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 Part 112

[Docket No. 96–034–1]

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 regulations concerning packaging and labeling of veterinary biological products by requiring the Animal and Plant Health Inspection Service product code number as well as an appropriate consumer contact telephone number to appear on labeling. The amendments would also clarify label requirements with respect to overshadowing the true name of the product and requirements for products shipped to a foreign country. In addition, this proposal contains label requirements concerning minimum age for product administration and the potential for maternal antibody interference. The effect of the proposed rule would be to update the regulations by providing additional information to users of veterinary biologics and to make regulatory labeling provisions more consistent with current practices.

DATES: Consideration will be given only to comments received on or before May 17, 1999.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–034–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 96–034–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Special Assistant to the Deputy Administrator, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 112 set forth packaging and labeling requirements for veterinary biological products. To make the regulations more consistent with current practices and provide for more completeness and uniformity in label instructions, we are proposing to require the Animal and Plant Health Inspection Service (APHIS) product code number and a consumer contact telephone number to appear on labeling, clarify label requirements with respect to overshadowing of the true name of the product, clarify label requirements for product shipped to a foreign country, and provide requirements for addressing minimum age for product administration and the potential for maternal antibody interference with vaccination.

Product Code Number and Consumer Contact Telephone Number

Section 112.2 includes requirements relating to product identification. According to this section, labeling must include the true name of the product, the producer's name and address (and the name and address of the permittee in the case of an imported product), the license or permit number associated with the domestic producer or permittee, and a serial number. Although this information is normally sufficient to uniquely identify a particular serial of a particular product, in some instances it may not be. Because two or more products of the same manufacturer may have the same true name, and the same serial number may be applied to a serial of each of these products, the current label regulations allow for serials of different products, and the products themselves, to be undifferentiable.

Administratively, APHIS uniquely identifies a product serial by serial number, license (or permit) number, and product code number (PCN). The PCN is a number APHIS assigns a product when a license application for the product is received and sufficient information on the product is provided. The PCN is unique for the product and its manufacturer—a given manufacturer has no more than one product with a particular PCN. The combination of PCN, license or permit number, and serial number provides a unique identification for any serial of any product. Accurate serial identification is essential to the proper reporting and handling of adverse events with veterinary biologicals. To ensure accurate serial identification, we propose to amend the regulations in § 112.2(a) to require that all labeling, except final container labels for diagnostic test kits, bear the PCN that APHIS assigned to the product. An exception is made for container labels for diagnostic kits because they are associated with components that often are common to several kits of the manufacturer and that are very unlikely to become separated from the kit as packaged (the carton label as well as the enclosure, if one is used, must carry the PCN).

Further on the subject of adverse events, APHIS believes it would be in the best interest of consumers and industry if the reporting of adverse events could be facilitated. To this end, we propose to amend § 112.2(a)(2) by requiring that an appropriate consumer contact telephone number appear on all labeling.

Overshadowing of the True Name

Section 112.2(c) currently states that veterinary biological product labels ''shall not include any statement, design, or device, which overshadows the true name of the product * * *'' In approving labels, APHIS requires that the true name be presented prominently and in a manner that renders it no less conspicuous than any trade name that may be used. Since questions have occasionally arisen concerning the interpretation of § 112.2(c), we propose to amend the section by requiring that labels bear the true name of the product in a prominent fashion and not bear any trade name more prominently than the true name.

Product Shipped to a Foreign Country

The first sentence of § 112.2(e) provides that labels which do not conform to part 112 requirements may

be approved for use with product shipped to a foreign country only if the label requirements of the foreign country conflict with those of this country. In APHIS' view, it does not appear that this limitation is necessary to properly regulate biological products. Therefore, we propose to amend § 112.2(e) by specifying that labels which do not conform to all part 112 requirements may be used with exported product as long as they are acceptable to the appropriate regulatory officials of the foreign country and do not contain false or misleading information. In addition, we propose to amend § 112.2(e) by specifying how the licensee or permittee should make APHIS aware that foreign regulatory acceptance of a nonconforming label has been received, namely, through the submission of a label mounting prepared as described in § 112.5(d)(2) and bearing a stamp or other mark of approval of the appropriate foreign regulatory agency.

Minimum Age and Maternal Antibody Interference

Section 112.2(a)(5) states that full instructions for the proper use of a product must appear on product labeling. APHIS believes that for all relevant product types, these instructions should include directions relating to the minimum age for product administration that are consistent with the efficacy and safety data developed for the product and that take into account the potential for maternal antibody interference with product efficacy. Currently, except for specific label regulations for rabies vaccines and feline panleukopenia vaccines, the label regulations provide no directive on how to address minimum age for administration. This has resulted in significant inconsistency in label recommendations, with the potential for product misuse. We propose to amend § 112.7(i) by replacing the current special label requirements, which cover only feline panleukopenia vaccines, with general label requirements regarding the minimum age for product administration as well as the potential for maternal antibody interference with vaccination. We propose to indicate that unless otherwise provided in the regulations or in a filed Outline of Production for the product, labels for vaccines, bacterins, bacterial extracts, toxoids, and combinations thereof, as well as immunomodulators, must specify a minimum age for product administration consistent with the efficacy and safety data developed for the product. Labels for products for the vaccination of dams to protect progeny need not specify a minimum age if it is clear from other label recommendations that animals are to be of breeding age when vaccinated. Furthermore, we propose that if a vaccine, bacterin, bacterial extract, toxoid, or combination thereof is recommended for use in animals of an age when maternal antibodies would be expected to cause interference [defined by proposed § 112.7(i) as less than 12 weeks of age in the case of canine and feline products (17 weeks in the case of canine parvovirus vaccines), 3 months of age in the case of products for other mammalian species, or 3 weeks of age in the case of products for avian species (except Marek's disease vaccines)], labels must recommend revaccination at appropriate intervals through the applicable age. If two doses of product are required for primary immunization, labels must indicate that two doses are to be given after the applicable age. The above revaccination recommendation will not be required for labels for products intended for the prevention or alleviation of diseases that are considered afflictions of only very young animals, for products where maternal antibodies do not interfere with efficacy, or for products where traditional U.S. animal industry practice is clearly inconsistent with such a recommendation. Such products include, but are not limited to, those for rotaviral and coronaviral enteritis, mammalian colibacillosis, and atrophic rhinitis in swine.

We believe our proposed rule will provide the consumer with more uniform and complete label instructions for product use without being overly burdensome to the veterinary biologics industry.

Executive Order 12866 and Regulatory Flexibility Act

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

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small businesses and governmental jurisdictions. The proposed rule changes would primarily affect manufacturers of veterinary biological products. At this time, there are no more than about 100 such manufacturers in the U.S. The number of those manufacturers that are considered small entities under the standards of the Small Business Administration (SBA) is unknown, since information as to their size (in terms of number of employees) is not available. However, based on composite data for manufacturers of the same and similar products in the U.S., it is reasonable to assume that most would be categorized as small entities. In 1993, only 25 percent of all 652 firms in standard industrial classification (SIC) category 2834 (SIC 2834; ''Pharmaceutical Preparations,'' which includes manufacturers of preparations for veterinary use) had 100 or more employees. Similarly, only 25 percent of all 205 firms in SIC 2836 (''Biological Products, Except Diagnostic Substances,'' which includes manufacturers of products for veterinary use) had 100 or more employees in 1993. According to SBA criteria, a business in SIC 2836 is considered a small entity if it has 500 or fewer employees, and a business in SIC 2834 is considered a small entity if it has 750 or fewer employees. It is very likely, therefore, that the potential impact of the proposed rule would fall primarily on small entities.

The proposal which would require the APHIS product code number and an appropriate consumer contact telephone number to appear on labels should result in easier and more accurate reporting of adverse events. This should be viewed positively by consumers and the veterinary biologics industry.

The proposal regarding labels for product shipped to a foreign country and overshadowing of the true name would amend the regulations by providing for the use of nonconforming labels with product shipped to a foreign country even if the label requirements of the foreign country do not conflict with ours and by specifying that the true name be prominent and that any trade name that may be used not appear more prominent than the true name. Since the proposed requirements would be less restrictive than the requirements currently in place, the economic impact of the proposal on veterinary biologics manufacturers should be positive.

The proposal regarding the requirement that a minimum age be specified for product administration should provide consumers with more uniform and precise information concerning use of these products to ensure safety and efficacy. Furthermore, the Agency does not intend to require that, for currently licensed mammalian products other than swine products, the minimum recommended age for administration be supported by efficacy and safety data from controlled laboratory studies or formal field trials as long as the age recommended is not less than 9 weeks for canine and feline products or 3 months for products for

other species (data to support the recommended minimum age for vaccination have been required for avian and swine products for many years). With this allowance, we believe the impact of the proposed rule on veterinary biologics manufacturers involved should be negligible.

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

Executive Order 12372

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 96–034–1. Please send a copy of your comments to: (1) Docket No. 96–034–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

If these proposed amendments to the regulations are adopted, manufacturers of veterinary biological products currently licensed would need to revise labels not in conformance and, in accordance with 9 CFR 112.5, submit the revised labels to APHIS for review and approval. Labels must be submitted with a transmittal form (APHIS Form 2015 or similar; one form for all labels submitted on the same date for the same product). Adopting the proposed amendments would constitute a one-time paperwork burden (viz., completion of transmittal forms) for manufacturers of currently licensed products with labels that are not in conformance.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. We need this outside input to help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average .12 hour per response.

Respondents: Veterinary Biologics Licensees and Permittees.

Estimated number of respondents: 88.

Estimated number of responses per respondent: 42.

Estimated number of responses: 3,696.

Estimated total burden on respondents: 444 hours.

Copies of this information collection can be obtained from: Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

List of Subjects in 9 CFR Part 112

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

Accordingly, we propose to amend 9 CFR part 112 as follows:

PART 112—PACKAGING AND LABELING

1. The authority citation for part 112 would continue to read as follows:

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

2. In § 112.2, paragraph (a)(2), paragraph (c), and the first sentence of paragraph (e) would be revised to read as follows:

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

(a) * * *

(1) * * *

(2) The Product Code Number and an appropriate consumer contact telephone number (except for container labels for diagnostic test kits); and, if the biological product is prepared in the United States, the name and address of the manufacturer (licensee or subsidiary) or, if the product is prepared in a foreign country, the name and address of the permittee and of the foreign manufacturer.

* * * * *

(c) Labels shall bear the true name of the product in a prominent fashion and not bear any trade name more prominently than the true name. Labels shall not bear anything that is false or misleading or that may otherwise deceive the purchaser.

* * * * *

(e) For product shipped to a foreign country, labels that do not bear false or misleading information but that do not otherwise conform to the regulations in this part may be approved for use if evidence of acceptability to the foreign country is provided. This evidence shall consist of a label mounting prepared as described in § 112.5(d)(2) and bearing the stamp or other mark of approval of the appropriate foreign regulatory agency. * * *

* * * * *

3. In § 112.7, paragraph (i) would be revised to read as follows:

§ 112.7 Special additional requirements.

* * * * *

(i) Unless otherwise provided in the regulations or in the filed Outline of Production for the product:

(1) Labels for vaccines, bacterins, bacterial extracts, toxoids, and combinations thereof, as well as immunomodulators, shall specify a minimum age for product administration consistent with the efficacy and safety data developed for the product: *Provided,* That, labels for products for administration to dams to protect progeny need not specify a minimum age if it is clear from other

label recommendations that the animals are to be of breeding age when treated.

(2) Labels for vaccines, bacterins, bacterial extracts, toxoids, and bacterin-toxoids which recommend product use in animals younger than 12 weeks of age in the case of canine and feline products (17 weeks in the case of canine parvovirus vaccine), or 3 months of age in the case of products for other mammalian species, must also recommend revaccination at intervals of 2–3 weeks through the applicable age (viz., 12 weeks, 17 weeks, or 3 months). In the case of avian products (except Marek's disease vaccines) recommended for use in birds under 2 weeks of age, revaccination at 3 weeks of age shall be recommended. If two doses of product are required for primary immunization, labels shall recommend that two doses be given after the applicable age (viz., 12 weeks, 17 weeks, 3 months, or 3 weeks). The revaccination recommendation is not required for labels for products intended for the prevention or alleviation of diseases that are considered afflictions of only very young animals, for products where maternal antibodies do not interfere with efficacy, or for products where traditional U.S. animal industry practice is clearly inconsistent with such a recommendation. Such products include, but are not limited to, those for rotaviral and coronaviral enteritis, mammalian colibacillosis, and atrophic rhinitis in swine.

* * * * *

Done in Washington, DC, this 12th day of March 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–6593 Filed 3–17–99;8:45am]

BILLLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

Public Meeting on Part 70 Rulemaking Activities

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of meeting.

SUMMARY: NRC will host a public meeting in Rockville, Maryland with representatives of the Nuclear Energy Institute (NEI) to discuss the NRC staff's proposed revisions to 10 CFR Part 70, Domestic Licensing of Special Nuclear Material.''

PURPOSE: This meeting will provide an opportunity to discuss any remaining, unresolved, industry or public comments on the staff's draft rule language prior to submitting the proposed rule to the Commission requesting approval to publish for public comments. In addition, it will provide an opportunity to discuss the NRC staff's evaluation of and approaches for resolving the public comments on the draft standard review plan.

DATES: The meeting is scheduled for Tuesday through Wednesday, March 23–24, 1999 from 9:30 am to 4:00 pm. The meeting is open to the public.

ADDRESSES: NRC's Licensing Board Hearing Room at Two White Flint North, Room 3B45, 11545 Rockville Pike, Rockville, Maryland. Visitor parking around the NRC building is limited; however, the meeting site is located adjacent to the White Flint Station on the Metro Red Line.

FOR FURTHER INFORMATION CONTACT: Theodore S. Sherr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415–7218, e-mail: *tss@nrc.gov*.

Dated at Rockville, Maryland this 15th day of March, 1999.

For the Nuclear Regulatory Commission.

Theodore S. Sherr,

Chief, Regulatory and International Safeguards Branch, Division of Fuel Cycle Safety and Safeguards.

[FR Doc. 99–6585 Filed 3–17–99; 8:45am]

BILLING CODE 7590–01–P

FEDERAL TRADE COMMISSION

16 CFR Part 241

Request for Comment Concerning Guides for the Dog and Cat Food Industry

AGENCY: Federal Trade Commission.

ACTION: Request for public comment.

SUMMARY: The Federal Trade Commission (''Commission'') requests public comment on the overall costs and benefits and the continuing need for its Guides for the Dog and Cat Food Industry (''the Dog and Cat Food Guides'' or ''the Guides''), as part of the Commission's systematic review of all current Commission regulations and guides.

DATES: Written comments will be accepted until May 17, 1999.

ADDRESSES: Mailed comments should be directed to: Secretary, Federal Trade Commission, Room H–159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Mailed comments should be identified as ''Dog and Cat Food Guides, 16 CFR Part 241—Comment.'' E-mail comments will be accepted at [petfood@ftc.gov]. Those who comment by e-mail should give a mailing address to which an acknowledgment can be sent.

FOR FURTHER INFORMATION CONTACT: Jock K. Chung, Attorney, Federal Trade Commission, Washington, DC 20580, telephone number (202) 326–2984.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission promulgated the Dog and Cat Food Guides on February 28, 1969, 34 FR 3619 (1969), under section 5 of the Federal Trade Commission Act (''FTC Act''), 15 U.S.C. 45.[1]

The Guides cover food for dogs or cats, including dry, semimoist, frozen, canned, and other commercial foods manufactured or marketed for consumption by domesticated dogs or cats, as well as special candy for dogs and cats, but not animal medicines or remedies. The Guides apply to any person, firm, corporation, or organization engaged in the importation, manufacture, sale or distribution of dog or cat food. In summary, the Dog and Cat Food Guides advise against:

(1) Misrepresenting dog or cat food in any material respect; for example, misrepresenting the composition, form, suitability, quality, color, flavor of any dog or cat food; misrepresenting that any dog or cat food meets the dietary or nutritional needs of dogs and cats; or misrepresenting that any dog or cat food will provide medicinal or therapeutic benefits;

(2) Misrepresenting that any dog or cat food is fit for human consumption or has been made under the same sanitary conditions as food for humans;

(3) Misrepresenting the processing methods used in the manufacture or processing of any dog or cat food;

(4) Making false statements about the conduct of competitors or about the quality of competitors' products;

(5) misrepresenting the length of time a dog or cat food company has been in business, its rank in the industry, or that it owns laboratory or other testing facilities;

(6) using deceptive endorsements or testimonials, or deceptively claiming that any dog or cat food has received an award;

(7) offering for sale any dog or cat food when the offer is not a bona fide effort to sell the product so offered as advertised and at the advertised price;

[1] Section 5 of the FTC Act declares unfair methods of competition and unfair or deceptive acts or practices to be unlawful.