etc. Finally, this rule will ensure that employers have sufficient time to seek a new beneficiary or beneficiaries in the event a petition is denied.

Executive Order 13132

This rule will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988 Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, Public Law 104–13, all Departments are required to submit to the Office of Management and Budget (OMB), for review and approval, any reporting requirements inherent in a rule. This rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects in 8 CFR Part 214

Administrative practice and procedures, Aliens, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

Accordingly, part 214 of chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 214—NONIMMIGRANT CLASSES

1. The authority citation for part 214 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305 and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note, and 1931 note, respectively, 8 CFR part 2.

2. Section 214.2 is amended by:

a. Revising the second sentence in paragraph (o)(2)(i) and adding a new sentence immediately thereafter; and by

b. Revising the tenth sentence in paragraph (p)(2)(i) and adding a new sentence immediately after.

The revisions read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(o) * * *

(2) * * *

(i) *General.* * * * The petition may be filed up to one year, but not earlier than 6 months, before the actual need for the alien's services. Exceptions may be granted in emergency situations at the discretion of the USCIS Service Center Director, and in special filing situations as determined by USCIS Headquarters. * * *

* * * * *

(p) * * *

(2) * * *

(i) *General.* * * * The petition may be filed up to one year, but not earlier than 6 months before the actual need for the alien's services. Exceptions may be granted in emergency situations at the discretion of the USCIS Service Center Director, and in special filing situations as determined by USCIS Headquarters. * * *

* * * * *

Dated: April 22, 2005.

Michael Chertoff,

Secretary.

[FR Doc. 05–8471 Filed 4–27–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 114

[Docket No. 04–064–1]

Viruses, Serums, Toxins, and Analogous Products; Expiration Date Required for Serials and Subserials and Determination of Expiration Date of Product

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations to require licensees and permittees to confirm the proposed expiration dating period of products by potency testing serials on multiple occasions throughout the proposed dating period, rather than only at release and at the approximate expiration date as is currently required. We would require that those stability test data be submitted to the Animal and Plant Health Inspection Service for review and filing, and that the approval date be specified in a filed Outline of Production. In addition, after a product is licensed and its dating period confirmed, the licensee or permittee would have to submit a plan to monitor the stability of the product and the suitability of its dating period; that plan would have to include regular testing of serials for potency during and at the end of dating. The proposed changes would help clarify the distinction between specifying an expiration date for an individual serial of a product and establishing the appropriate expiration dating period for the product. The effect of these proposed changes would be to establish a single uniform standard for determining expiration dates for veterinary biological products.

DATES: We will consider all comments that we receive on or before June 27, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–064–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–064–1.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: 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.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy

Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 114, ''Production Requirements for Biological Products'' (referred to below as the regulations), include requirements applicable to designating the expiration date of a serial or subserial of veterinary biologics and determining the expiration dating period (stability) for veterinary biologics. Currently, § 114.12 of the regulations requires each serial or subserial of veterinary biological product prepared in a licensed establishment to be given an expiration date determined in accordance with the requirements prescribed in § 114.13 of the regulations. The regulations in § 114.13 require the expiration date described under § 114.12 to be computed from the date of the initiation of the potency test.

The expiration date of a product designates the end of the period during which a biological product, when properly stored and handled, can be expected, with reasonable certainty, to be efficacious. Thus, the most precise determination of the expiration date occurs when the product is tested at the end of its predicted shelf life. However, the typical product may be released for distribution and sale before its dating period is confirmed, which necessitates a mechanism for predicting the product's shelf life. Prior to licensure, the stability of each fraction of a product must be determined by methods acceptable to Animal and Plant Health Inspection Service (APHIS). Typically, such methods involve subjecting the product to extreme temperatures and measuring its relative strength by conducting a potency test. Products that pass the potency test are licensed with the provision that such expiration dates must be confirmed by real-time testing as follows: For products consisting of viable organisms each (prelicensing) serial shall be tested for potency at release and at the approximate expiration date until a statistically valid stability record has been established; for nonviable biological products, each (prelicensing) serial presented in support of licensure shall be tested for potency at release and at or after the dating requested.

We are proposing to amend the title of § 114.12 to read: ''Expiration date required for a serial.'' In addition, we propose to amend this section by adding the wording ''computed from the date of the initiation of the potency test'' and remove it from § 114.13 where it is currently found. This change is intended to clarify the fact that the expiration date of a serial, and not the dating period of a product, is computed from the date of the initiation of the potency test.

We are proposing to amend the title of § 114.13 to read: ''Determination of the expiration dating period of a product.'' This change will show that it deals with a product's dating period rather than the expiration date of a serial. The proposed revision of this section would define a single uniform standard for determining the dating period for all veterinary biologics; require the expiration dating periods of a product to be confirmed by testing serials or subserials on multiple occasions throughout their dating period in place of the current requirement which only requires testing at the beginning and end of the dating period in order to confirm stability; require a report of the expiration dating period testing to be submitted to APHIS for review and filing and the date of approval to be specified in section VI of the filed Outline of Production; and after the dating period has been approved, require that the stability of the product and the suitability of the dating period be monitored by regularly testing serials during and after their dating period.

APHIS is proposing these amendments because it has been shown that the potency of most veterinary biologics degrades in a nonlinear fashion, which could result in their potency reaching its lowest point during the middle of the dating period rather than at the end. Testing on only two occasions would be reasonable only if potency loss has a strictly linear pattern, and this is usually not the case. Thus, APHIS is proposing to evaluate a product's stability as a function of time by requiring serials to be tested on multiple occasions when confirming the dating period, and thereafter by monitoring stability on a regular basis.

The proposed amendment would update and standardize testing to establish/confirm the stability of veterinary biologics and improve the reliability of expiration dating periods currently specified on the labeling of veterinary biologics, thereby providing greater assurance that the product, when properly stored and handled, will be efficacious. We are therefore proposing to amend §§ 114.12 and 114.13 as set forth below.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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 proposed rule would amend the Virus-Serum-Toxin Act regulations in §§ 114.12 and 114.13 concerning expiration dates and the determination of the stability of veterinary biologics to: Change the title of the sections; require veterinary biologics licensees and permittees to evaluate the stability of veterinary biologics as a function of time by testing serials for potency throughout and after their proposed dating period beginning at the date of final formulation; require that the expiration dating period be determined by testing serials for potency on multiple occasions throughout and after the proposed dating period; require that a report of the results of the testing to confirm expiration dating be submitted to APHIS for review and filing and that the date of approval be specified in the filed Outline of Production; and require monitoring of the stability of the product and the suitability of the dating period. The overall effect of these proposed amendments would be to establish a single uniform standard for confirming the expiration dating period of veterinary biologics.

This proposed rule would affect all licensed manufacturers of veterinary biologics. Currently, there are approximately 152 veterinary biologics manufacturers, including permittees. According to the standards of the Small Business Administration, most veterinary biologics establishments are small entities. We believe that this proposed rule would not have a significant effect on small entities because all veterinary biologics manufacturers are currently required to confirm the expiration dating of the products that they produce and to submit a report to APHIS for review and filing. In addition, the proposed requirements to test serials on multiple occasions when confirming expiration dating and to require post-licensing stability monitoring are not expected to have a significant effect, as most veterinary biologics manufacturers routinely test and monitor the stability of products throughout their dating period.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not

have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the category 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 proposed 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. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed 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 114

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 114 as follows:

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 114 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. Section 114.12 would be revised to read as follows:

§ 114.12 Expiration date required for a serial.

Unless otherwise provided for in a Standard Requirement or filed Outline of Production, each serial or subserial of biological product prepared in a licensed establishment must be given an expiration date computed from the date of the initiation of the first potency test. A licensed biological product shall be considered worthless under the Virus-Serum-Toxin Act subsequent to the expiration date appearing on the label.

3. Section 114.13 would be revised to read as follows:

§ 114.13 Determination of the expiration dating period of a product.

(a) An expiration dating period shall be assigned to each product. When tested at any time during the dating period, the potency of the product must not be less than the minimum specified in the filed Outline of Production.

(b) Prior to licensure, a proposed expiration dating period for the product should be determined by assessing the stability of each of its fractions by methods acceptable to Animal and Plant Health Inspection Service. The proposed dating period must be confirmed by testing the serials for potency on multiple occasions throughout the proposed dating period beginning at the date of final formulation specified in the filed Outline of Production. A report of the study should be submitted to Animal and Plant Health Inspection Service for review and filing and the date of approval should be specified in section VI of the filed Outline of Production.

(c) After the product is licensed and its dating period confirmed, the licensee or permittee must submit a plan to monitor the stability of the product and the suitability of its dating period that includes regularly testing serials for potency during and at the end of dating.

(d) Subsequent changes in the dating period for a product may be granted, based on the submission of a study to support a revision of the Outline of Production.

Done in Washington, DC, this 22nd day of April 2005.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–8516 Filed 4–27–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AT84

Endangered and Threatened Wildlife and Plants; Extension of the Comment Period for Proposed Designation of Critical Habitat for the Arkansas River Basin Population of the Arkansas River Shiner

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the extension of the public comment period for the proposal to designate critical habitat for the Arkansas River Basin population of the Arkansas River Shiner (*Notropis girardi*) (October 6, 2004; 69 FR 59859). This action will allow all interested parties an opportunity to comment on the proposed critical habitat designation under the Endangered Species Act of 1973, as amended.

DATES: Comments must be submitted directly to the Service (*see* **ADDRESSES** section) on or before June 17, 2005. Any comments received after the closing date may not be considered in the final determination on the proposal.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, Oklahoma Ecological Services Office, U.S. Fish and Wildlife Service, 222 South Houston, Tulsa, Oklahoma 74127–8909.

2. You may hand-deliver written comments and information to our Oklahoma Office, at the above address, or fax your comments to 918–581–7467.

3. You may send your comments by electronic mail (e-mail) to *r2arshinerch@fws.gov*. For directions on how to submit electronic filing of comments, see the ''Public Comments Solicited'' section.

All comments and materials received, as well as supporting documentation used in preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Jerry Brabander, Field Supervisor, Oklahoma Office (telephone 918–581–7458; facsimile 918–581–7467).

SUPPLEMENTARY INFORMATION:

Background

On October 6, 2004 (69 FR 59859), we proposed to designate as critical habitat a total of approximately 2,002 kilometers (1,244 miles) of linear distance of rivers, including 91.4 meters (300 feet) of adjacent riparian areas measured laterally from each bank. This distance includes areas that we are proposing to exclude that are discussed below. The areas that we have determined to be essential to the conservation of the Arkansas River Shiner include portions of the Canadian River (often referred to as the South Canadian River) in New Mexico, Texas, and Oklahoma, the Beaver/North Canadian River of Oklahoma, the Cimarron River in Kansas and Oklahoma, and the Arkansas River in Arkansas, Kansas, and Oklahoma.