use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Regarding outreach efforts, USDA announced at the Board's meeting on May 25, 2016, that the referendum scheduled for August 2016 would be postponed to a future to-be-determined date. USDA also announced at the meeting that it would publish a notice in the **Federal Register** on the postponement. After the meeting, the Board issued a newsflash to industry members advising them accordingly.

A 60-day comment period is provided to allow interested persons to respond to this interim rule. All written comments received in response to this rule by the date specified will be considered prior to finalizing this action.

After consideration of all relevant material presented, and other information, it is found that this interim rule, as hereinafter set forth, will tend to effectuate the declared purposes of the 1996 Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This interim rule extends the time frame for USDA to conduct a referendum under the Order from five years (2016) after the program took effect to no later than seven years (2018); (2) postponing the 2016 referendum will give USDA time to complete a separate rulemaking action on the Order's exemption threshold that is being initiated in response to a May 2016 federal district court decision in *Resolute;* (3) USDA announced at the Board's meeting on May 25, 2016, that the 2016 referendum would be postponed, and the Board subsequently issued a newsflash to industry members advising them of the postponed referendum; and (4) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 1217

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Promotion, Reporting and recordkeeping requirements, Softwood lumber.

For the reasons set forth in the preamble, 7 CFR part 1217 is amended as follows:

PART 1217—SOFTWOOD LUMBER RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1217 continues to read as follows:

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. In § 1217.81, revise paragraph (b)(2) to read as follows:

§ 1217.81 Referenda.

* * * * *

(b) * * *

(2) No later than seven years after this Order becomes effective and every five years thereafter, to determine whether softwood lumber manufacturers for the U.S. market favor the continuation of the Order. The Order shall continue if it is favored by a majority of domestic manufacturers and importers voting in the referendum who also represent a majority of the volume of softwood lumber represented in the referendum who, during a representative period determined by the Secretary, have been engaged in the domestic manufacturing or importation of softwood lumber;

* * * * *

Dated: August 25, 2016.

Elanor Starmer,

Administrator.

[FR Doc. 2016–20805 Filed 8–29–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101, 103, 112, 113, and 114

[Docket No. APHIS–2008–0008]

RIN 0579–AD19

Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations regarding the packaging and labeling of veterinary biological products to provide for the use of an abbreviated true name on small final container labeling for veterinary biologics; require labeling to bear a consumer contact telephone number; change the format used to show the establishment or permit number on labeling and require such labeling to show the product code number; change the storage temperature recommended in labeling for veterinary biologics; require vaccination and revaccination recommendations in labeling to be consistent with licensing data; require labeling information placed on carton tray covers to appear on the outside face of the tray cover; remove the restriction requiring multiple-dose final containers of veterinary biologics to be packaged in individual cartons; require labeling for bovine virus diarrhea vaccine containing modified live virus to bear a statement warning against use in pregnant animals; reduce the number of copies of each finished final container label, carton label, or enclosure required to be submitted for review and approval; require labels for autogenous biologics to specify the organism(s) and/or antigen(s) they contain; and require labeling for conditionally licensed veterinary biologics to bear a statement concerning efficacy and potency requirements. In addition, we are also amending the regulations concerning the number of labels or label sketches for experimental products required to be submitted for review and approval, and the recommended storage temperature for veterinary biologics at licensed establishments. These changes are necessary in order to update and clarify labeling requirements and to ensure that information provided in labeling is accurate with regard to the expected performance of the product.

DATES: Effective October 31, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 851–3426.

SUPPLEMENTARY INFORMATION:

Background

Under the Virus-Serum-Toxin Act (the Act, 21 U.S.C. 151–159) and regulations issued under the Act, the Animal and Plant Health Inspection Service (APHIS) grants licenses or permits for biological products which are pure, safe, potent, and efficacious when used according to label instructions. The regulations in 9 CFR part 112, ''Packaging and Labeling'' (referred to below as the regulations), prescribe requirements for the packaging and labeling of veterinary biological products including requirements applicable to final container labels, carton labels, and enclosures. The main purpose of the

regulations in part 112 is to regulate the packaging and labeling of veterinary biologics in a comprehensive manner, which includes ensuring that labeling provides adequate instructions for the proper use of the product, including vaccination schedules, warnings, and cautions. Complete labeling (either on the product or accompanying the product) must be reviewed and approved by APHIS in accordance with the regulations in part 112 prior to their use.

Although the science of immunology and our understanding of how veterinary biologics work have advanced substantially in recent years, communicating such information to consumers and veterinarians by way of updated labeling claims, cautions, and warnings is a top priority of APHIS. Therefore, on January 13, 2011, we published in the **Federal Register** (76 FR 2268–2277, Docket No. APHIS–2008–0008) a proposal [1] to amend the regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice.

We solicited comments concerning our proposal for 60 days ending March 14, 2011. We received six comments from five commenters by that date. The comments were from licensees, permittees, veterinary biologics industry associations, and a veterinary medical association. All of the commenters were generally supportive of the proposed rule, but raised a number of questions and concerns about its provisions. They are discussed below by topic.

True Name, Abbreviated True Names, Functional/Chemical Name

Two commenters noted that the proposed rule states that the abbreviated true name must be identical to that shown on the product license. One commenter stated that the use of abbreviations for true names on small labels would be beneficial only if they are standardized. This commenter expressed concern that without standardization, the use of such abbreviations could result in confusion. The other commenter stated that it was unclear whether the proposal means that a standardized abbreviation that corresponds to the true name shown on the license must be used, that the abbreviation will be negotiated on a case-by-case basis and noted on the product license, or that no abbreviations may be used unless they are also reflected on the product license. The commenter further stated that reissuing licenses for every approved biologic product simply to add abbreviations is unreasonable, and that APHIS should issue a memorandum with a list of standardized abbreviations for use by licensees.

APHIS will assign abbreviated true names when issuing new product licenses, when there is a need to reissue a product license (*e.g.,* renewal of Conditional Licenses, or change in ownership) or upon specific request.

One commenter stated that container labels for diagnostic kits should not be required to include both the true name of the kit and the functional and/or chemical name of the reagent. The commenter noted that the proposed rule includes a requirement to add product code numbers and that this will provide consumers with a reference to connect the component with the specific kit. The commenter further stated that adding the true name would not give consumers any additional useful information, but would significantly increase the amount of text required on the label.

APHIS agrees that reagents can be linked to a particular kit through the product code as well as the true name, and we have amended § 112.2(a)(3)(ii) to specify that the product code number may be used in lieu of the true name on small containers for critical components of diagnostic kits. In the case of small reagent containers within a diagnostic kit, those reagents that should not be used with other kits must bear functional/chemical name of the reagent and the applicable kit product code, but not necessarily the true name of the kit. Reagents that are considered interchangeable need not have the kit product code, but must bear the functional/chemical name of the reagent.

One commenter stated that the proposed rule's ''Background'' section indicates that carton labels and enclosures would be required to contain both the full true name and the associated abbreviation, but that the regulatory text does not include such a provision. Two commenters also stated that if a licensee does not use an abbreviation on the final container label, then an explanation of the abbreviation should not be required on the carton label and enclosure.

APHIS acknowledges that there was an inconsistency between the preamble and regulatory text in the proposed rule; the provisions in the regulatory text are correct. APHIS also agrees with the commenters that an explanation of an abbreviation should not be required on the carton label and enclosure when the abbreviation is not used on the final container label. We note that § 112.2(a)(1)(i) states that the abbreviation may be used on small final containers, provided that the complete true name must appear on the carton label and enclosures, but does not require explanations of abbreviation if abbreviations are not used.

One commenter stated that firms should be allowed to use existing abbreviated names and have input on newly assigned abbreviated names. The commenter noted that abbreviated names are currently used as part of foreign registrations and that any changes would require significant submission and label review (including registration fees) by several authorities. The commenter also noted that these names are often part of corporate branding strategies that are costly to develop and implement. The commenter stated that unless there are specific concerns with an existing or requested abbreviated name (*e.g.,* mislabeling), APHIS should not require changes in existing products nor reject reasonable suggestions by the firms.

APHIS is aware that there are a variety of issues associated with changing established abbreviations and may allow licensees to use established abbreviations on export labels on a case-by-case basis.

Consumer Contact Telephone Number

Two commenters stated that in the case of small final container labels, the requirement for a consumer contact telephone number in § 112.2(a)(2) should be waived when the telephone number is included on the carton label or enclosure. Another commenter stated that there will likely be instances where it will be difficult to include all contact information on a small final container without rendering the text illegible. This commenter stated that in these instances, there should be an exception allowing this information to be provided on a minimum of one labeling component (*e.g.,* carton label or enclosure).

For small, single-dose containers, APHIS will consider this requirement to be satisfied if all contact information, including the telephone number, is provided on the carton and enclosure labeling materials. We have amended the regulatory text to read ''Provided, that in the case of a biological product exported from the United States in labeled final containers, a consumer contact telephone number is not required; however, small single dose containers marketed in the United States must include contact telephone

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0008.*

information on carton and enclosures,'' to clarify this requirement.

Veterinary License/Permit Number and Product Code Number

Two commenters opposed requiring a product code number on labeling materials. The commenters stated that instead of facilitating product identification in the field, it would more likely add to confusion by those trying to identify a product in distribution channels and in the field. The commenters stated that historically there has been no difficulty using a licensee's product serial number to trace it back to a specific product code.

APHIS disagrees with the commenters. We believe that adding the product code will provide a valuable piece of information that will allow the consumer to differentiate between products with the same trade name. For example, if a company makes a product which contains a dye, and another which does not, the products would have different products codes but the same true name. If a consumer reports a problem with one of these products, we would not be able to identify which product caused the problem using only the true name.

One commenter asked whether peel-off labels intended for insertion in medical records would be required to contain the veterinary license number or veterinary permit number, the Product Code number, and the serial number. The commenter expressed concern that this may not be possible without rendering text illegible.

APHIS notes that there are currently no regulations that specify the information that must appear on a peel-off portion of a label, nor would this final rule establish any. Instead, it requires certain information appear on container labels, with exceptions given to small final containers and containers of interchangeable reagents included in diagnostic test kits.

One commenter asked how the proposal addresses combination packages, where the product code for the combination package is different from the product code for the lyophilized cake, which is different from the product code for the diluent vaccine. Similarly, one commenter stated that if the requirement for the product code number is kept, then biological product container labels should also be exempt from the requirement unless they are stand-alone presentations. The commenter stated that there are situations in which desiccated and diluent components can be used in multiple licensed combinations.

APHIS agrees with the commenters that having different product codes on components and a combination package carton could be confusing to consumers. We have amended the regulatory text by adding a new paragraph (iii) to § 112.2(a)(3) that allows container labels for components of combination packages to read ''see carton for product code.'' In addition, we are adding a definition of ''combination package'' to § 101.3. Because combination packages, which contains two or more licensed biological products, are not a new concept to the regulated industry, and further, the term ''combination package'' is used in the regulations, specifically in § 101.3(h) and § 112.2(a)(9)(iv), we believe that it would be beneficial to define this term in order to clarify these new packaging and labeling requirements.

Instructions for Use of the Product

One commenter did not object to the revision of the description of ''full directions for use'' in § 112.2(a)(5)(i) but suggested two changes. The commenter stated first that the phrase ''very small'' should be deleted in the first line, because this would make the question of applicability needlessly complicated and second that ''carton tray covers'' should be added to the list of locations that may be too small. Another commenter suggested revising § 112.2(a)(5)(i) to read ''In case of limited space on final container labels, cartons, or carton tray covers, a statement shall be used as to where such information is to be found . . .''. This commenter stated that APHIS currently allows the reference to a carton or insert for complete information, and requested the revision to ensure that the practice can be continued.

APHIS does not agree that limited space is a problem with cartons or carton tray covers. We believe that with the exception of small containers, there is ample space for this information. We agree with the second commenter that limited space on final container labels may present a problem and have amended the requirements to allow a statement referring to a carton or insert on final container labels. We have also removed the words ''very small'' as requested by the first commenter. The provisions now appear in § 112.2(a)(5).

Disposal of Containers and Warnings

One commenter stated that as written, the proposed requirements in § 112.2(a)(7) would apply to both viable and killed products, but that they should instead apply only to products containing viable organisms because there is no rationale for requiring inactivation of inactivated products.

APHIS agrees with the commenter. We have amended the regulatory text to clarify that the requirement to inactivate applies only to product containing viable organisms.

One commenter stated that § 112.2(a)(7) should give licensees the added flexibility of recognizing situations in which the warning would not be on the container label. The commenter suggested rephrasing the warning to read ''Do not mix with other biological products except as specified on this label [or carton, or insert, as applicable].''

APHIS agrees that minor modifications of the text in the regulations may be appropriate. We have amended the introductory text of § 112.2(a)(7) to allow added flexibility for statements of equivalent intent.

Two commenters stated that there should be a shortened version of the warning for small-label situations, such as, ''Do not mix with other products.'' This would allow for use of a larger, more legible font size for the warning. The same two commenters stated that the warning in § 112.2(a)(7)(ii) should be revised to read ''In case of human exposure, contact a physician.'' The commenters stated that this language would convey the same information, would be more concise, and would allow the use of a larger, more legible font size for the warning.

APHIS agrees with the commenters that these shorter warning statements are appropriate. We have amended the recommended statements to read ''Do not mix with other products, except as specified on this label'' and ''In case of human exposure, contact a physician.'' As we explained above, we have also amended the introductory text of § 112.2(a)(7) to allow equivalent statements.

Two commenters stated that there should be a shortened version of the inactivation notice for small-container labels, such as ''Inactivate unused contents.'' This would allow for use of a larger, more legible font size for the warning. Another commenter stated that the additional statements will contribute to space and legibility issues on labels. The commenter stated that the additional statements should be allowed to be included on an insert or carton label.

APHIS will consider shortened versions on a case-by-case basis to accommodate space issues.

One commenter stated that the preamble of the proposed rule states that chemical treatment will be required prior to disposal of containers

containing viable or dangerous organisms or viruses; however, § 112.2(a)(7)(iii) states ''inactivate'' which suggests that other forms of inactivation other than chemical will be allowed. The commenter asked if that was the intent.

The commenter is correct that there was a discrepancy between the preamble and proposed regulatory text. Consumers may use any suitable means to inactivate unused contents.

One commenter stated that the proposed changes to § 112.7(g)(4) would require changes in revaccination recommendations for all instances in which there are not sufficient data for specific recommendations. The commenter stated that these changes should be applied only prospectively as the labeling for such products are otherwise modified.

APHIS does not agree that this rule should apply only to new labels that are submitted for approval, and not to labels that are currently approved. We believe that having two standards for information that appears on labels would be confusing to the public and to the industry. We note that we have made nonsubstantive, editorial changes to § 112.7 and this requirement now appears in paragraph (f) rather than paragraph (g)(4).

One commenter supported the proposed changes to § 112.6(a) to allow flexibility in the packaging of diluent with biological products. The commenter stated, however, that proposed § 112.2(f)(1) has not been revised to authorize this flexibility, and recommended that it be changed accordingly.

The commenter is correct. We have amended the paragraph to read ''If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container, with a container of diluent if applicable, shall be packaged in each carton: *Provided,* That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers, and a corresponding number of diluent containers, may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information, but need not be submitted to APHIS for approval.''

Non-Antibiotic Preservatives

One commenter stated that the term ''non-antibiotic preservative'' is not defined in § 101.3 and asked for additional clarification so that firms could comply with the labeling requirement.

The regulations previously restricted disclosure to antibiotic preservatives, but APHIS believes that non-antibiotic preservatives may need to be disposed of properly (*e.g.,* merthiolate, phenol) or have consumer safety impact (*e.g.,* sodium azide). This information needs to be readily available to consumers. Any preservative, regardless of nature, should be disclosed. We have amended § 112.2(a)(10) to remove the specific references to antibiotic and non-antibiotic preservatives.

One commenter asked whether residual traces of an inactivating agent would be considered a preservative under proposed § 112.2(a)(10).

Under § 112.2(a)(10), inactivants are not considered preservatives.

One commenter also asked whether, if this change is adopted, there would not be any reason to maintain a distinction between antibiotic and non-antibiotic preservatives.

APHIS agrees that there is no need to maintain that distinction. We have amended § 112.2(a)(10) to specify only that a statement naming the preservative used must appear on the final container label, or on cartons and enclosures, if used.

Two commenters noted that there are differing opinions about what is or is not a preservative. Both commenters stated these concerns could be resolved by revising the paragraph to state that the labeling will include the preservatives as listed in section IV.B of the Outline of Production. One commenter stated that if APHIS does not modify the proposed rule to identify only those items in section IV.B of the Outline of Production, label identification should not apply simply because a non-antibiotic preservative is used at any step in the production process. The commenter stated that such materials may be used in stages of the manufacturing process, yet through a dilution effect or processes the residual levels are determined to be nominal. The commenter stated that APHIS should consider the establishment of a threshold for determining the level of non-antibiotic preservatives at which this requirement is triggered.

Any preservatives still remaining at detectable levels in completed products should be declared on labeling. We have amended § 112.2(a)(10) to clarify this requirement. We will develop guidance on this issue and make it available in an update to VS Memorandum 800.54 (Guidelines for the Preparation and Review of Labeling Materials). This memorandum is available on the APHIS Web site at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/biologics-regulations-and-guidance/ct_vb_vs_memos.*

One commenter stated that concerns for potential residues in food and unfavorable reactions in animals are not applicable to diagnostic test kits, regardless of whether the preservatives used are antibiotic or non-antibiotic.

APHIS agrees, but describing the potentially hazardous ingredients in any biological product is also important from a standpoint of proper disposal. For this reason, this rule applies to diagnostic test kits.

One commenter stated that potential environmental harm is not based on whether the preservative is antibiotic or non-antibiotic. The commenter further stated that the distinction is arbitrary in assessing environmental harm and does not support a requirement to include non-antibiotic preservatives but rather to exempt antibiotic preservatives. The commenter also expressed concern that extending the rule to include considerations of environmental harm seems to go beyond the scope of the Virus-Serum-Toxin Act.

Several States and municipalities have legislation regarding the disposal of certain products, such as those containing mercury. Disclosing all preservatives facilitates proper disposal of products in accordance with State laws and local ordinances.

For Animal Use Only

Two commenters stated that the preamble of the proposed rule indicates that the change in § 112.2(d)(3) to require the statement ''for use in animals only'' instead of ''for veterinary use only'' is intended to clarify that the product is for use in animals rather than for use in humans. The commenters stated that they did not believe this was an issue of significant confusion. One commenter further stated that because this change is not related to concerns regarding the purity, potency, safety, or efficacy of veterinary biological products, APHIS should allow for the use of alternative similar statements, including the current ''for veterinary use only.'' The other commenter stated that providing for alternatives would allow the use of a single label, both domestically and internationally, for a product that may be exported to a jurisdiction where minor differences in wording are required. The commenter stated that such a policy would promote the export of veterinary biologics from the United States. The commenter also noted that Canada requires the label statement ''Veterinary use only.''

APHIS prefers the warning ''for animal use only'' as a replacement for

''for veterinary use only'' on domestic labeling but § 112.2(d)(3) states that ''for animal use'' may be used, not that it must be used. This does not preclude alternative wording where justified.

Two commenters stated that it is not clear why the proposed regulations direct the licensee to put the warning on ''carton labels and enclosures'' rather than the more general ''labeling as appropriate.'' The commenter recommended that the more general language be used.

APHIS agrees with the commenters and has amended § 112.2(d)(3) to use the more general language suggested.

Special Labels for Export

Three commenters noted that proposed § 112.2(e) contains requirements that differ significantly from the provisions of VS Memorandum 800.208 (Special Labels for Product for Export). One commenter stated that this section should not be amended at all and the proposed changes should be rejected. Another commenter stated that the section needs to be rewritten to reflect the more practical policy of the memorandum. One commenter also stated that the proposed rule does not include consideration for foreign-language portions of multi-language kit labeling. The commenter pointed out that a variation in a test protocol might be required in a specific country and asked that APHIS allow the protocol to appear in the specific language with an accompanying statement that it is approved only in the identified country.

APHIS is aware that some foreign regulatory authorities do not provide label approvals per se. We have amended § 112.2(e) to provide flexibility in the type of foreign documentation provided and to be consistent with established guidelines currently in VS Memorandum 800.208.

Carton Tray Covers

Two commenters raised concerns about the proposed requirements for carton tray covers. One commenter stated that it is appropriate to address labeling on tray covers, but that the language of proposed § 112.2(f)(2) would require all labeling to be on the outside face of the tray. The commenter stated that in the case of small covers, there should be flexibility to allow a sentence referring the user to another location of full labeling information. The commenter also stated that § 112.2(f)(2) should be amended to be consistent with, or combined with § 112.2(a)(5). The commenter further stated that the regulations should indicate which information should be immediately visible to the consumer and which could be provided elsewhere with reference to that location on the carton. The other commenter stated that § 112.2(f)(2) should be amended to read ''In case of limited space on final container labels, carton labels, or carton tray covers, a statement shall be used as to where such information is to be found . . .'' This commenter stated that APHIS currently allows the reference to an enclosure for complete information and the proposal should be amended to allow that practice to continue.

As we explained in the proposed rule, carton tray covers have come to be extensively used in the packaging of diagnostic test kits. They are also used in the packaging of multi-packs of single-dose vaccine. The proposed change would ensure that the information shown on carton tray covers is equivalent to other types of cartons and is presented in a manner that is accessible to the consumer without having to open the product. We are making no changes in response to this comment.

Packaging Multiple-Dose Final Containers

The commenter stated that, according to the preamble of the proposed rule, the changes to § 112.6(a) are intended to remove the requirement for a multiple-dose final product to be packaged with only one vial of diluent. The commenter stated, however, that the last sentence as proposed requires ''a carton or enclosure in order to provide all information required under the regulations.''

The regulatory provisions are intended to allow multiple containers in one carton if the container labels contain all the information required by regulations. If the containers do not have all the information, and instead rely on a carton or enclosure for additional information, then the containers must continue to be packaged one per carton to ensure complete labeling for each product unit.

Special Additional Requirements

One commenter stated that the proposed revisions to § 112.7(f) would require a pregnancy warning on all modified live and inactivated vaccines for use in mammals unless the vaccine has been shown to be safe in pregnant animals. The commenter stated that this requirement should be applied only to new products and to products with antigens recognized as having a risk in pregnant animals. The commenter stated further that these changes should be applied only prospectively as the labeling for such products are otherwise modified.

APHIS believes that it is appropriate for the label to convey information on whether or not the product has been tested in pregnant animals in order to convey meaningful care information regarding the health of the fetus. We have amended the required statement to read ''This product has not been tested in pregnant animals'' and we will continue to allow equivalent statements acceptable to APHIS. As a result of editorial changes made to § 112.7, these requirements now appear in paragraph (e).

One commenter stated that the preamble of the proposed rule states that the regulations would require labeling to bear the following statement: ''A specific revaccination schedule has not been established for this product; consultation with a veterinarian is recommended.'' The commenter agreed that this is an appropriate label statement, but noted that the actual language proposed is different, stating ''The need for annual booster vaccinations has not been established for this product.'' The commenter requested that the language be amended to allow for the use of equivalent statements and to be provided in an enclosure or other location, with an appropriate reference to the location, when space is limited on labels or outer packaging. The commenter stated that this would allow flexibility to tailor statements where necessary to meet differences unique to species and/or antigens. Another commenter stated that the requirement for a revaccination statement should only be applied prospectively as the labeling for such products is otherwise modified.

APHIS has amended the regulatory text to agree with the preamble, as the latter is more inclusive. We disagree that the requirement should be applied prospectively. Having two standards for the information that appears on labels would be confusing to the public and to the industry.

Miscellaneous Changes

Three commenters asked that the implementation schedule be changed from 3 years to 5 years. One commenter stated that the proposed changes have in most cases been under discussion for more than a decade, which argues against the need for urgency in the implementation of the new requirements. This commenter stated further that APHIS underestimates the magnitude of the tasks required to implement the changes.

APHIS notes that a recent final rule (80 FR 39669–39675, Docket No. APHIS–2011–0049), which amended the regulations to provide for the use of a

simpler labeling format, provided for a 4-year phase-in of the labeling and data summary requirements, with additional extensions of up to 2 years allowed under certain conditions. In order to be consistent with that rule and to minimize sequential label changes, we will also adopt a 4-year phase-in of the packaging and labeling requirements in this rule, with additional extensions of up to 2 years allowed under certain conditions. As we explained in that final rule, we intend to implement that rule and this one concurrently, and we will coordinate implementation with industry.

Section 103.3(d) currently requires that a request for authorization to ship an unlicensed biological product for experimental study include, among other things, two copies of labels or label sketches which show the name or identification of the product and bear the statement ''Notice! For experimental use only—Not For Sale'' or equivalent statement. However, most applicants submit these requests electronically, and those that still arrive on paper are scanned upon receipt. The requirement that two copies be submitted is no longer necessary, and we are amending this paragraph to require only one copy of the labels or label sketches.

We are amending § 112.5(a) to indicate that transmittal forms to be used with submissions of sketches and labels may be found on the APHIS Web page.

We proposed to amend § 112.7(j)(1) and (2) to require that all but very small final container labels for feline panleukopenia vaccines contain recommendations for use. Specifically, we would have required that these recommendations state that for healthy cats vaccinated at less than 12 weeks of age, a second dose of the vaccine should be given at 12 to 16 weeks of age. Since the proposed rule was published, however, research has shown that the booster for the feline panleukopenia vaccine should not be given earlier than 16 weeks. Therefore we are amending the requirements in new paragraphs (i)(1) and (2) to read ''. . . a second dose should be given no earlier than 16 weeks of age.''

We are amending § 113.206(d)(2) to update a reference to labeling requirements that now appear in § 112.7(h).

Issues Outside the Scope of the Rulemaking

One commenter stated that the current ''true name'' system fails to uniquely and accurately identify products. The commenter stated that the system should be changed to correct this problem but did not specify how.

We did not propose to make any changes to the true name system in this rulemaking. We are aware of issues associated with the current system and will consider addressing this issue in a future action.

One commenter asked that APHIS remove the restriction upon the use of trade names for conditionally licensed products. Two commenters requested changes to § 112.8(c), which sets out requirements for labels on shipping containers of products for export. These issues are outside the scope of this rulemaking.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* Web site (see footnote 1 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS is amending the Virus-Serum-Toxin Act regulations regarding the packaging and labeling requirements for veterinary biologics products. Most of the changes are intended to increase the information readily available to consumers (such as veterinarians, livestock and dairy producers, pet stores, and animal health technicians). These changes are necessary to update and clarify labeling requirements for veterinary biologics licensees (manufacturers of veterinary biologics) and permittees (importers of veterinary biologics) to ensure that information provided in labeling is accurate with regard to the expected performance of the product.

This action will affect all veterinary biologics product licensees and permittees. Currently, there are approximately 100 veterinary biological establishments, including permittees, and the majority of them are small entities. These companies produce about 1,900 different products, and there are about 11,700 active approved labels for veterinary biologics. There were about 3,100 labels submitted for approval from June 2012 through May 2013 by about two-thirds of the companies. The average number of labels submitted per company over that time frame was 46 and the median was 8.

The veterinary biologics industry has grown substantially in the United States in recent years; the Census Bureau's Annual Survey of Manufacturers (ASM) reports that the annual shipment value of veterinary biological products increased by $2.06 billion (or 88 percent) from $2.34 billion in 2006 to $4.40 billion in 2010 and have been stable at around $4.33 to $4.60 billion from 2010 to 2014. In 2015, the United States exported about $1.2 billion and imported about $0.9 billion of veterinary biologic products, including exports and imports of veterinary medicaments which were packaged for retail sale.

The action will benefit consumers of veterinary biologic products and, ultimately, the animals they treat with those products. This is because the action aims to ensure that consumers have complete and up-to-date instructions for the proper use of those products, including vaccination schedules, warnings, and cautions.

We anticipate that the costs associated with this rule will be one-time costs to the industry that will overlap with the expected one-time costs of the single label claim rule (80 FR 39669–39675, Docket No. APHIS–2011–0049), which became effective on September 8, 2015. APHIS is allowing the manufacturers to delay implementing the single label claim rule until this rule becomes effective, so that the required label revisions by these two rules are being carried out concurrently. As addressed in the economic analysis of the single label claim rule, we expect the industry's one-time implementation costs associated with the labeling changes in these two rules will fall between about $1.1 million and $4.1

million, with a median estimate of about $2.4 million. Labor costs to plan and implement the required changes (about one-third of the total) and material costs for labeling and packaging (about 40 percent of the total) are key cost components. Other costs are: Label designing (about 20 percent of the total) and standardized summaries for efficacy and safety that are necessary for the single label claim rule (about 6 percent of the total, based on the median cost estimate). We expect that the costs for the industry will not cause significant economic impacts for most veterinary biologics licensees and permittees, and the benefits of this rule justify the costs.

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 2 CFR chapter IV.)

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 will not preempt any State or local laws, regulations, or policies where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the Agency's intent to occupy the field. This includes, but is not limited to, the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Animal and Plant Health Inspection Service has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under Executive Order 13175.

Paperwork Reduction Act

There are information collection activities in this rule. Therefore, in accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we published a notice [2] in the **Federal Register** (80 FR 59725, Docket No. APHIS–2015–0066), announcing our intention to initiate this information collection to solicit comments. We are asking the Office of Management and Budget (OMB) to approve our use of this information collection for 3 years. When OMB notifies us of its decision, we will publish a document in the **Federal Register** providing notice of the assigned OMB control number.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Parts 103 and 114

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 112

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

9 CFR Part 113

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

Accordingly, we are amending 9 CFR parts 101, 103, 112, 113, and 114 as follows:

[2] To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0066.*

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 371.4.

■ 2. In § 101.3, paragraph (q) is added to read as follows:

§ 101.3 Biological products and related terms.

* * * * *

(q) *Combination package.* Biological product consisting of two or more licensed biological products. Each completed product in final container is packaged together and mixed prior to administration. A combination package is issued a separate U.S. Veterinary Biological Product License and assigned a product code number to distinguish it from its component products, which also may be marketed individually unless otherwise restricted.

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

■ 3. The authority citation for part 103 continues to read as follows:

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

■ 4. In § 103.3, paragraph (d) is revised to read as follows:

§ 103.3 Shipment of experimental biological products.

* * * * *

(d) A copy of the labels or label sketches which show the name or identification of the product and bear the statement ''Notice! For experimental use only-Not For Sale'' or equivalent. Such statement shall appear on final container labels, except that it may appear on the carton in the case of very small final container labels and labeling for diagnostic test kits. The U.S. Veterinary License legend shall not appear on such labels; and

* * * * *

PART 112—PACKAGING AND LABELING

■ 5. The authority citation for part 112 continues to read as follows:

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

■ 6. Section 112.2 is amended as follows:

■ a. By revising paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(7), and (a)(10).

■ b. At the end of paragraphs (a)(6) and (a)(9)(iv), by removing the semicolon and adding a period in its place.

■ c. By revising paragraphs (d)(3), (e), and (f).

The revisions read as follows:

§ 112.2 Final container label, carton label, and enclosure.

(a) * * *

(1) The complete true name of the biological product which name shall be identical with that shown in the product license under which such product is prepared or the permit under which it is imported, shall be prominently lettered and placed giving equal emphasis to each word composing it. Descriptive terms used in the true name on the product license or permit shall also appear. Abbreviations of the descriptive terms may be used on the final container label if complete descriptive terms appear on the carton label and enclosure. The following exceptions are applicable to small final containers, and containers of interchangeable reagents included in diagnostic test kits:

(i) For small final containers, an abbreviated true name of the biological product, which shall be identical with that shown in the product license under which the product is prepared or the permit under which it is imported, may be used: *Provided,* That the complete true name of the product must appear on the carton label and enclosures;

(ii) In addition to the true name of the kit, the functional and/or chemical name of the reagent must appear on labeling for small final containers of reagents included in diagnostic kits: *Provided,* That the true name is not required on labeling for small final containers of interchangeable (non-critical) components of diagnostic kits.

(2) For biological product prepared in the United States or in a foreign country, the name and address of the producer (licensee, or subsidiary) or permittee and of the foreign producer, and an appropriate consumer contact telephone number: *Provided,* That in the case of a biological product exported from the United States in labeled final containers, a consumer contact telephone number is not required; however, small single dose containers marketed in the United States must include contact telephone information on carton and enclosures.

(3) The United States Veterinary Biologics Establishment License Number (VLN) or the United States Veterinary Biological Product Permit Number (VPN), and the Product Code Number (PCN) assigned by the Department, which shall be shown only as ''VLN/PCN'' and ''VPN/PCN,'' respectively, except that:

(i) Only the VLN or VPN is required on container labels of interchangeable (non-critical) components of diagnostic kits and container labels for individual products packaged together for co-administration.

(ii) The PCN may be used in lieu of the true name of the kit on small container labels for critical components of diagnostic kits.

(iii) Container labels for individually licensed biological products, when marketed as components of combination packages, must include a statement referring the consumer to the carton or enclosure for the PCN of the combination package.

(4) Storage temperature recommendation for the biological product stated as 2 to 8 °C or 35 to 46 °F, or both.

(5) Full instructions for the proper use of the product, including indications for use, target species, minimum age of administration, route of administration, vaccination schedule, product license restriction(s) that bear on product use, warnings, cautions, and any other vital information for the product's use; except that in the case of limited space on final container labels, a statement as to where such information is to be found, such as ''See enclosure for complete directions,'' ''Full directions on carton,'' or comparable statement.

* * * * *

(7) The following warning statements, or equivalent statements, shall appear on the labeling as applicable:

(i) Products other than diagnostic kits: ''Do not mix with other products, except as specified on this label.''

(ii) Injectable products and other products containing hazardous components: ''In case of human exposure, contact a physician.''

(iii) Products containing viable organisms: ''Inactivate unused contents before disposal.''

* * * * *

(10) In the case of a product that contains a preservative that is added during the production process and is not reduced to undetectable levels in the completed product through the production process, the statement ''Contains [name of preservative] as a preservative'' or an equivalent statement must appear on cartons and enclosures, if used. If cartons are not used, such information must appear on the final container label.

* * * * *

(d) * * *

(3) The statement ''For use in animals only'' may appear on the labeling as appropriate for a product to indicate that the product is recommended specifically for animals and not for humans.

(e) When label requirements of a foreign country differ from the requirements as prescribed in this part, special labels may be approved by APHIS for use on biological products to be exported to such country upon receipt of written authorization, acceptable to APHIS, from regulatory officials of the importing country, provided that:

(1) If the labeling contains claims or indications for use not supported by data on file with APHIS, the special labels for export shall not bear the VLN.

(2) All other labels for export shall bear the VLN unless the importing country provides documentation that the VLN is specifically prohibited. When laws, regulations, or other requirements of foreign countries require exporters of biological products prepared in a licensed establishment to furnish official certification that such products have been prepared in accordance with the Virus-Serum-Toxin Act and regulations issued pursuant to the Act, such certification may be made by APHIS.

(f) Multiple-dose final containers of liquid biological product and carton tray covers showing required labeling information are subject to the requirements in this paragraphs.

(1) If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container, with a container of diluent if applicable, shall be packaged in each carton: *Provided,* That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers, and a corresponding number of diluent containers, may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information, but need not be submitted to APHIS for approval.

(2) When required labeling information is shown on a carton tray cover, it must be printed on the outside face of such tray cover where it may be read without opening the carton. The inside face of the tray cover may contain information suitable for an enclosure.

* * * * *

■ 7. In § 112.3, paragraph (f)(2) is revised to read as follows:

§ 112.3 Diluent labels.

* * * * *

(f) * * *

(2) The biological product is composed of viable or dangerous

organisms or viruses, the notice, ''Inactivate unused contents before disposal.''

* * * * *

■ 8. Section 112.5 is amended as follows:

■ a. In paragraph (a), by removing the words ''available on the Internet at (*http://www.aphis.usda.gov/animalhealth/cvb/forms*)'' and adding in their place the words ''available on the APHIS Web page at *http://www.aphis.usda.gov/animalhealth/cvb/forms*''.

■ b. By revising paragraphs (d)(2)(ii) and (d)(2)(v), and at the end of paragraph (d)(2)(vi), by removing the period and adding a semicolon in its place.

■ c. By adding paragraphs (d)(2)(vii) through (d)(2)(x).

■ d. By revising paragraphs (e)(1)(iii), (e)(1)(iv), (e)(4), and (f)(1).

■ e. By removing paragraph (f)(2) and redesignating paragraph (f)(3) as new paragraph (f)(2).

The additions and revisions read as follows:

§ 112.5 Review and approval of labeling.

* * * * *

(d) * * *

(2) * * *

(ii) Changes in the color of label print or background, provided that such changes do not affect the legibility of the label;

* * * * *

(v) Adding, changing, deleting, or repositioning label control numbers, universal product codes, or other inventory control numbers;

* * * * *

(vii) Changing the telephone contact number;

(viii) Adding, changing, or deleting an email and/or Web site address;

(ix) Changing the establishment license or permit number assigned by APHIS, and/or changing the name and/or address of the manufacturer or permittee, provided that such changes are identical to information on the current establishment license or permit; and

(x) Adding or changing the name and/or address of a distributor.

(e) * * *

(1) * * *

(iii) For finished labels, submit two copies of each finished final container label, carton label, and enclosure: *Provided,* That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. One copy of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Labels to which exceptions are taken shall be marked as sketches and handled under paragraph (e)(1)(i) of this section.

(iv) For finished master labels, submit for each product two copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use concurrent with the approval of the appropriate finished master label, provided that the marketing of larger size final containers is approved in the filed Outline of Production, and the appropriate larger sizes of containers or cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy for each additional product shall be submitted. One copy of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Master labels to which exception are taken will be marked as sketches and handled under paragraph (e)(1)(ii) of this section.

* * * * *

(4) To appear on the bottom of each page in the lower left hand corner, if applicable:

(i) The dose size(s) to which the master label applies.

(ii) The APHIS assigned number for the label or sketch to be replaced.

(iii) The APHIS assigned number for the label to be used as a reference for reviewing the submitted label.

(f) * * *

(1) An accurate English translation must accompany each foreign language label submitted for approval. A statement affirming the accuracy of the translation must also be included.

* * * * *

■ 9. In § 112.6, paragraph (a) is revised to read as follows:

§ 112.6 Packaging biological products.

(a) Multiple-dose final containers of a biological product with final container labeling including all information required under the regulations may be packaged one or more per carton with a container(s) of the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production: *Provided,* That cartons containing more than one final container of product must comply with the conditions set forth in paragraphs (c)(1) through (4) of this section. Multiple-dose final containers of a product that require a carton or enclosure in order to provide all information required under the regulations shall be packaged one container per carton with the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production.

* * * * *

■ 10. Section 112.7 is amended as follows:

■ a. By revising paragraphs (e), (f), (i), and (l).

■ b. By adding paragraph (n).

The addition and revisions read as follows:

§ 112.7 Special additional requirements.

* * * * *

(e) Labeling for all products for use in mammals must bear an appropriate statement concerning use in pregnant animals.

(1) For bovine rhinotracheitis vaccine or bovine virus diarrhea vaccine containing modified live virus, all labeling except small final container labels shall bear the following statement: ''Do not use in pregnant cows or in calves nursing pregnant cows.'': *Provided,* That such vaccines which have been shown to be safe for use in pregnant cows may be excepted from this label requirement by the Administrator.

(2) For other modified live and inactivated vaccine, labeling shall bear a statement appropriate to the level of safety that has been demonstrated in pregnant animals.

(i) Products known to be unsafe in pregnant animals shall include statements such as ''Do not use in pregnant animals,'' or ''Unsafe for use in pregnant animals,'' or an equivalent statement acceptable to APHIS.

(ii) Products without safety documentation acceptable to APHIS, but not known to be unsafe, labeling shall include the statement ''This product has not been tested in pregnant animals'' or an equivalent statement acceptable to APHIS.

(3) For modified live vaccines containing agents with potential reproductive effects but having acceptable pregnant animal safety data on file with APHIS, labeling still must bear the following statement concerning residual risk: ''Fetal health risks associated with the vaccination of pregnant animals with this vaccine cannot be unequivocally determined during clinical trials conducted for licensure. Appropriate strategies to address the risks associated with vaccine use in pregnant animals should be discussed with a veterinarian.''

(f) For biological products recommending annual booster

vaccinations, such recommendations must be supported by data acceptable to APHIS. In the absence of data that establish the need for booster vaccination, labeling must bear the following statement: ''The need for annual booster vaccinations has not been established for this product; consultation with a veterinarian is recommended.''

* * * * *

(i) All but very small final container labels for feline panleukopenia vaccines shall contain the following recommendations for use:

(1) *Killed virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than 16 weeks of age.

(2) *Modified live virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than16 weeks of age.

* * * * *

(l) All labels for autogenous biologics must specify the name of the microorganism(s) or antigen(s) that they contain, and shall bear the following statement: ''Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist.''

* * * * *

(n) All labels for conditionally licensed products shall bear the following statement: ''This product license is conditional; efficacy and potency have not been fully demonstrated.''

* * * * *

PART 113—STANDARD REQUIREMENTS

■ 11. 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 371.4.

§ 113.206 [Amended]

■ 12. In § 113.206, paragraph (d)(2) is amended by removing the reference ''§ 112.7(i)'' and adding the reference ''§ 112.7(h)'' in its place.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

■ 13. The authority citation for part 114 continues to read as follows:

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

■ 14. Section 114.11 is revised to read as follows:

§ 114.11 Storage and handling.

Biological products at licensed establishments must be protected at all times against improper storage and handling. Completed product must be kept under refrigeration at 35 to 46 °F (2 to 8 °C), unless the inherent nature of the product makes storage at different temperatures advisable, in which case, the proper storage temperature must be specified in the filed Outline of Production. All biological products to be shipped or delivered must be securely packed.

Done in Washington, DC, this 24th day of August 2016.

Elvis S. Cordova,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2016–20749 Filed 8–29–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 590

Notice of Revised Procedures Affecting Applications and Authorizations for the In-Transit Movement of Natural Gas

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of procedures.

SUMMARY: Pursuant to section 3(a) of the Natural Gas Act (NGA), no person may import or export natural gas without authorization from the Department of Energy (DOE), and DOE will approve such imports or exports unless, after opportunity for a hearing, it determines that the imports or exports are not consistent with the public interest. Section 3(c) of the NGA provides that imports and exports of natural gas from or to countries with which the United States has entered into a free trade agreement (FTA) providing for national treatment for trade in natural gas (FTA countries), and all imports of liquefied natural gas (LNG) from any country, are deemed in the public interest and must be granted without modification or delay. This notice serves to clarify that in-transit shipments of natural gas, *i.e.,* shipments of natural gas that only temporarily pass through the United States before returning to their country of origin, or temporarily pass through a foreign country before returning to the United States, for consumption or other disposition, are not ''imports'' or ''exports'' within the meaning of section 3 of the Natural Gas Act. However, DOE will impose monthly reporting requirements on persons making such shipments in order to ensure these movements meet the criteria defining in-transit shipments, and are tracked accordingly.

DATES: Effective August 30, 2016.

FOR FURTHER INFORMATION CONTACT:

Brian Lavoie or Larine Moore, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–2459; (202) 586–9478.

Edward Myers, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–3397.

SUPPLEMENTARY INFORMATION:

I. Background

In DOE/FE Order No. 3769,[1] DOE concluded that ''Congress likely did not intend the words ''import'' and ''export'' to capture *any* movement of natural gas across the U.S. border, but rather intended to leave some discretion to the Federal Power Commission (the [DOE's] predecessor in administering NGA Section 3, 15 U.S.C. 717b) on that question.'' [2] Further, DOE concluded that ''in-transit shipments returning to the country of origin are not imports or exports within the meaning of section 3 of the Natural Gas Act.'' [3] Consequently, DOE concluded ''that in-transit shipments returning to the country of origin fall outside [DOE's] jurisdiction under NGA section 3.'' [4] This Notice sets forth procedures for the submission of information concerning in-transit shipments returning to the country of origin.

DOE considers an ''in-transit shipment returning to the country of origin'' as a shipment of natural gas through the United States between points of a single foreign nation, or through a single foreign nation between points in the United States, that are physical and direct. ''Physical'' means that the natural gas will be transported between two cross-border points. Thus, exchanges by backhaul or displacement, or other virtual shipments, do not qualify as in-transit shipments for

[1] *Bear Head LNG Corporation & Bear Head LNG, LLC,* DOE/FE Order No. 3769, FE Docket No. 15–14–NG, Opinion and Order Dismissing Application for In-Transit Shipments of Canadian-Sourced Natural Gas and Directing Submission of Information Concerning In-Transit Shipments Returning to the Country of Origin (Feb. 5, 2016).

[2] *Id.* at 8.

[3] *Id.* at 9.

[4] *Id.* at 10.