Respondents (adults with asthma)	Number of respondents	Number of responses/ respondent	Average burden per response (in hours)	Total burden (in hours)
Validation Study	200	1	7.51	500
Follow-up Study	465	1	30/60	233
Total	665			1733

Dated: July 17, 2003.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–18801 Filed 7–23–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0319]

Draft Guidance for Industry and FDA Staff; Premarket Assessment of Pediatric Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Assessment of Pediatric Medical Devices.'' This draft guidance presents FDA's current thinking on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by October 22, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Premarket Assessment of Pediatric Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues contact: Joy Samuels-Reid, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287 ext. 177.

For biologics issues contact: Edward Tabor, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, was signed into law. Among other things, MDUFMA amends the Federal, Food, Drug, and Cosmetic Act (the act) by adding several new provisions concerning devices intended for pediatric use. MDUFMA requires FDA, within 270 days of enactment, to issue guidance on the safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products. This guidance, as well as a collateral guidance on procedures for ensuring appropriate pediatric expertise on FDA Advisory Panels, ''Pediatric Expertise for Advisory Panels'' (*http://www.fda.gov/cdrh/ode/guidance/1208.html*), will help the agency achieve the intent of the pediatric provisions of MDUFMA.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Premarket Assessment of Pediatric Medical Devices.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Premarket Assessment of Pediatric Medical Devices'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1220) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) . The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket

notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120) and premarket approval applications (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number 202–395–6974.

Dated: July 18, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–18764 Filed 7–23–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Grant Awards

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Announcement of grant awards.

SUMMARY: The Office of Rural Health Policy (ORHP), HRSA is awarding the following grants to the State Offices of Rural Health (SORH), as authorized by Section 338J of the Public Health Service Act 42 U.S.C. 254r. The purpose of this notice is to announce the grant awards. The grant year began on July 1, 2003.

State Office of Rural Health Awards (CFDA# 93.913). These grants allow each State to designate a focal point of contact for rural health. They also play a vital role in helping coordinate rural health activities statewide such as collecting and disseminating health-related information within the State, improving the recruitment and retention of health professionals into rural areas, providing technical assistance to attract more Federal, State, and foundation funding, and coordinating rural health interests and activities across each State.

The following grantees have received awards for the first year of a 5-year project period.

- Alabama Department of Public Health; $150,000;
- Alaska Department of Health and Social Services; $150,000;
- Arizona Prevention Center, Office of Rural Health; $150,000;
- Arkansas Department of Health; $150,000;
- California Department of Health Services; $150,000;
- Colorado Rural Health Center; $150,000;
- Connecticut Community College Northwestern; $150,000;
- Delaware Department of Health and Social Services; $108,000;
- Florida Department of Health; $150,000;
- Georgia Department of Community Health, $150,000;
- Hawaii State Department of Health; $150,000;
- Idaho Department of Health and Welfare; $147,418;
- Illinois Department of Public Health; $150,000;
- Indiana State Department of Health; $150,000;
- Iowa Department of Public Health; $150,000;
- Kansas Department of Health and Environment; $150,000;
- Kentucky Research Foundation, University of Kentucky; $150,000;
- Louisiana Department of Health and Hospitals; $150,000;
- Maine Department of Human Services; $136,968;
- Maryland Office of Primary Care and Rural Health; $150,000;
- Massachusetts Department of Public Health; $150,000;
- Michigan Department of Community Health; $58,916;
- Minnesota Department of Health; $150,000;

Dated: July 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18909 Filed 7–21–03; 4:25 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Faculty Loan Repayment Program (FLRP) Application (OMB No. 0915–0150)—Extension

Under the Health Resources and Services Administration Faculty Loan Repayment Program, disadvantaged graduates from certain health professions may enter into a contract under which HRSA will make payments on eligible educational loans in exchange for a minimum of two years of service as a full-time or part-time faculty member of an accredited health professions school. Applicants must complete an application and provide current loan balances on all eligible educational loans.

The estimated burden hours for the form is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Applicants	94	1	94	1	94