■ 10. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3—Electronics, Export Control Classification Number (ECCN) 3A992 is amended by revising the License Requirements section to read as follows:

3A992 General purpose electronic equipment not controlled by 3A002.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to entire entry	AT Column 1.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 11. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3—Electronics, Export Control Classification Number (ECCN) 3B992 is amended by revising the License Requirements section to read as follows:

3B992 Equipment not controlled by 3B002 for the inspection or testing of Electronic components and materials, and specially designed components and accessories therefor.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to entire entry	AT Column 1.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 12. In Supplement No. 1 to part 774 (the Commerce Control List), Category 4—Computers, Export Control Classification Number (ECCN) 4A994 is amended by revising the License Requirements section to read as follows:

4A994 Computers, ''electronic assemblies'', and related equipment not controlled by 4A001 or 4A003, and specially designed components therefor.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to entire entry	AT Column 1.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 13. In Supplement No. 1 to part 774 (the Commerce Control List), Category 5—Telecommunications and Information Security''—Telecommunications, Export Control Classification Number (ECCN) 5A991 is amended by revising the License Requirements section to read as follows:

5A991 Telecommunication equipment, not controlled by 5A001.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to entire entry	AT Column 1.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 14. In Supplement No. 1 to part 774 (the Commerce Control List), Category 5—Telecommunications and ''Information Security''—Information Security, Export Control Classification Number (ECCN) 5A992 is amended by revising the License Requirements section to read as follows:

5A992 Equipment not controlled by 5A002.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to 5A992.a	AT Column 1.
AT applies to 5A992.b	AT Column 2.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 15. In Supplement No. 1 to part 774 (the Commerce Control List), Category 5—Telecommunications and ''Information Security''—Information Security, Export Control Classification Number (ECCN) 5D992 is amended by revising the License Requirements section to read as follows:

5D992 ''Information Security'' ''software'' not controlled by 5D002.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to 5D992.a.1 and .b.1.	AT Column 1.
AT applies to 5D992.a.2, b.2 and c.	AT Column 2.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

■ 16. In Supplement No. 1 to part 774 (the Commerce Control List), Category 9—Propulsion Systems, Space Vehicles and Related Equipment, Export Control Classification Number (ECCN) 9A990 is amended by revising the License Requirements section to read as follows:

9A990 Diesel engines, n.e.s., and tractors and specially designed parts therefor, n.e.s.

License Requirements

Reason for Control: AT.

Control(s)	Country chart
AT applies to entire entry except 9A990.a.	AT Column 1.
AT applies to 9A990.a only ...	AT Column 2.

See §§ 740.19 and 742.20 of the EAR for additional information on Libya.

* * * * *

Dated: November 9, 2005.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 05–22674 Filed 11–15–05; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2004F–0374]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of vitamin D_3 as a nutrient supplement in cheese and cheese products at a level above that currently allowed by the regulations. This action is in response to a petition filed by Kraft Foods Global, Inc. (Kraft).

DATES: This rule is effective November 16, 2005. Submit written or electronic objections and requests for a hearing by December 16, 2005. See Section VI of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2004F–0374, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

• Federal eRulemaking Portal: *http://www.regulations.gov*.

Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:

Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith L. Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of September 9, 2004 (69 FR 54687), FDA announced that a food additive petition (FAP 4A4758) had been filed by Kraft Foods Global, Inc., c/o Hogan and Hartson, 555 13th St. NW., Washington, DC 20004. The petition proposed to amend the food additive regulations in § 172.380 *Vitamin D_3* (21 CFR 172.380) to permit the use of vitamin D_3 in cheese and cheese products at a level above that permitted in § 184.1950 *Vitamin D* (21 CFR 184.1950). Currently, under § 184.1950, milk products, which include cheese and cheese products, may be fortified with vitamin D at a level up to 89 International Units (IU) per (/) 100 grams (g). The petitioner requested that the maximum amount of vitamin D permitted in certain natural and processed cheeses be increased to 81 IU vitamin D_3/30 g. Cheese and cheese products identified in the petition for increased fortification levels are those with a reference amount customarily consumed (RACC) of 30 g as defined in § 101.12 (21 CFR 101.12), including standardized and nonstandardized natural cheese, processed cheese, cream cheese, and cheese spreads and dips. Hard grating cheeses with smaller reference amounts, such as Parmesan and Romano as defined in §§ 133.165 and 133.183 (21 CFR 133.165 and 133.183), respectively, and those defined by the standards of identity in § 133.148 (21 CFR 133.148), are not included, nor are cheeses with larger reference amounts, such as cottage cheese or ricotta cheese. Cheese-like products made from nondairy starting materials (e.g., soy-based products) are not considered to be cheese and are not included. The new limit would permit vitamin D to be added to cheese and cheese products at a level slightly more than 20 percent of the reference daily intake (RDI) of vitamin D/30 g serving. Under § 101.54 (21 CFR 101.54), food containing 10 to 19 percent of the RDI of a nutrient is allowed to carry a label claim such as ''good source'' and if the level is 20 percent or more of the RDI, the food label may claim ''excellent source.''

Under § 172.380, vitamin D_3 is approved for use as a nutrient supplement in calcium-fortified fruit juices, calcium-fortified fruit juice drinks, meal replacement and other-type bars, and soy-protein based meal replacement beverages represented for special dietary use in reducing or maintaining body weight. Vitamin D [1], including vitamin D_3, also is affirmed as generally recognized as safe (GRAS) for use in food under § 184.1950 with the following limitations:

Category of Food	Maximum Levels in Food (as served)
Breakfast cereals	350 IU/100 g
Grain products and pasta	90 IU/100 g
Milk	42 IU/100 g
Milk products	89 IU/100 g

Additionally, under § 184.1950(c)(2) and (c)(3) vitamin D is affirmed as GRAS for use in infant formula and margarine, respectively.

[1]Vitamin D comprises a group of fat-souble secosterols and comes in many forms. The two major physiologically relevant forms are vitamin D_2 and vitamin D_3. Vitamin D without a subscript represents either D_2 or D_3. As used in § 184.1950, the meaning of the term vitamin D includes crystalline vitamin D_2, crystalline vitamin D_3, vitamin D_2 resin, and vitamin D_3 resin. Section 172.380 includes only crystalline vitamin D_3.

Vitamin D_3, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Humans synthesize vitamin D_3 in skin from its precursor, 7–dehydrocholesterol under exposure to ultraviolet B radiation in sunlight. Other sources of naturally occurring vitamin D are foods such as butter, buttermilk, cheese, cream, eggs, fish, goat milk, meat fats and organ meats, and mushrooms.

Vitamin D is essential for human health. The major function of vitamin D is to maintain blood serum concentrations of calcium and phosphorus by enhancing the absorption of these minerals from the small intestine. Vitamin D deficiency can lead to abnormalities in calcium and bone metabolism such as rickets in children or osteomalacia in adults. At high levels vitamin D may be toxic. Excessive intake of vitamin D elevates blood plasma calcium levels by increased intestinal absorption and/or mobilization from the bone.

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, FDA affirmed vitamin D as GRAS with specific limitations, as listed in § 184.1950. Under 21 CFR 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950.

To support the safety of the proposed uses of vitamin D_3, Kraft submitted dietary intake estimates from current and proposed uses and from naturally-occurring sources of vitamin D and compared these intake estimates to the tolerable upper intake level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. Kraft also submitted a number of publications pertaining to human clinical studies on vitamin D. Based on this information, which is discussed in section II of this document, the petitioner concluded that the proposed use of vitamin D_3 in cheese and cheese products is safe.

II. Evaluation of Safety

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, the additive's toxicological data, and other

relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. Estimated Daily Intake for Vitamin D

The petitioner provided mean and 90th percentile vitamin D intake estimates for consumers of cheese and cheese products from the following: (1) The proposed food uses; (2) current regulated food uses (including naturally occurring sources of vitamin D); and (3) dietary supplements.[2] Intake estimates for the U.S. population 2 years of age and older were provided, as well as estimates for 18 population subgroups, including breast-fed and nonbreast-fed infants 0 to 11 months of age. The agency agrees with the methodology used to calculate these estimates, with the exception of intake estimates from dietary supplements for infants 0 to 11 months of age.

For consumers 2 years of age and older, Kraft estimated mean and 90th percentile dietary intakes from current (including naturally occurring sources) and proposed food uses of vitamin D to be 335 IU per person per day (IU/p/d) and 582 IU/p/d, respectively. For breast-fed infants 0 to 11 months of age, mean and 90th percentile intakes were estimated to be 180 IU/p/d and 322 IU/p/d, respectively. For nonbreast-fed infants 0 to 11 months of age, mean and 90th percentile intakes were estimated to be 443 IU/p/d and 696 IU/p/d, respectively. For children 1 to 3 years of age, mean and 90th percentile intake estimates were 383 IU/p/d and 583 IU/p/d, respectively.

The petitioner also considered the intake of vitamin D from dietary supplements. The National Health and Nutrition Examination Survey III (NHANES III) data indicate that approximately 33 percent of the U.S. population 2 years of age and older take dietary supplements. The NHANES III data also show that, when vitamin D is taken as a dietary supplement, the most frequent level is 400 IU/p/d. As a conservative estimate of intake of vitamin D from dietary supplements and conventional food, Kraft considered it appropriate to assume that consumers of cheese and cheese products who take dietary supplements likely would take dietary supplements containing 400 IU of vitamin D. They then added this value to the mean and 90th percentile intake estimates from current and proposed food uses for consumers 2 years of age and older. For consumers of cheese and cheese products, mean and 90th percentile dietary intakes from current and proposed food uses and dietary supplements were estimated to be 735 IU/p/d and 982 IU/p/d, respectively, for consumers 2 years of age and older. Kraft chose not to add a value of 400 IU from supplement use to intake estimates for infants 0 to 11 months of age due to the low percentage of infants reported to use supplements (7 percent) in the NHANES III study. While we do not agree with Kraft's choice to exclude supplement use in the vitamin D intake for infants, we believe that, in light of recent recommendations from the American Academy of Pediatrics (AAP),[3] estimating a supplement intake of 200 IU/p/d is more appropriate than 400 IU/p/d for infants.

Based on AAP recommendations, the agency assumed a vitamin D intake of 200 IU from supplement use for infants 0 to 11 months of age, resulting in exposure estimates at the 90th percentile of 522 IU/p/d and 896 IU/p/d for breast-fed and nonbreast-fed infants, respectively. For all other populations (including children and adolescents) we assumed a supplement intake of 400 IU/p/d (Ref. 1).

B. Acceptable Daily Intake for Vitamin D

In 1997, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at IOM conducted an extensive review of toxicology and metabolism studies on vitamin D published through 1996. The IOM published a detailed report that included a UL for vitamin D for infants, children, and adults. The IOM UL for vitamin D for children 1 to 18 years of age and adults is 2,000 IU/p/d. The UL for infants less than 1 year of age is 1,000 IU/p/d.

The IOM considers the UL as the highest daily intake level of a nutrient that is unlikely to pose a risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients and considers intake from all sources: Food, water, nutrient supplements, and pharmacological agents. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and an uncertainty factor.

C. Safety Assessment

To support the safety of their proposed uses for vitamin D_3, Kraft submitted scientific articles published subsequent to the IOM report and issuance of the February 2003 final rule for the use of vitamin D_3 in calcium-fortified fruit juices and fruit juice drinks (68 FR 9000, February 27, 2003), including 12 clinical studies in humans in which subjects received both vitamin D and calcium supplementation for periods of up to 3 years. Kraft concluded that the recent publications continue to support the safe use of vitamin D supplementation in both animals and humans. FDA concurs with Kraft's conclusions.

FDA considered the UL established by IOM for infants, children, and adults relative to the intake estimates provided by the petitioner as the primary basis for assessing the safety of the proposed use of vitamin D_3 in cheese and cheese products. For all children and adults 2 years of age and older, mean and 90th percentile intake estimates from current and proposed food uses of vitamin D are well below the IOM UL of 2,000 IU/p/d. For infants 0 to 11 months of age, mean and 90th percentile intakes are below the UL of 1000 IU/p/d. Additionally, when dietary supplements are included in the calculations, intake estimates remain below the UL. Because the EDI of vitamin D from all sources is less than the UL, the agency concludes that dietary exposure of vitamin D_3 from its proposed use as a nutrient supplement in cheese and cheese products will not pose a safety concern.

[2] The intake estimate included Parmesan cheese; however, fortification of hard grating cheeses such as Parmesan was not requested.

[3] ''Prevention of Rickets and Vitamin D Deficiency: New Guidelines for Vitamin D Intake,'' from the American Academy of Pediatrics in: Pediatrics Vol. III No. 4, pp. 908–910, April 2003. The AAP recommends a daily vitamin D supplement of 200 IU for the following groups:

- All breast-fed infants unless they are weaned to at least 500 milliliter (mL)/d of vitamin D-fortified formula or milk.
- All nonbreast-fed infants who are ingesting less than 500 mL/d of vitamin D-fortified formula or milk.
- Children and adolescents who do not get regular sunlight exposure, do not ingest at least 500 mL/d of vitamin D-fortified milk, or do not take a daily multivitamin supplement containing at least 200 IU of vitamin D.

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