TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights Complaint Form	Individuals or households, Not-for-profit institutions.	3,493	1	45/60	2,620
Health Information Privacy Complaint Form.	Individuals or households, Not-for-profit institutions.	10,286	1	45/60	7,715
Total	.....	.....	.....	.....	10,335

Keith A. Tucker,

Information Collection Clearance Officer, Department of Health and Human Services.

[FR Doc. 2012–23776 Filed 9–26–12; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Supplemental Funding for Cooperative Agreements to the New Mexico Department of Health, Office of Border Health; Arizona Department of Health Services, Office of Border Health; California Department of Public Health, Office of Binational Border Health; Texas Department of State Health Services, Office of Border Health to Improve the Health of Persons and Communities Along the U.S.-Mexico Border

AGENCY: Office of Global Affairs, Office of the Secretary, DHHS.

Announcement Type: Cooperative Agreement—FY 2012 Supplemental Funding Announcement. Non-competitive.

Catalog of Federal Domestic Assistance: 93.018.

Projects Period: September 30, 2012—August 31, 2013.

SUMMARY: The Office of Global Affairs (OGA) announces that up to $150,000.00 ($37,500.00 to each State) in fiscal year (FY) 2012 funds are being awarded for supplemental funding to existing cooperative agreements to the Department of Health Services of the states of New Mexico, Arizona, Texas and California, whom will work through the U.S.–Mexico Border Health Commission, to improve the health of persons and communities along the U.S.-Mexico border. This initiative addresses Border Binational Health Week; Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border; U.S.-Mexico Border Tuberculosis Consortium and Legal Issues Forum; Border Binational Obesity Prevention Summit; Border Health Research Forum, Work Group and Expert Panel Meeting; Healthy Border 2010/2020 Strategic Plan; the Outreach Office Planning Meeting, and programmatic and administrative support to the members and staff of the U.S.-Mexico Border Health Commissions. The budget period will be one year with a project period of five years for a total of $150,000.00 (including indirect costs).

I. Funding Opportunity Description

Under the authority of 22 U.S.C. 290n, OGA announces the allocation of fiscal year (FY) 2012 funds as supplemental funding to already existing cooperative agreements to the New Mexico Department of Health, Office of Border Health; Arizona Department of Health Services, Office of Border Health; California Department of Public Health, Office of Binational Border Health; Texas Department of State Health Services, Office of Border Health to strengthen the binational public health projects and programs along the U.S.-Mexico border. Activities to be addressed through the cooperative agreement will relate to the following topic areas: (1) Border Binational Health Week; (2) Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border; (3) U.S.-Mexico Border Tuberculosis Consortium and Legal Issues Forum; (4) Border Binational Obesity Prevention Summit; (5) Border Health Research Forum, Work Group and Expert Panel Meeting; (6) Healthy Border 2010/2020 Strategic Plan; and (7) the Outreach Office Planning Meeting.

This assistance will support current, on-going and proposed public health initiatives in this border region, under ongoing, cooperative agreements already awarded to the border health offices in the States of California, Arizona, New Mexico, and Texas. that support the goals and objectives of the U.S.-Mexico Border Health Commission, serve to strengthen access to health care, disease prevention, and public health along the U.S.-Mexico border.

Background: The U.S.-Mexico Border Health Commission (USMBHC), in collaboration with the U.S. Department of Health and Human Services, works toward creating awareness about the U.S.-Mexico border, its people, and its environment. It educates others about the unique challenges at the border through outreach efforts, data collection and analysis, and joint collaborative efforts with public and private partners in the border health community. The USMBHC serves as a rallying point for shared concerns about the U.S.-Mexico border and as a catalyst for action to develop plans directed toward solving specific health related problems. Outreach offices of the USMBHC work with the border states to address public health concerns and needs affecting the border region. The Department of Health Services of the states of New Mexico, Arizona, Texas and California will work with their Mexican counterparts to promote and strengthen binational health initiatives along the U.S.-Mexico border.

Purpose: The overall objective of the five-year cooperative agreements with the Offices of Border Health in California, Arizona, New Mexico and Texas, initiated in 2011, is to support and coordinate the USMBHC's objectives and the development of the outreach health activities along the U.S. and Mexico border. The cooperative agreements focus on time-limited, product-oriented, and measurable outputs that may contribute to and help to inform the binational dialogue at local, state, and federal levels, regarding mutual challenges in border health, including tuberculosis; obesity/diabetes; infectious disease and public health emergencies; strategic planning; access to care; and research, data collection, and academic alliances.

Activities: Each state will use these supplemental funds in support of the goals of the Commission, to expand and enhance ongoing activities. Specifically:

- Arizona will expand participation in the Leaders Across Borders Program, which addresses major public health problems along the border through developing leadership skills and facilitating collaborative partnerships among U.S. and Mexico health officials.

• California will increase the number of participants attending the Border Health Research Forum and will host a stakeholders meeting in support of the Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border Initiative.

• Texas will increase the number of participants attending the Border Binational Obesity Prevention Summit, to share knowledge and best practices regarding a critical problem affecting border populations.

• New Mexico will plan, coordinate, and execute Phase IV of the Healthy Border 2010/2020 Strategic Plan, and will increase the number of regional activities of the Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border Initiative, to improve health outcomes of vulnerable populations living on the U.S.-Mexico Border.

II. Award Information

The administrative and funding instrument to be used for this program will be cooperative agreements in which substantial OGA/HHS scientific and/or programmatic involvement is anticipated during the performance of these projects. Under the cooperative agreements, OGA/HHS will support and/or stimulate awardees activities by working with them in a non-directive partnership role. Awardees will also be expected to work directly with and in support of the U.S.-Mexico Border Health Commission and its stated goals and initiatives as outlined in the submitted work plan.

Approximately $150,000.00 ($37,500.00 to each State) in fiscal year (FY) 2012 funds are available as supplemental funding to the already existing agreements. The anticipated start date is September 30, 2012 through August 31, 2013. There will only be four awards made from this announcement.

III. Justification for the Exception to Competition

The supplemental funding is for ongoing, cooperative agreements already awarded to the border health offices in the States of California, Arizona, New Mexico, and Texas. The purpose of the activities of the cooperative agreements is to accomplish the goals and objectives of the US-Mexico Border Health Commission. State border health offices have both extensive experience working with the Border Health Commission, and have existing relationships and ongoing initiatives with Mexican border states. This experience and relationships make the offices unique in helping the Commission carry out its binational health initiatives and activities along the border.

The supplemental funds are to provide additional support for several key activities of the cooperative agreements. Because the activities are ongoing, and being planned and carried out by the State border health offices, awarding the funds to the border health offices is the only practicable way to accomplish the objectives of enhancing and extending the activities.

IV. Agency Contacts

For programmatic requirements, please contact: Craig Shapiro MD, Office of Global Affairs, DHHS, Mary E. Switzer Building, 330 C Street, SW., Washington, DC 20201, Phone: (202) 260–0399.

For administrative requirements please contact: Alice Bettencourt, Director, Office of Grants Management, Office of the Assistant Secretary for Health, 1101 Wotton Parkway, Suite 550, Rockville, MD 20852, Telephone: (240) 453–8822.

Dated: September 20, 2012.

Jimmy Kolker,

Principal Deputy Director.

[FR Doc. 2012–23722 Filed 9–26–12; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0190]

Determination That ENDURON (methyclothiazide) Tablets and Six Other Drug Products Were 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 the seven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6206, Silver Spring, MD 20993–0002, 301–796–6925.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 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 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 (21 CFR 314.162).

Under 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

As requested by the applicants, FDA withdrew approval of NDA 012524 for Enduron (methyclothiazide) Tablets and NDA 017577 for Ditropan (oxybutynin chloride) Tablets in the **Federal Register** of March 19, 2012 (77 FR 16039). In addition, FDA has become aware that