent literature indicates that the NIOSH recommended exposure limit (REL) of 100 ppm as an 8-hr time-weighted average (TWA) does not sufficiently protect workers from the adverse effects of exposure to toluene. NIOSH is requesting (1) comments and information relevant to the evaluation of the health risks associated with occupational exposure to toluene, (2) reports or other data that demonstrate adverse health effects in workers exposed to toluene at or below the NIOSH REL, and (3) information pertinent to establishing a more protective REL for toluene.

Comments concerning this notice must be received within 60 days after date of publication.

ADDRESSES: Comments may be transmitted either electronically to niocindocket@cdc.gov, by facsimile to 513/533-8230, or by regular mail or hand delivery to NIOSH Docket Office, M/S C-34, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226. E-mail attachments should be formatted as WordPerfect 7/8/9 or Microsoft Word.

FOR FURTHER INFORMATION CONTACT: Henryka Nagy, M/S C-32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, 513/533-8369.

SUPPLEMENTARY INFORMATION: In the document "Criteria for a Recommended Standard: Occupational Exposure to Toluene" [NIOSH 1973] (<http://www.cdc.gov/niosh/73-11023.html>), NIOSH recommended that exposure to toluene be limited to 100 ppm as an 8-hr TWA. This exposure limit was expected to prevent acute and chronic effects on the central and peripheral nervous system from exposures to toluene. NIOSH has conducted a literature review of the health effects data on toluene exposure and finds evidence that adverse effects on the central and peripheral nervous systems and reproductive system, as well as irritation of the eye and respiratory tract may occur in workers exposed to concentrations at and below the current NIOSH REL of 100 ppm [Andersen *et al.* 1983; Larsen and Leira 1988; Ørbæk and Nise 1989; Foo *et al.* 1990; Ng *et al.* 1992; ATSDR 2000; NEG 2000].

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to toluene at concentrations below 100 ppm. Examples of requested information include, but are not to be limited to, the following:

1. Identification of industries or occupations in which exposures to toluene may occur.
2. Trends in production, use, and import of toluene over the past 10 years.
3. Description of work tasks and scenarios with a potential for exposure to toluene.
4. Current occupational exposure concentrations in various types of industries and jobs and, if available, data to document these concentrations.
5. Case reports or other health data that demonstrate adverse health effects in workers exposed to toluene, or animal data (published or peer-reviewed data are preferred).
6. Description of work practices and engineering controls used to reduce or prevent workplace exposure.
7. Educational materials for worker safety or training on the safe handling of toluene.
8. Data pertaining to the technical feasibility of establishing a more protective REL for toluene.

NIOSH will use this information to determine the need for developing new recommendations for reducing occupational exposure to toluene.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

References

- Andersen I, Lundqvist GR, Molhave L, Pedersen OF, Proctor DF, Væth M, Wyon DP [1983]. Human response to controlled levels of toluene in six-hour exposures. *Scand J Work Environ Health* 9:405-418.
- ATSDR [2000]. Toxicological profile for toluene (update). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.
- Foo SC, Jeyaratnam J, Koh D [1990]. Chronic neurobehavioural effects of toluene. *Br J Ind Med* 47:480-484.
- Larsen F, Leira HL [1988]. Organic brain syndrome and long-term exposure to toluene: a clinical, psychiatric study of vocationally active printing workers. *J Occup Med* 30(11):875-878.
- NEG [2000]. Toluene. Stockholm, Sweden: The Nordic Expert Group

for Criteria Documentation of Health Risks from Chemicals.

Ng TP, Swee CF, Yoong T [1992]. Risk of spontaneous abortion in workers exposed to toluene. *Br J Ind Med* 49:804-808.

NIOSH [1973]. Criteria for a recommended standard occupational exposure to toluene. Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 73-11023.

Ørbæk P, Nise G [1989]. Neurasthenic complaints and psychometric function of toluene-exposed rotogravure printers. *Am J Ind Med* 16:67-77.

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 Agency for Toxic Substances and Disease Registry.

Dated: July 23, 2003.

Alvin Hall,

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

[FR Doc. 03-22102 Filed 8-26-03; 10:03 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0199]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a 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: Fax written comments on the collection of information by September 29, 2003.

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 written 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:

Importer's Entry Notice—(OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products, and (2) preventing

shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods, (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of goods to their final destinations; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Custom Service. FDA uses this information to make admissibility decisions about

FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2002 was 5,496,954. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

In the **Federal Register** of May 23, 2003 (68 FR 28235), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801 for FY 2002 Updated	3,406	652	2,955,595	.14	413,833

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

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-21982 Filed 8-27-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0191]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submission of Validation Data for Reprocessed Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Submission of Validation Data for Reprocessed Single-Use Devices" has been approved by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 2003 (68 FR 40676), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0514. The approval expires on January 31, 2004.

A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-21983 Filed 8-27-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0364]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications; 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 "Providing Regulatory Submissions in Electronic Format—