

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.

**State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910-0275—Extension)**

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

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

The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343-1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-13587 Filed 5-29-02; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02N-0053]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; State Petitions for Exemption From Preemption**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the 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.

**DATES:** Submit written comments on the collection of information by July 1, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235,

Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

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

**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.

**State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910-0277)—Extension**

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343-1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the act for

granting exemption from Federal preemption.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions; therefore, the agency estimates that one or fewer petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the act.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-13588 Filed 5-29-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Safety and Effectiveness of Products for the Treatment of Naturally Occurring Human Plague (Bubonic, Pneumonic, Meningitic, or Septicemic); Availability of Grants; Request for Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing its Office of Pediatric Drug Development and Program Initiatives (OPDDPI) grant program for fiscal year (FY) 2002. FDA is announcing the expected availability of FY 2002 funds for awarding grants to support clinical trials on the safety and effectiveness of drug products for the treatment of human plague (bubonic, pneumonic, meningitic, or septicemic) caused by

*Yersinia pestis*. This grant program is part of FDA's counter-terrorism efforts.

**DATES:** The application receipt date is July 29, 2002.

**ADDRESSES:** Application forms are available from, and completed applications should be sent to: Rosemary Springer, Grants Management Specialist, Division of Contracts and Procurement Management (HFA-522), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182, rspringe@oc.fda.gov. Application forms can also be found at [http://www.nih.gov/grants/phs398/forms\\_toc.html](http://www.nih.gov/grants/phs398/forms_toc.html). Please do not send applications to the Center for Scientific Review (CSR), National Institutes of Health (NIH). Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. (Note: completed applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.) FDA is unable to receive applications electronically.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding the administrative and financial management issues of this notice:* Rosemary Springer (see **ADDRESSES**).

*Regarding the programmatic issues of this notice:* Joanne M. Holmes, Office of Pediatric Drug Development and Program Initiatives (HFD-950), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2350, e-mail: [holmesj@cder.fda.gov](mailto:holmesj@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the expected availability of FY 2002 funds for awarding grants to support clinical trials on the safety and effectiveness of drug products for the treatment of human plague (bubonic, pneumonic, meningitic, or septicemic). Subject to the availability of FY 2002 funds, it is anticipated that \$2.1 million should be available. FDA anticipates making up to three awards each for up to \$700,000 (direct and indirect costs). Funding will be provided one time at the beginning of the project and will

cover both years of the project period. The budget and project periods will coincide for these awards. These awards will start before September 30, 2002.

FDA will support the clinical studies covered by this notice under the authority of section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort to reduce morbidity and mortality and to improve the quality of life. Applicants may obtain a hard copy of the "Healthy People 2010" objectives, vols. I and II, conference edition (B0074) for \$22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013-7366. Each of the 28 chapters of "Healthy People 2010" is priced at \$2 per copy. Telephone orders can be placed to the Center on 301-468-5690. The Center also sells the complete conference edition in CD-ROM format (B0071) for \$5. This publication is available as well on the Internet at <http://www.health.gov/healthypeople/>. Internet viewers should proceed to "Publications."

PHS policy is that applicants for PHS clinical research grants should include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to research subjects of all ages. If women or minorities are