§ 301.27 Label and method of affixing.

At all times during the marketing of a fur product the required label shall have a minimum dimension of one and three-fourths (1¾) inches by two and three-fourths (2¾) inches (4.5 cm×7 cm). Such label shall be of a material of sufficient durability and shall be conspicuously affixed to the product in a secure manner and with sufficient permanency to remain thereon throughout the sale, resale, distribution and handling incident thereto, and shall remain on or be firmly affixed to the respective product when sold and delivered to the purchaser and purchaser-consumer thereof.

6. Section 301.43 is revised to read as follows:

§ 301.43 Use of deceptive trade or corporate names, trademarks or graphic representations prohibited.

No person shall use in labeling, invoicing or advertising any fur or fur product a trade name, corporate name, trademark or other trade designation or graphic representation which misrepresents directly or by implication to purchasers, prospective purchasers or the consuming public:

(a) The character of the product including method of construction;

(b) The name of the animal producing the fur;

(c) The method or manner of distribution; or

(d) The geographical or zoological origin of the fur.

By the direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–32259 Filed 12–23–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0094]

Uniform Compliance Date For Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing January 1, 1998, as its new uniform compliance date for all food labeling regulations that are issued after the publication of this final rule and before January 1, 1997. FDA has periodically announced uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. In 1992, FDA suspended this practice pending the issuance of regulations implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). With the adoption and implementation of those regulations, FDA is reinstating its previous practice of periodically announcing, as final rules, uniform compliance dates for food labeling regulations.

EFFECTIVE DATE: December 24, 1996.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 15, 1996 (61 FR 16422), FDA published a notice of proposed rulemaking entitled ''Uniform Compliance Date for Food Labeling Regulations'' (hereinafter referred to as the compliance date proposal) to establish a new uniform compliance date of January 1, 1998. FDA proposed that the new uniform compliance date would apply to all FDA regulations issued after publication of a final rule to the rulemaking and before December 31, 1996, that require changes in food labels or labeling, except where special circumstances require a different compliance date. The agency also proposed to reinstate its previous practice of periodically announcing uniform compliance dates for food labeling regulations by final rule. Interested persons were given until July 1, 1996, to comment.

FDA received five letters, each containing one or more comments, from trade associations and other representatives of the food industry, in response to the compliance date proposal. All of the comments supported the proposal generally. Some comments suggested modifications or revisions of aspects of the compliance date proposal. A summary of these comments and the agency's responses are provided below.

II. Comments

A. Uniform Compliance Date

1. Four comments opposed establishing January 1, 1998, as the next uniform compliance date on the grounds that it resulted in a ''compliance period'' that at its shortest possible length would be only 12 months long. The comments used the term ''compliance period'' to refer to the time interval between the publication of a final rule and the uniform compliance date; e.g., a final rule that publishes on December 30, 1996, would have a ''compliance period'' of just over 12 months before the January 1, 1998, uniform compliance date. Two of the comments suggested that the compliance period should be a minimum of 18 months and applicable to products labeled on or after the compliance date. One of these comments stated that the 18-month period for the final rules implementing the 1990 amendments provided sufficient time for manufacturers to process the required label changes such that incremental costs were minimized.

One of the comments stated that 2 years would be more appropriate if FDA insists on having the compliance date apply to the initial date of introduction of the food product into interstate commerce. This latter comment supported its arguments by including with its submission information on the costs of complying with the proposals to implement the 1990 amendments that it had developed and submitted as comments in response to FDA's ''Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations,'' which published in the Federal Register of November 27, 1991 (56 FR 60856). The comment noted that the evidence submitted had persuaded FDA to establish a compliance period of 18 months for those regulations. The other two comments also suggested a 2-year compliance period. One of the comments argued that 1 year does not provide manufacturers with sufficient time to manage and exhaust existing label inventories. The comment stated that it anticipated that most manufacturers would be forced to request an extension of the uniform compliance date if FDA's final rule provided only a 12-month compliance period.

FDA disagrees with the comments. A compliance period that is 18 months or 2 years at its shortest is too long.

The agency points out that the comments are primarily concerned with the minimum time that a firm might face in bringing its labeling into compliance if a labeling final regulation were to publish at the end of a compliance period cycle, e.g., December 30, 1996. Manufacturers would have 1 year and 1 day to comply with the January 1, 1998, effective date. It is this time period that the comments claim is inadequate.

However, in establishing the uniform compliance date, FDA must consider the costs and benefits to both the food producer and the consumer. That is why

the agency did not choose a minimum compliance period of only 6 months. A compliance period of 6 months would increase the benefit to the consumer but would result in an even greater cost to the food producers than caused by a compliance period of 12 months. Although a lengthier compliance period would reduce the cost to food producers, it would delay implementation of the labeling changes thus decreasing the value of any benefits to the consumer.

The agency points out that the minimum compliance period of 1 year is the same compliance period that it used for all of its uniform effective date final rules, dating back to the 1970's, until it issued the labeling regulations that implemented the 1990 amendments. The agency is unaware, nor has anyone submitted, any information to demonstrate any problems with respect to bringing labels into compliance with the various uniform effective dates that it had established over the period of approximately 20 years during which it had announced uniform compliance dates. While there were instances in which the agency granted extensions beyond the uniform compliance date, generally firms came into compliance with little complaint to the agency. The agency is merely, as it proposed, reinstating its former practice.

The agency acknowledges that an 18-month compliance period was given for the labeling final rules implementing the 1990 amendments. However, the agency points out that additional time was necessary in that instance because of the extensive changes being made in the labeling requirements, the complicated nature of those changes, and the fact that the changes affected the entire food industry. Future food labeling regulations promulgated by FDA will not likely be as complicated or as comprehensive. If such a situation were to arise, the agency can and will adjust the compliance period to fit that particular situation.

FDA recognizes that some manufacturers believe that a 12-month compliance period for a particular regulation might create an economic hardship. The agency points out that any final rule that it promulgates is preceded by a proposal setting forth the labeling changes the agency intends to require. The proposal, as a general rule, precedes the final rule by a year or more and, therefore, gives manufacturers more than ample notice that they should start thinking about how they will respond if the changes are finalized.

Finally, the agency reiterates its statement in the proposal concerning its willingness to consider comments (to a particular labeling proposal) as to why a particular labeling regulation should not be subject to the uniform compliance date and modify the effective date for an individual regulation accordingly.

B. Applicability of Compliance Date

2. One comment urged that FDA make clear in its final rule the basis for the uniform compliance date, i.e., whether the uniform compliance date would apply to products labeled on or after the compliance date or to products introduced into interstate commerce on or after the compliance date. The comment stated that, if the compliance date applied to products labeled on or after that date, 18 months would be adequate as the minimum compliance period. If, however, the compliance date applies to the initial date of introduction of the product into interstate commerce, the comment recommended that FDA establish the uniform compliance date as being no shorter than 2 years after any such labeling regulations are published as final rules. The comment argued that 2 years would provide an adequate opportunity for many food processors, especially those who manufacture seasonal products, to exhaust remaining label and package inventories before they would be required to introduce products with new labels and packages into interstate commerce.

The agency advises that the uniform compliance date will apply to food products initially introduced into interstate commerce on or after that date. FDA does not agree with the suggestion that the compliance date be tied to the date that products are labeled. The agency has for many years used the date of initial introduction into interstate commerce as the effective date for compliance with regulations because the Federal Food, Drug, and Cosmetic Act (the act) applies to products when they are introduced or delivered for introduction into interstate commerce. Using the date of initial introduction into interstate commerce is a more efficient enforcement approach because this date is easier for FDA to determine (e.g., from shipping documents) than the date the food was labeled (e.g., from manufacturers' records that are not necessarily available to the agency). An exception to this approach was in the case of the 1990 amendments that established the effective date as the date on which the label was applied to the food (see section 10(a)(2) of the 1990 amendments). However, there is no indication in the 1990 amendments or in their legislative history that Congress intended this exception to change the approach to effective dates for labeling changes that the agency has traditionally used.

C. Safe Harbors

3. One comment, which stated that the compliance date should apply to the date the food product is packaged, requested that the agency provide ''safe harbors'' for companies to follow in determining when their products will have been considered to have been introduced into interstate commerce if the agency concludes that the uniform effective date should be applicable to the initial introduction of a food product into interstate commerce. The comment stated that doing so would provide companies some assistance in coordinating label changes and in minimizing their costs.

FDA presumes that the comment concerning ''safe harbor'' is asking FDA to define what is meant by ''initial introduction into interstate commerce.'' In other words, the comment is asking FDA to advise what a firm has to do to initially introduce a product into interstate commerce before a new uniform compliance date so that the product would not be subject to the requirements that become effective on the new uniform compliance date. FDA is concerned that an attempt to provide a detailed discussion of all instances that are considered or are not considered to represent ''initial introduction into interstate commerce'' would be incomplete and, therefore, misleading. A clear understanding of this term is available from the act and the applicable case law. Thus, FDA is not defining ''initial introduction into interstate commerce'' in this final rule.

D. Harmonious Uniform Compliance Date for U.S. Department of Agriculture (USDA)–FDA Food Labeling Regulations

4. One comment urged that FDA work with USDA–Food Safety and Inspection Service to establish a harmonious uniform compliance date for all food labeling regulations.

FDA agrees to the extent both agencies are issuing regulations that will affect similar foods or address similar concerns, it would be best for FDA and USDA to have a consistent uniform compliance date. However, FDA does not agree that it is necessary as part of this rulemaking to ''establish a harmonious uniform compliance date for all food labeling regulations'' issued by the two agencies. Where it is appropriate, FDA works with USDA to coordinate, to the extent possible, the issuance of food labeling regulations. For example, in issuing regulations on

the nutrition labeling of foods, FDA and USDA coordinated the publication of proposals and final rules, including consideration of the best approaches for each to use to address specific issues, such as the nutrition facts format and the wording of nutrient content claims. However, even then, because of differences between the two agencies and their authorities, there were slight differences in the effective dates for their respective final rules concerning nutrition labeling.

Moreover, to establish harmonious compliance dates as suggested by the comment would require a separate rulemaking on the part of USDA, which would act to delay final action on this rulemaking. Therefore, FDA concludes that it is not necessary or appropriate at this time for FDA and USDA to establish a harmonious uniform compliance date for their labeling regulations. FDA notes that comments on future FDA or USDA proposals are free to urge consistent effective dates as they consider appropriate.

E. Establishment of Future Uniform Compliance Dates

5. Three of the comments specifically supported the agency's returning to its practice of periodically establishing uniform compliance dates and doing so as final rules without providing an opportunity for public comment. No comments were opposed.

Having received only favorable comments that it reinstate this practice, FDA is announcing that it will establish future uniform compliance dates for its food labeling regulations under the provisions of § 10.40(e)(1) (21 CFR 10.40(e)(1)). Section 10.40(e)(1) does provide for the submission of comments to the final rule. FDA will publish before December 31, 1996, a final rule establishing the next uniform compliance date of January 1, 2000, for all final regulations published in the Federal Register between January 1, 1997, and December 31, 1998. After that, every other year, FDA will publish additional final rules to establish subsequent uniform compliance dates.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the economic implications of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 606–612). Executive Order 12866 directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of conditions, including having an annual effect on the economy of $100 million, or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the impact of that rule on small entities.

Four of the comments stated that a uniform compliance date that provided a minimum compliance period of 12 months would have a substantial financial impact on the food industry.

This final rule will potentially reduce costs by providing a uniform compliance date that will provide firms with the opportunity to combine required label changes in one label redesign effort rather than potentially suffering from sequential, duplicative efforts. Alternative approaches that FDA considered included setting a uniform compliance date such that firms have either more or less time to comply with labeling regulations. In general, providing a minimum compliance period of 2 years would be half as expensive as the proposed compliance date but would delay implementation of labeling changes, thus decreasing the value of any benefits. A minimum compliance period of 6 months, although providing earlier labeling changes that would increase the value of the benefits, would be twice as expensive as the proposed 1 year.

For future labeling requirements, FDA will assess the costs and benefits of the uniform compliance date as well as the options of setting alternative dates, especially with regard to the impact on small entities. Because the establishment of a uniform compliance date imposes neither costs nor benefits, the agency certifies that the final rule is not a significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act that the final rule will not have a significant economic impact on a substantial number of small entities. Similarly, FDA has determined that this rule is not a major rule for the purpose of Congressional review (Pub. L. 104–121).

V. Conclusion

Having considered all comments to the proposal on this matter, the agency has decided that a new uniform compliance date of January 1, 1998, should be established for future FDA regulations requiring changes in food labels where special circumstances do not justify a different compliance date. The agency has selected January 1, 1998, to ensure adequate time for implementation of the pending changes in food labeling.

The agency generally encourages industry to comply with new labeling regulations as quickly as is feasible, however. Thus, when industry members voluntarily change their labels, it is appropriate that they incorporate any new requirements that have been published as final regulations up to that time.

The new uniform compliance date will apply only to final FDA food labeling regulations published before January 1, 1997. Those regulations will specifically identify January 1, 1998, as their compliance date. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 1998, the agency will determine for that regulation an appropriate compliance date that will be specified when the regulation is published.

This final rule is not intended to change existing requirements for compliance dates that have been set in final rules. Therefore, all final FDA regulations that have published in the Federal Register but that are not yet effective and that have effective dates other than January 1, 1998, will still go into effect on the date stated in the respective final rule.

FDA is making this document effective upon publication because of the short time to January 1, 1997.

In the absence of comments to the contrary and following publication of this final rule, FDA will return to its former practice of establishing uniform compliance dates through issuance of a final rule without the opportunity for comment. Thus, for example, on or before December 31, 1996, FDA will issue a final rule establishing January 1, 2000, as the uniform compliance date for regulations published in the Federal Register between January 1, 1997, and December 31, 1998. Subsequently, on or before December 31, 1998, FDA will issue a final rule establishing January 1, 2002, as the uniform compliance date for regulations published in the Federal

Register between January 1, 1999, and December 31, 2000.

Dated: December 13, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–32552 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of tylosin Type A medicated articles to make Type C medicated swine feeds for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

EFFECTIVE DATE: December 24, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 12–491, which provides for use of 40 and 100 grams per pound (g/lb) tylosin Type A medicated articles to make 100 g/ton tylosin Type C medicated feeds to be fed for 21 days for the prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*. The supplemental NADA is approved as of November 8, 1996, and the regulations are amended by adding new 21 CFR 558.625(f)(1)(vi)(*e*) to reflect the approval.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning November 8, 1996, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.625 is amended by adding new paragraph (f)(1)(vi)(*e*) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(1) * * *

(vi) * * *

(*e*) (1) *Indications for use*. Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

(2) *Limitations*. As tylosin phosphate, administer for 21 days.

Dated: December 5, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–32549 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 884

[Docket No. 95N–0139]

Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying scented or scented deodorized menstrual pads from class II into class I based on new information respecting such device. FDA is also exempting this device, and one already classified generic type of class I device, unscented menstrual pads, from the requirement of premarket notification, with limitations. FDA has determined that manufacturers' submissions of premarket notifications for these devices are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. These exemptions allow the agency to make better use of its resources and thus better serve the public.

DATES: Effective February 24, 1997. Beginning on February 24, 1997, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category that is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 28, 1995 (60 FR 38902), FDA issued a proposed rule to reclassify 112 generic types of class II devices into class I based on new information respecting such devices and to exempt the 112 generic types of devices, and 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. Interested persons were given until October 11, 1995, to comment on the proposed rule.

In the Federal Register of January 16, 1996 (61 FR 1117), FDA issued a final rule reclassifying 111 of the 112 generic