Dated: March 8, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–5738 Filed 3–12–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[60 Day–04–33]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project—Community Guide Surveillance and Evaluation Survey—New—Epidemiology Program Office (EPO), Centers for Disease Control and Prevention (CDC).

The Community Guide Surveillance and Evaluation Survey will be used to collect information about the degree to which segments of the target audience for the Guide to Community Preventive Services (Community Guide) is aware of and using findings in public health planning decisions. Public health practitioners, including state and local health officials and faculty from schools of public health throughout the United States and its territories, will be invited to participate. The Community Guide is based on systematic reviews of published evidence of effectiveness of selected population based interventions across a range of health topics. The data from this survey will be used to assess familiarity with, understanding of use, and dissemination of findings from the Community Guide. The results of this study will be used by the independent Task Force on Community Preventive Services and staff supporting the Task Force from the Centers for Disease Control and Prevention to improve dissemination and use of Community Guide reviews and recommendations. The sample will include 9 people from each of the 56 states and territories, including Puerto Rico, Guam, U.S. Virgin Islands, and the Northern Mariana Islands, for a total sample size of 504 people. The total annual burden estimate is 101 hours. The survey will be administered annually, contingent on availability of funds, through a Web-based format.

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|
| Public Health Practitioners | 504 | 1 | 12/60 | 101 |
| Total | | | | 101 |

Dated: March 8, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–5739 Filed 3–12–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Program Announcement 04074]**

### Achieve and Sustain Measles, Rubella, and Congenital Rubella Syndrome (CRS) Elimination in the Americas Notice of Intent To Fund Single Eligibility Award

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to achieve and sustain measles, rubella, and congenital rubella syndrome (CRS) elimination in the Americas. The Catalog of Federal Domestic Assistance number for this program is 93.185.

#### B. Eligible Applicant

Assistance will be provided only to Pan American Health Organization (PAHO). PAHO is the most appropriate and qualified agency to conduct the activities under this cooperative agreement because:

1. PAHO has the lead responsibility among the United Nations organizations for implementing activities to achieve the Pan American Sanitary Conference resolution of 1994 calling for the regional elimination of measles, and the year 2003 resolution calling for the elimination of rubella and CRS by year 2010. PAHO is the only organization in the Americas with a regional mandate for the control and prevention of vaccine-preventable diseases (VPD).

2. The proposed program is strongly supportive of, and directly related to, the achievement of PAHO and CDC/National Immunization Program objectives for the control and prevention of VPDs with emphasis on CDC's objectives.

3. PAHO, in collaboration with the Governments of Brazil, Canada, Netherlands, Spain, USAID, March of Dimes, Sabin Institute, American Red Cross and CDC, are partners in an international effort to increase support and visibility for both the measles and rubella elimination initiatives.

#### C. Funding

Approximately $6,000,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before May 1, 2004, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

**D. Where To Obtain Additional Information**

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Leo F. Weakland, Project Officer, Global Immunization Division, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E–05, Atlanta, Georgia 30333, telephone: 404–639–8252, E-mail Address: *lfwo@cdc.gov.*

Dated: March 9, 2004.

**Sandra R. Manning,**

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

[FR Doc. 04–5740 Filed 3–12–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003P–0393]**

### Determination That DIAZEPAM Injection United States Pharmacopeia (5 Milligrams/Milliliter in a 1-Milliliter Container) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that DIAZEPAM Injection United States Pharmacopeia (USP) (5 milligrams/milliliter (mg/mL) in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DIAZEPAM Injection USP (5 mg/mL in a 1-mL container).

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness §314.162 (21 CFR 314.162).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is the subject of approved ANDA 72–079 held by Abbott Laboratories, Inc. (Abbott). DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. PharmaForce, Inc., submitted a citizen petition dated August 25, 2003 (Docket No. 2003P–0393/CP1), under 21 CFR 10.30, requesting that the agency determine whether DIAZEPAM Injection USP (5 mg/mL, 1 mL) was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DIAZEPAM Injection USP in a 5-mg strength (5 mg/mL in a 1–mL container) was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, DIAZEPAM Injection USP currently is being marketed in a 10-mg strength (5 mg/mL in a 2-mL container). Adverse drug events would be less likely with the discontinued lower dose than the currently marketed higher dose. In addition, by using only a portion of the amount currently marketed, the 5-mg strength in question still can be obtained. Second, the lower 5-mg strength of DIAZEPAM Injection USP would be considered an effective dosage form because it is still within the dosing range. The usual recommended dose for older children and adults ranges from 2 to 20 mg intramuscularly or intraveneously, depending on the indication and its severity.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DIAZEPAM Injection, USP (5 mg/mL in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DIAZEPAM Injection USP (5 mg/mL, 1 mL) may be approved by the agency.

Dated: March 8, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–5756 Filed 3–12–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003E–0419]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; IPRIVASK

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for IPRIVASK 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit