NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to toluene at concentrations below 100 ppm.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, if 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. E-mail attachments should be formatted as WordPerfect 7/8/9 or Microsoft Word.

FOR FURTHER INFORMATION CONTACT: Alvin Hall, Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, 4676 Columbia Parkway, Cincinnati, Ohio 45226. E-mail attachments should be formatted as WordPerfect 7/8/9 or Microsoft Word. Comments concerning this notice must be received within 60 days after date of publication.

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.

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 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, if 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.
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 Burden**

<table>
<thead>
<tr>
<th>Section of the Act</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 801 for FY 2002 Updated</td>
<td>3,406</td>
<td>652</td>
<td>2,955,595</td>
<td>.14</td>
<td>413,833</td>
</tr>
</tbody>
</table>

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


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–21983 Filed 8–27–03; 8:45 am]
BILLING CODE 4160–01–S

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.


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–21983 Filed 8–27–03; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0364]


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—