301–496–7005; fax 301–402–0527; e-mail: *LBall@osophs.dhhs.gov;* or Ms. Patricia M. Beers Block, Office for Good Clinical Practice, OSHC, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, HF–34, Rockville, MD 20857; telephone 301–827–3340; fax 301–827–1169; *e-mail: pbeersblock@oc.fda.gov.*

**SUPPLEMENTARY INFORMATION:** All studies conducted or supported by HHS which are not otherwise exempt and which propose to involve children as subjects require Institutional Review Board (IRB) review in accordance with the provisions of HHS regulations at 45 CFR part 46, subpart D. Under FDA's Interim Final Rule effective April 30, 2001 (21 CFR part 50, subpart D), FDA adopted similar regulations to provide safeguards for children enrolled in clinical investigations of FDA-regulated products.

Pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54, if an IRB reviewing a protocol conducted or supported by HHS for a clinical investigation regulated by FDA does not believe that the proposed research or clinical investigation involving children as subjects meets the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406, and FDA regulations at 21 CFR 50.51, 50.52, or 50.53, respectively, the research or clinical investigation may proceed only if the following conditions are met: (a) The IRB finds and documents that the research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children; and (b) the Secretary (HHS) and the Commissioner (FDA), respectively, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment determine either:

(1) That the research or the clinical investigation in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406 under HHS regulations, and 21 CFR 50.51, 50.52, or 50.53 under FDA regulations, or (2) that the following conditions are met: (i) The research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research or clinical investigation will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and 21 CFR 50.55.

HHS received a request from Harbor-UCLA Medical Center to review a protocol entitled ''A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax® Administered to Children 2 to 5 Years of Age'' pursuant to the provisions of HHS regulations at 45 CFR 46.407. The sponsor of this research, the National Institute of Allergy and Infectious Diseases (NIAID), NIH, proposes to study the safety and immune response to Dryvax® (vaccinia virus vaccine), when administered to children 2 to 5 years of age. This study proposes to evaluate Dryvax® at its full, licensed strength and at a 1:5 dilution, in children enrolled in a number of sites, including Harbor-UCLA Medical Center and Cincinnati Children's Hospital Medical Center. Use of Dryvax® in this protocol is being performed under an FDA IND primarily because there are no data to support the efficacy of the 1:5 dilution of this product in children. This protocol was developed by NIAID in the context of current HHS bioterrorism preparedness plans, given the potential risk of smallpox being used as a weapon of bioterrorism, and has been approved by two IRBs.

However, after reviewing this research proposal, the Harbor-UCLA Medical Center IRB determined that this study could not be approved under 45 CFR 46.404, 46.405, or 46.406 but was suitable for review under 45 CFR 46.407. Because this clinical investigation is regulated by FDA, FDA's regulations at 21 CFR part 50, subpart D, apply as well. The Harbor-UCLA Medical Center IRB was unable to assess the prospect of direct benefit to the participants but found that the research presented a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children. NIAID has not initiated this clinical trial pending the Secretary's and Commissioner's determination. Experts in relevant disciplines have reviewed this protocol (see discussion below regarding access to each expert's report), but prior to the Secretary and Commissioner making a final determination, public review and comment are hereby solicited pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54. In particular, comments are solicited on the following questions: (1) What are the potential benefits of the research, if any, to the subjects and to children in general; (2) what are the types and degrees of risk that this research presents to the subjects; (3) are the risks to the subjects reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?

All written comments concerning this matter should be submitted to FDA's Dockets Management Branch pursuant to 21 CFR 10.20. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets/dockets/02n0466/02n0466.htm* or may be seen in the Dockets Management Branch between the 9 a.m. and 4 p.m., Monday through Friday.

Materials available for review on the OHRP Web page (available at *http://ohrp.osophs.dhhs.gov/dpanel/dpindex.htm)* include: The NIH protocol, site-specific protocol application reviewed by the Harbor-UCLA Medical Center IRB, sample parental permission document, relevant package inserts, and reports of each of the experts pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54. A paper copy of the information referenced here is available upon request.

Dated: October 23, 2002.

**Lester M. Crawford,**

*Deputy Commissioner, FDA.*

Dated: October 24, 2002.

**Eve E. Slater,**

*Assistant Secretary for Health.*

[FR Doc. 02–27769 Filed 10–30–02; 8:45 am]

**BILLING CODE 4150–28–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0454]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

**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 the procedures used for submitting a generally recognized as safe (GRAS) notice stating that a particular use of a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on the collection of information by December 30, 2002.

**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.

**Notice of a Claim for GRAS Exemption Based on a GRAS Determination (OMB Control Number 0910–0342)—Extension**

*Description*: Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

*Description of Respondents*: Manufacturers of Substances Used in Food and Feed.

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 |
|---|---|---|---|---|---|
| 170.36 | 50 | 1 | 50 | 150 | 7,500 |
| 570.36 | 10 | 1 | 10 | 150 | 1,500 |
| Total | | | | | 9,000 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 170.36(c)(v) | 50 | 1 | 50 | 15 | 750 |
| 570.36(c)(v) | 10 | 1 | 10 | 15 | 150 |
| Total | | | | | 900 |

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

The reporting requirement is for a proposed rule (62 FR 18937, April 17, 1997) that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were

submitted under the terms of the proposed rule. FDA received 23 notices in 1999, 30 notices in 2000, and 28 notices in 2001. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: October 25, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–27741 Filed 10–30–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0208]**

### Agency Information Collection Activities; Announcement of OMBApproval; State Enforcement Notifications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration is announcingthat a collection of information entitled ''State EnforcementNotifications'' has been approved by the Office of Management andBudget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 9, 2002 (67 FR 51860),the agency announced that the proposed information collection had beensubmitted to OMB for review and clearance under 44 U.S.C. 3507. An agencymay not conduct or sponsor, and a person is not required to respond to, acollection of information unless it displays a currently valid OMB controlnumber. OMB has now approved the information collection and has assignedOMB control number 0910–0275. The approval expires on October 31,2005. A copy of the supporting statement for this information collectionis available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 25, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–27740 Filed 10–30–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

*Comments are invited 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) ways to enhance 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.

**Proposed Project: HRSA Grantee Telecommunications and Telehealth Inventory and Database—New**

The Health Resources and Services Administration's (HRSA) mission is to improve and expand access to quality health care for all. Through its grant program, HRSA provides funds to ensure the availability of quality health care to low income, uninsured, isolated, vulnerable and special needs populations.

Within HRSA, the Office for the Advancement of Telehealth (OAT) increases access to quality health care services for the underserved by promoting the use of advanced telecommunications and information technologies by health care providers across America. HRSA is a leading national supporter and developer of telehealth, which is the use of electronic information and telecommunications technologies for a wide variety of health-related activities. These include long-distance clinical care, patient and professional education, and health administration.

HRSA provides grant funding to over 8000 recipients to improve healthcare delivery in the United States. Those offices and programs increasingly depend on the emerging technologies and telecommunications systems to deliver healthcare, yet no data is available on grant recipients' access to or utilization of those technologies. The proposed inventory will serve as a model for collecting this type of information across a disparate group of projects nationally and if successful will be ultimately integrated into HRSA's overall data system.

All grantees will be asked to address access to telehealth technologies at their respective institutions. Telehealth activities include the practice of telemedicine, delivery of distance education, health informatics, healthcare staff supervision from remote sites, and the provision of consumer health information using telecommunications technologies. Additionally, grantees will be asked to provide information on their network members or satellite site. For those grantees practicing telemedicine, the survey will include a section on diagnostic tools and clinical capabilities.

The survey will be delivered via the world wide web; hard copy will be made available for those grantees with no Internet access. Substantive questions may be systematically included in the grantees' progress reporting.

Estimated burden hours:

| Type of survey | Number of respondents | Number of responses per respondent | Total Number of responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Web-based | 7,965 | 1 | 7,965 | .17 | 1,355 |
| Hard-copy | 885 | 1 | 885 | .20 | 177 |