III. Conclusion

Based on all data relevant to vitamin D_3 reviewed by the agency, FDA concludes that there is a reasonable certainty that no harm will result from the use of vitamin D_3 as a nutrient supplement in cheese and cheese products, excluding cottage cheese, ricotta cheese, and hard grating cheeses, such as Parmesan and Romano as defined in §§ 133.165 and 133.183, respectively, and those defined by the standard of identity in § 133.148, at levels up to 81 IU/30 g of cheese. Thus, vitamin D_3 is safe for the proposed use and the agency concludes that the food additive regulations should be amended as set forth in this document. To ensure that only food grade vitamin D_3 is used in food, the additive must meet the specifications set forth in § 172.380.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Effects

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 4A4758. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

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

VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. For written objections, three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

The following reference has been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Folmer, Division of Petition Review, Chemistry Review Group, to Kidwell, Division of Petition Review, February 2, 2005.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.380 is amended by adding paragraph (c)(5) to read as follows:

§ 172.380 Vitamin D_3.

* * * * *

(c) * * *

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under § 170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§ 133.165 and 133.183 of this chapter, and those defined by standard of identity in § 133.148 of this chapter.

Dated: November 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–22670 Filed 11–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; 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. The supplemental NADA provides for use of tylosin soluble powder in honey bees for the control of American foulbrood (*Paenibacillus larvae*).

DATES: This rule is effective November 16, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 13 076 that provides for the use of TYLAN (tylosin tartrate) Soluble in honey bees for the control of American foulbrood (*Paenibacillus larvae*). The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5783 which were compiled under National Research Support Project 7 (NRSP 7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. The supplemental NADA is approved as of October 17, 2005, and the regulations in 21 CFR 520.2640 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 520.2640, revise paragraph (e) introductory text, and add paragraph (e)(4) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(e) *Conditions of use*—

* * * * *

(4) *Honey bees*—(i) *Amount.* Mix 200 milligrams tylosin in 20 grams confectioners'/powdered sugar. Use immediately. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

Dated: November 3, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–22752 Filed 11–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–05–100]

Drawbridge Operation Regulations: Connecticut River, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Amtrak Old Saybrook-Old Lyme Bridge, mile 3.4, across the Connecticut River, Connecticut. This deviation from the regulations allows the bridge to operate on a fixed schedule for bridge openings from November 21, 2005 through December 22, 2005. This deviation is necessary in order to facilitate necessary scheduled bridge maintenance.

DATES: This deviation is effective from November 21, 2005 through December 22, 2005.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668–7195.

SUPPLEMENTARY INFORMATION: The Old Saybrook-Old Lyme Bridge, at mile 3.4, across the Connecticut River has a vertical clearance in the closed position of 19 feet at mean high water and 22 feet at mean low water. The existing drawbridge operating regulations are listed at 33 CFR 117.205(b).

The owner of the bridge, National Railroad Passenger Corporation (Amtrak), requested a temporary deviation from the drawbridge operating regulations to facilitate scheduled electrical bridge repairs. In order to complete the above repairs the bridge must open on a fixed bridge opening schedule.

This deviation to the operating regulations allows the Old Saybrook-Old Lyme Bridge to operate from November 21, 2005 through December 22, 2005, as follows:

From Monday through Friday, the bridge shall open on signal at 8:15 a.m., 12:15 p.m., and 2:15 p.m., daily. From 4 p.m. through 8 a.m. the bridge shall open on signal after a four-hour advance notice is given by calling the number posted at the bridge.

On Saturday and Sunday, the bridge shall open on signal at 8 a.m., 10 a.m., 1 p.m., and 4 p.m., daily. From 4 p.m. through 8 a.m. the bridge shall open on signal after a four-hour advance notice is given by calling the number posted at the bridge.

The bridge shall open on signal for commercial vessels at any time after a four-hour advance notice is given by calling the number posted at the bridge.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 4, 2005.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 05–22647 Filed 11–15–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–052]

Drawbridge Operation Regulations; Berwick Bay, Morgan City, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Burlington Northern Railway Vertical Lift Span Railroad Bridge across Berwick Bay, mile 17.5 [Gulf Intracoastal Waterway (Morgan City to Port Allen Alternate Route), mile 0.4], at Morgan City, St. Mary Parish, Louisiana. This deviation provides for two (2) four-hour bridge closures to conduct scheduled maintenance to the railroad on the drawbridge.

DATES: This deviation is effective from 8 a.m. on Tuesday, November 29, 2005 until noon on Wednesday, November 30, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 500 Poydras Street, New Orleans, Louisiana 70130–3310 between