Done in Washington, DC, this 28th day of January 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–2383 Filed 2–2–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 99–068–1]

Draft Guideline on Stability Testing of Biotechnological/Biological Veterinary Medicinal Products, VICH Topic GL17

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: A draft guideline titled ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guideline contains proposed international standards for the generation and submission of stability data for products such as cytokines (interferons, interleukins, colony-stimulating factors, tumor necrosis factors), monoclonal antibodies, and vaccines consisting of well-characterized proteins or polypeptides, including some conventional vaccines. Because the draft guidelines pertain to veterinary biological products regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, 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.

DATES: We invite you to comment on the draft guidelines. We will consider all comments that we receive by April 3, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 99–068–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 99–068–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

You may request a copy of the draft ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' by writing to or calling the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, CVB-LPD, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245.

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 International Office of Epizootics (OIE, the Office International des Epizooties) 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 regarding 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 document that is the subject of this notice, ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' (VICH Topic GL17), has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to function as an international standard for the generation and submission of stability data for products such as cytokines (interferons, interleukins, colony-stimulating factors, and tumor necrosis factors), monoclonal antibodies, and vaccines consisting of well-characterized proteins or polypeptides. Because the guideline pertains to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to prelicensing stability studies—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 document pertains to the generation and submission of studies testing the stability of veterinary biological products that consist of well-characterized proteins and polypeptides, their derivatives, and products of which they are components. (The draft guideline refers to such studies as ''stability studies.'') In accordance with the VICH process, once a final draft of ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' 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, the 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 guidance document for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS will consider its use as a basis for the approval of stability studies conducted to establish and extend expiration dates for applicable veterinary biological products under 9 CFR 114.13 and 114.14. APHIS may also use the final guidance document as the basis for proposed additions or amendments to its 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 version of ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft version.

Authority: 21 U.S.C. 151 *et seq.*

Done in Washington, DC, this 28th day of January 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–2379 Filed 2–2–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Farm Service Agency

National Drought Policy Commission

AGENCY: Farm Service Agency, USDA.

ACTION: Notice of Commission public hearing.

SUMMARY: The National Drought Policy Commission (Commission) shall conduct a thorough study and submit a report to the President and Congress on national drought policy. This notice announces a public hearing to be held on February 17–18, 2000, in Billings, Montana, and seeks comments on issues that the Commission should address and recommendations that the Commission should consider as part of its report. The hearing is open to the public.

DATES: The Commission will conduct a public hearing on February 17, 2000, from 1:00 p.m. to 5:00 p.m. and February 18, 2000, from 9:00 a.m. to 12:00 p.m. at the Lincoln Center, Auditorium, 415 N 30th Street, Billings, Montana. All times are Mountain Standard Time.

Anyone wishing to make an oral presentation to the Commission at the public hearing, must contact the Executive Director, Leona Dittus, in writing (by letter, fax or internet) no later than COB, February 11, 2000, in order to be included on the agenda. Presenters will be approved on a first-come, first-served basis. The request should identify the name and affiliation of the individual who will make the presentation and an outline of the issues to be addressed. Thirty-five copies of any written presentation material shall be given to the Executive Director by all presenters no later than the time of the presentation for distribution to the Commission and the interested public. Those wishing to testify, but who are unable to notify the Commission office by February 11, 2000, will be able to sign up as a presenter the day of the hearing, February 17, 2000, between 12:00 p.m. and 2:00 p.m. and February 18, 2000, between 8:00 a.m. and 10:00 a.m. All times are Mountain Standard Time. These presenters will testify on a first-come, first-served basis and comments will be limited based on the time available and the number of presenters. Written statements will be accepted at the public hearing, or may be mailed or faxed to the Commission office.

Persons with disabilities who require accommodations to attend or participate in this public hearing should contact Leona Dittus, on 202–720–3168, Federal Relay Service at 1–800–877–8339, or Internet: leona.dittus@usda.gov, by COB February 11, 2000.

COMMENTS: The public is invited to respond and/or to submit additional comments, concerns, and issues for consideration by the Commission by March 29, 2000.

ADDRESSES: Comments and statements should be sent to Leona Dittus, Executive Director, National Drought Policy Commission, U.S. Department of Agriculture, 1400 Independence Avenue, SW, Room 6701–S, STOP 0501, Washington, D.C. 20250–0501.

FOR FURTHER INFORMATION CONTACT: Leona Dittus (202) 720–3168; FAX (202) 720–9688; Internet: leona.dittus@usda.gov.

SUPPLEMENTARY INFORMATION: The purpose of the Commission is to provide advice and recommendations to the President and Congress on the creation of an integrated, coordinated Federal policy, designed to prepare for and respond to serious drought emergencies. Tasks for the Commission include developing recommendations that will (a) better integrate Federal laws and programs with ongoing State, local, and tribal programs, (b) improve public awareness of the need for drought mitigation, prevention, and response and (c) determine whether all Federal drought preparation and response programs should be consolidated under one existing Federal agency, and, if so, identify the agency.

Below is a draft vision statement and set of principles to guide the Commission. Draft Vision Statement: Our vision is of a well-informed, involved U. S. citizenry and its governments prepared for and capable of lessening the impacts of drought—consistently and timely—in the new millennium.

This vision is based on the following principles:

Consideration of all affected entities and related issues, including legal, economic, geographic, climate, religious, and cultural differences; fairness and equity; and environmental concerns;

Comprehensive, long-term strategies that emphasize drought planning and measures to reduce the impacts of drought;

Federal role focused on appropriate coordination, technical assistance, education, and incentives while at all times respecting the rights and responsibilities of

Federal, State, and local governments, and tribal sovereignty;

Self-reliance and self-determination;

Lessons learned from past drought experiences;

Shared drought-related expertise and knowledge across international borders.

In addition to your own views and thoughts regarding a national drought policy, as you review the draft vision and guiding principles, the Commission would be interested in your thoughts regarding the following questions:

1. What is the best means for informing the public of Federal assistance for drought planning and mitigation?

2. What type of information do you need for responding to the drought?

3. What needs do you or your organization presently have with respect to addressing drought conditions?

4. What do you see as the Federal role with respect to drought preparedness? Drought response? Should Federal emergency assistance be contingent on advance preparedness?

5. Are there any ways you feel that the Federal Government could better coordinate with State, regional, tribal, and local governments in mitigating or responding to droughts?

6. What lessons have you or your organization learned from past drought experiences that would be beneficial in the creation of a national drought policy?

Signed at Washington, D.C., on January 31, 2000.

George Arredondo,

Acting Administrator, Farm Service Agency.

[FR Doc. 00–2445 Filed 1–1–00; 5:03 pm]

BILLING CODE 3410–05–P