

# proposed rules

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.

[ 3410-34 ]

## DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[ 9 CFR Parts 1, 3 ]

### HUMANE HANDLING, CARE, TREATMENT, AND TRANSPORTATION OF MARINE MAMMALS; PROPOSED REGULATIONS AND STANDARDS

Informal Public Hearing on Proposed Rules

AGENCY: Animal and Plant Health Inspection Service (APHIS), USDA.

ACTION: Notice of informal public hearing.

**SUMMARY:** On August 19, 1977, the Deputy Administrator, Veterinary Services, APHIS, published in the FEDERAL REGISTER proposed rulemaking under the authorities of the Animal Welfare Act (7 U.S.C. 2131) to provide for the humane handling, care, treatment, and transportation of marine mammals maintained in captivity. The notice gave all interested persons a period of 60 days for the filing of written comments concerning the proposed regulations and standards. On September 13, 1977, a notice concerning public hearings to be held in Los Angeles, Calif., and Miami Springs, Fla., on September 26 and 29, 1977, respectively, was published in the FEDERAL REGISTER to further allow interested persons an opportunity to participate in this rulemaking proceeding. This document announces another informal public hearing to be held in College Park, Md., to give interested persons a further opportunity to participate in this rulemaking proceeding through the submission of written comments with an opportunity for oral presentation.

**DATE:** The hearing will be held on Tuesday, October 18, 1977, at College Park, Md., between the hours of 10 a.m. and 4 p.m.

**ADDRESS:** The informal public hearing will be held at the Terrapin Room, Quality Inn Motel, 7200 Baltimore Avenue, College Park, Md. 20740, telephone number (301-864-5820).

**FOR FURTHER INFORMATION CONTACT:**

Dale F. Schwindaman, Senior Staff Veterinarian, Animal Care Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 703, Federal Building, 6505 Belcrest Road, Hyattsville, Md. 20782, telephone number 301-436-8271.

**SUPPLEMENTARY INFORMATION:** The allegation has been made that the marine mammal hearings to be held in

Los Angeles, Calif., and Miami Springs, Fla., by the Department will allow for presentations by the regulated industry, but will not allow for presentations of opposing views by other interested parties based in and around the Washington, D.C., area. In order to provide for such public participation, an informal public hearing is scheduled to be held in the Washington, D.C., area so that interested parties in such area may present their views concerning the proposed regulations and standards covering marine mammals.

A Veterinary Services representative will serve as chairman at the informal public hearing. The procedure to be followed will be informal and without a structured agenda. Individual presentations will not be scheduled in advance. A written copy of a speaker's comments must be given to the chairman prior to the speaker's oral presentation, but is not required to be read into the record. Individuals making presentations may verbally summarize or emphasize certain points of their written comments. Opportunity will be provided for the chairman or other persons at the hearing to ask questions relating to each presentation made. The time for oral presentations and questions may be limited at the discretion of the chairman in order to give all persons at the hearing an opportunity to be heard. Transcripts of the oral hearing will be made, and copies of the transcripts and any written comments submitted at the hearing, will be made a part of the record in this rulemaking proceeding and will be available for public inspection together with all other comments received in this proceeding in accordance with the notice dated August 19, 1977.

Done at Washington, D.C. this 28th day of September 1977.

**NOTE.**—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 and OMB Circular A-107.

NORVAN L. MEYER,  
Acting Deputy Administrator,  
Veterinary Services.

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[ 3410-34 ]

[ 9 CFR Part 114 ]

### VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS

Miscellaneous Amendments; Proposed Rulemaking

AGENCY: Animal and Plant Health Inspection Service (APHIS).

ACTION: Proposed rule.

**SUMMARY:** This proposed amendment clarifies and simplifies the requirements for extending the expiration date for a biological product. A "U.S. Standard of Potency" for each fraction of a product is presently required before an extension of expiration date is granted, although the meaning of that term is unclear. The present regulations also require that the extended expiration date must be computed from the harvest date. This proposed amendment would delete the necessity of establishing a "U.S. Standard of Potency", would provide for different potency evaluation tests, and would delete the "from harvest" requirement.

**DATES:** Comments must be received on or before October 31, 1977.

**ADDRESS:** Interested persons are invited to submit written data, views, or arguments regarding the proposed regulations to: Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 828-A, Federal Building, Hyattsville, Md. 20782.

**FOR FURTHER INFORMATION CONTACT:**

Dr. R. J. Price, 301-436-8245.

**SUPPLEMENTARY INFORMATION:** The present regulations prescribe conditions for permitting an extension of dating for a biological product. One of the conditions is that "U.S. Standard of Potency" be available for all fractions of the product (see § 114.14(a) of the regulations), and another condition is that the new date be determined "from harvest" (see § 114.14(b) of the regulations).

"U.S. Standard of Potency" is an undefined and unclear term. Some potency tests are part of the Standard Requirements. Others are written into the field Outline of Production and are accepted by Veterinary Services. Misunderstandings as to meaning of the term "U.S. Standard of Potency" have resulted. This proposed amendment of the regulations removes the necessity of having a "U.S. Standard of Potency" for all fractions of a product before an extension of expiration date may be granted for such product, and requires instead, that in order to be granted such extension, a product must be evaluated for potency by tests approved by the Deputy Administrator which are filed in an Outline of Production for such product.

The harvest date is used as the point in time from which expiration dates are computed for certain biological products. As a result, the harvest date was made the point in time from which an extension would be granted for all biological products. Adjustments have been made