Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 103, 112, 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: Proposed rule.

SUMMARY: We are proposing to amend 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 labeling for autogenous biologics to specify the microorganism(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 also propose to amend 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 proposed amendments are necessary in order to update and clarify labeling requirements and ensure that information provided in labeling is accurate with regard to the expected performance of the product.

DATES: We will consider all comments that we receive on or before March 14, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0008* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2008–0008, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0008.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

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 by way of updated labeling claims, cautions, and warnings has not kept pace. Therefore, we are proposing to amend several sections of the regulations in part 112 to make veterinary biologics labeling requirements more consistent with current science and veterinary practice.

True Name, Abbreviated True Name, Functional/Chemical Name

We are proposing to amend § 112.2(a)(1) of the regulations concerning required labeling information to provide for the use of an abbreviated true name on labeling for small final containers of veterinary biologics. Currently, the regulations require the true name shown in the product license or permit under which a product is imported to be used in veterinary biologics labeling. However, due to the small size of the labeling used on small final containers of some veterinary biologics and the amount of label surface that must be devoted to

emphasizing the true name of the product, there may not be adequate remaining space on such labeling for the legible presentation of other required information. Under the proposed amendment, when issuing or reissuing licenses for veterinary biologics, APHIS would assign abbreviated true names–shortened forms of the true name of the product shown in the product license/permit—which may be used in place of the long form of the true name on labeling for small final containers of veterinary biologics. While abbreviated true names may be used on small final container labels, the complete true name along with the abbreviation for such true name would be shown on carton labels and enclosures. Thus, the association between the true name of the product and its abbreviated true name would be readily apparent to consumers, veterinarians, and others who utilize veterinary biological products. The proposed change would mean that a greater proportion of the (small) container label surface may be used to improve the presentation and legibility of other required information. The proposed amendment also would clarify in this section the requirements for showing the true name of the product and/or a functional or chemical name for the reagent on labeling for cartons, and containers of interchangeable (non-critical) reagents included in diagnostic test kits. Carton or box labeling for diagnostic test kits is required to show the true name of the test kit as it appears on the product license or permit under which such kit is imported; labeling for containers of interchangeable reagents included in test kits may show the functional and/or chemical name of such reagent(s). The proposed change would facilitate the use of a single lot of such interchangeable reagent in a variety of test kit configurations.

Consumer Contact Telephone Number

We are proposing to amend the regulations in § 112.2(a)(2) to require labeling for veterinary biologics to bear a telephone number that consumers may use to contact the licensee or permittee to report adverse events or other unfavorable experiences associated with the use of such products. Currently, veterinary biologics labeling is not required to bear a telephone number for reporting adverse experiences to APHIS and/or the licensee or permittee. In the absence of immediately available contact information for reporting such adverse experiences, the probability of harm to animals and hazards to humans posed by the use of veterinary biologics may increase. The addition to veterinary biologics labeling of a telephone number that consumers may use to report adverse events and other unfavorable experiences to the manufacturer and to APHIS would facilitate the reporting of such adverse vaccine experiences and help to ensure that the licensee/permittee is able to initiate appropriate corrective action in a timely manner.

Veterinary License/Permit Number and Product Code Number

In order to better facilitate product identification, we are proposing to amend the regulations in § 112.2(a)(3) to: (1) Require labeling for veterinary biologics to bear the product code number (PCN) that APHIS assigns to such product and communicates to the manufacturer when the product license application is submitted, and (2) specify a revised format for showing the veterinary establishment license number (VLN) or veterinary establishment permit number (VPN) in veterinary biologics labeling. The license or permit number would be shown side-by-side with the product code number using the format VLN/PCN or VPN/PCN, as applicable. For example, the VLN/PCN relationship for a product prepared by veterinary biologics licensee number 100 (VLN 100) under product code number 1A34.XX (PCN 1A34.XX) would be shown in labeling as: VLN/PCN 100/1A34.XX. Currently, the regulations in § 112.2(a)(3) specify that the license number must be shown in labeling as "U.S. Veterinary License No. __," or "U.S. Vet License No. __," or "U.S. Vet Lic. No. __," and the permit number must be shown as "U.S. Veterinary Permit No. __," or "U.S. Permit No. __," but there is no requirement for the PCN to appear in labeling. The true name of the product, the veterinary license or permit number, and the product serial or lot number, all currently required to be shown in labeling, are used for product identification. In most instances, such information is sufficient for product identification. However, such information may be insufficient if the licensee or permittee prepares or distributes two or more products that have the same true name and use an overlapping sequence of serial numbers; in those instances, consumers may need additional information in order to accurately identify a product. The addition of the PCN to veterinary biologics labeling would provide that additional piece of information. The side-by-side presentation of the VLN/VPN and PCN in veterinary biologics labeling, along with the true name of the product and its serial or lot number, would better facilitate product identification and help to ensure the accuracy of information provided to the manufacturer and/or APHIS concerning product performance.

Storage Temperature

We are proposing to amend the regulations in §§ 112.2(a)(4) and 114.11 regarding the storage temperature recommendation for veterinary biologics to prescribe a range of 2 to 8 °C (35 to 46 °F) as the recommended storage temperature for both released serials of veterinary biologics stored in distribution channels and completed serials of veterinary biologics stored at a licensed establishment. Currently, the regulations provide that the storage temperature for veterinary biological product in distribution channels should be stated as "not over 45 °F or stated as not over 7 °C or stated as not over 45 °F or 7 °C." The regulations do not prescribe a minimum recommended storage temperature for released product in distribution channels. Under § 114.11 of the regulations, completed product stored at licensed establishments should be kept under refrigeration at temperatures that may range from 35 to 45 °F (2 to 7 °C). Under the proposed amendment, the maximum recommended storage temperature for released product in distribution channels would increase to 8 EC (the widely recognized standard, and 1 °C above the currently prescribed 7 °C), and 2 °C would be established as the minimum recommended storage temperature. For completed product stored in bulk or final containers at licensed establishments, the minimum recommended storage temperature of 2 °C would remain unchanged, and the maximum recommended storage temperature would be increased to 8 °C (1 °C above the currently prescribed 7 °C). The proposed amendment would standardize veterinary biologics storage temperature recommendations in the regulations and, thereby, reduce the likelihood that dissimilar recommendations may result in mishandling during storage.

Instructions for Use of the Product

We propose to amend the regulations in § 112.2 (a)(5) to clarify that "full instructions for the proper use of the product" refers to vaccination schedules, revaccination schedules (if necessary), indications for use, target species, recommended age for vaccination, vaccination route(s), and product license restrictions prescribed by APHIS that have a bearing on product use. Currently, the regulations in § 112.2(a)(5) specify that "full instructions for the proper use of the product" refers to "vaccination

schedules, warnings, cautions, and the like." Although APHIS has always considered indications for use, target species, age of vaccination, route of vaccination, and product license restrictions to be included under "full instructions for the proper use of the product," the fact that such information is not specifically identified as "required" in the regulations may have caused some confusion with regard to interpretation, which resulted in requests for clarification from licensees and permittees. The proposed amendment would ensure consistency in labeling by setting forth under the regulations the minimum information that must be provided under instructions for use of the product.

Disposal of Containers and Warnings

We are proposing to amend the regulations in §§ 112.2(a)(7) and 112.3(f)(2) to require chemical treatment prior to disposal of containers of veterinary biologics containing viable or dangerous organisms or viruses. In addition, under § 112.2(a)(7) of the regulations, the proposed amendment would require labeling to bear statements that: (1) Warn persons who inject themselves with veterinary biologics to seek medical attention and, (2) warn against treating animals with mixtures of veterinary biologics that are not approved for administration as combination products. Currently, the regulations require labeling to bear the warning "Burn this container and all unused contents" if a biological product contains viable or dangerous organisms or viruses. At the time the regulation was promulgated, disposal of discarded veterinary biologics containers by burning was in accordance with existing environmental guidelines. At this time, however, environmental guidelines in many States prohibit disposal of potentially environmentally harmful materials by burning. The proposed amendment would update the regulations by specifying chemical inactivation as the method for ensuring that the unused contents of vaccine containers are made non-hazardous prior to disposal.

With regard to the use of unapproved combinations of veterinary biologics in the treatment of animals and what constitutes an appropriate course of action in the event of accidental self injection of a veterinary biologic, the regulations do not currently address either topic. In the case of using unapproved combinations of veterinary biologics in the treatment of animals, many veterinarians (and consumers) have made "judgment" decisions to inoculate animals using mixtures of two or more veterinary biologics that are not approved for administration as combination products. In addition to the fact that such mixing of product(s) is not recommended in labeling, such off-label use disregards the important consideration that antigen interference, a frequent occurrence when administering two or more antigens concurrently, may render the combined products ineffective and could present a disease and/or safety risk in animals. A label statement warning against administering unapproved combinations of veterinary biologics to animals would ensure that veterinary professionals and consumers have the information necessary to use veterinary biologics in a safe and effective manner. We propose to require labeling to bear a statement advising users to seek medical attention should they accidentally inject themselves with veterinary biologics because such products frequently contain chemical compounds that may cause serious injury or harm when left untreated. We believe that it is prudent to make consumers aware of the possibility of serious injury as a result of accidental injection of a veterinary biologic, and encourage such persons to seek immediate medical attention.

Non-Antibiotic Preservatives

We are proposing to amend the regulations in § 112.2(a)(10) to require labeling to indicate the presence of non-antibiotic preservatives (anti-infective substances) added during the preparation of veterinary biologics. Currently, the regulations only require labeling to disclose the presence of antibiotics added at preservative levels during the production process. Such disclosure may help to identify, and aid in testing for drug residues that may be present in the edible portions of food-producing animals that are treated with veterinary biologics. In addition to antibiotic preservatives, many veterinary biologics also may contain non-antibiotic preservatives that are added during the production process. Non-antibiotic preservatives also may cause residues in food, unfavorable reactions in animals, and/or environmental harm. The proposed amendment would treat non-antibiotic preservatives added during the production process the same as antibiotic preservatives, and require labeling disclosure. Antibiotic preservatives used in the reagents that are included in diagnostic test kits would be exempted from this labeling requirement because they are not administered to animals and would not be expected to cause food residues. The proposed amendment would ensure that all anti-infective substances with the potential to cause harm would be disclosed in labeling.

For Animal Use Only

We are proposing to amend the regulations in § 112.2(d)(3) to provide that carton labels and enclosures for veterinary biologics may bear the statement "For animal use only" in place of the statement "For veterinary use only." Currently, the regulations specify that veterinary biologics labeling may bear the statement "For veterinary use only" or an equivalent statement when referring to product that is recommended specifically for animals, and not for humans. However, "For veterinary use only" is often confused with the similar statement in the regulations, "Restricted to use by or under the direction of a veterinarian," which is required to be shown on labeling for products that have a restriction on the license specifying use by or under the direction of a veterinarian. Typically, special knowledge and/or expertise is not required when using veterinary biologics labeled for "animal use only," whereas professional training and/or knowledge may be required for proper use of veterinary biologics that are labeled "restricted to use by or under the direction of a veterinarian." For example, veterinary biologics for use in animal disease control and eradication and wildlife vaccination programs may be restricted to use by or under the direction of a veterinarian because of concern about disease spread and/or public health implications. The proposed amendment would help to clarify the distinction between product recommended for use in animals and product that should only be administered by or under the direction of a veterinarian.

Special Labels for Export

We are proposing to amend the regulations in § 112.2(e) pertaining to the approval of special labels for use on biological products to be exported to a foreign country to specify that when the labeling requirements of a foreign country conflict with the requirements prescribed in the regulations in 9 CFR part 112, such request for the approval of special labeling for use on product to be exported must be accompanied by a signed document issued by the appropriate regulatory official of the importing country that affirms the need for such special labeling in order to satisfy the country's regulatory requirements. As a condition for the approval, we would specify that such

special labeling may not contain false or misleading information. Currently, the regulations provide for the approval of special labels for use on biological products for export to a country in which labeling requirements conflict with the requirements of the United States; however, the regulations do not prescribe the requirements for obtaining approval of such special labeling. The proposed amendment would clarify the procedure for obtaining approval of special labeling for veterinary biological product for export.

Carton Tray Covers

We are proposing to amend the regulations in § 112.2(f) to specify that when carton tray covers are used to show required labeling information concerning veterinary biologics, all such information should appear on the outer face of the tray cover where it can be read without opening the carton. Currently, the use of carton tray covers to show required labeling information is not addressed under the regulations concerning packaging and labeling. However, carton tray covers have come to be extensively used in the packaging of diagnostic test kits. Frequently, such tray covers may be used for the presentation of required labeling information; and some firms have been placing required information on both the outer and inner faces of the tray covers. In such situations, information on the inner face of the tray cover cannot be read by the consumer because of its placement. The proposed change would ensure that required labeling information shown on carton tray covers is presented in a manner that is accessible to the consumer and consistent with the requirements in the regulations that pertain to other labeling media.

Minor Label Changes

We are proposing to amend the regulations in § 112.5(c)(2) to specify additional minor changes that may be made to labeling for products with approved labels or master labels without prior approval from APHIS. The minor label changes that may be made include changes to labeling background color that do not affect legibility of the label; changing the telephone number used to contact the licensee or permittee; changing or revising an e-mail or Web site address; changing the name and/or address of a distributor; or adding, revising, or repositioning universal product code bars or other inventory control numbers. Changes to the name and/or address of the licensee or permittee and changes to the Veterinary License Number or Veterinary Permit Number that are made pursuant to the reissuance of an Establishment License or Product Permit by APHIS also would be considered minor label changes. Currently, § 112.5 of the regulations specifies that labeling for veterinary biological product must be submitted to APHIS for review for compliance with the regulations and approval in writing prior to use. In § 112.5, paragraph (c) provides that certain minor changes may be made in labels for products with approved labels or master labels, and the revised labels may be used prior to review by APHIS if the specified requirements are met. In § 112.5, paragraph (c)(2) provides a listing of such minor changes that may be made to approved labels and master labels. The proposed amendment would specify additional minor changes to labeling that need not be submitted to APHIS for review and written approval prior to use and, thereby, help to reduce and/or eliminate marketing delays.

Submission of Labels

We are proposing to amend the regulations in §§ 112.5(d)(1)(iii) and (iv) and 103.3(d) to specify that only two copies of each finished final container label, carton label, enclosure, and experimental label should be submitted for APHIS review and approval. Currently, the regulations require three copies of each finished final container label, carton label, enclosure, and experimental label to be submitted. The third copy of labeling is no longer needed as the result of a restructuring of the Center for Veterinary Biologics.

Designation of Label Specimens

Currently, the regulations in § 112.5(d)(4) require that the reason for, and information relevant to, the submission of labels and sketches be added to the bottom of each page of label mounting sheets for the purpose of facilitating label review. The designations of label specimens are to be presented as:

- Master label dose sizes approved for code _____.
- Replacement for label, master label, and/or sketch No. _____.
- Reference to label or master label No. _____.
- Addition to label No. _____.
- License Application Pending _____.
- Foreign language copy of label No. _____.

We would amend paragraph (d)(4) of § 112.5 to make it clear that only the applicable designation or designations, and not all of them, need to appear at the bottom of the label mounting sheets. In addition, we would reduce the number of designations by combining some and eliminating others. Specifically, the specimen designations "Reference to label or master label No." and "Addition to label No." would be combined into a single "Refer to APHIS-assigned label number" designation, and the "License Application Pending" and "Foreign Language copy of Label No." designations would be removed. These proposed amendments would clarify the regulations with regard to specimen designation and facilitate a more efficient label submission and review process.

Foreign Language Labels

We are proposing to amend the regulations in § 112.5(e) pertaining to special requirements for foreign language labels to require that an accurate English translation be provided with all foreign language labeling submitted for review and approval. The proposal also would require that the foreign language text of multilingual labeling for a veterinary biological product distributed in the United States must be an accurate translation of the approved English text. Currently, the regulations in § 112.5(e)(1) and (e)(2) provide, respectively, that either the addition of a statement affirming the wording of the foreign language label to be a direct translation from a corresponding domestic label, or the submission of an English version of the foreign language label with an explanation for the difference in texts may be used to certify that foreign language text in labeling complies with the regulations. Under the proposed amendment, the option to either affirm the foreign language label to be a direct translation of an approved domestic label or explain the difference in the English and foreign language text would be removed from the regulations. Instead, all foreign language labels would be required to include an accurate English translation and a statement affirming the accuracy of such translation that APHIS would keep on file.

The presence of foreign language text in labeling for product intended for domestic distribution is not currently addressed in the regulations. However, foreign language text and its translation have become a domestic labeling issue due to the implementation of multilingual labeling by multinational firms that market globally and the fact that such foreign language text may not translate word for word into English. The proposed amendment would standardize the presentation of information in multilingual labeling and help to facilitate the timely resolution of

questions concerning approved labeling content.

Packaging Multiple-Dose Final Containers

We propose to amend the regulations in § 112.6(a) pertaining to the packaging of biological products by removing a requirement which specifies that multiple-dose final containers of veterinary biological products that require a diluent for administration must be packaged in an individual carton with a container of the proper volume of diluent for that dose. Currently, the regulations require multiple-dose containers of veterinary biologics to be packaged in individual containers in order to ensure that vaccine will be used within a reasonable time after reconstitution in order to prevent a significant loss of vaccine potency. This requirement was promulgated when much less was known about the stability of vaccines, and it was assumed that vaccine would lose potency after dilution faster than animals could be treated. However, advances in vaccine technology, improved husbandry practices, and new methods for administering vaccines have made the continued imposition of this requirement an unnecessary burden on the veterinary biologics industry.

Special Additional Requirements

Currently, the regulations in § 112.7 provide for labeling requirements that are "additional to" the labeling requirements prescribed elsewhere in 9 CFR part 112. These additional labeling requirements are only applicable to products that have characteristics which make the "special requirements" necessary. Paragraph (f) of § 112.7 requires that, unless otherwise authorized in a filed Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization to be given at an appropriate time interval. Similarly, paragraph (i) of that section has the special requirement that labels for feline panleukopenia vaccines shall include a recommendation for annual revaccination of cats.

Such recommendations for annual boosters and/or revaccination are predicated on the premise that the protective immunity achieved with the primary immunization diminishes with time and, in order to ensure continued protection, animals must be revaccinated; the typical recommendation is to revaccinate annually. Although all veterinary biologics must be shown to provide protective immunity prior to the issuance of a license, firms have not been required, except for rabies vaccines, to provide data to establish the duration of protective immunity and/or the need for and frequency of revaccination to maintain such immunity. Despite not having demonstrated that revaccination is needed, it is now common practice for veterinary biologics labeling to recommend annual booster vaccinations for most products. Consequently, for products that were licensed without duration of immunity data, the need for annual revaccination is uncertain, and may not benefit the animal under certain circumstances. In fact, annual revaccination may be harmful in some situations such as with administering feline panleukopenia vaccine to cats annually. Alternatively, it could be that optimal protection of the animal requires that booster vaccinations be administered more frequently that on an annual basis.

In the absence of data, it is difficult or impossible to prescribe the appropriate revaccination interval for the animal. Thus, we are proposing to amend § 112.7(f) to require annual booster (annual revaccination) recommendations in labeling to be supported by data acceptable to APHIS. If such data are not available, we 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." In keeping with the above proposed requirement that annual revaccination recommendations should be based on a demonstrated need for same, we would also amend § 112.7(i) by removing the recommendation for annual revaccination of cats with feline panleukopenia vaccine.

We are also proposing to amend § 112.7 to require that labeling for all modified live and inactivated vaccines for use in mammals bear an appropriate statement concerning the use of the product in pregnant animals. Currently, the regulations in § 112.7(e) require that labeling for (infectious) bovine rhinotracheitis (IBR) vaccine containing modified live virus bear the statement: "Do not use in pregnant cows or calves nursing pregnant cows" unless the vaccine has been shown to be safe for use in pregnant cows and has been exempted from the labeling requirement by the Administrator. The purpose of the warning statement concerning use in pregnant animals is to inform users of the risk to the developing fetus should pregnant cows be treated with or exposed to IBR vaccine containing modified live virus. We would extend the requirement for such a warning statement to bovine virus diarrhea vaccine (BVDV) containing modified live virus.

For IBR vaccine containing modified live virus and BVDV containing modified live virus, labeling would have to bear the statement "Do not use in pregnant animals or in calves nursing pregnant animals." However, the current exemption found in § 112.7(e) that states that a vaccine that has been shown by data acceptable to APHIS to be safe for use in pregnant animals may be exempted from this label requirement would remain. It should be noted that even when an exemption is granted, the label would still have to include a statement concerning residual risks, *i.e.:* "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."

In the case of other modified live and inactivated vaccines, we would require that the labeling bear a statement that is appropriate to the level of safety that has been demonstrated in pregnant animals. For example, a statement such as "Do not use in pregnant animals" or "Unsafe for use in pregnant animals" would be an appropriate statement for a product that scientific evidence has shown to be unsafe in pregnant animals. For products that do not have safety documentation acceptable to APHIS, but are not known to be unsafe, the labeling would have to include the statement "This product has not been evaluated for safety in pregnant animals" or an equivalent statement that is acceptable to APHIS.

The extension of such a warning statement to labeling for BVDV, and the proposal that both IBR vaccine and BVDV bear a residual risk statement concerning the reliability of data developed during limited clinical trials in pregnant animals would be new requirements. APHIS is proposing to require labeling for BVDV containing modified live virus to bear this warning in response to reports in the veterinary literature showing that vaccination and/or exposure of pregnant cows to BVDV represents a risk to the developing fetus similar to that of IBR vaccine containing modified live virus. In proposing to require labeling for vaccine for use in pregnant animals to bear a residual risk safety statement, APHIS is responding to concerns expressed within the veterinary community about vaccine

safety. The proposed amendment acknowledges the safety and risk considerations associated with vaccine use and would convey such considerations to consumers.

Currently, the regulations in § 112.7(l) require that all labels for autogenous biologics bear the 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," but there is no requirement for the label to identify the microorganism(s) used in the preparation of the product and the animal species for which the product is recommended. However, for all other veterinary biologics, the identity of the microorganism(s) and/or antigen(s) used in the preparation of the product and the species of animal for which it is intended are incorporated into the true name and indications for use statement shown in the labeling. We would amend § 112.7(l) to require that labeling for autogenous biologics identify the microorganism(s) used in its preparation, and the species for which it is prepared. This proposed change would standardize veterinary biologics labeling requirements across product categories.

The regulations in § 102.6(c) set forth the requirements for the issuance of conditional licenses. These requirements include a restriction which specifies that "Labeling for the [conditionally licensed] product may be required to contain information on the conditional status of the license." This restriction prescribes a special requirement applicable to labeling for conditionally licensed product, and therefore should be included in the packaging and labeling requirements specified in 9 CFR part 112. We would amend the regulations in § 112.7 by adding a new paragraph (o) to require that labeling for all conditionally licensed products must bear the statement, "This product license is conditional, efficacy and/or potency requirements have not been completed." This proposed requirement would ensure that consumers receive clear information regarding a product's conditionally licensed status.

If adopted, veterinary biologics manufacturers would have 3 years to bring all of their product labeling into compliance with the rule.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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.

For this proposed rule, we have prepared an economic analysis. The analysis, which is set out below, provides a cost-benefit analysis, as required by Executive Order 12866, as well as an initial regulatory flexibility analysis that considers the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq*.).

This proposed rule would amend 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 veterinary biologics 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 labeling for autogenous biologics to specify the microorganism(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, this proposed rule would amend 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 proposed amendments are necessary in order to update and clarify labeling requirements and ensure that information provided in labeling is accurate with regard to the expected performance of the product.

The proposed rule is not expected to have a significant economic impact on most veterinary biologics manufacturers. There are several reasons. First, most manufactures should be able to comply with the rule without having to acquire new labeling equipment or new supplies of labels; their existing equipment for generating labels, as well as their existing inventory of blank labels, should still be usable if the proposal is adopted. This is because the proposed rule primarily affects the type of information required to be shown on the label, not the volume of that information. Since any increase in the volume of information required on labels as a result of the rule should be small, most manufacturers should be able to continue using their existing label equipment and their existing inventory of blank labels. Even manufacturers' existing inventory of preprinted labels (based on the current label requirements) would still likely be usable under the proposal, since it would give manufacturers a total of 3 years to bring all their product labeling into compliance with the rule. It is very likely, therefore, that most or all manufacturers would be able to fully exhaust their existing inventories of preprinted labels before the new label requirements became effective.

Second, the new information that would be required on labels as a result of the rule is basic in nature and should be readily available from manufacturers' existing records; accordingly, manufacturers' cost of obtaining the new information should be negligible, at most.

Third, manufacturers' cost to prepare the new label prototypes (for submission to APHIS) should be minimal, since it is largely an exercise in label editing and formatting.

Finally, any cost increases stemming from the inclusion of the new information on labels should be minimal for most manufacturers.

Benefits of the Proposed Changes: The proposed rule has the potential to benefit consumers of veterinary biologic products (*e.g.,* farmers, veterinarians, and pet stores) and, ultimately, the animals they treat with those products. This is because it ensures that consumers have complete and up-to-date instructions for the proper use of those products, including vaccination schedules, warnings, and cautions. For animal owners, the monetary benefits are difficult to estimate, because they would depend on several factors that are currently unknown, *i.e.,* the significance, or gravity, of the harm to animals that would be avoided with the rule in effect, and the number, and value, of animals that would avoid harm with the rule in effect. For some animal owners, especially those with large numbers of high value animals, the

potential monetary benefits could be substantial.

Costs of the Proposed Changes: For the reasons discussed above, costs to comply with the rule should be minimal for most manufacturers.

Effects on Small Entities

The RFA requires agencies to evaluate the potential effects of their proposed and final rules on small entities. Section 603 of the RFA calls for an agency to prepare and make available for public comment an initial regulatory flexibility analysis describing the expected impact of a proposed rule on small entities, unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The following initial regulatory flexibility analysis is presented in order that the public may have the opportunity to offer comments on expected small-entity effects of the proposed rule.

The businesses most directly affected by the proposed rule are the approximately 125 U.S. veterinary biologics manufacturers, including permittees. We believe that all of these entities would be affected, as none is currently in full compliance with the proposed requirements on a voluntary basis. However, for the reasons stated above, the proposed rule is not expected to have a significant economic impact on most veterinary biologics manufacturers.

The size of the affected manufacturers is unknown. However, it is reasonable to assume that most are small in size, under the U.S. Small Business Administration's (SBA) standards (13 CFR 121.201). This assumption is based on composite data for providers of the same and similar services in the U.S. In 2002, there were 296 U.S. establishments in the North American Industry Classification System (NAICS) 325414, a classification comprised of establishments primarily engaged in manufacturing vaccines, toxoids, blood fractions, and culture media of plant or animal origin (except diagnostic). Of the 296 establishments, 285 (or 96 percent) had fewer than 500 employees, the SBA's small entity threshold for establishments in that NAICS category. Similarly, in 2002, there were 236 U.S. establishments in NAICS 325413, a classification comprised of establishments primarily engaged in manufacturing in-vitro diagnostic substances, including biological substances. Of the 236 establishments, 223 (or 95 percent) had fewer than 500 employees, the SBA's small entity threshold for establishments in NAICS 325413.[1]

The proposed rule has no mandatory reporting, recordkeeping, or other compliance requirements for biologic manufacturers, other than the requirement that noncompliant labels would need to be revised and submitted to APHIS for review and approval.

APHIS has not identified any relevant Federal rules which may duplicate, overlap, or conflict with this proposed rule.

Finally, the RFA requires agencies to describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities. One alternative would be to leave the regulations unchanged. Leaving the regulations unchanged would be unsatisfactory, because it would perpetuate the current situation, *i.e.,* one that does not provide full information to users of veterinary biologic products. Another alternative would be to require that manufacturers show less, or different, information on their labels. That alternative was rejected because APHIS considers the proposed label information to be of the type, and the minimum, necessary to accomplish the rule's objectives. A third alternative would be to require that manufacturers bring all their product labeling into compliance with the rule immediately, rather than 3 years after the rule becomes effective. This third alternative was unacceptable because it does not minimize the impact on manufacturers, especially those with an inventory of preprinted labels based on the current label requirements.

Notwithstanding the analysis above, APHIS invites public comment on the proposed rule's expected economic impact, including any comment on the impact for small entities.

Executive Order 12372

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies 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.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects

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.

Accordingly, we propose to amend 9 CFR parts 103, 112, and 114 as follows:

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

1. 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.

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

§ 103.3 Shipment of experimental biological products.

* * * * *

(d) 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. 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

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

[1] *Source:* U.S. Census Bureau (2002 Economic Census) and SBA.

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

4. Section 112.2 is amended as follows:

a. By revising paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(7), (a)(10), (d)(3), (e), and (f) to read as set forth below.

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

§ 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.

(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 only the VLN or VPN is required on container labels of interchangeable (non-critical) components of diagnostic kits.

(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:

(i) In the case of very small final container labels or carton, 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; and,

(ii) The true name or abbreviated true name, and product code number are not required on very small final container labels for interchangeable (non-critical) components of diagnostic kits.

* * * * *

(7) If the product is an injectable biological product, and/or if it contains viable or dangerous organisms or viruses, the following warning statements shall appear on the labeling as applicable:

(i) "Do not mix with other biological products, except as specified on this label."

(ii) "In the case of accidental human exposure, contact a physician or other health care provider."

(iii) "Inactivate all unused contents prior to disposal."

* * * * *

(10) In the case of a product that contains an antibiotic or non-antibiotic preservative that is added during 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. Labels for diagnostic test kits are exempt from the antibiotic statement, but must specify non-antibiotic preservatives.

* * * * *

(d) * * *

(3) The statement "For use in animals only" may appear on the carton labels and enclosures 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 conflict with 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 signed written certification from regulatory officials of the importing country that such labeling has been approved by those officials, provided that the labeling does not contain information which is false or misleading. 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 the Animal and Plant Health Inspection Service upon request of the licensee.

(f) Multiple-dose final containers of liquid biological product and carton tray covers showing required labeling information are subject to paragraphs (f)(1) and (f)(2) of this section, respectively.

(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 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 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.

* * * * *

5. 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 all unused contents prior to disposal."

* * * * *

6. Section 112.5 is amended as follows:

a. By revising paragraphs (c)(2)(ii), (c)(2)(v), (d)(1)(iii), (d)(1)(iv), (d)(4), and (e)(1) to read as set forth below and, at

the end of paragraph (c)(2)(vi), by removing the period and adding a semicolon in its place.

b. By adding new paragraphs (c)(2)(vii) through (c)(2)(x) to read as set forth below.

c. By removing paragraph (e)(2) and redesignating paragraph (e)(3) as paragraph (e)(2).

§ 112.5 Review and approval of labeling.

* * * * *

(c) * * *

(2) * * *

(ii) Changes in the color of label print or background, provided that such a change does 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 e-mail 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.

(d) * * *

(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 (d)(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 (d)(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.

(e) * * *

(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.

* * * * *

7. 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 whose final container labeling includes 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 (c)(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 in an individual carton with the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production.

* * * * *

8. Section 112.7 is amended as follows:

a. By redesignating paragraphs (a) through (m) as paragraphs (b) through (n), respectively, and by adding new paragraphs (a) and (o) to read as set forth below.

b. By revising newly redesignated paragraphs (f), (j), and (m) to read as set forth below.

c. In newly redesignated paragraph (g), by adding a new paragraph (g)(4) to read as set forth below.

§ 112.7 Special additional requirements.

* * * * *

(a) In the case of biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to APHIS. In the absence of data that establishes the need for annual booster vaccinations, 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."

* * * * *

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

(1) For bovine rhinotracheitis vaccine containing modified live virus and 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 animals or in calves nursing pregnant animals.": *Provided,* That such vaccine which has been shown to be safe for use in pregnant animals may be exempted from this label requirement by the Administrator. However, if an exemption is granted, the label must include 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."

(2) In the case of other modified live and inactivated vaccine, labeling shall bear a statement appropriate to the level of safety that has been demonstrated in pregnant animals, for example, either "Do not use in pregnant animals" or "Unsafe for use in pregnant animals" would be an appropriate statement for products known to be unsafe in pregnant animals. For those products without safety documentation acceptable to APHIS, but not known to be unsafe, labeling shall include the statement "This product has not been evaluated for safety in pregnant animals" or an equivalent statement acceptable to APHIS.

(g) * * *

(4) In the case of biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to

APHIS. In the absence of data establishing the need for annual booster vaccinations, labeling must bear the following statement: "The need for annual booster vaccination has not been established for this product; consultation with a veterinarian is recommended."

* * * * *

(j) 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 at 12 to 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 at 12 to 16 weeks of age.

* * * * *

(m) 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."

* * * * *

(o) 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 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

9. 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.

10. 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 7th day of January 2011.

John Ferrell,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2011–648 Filed 1–12–11; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150—AI89

[NRC–2011–0002]

List of Approved Spent Fuel Storage Casks: NUHOMS® HD System Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its spent fuel storage cask regulations by revising the Transnuclear, Inc. (TN) NUHOMS® HD System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 1 to Certificate of Compliance (CoC) Number 1030. Amendment No. 1 would revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from −20 °F to −21 °F; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of nitrogen for draining the water from the dry shielded canister (DSC), and allow only helium as a cover gas during DSC cavity water removal operations; and make corresponding changes to the technical specifications (TS).

DATES: Comments on the proposed rule must be received on or before February 14, 2011.

ADDRESSES: Please include Docket ID NRC–2011–0002 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0002. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668, e-mail: *Carol.Gallager@nrc.gov.*

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1677.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (Telephone 301–415–1677).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

FOR FURTHER INFORMATION CONTACT: Gregory Trussell, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6445, e-mail: *Gregory.Trussell@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal Rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have