FOR FURTHER INFORMATION CONTACT:

Deb A. Baclawski, Center for Devices and Radiological Health (HFZ–026), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–1060, or

Donna G. Page, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority under § 5.22 *Certification of true copies and use of the Department seal* (21 CFR 5.22); § 5.23 *Disclosure of official records* (21 CFR 5.23); § 5.37 *Issuance of reports of minor violations* (21 CFR 5.37); and § 5.98 *Authority relating to medical device reporting procedures* (21 CFR 5.98) to reflect redelegations to other officials within CDRH. These redelegations will improve the efficiency of operations for the center.

Further redelegation of the authorities delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.22 is amended by revising paragraph (a)(10)(v) and by adding paragraph (a)(10)(vi) to read as follows:

§ 5.22 Certification of true copies and use of Department seal.

(a) * * *

(10) * * *

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) Freedom of Information Officers, CDRH.

* * * * *

3. Section 5.23 is amended by adding paragraph (c)(5) to read as follows:

§ 5.23 Disclosure of official records.

* * * * *

(c) * * *

(5) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, and the Chief Reporting Systems Monitoring Branch, DSS, OSB, CDRH.

* * * * *

3. Section 5.37 is amended by adding paragraphs (a)(2)(iv) and (b)(4) to read as follows:

§ 5.37 Issuance of reports of minor violations.

(a) * * *

(2) * * *

(iv) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

* * * * *

(b) * * *

(4) The Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH.

* * * * *

5. Section 5.98 is revised to read as follows:

§ 5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics, (OSB), CDRH and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

Dated: January 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2357 Filed 2–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Narasin and Nicarbazin With 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 a new animal drug application (NADA) filed by Elanco Animal Health, a Division of Eli Lilly & Co. The NADA provides for combining approved narasin/nicarbazin (1:1 fixed ratio) and bacitracin methylene disalicylate (BMD) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: February 2, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140–926 that provides for combining approved narasin/nicarbazin (1:1 fixed ratio) Maxiban® and BMD Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The feeds contain 27 to 45 grams per ton (g/t) each of narasin and nicarbazin and 4 to 50 g/t BMD. The feeds are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of January 4, 1999, and the regulations are amended in 21 CFR 558.76, 558.363, and 558.366 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

This approval is for use of approved Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, nicarbazin, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required for making a Type B or C medicated feed as in this application. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for manufacture in a licensed feed mill. Therefore, use of narasin/nicarbazin and BMD Type A medicated articles to make Type C medicated feeds as in NADA 140–926 requires manufacture in a licensed feed mill.

The agency has determined under 21 CFR 25.33(a)(2) 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: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xix) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xix) Narasin and nicarbazin as in § 558.366.

3. Section 558.363 is amended by adding paragraph (d)(2)(ii) to read as follows:

§ 558.363 Narasin.

* * * * *

(d) * * *

(2) * * *

(ii) Nicarbazin and bacitracin methylene disalicylate as in § 558.366.

4. Section 558.366 is amended in the table in paragraph (c) under entry ''27 to 45'' by alphabetically adding an entry for ''Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50'' to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(c) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. mivati*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate by 046573.	000986
* *	*	*	*	* *

Dated: January 22, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–2411 Filed 2–1–99; 8:45 am]

BILLING CODE 4160–01–F

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 542

RIN 3141–AA11

Minimum Internal Control Standards

AGENCY: National Indian Gaming commission.

ACTION: Final Rule; Correction.

SUMMARY: The National Indian Gaming Commission published the Final Rule on Minimum Internal Control Standards (MICS) on January 5, 1999. The compliance dates stated in the preamble under ''Dates'' were incorrect. This publication is to correct the mistakes.

EFFECTIVE DATE: February 2, 1999.

FOR FURTHER INFORMATION CONTACT: Mai Dinh, National Indian Gaming Commission, 1441 L Street, NW, Suite 9100, Washington, DC 20005. Telephone: 202–632–7003.

SUPPLEMENTARY INFORMATION: The Final Rule on Minimum Internal Control Standards, published on January 5, 1999, in Part III of the **Federal Register**, should be corrected as follows. On page