

**FOR FURTHER INFORMATION CONTACT:** Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of July 12, 1995 (60 FR 35912), FDA announced that a food additive petition (FAP 5B4469) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphin-6-yl]oxy]-N,N-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphin-6-yl]oxy]ethyl]ethanamine as a process stabilizer in high density olefin copolymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have the intended technical effect, and that the regulations in § 178.2010 should be amended as set forth below.

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

listed above. As provided in 21 CFR 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.

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

Any person who will be adversely affected by this regulation may at any time on or before February 23, 1996, file with the Dockets Management Branch (address above) written objections thereto. 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. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

#### **PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS**

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

#### **§ 178.2010 Antioxidants and/or stabilizers for polymers.**

*	*	*	*	*
(b)	*	*	*	*

Substances	Limitations
*	*
*	*
*	*
2-[[2,4,8,10-Tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphin-6-yl]oxy]-N,N-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphin-6-yl]oxy]ethyl]ethanamine (CAS Reg. No. 80410-33-9).	For use only: 1. At levels not to exceed 0.075 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1a or 3.2a (where the density of each of these polymers is not less than 0.94 gram per cubic centimeter), and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
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*	*
*	*

Dated: January 5, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-972 Filed 1-23-96; 8:45 am]

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#### **21 CFR Part 558**

#### **New Animal Drugs for Use in Animal Feeds; Nicarbazin and Bacitracin Methylene Disalicylate**

**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 Planalquímica Industrial Ltda. The ANADA provides for use of nicarbazin and bacitracin methylene disalicylate in Type C broiler feed for the prevention of certain forms of coccidiosis and for

increased rate of weight gain and improved feed efficiency.

**EFFECTIVE DATE:** January 24, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

**SUPPLEMENTARY INFORMATION:**

Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil, has filed ANADA 200-164, which provides for the use of single ingredient nicarbazin and bacitracin methylene disalicylate Type A articles to make combination drug Type C broiler feed containing 113.5 grams per ton (g/t) nicarbazin with 30 g/t bacitracin methylene disalicylate. The feed is used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis and for increased rate of weight gain and improved feed efficiency in broiler chickens.

The ANADA is approved as a generic copy of Merck Research Laboratories' NADA 98-378, which was approved on March 15, 1995, and announced in the Federal Register of June 5, 1995 (60 FR 29483). ANADA 200-164 is approved as of January 24, 1996, and the regulations are amended in § 558.366 (21 CFR 558.366) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Additionally, § 558.366(a) is revised to clarify that the listed sponsors are only approved for those uses of the 25 percent nicarbazin Type A medicated article in the table accompanied by their drug labeler code in the "Sponsor" column. Consistent with this, the code for Planalquimica is being added to the "Sponsor" column because it was inadvertently omitted when the firm's approval for use of nicarbazin alone in chicken feed was announced in the Federal Register of June 28, 1995 (60 FR 33342).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

ANADA 200-164 provides for use of nicarbazin and bacitracin methylene disalicylate Type A medicated articles

to make Type C medicated feeds. Nicarbazin is a Category II drug which, as provided in 21 CFR 558.4, requires an approved Form FDA 1900 for making Type C medicated feeds. Therefore, use of nicarbazin Type A medicated articles in making Type C medicated feeds as in this ANADA requires an approved Form FDA 1900.

The agency has determined under 21 CFR 25.24(d)(1)(ii) 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 558.366 is amended by revising paragraph (a), and in the table in paragraph (c) under the "Sponsor" column in the entry for "113.5 (0.0125 pct)" by numerically adding "060728", and in the same column in the item "Bacitracin methylene disalicylate 30" by numerically adding "060728" to read as follows:

**§ 558.366 Nicarbazin.**

(a) Type A medicated articles: 25 percent to 000006, 000986, and 060728 in § 510.600(c) of this chapter for use as indicated in the table in paragraph (c) of this section.

\* \* \* \* \*

Dated: December 28, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-941 Filed 1-23-96; 8:45 am]

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**DEPARTMENT OF STATE**

**Bureau of Consular Affairs**

**22 CFR Parts 40 and 41**

[Public Notice 2312]

**Visas: Regulations Pertaining to Nonimmigrants and Immigrants Under the Immigration and Nationality Act, as Amended**

**AGENCY:** Bureau of Consular Affairs, DOS.

**ACTION:** Final rule.

**SUMMARY:** On March 4, 1995, the President, as part of the Administration's regulatory reinvention initiative, directed all heads of departments and agencies, *inter alia*, to conduct a page-by-page review of all regulations and to "eliminate or revise those that are outdated or otherwise in need of reform." (Memorandum for Heads of Departments and Agencies, Regulatory Reinvention Initiative, March 4, 1995.) In response, the Visa Office of the Department of State has undertaken a review of its visa regulations to determine whether they may be eliminated, shortened, or rewritten in a more understandable fashion.

**EFFECTIVE DATES:** January 24, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Stephen K. Fischel, Chief, Legislation and Regulations Division, Visa Office, (202) 663-1204.

**SUPPLEMENTARY INFORMATION:** The President has directed each agency to undertake a review of its regulations for the purpose of reducing the regulations or, when possible, rendering them more readable and comprehensible. The Visa Office of the Department of State has engaged in a thorough line-by-line review of all visa related regulations in parts 40 through 45 and part 47 of Title 22 of the Code of Federal Regulations. As a result, the Visa Office is proposing various amendments to the regulations consistent with the President's directive. The Visa Office is also using this opportunity to make other necessary changes to the regulations. The Visa Office will be publishing the proposed changes in a series of publications.

**Editing**

This rule makes editorial changes to two sections in 22 CFR Part 40 and to five sections in Part 41.

**Part 40 Amendments**

The amendment to § 40.62 changes the section by incorporating the statutory period of time one must