Supplementary Information: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L’Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise on veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based, harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

The draft guideline “Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms” (VICH Topic GL30) has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to provide guidance for the development and maintenance of the controlled lists of terms required to complete the controlled data fields contained in adverse event reports concerning the use of marketed veterinary medicinal products. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to development and maintenance of the controlled lists of terms—we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency’s comments to the VICH Steering Committee. The draft guideline reflects current APHIS thinking on the development and maintenance of the controlled lists of terms required to complete the controlled data fields used for the submission and exchange of spontaneous adverse events reports between marketing authorization holders (licensees/permittees) and regulatory authorities concerning the clinical effects of marketed veterinary medicinal products. In accordance with the VICH process, once a final draft of each document has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, each final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy applicable regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee’s final guideline for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, we may consider using the final guideline as the basis for proposed amendments to the regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final versions of “Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms” may be introduced into APHIS’ veterinary biologics regulatory program in the future, we encourage your comments on the draft guideline. The draft guideline may be viewed on the Regulations.gov Web site or in our reading room (see ADDRESSES above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the draft guideline by calling or writing to the person listed under FOR FURTHER INFORMATION CONTACT.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

Crop Insurance Education in Targeted States (Targeted States Program)

Announcement Type: Modification—Competitive Cooperative Agreements.

This announcement modifies the Request for Application Notice published in the Federal Register, March 14, 2007 (Vol. 72, No. 49, Pages 11839–11846). The Dates and Summary portions have been modified.

CFDA Number: 10.458.

DATES: Applications are due 5 p.m. EDT, June 4, 2007.

SUMMARY: The following paragraph has been added to the beginning of the...
ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Meeting

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has scheduled its regular business meetings to take place in Washington, DC., Wednesday through Friday, May 30–June 1, 2007, at the times and location noted below.

DATES: The schedule of events is as follows:

Wednesday, May 30, 2007
10:30 a.m.—Noon—Electronic and Information Technology Ad Hoc Committee.

1:30 p.m.—3:30 p.m.—Briefing on Outdoor Developed Areas Proposed Rule (Closed Session).

3:30 p.m.—5 p.m.—Passenger Vessels Guidelines Ad Hoc Committee (Closed Session).

Thursday, May 31, 2007
9 a.m.—10:30 a.m.—Standard Taxi Demonstration.

10:30 a.m.—Noon—Briefing on Public Rights-of-Way Rulemaking (Closed Session).

1:30 p.m.—5 p.m.—Transportation Vehicle Guidelines Ad Hoc Committee (Closed Session).

Friday, June 1, 2007
9 a.m.—10:30 a.m.—Planning and Evaluation Committee.

10:30 a.m.—Noon—Executive Committee.

1:30 p.m.—3 p.m.—Board Meeting.

ADDRESS: All meetings will be held at The Madison Hotel, 1177 15th Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For further information regarding the meetings, please contact Lawrence W. Roffee, Executive Director, (202) 272-0001 (voice) and (202) 272-0082 (TTY).

SUPPLEMENTARY INFORMATION: At the Board meeting, the Access Board will consider the following agenda items:

- Approval of the March 2007 draft Board Meeting Minutes.
- Planning and Evaluation Committee Report.
- Executive Committee Report.
- Electronic and Information Technology Ad Hoc Committee Report.
- Passenger Vessels Guidelines Ad Hoc Committee Report.
- Transportation Vehicle Guidelines Ad Hoc Committee Report.

All meetings are accessible to persons with disabilities. An assistive listening system, computer assisted real-time transcription (CART), and sign language interpreters will be available at the Board meetings. Persons attending Board meetings are requested to refrain from using perfume, cologne, and other fragrances for the comfort of other participants.

Lawrence Roffee,
Executive Director.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletion from the procurement list.

SUMMARY: The Committee is proposing to add to the Procurement List a product and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a service previously furnished by such agencies.

Comments Must Be Received On or Before: June 17, 2007.


For Further Information Or To Submit Comments Contact: Kimberly M. Zeich, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail CMTEFedReg@jwod.gov.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O’Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the