§ 77.1 [Amended]

2. In § 77.1, in the definition for ''Modified accredited state'', paragraph (2) is amended by removing ''Oklahoma,''.

3. In § 77.1, in the definition for ''Accredited-free state'', paragraph (2) is amended by adding ''Oklahoma,'' immediately before ''Oregon,''.

Done in Washington, DC, this 16th day of December 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–32724 Filed 12–24–96; 8:45 am]

BILLING CODE 3410–34–P

9 CFR Part 113

[Docket No. 93–128–2]

Viruses, Serums, Toxins, and Analogous Products; Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the standard requirement for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying requirements for killed Venezuelan equine encephalomyelitis vaccines and revising the standard potency test for Eastern and Western equine encephalomyelitis vaccines. The amendments require the use of Vero 76 cells in the test to evaluate the potency of Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, and establish minimum antibody titers which must be elicited by each of the indicated fractions, as determined by a plaque reduction, serum neutralization assay in which Vero 76 cells are used.

EFFECTIVE DATE: January 27, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Director, Licensing and Policy Development, Center for Veterinary Biologics, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR part 113, standard requirements are prescribed for the preparation of veterinary biological products. A standard requirement consists of specifications, procedures, and test methods that define the standards of purity, safety, potency, and efficacy for a veterinary biological product. Where a standard requirement for a product has not been established, production procedures and specifications for purity, safety, and potency of a biological product are provided in an Outline of Production filed with the Animal and Plant Health Inspection Service (APHIS).

On November 27, 1995, we published in the Federal Register (60 FR 58255–58256, Docket No. 93–128–1) a proposed rule to amend the regulations in § 113.207 by providing requirements for killed Venezuelan equine encephalomyelitis vaccines and amending the potency test provisions for killed Eastern and Western equine encephalomyelitis vaccines. The proposed amendments required the use of Vero 76 cells in the test to evaluate the potency of Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus and establish minimum antibody titers which must be elicited by each of the indicated fractions, as determined by a plaque reduction, serum neutralization assay in which Vero 76 cells are used.

We solicited comments concerning our proposal for 60 days ending January 26, 1996. We received two comments by that date from a manufacturer of veterinary biological products and a veterinary biologics industry consultant. They are discussed below.

One commenter expressed support for the rule provided adequate data are available to justify the proposed revisions. Adequate data are available to support the revisions. Antibody titers in guinea pigs, as measured by duck embryo fibroblasts, were correlated with protection in horses. Antibody titers in guinea pigs measured by Vero 76 cells were, in turn, correlated with those measured by duck embryo fibroblasts. Therefore, the Agency believes that there is justification for the proposed revisions. No changes to the regulations are made in response to this comment.

The other commenter, who claimed to have considerable experience with the plaque reduction, serum neutralization assay in which Vero cells are used, stated that ''less than 1:10'' rather than ''less than 1:4'' should be set as the acceptable titer for control guinea pigs in the tests for the Eastern and Western type fractions because nonspecific titers up to 1:10 are commonly encountered. In response to the commenter, the Agency notes that the correlative studies to support the rule were conducted with guinea pigs with prevaccination titers of less than 1:4. APHIS believes that extrapolation of the results of the studies to a situation where the sera of test animals prior to vaccination are negative at a 1:10 dilution but positive at a 1:4 dilution is inappropriate. No change to the regulations is made in response to this comment.

The second commenter also requested that, in proposed § 113.207(b)(4), ''three or four vaccinate serum samples'' instead of ''two or three vaccinate serum samples'' be specified to ''be consistent with the initial tests being satisfactory if 80 percent of the vaccinates show protective titers.'' In response to the commenter, APHIS notes that the proposed ''two or three vaccinate serum samples'' does not differ from the requirement specified under the current regulations. Moreover, paragraph (b)(6) of § 113.207 of the current regulations not proposed for amendment specifies that four or more failures is a basis for an unsatisfactory test, and that for a given fraction, at least 9 of the 10 vaccinated guinea pigs, or 90 percent, must have an acceptable titer for a satisfactory first-stage test. Therefore, ''three or four vaccinate serum samples'' and ''80 percent of the vaccinates show[ing] protective titers'' would be inconsistent with current regulations. No change to the regulations is made in response to this comment.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposed rule as a final rule without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule revises the standard requirement in § 113.207 for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying a different cell type for use in the potency test assay and specifying different minimum specific antibody titers that must be achieved for a satisfactory test. In addition, the rule revises the standard requirement so that it would also apply to Encephalomyelitis Vaccine, Venezuelan, Killed Virus. The Agency believes the titers given in the standard requirement are adequately correlated with claimed efficacy and that they would be readily obtained by all relevant vaccines currently licensed. We do not expect any increase in cost to the biologics manufacturers affected by this rule. The changes should actually decrease costs for most impacted manufacturers, since fewer repeat tests will be needed and obtaining Vero 76 cells should prove less expensive than procuring primary DEF.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures that must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 is amended as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 113.207, the section heading, the introductory text, the introductory text of paragraph (b), and paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) are revised to read as follows:

§ 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in § 113.200, except those in § 113.200(d). Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

* * * * *

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency in accordance with the two-stage test provided in this paragraph. For each fraction contained in the product—Eastern type, Western type, or Venezuelan type—the serological interpretations required in this test shall be made independently. A serial or subserial found unsatisfactory for any of the fractions shall not be released.

(1) * * *

(2) Fourteen to 21 days after the second injection, serum samples from each vaccinate and each control shall be tested by a plaque reduction, serum neutralization test using Vero 76 cells.

(3) If the control serum samples show a titer of 1:4 or greater for any fraction, the test is inconclusive for that fraction and may be repeated: *Provided,* That, if four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory without further testing.

(4) If two or three of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the second stage of the test may be used for the relevant fraction(s): *Provided,* That, if a fraction is found acceptable by the first stage of the test, the second stage need not be conducted for that fraction.

(5) If the second stage is used and four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction or the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory.

* * * * *

Done in Washington, DC, this 16th day of December 1996.

A. Strating.

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–32725 Filed 12–24–96; 8:45 am]

BILLING CODE 4310–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 206

[Docket No. FR–2958–C–06]

RIN 2502–AF32

Home Equity Conversion Mortgage Insurance Demonstration: Additional Streamlining; Correction and Delay of Effective Date for the Definition of ''Principal Limit'' in § 206.3

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule correction and delay of effective date.

SUMMARY: On September 17, 1996 (61 FR 49030), the Department issued a final rule to changes proposed on May 10, 1996, to the Home Equity Conversion Mortgage (HECM) Insurance Demonstration. The final rule had an effective date of October 17, 1996, except that the amendment to the definition of ''principal limit'' in § 206.3, had a delayed effective date of January 5, 1997. This document further delays the effective date of the definition of ''principal limit'' in § 206.3 until May 1, 1997. In addition, § 206.121(c) is corrected to remove language that should have been omitted which allowed HUD to change a monthly adjustable ARM to annual interest rate adjustments if assigned to HUD.

DATES: Effective date of this document: October 17, 1996.

Effective date for amended definition of ''principal limit'' in § 206.3 is delayed until May 1, 1997.

FOR FURTHER INFORMATION CONTACT: Richard K. Manuel, Director, Home Mortgage Insurance Division, Office of Insured Single Family Housing, Room number 9272, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2700; TTY (202) 708–4594. (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION: The September 17, 1996 final rule delayed the effective date for the amendment to the definition of ''principal limit'' in § 206.3, until January 5, 1997. The Department recognized at that time that the Lockheed/Martin (CDSI) system would have to be changed to accommodate the new calculation. The Department now realizes that the change will not be completed by the January 5, 1997 effective date and by this notice delays further the effective date.