## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

**[ATSDR–115]**

### Availability of Draft Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** This notice, prepared by ATSDR for the Department of Defense, announces for review and comment the availability of five new draft toxicological profiles on unregulated hazardous substances. All profiles issued as ''Drafts for Public Comment'' represent the agency's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

**DATES:** To ensure consideration, comments on these draft toxicological profiles must be received on or before January 27, 1997. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

**ADDRESSES:** Requests for copies of the draft toxicological profiles or comments regarding the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the profiled hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR–115. Send one copy of all comments and three copies of all supporting documents to the Division of Toxicology at the above address by the end of the comment period. All written comments and draft profiles will be available for public inspection at ATSDR, Building 4, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8:00 a.m. until 4:30 p.m., Monday through Friday, except for legal holidays. Because all public comments regarding ATSDR toxicological profiles are available for public inspection, no confidential business information should be submitted in response to this notice.

**FOR FURTHER INFORMATION CONTACT:** Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–6322.

**SUPPLEMENTARY INFORMATION:** The Superfund Amendments and Reauthorization Act (SARA) of 1986 (Public Law 99–499) amended the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). Section 211 of SARA also amended Title 10 of the U.S. Code, creating the Defense Environmental Restoration Program. Section 2704(a) of Title 10 of the U.S. Code directs the Secretary of Defense to notify the Secretary of Health and Human Services (HHS) of not less than 25 of the most commonly found unregulated hazardous substances at defense facilities. The Secretary of HHS is to prepare toxicological profiles of these substances. Each profile includes an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information is used to ascertain the level of significant human exposure for the substance and the associated health effects. The profiles include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), may plan a program of research designed to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this Federal Register notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles were made available to the public on October 27, 1996.

| Document | Hazardous substance | CAS No. |
|---|---|---|
| 1 | 2-BUTOXYETHANOL AND | 111–76–2 |
| | 2-BUTOXYETHANOL ACETATE | 112–07–2 |
| 2 | DIISOPROPYL METHYLPHOSPHONATE | 1445–75–6 |
| 3 | HEXAMETHYLENE DIISOCYANATE | 822–06–0 |
| 4 | JET FUEL (JP–5) | 8008–20–6 |
| | JET FUEL (JP–8) | 70892–10–3 |
| 5 | METHYLENEDIANILINE | 101–77–9 |

Dated: November 19, 1996.

Georgi Jones,

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 96–30098 Filed 11–25–96; 8:45 am]

**BILLING CODE 4163–70–P**

## Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

Proposed Projects

*Title:* Head Start Family and Child Experiences Survey (FACES).

*OMB No.:* New Collection.

*Description:* The Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF) of the Department of Health and Human Services (DHHS) is requesting Office of Management and Budget (OMB) clearance for interview instruments to be used in the Head Start Family and Child Experience Survey (FACES). This study is being conducted under contracts with Abt Associates Inc.

(with The CDM Group, Inc. as their subcontractor (#105–96–1930)) to collect descriptive information on Head Start families, and Westat, Inc. (with Ellsworth Associates as their subcontractor (#105–96–1912)) to collect information on Head Start performance measures. The design calls for three rounds of data collection. A nationally representative group of 2,400 families with children enrolled in approximately 160 centers in 40 Head Start programs will be identified in Spring, 1997. At that time, Head Start staff and parents will be interviewed, classroom observations will be completed, and children will be assessed. The second data collection period will occur in Fall, 1997. Again, staff and parents will be interviewed, and children will be assessed and observed in their classrooms. At that time children from the Spring, 1997 sample that left Head Start to enter kindergarten following the 1996–97 Head Start year will be replaced by a representative sample of children just entering Head Start. All families, including those whose children entered kindergarten in Fall, 1997 will be tracked through the school year. The final data collection effort will occur in Spring, 1998 and involve all families and children identified in the earlier two data collection periods.

A subgroup of 120 families will be identified from the Spring and Fall, 1997 samples for participation in the Validation Substudy. The Validation Substudy data collection will require home visits to participating families at each major data collection point and a series of monthly contacts between data collections periods. The monthly contacts will begin with the Spring, 1997 data collection and continue through December, 1998.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures, and by the 1994 reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649 (d)), which requires assessment of Head Start's quality and effectiveness.

*Respondents:* Federal Government, Individuals or Households, and Not-for-profit institutions.

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Spring, 1997 | 7,840 | 1 | 0.652 | 5,110 |
| Fall, 1997 | 8,400 | 1 | 0.648 | 5,440 |
| Spring, 1998 | 11,460 | 1 | 0.654 | 7,500 |

Estimated Total Annual Burden Hours: 9,025.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 20, 1996.

Bob Sargis,

*Acting Reports Clearance Officer.*

[FR Doc. 96–30145 Filed 11–25–96; 8:45 am]

**BILLING CODE 4184–01–M**

## Food and Drug Administration

**[Docket No. 96E–0315]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; Nuflor®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Nuflor® 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 animal 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval