1. Quarterly data progress reports. These quarterly reports are required by the Office of Management and Budget (OMB) authorizing legislation (OMB Form 0920–0282.) The reports are due 30 days after the end of each quarter.

2. An interim progress narrative report, due no less than 90 days before the end of the budget period. This progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Progress on Current Budget Period Objectives and Activities.

b. Current Budget Period Financial Progress.

c. New Budget Period Proposed Program Objectives and Activities.

d. Detailed Line-Item Budget and Justification.

3. Calendar-year surveillance data, submitted annually in the approved OMB format, no later than April 30. In addition, a written surveillance summary must be disseminated to state and local public health officials, policy makers, the CDC project officer, and others.

4. Financial Status Reports, due within 90 days of the end of the budget period.

5. Final financial reports and performance reports, due within 90 days after the end of the project period.

6. Projects that involve the collection of information from 10 or more individuals, and are funded by a cooperative agreement will be subject to review by OMB under the Paperwork Reduction Act. Data collection initiated under this cooperative agreement program has been approved by OMB under OMB number 0920–0337, ''National Childhood Blood Lead Surveillance System'', Expiration Date: 6/30/2004.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement as posted on the CDC Web site.

AR–9, Paperwork Reduction Act Requirements
AR–10, Smoke-Free Workplace Requirements
AR–11, Healthy People 2010
AR–12, Lobbying Restrictions
AR–21, Small, Minority & Women-Owned Businesses

Executive Order 12372 does not apply to this program.

*J. Where To Obtain Additional Information*

Two telephone conference calls for application technical assistance will be held during the application period. For further information, please contact Rob Henry at (770) 488–4024. This, and other CDC announcements, necessary applications, and associated forms can be found on the CDC home page Internet address: *http://www.cdc.gov.* Click on ''Funding'', then ''Grants and Cooperative Agreements.''

For general questions regarding this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2700.

For business management and budget assistance, contact: Mildred Garner, Grants Management Officer, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2745, E-mail address: *mgarner@cdc.gov.*

For business management and budget assistance in the territories, contact: Charlotte Flitcraft, Grants Management Officer, CDC Procurement and Grants Office, 2020 Brandywine Rd., Room 3000, Atlanta, GA 30319, Telephone: 770–488–2632, E-mail address: *caf5@cdc.gov.*

For program technical assistance, contact: Rob Henry, Acting Team Leader, Program Services Section, Lead Poisoning Prevention Branch, Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, MS E–25, Atlanta, GA 30333, Telephone: (770) 488–4024, E-mail address: *rhenry@cdc.gov.*

Dated: December 31, 2002.

**Sandra R. Manning,**

*CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 03–1434 Filed 1–22–03; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03N–0009]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Exemption From Federal Preemption of State and Local Medical Device Requirements

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's requirements for State and local governments' applications for exemption from preemption for medical device requirements.

**DATES:** Submit written or electronic comments on the collection of information by March 24, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

**Application for Exemption From Federal Preemption of State and Local Medical Device Requirements—21 CFR Part 808 (OMB Control No. 0910–0129)—Extension**

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)) provides that no State or local government may establish, or continue in effect, any requirement with respect to a medical device that is different from, or in addition to, any Federal requirement applicable to the device under the act. Under section 521(b) of the act, following receipt of a written application from the State or local government involved, FDA may exempt from preemption a requirement that is more stringent than the Federal requirement, or that is necessitated by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any portion of any requirement under the act. Exemptions are granted by regulation issued after notice and opportunity for an oral hearing.

The regulations in 21 CFR 808.20 require a State or local government that is seeking an exemption from preemption to submit an application to FDA. The application must include a copy of the State or local requirement, as well as information about its interpretation and application, and a statement as to why the applicant believes that the requirement qualifies for exemption from preemption under the act. FDA will use the information in the application to determine whether the requirement meets the criteria for exemption in the act and whether granting an exemption would be in the interest of the public health.

In addition, 21 CFR 808.25 provides that an interested person may request a hearing on an application by submitting a letter to FDA following the publication by FDA of a proposed response to the application.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 808.20 | 3 | 1 | 3 | 100 | 300 |
| 808.25 | 3 | 1 | 3 | 10 | 30 |
| TOTAL | | | | | 330 |

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

FDA based its estimates of the number of submissions expected in the future contained in table 1 of this document on the number of submissions submitted in the last 3 years and on the number of inquiries received indicating that applications would be submitted in the next year. FDA based its estimates of the time required to prepare submissions on discussions with those who have prepared submissions in the last 3 years.

Dated: January 14, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–1435 Filed 1–22–03; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0400]**

### Agency Information Collection Activities; Announcement of OMB Approval; Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 13, 2002 (67 FR 52726), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0392. The approval expires on October 31, 2005. A copy of the supporting statement for this information collection is available on