these three combination drug medicated feeds.

The NADAs are approved as of February 15, 2006, and the regulations are amended in 21 CFR 558.76, 558.78, 558.369, and 558.680 to reflect the approval. Approval of these supplemental NADAs did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The agency has determined under 21 CFR 25.33(a)(2) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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.

§ 558.76 [Amended]

■ 2. In § 558.76, amend paragraph (d)(3)(xviii) by adding ''or roxarsone'' after ''arsanilic acid''.

■ 3. In § 558.78, amend paragraph (d)(3) by redesignating paragraphs (d)(3)(x) through (d)(3)(xii) as paragraphs (d)(3)(xi) through (d)(3)(xiii); and add new paragraph (d)(3)(x) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) * * *

(x) Nitarsone as in § 558.369.

* * * * *

§ 558.369 [Amended]

■ 4. In § 558.369, amend paragraph (d)(2)(i) by adding ''or bacitracin zinc'' after ''disalicylate''.

■ 5. In § 558.680, amend the table in paragraph (d)(1)(i), after the entry for ''Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50'' by adding entries for ''Bacitracin 4 to 50'' and ''Bacitracin methylene disalicylate 4 to 50 plus roxarsone 22.7 to 45.4'' to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) * * *	Bacitracin 4 to 50	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. As bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter
	Bacitracin methylene disalicylate 4 to 50 plus roxarsone 22.7 to 45.4	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. Discontinue use 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. As bacitracin methylene disalicylate and roxarsone provided by No. 046573 in § 510.600(c) of this chapter
*	*	*	* * * *

* * * * *

Dated: March 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–3122 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. 2003N–0324]

New Animal Drugs for Use in Animal Feeds; Bacitracin; Nicarbazin; Oxytetracycline and Neomycin; Penicillin

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 four supplemental new animal drug applications (NADAs) filed by Phibro Animal Health. One supplemental NADA provides for the use of fixed-combination Type A medicated articles containing oxytetracycline and neomycin sulfate to formulate two-way fixed-combination drug Type B and Type C medicated feeds for chickens, turkeys, swine, cattle, and sheep. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing nicarbazin and penicillin, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for broiler chickens. The fourth supplemental NADA provides for the use of approved, single-ingredient Type A medicated articles nicarbazin, bacitracin methylene disalicylate, and roxarsone to formulate three-way combination drug Type C

medicated feeds for broiler chickens. These approvals reflect FDA's effectiveness conclusions which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

DATES: This rule is effective March 31, 2006.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–50), 7519 Standish Pl., Rockville, MD 20855, 240–276–9090, e-mail: *andrew.beaulieu@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57919), as part of the Drug Efficacy Study Implementation (DESI) program, CVM announced the effective conditions of use for several drug products and use combinations listed in 21 CFR 558.15. CVM proposed to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. Phibro Animal Health, 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660, filed supplements to four of its approved NADAs to revise the labeling of its products to comply with these findings of effectiveness.

Phibro Animal Health filed a supplement to approved NADA 94–975 for NEO–TM 50/50D and NEO–TM 100/100D (oxytetracycline and neomycin sulfate) Type A medicated articles. The supplemental NADA provides for use of these fixed-combination Type A medicated articles to formulate two-way fixed-combination drug Type B and Type C medicated feeds containing oxytetracycline and neomycin sulfate, in a 1:1 ratio, for several production and therapeutic indications in chickens, turkeys, swine, cattle, and sheep.

Phibro Animal Health also filed a supplement to approved NADA 98–371 for use of nicarbazin, procaine penicillin, and roxarsone single-ingredient Type A medicated articles to make three-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing NICARBAZIN (nicarbazin) at 90.8 to 181.6 grams per ton (g/ton), PENICILLIN G PROCAINE (procaine penicillin) at 2.4 to 50 g/ton, and 3–NITRO (roxarsone) at 22.7 to 45.4 g/ton of feed in broiler chickens as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency; and for improved pigmentation.

Phibro Animal Health also filed a supplement to approved NADA 98–374 for use of nicarbazin and procaine penicillin G Type A medicated articles to formulate two-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing NICARBAZIN (nicarbazin) at 90.8 to 181.6 g/ton and PENICILLIN G PROCAINE (procaine penicillin) at 2.4 to 50 g/ton of feed in broiler chickens 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.

Phibro Animal Health also filed a supplement to approved NADA 100–853 for use of nicarbazin, bacitracin methylene disalicylate, and roxarsone single-ingredient Type A medicated articles to make three-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing NICARBAZIN (nicarbazin) at 90.8 to 181.6 g/ton, BMD (bacitracin methylene disalicylate) at 4 to 50 g/ton, and 3–NITRO (roxarsone) at 22.7 to 45.4 g/ton of feed in broiler chickens 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, improved feed efficiency, and improved pigmentation.

The DESI evaluation is concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying, as described in the *Generic Animal Drug and Patent Term Restoration Act Policy Letter Eight*, August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for this fixed combination Type A medicated article and three combination drug medicated feeds.

The supplemental NADAs are approved as of February 15, 2006, and the regulations are amended in 21 CFR 558.76, 558.460, and 558.366, and also in 21 CFR part 558 by adding new § 558.455 to reflect these approvals. Approval of these supplemental NADAs did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The agency has determined under 21 CFR 25.33(a)(2) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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. In § 558.76, revise paragraph (d)(3)(xiii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xiii) Nicarbazin alone or with narasin or roxarsone or with narasin and roxarsone as in § 558.366.

* * * * *

■ 3. In § 558.366, amend the table in paragraph (d) after the entry for ''Narasin 27 to 45 and roxarsone 22.7 to 45.4'' by adding three entries to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(d) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
90.8 to 181.6 (0.01 to 0.02 pct)	Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4	Broiler chickens: 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, and improved pigmentation	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashes. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by No. 066104; bacitracin methylene disalicylate and roxarsone by No. 046573 in § 510.600(c) of this chapter	066104
	Penicillin 2.4 to 50	Broiler chickens: 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	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to chickens producing eggs for human consumption. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104 in § 510.600(c) of this chapter	066104
	Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4	Broiler chickens: 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, and improved pigmentation	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashes. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104; roxarsone by No. 046573 in § 510.600(c) of this chapter	066104
*	*	* *	* *	*

■ 4. Add § 558.455 to read as follows:

§ 558.455 Oxytetracycline and neomycin.

(a) *Specifications.* Type A medicated articles containing oxytetracycline equivalent to 50 grams per pound (g/lb) oxytetracycline hydrochloride and 50 g/lb neomycin sulfate or oxytetracycline equivalent to 100 g/lb oxytetracycline hydrochloride and 100 g/lb neomycin sulfate.

(b) *Sponsors.* See No. 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.430 and 556.500 of this chapter.

(d) *Indications for use*—(1) *Chickens.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) 10 to 50	Chickens: For increased rate of weight gain and improved feed efficiency	Feed continuously; do not feed to chickens producing eggs for human consumption	066104
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter	066104
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter	066104
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac-infection) caused by *E. coli* susceptible to oxytetracycline	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter	066104

(2) *Turkeys*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 g/ton of feed	Growing turkeys: For increased rate of weight gain and improved feed efficiency	Feed continuously; do not feed to turkeys producing eggs for human consumption	066104
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption	066104
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption	066104
(iv) To provide 25 mg/lb of body weight daily	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption	066104

(3) *Swine*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton of feed	Swine: For increased rate of weight gain and improved feed efficiency		066104
(ii) To provide 10 mg/lb of body weight daily	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter	066104
	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	Feed continuously for not more than 14 d; withdraw 5 d before slaughter	066104

(4) *Cattle and sheep*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 grams per ton of feed	Sheep: For increased rate of weight gain and improved feed efficiency		066104
(ii) To provide 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency	Feed continuously; in milk replacers or starter feed	066104
(iii) To provide 10 mg/lb of body weight daily	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter	066104
	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter	066104
	3. Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter	066104
(iv) To provide 25 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency		066104
(v) To provide 75 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses		066104
(vi) To provide 0.5 to 2.0 g/head/day	Cattle: For prevention and treatment of the early stages of shipping fever complex	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older	066104

■ 5. In § 558.460, redesignate paragraphs (d)(2)(vi), (d)(2)(vii), and (d)(2)(viii) as paragraphs (d)(2)(iii), (d)(2)(v), and (d)(2)(vi); and add new paragraph (d)(2)(iv) to read as follows:

§ 558.460 Penicillin.

* * * * *

(d) * * *

(2) * * *

(iv) Nicarbazin alone or with roxarsone as in § 558.366.

* * * * *

Dated: March 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–3120 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 814 and 820

[Docket No. 2006N–0127]

Medical Device Reporting; Premarket Approval of Medical Devices; Quality System Regulation; Technical Amendment

AGENCY: Food and Drug Administration, HHS.