

regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC, on March 22, 1996.

Thomas C. Accardi,
Director, Flight Standard Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.27, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.27 NDB, NDB/DME; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective April 25, 1996*

Alturas, CA, Alturas Muni, NDB or GPS RWY 31, Amdt 1 CANCELLED

Alturas, CA, Alturas Muni, NDB RWY 31, Amdt 1

[FR Doc. 96-7765 Filed 3-28-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazine; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations regarding the use of nicarbazine in Type C broiler feeds. Because of incorrect amendatory instructions in a final rule that appeared in the Federal Register of June 5, 1995 (60 FR 29483), certain uses of nicarbazine combination Type C broiler feeds were removed from the regulations. This document corrects those errors.

EFFECTIVE DATE: March 29, 1996

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center For Veterinary Medicine (HFV-238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1739.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 5, 1995 (60 FR 29483), the animal drug regulations were amended to codify Merck Research Laboratories, Division of Merck & Co.'s NADA 98-378 for use of single ingredient nicarbazine and bacitracin

methylene disalicylate Type A articles to make combination drug Type C medicated broiler feeds. The document published with incorrect amendatory language resulting in the removal of certain approved uses of the drug from the regulation. FDA is correcting these errors.

Publication of this document constitutes final action on these changes under the Administrative Procedures Act (5 U.S.C. 553). Notice and public procedures on these corrections is unnecessary because FDA is merely republishing previously approved regulations.

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 in the table in paragraph (c) by alphabetically adding two new entries to read as follows:

§ 558.366 Nicarbazine.

* * * * *

(c) * * *

Nicarbazine in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	* Roxarsone 22.7 (0.0025).	* * * do	* Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; as sole source of organic arsenic; do not use a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 5 days before slaughter.	* 000006
	Rosarsone 22.7 (0.0025) plus lincomycin 2 (0.0004).	do	do	000006

Dated: March 14, 1996.
 Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
 [FR Doc. 96-7679 Filed 3-28-96; 8:45 am]
 BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA-135F]

RIN 1117-AA30

Manufacturer Reporting

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule.

SUMMARY: This rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to implement provisions of the Domestic Chemical Diversion Control Act of 1993 (Pub. 103-200) (DCDCA) to specify certain reporting requirements for manufacturers of listed chemicals. This rule requires bulk manufacturers of listed chemicals to provide annual reports containing certain production data to the DEA.

EFFECTIVE DATE: April 29, 1996. The first annual reports which detail data for calendar year 1995, shall be submitted on or before June 27, 1996.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537 Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION: The Domestic Chemical Diversion Control Act 1993 (Pub. 103-200) (DCDCA) amended 21 U.S.C. 830(b) to require that regulated persons who manufacture listed chemicals (other than a drug product that is exempted under 21 U.S.C. 802(39)(A)(iv)) report annually to DEA information detailing the specific quantities manufactured. This rule specifies certain reporting requirements for manufacturers of listed chemicals and finalizes a proposed rule published in the Federal Register on September 26, 1995 (60 FR 49529). Interested parties were given 60 days to submit written comments regarding the proposed rule.

Comments

Five organizations submitted comments in response to the proposed regulations. One comment suggested that Section 1310.03(b) be modified in order to clarify that the reporting

requirements pertain to both List I and List II chemicals. Therefore Section 1310.01(b) has been amended to clarify that "Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05."

Another comment stated that DEA had not clearly established its basis for needing information requested under the reporting requirement. This requirement, which was established by the Domestic Chemical Diversion Control Act of 1993, will provide the DEA with information on the amounts of listed chemicals available in the U.S. and provide specific strategic information and parameters on the size and direction of the legitimate listed chemical market and the availability of such chemicals for diversion. It will also enable the DEA to provide the International Narcotics Control Board (INCB) with aggregate data regarding the production and availability of chemicals controlled under provisions of the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

Two comments requested that hydrochloric acid be exempted and one comment suggested that sulfuric acid be exempted since only exports of these chemicals to certain countries are currently regulated. However, both these chemicals are controlled in Table II of the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. This reporting provision will enable the DEA to provide the INCB with aggregate manufacturing data on hydrochloric and sulfuric acid.

The DEA recognizes that bulk manufacturers must file other similar reports to other government agencies. For example, one of the comments stated that the requested information is provided to the U.S. Environmental Protection Agency (EPA) four times per year. Therefore, as stated in the Notice of Proposed Rulemaking, if an existing standard industry report contains the information required in Section 1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official.

One comment stated that even though the DEA has specified that an existing standard industry report may satisfy the reporting requirements, the reporting obligation would end up as a special report for each listed material at each location and therefore would be

extremely burdensome. In addition, two comments dealt with the issue of whether data must be reported by individual facility, as opposed to submitting one corporate report which includes data for all facilities.

In response to these concerns, the DEA has determined that either reporting method is acceptable. Therefore, each business entity which manufactures a listed chemical may elect to (1) report separately by individual location or (2) report as an aggregate amount for the entire business entity. These manufacturers, however, must inform the DEA of which method they will use.

One commentator asked whether inventories should be reported for listed chemicals stored in foreign locations. The DEA has determined that such foreign inventories are not subject to the inventory reporting requirements since such material would have already been reported to the DEA under existing export notification requirements if it were manufactured in the U.S. and shipped to a foreign location.

One commentator requested clarification of the term year-end inventory as used in Section 1310.06(h)(3). For purposes of this annual reporting requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material. The DEA recognizes that bulk manufacturers may have specific situations which will affect the complexity of inventory reporting. Therefore, the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration is available to provide guidance in response to questions bulk manufacturers may have regarding what material should be included as inventory.

One commentator requested clarification of the terms "product" and "converted" as used in Section 1310.06(h)(5). The term product refers to all pharmaceutical preparations and chemical mixtures exempted under Sections 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) intended for later distribution. In order to provide clarification of Section 1310.06(h)(5), the term "converted" is being removed. This section will now specify that each annual report required by Section 1310.05(d) shall provide "[t]he aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted