Proposed Rules

Federal Register
Vol. 60, No. 137
Tuesday, July 18, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 113

[Docket No. 94–051–2]

RIN 0579–AA66

Viruses, Serums, Toxins, and Analogous Products; In Vitro Potency Testing for Serial Release

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; extension of comment period and notice of public hearing.

SUMMARY: We are extending by 30 days the comment period for our proposed rule that would amend the regulations regarding the use of in vitro potency testing for serial release. The regulations pertaining to in vitro testing for serial release would require that such immunoassays be parallel line assays based upon unexpired reference preparations and would specify procedures and requirements for qualifying reference preparations for inactivated products. This extension will provide interested persons with additional time to prepare comments on the proposed rule.

We are also advising the producers of veterinary biologics and other interested persons that the Animal and Plant Health Inspection Service will be holding a public hearing in Ames, IA, at our Veterinary Biologics Public Meeting to discuss issues related to in vitro potency testing.

DATES: Consideration will be given only to comments received on or before September 14, 1995. We will also consider comments made at a public hearing to be held in Ames, IA, on Tuesday, August 1, 1995, from 3:00 p.m. to 5:00 p.m.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 94–051–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 94–051–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room. The public hearing will be held at the Scheman Building, Iowa State Center, Ames, IA, on Tuesday, August 1, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, telephone (301) 734–8245, fax (301) 734–8669.

SUPPLEMENTARY INFORMATION: On May 17, 1995, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (60 FR 26381–26384, Docket No. 94–051–1) a proposed rule to amend the regulations regarding the use of in vitro tests for serial release. The proposed rule would, among other things, prescribe requirements for in vitro immunoassays used to determine the relative antigen content of inactivated biological products; require that such immunoassays be parallel line assays based upon unexpired reference preparations; and specify procedures and requirements for qualifying or requalifying reference preparations for inactivated products. Comments on the proposed rule were required to be received on or before August 15, 1995.

So that we may consider comments received after that date, we are extending the public comment period on Docket No. 94–051–1 until September 14, 1995. During this period, interested persons may submit their comments for our consideration.

APHIS is also conducting a public hearing to discuss in vitro potency testing on August 1, 1995, at the Scheman Building, Iowa State Center, Ames, IA. The public hearing is scheduled as part of the public meeting on veterinary biologics that is being held at the Scheman Building on August 1 and 2, 1995, in Ames, IA. The agenda for the public hearing will be limited to issues related to in vitro potency testing. The purpose of the hearing is to have further discussion of this topic by interested persons. We may also hold a second hearing on August 15, 1995, from 8:30 a.m. to 11 a.m. at the Holiday Inn Gateway Center, Ames, IA, in the event that additional time is needed for further discussion of the topic. We shall announce at the conclusion of the first hearing whether the second hearing shall be held. We will publish a notice in the **Federal Register** if we decide to hold the hearing on August 15, 1995. Interested persons may also call the person listed under **FOR FURTHER INFORMATION CONTACT** after August 1, 1995, to find out whether the second hearing will be held.

Persons wishing either to attend or participate in the public hearing are requested to notify the person listed under **FOR FURTHER INFORMATION CONTACT** at least two business days before the public hearing. Please indicate whether you wish to make a prepared statement at the public hearing, the subject of your remarks, and the approximate amount of time you would like to speak. APHIS welcomes and encourages the presentation of comments at the public hearing.

A representative of APHIS will preside at the public hearing. Any interested person may appear and be heard in person, by attorney, or by other representative. Persons who wish to speak at the public hearing will be asked to sign in with their name and organization, to establish a record for the hearing.

The public hearing is scheduled for the times specified under ''**DATES**.'' The hearing, however, may be terminated at any time after it begins if all persons desiring to speak have been heard. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

The purpose of the hearing is to give interested persons an opportunity for oral presentation of data, views, and arguments. Questions about the content of the proposed rule may be part of the commenters' oral presentations. Neither the presiding officer nor any other representative of APHIS, however, will respond to comments at the hearing,