

accuracy and completeness of the information and submit the form electronically. After refreshing the page, the system will automatically issue a steel import license number. The refreshed form containing the submitted information and the newly issued license number will appear on the screen (the "license form"). Filers can print the license form themselves only at that time. For security purposes, users will not be able to retrieve licenses themselves from the license system at a later date for reprinting. If needed, copies of completed license forms can be requested from Commerce during normal business hours.

(d) *Duration of the steel import license.* The steel import license can be applied for up to 60 days prior to the expected date of importation and until the date of filing of the entry summary documents, or in the case of FTZ entries, the filing of Customs form 214. The steel import license is valid for 75 days; however, import licenses that were valid on the date of importation but expired prior to the filing of entry summary documents will be accepted.

(e) *Correcting submitted license information.* Due to data security issues, it will not be possible to alter an existing license electronically once it has been issued. However, prior to the date of entry summary, filers will be able to cancel previously issued licenses and file for a new license with the correct information. If the filer prefers to have Commerce personnel change the license, there will be a phone/fax option.

#### **§ 360.104 Steel import surge monitoring system.**

(a) *In general.* (1) Throughout the duration of the licensing system, Commerce will maintain a surge monitoring Web site that will report certain aggregate information on imports of section 201 product categories obtained from the steel licenses. Aggregate data will be reported on a monthly basis by country of origin and section 201 product category and will include import quantity (metric tons), import Customs value (\$U.S.), and average unit value (\$/metric ton). The monitoring Web site will also present a range of historical data for comparison purposes.

(2) Reported monthly import data will be refreshed each week with new data on licenses issued during the previous week. This data will also be adjusted periodically for cancelled or unused steel import licenses, as appropriate.

(b) *Excluded products.* At this time, Commerce will not be separately reporting aggregate data on excluded

products. However, this information will be available for review by the appropriate government agencies.

#### **§ 360.105 Duration of the steel import licensing program.**

The licensing program will be in effect for the duration of the safeguard measures only. Licenses will be required on all subject imports entered during this period, even if the entry summary documents are not filed until after the expiration of the measures. The licenses will be valid for 10 business days after the expiration of the safeguard measures to allow for the final filing of required Customs documentation. Information collected under this system will not be kept longer than the period of time legally required beyond the expiration of these remedies.

#### **§ 360.106 Fees.**

No fees will be charged for obtaining a user identification number, issuing a steel import license or accessing the steel import surge monitoring system.

#### **§ 360.107 Hours of operation.**

The automatic licensing system will generally be accessible 24 hours a day, 7 days a week but may be down at selected times for server maintenance. If the system is down for an extended period of time, parties will be able to obtain licenses from Commerce directly via fax during regular business hours. Should the system be inaccessible for an extended period of time, Commerce would advise Customs to consider this as part of mitigation on any liquidated damage claims that may be issued.

#### **§ 360.108 Loss of electronic licensing privileges.**

Should Commerce determine that a filer consistently files inaccurate licensing information or otherwise abuses the licensing system, Commerce may revoke its electronic licensing privileges. The filer will then only be able to obtain a license directly from Commerce. Because of the additional time need to review such forms, Commerce may require up to 10 working days to process such forms. Delays in filing caused by the removal of a filer's electronic filing privilege will not be considered a mitigating factor by the U.S. Customs Service.

Dated: December 20, 2002.

**Bernard T. Carreau,**

*Acting Assistant Secretary for Import Administration.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 101**

[Docket No. 00N-1596]

#### **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, 2006, as the uniform compliance date for food labeling regulations that are issued between January 1, 2003, and December 31, 2004. FDA periodically announces uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. On November 20, 2000, FDA established January 1, 2004, as the uniform compliance date for food labeling regulations that issued between January 1, 2001, and December 31, 2002.

**DATES:** This rule is effective December 31, 2002. Submit written or electronic comments by March 17, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Louis B. Brock, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

**SUPPLEMENTARY INFORMATION:** FDA periodically issues regulations requiring changes in the labeling of food. If the effective dates of these labeling changes were not coordinated, the cumulative economic impact on the food industry of having to respond separately to each change would be substantial. Therefore, the agency periodically has announced uniform compliance dates for new food labeling requirements (see, e.g., the **Federal Registers** of October 19, 1984 (49 FR 41019), December 24, 1996 (61 FR 67710), December 27, 1996 (61 FR 68145), December 23, 1998 (63 FR 71015), and November 20, 2000 (65 FR 69666)). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the

development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

The agency has determined under 21 CFR 25.30(k) 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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified 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. A regulation also is considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, OMB has determined that this final rule is not a major rule for purposes of congressional review. The establishment of a uniform compliance date does not impose either costs or benefits. For future labeling regulations, FDA will assess the costs and benefits of the uniform compliance date as well as the option of setting other dates.

Because FDA has issued this final rule without first publishing a general notice of proposed rulemaking, a final regulatory analysis is not required by the Regulatory Flexibility Act (5 U.S.C. 601–612). Nonetheless, the uniform compliance date does not impose any burden on small entities. The agency will assess the costs and benefits of setting alternative dates as part of the regulatory flexibility analyses of future labeling regulations.

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$112 million. FDA has determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

This action is not intended to change existing requirements for compliance dates contained in final rules published before January 1, 2003. Therefore, all final FDA regulations published in the **Federal Register** before January 1, 2003, will still go into effect on the date stated in the respective final rule.

The agency generally encourages industry to comply with new labeling regulations as quickly as 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.

In rulemaking that began with publication of a proposal on April 15, 1996 (61 FR 16422), and ended with a final rule on December 24, 1996, FDA provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date. Receiving no comments objecting to this practice, FDA finds any further rulemaking unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this uniform compliance date should be modified or revoked.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic

comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After its review of any comments received to this final rule, FDA will either publish a document providing its conclusions concerning the comments or will initiate notice and comment rulemaking to modify or revoke the uniform compliance date established by this final rule.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 2003, and before December 31, 2004. Those regulations will specifically identify January 1, 2006, as their compliance date. All food products subject to the January 1, 2006, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2006. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2006, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 24, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Praziquantel Injectable Solution

**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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the veterinary prescription