

(3) Open and closing dates, plus any other information dealing with how application receipt will be controlled, such as the use of early cut-off dates;

(4) Name of issuing agency and announcement number;

(5) Qualification requirements, including knowledges, skills, and abilities;

(6) Entrance pay;

(7) Brief description of duties;

(8) Basis of rating;

(9) What to file;

(10) Instructions on how to apply;

(11) Information on how to claim veterans' preference, if applicable;

(12) The agency's definition of well-qualified and information on how CTAP and/or ICTAP candidates may apply, including proof of eligibility required; and

(13) Equal employment opportunity statement.

§ 330.708 Application and selection.

(a) Application.

(1) To receive this special selection priority, eligible employees must apply directly to agencies for specific vacancies in the local commuting area within the prescribed time frames, attach the appropriate proof of eligibility as described in paragraph (a)(2) of this section, and be determined well-qualified by the agency for the specific position.

(2) Employees may submit the following as proof of eligibility for the special selection priority:

(i) RIF separation notice, or notice of proposed removal for declining a directed reassignment or transfer of function to another commuting area;

(ii) Documentation, e.g., SF-50, Notification of Personnel Action, showing that they were separated as a result of reduction in force, or for declining a transfer of function or directed reassignment to another commuting area;

(iii) Official certification from an agency stating that it cannot place an individual whose injury compensation has been or is being terminated;

(iv) Official notification from OPM that an individual's disability annuity has been or is being terminated; or

(v) Official notification from the Military Department or National Guard Bureau that the employee has retired under 5 U.S.C. 8337(h) or 8456.

(b) Selection. In making selections, an agency will adhere to the overall order of selection set forth in § 330.705. In addition, the following apply:

(1) An agency cannot select another candidate from outside the agency if eligible employees are available for the vacancy or vacancies.

(2) If two or more eligible employees apply for a vacancy and are determined to be well-qualified, any of these eligible employees may be selected.

(3) If no eligible employees apply or none is deemed well-qualified, the agency may select another candidate without regard to this subpart. (This flexibility does not apply to selections made from the agency's Reemployment Priority List as described in subpart B of this part.)

(c) An agency may select a candidate from its Career Transition Assistance Plan or Reemployment Priority List, as described in subparts F and B of this part respectively, or another current agency employee (if no eligible employees are available through its CTAP) at any time.

§ 330.709 Qualification reviews.

Agencies will ensure that a documented, independent second review is conducted whenever an otherwise eligible employee is found to be not well-qualified. The applicant must be advised in writing of the results of the second review.

§ 330.710 Reporting.

(a) Each agency shall submit an annual report covering each fiscal year activity under this subpart to OPM no later than December 31 of each year.

(b) Each report will include data specified in § 330.610 of subpart F of this part, and will also include information on:

(1) The number of selections of ICTAP eligible employees from other Federal agencies;

(2) The number of ICTAP candidates found not well-qualified;

(3) The number of ICTAP candidates found well-qualified;

(4) The number of selections of competitive service tenure group 1 or 2 employees from other Federal agencies who are not displaced;

(5) The number of declinations from ICTAP eligible candidates;

(6) The number of competitive service tenure group 1 or 2 appointments from outside the Federal Government; and

(7) The number of placements made from the agency's Reemployment Priority List.

§ 330.711 Oversight.

OPM is responsible for oversight of the Interagency Career Transition Assistance Plan for Displaced Employees and may conduct reviews of agency activity at any time.

[FR Doc. 97-14905 Filed 6-6-97; 8:45 am]

BILLING CODE 6325-01-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 101

[Docket No. 93-152-2]

RIN 0579-AA65

Viruses, Serums, Toxins, and Analogous Products; Definition of Biological Products and Guidelines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations by revising the definition of "biological products." The amendment is necessary in order to reflect current usage and advances in scientific knowledge, and to clarify certain parts of the definition. We are also adding a definition of "guidelines" to the regulations. Guidelines are issued to assist manufacturers of veterinary biological products and others in understanding test procedures, standards, and regulatory requirements pertaining to such products. This addition clarifies the purpose and intent of guidelines.

EFFECTIVE DATE: July 9, 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 20737-1231, (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

Veterinary biological products are licensed under the Virus-Serum-Toxin Act (hereinafter referred to as the VSTA) on the basis of purity, safety, potency, and efficacy. A product which is a "virus, serum, toxin, or analogous product" and which is intended for use in the treatment of animals is subject to regulation under the VSTA. Such products are commonly referred to as biologics or biological products. The definitions of terms related to veterinary biological products appear in 9 CFR part 101.

The Food and Drug Administration (FDA) regulates drugs for use in animals. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines "drugs" to include, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

Articles that are used to improve animal performance, such as increased rate of gain and enhanced feed efficiency, are "drugs" under the FFDCA. Section 902(c) of the FFDCA states that nothing in the FFDCA shall affect, modify, repeal, or supersede the provisions of the VSTA. FDA regulations under 21 U.S.C. 510.4 provide that an animal drug produced in full conformance with the VSTA will not be subject to the new animal drug approval requirements of the FFDCA.

Definition of Biological Product

The definition of "biological products" in 9 CFR 101.2 was last amended on April 2, 1973 (See 38 FR 8426-8428). Since that time, the VSTA has been amended by the 1985 Food Security Act (Pub. L. 99-198) and scientific advances have improved our understanding of how veterinary biologics work.

The 1985 Food Security Act provided for additional enforcement authorities under the VSTA. These authorities include detention, seizure, and condemnation and injunctive procedures. In addition, unless otherwise exempted, all veterinary biological products shipped in or from the United States must meet Federal standards for licensure related to purity, safety, potency, and efficacy. Products manufactured in foreign countries may not be imported without a permit issued under the VSTA and regulations. The main purpose of the VSTA is to protect those who use veterinary biologics from products which are worthless, contaminated, dangerous, or harmful. In this regard, products which are represented to be biological products also fall under the jurisdiction of the VSTA.

Since 1973, our understanding of how veterinary biologics work has advanced substantially. It is now recognized in the scientific literature that the generation or stimulation of an immune response involves both antigens and certain protein regulatory factors referred to as cytokines. Some cytokines (e.g. interleukins) serve as essential components in the generation and expression of an immune response, without which the vaccine would be worthless. These cytokines may be elicited through stimulation with antigens or certain "immunomodulators".

Cytokines are also produced in many body tissues and act on cell types other than those of the immune system. Cytokines of natural or synthetic origin can be prepared as products for administration to animals. Because of the diverse biological activity of the

cytokines, not all products consisting of these substances would be regulated under the VSTA. Many of these cytokines intended to be used as drugs would fall under the jurisdiction of the Food and Drug Administration. In such instances, the VSTA would not apply.

Both cytokines and immunomodulators are analogous to biological products when they are used to stimulate, supplement, enhance, or modulate the immunity of animals in the treatment of disease. Products consisting of these substances that work through these immune mechanisms in the treatment of specific disease appropriately fall within the definition of "biological products". Certain immunomodulators (e.g. cell wall extracts and products derived from the aloe vera plant) that are used in the treatment of specific diseases of animals have been regulated by the Animal and Plant Health Inspection Service (APHIS) since 1980.

APHIS received a petition dated September 14, 1993, from the Animal Health Institute, a national trade association, requesting that the definition of "biological products" be amended.

In drafting the amended definition, APHIS considered various points raised in the petition and reviewed the definition of "biological products" in 9 CFR 101.2. Such review has been ongoing for some time because it has been apparent that a clarification and an update of the definition is necessary. Therefore, in response to the petition and as a result of its own efforts to update the definition, APHIS issued a proposal amending the definition of "biological products" in § 101.2. The definition proposed by APHIS is applicable to all viruses, serums, toxins (excluding antibiotics), or analogous products at any stage of production, shipment, distribution, or sale. APHIS also proposed to add a definition of guidelines to § 101.2. The purpose of guidelines is to assist licensees and applicants in matters related to procedures, methods, and other considerations pertaining to the regulation and licensure of biological products. Guidelines also clarify and explain agency practice and requirements.

The proposed rule was published in the **Federal Register** (61 FR 43483-43486, Docket No. 93-152-1) on August 23, 1996.

We solicited comments concerning our proposal for 60 days ending October 22, 1996. Three comments were received by that date. They were from a professional association and two trade associations. We carefully considered

all of the comments we received. They are discussed below.

One commenter supported the rule as proposed. The commenter agreed that the revised definition is necessary to reflect current usage and advances in science. In addition, the commenter commended the agency for clarifying matters covered under the VSTA.

Another commenter believed that the rule would benefit biologics manufacturers and the animal health industry. The commenter supported the rule as proposed but requested clarification of several points related to the definition. The first point raised by the commenter related to the term "treatment of specific diseases." The commenter inquired whether the term excluded products for the control of fertility from the definition of "biological products." In response to the commenter, it is the position of APHIS that products intended for the control of fertility are not intended for the "treatment of specific diseases" and therefore fall outside of the definition of "biological products."

Two comments were received regarding section 4 of the preamble which deals with analogous products. There seemed to be some confusion about the reference to water and coloring and the statement concerning any stage of production. A question was also raised about the regulation of oral claims by APHIS. A careful reading of section 4 of the preamble will reveal that it merely meant to distinguish between the types of products which would be considered "analogous." These are products having a legitimate use which are similar in function to biological products, and products which may resemble, or are represented as, biological products, but may consist of nothing but water and coloring. Both types fall under the definition of products regulated under the Act. Furthermore, products would not be exempted from regulation simply because they failed to reach some step in their manufacture or packaging. To further clarify the definition, an additional statement concerning the interpretation of the meaning of intended use, which appears in the discussion of analogous products in the proposal, has been added to § 101.2.

The same two commenters inquired whether "guidelines" would become requirements. In response to the commenters, the purpose of the guidelines is to assist manufacturers and others with questions concerning licensing, testing, regulatory requirements, and other areas dealing with biologics. Therefore, while "guidelines" clarify and explain agency

policy and regulatory requirements, "guidelines" themselves do not have the force and effect of regulations. No change to the regulations is made in response to these comments.

One commenter recommended that the definition of "biological products" also include "natural products" and "live or killed vector carrier systems." In response to this comment, APHIS believes that "natural products" that fit the definition of "biological products" are already included under the proposed definition under the phrase "that are of natural or synthetic origin." In addition, "live or killed vector systems" that carry "immune components of live organisms" intended for the treatment of specific diseases already fall under the proposed definition. 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 proposal as a final rule, with the change discussed in this document.

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.

APHIS is amending the definition of the term "biological products" in its regulations under the Virus-Serum-Toxin Act, based on a petition that APHIS received from the Animal Health Institute, a national trade association, requesting that the definition be updated to reflect current scientific usage. The agency is also amending the definition based on its own efforts to update the definition.

This action has been coordinated with the Food and Drug Administration.

The primary effect of the rule is to update the definition of "biological products" and add a definition of the term "guidelines." This amendment to the regulations should have no adverse economic impact on firms and may even provide a benefit since the issuance of "guidance" documents may help to reduce the amount of time or resources required to complete licensure or testing of a biological product. It is anticipated that the amendment will benefit manufacturers of veterinary biologics by providing definitions that reflect current usage and accommodate advances in scientific knowledge.

The rule also provides guidance to manufacturers of veterinary biologics as to the scope of the term "biological

products." Biologics manufacturers should thus be aided in their decisionmaking related to the choice of submissions to APHIS for licensure of veterinary biological products or to the Food and Drug Administration for the approval of veterinary drugs.

There are currently approximately 118 veterinary biologics establishments that may be affected by this rule. According to the Small Business Administration regulations, many of them would be classified as small entities.

Three comments were received for the proposed rule on the definition of "biological products" and "guidelines." All three comments supported the definition as proposed and believed that the definition would reflect current usage and advances in science and provide a benefit to manufacturers of veterinary biologics and the animal health industry.

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 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 which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

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

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 9 CFR Part 101

Animal biologics.

Accordingly, 9 CFR part 101 is amended as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 continues to read as follows:

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

2. Section 101.2 is amended by revising the definition of *Biological products* and by adding a definition for *Guidelines*, in alphabetical order, to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Biological products. The term "biological products," also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term "biological products" includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term analogous products shall include:

(i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or

(ii) Substances, at any stage of production, shipment, distribution, or

sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term "treatment" shall mean the prevention, diagnosis, management, or cure of diseases of animals.

* * * * *

Guidelines. Guidelines establish principles or practices related to test procedures, manufacturing practices, product standards, scientific protocols, labeling, and other technical or policy considerations. Guidelines contain procedures or standards of general applicability that are usually not regulatory in nature, but that are related to matters that fall under the Virus-Serum-Toxin Act. Guidelines issued by the agency include Veterinary Biologics Licensing Considerations, Memoranda, Notices, and Supplemental Assay Methods.

* * * * *

Done in Washington, DC, this 3rd day of June 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97-14997 Filed 6-6-97; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 92-090-2]

Viruses, Serums, Toxins, and Analogous Products; Revision of Standard Requirements for *Clostridium Perfringens* Types C and D Toxoids and Bacterin-Toxoids

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations pertaining to the Standard Requirements for *Clostridium Perfringens* Type C and *Clostridium Perfringens* Type D toxoids and bacterin-toxoids. The amendments will reduce the minimum number of rabbits required in order to pool their serum for testing. This amendment will also

clarify the method of determining the test vaccine dose in rabbits based on the recommended vaccine dosage in cattle and other host animal species.

These amended regulations will not change the accuracy of the assays and, under certain circumstances, will reduce the number of required tests as well as the number of mice needed for testing. The amendment is necessary to make the potency assays conform more closely to the revised standard requirements for *Clostridium Novyi* and *Clostridium Sordellii* Bacterin-Toxoids and more economical to run when combination products containing these fractions are tested.

EFFECTIVE DATE: July 9, 1997.

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

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 113 pertain to standard requirements for the preparation of veterinary biological products. A standard requirement consists of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service (APHIS) to determine that a veterinary biological product is pure, safe, potent, and efficacious and not worthless, dangerous, contaminated, or harmful.

These regulations concerning potency testing of *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid in § 113.111 and *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid in § 113.112 reduce certain test requirements and decrease the cost of performing these tests. This has been accomplished without affecting the accuracy and reliability of the tests.

On March 22, 1993, we published a proposed rule in the **Federal Register** (58 FR 15301-15303, Docket No. 92-090-1) to amend the regulations in § 113.111 pertaining to *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid and in § 113.112 pertaining to *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid.

We proposed to reduce the number of mice needed for serum neutralization testing in certain circumstances. Also, the current test method uses half of the recommended cattle or sheep dose. The proposed rule provided for potency testing of product recommended for use in host animal species other than cattle and sheep. The test method in the proposed rule provided for recommendations for a variety of host

animal species by prescribing the use of half of the smallest host animal dose.

Current regulations in §§ 113.111(c) and 113.112(c) provide for at least four of eight rabbits which are initially injected to be bled in the potency determination of *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid and *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid. The amount of antitoxin found in the rabbit sera after injection with the toxoid or bacterin-toxoid is proportional to the potency of the antigen in the product tested.

The antitoxin response of vaccinated rabbits is measured by a toxin neutralization assay in mice. A standard amount of *Clostridium perfringens* Beta or Epsilon toxin is mixed with a designated amount of the test rabbits' sera. The mixture is allowed to neutralize for one hour. Swiss white mice are then injected with this toxin-sera mixture to determine if the standard amount of toxin was neutralized by the test rabbit sera. Since mice are particularly sensitive to these toxins, the absence of mouse mortality indicates sufficient toxin neutralization and thus an adequate antitoxin response in the rabbits tested. The result would indicate an acceptable potency for the toxoid or bacterin-toxoid antigen in the product tested.

Under the current regulations in §§ 113.111(c) and 113.112(c), if four to seven rabbits are bled for potency testing, the sera from each rabbit must be assayed individually. This requires the use of at least 20 to 35 mice (each rabbit serum is tested in a minimum of 5 mice) for serum neutralization testing as compared to a minimum of 5 mice with the single pooled serum sample which was proposed.

The proposed rule required the use of at least seven rabbits in order for the sera to be pooled into a single sample. The potency test would then be conducted on the single pooled sample. Pooling the serum samples of seven instead of eight rabbits would reduce the number of toxin-antitoxin neutralization tests required, the number of mice needed, the time spent, and the expense of the procedure.

We solicited comments concerning our proposal for 60 days ending May 21, 1993. We received six comments by that date from manufacturers of animal health products and a national trade association. One of the commenters supported the proposed rule as written, while five raised specific issues concerning the proposed rule. Those comments are discussed below.

One commenter expressed concern that, as proposed, the rule had the