

applicants 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. ANDA applicants 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 known generally as the "Orange Book." Under FDA regulations, drugs are removed 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, is the subject of ANDA 89-420, held by Schwarz Pharma, Inc., and initially approved on January 25, 1988. AZDONE is indicated for the relief of moderate to moderately severe pain. AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 23, 2010 (Docket No. FDA-2010-P-0338), under 21 CFR 10.30, requesting that the Agency determine whether AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg was not withdrawn for reasons of safety or effectiveness. The petitioner has

identified no data or other information suggesting that AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, 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 AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 29, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-24902 Filed 10-4-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0497]

#### Global Implementation of the Veterinary Medicinal Products Guidelines

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for a cooperative agreement to the World Organization for Animal Health (OIE). The OIE is the intergovernmental organization responsible for improving animal health worldwide and is recognized by the World Trade Organization (WTO) as a reference for international sanitary

rules, with 175 Member Countries and Territories. The purpose of this agreement is to continue outreach that began in fiscal year (FY) 2009 to expand capacity building to support OIE's services and activities that are needed to carry out OIE's Veterinary International Conference on Harmonization (VICH) Global Outreach to disseminate and implement VICH guidelines at the country level.

#### FOR FURTHER INFORMATION CONTACT:

*Program Contact:* Merton V. Smith, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., rm. 177, Rockville, MD 20855, 240-276-9025, FAX: 240-276-9030, email: [Merton.Smith@fda.hhs.gov](mailto:Merton.Smith@fda.hhs.gov).

*Management Contact:* Katherine C. Bond, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 32, rm. 3300, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8318, FAX: 301-595-5058, email:

[Katherine.Bond@fda.hhs.gov](mailto:Katherine.Bond@fda.hhs.gov).

*Grants Contact:* Kimberly Pendleton, Division of Acquisition and Grants (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2104, Rockville, MD 20857, 301-827-9363, FAX: 301-827-7101, email:

[kimberly.pendleton@fda.hhs.gov](mailto:kimberly.pendleton@fda.hhs.gov).

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please contact Kimberly Pendleton.

#### SUPPLEMENTARY INFORMATION:

##### I. Funding Opportunity Description

RFA-FD-10-010

Catalog of Federal Domestic Assistance Number(s): 93.103 <https://www.cfda.gov>

##### A. Background

FDA announces its intention to accept and consider a single source application for award of a cooperative agreement to the OIE in support of international technical capacity building activities that help to assure that U.S. imports of veterinary medicinal products are safe, effective, and of high quality and that food from treated animals is safe and wholesome; to assist foreign regulators in developing and using rigorous safety standards; to develop and foster mutually beneficial regulatory partnerships; and to leverage resources for capacity building through appropriate training and other activities.

##### B. Research Objectives

- Promote and enhance in OIE Members good veterinary governance, which includes the compliance of Veterinary Services with OIE

international standards, as an instrumental and essential prerequisite to the establishment and effective implementation of adequate and appropriate legislation covering all aspects of products for veterinary use, including registration, quality control, distribution, monitoring of quantities and final use.

- Develop and improve international and regional cooperation in the establishment and enforcement of legislation to harmonize the regulatory framework between OIE Member States so as to assist countries in need to effectively institute and maintain such mechanisms.

- Encourage countries to allocate appropriate human and financial resources to veterinary services and laboratories to correctly implement the OIE standards and guidelines related to veterinary products and their control.

- Enhance capacities of national focal points for OIE on matters related to veterinary products according to the suggested terms of reference and encourage his/her participation in training sessions and appropriate international gatherings and meetings.

- Promote the responsible and prudent use of veterinary medicinal products, in particular of antimicrobials used in veterinary medicine, and the monitoring of the quantities used and potential existence or development of antimicrobial resistance in disease-causing organisms affecting both humans and animals.

- Actively encourage the recognition and application of the international recommendations, guidelines and tools developed by the OIE and adopted by the World Assembly of Delegates on veterinary products.

### C. Eligibility Information

The following organizations/institutions are eligible to apply: The OIE.

## II. Award Information/Funds Available

### A. Award Amount

FDA anticipates providing one award of \$565,000 (total costs including indirect costs) in fiscal year (FY) 2010 in support of this project. Subject to the availability of funds and successful performance, 1 additional year of support up to \$565,000 per year will be available.

### B. Length of Support

The support will be 1 year with the possibility of an additional year of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the

preceding year, receipt of a non-competing continuation application and available Federal FY appropriations.

Dated: September 29, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-24905 Filed 10-4-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2010 Performance Review Board (PRB)

The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2010 Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board, which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members:

Ms. Colleen Barros (Chair), Dr. Michael Gottesman, Ms. Lenora Johnson, Ms. Robin Kawazoe, Dr. Sally Rockey, Dr. Lawrence Tabak, Dr. Samir Zakhari.

For further information about the NIH Performance Review Board, contact the Office of Human Resources, Workforce Relations Division, National Institutes of Health, Building 31, Room B3C07, Bethesda, Maryland 20892, telephone 301-402-9203 (not a toll-free number).

Dated: September 27, 2010.

**Francis S. Collins,**

*Director, National Institutes of Health.*

[FR Doc. 2010-24929 Filed 10-4-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

*Correction:* This notice was published in the **Federal Register** on September 1, 2010, Volume 75, Number 169, page 53703. A quorum of the subcommittee's membership was not able to participate; therefore, the meeting was adjourned. The subcommittee will reconvene as follows:

Time and Date: 2 p.m.–3 p.m., October 21, 2010.

Place: Teleconference.

Status: Open to the public.

Teleconference access limited only by the availability of telephone ports. The public is welcome to participate during the public comment period, which is tentatively scheduled from 2:45 p.m. to 2:50 p.m. To participate in the teleconference please dial (877) 394-7734 and enter conference code 9363147.

Purpose: The Subcommittee will provide recommendations for consideration to the ACD on strategic and other broad issues facing CDC.

Matters To Be Discussed: Policy brief on health equity and social determinants of health; update on collaboration with the CDC Health Equity Workgroup; CDC Director's Annual Health Disparity Report; and briefing on the realignment of the CDC Office of Minority Health and Health Disparities. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Walter W. Williams, M.D., M.P.H., Designated Federal Officer, HDS, ACD, CDC, 1600 Clifton Road, NE., M/S E-67, Atlanta, Georgia 30333. Telephone (404) 498-2310, E-mail: <http://www1@cdc.gov>.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 29, 2010.

**Elaine L. Baker,**

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

[FR Doc. 2010-24911 Filed 10-4-10; 8:45 am]

**BILLING CODE 4163-18-P**