



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.

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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