

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

ALPHARMA INC.)
One Executive Drive)
Fort Lee, NJ 07024,)

Plaintiff,)

v.)

MARK B. MCCLELLAN, M.D., PH.D.)
COMMISSIONER OF FOOD AND)
DRUGS, FOOD AND DRUG)
ADMINISTRATION,)
5600 Fishers Lane)
Rockville, Maryland 20857)
Montgomery County, Maryland,)

FOOD AND DRUG)
ADMINISTRATION,)
5600 Fishers Lane)
Rockville, Maryland 20857,)
Montgomery County, Maryland,)

Defendants.)

Civil Action No. _____

**COMPLAINT SEEKING REVIEW OF ADMINISTRATIVE AGENCY ACTION,
DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF**

1. This is an action under the Administrative Procedure Act, 5 U.S.C. §§ 701 to 706, the Federal Food, Drug, and Cosmetic Act (“FDC Act”), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. §§ 501, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a), 2202, for declaratory, injunctive, and other appropriate relief.

2. Plaintiff Alpharma Inc. (“Alpharma”) seeks: (1) a declaratory judgment that the Food and Drug Administration (“FDA”) unlawfully granted PennField Oil Company and/or its subsidiary or division, PennField Animal Health (hereinafter “PennField”), approval to sell and

market a new animal drug called bacitracin methylene disalicylate (hereinafter “Bacitracin MD”) in violation of the FDC Act and its implementing regulations or, in the alternative, (2) a declaratory judgment that the FDA unlawfully facilitated PennField’s false representation of FDA approval for Bacitracin MD.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action pursuant to 5 U.S.C. §§ 702 to 706 and 28 U.S.C. § 1346.

4. The Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1331.

5. Venue lies in this district under 28 U.S.C. § 1391(e).

PARTIES

6. Plaintiff Alpharma is a pharmaceutical company incorporated in Delaware, with its principal place of business in New Jersey. Alpharma’s products include animal drugs for use as feed additives that foster health and treat and prevent disease in poultry and livestock. One of Alpharma’s animal drug products is a Type A Medicated Article containing Bacitracin MD.

7. Defendant Mark B. McClellan, M.D., Ph.D., sued only in his official capacity, is the Commissioner of Food and Drugs, FDA.

8. Defendant FDA is an administrative agency of the United States within the meaning of 5 U.S.C. § 701(b). The FDA is the administrative agency granted authority by Congress to regulate the interstate manufacture, sale, and distribution of foods, human and animal drugs, cosmetics, biologics, and medical devices in the United States. The FDA is the

federal agency responsible for regulating drugs administered to animals directly and/or as a mixture in animal feed.

FACTS

I. THE FDA APPROVAL PROCESS FOR NEW ANIMAL DRUGS INTRODUCED AFTER 1968.

9. In 1968, the FDC Act was amended to consolidate the FDA's authority to review, approve, and regulate animal drugs, including animal drugs (such as antibiotics) added to animal feed (hereinafter "Animal Drug Amendments"). *See* 21 U.S.C. § 360b.

10. Under the Animal Drug Amendments, a new animal drug is deemed "unsafe," and therefore may not be marketed lawfully, unless the new animal drug has been approved by the FDA and its labeling, distribution, holding, and use conform to the conditions of that approval. *Id.* at § 360b(a)(2).

11. In order to obtain approval for a new animal drug, the manufacturer or its agent (hereinafter "Applicant") must submit a new animal drug application (hereinafter "NADA") to the FDA. *Id.* at § 360b(a), (b).

12. The NADA for a new animal drug must include full reports of adequate and well controlled investigations (including studies in a target species, studies in laboratory animals, and field investigations) that show by substantial evidence that the drug is safe and effective for its intended use. *Id.* at §§ 360b(b)(1), (d)(1), (d)(3).

13. The NADA for a new animal drug for use in feed must also include: (a) a list of the drug's components; (b) a statement of the drug's composition; (c) a description of the drug's manufacturing, processing, and packaging procedures; (d) samples of the drug and intended animal feed; (e) proposed labeling for each intended use in animal feed; (f) a description of

methods for determining the quantity of the drug within the feed; and (g) the tolerance, withdrawal period, or other use restrictions that are required in order to assure drug safety. *Id.* at § 360b(b)(1).

14. The Applicant may incorporate into the NADA any pertinent information by specific reference. 21 C.F.R. §514.1(a). However, “[a]ny reference to information furnished by a person other than the Applicant may not be considered [by the FDA] unless its use is authorized in a written statement signed by the person who submitted it.” *Id.*

15. Investigations required to support a NADA approval must provide substantial evidence of the safety and efficacy of the drug for each intended use under which approval is sought. 21 U.S.C. § 360b(d)(1); 21 C.F.R. §§ 514.4, 514.11(a)(5)(ii).

16. Animal drugs are often used in combination with other animal drugs in animal feed. Each such animal drug combination requires FDA approval specific to that combination. 21 U.S.C. § 360b(d)(4).

17. Animal drugs (such as antibiotics) for use in feed are often intended for multiple uses, *i.e.*, to promote the growth of multiple species of animals and/or to promote multiple aspects of animal health (each aspect in each species being a specific intended use). Each intended use requires FDA approval specific to that use. 21 U.S.C. § 360b(a)(2).

18. After a NADA is approved for a specific new animal drug, a supplemental NADA must be submitted and approved by the FDA to enlarge the scope of the NADA (*e.g.*, to add a new indication for use). 21 U.S.C. §§ 360b(a)(2), (d)(4); 21 C.F.R. § 514.8.

19. In determining whether a new animal drug is safe for its intended use(s), the FDA must consider, among other things, “safety factors which in the opinion of experts, qualified by

scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data.” 21 U.S.C. § 360b(d)(2). The FDA does not have the discretion to do otherwise. *See id.*

20. In determining whether a new animal drug is effective for its intended use(s), the FDA must ascertain that the NADA investigations were designed and interpreted “by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.” *See id.* at 360b(d)(3). The FDA does not have the discretion to do otherwise. *See id.*

21. Where NADA investigations are inadequate to show that a drug is safe and effective for its intended use(s), the FDA must issue an order refusing to approve the NADA. 21 U.S.C. § 360b(d)(1). The FDA does not have the discretion to do otherwise. *See id.*

22. After the FDA approves a new animal drug, the agency advises the public of the fact and scope of the approval by publication in the Federal Register. 21 U.S.C. § 360b(i). To date, the FDA has not published notice of the NADA approval for Bacitracin MD granted to PennField.

23. The FDC Act permits approval of “generic” versions of new animal drugs upon satisfying the requirements of the Abbreviated New Animal Drug Application (“ANADA”) procedure. 21 U.S.C. § 360b(n). On information and belief, the ANADA process is not involved in the instant dispute.

II. THE APPROVAL PROCESS FOR ANIMAL DRUGS INTRODUCED PRIOR TO 1968.

24. The FDC Act was enacted in 1938 to ensure that drugs were safe for their intended use. The Act was amended in 1962 to require that human and animal drugs be shown to be effective, as well as safe, for their intended use (hereinafter “1962 Amendments”). *See* 21 U.S.C. §§ 301, *et seq.* Prior to the passage of the Animal Drug Amendments, there were multiple ways for an animal drug to be approved for marketing. Such a product could be approved via a NADA; new drug application; master file; antibiotic regulation; or food additive regulation. The Animal Drug Amendments consolidated the FDA’s regulatory authority over new animal drugs and deemed existing products to be approved under this statute if certain conditions were met.

25. In order to carry out a retroactive evaluation of the effectiveness of preexisting drugs (hereinafter “preexisting drugs”), the FDA arranged with the National Academy of Sciences/National Research Council (“NAS/NRC”) to conduct an efficacy review.

26. The results of this review process, known as the Drug Efficacy Study Implementation (“DESI”), were published in the Federal Register (“DESI Notices”). DESI Notices indicate which preexisting drugs are “effective” for a particular use. Companies seeking approval of claims subject to such DESI Notices may not need to submit full effectiveness data to the FDA to gain that approval.

27. However, any new use, combination, or other major variations of a preexisting animal drug still requires a new or supplemental NADA, including full reports of studies that establish proof of safety and effectiveness. *See* 21 U.S.C. §§ 360b(a)(1), (d)(4); 21 C.F.R. § 514.8.

III. BACITRACIN MD APPLICATIONS AND THE FDA APPROVAL PROCESS.

28. Bacitracin MD is an antibiotic animal drug that is added to the feed of various animal species (*e.g.*, chicken, turkeys, quail, swine, and cattle) to promote growth and prevent or control various disease conditions.

29. Bacitracin MD is regulated by the FDA with respect to: (a) the animal species in which it may be used; (b) the amounts that may be added to animal feed; (c) the specific indications for use that may be included on the product label; and (d) the particular companies that have approval for the product. *See* 21 C.F.R. § 558.76.

30. Bacitracin MD has been widely used for decades. The FDA has recognized four Bacitracin MD claims that were found to be “effective” under the DESI review (hereinafter “4 DESI Claims”):

- (a) Chickens: Four to 50 grams per ton of feed for increased rate of weight gain and improved feed efficiency.
- (b) Turkeys: Four to 50 grams per ton of feed for increased rate of weight gain and improved feed efficiency.
- (c) Pheasants: Four to 50 grams per ton of feed for increased rate of weight gain and improved feed efficiency.
- (d) Quail (not over five weeks in age): Five to 20 grams per ton of feed for increased rate of weight gain and improved feed efficiency.

21 C.F.R. § 558.76(d)(1)(i), n.1 (“These conditions are NAS/NRC [DESI] reviewed and found effective.”); *see also* 35 Fed. Reg. 15408 (October 2, 1970) (amending the notice published at 35 Fed. Reg. 11531 (July 17, 1970)).

31. Any use or combination of Bacitracin MD, other than the above 4 DESI Claims, must be approved by the FDA based on a submitted NADA or supplemental NADA. See 21 U.S.C. § 360b(a)(2).

A. ALPHARMA LAWFULLY OBTAINED FDA APPROVAL FOR ALL POST-DESI BACITRACIN MD USES.

(1) Alpharma Has NADA and Supplemental NADA Approvals for All Post-DESI Uses of Bacitracin MD.

32. In the 1960's, S. B. Pennick & Company (hereinafter "Pennick") received approval for two new (Post-DESI) uses of Bacitracin. Alpharma now owns the rights to these uses.

33. On December 9, 1975, A.L. Laboratories, Inc. (hereinafter "A.L. Labs") obtained the rights to NADA 046-592 for Bacitracin MD. A.L. Labs is Alpharma's predecessor and Alpharma now owns NADA 046-592. In 1981, for administrative reasons, the FDA transferred the two Pennick claims to NADA 046-592.

34. In the 1980's and 1990's, A.L. Labs and/or Alpharma filed supplements to NADA No. 046-592, and obtained FDA approval for 10 new uses of Bacitracin MD relevant to this case. Alpharma's two claims through Pennick, and 10 claims cited above (collectively, "12 Post-DESI Claims") and their approval dates are listed in 21 C.F.R. §§ 558.76(d)(1), (d)(2) as follows:

Claim Number*	Species	Grams per Ton of Feed	Indications for Use	Approval Publication Date
1	Chickens	10 to 25	For increased egg production and improved feed efficiency for egg production. Limitations: For first 7 months of	Apr. 10, 1981 (46 Fed. Reg. 21363)

			production.	
2	Swine	10 to 30	For increased rate of weight gain and improved feed efficiency. Limitations: For growing and finishing swine.	Apr. 21, 1981 (46 Fed. Reg. 22754).
3	Broiler Chickens	50	As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Apr. 14, 1981 (46 Fed. Reg. 21748)
4	Replacement Chickens	50	As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. Limitations: Feed continuously as sole ration.	July 31, 1998 (63 Fed. Reg. 40824)
5	Broiler Chickens	100 to 200	As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Apr. 14, 1981 (46 Fed. Reg. 21748)
6	Replacement Chickens	100 to 200	As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. Limitations: Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 grams per ton).	July 31, 1998 (63 Fed. Reg. 40824)
7	Turkeys	200	As an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin MD.	Apr. 17, 1981 (46 Fed. Reg. 22361)

8	Quail	200	<p>For the prevention of ulcerative enteritis in growing quail due to <i>Clostridium colinum</i> susceptible to Bacitracin MD.</p> <p>Limitations: From Type A medicated articles containing 25, 40, or 50 grams of bacitracin methylene disalicylate. Feed continuously as the sole ration.</p>	Feb. 17, 1989 (54 Fed. Reg. 7189)
9	Swine (growing/ finishing)	250	<p>For control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition.</p> <p>Limitations: As sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.</p>	Apr. 30, 1982 (47 Fed. Reg. 18591)
10	Pregnant Sows	250	<p>For control of clostridial enteritis caused by <i>C. perfringens</i> in suckling piglets.</p> <p>Limitations: As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.</p>	May 7, 1991 (56 Fed. Reg. 21076)
11	Feedlot Beef Cattle	70 mg per head per day	<p>For reduction in the number of liver condemnations due to abscesses.</p> <p>Limitations: Administer continuously throughout the feeding period.</p>	June 16, 1970 (35 Fed. Reg. 9855)

12	Feedlot Beef Cattle	250 mg per head per day	For reduction in the number of liver condemnations due to abscesses. Limitations: Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	June 16, 1970 (35 Fed. Reg. 9855)
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*Numbers are for clarification only. They are based on the sequential listing order of 21 CFR §§ 558.76(d)(1), (2) (excluding the 4 DESI Claims and 2 “combination” claims not cited above).

35. Pennick, A.L. Labs, and/or Alharma (collectively, “Alharma”) received approvals for each of the 12 Post-DESI Claims based on proprietary data that Alharma generated and submitted to the FDA for review (hereinafter “Proprietary Data”).

36. On information and belief, Alharma has not authorized the FDA to rely on Alharma’s safety and effectiveness data for Bacitracin MD on behalf of PennField or its predecessor(s).

37. Thus, any manufacturer seeking to obtain approval for any of the 12 Post-DESI Claims must submit its own original data that meet the application submission requirements of the Animal Drug Amendments. *See* 21 U.S.C. §§ 360b(b), (n).

(2) Alharma Is the Only Party Listed by the FDA in 21 C.F.R. § 558.76 as Having FDA Approval for All Post-DESI Uses of Bacitracin MD.

38. Alharma is the only party listed in 21 C.F.R. § 558.76 as having received approval for 10 of the 12 Post-DESI Claims (Claims 1-10 in ¶ 34) and the 4 DESI Claims for Bacitracin MD. *See* §558.76(d)(1) (citing claims’ sponsor as “046573,” Alharma’s drug labeler code assigned by the FDA pursuant to 21 C.F.R. § 510.600(c)(1)). In addition, Alharma is the only sponsor of the remaining two Post-DESI claims (Claims 11-12 in ¶ 34) *See* §558.76(d)(2).

39. In the past, there were two Bacitracin MD sponsors for uses listed in what would later become 21 C.F.R. § 558.76: A.L. Labs, Alpharma's predecessor, and Diamond Shamrock Chemical Company (hereinafter "Diamond"). At that time, there were approximately eleven intended uses of Bacitracin MD listed in that Section of the Code.

40. Then, in the early 1970's, safety issues arose regarding the potential of antibiotic animal drugs to contribute to the antibiotic resistance of certain strains of bacteria. To gather data on the subject, the FDA published a regulation requiring data submissions as a condition of continuing to enjoy any then-existing "interim marketing" rights for various antibiotics and combinations of antibiotics. *See* 38 Fed. Reg. 8282 (February 25, 1976). A.L. Labs and Diamond agreed to provide requested information about antibiotic resistance.

41. After review, the FDA subsequently withdrew approval for those eleven intended uses and removed them from 21 C.F.R. § 558.76. *See* 44 Fed. Reg. 39387 (July 6, 1979); 47 Fed. Reg. 42100 (September 9, 1982).

42. Since only Alpharma and/or its predecessors submitted NADAs or NADA supplements and received valid approval for all new uses of Bacitracin MD, Alpharma is the only company with approval for all of the drug's claims under 21 C.F.R. § 558.76.

B. PENNFIELD HAS NOT LAWFULLY OBTAINED FDA APPROVAL FOR ALL POST-DESI BACITRACIN MD USES, BUT CLAIMS THAT IT HAS SUCH APPROVAL.

43. PennField is a manufacturer and seller of animal drug products incorporated in Nebraska, with its principal place of business in Omaha, Nebraska.

44. On information and belief, PennField obtained unlawful FDA approval of 10 Post-DESI Bacitracin MD Claims as successor in interest to Boehringer Ingelheim Vetmedica

Inc. (“Boehringer”), Fermenta Animal Health Co. (“Fermenta”), SDS Biotech Corporation, Diamond Shamrock Chemical Company, and/or Nopco.

45. On or around December 23, 2002, PennField began advertising in *Feedstuffs* weekly newspaper that it was introducing to the market a Bacitracin MD product called “Pennitracin MD 50-G.” A copy of PennField’s advertisement (including an enlargement of same for ease of viewing) is attached as Exhibit A.

46. Shortly thereafter, Pennitracin MD 50-G became available for sale. A copy of the label from a bag of Pennitracin MD 50-G is attached as Exhibit B. PennField states on the Pennitracin MD 50-G label that it has FDA approval for the 4 DESI and 10 of Alpharma’s 12 Post-DESI Bacitracin MD Claims. *Compare* Pennitracin MD 50-G Label, Exhibit B, *with* 21 C.F.R. § 558.76 summary chart in ¶ 34, *supra* (PennField’s 10 Post-DESI Claims correspond to chart numbers 2, 9-12, 3, 5, 1 and 7-8, respectively).

47. However, neither PennField nor its predecessors in interest were granted lawful approval for PennField’s 10 Post-DESI Claims.

48. On its product packaging, PennField identifies the basis of its claims to be “NADA 141-137, Approved by FDA.”

49. PennField’s Bacitracin MD is promoted in the marketplace for uses consistent with the 10 Post-DESI Claims. For example, Pennitracin MD 50-G is advertised on at least one medicated feed distributor’s website as “a granulated Type A medicated feed additive that is an antibacterial fermentation product for supplementing rations for swine, cattle, chickens, turkeys, pheasants and quail.” *See* <http://www.asp-inc.com/products/fa.php>, at 10, attached as Exhibit C.

As there are no Bacitracin MD DESI Claims for swine and cattle, *see* ¶ 30, *supra*, this advertisement lists product uses for which PennField does not have FDA approval.

50. On information and belief, PennField does not now and has never represented that it obtained FDA approval for Pennitracin MD 50-G via the ANADA process. If PennField had approval under ANADA, the FDA would have assigned an application number beginning with “ANADA,” rather than the “NADA” number stated on PennField’s product label. *See* Exhibit B.

C. THE FDA’S ACTIONS ALLOWED PENNFIELD TO MAKE UNLAWFUL BACITRACIN MD APPROVAL CLAIMS.

(1) The FDA Unlawfully Granted PennField Approval to Sell Bacitracin MD and/or Provided It with “Proof” of Approval to Third Parties.

51. On information and belief, in 1998, the FDA sent a letter to PennField or its predecessor unlawfully granting it approval to market and sell Bacitracin MD for multiple Post-DESI uses and/or providing it with false documentation of such approval, as described in more detail below.

52. On information and belief, the process through which the FDA came to grant PennField unlawful approval to sell Bacitracin MD is as follows. It is believed and therefore averred that, in the late 1990s, the FDA recognized that, in some cases, the documentation available in the Agency’s files regarding the approval status of animal drug products listed for the various sponsors in 21 C.F.R. § 558.15 (hereinafter “Sponsors”) was incomplete.

53. During the summer of 1998, the FDA began an effort to complete the administrative records of the approvals for the animal drug products and combinations identified in 21 C.F.R. § 558.15(g)(1) and (2). As a result, the FDA sent letters to the Sponsors (many

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dated July 29, 1998), including marketers of antibiotics and combinations of antibiotics used in animal feed (hereinafter “Certification Request”).

54. Specifically, the FDA requested that the Sponsors provide any available information establishing that an approval corresponding to a specific listing in 21 C.F.R. § 558.15 was granted prior to February 25, 1976. The Sponsors were asked to identify the products involved, certify the truthfulness and accuracy of the information presented under penalty of law, and provide “labeling consistent with the approval but no greater in scope than the listing in section 558.15” (hereinafter “Sponsor Certifications”). *See* July 29, 1998 Letter from Stephen F. Sundlof of the Center for Veterinary Medicine, FDA, to Donald A. Gable, of Boehringer (obtained via a Freedom of Information Act request (FDA File No. FO1-10927), with redactions as shown), attached as Exhibit D.

55. On information and belief, the FDA relied upon the Sponsor Certifications alone to establish that the sponsors were entitled to immediate NADA approval, in violation of 21 U.S.C. § 360b.

56. The agency then sent the sponsors letters as proof of that approval (hereinafter “FDA Closure Letters”). *See, e.g.*, November 12, 1998 Letters from Dr. Sundlof of the FDA, to Sondra C. Flick of Alparma, with respect to Alparma’s NADAs 141-130, 141-131, and 141-132, respectively, at 1 (“[Y]our certification will be used along with information in our files as the administrative record of an approval for NADA [#] . . . for use for the indications and under the conditions of use specified in the labeling attached to your [Sponsor Certification] letter.”). These three letters are attached as Exhibit E.

57. Alternatively, the FDA did not make a final approval determination based on the Sponsor Certification, but nevertheless sent sponsors FDA Closure Letters worded in such a manner as to provide the sponsors with evidence that made it possible for them to falsely represent to third parties that they had FDA approval. *See id.* (“[Y]ou may rely on this letter to verify the approval status of NADA [#].”).

58. On information and belief, in 1998, the FDA requested that PennField’s predecessor in interest, Boehringer, provide the agency with Sponsor Certification regarding its Bacitracin MD approvals.

59. On information and belief, although Boehringer was not entitled to do so, it submitted a Sponsor Certification stating that it was entitled to the 4 DESI and 10 PennField Post-DESI Bacitracin MD Claims. *See* PennField’s Pennitracin MD-G Label, Exhibit B.

60. On information and belief, despite Boehringer’s failure to file NADAs for any Post-DESI Bacitracin MD Claims, the FDA sent the company an FDA Closure Letter approving and/or providing “proof” of approval for all 4 DESI and 10 Post-DESI Claims under NADA 141-137. Boehringer named its Bacitracin MD “approved” under NADA 141-137 “Noptracin MD-50.”

61. On information and belief, PennField purchased or otherwise came to own Boehringer’s “approval interest” in NADA 141-137 and recently began advertising and marketing the NADA “approval” under the name “Pennitracin MD G-50.”

62. Prior to PennField’s entry into the Bacitracin MD market, Alpharma was the only company approved to sell Bacitracin MD. Since that time, based on the FDA’s actions,

PennField has been selling Bacitracin MD in competition with Alpharma, resulting in lost sales, profits, and good will to Alpharma and causing it continuing irreparable harm.

COUNTS

Count I: The FDA Granted PennField Approval for 10 Post-DESI Uses of Bacitracin MD in Violation of 21 C.F.R. §360b

63. Paragraphs 1 – 62 are incorporated herein as though the same were set forth in their entirety.

64. On information and belief, in 1998, the FDA sent PennField and/or its predecessor(s) in interest (collectively “PennField”) an FDA Closure Letter in response to PennField’s Sponsor Certification.

65. On information and belief, the FDA Closure Letter to PennField granted PennField approval to sell and market Bacitracin MD for all of the Pennitracin MD 50-G label claims, including the following 10 Post-DESI Claim uses (hereinafter “PennField’s 10 Post-DESI Claims”):

- i. Swine: For 10 to 30 grams per ton of feed for increased rate of weight gains and improved feed efficiency.
- ii. Swine: For 250 grams per ton of feed for control of swine dysentery.
- iii. Pregnant Sows: For 250 grams per ton of feed for control of clostridial enteritis in suckling piglets.
- iv. Feedlot Beef Cattle: For 70 mg per head per day for reduction in the number of liver condemnations.
- v. Feedlot Beef Cattle: For 250 mg per head per day for reduction in the number of liver condemnations.
- vi. Broiler Chicken: For 50 grams per ton of feed as an aid in prevention of necrotic enteritis.
- vii. Broiler Chicken: For 100 to 200 grams per ton of feed as an aid in prevention of necrotic enteritis.
- viii. Laying Hens: For 10 to 25 grams per ton of feed for increased egg production and improved feed efficiency.
- ix. Turkeys: For 200 grams per ton of feed as an aid in control of transmissible enteritis.

x. Quail: For 200 grams per ton of feed for prevention of ulcerative enteritis.

See PennField's Pennitracin MD-G Label, Exhibit B.

66. On information and belief, the FDA granted approval for PennField's 10 Post-DESI Claims based solely or substantially upon PennField's Sponsor Certification in which PennField erroneously claimed that it was entitled to the above 10 Claims.

67. On information and belief, the FDA did not take any actions to investigate or verify PennField's Sponsor Certification prior to granting approval of PennField's 10 Post-DESI Claims.

68. FDA's granting PennField approval for PennField's 10 Post-DESI Claims is final agency action for which there is no other adequate remedy than this suit.

69. The FDA's granting PennField approval for PennField's 10 Post-DESI Claims was arbitrary and capricious and outside the discretion of the agency's statutory authority.

70. The FDA granted PennField approval for PennField's 10 Post-DESI Claims without considering necessary data, articulating an explanation establishing a rational connection between the facts found and the choice made, and/or weighing the relevant factors that Congress intended the FDA to weigh.

71. The FDA approval for PennField's 10 Post-DESI Claims violates statutory authority in that the:

- (a) FDA failed to require that PennField submit a NADA or NADA supplements for PennField's 10 Post-DESI Claims, as required by 21 U.S.C. § 360b(a), (b) and 21 C.F.R. §§ 514.4, 514.11(a)(5)(ii);
- (b) FDA failed to require that PennField submit full reports of adequate and well controlled investigations that show by "substantial evidence" that each of PennField's 10 Post-DESI Claims are safe and effective for use, as required by 21 U.S.C. §§ 360b(b)(1), (d)(1), (d)(3);

- (c) PennField failed to submit a list of the Bacitracin MD components, as required by § 360b(b)(1);
- (d) FDA failed to require that PennField submit a statement of Bacitracin MD composition, as required by § 360b(b)(1);
- (e) FDA failed to require that PennField submit a description of PennField's Bacitracin MD manufacturing, processing, and packaging procedures, as required by § 360b(b)(1);
- (f) FDA failed to require that PennField submit samples of its Bacitracin MD product and intended animal feed, as required by § 360b(b)(1);
- (g) FDA failed to require that PennField submit proposed labeling for each PennField Post-DESI claim, as required by § 360b(b)(1);
- (h) FDA failed to require that PennField submit a description of methods for determining the quantity of the drug within the feed, as required by § 360b(b)(1);
- (i) FDA failed to require that PennField submit the tolerance, withdrawal period, or other use restrictions that are required in order to assure drug safety, as required by § 360b(b)(1);
- (j) FDA failed to consider, among other things, "safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data," as required by 21 U.S.C. § 360b(d)(2);
- (k) FDA failed to require that PennField conduct investigations designed and interpreted "by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof," as required by § 360b(d)(3);
- (l) FDA failed to ascertain that PennField Bacitracin MD drug labeling, distribution, holding, and use conform to the conditions of lawful FDA approval, as required by § 360b(a)(2); and
- (m) FDA failed to publish PennField's approval for Bacitracin MD in the Federal Register, as required by § 360b(i).

72. It was not within the FDA's discretion to grant PennField approval for PennField's 10 Post-DESI Claims under § 360b(b)(1) of the FDC Act.

Count II: Alternatively, the FDA Acted in a Manner That Enabled PennField to Falsely Represent to Third Parties That It Had FDA Approval for 10 Post-DESI Uses of Bacitracin MD

73. Paragraphs 1 – 62 are incorporated herein as though the same were set forth in their entirety.

74. Alternatively, the FDA's 1998 Closure Letter to PennField did not grant the company approval for PennField's 10 Post-DESI Claims, nor did the Agency intend for the FDA Closure Letter to grant such approval. Nevertheless, the language employed in the 1998 FDA Closure Letter appears to third parties to grant PennField approval for all of its Pennitracin MD 50-G label claims, including PennField's 10 Post-DESI Claims, in violation of 21 U.S.C. § 360b.

75. On information and belief, the FDA's 1998 Closure Letter to PennField enabled the company to mislead third parties regarding FDA approval of Bacitracin MD and introduce an adulterated animal drug into the market in violation of 21 U.S.C. § 360b.

76. On information and belief, the FDA's failure to timely amend 21 C.F.R. § 558.76 to clarify that only Alpharma is entitled to the 12 Post-DESI Bacitracin MD Claims further enabled PennField to mislead third parties regarding FDA approval of Bacitracin MD and introduce an adulterated animal drug into the market in violation of 21 U.S.C. § 360b.

77. On information and belief, the FDA's failure to take enforcement actions against PennField to stop unlawfully marketing and selling Bacitracin MD further enabled PennField to mislead third parties regarding FDA approval of Bacitracin MD and introduce an adulterated animal drug into the market in violation of 21 U.S.C. § 360b.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Enter a Declaratory Judgment holding unlawful and void the FDA's approval of PennField's 10 Post-DESI Claims as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

B. Enter a Declaratory Judgment holding unlawful and void the FDA's approval of PennField's predecessor(s)' 10 Post-DESI Claims as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

C. Enter a Declaratory Judgment holding that the FDA's 1998 Closure Letter to PennField and/or its predecessors does not confer FDA approval for Post-DESI Bacitracin MD Claims;

D. Enter a Declaratory Judgment holding unlawful and void any other FDA approval(s) of any other Bacitracin MD claims made by PennField and/or its predecessors without appropriate application submissions to the FDA as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

E. Enjoin the FDA to take appropriate enforcement actions to stop PennField from making unauthorized Bacitracin MD approval claims;

F. Enjoin the FDA from approving any new NADAs, supplemental NADAs, and/or ANADAs for Bacitracin MD claims made by PennField without appropriate application submissions to the FDA;

G. Award Plaintiff its costs and reasonable attorneys fees incurred in this action; and

Exhibit

A

237 FOS

Freedom of Choice

Unhappy with limited competition in feed additives?
Tired of exclusive contracts, load up programs and
complicated promotions that don't work?

PennField® again provides you with freedom of choice!

Announcing a new product from the proven leader
in feed additives, PennField.®

Pennitracin MD 50-G™

Bacitracin Methylene Disalicylate

*You expect more from the American leader
in feed additives and you get it with PennField®!*



14040 Industrial Road ■ Omaha, NE 68144
(402) 330-6000 ■ (800) 832-8303
FAX (402) 330-6004

Exhibit B

Pennitracin

bacitracin methylene disalicylate

Type A Medicated Article
Antibacterial

For supplementing rations of swine, cattle, chickens, turkeys, pheasants and quail.

ACTIVE INGREDIENT: Each pound contains feed grade bacitracin methylene disalicylate equivalent to 50 grams bacitracin (Master Standard)

COMPOSITION: A dried precipitated fermentation product obtained by culturing *Bacillus licheniformis* Tracy on media adapted for microbiological production of bacitracin; calcium carbonate, mineral oil.

FOR MANUFACTURING REGISTERED POULTRY AND LIVESTOCK FEED ONLY.

MIXING DIRECTIONS: To prepare an intermediate premix containing 5 grams per lb by mixing 1.0 lb of PENNITRACIN MD 50-G with 9.0 lbs of ground corn or soybean meal. Then mix 0.8 to 50 lbs of the intermediate premix per ton of finished feed.

SPECIES	GRAMS PENNITRACIN MD 50-G* PERTON OF FEED	INDICATION FOR USE
	10-50 250	For increased rate of weight gain and feed efficiency. For control of enteric dysentery (diarrhea) associated with increased fecal excretion in piglets up to 200 lbs body weight. Feed 250 grams per ton of complete ration premises with a history of enteric dysentery, but where signs of disease have not yet occurred or following an approved treatment of the disease condition. The 100 grams per ton level will provide 5 to 7 mg/lb in rations weighing 40 to 500 lbs. CAUTION: Observe clinical condition of pigs when signs are not satisfactory. Feed containing an approved level of bacitracin methylene disalicylate should be fed as the sole ration.
Pregnant sows	250	For control of diarrhea or milk oozing by 12 per cent in sows fed to sows from 14 days before through 21 days after farrowing to prevent with a history of diarrhea. CAUTION: Therapies should be confirmed by a veterinarian when results are not satisfactory. Feed containing an approved level of bacitracin methylene disalicylate should be fed as the sole ration.
Feedlot beef cattle	mg per head per day 70 (continuously) 250 (8 days to 30)	For reduction in the number of fecal excretions due to abscesses in feedlot beef cattle. For reduction in the number of fecal excretions due to abscesses in feedlot beef cattle.
	4-50 30 100-250	For increased rate of weight gain and feed efficiency. For control of enteric dysentery (diarrhea) associated with increased fecal excretion in piglets up to 200 lbs body weight. Feed 250 grams per ton of complete ration premises with a history of enteric dysentery, but where signs of disease have not yet occurred or following an approved treatment of the disease condition. The 100 grams per ton level will provide 5 to 7 mg/lb in rations weighing 40 to 500 lbs. CAUTION: Observe clinical condition of pigs when signs are not satisfactory. Feed containing an approved level of bacitracin methylene disalicylate should be fed as the sole ration.
Laying hens	10-25	For increased egg production and improved feed efficiency during the first seven months of production.
Pheasants	4-50	For increased rate of weight gain and feed efficiency.

NOTE: Where minimum levels are shown, increase the antibiotic concentration within approved range when necessary to fit the feeding program and to insure adequate levels of antibiotic in the complete feed.

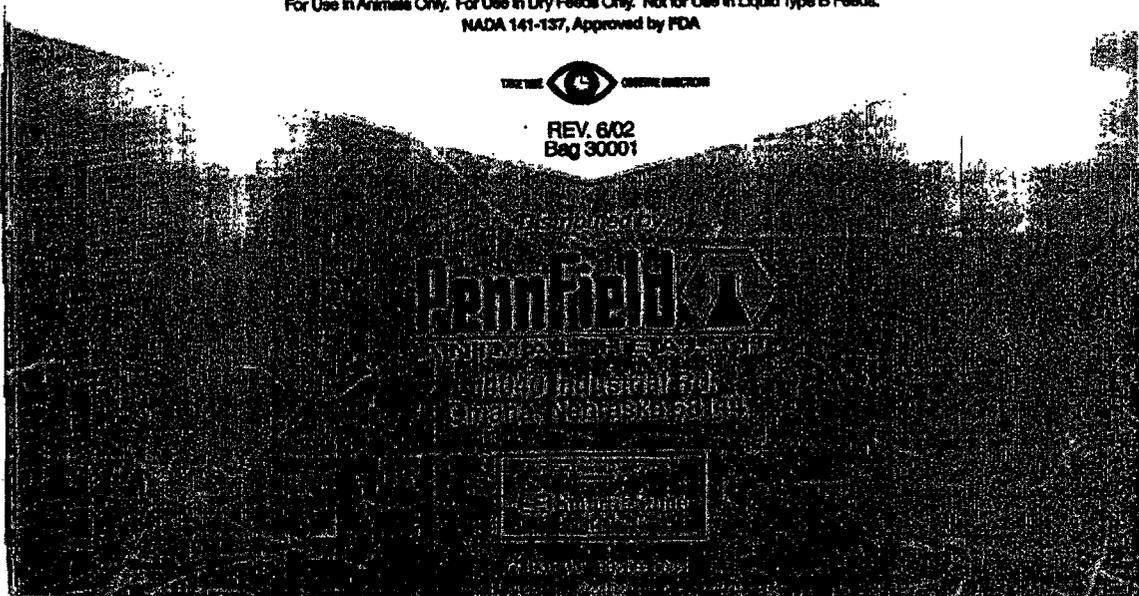
RESTRICTED DRUG: Use only as directed (CA).

For Use in Animals Only. For Use in Dry Feeds Only. Not for Use in Liquid Type B Feeds.

NADA 141-137, Approved by FDA



REV. 6/02
Bag 30001

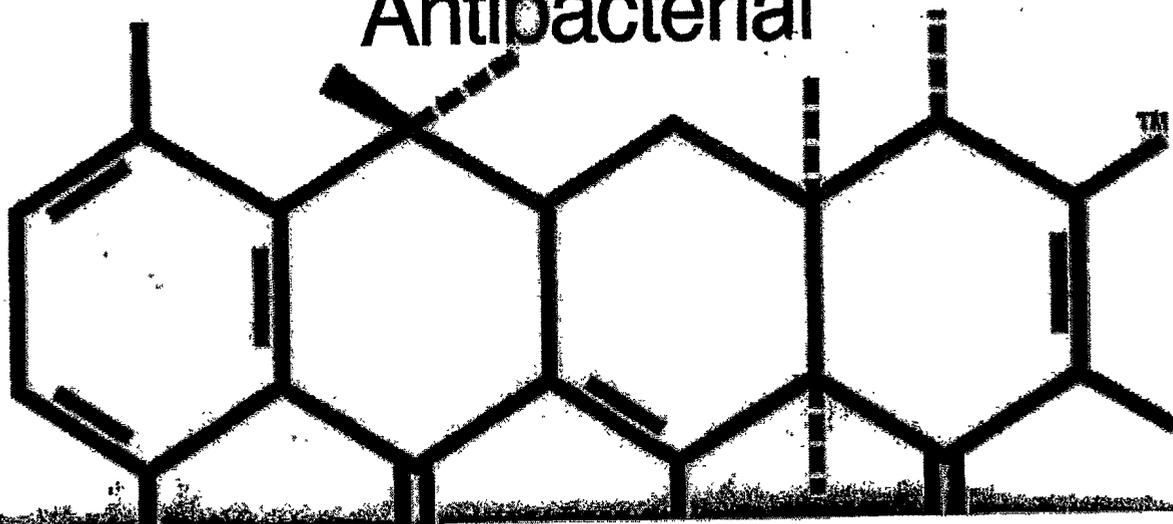


Label - back

Pennitracin MD 50·G™

Bacitracin Methylene Disalicylate

Type A Medicated Article
Antibacterial



Label - front (top) enlarged

ACTIVE DRUG INGREDIENTS:

Each pound contains feed grade bacitracin methylene disali
equivalent to 50 grams bacitracin
(Master Standard)

**FOR MANUFACTURING REGISTERED POULTR
AND LIVESTOCK FEEDS**

NADA 141-137 APPROVED BY FDA

**NET WT.
50 lb (22.7 kg)**

**LOT
EX**

PennField®

ANIMAL HEALTH

Label - front (bottom) enlarged

Pennitracin

bacitracin methylene disalicylate

Type A Medicated Article
Antibacterial

For supplementing rations of swine, cattle, chickens, turkeys, pheasant

ACTIVE INGREDIENT: Each pound contains feed grade bacitracin methylene disalicylate equivalent (Master Standard)

COMPOSITION: A dried precipitated fermentation product obtained by culturing *Bacillus licheniformis* T1 microbiological production of bacitracin; calcium carbonate, mineral

FOR MANUFACTURING REGISTERED POULTRY AND LIVESTOCK FEEDS

MIXING DIRECTIONS: To prepare an intermediate premix containing 5 grams per lb by mixing 1.0 lb of Pennitracin with 9.0 lbs of ground corn or soybean meal. Then mix 0.8 to 50 lbs of the intermediate premix

Label back (top) enlarged

SPECIES	GRAMS PENNITRACIN MD 50-G™ PERTON OF FEED	INDICATION FOR USE
Growing/finishing swine	10-30 250	For increased rate of weight gain and feed efficiency. For control of swine dysentery (bloody Scours) associated with <i>Yersinia</i> spp. weight. Feed 250 grams per ton of complete feed on premises with a history of disease have not yet occurred or following an approved treatment of the disease will provide 5 to 7 mg/lb in swine weighing 40 to 250 lbs. CAUTION: Diagnosis should be confirmed by a veterinarian when results are approved level of bacitracin methylene disalicylate should be feed as the sole
Pregnant sows	250	For control of clostridial enteritis caused by <i>C. perfringens</i> in suckling pigs within 21 days after farrowing on premises with a history of clostridial enteritis. CAUTION: Diagnosis should be confirmed by a veterinarian when results are approved level of bacitracin methylene disalicylate should be feed as the sole
Feedlot beef cattle	mg per head per day 70 (continuously) 250 (5 days in 30)	For reduction in the number of liver condemnations due to abscesses in feedlot For reduction in the number of liver condemnations due to abscesses in feedlot
Broiler chickens	4-50 50 100-200	For increased rate of weight gain and improved feed efficiency. As an aid in prevention of necrotic enteritis caused by or complicated by <i>Clostridium</i> bacitracin methylene disalicylate. As an aid in the control of necrotic enteritis caused by or complicated by <i>Clostridium</i> bacitracin methylene disalicylate. CAUTION: To control a necrotic enteritis outbreak, start medication at the first range permitted provides for different levels based on severity of the disease. pathologist to determine the diagnosis and advice regarding the optimal level of days or as long as clinical signs persist, and then reduce medication to prevent

Label - back (bottom) enlarged

Laying Hens	10-25	For increased egg production and improved feed efficiency during the first seven months of laying.
Growing turkeys	4-50 200	For increased rate of weight gain and improved feed efficiency. As an aid in control of transmissible enteritis in growing turkeys complicated by organisms methylene disicyclate. Feed continuously as the sole ration.
		For increased rate of weight gain and improved feed efficiency.
Quail	5-50 200	For increased rate of weight gain and improved feed efficiency in quail not over 5 weeks of age. For prevention of ulcerative enteritis in growing quail due to Clostridium colinum subspecies disicyclate. Feed continuously as the sole ration.

NOTE: Where minimum levels are shown, increase the antibiotic concentration within approved range when in a continuous feeding program and to insure adequate levels of antibiotic in the complete feed.

RESTRICTED DRUG: Use only as directed (CA).

For Use in Animals Only. For Use in Dry Feeds Only. Not for Use in Liquid Type B Feeds.

NADA 141-137, Approved by FDA



REV. 6/02
Bag 30001

Distributed by

Pennfield

10040 Industrial Rd.
Omaha, Nebraska 68114

SmithKline Beecham

Exhibit C

For your convenience, we have setup the quickfinder. Just click on a letter...

Quickfinder

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#)
[N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

0-9

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4 Plex

[Login to view product info.](#)

A blend of Zinc Methionine Complex, Manganese Methionine Complex, Copper Lysine Complex, and Cobalt Glucoheptonate. All ingredients are manufactured for use in animal feeds.

4 Plex C

[Login to view product info.](#)

A highly concentrated form of Zinc Methionine Complex, Manganese Methionine Complex, Copper Lysine Complex, and Cobalt Glucoheptonate. All ingredients are manufactured for use in animal feeds.

A

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A-30 Vitamin Premix

[Login to view product info.](#)

A-30 Vitamin Premix is specifically formulated for uniform dispersion in animal feeds. Vitamin A is essential to maintenance of vision, skin, hair, feathers, and nerves. It also helps maintain resistance to various infectious diseases.

AD3E-10

[Login to view product info.](#)

AD3E-10 is a vitamin premix specifically formulated for uniform dispersion in animal feeds. Vitamin A is necessary for normal functions of vision, skin, nerves, and hair. Vitamin D is necessary for calcium and phosphorus metabolism.

AD3E-30

[Login to view product info.](#)

AD3E-30 is a vitamin premix specifically formulated for uniform dispersion in animal feeds. Vitamin A is necessary for normal functions of vision, skin, hair, and nerves. Vitamin D is necessary for calcium and phosphorus metabolism.

Ammonium Chloride

[Login to view product info.](#)

A dry free flowing white powder. The chemical formula is NH₄CL. Labeled for use in animal feeds.

Ammonium Sulfate

[Login to view product info.](#)

A dry white prilled material labeled for feed use.

Amprol @ 25%

[Login to view product info.](#)

Amprol is for use in poultry feeds as an aid in prevention or treatment of coccidiosis.

Amprol @ Plus

[Login to view product info.](#)

Amprol Plus is for use in poultry feeds as an aid in prevention

of coccidiosis. It is supplied as a premix for convenience in handling and uniform incorporation in feed.

Anise-Kist

[Login to view product info.](#)

Anise-Kist is a well-rounded anise licorice aroma. Ideal for adding a consistent aroma to animal feeds of any type. 40 lbs of product shipped in 6 gallon poly pails with ZipLock poly liners.

Anti-Cox

[Login to view product info.](#)

Anti-Cox is used for the prevention of coccidiosis in ruminating and non-ruminating calves and cattle caused by Elmeria Bovis and E. Zurnii.

Apple-Kist

[Login to view product info.](#)

Apple-Kist is a well-rounded aroma. Ideal for adding a consistent aroma to animal feeds of any type. 40 lbs of product shipped in 6 gallon poly pails with ZipLock poly liners.

AS 10/10

[Login to view product info.](#)

AS 10/10 aids in the maintenance of weight gains in the presence of respiratory disease such as shipping fever in beef cattle.

AS PROP-50

[Login to view product info.](#)

AS PROP-50 is a dry free flowing mold inhibitor for use in all types of animal feeds.

Aureo S 700 2G Crumbles

[Login to view product info.](#)

This antibiotic sulfa crumbles form is designed to be mixed in feeds for beef cattle for the maintenance of weight gains in the presence of respiratory diseases such as shipping fever.

Aureo S 700 Granular

[Login to view product info.](#)

Aureo S 700 Granular is designed for use in beef cattle feeds as an aid in the maintenance of weight gains in the presence of respiratory disease.

Avail Zn 40

[Login to view product info.](#)

A dilute form of Zinc Amino Acid complex for use in animal feeds.

Availa CU 100

[Login to view product info.](#)

A source of Copper Amino Acid Complex for use in animal feeds.

Availa MN 80

[Login to view product info.](#)

A nutritional source of Manganese Amino Acid Complex for use in animal feeds.

Availa Z/M

[Login to view product info.](#)

A combination of product that includes both Zinc and Manganese Amino Acid Complexes. This product is a nutritional product for use in animal feeds.

Availa ZN 100

[Login to view product info.](#)

A dilute form of Zinc Amino Acid complex for use in animal feeds.

Availa-4

[Login to view product info.](#)

A blend of Zinc Amino Acid Complex, Manganese Amino Acid Complex, Copper Amino Acid Complex and Cobalt Glucoheptenate. This product is designed to supplement trace elements in animal feeds.

Availa-FE 60

[Login to view product info.](#)

A nutritional feed additive for Iron supplementation. The Iron is bound to an amino acid complex. For use in animal feeds only.

B

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Ban-Pack

[Login to view product info.](#)

Ban-Pack aids in the prevention, migration, and establishment of large roundworms (*Ascaris Suum*) infections in swine. It also aids in the prevention of establishment of nodular worms (*Oesophagostomum*) infections in swine.

Bicarb

[Login to view product info.](#)

Sodium bicarbonate for animal feed buffer.

Biotin H-100

[Login to view product info.](#)

Biotin H-100 is a vitamin premix for dispersion in animal feeds. Biotin is necessary for skin and coat. Biotin is essential to carbohydrate, fat, and protein metabolism. Biotin is related to hatchability in poultry.

Bovatec 68

[Login to view product info.](#)

Bovatec 68 is used for the enhancement of feed utilization and weight gain in cattle.

Buttery Maple-Kist

[Login to view product info.](#)

Buttery Maple-Kist is a well-rounded buttery maple aroma. Ideal for adding a consistent aroma to animal feeds of any type. 40 lbs of product shipped in 6 gallon poly pails with ZipLock poly liners.

C

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Calcium Chloride

[Login to view product info.](#)

A source of the element calcium in the chloride form. This form is water soluble and is for use in animal feeds.

Calcium Iodate [Login to view product info.](#)
Calcium Iodate is a good source of nutritional iodine for animals.

Calcium Propionate [Login to view product info.](#)
A dry mold inhibitor for use in animal feeds. More user friendly dry product than some competitive products.

Calcium Sulfate [Login to view product info.](#)
A source of calcium in the sulfate form for use in animal feeds.

Choline Bitartrate [Login to view product info.](#)
A water soluble form of the vitamin Choline.

Choline Chloride 60% [Login to view product info.](#)
Choline Chloride 60% is an essential factor in the normal development of animals and is necessary for maximum growth of animals. Choline is essential for the transmission of nerve impulses and the prevention of fat accumulation in the liver.

Cobalt Carbonate [Login to view product info.](#)
The element cobalt in the carbonate form. A dry free flowing powder for use in animal feeds.

Cobalt Sulfate [Login to view product info.](#)
A source of the element cobalt for use in animal feeds. This source is highly water soluble.

Coban™ 60 [Login to view product info.](#)
Coban™ 60 is an aid in the prevention of coccidiosis. In broiler chickens and replacement chickens intended for use as caged layers. Also for turkey and quail.

Copper Sulfate [Login to view product info.](#)
A beautiful blue crystalline powder which is water soluble. This source of the element copper is for use in animal feeds and also carries a water treatment label.

CTC-10 [Login to view product info.](#)
CTC-10 aids in the growth promotion and feed efficiency in chickens, turkeys, swine, growing beef cattle, lambs, sheep, and mink. It also aids with egg production, the treatment of blue comb in turkeys, and the prevention of liver abscesses in cattle.

Cuplex 100 [Login to view product info.](#)
A concentrated form of Copper Lysine for use in animal feeds.

D

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D3-30 [Login to view product info.](#)
D3-30 is a vitamin premix for dispersion in animal feeds. Vitamin D is necessary for proper function of bones and for calcium and phosphorus metabolism.

Deccox ® [Login to view product info.](#)
Deccox is an anticoccidial feed additive containing 6% decoquinate which stops development of the coccidia early in the life cycle.

DL Methionine Feed Grade [Login to view product info.](#)
DL-Methionine Feed Grade is approved for use in all animal species, Particularly for use in monogastrics, it ensures the adequate supply of sulfur amino acids, especially of the essential methionine.

DYNA-K [Login to view product info.](#)
A source of highly available potassium (K) and chloride (Cl) that will help meet animal and poultry requirements for these essential nutrients.

Dynamate ® [Login to view product info.](#)
Dynamate is a mineral consisting of the sulfate form of potassium and magnesium specially produced for the feed industry. It is a source of sulfur, potassium, and magnesium.

E [Back to Top](#)

E-125 [Login to view product info.](#)
E-125 is a vitamin premix for dispersion in animal feeds. Vitamin E is necessary for normal fertility and gestation.

E-20 [Login to view product info.](#)
E-20 is a vitamin premix for dispersion in animal feeds. Vitamin E is necessary for normal fertility and gestation.

EDDI 79.5% [Login to view product info.](#)
EDDI 79.5% (ethylenediamine dihydriodide) is an excellent organic iodine source for animal nutrition. It is used in feeds, premixes, and salt blocks.

Endox ® Dry [Login to view product info.](#)
Endox Dry is a dry antioxidant for all processed animal feeds.

Ener GII ™ [Login to view product info.](#)
Ener GII ™ is a palatable, patented formula of calcium salts of long-chain fatty acids. Ener GII ™ is an essential, safe, concentrated source of rumen bypass energy used to decrease per unit cost of milk production and maximize profit.

Equine Science Premix [Login to view product info.](#)



Equine Science Premix is a complete vitamin premix designed for use in equine feeds and supplements.

F

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FAT PAC 99™

[Login to view product info.](#)

FAT PAC 99™ is a highly concentrated fat source for economical use. FAT PAC 99™ is used when a high energy ration is required for cattle, horse, swine, or sheep.

Feed Curb © Liquid

[Login to view product info.](#)

Feed Curb Liquid is a broad spectrum acidic mold and microorganism inhibitor for feeds and feed ingredients.

Feed Savor © Liquid

[Login to view product info.](#)

Feed Savor Liquid is a liquid non-corrosive broad spectrum microorganism and mold inhibitor for animal feed.

Fenbendazole 0.6%

[Login to view product info.](#)

Fenbendazole 0.6% is used in swine for the removal of large round worms, whip worms, and other types of worms. It is used in cattle for the removal of lungworms, stomach worms, many other types of worms.

Fish Meal

[Login to view product info.](#)

This fish meal is ruminant grade with a high protein quality. It shows enhanced digestibility and ruminal undegradability.

G

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Garlic-Kist

[Login to view product info.](#)

Garlic-Kist is a well rounded garlic aroma. Ideal for adding a consistent aroma to animal feeds of any type. 40 lbs of product shipped in 6 gallon poly pails with ZipLock poly liners.

H

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H-100 Biotin

[Login to view product info.](#)

H-100 Biotin is a vitamin premix for dispersion in animal feeds. Biotin is necessary for skin and coat. Biotin is essential to carbohydrate, fat, and protein metabolism. Biotin is related to hatchability in poultry.

I

[Back to Top](#)

Iron Carbonate

[Login to view product info.](#)

Also known as ferrous carbonate this source of the element Iron is in the carbonate form and is for use in animal feeds.

Iron Oxide

[Login to view product info.](#)

This red form of the element Iron is used primarily as a colorant in animal feeds and has little if any bioavailability to the animal.

Iron Sulfate

[Login to view product info.](#)

This dry free flowing form of the element Iron is the water soluble form and is labeled for animal feed use.

K

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Kem Lac ® Dry

[Login to view product info.](#)

Kem Lac is a concentrated stabilized source of microorganisms and enzymes which are beneficial to silage fermentation.

Kem Sorb™ Dry

[Login to view product info.](#)

Kem Sorb™ Dry is a flow agent (anti-caking agent) that improves flowability of feed ingredients and feeds by absorbing and binding inorganic and organic liquids and materials that cause flow problems.

L

[Back to Top](#)

Linco 10

[Login to view product info.](#)

Linco 10 increases rate of gain in growing-finishing swine. It also controls swine dysentery and reduces the severity of swine mycoplasma pneumonia cause by mycoplasma hypopneumoniae.

Linco 4

[Login to view product info.](#)

Linco 4 improves feed efficiency of broiler chickens and also controls necrotic enteritis caused by Clostridium species.

Lysine HCL

[Login to view product info.](#)

A synthetic amino acid for use in poultry and livestock feeds.

M

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MagnaFerm Yeast Culture

[Login to view product info.](#)

MagnaFerm Yeast Culture is a high-quality source of fermentation media and live, active Saccharomyces Cerevisiae yeast cells that are matured in a multi-stage fermentation.

Magnesium Oxide 54%

[Login to view product info.](#)

Magnesium Oxide is a free flowing, granular, calcined magnesite.

Magnesium Sulfate

[Login to view product info.](#)

A source of the element magnesium in a sulfate form. This form is water soluble and is for use in animal feeds.

Manganese Sulfate

[Login to view product info.](#)

The sulfate form of the element manganese. This form is both highly bioavailable and the most water soluble animal feed form.

Manganous Oxide

[Login to view product info.](#)

The oxide form of Manganese, an essential element. This product is approved for use in animal feeds.

Manpro 160

[Login to view product info.](#)

A concentrated form of the complex of Manganese Methionine. Labeled for use in animal feeds.

Mec-Pack

[Login to view product info.](#)

Mec-Pack helps control swine dysentery, vibronic dysentery, bloody scours, or hemorrhagic dysentery. It also helps control bacterial swine enteritis. It also increases the rate of weight gain and improves feed efficiency in swine.

MicroAid

[Login to view product info.](#)

A concentrated brownish-gray granular material which contains the naturally occurring biologically active compound derived from the Yucca Shidigera plant.

Microzyme

[Login to view product info.](#)

A Source of live, viable direct-fed microorganisms, supplemental enzyme activity, and live, active yeast for use in livestock and pet nutrition.

Molastik

[Login to view product info.](#)

Molastik is a binding agent designed for use with molasses in blocks, range cubes, and pellets.

Myco Curb S ® Liquid

[Login to view product info.](#)

Myco Curb S Liquid is a surfactant / mold inhibitor for processed feed ingredients, animal feeds, and pet foods.

Myco Curb ® Dry

[Login to view product info.](#)

Myco Curb is a dry non-corrosive broad spectrum mold inhibitor that is non-corrosive to users.

Mycoflake™ Liquid

[Login to view product info.](#)

Mycoflake Liquid is a non-corrosive liquid surfactant for treatment of grain intended as cattle feed. Grain is to be treated before flaking to reduce the amount of moisture required.

N

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Naturox™ Liquid

[Login to view product info.](#)

Naturox Liquid is an all-natural antioxidant for preservation of

fats, oils, fat soluble vitamins, flavors, aromas, carotenoids, and other oxygen-sensitive materials.

Naturox™ Plus Dry

[Login to view product info.](#)

Naturox Plus Dry is an all-natural free flowing antioxidant for use in the preservation of oils, fats, fat soluble vitamins, flavors, aromas, carotenoids and other oxygen-sensitive materials.

Neo-Oxy 10/10

[Login to view product info.](#)

Neo-Oxy 10/10 aids in the maintenance of weight gain and feed consumption in the presence of atrophic rhinitis in swine. It also aids in the control and prevention of bacterial enteritis in poultry and swine.

Neo-Oxy 50/50

[Login to view product info.](#)

A combination of two proven broad spectrum antibiotics - Neomycin and Oxytetracycline.

Niacinamide, 99%

[Login to view product info.](#)

Niacinamide is a supplement for animal nutrition to be added to premixes, concentrates, and complete feeds to supply the vitamin B3 requirement of the animal.

Nutri-Pro™

[Login to view product info.](#)

A highly digestible source of protein for use in commercial feeds.

NutroCAL™ Non-Medicated Dry

[Login to view product info.](#)

NutroCAL is a supplement of essential minerals and gluconeogenic sources to assist in maintaining a transition cow in excellent condition. NutroCAL is also an excellent mold inhibitor.

O

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Oro Glo® Dry

[Login to view product info.](#)

Oro Glo provides natural yellow oxycarotenoids for poultry diet formulations. Oro Glo can be used as the source of yellow, but for best results should be used along with other natural ingredients.

P

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Pel-Aid®

[Login to view product info.](#)

Pel-Aid is a unique pelleting aid that serves as both a lubricant and a binder.

Pel-Stik®

[Login to view product info.](#)

Pel-Stik is an all purpose, low inclusion pellet binder that improves pellet quality.

Pennchlor 50

[Login to view product info.](#)

Pennchlor 50 is a Type A Medicated Article that contains chlortetracycline as the calcium complex. Chlortetracycline is used in livestock and poultry to treat disease, to aid in weight increase, and to improve feed/grain ratio.

Pennchlor 50 G

[Login to view product info.](#)

Pennchlor 50 G contains the broad spectrum antibiotic chlortetracycline. Pennchlor 50 G is used in livestock and poultry to treat disease, to aid in weight increase, and to improve feed/gain ratio.

Pennchlor S 700 35-G

[Login to view product info.](#)

Pennchlor S 700 is a broad spectrum combination feed additive for cattle. It is also an aid in the maintenance of weight gains in the presence of respiratory diseases.

Pennchlor SP 250™

[Login to view product info.](#)

Pennchlor SP 250™ is a triple feed grade antibiotic combination. Provides a broader spectrum of activity than a single drug product.

Pennchlor™ 100 HI-Flo

[Login to view product info.](#)

Pennchlor™ 100 HI-Flo is used in livestock and poultry feeds to treat disease, to aid in weight increase, and to improve feed/gain ratio.

Pennchlor™ 90 G

[Login to view product info.](#)

Pennchlor™ 90 G is a broad spectrum antibiotic used in livestock and poultry feeds. Pennchlor™ 90 G is used to treat disease, to aid in weight increase, and to improve feed/gain ratio.

Pennitracin MD 50-G

[Login to view product info.](#)

Pennitracin is a granulated Type A medicated feed additive that is a antibacterial fermentation product for supplementing rations for swine, cattle, chickens, turkeys, pheasants and quail.

Pennox™ 100 HI-Flo

[Login to view product info.](#)

Pennox™ 100 HI-Flo is a feed grade antibiotic containing Oxytetracycline. Oxytetracycline is highly effective in treatment of various diseases and for an increased weight gain and improved feed efficiency.

Pennox™ 50

[Login to view product info.](#)

Pennox™ 50 is a feed grade antibiotic containing oxytetracycline for use in livestock and poultry feeds. Pennox™ 50 is used for disease control and treatment for an increased rate of weight gain and improved feed efficiency.

Pennox™ 200 HI-Flo

[Login to view product info.](#)

Pennox™ 200 HI-Flo is a feed grade antibiotic containing oxytetracycline. Pennox™ 200 HI-Flo is highly effective in treatment of various diseases and for an increased rate of weight gain and improved feed efficiency.

PET-OX @ DRY

[Login to view product info.](#)

PET-OX @ DRY is a dry antioxidant for all processed pet foods.

PET-OX @ LIQUID

[Login to view product info.](#)

PET-OX @ LIQUID is a liquid antioxidant for all processed pet foods and food ingredients. This product does not contain ethoxyquin.

Phos 18%

[Login to view product info.](#)

A dry free flowing powder for use in animal feeds to supplement phosphorus.

Phos 18.5%

[Login to view product info.](#)

A dry free flowing powder for use in animal feeds to supplement phosphorus

Phos 21%

[Login to view product info.](#)

A dry free flowing powder for use in animal feeds to supplement phosphorus

Phos 24%

[Login to view product info.](#)

A dry free flowing powder for use in animal feeds to supplement phosphorus

Potassium Chloride

[Login to view product info.](#)

A source of highly available potassium (K) and chloride (Cl) that will help meet animal and poultry requirements for these essential nutrients.

Potassium Iodide

[Login to view product info.](#)

Potassium Iodide is a nutritional source of iodine in animal feeds.

Poultry Science Premix™

[Login to view product info.](#)

Poultry Science Premix is a complete vitamin and trace mineral premix specifically formulated for use in poultry feeds and supplements.

R

[Back to Top](#)

Rabon 7.76%

[Login to view product info.](#)

An oral larvicide for fly control in the following species; horses, lactating dairy cows, beef cattle, swine, and mink.

Rabon @ 97.3%

[Login to view product info.](#)

Rabon is an oral larvacide premix for use with horses. Rabon kills all types of flies in the larval stage.

Rendox™ A Liquid [Login to view product info.](#)
Rendox A Liquid is an antioxidant for fats, meal, and feeds.

Rendox™ Liquid [Login to view product info.](#)
Rendox Liquid is an antioxidant which can be used in a variety of fats, oils, and poultry meal. This is for use when ethoxyquin and BHA are restricted.

Rendox® AET Liquid [Login to view product info.](#)
Rendox AET is a general purpose liquid antioxidant for use in fats, oils, and meat meal.

Rumensin® 80 [Login to view product info.](#)
Rumensin® 80 is used for improved feed efficiency, for increased rate of gain, and for the prevention and control of coccidiosis.

Ruminant Science Premix™ [Login to view product info.](#)
Ruminant Science Premix is a complete vitamin and trace mineral premix specifically formulated for use in ruminant feeds and supplements.

S

[Back to Top](#)

Selenium .02% [Login to view product info.](#)
A selenium premix specifically formulated for uniform dispersion in finished feed.

Selenium .06% [Login to view product info.](#)
A selenium premix specifically formulated for uniform dispersion in finished feed.

Selenium .20% [Login to view product info.](#)
Selenium .20% is a selenium premix specifically formulated for uniform dispersion in finished feed.

Selenium 1% [Login to view product info.](#)
Selenium 1% is a selenium premix specifically formulated for uniform dispersion in finished feed.

Sodium Bentonite [Login to view product info.](#)
A mined clay for use as a pellet binder in animal feeds.

Sodium Bicarbonate [Login to view product info.](#)
Sodium Bicarbonate for animal feed buffer.

Sulphur Dust 99.5% [Login to view product info.](#)

A source of the element sulphur in a dry free flowing powder for use in animal feeds.

Super-Lube™ [Login to view product info.](#)

Super-Lube is a lubricant for pelleting hard-to-pellet feeds. That is, those difficult to get through the diet.

Swine Science Premix™ [Login to view product info.](#)

Swine Science Premix is a complete vitamin premix specifically formulated for use in swine feeds and supplements.

T

[Back to Top](#)

Threonine 98.5% [Login to view product info.](#)

A synthetic amino acid for use in animal feeds.

Tra-Min Ruminant™ [Login to view product info.](#)

Tra-Min Ruminant is a complete source of trace elements for ruminants.

Tra-Min Sheep™ [Login to view product info.](#)

Tra-Min Sheep is a complete source of trace elements for use in sheep feeds and supplements.

Tra-Min Swine/Poultry™ [Login to view product info.](#)

Tra-Min Swine/Poultry is a complete source of trace elements for use in swine and poultry feeds and supplements.

Tryptophan 98.5% [Login to view product info.](#)

A synthetic amino acid for use in animal feeds.

Turkey Breeder Premix [Login to view product info.](#)

Turkey Breeder Premix is specifically formulated for uniform dispersion in turkey feeds. Contains both water soluble and fat soluble vitamins for complete vitamin fortification.

Tylan® 10 [Login to view product info.](#)

Tylan 10 is used for increased rate of weight gain and improved feed efficiency. It also helps prevent and or control porcine proliferative enteropathies. It also can be used for the prevention of swine dysentery.

Tylan® 40 [Login to view product info.](#)

Tylan 40 is used for increase rate of weight gain and improved feed efficiency. Also used for the prevention and control of swine dysentery and porcine proliferative enteropathies.

U

[Back to Top](#)

Ultra Curb® [Login to view product info.](#)

A liquid mold inhibitor/surfactant for processed feed ingredients and animal feeds.

Urea

[Login to view product info.](#)

Urea is used as a source of non-protein nitrogen in commercial feeds for ruminant animals (cattle, sheep, goats) for a source of equivalent crude protein.

W

[Back to Top](#)

Whey

[Login to view product info.](#)

A dry powdered form of both milk protein and milk sugars.

X

[Back to Top](#)

XP-4 Sodium Phosphate

[Login to view product info.](#)

A source of phosphorus for animal feeds. This source is a dry free flowing powder, however it is water soluble

Y

[Back to Top](#)

Yeast Culture XP

[Login to view product info.](#)

This product begins with a live yeast, which is then placed on a blended protein source, goes through a full fermentation, is then dried and sold as a yeast culture. The product is for use in all types of animal feeds.

Z

[Back to Top](#)

Zinpro 100

[Login to view product info.](#)

A nutritional feed additive for livestock and poultry. When used as a commercial feed ingredient it must be declared as zinc methionine.

Zinpro 40

[Login to view product info.](#)

A nutritional feed additive for livestock and poultry. When used as a commercial feed ingredient it must be declared as zinc methionine.

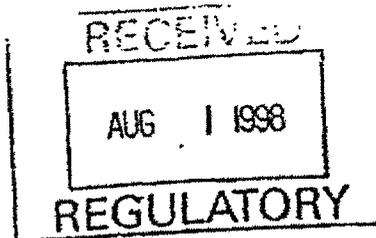
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Nacogdoches, Texas USA
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Exhibit D



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Food and Drug Administration
Rockville MD 20857

JUL 29 1998

Donald A. Gable, D.V.M.
Manager, Pharmaceutical Regulatory Affairs
Boehringer Ingelheim Vetmedica, Inc.
15th & Oak
P.O. Box 338
Elwood, Kansas 66024

Dear Dr. Gable;

As you are aware, Bacitracin Methylene Disalicylate and [] appear as listings for Boehringer Ingelheim in 21 CFR § 558.15 (the Food and Drug Administration's (FDA) regulation providing for interim marketing of antibiotics and combinations of antibiotics). The preamble to 21 CFR § 558.15 states that only new animal drugs which had been determined to be approved for use by a new animal drug application, a new drug application, a master file, an antibiotic regulation or a food additive regulation were listed as having interim marketing rights. (41 FR 8282, 8285, February 25, 1976). This statement was made in response to a comment regarding the impact on section 558.15 of the court decision in Hoffman-LaRoche v. Weinberger, 425 F.Supp. 890 (D.D.C. 1975). That decision held that an Agency policy that allowed the marketing of unapproved drugs was inconsistent with the Federal Food, Drug, and Cosmetic Act. Therefore, the Agency intended to include in the 21 CFR § 558.15 listings only new animal drugs or combinations of new animal drugs and conditions of use approved by one of the mechanisms described above.

When the Agency attempted to reconstruct its records of the approvals for new animal drugs or combinations of new animal drugs and conditions of use subject to the listings in 21 CFR § 558.15, it found the records for some of them to be incomplete. The Agency previously advised sponsors of some new animal drugs listed in section 558.15 of the incomplete state of the Agency's records in the Notices of Opportunity for Hearings (NOOHs) on proposed withdrawal of approvals for certain antibiotic uses (42 FR 43772, 43773, August 30, 1977; 42 FR 56264, 56265, October 21, 1977). The notices state that:

[u]nder section 108(b)(2) of the Animal Drug Amendments of 1968 (Pub. L. 90-399), any approval of a new animal drug granted prior to the effective date of the amendments whether through approval of a new drug application, master file, antibiotic regulation, or food additive regulation, continues in effect until withdrawn in accordance with the provisions of section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Many such approvals were issued long ago, and some may never have been used by the holder of the approval.

Consequently, the current files of the ... FDA may be incomplete and may fail to reflect the existence of some approvals.

The NOOH requested sponsors with approved new animal drugs that were within the scope of the notices but not listed in the notices to submit proof of the existence of approvals to the Agency. In addition, the Agency has found that the records for other new animal drugs listed in section 558.15 that were outside the scope of the 1977 NOOHs are incomplete.

The Agency has been unable to reconstruct from its records the existence of an approval for a product or products represented by the following listings for Boehringer Ingelheim in section 558.15: Bacitracin Methylene Disalicylate and the combination of

While the agency does have its statement in the preamble to 21 CFR § 558.15 that all new animal drugs listed in the regulation were subject to approvals, the Agency has inadequate documentation to support an approval for new animal drugs subject to the listings noted above.

The Agency would like to resolve the factual issues resulting from the incomplete nature of the Agency's current records and confirm the approval status of new animal drugs for the conditions of use listed in section 558.15. In this regard, we are requesting assistance from all sponsors of new animal drugs listed in section 558.15 for which our records are incomplete. We are asking that such sponsors, if they have information (including statements from persons with personal knowledge) establishing that an approval corresponding to a specific listing in section 558.15 was granted prior to the February 25, 1976, publication date of 21 CFR § 558.15, identify the involved product(s) and certify the approval status to the Agency.

If you have information regarding the approval status of new animal drugs or combinations of new animal drugs corresponding to the listings cited in this letter, we ask that you identify each such new animal drug or combination of new animal drugs, attach associated product labeling, and certify its approval status. The Agency will use the certification you provide along with the statement in the preamble to 21 CFR § 558.15 and other information in the Agency's files regarding the approval status of the new animal drug as the administrative record of the approval

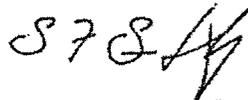
This record would help ensure that Agency actions are consistent with the actual approval status of your new animal drug(s). Furthermore, this record will be used to respond to any judicial challenge to a new animal drug's approval status. While the Agency cannot guarantee that a court would find this record sufficient if the approval status is challenged, the Agency believes it can make arguments in light of the history surrounding new animal drugs in this class (e.g., the transition under the 1968 amendments, the long passage of time since the approvals were granted, etc.) to support a finding by a court that the record is adequate.

Your certification should be in the form of a letter signed by an individual with the authority to bind the firm in matters relating to new animal drug applications, and should contain the following language: "I (name and title of the responsible individual at the firm, including the

firm's name) CERTIFY that (name of new animal drug or combination of new animal drugs) was approved for (firm name) by the Food and Drug Administration by (specify the type of approval: 1) new animal drug application; 2) new drug application; 3) antibiotic regulation; 4) food additive regulation; or 5) master file) prior to February 25, 1976, for the following species, use levels, and indications for use listed in 21 CFR 558.15: (specify same)." If you are certifying the approval status of several products, repeat this statement for each product. If the approval was granted to any entity other than the present firm, your certification should include a description tracing the ownership of the approval from the original recipient to the firm named in the current certification. You should attach to the certification labeling consistent with the approval but no greater in scope than the listing in section 558.15 for each new animal drug for which certification is being made. Your certification letter should also include the following statements "I CERTIFY that all the statements made in this letter are true and complete to the best of my knowledge and ability and that the attached new animal drug labels are true and complete copies. I understand that, as with any other statements provided to the Food and Drug Administration, wilfully making a false certification is a criminal offense under U.S. Code, Title 18, Sec. 1001."

We ask that you provide the above certification within 60 days. Once the approval status of products subject to a small group of listings in section 558.15 is clarified, the Agency at present anticipates codifying elsewhere in Part 558 as approval regulations products for which certification is received, and subsequently taking steps to withdraw section 558.15. If you have any questions, please contact Andrew J. Beaulieu, Deputy Director, Office of New Animal Drug Evaluation at the Center for Veterinary Medicine. We thank you for your assistance in this matter.

Sincerely yours,



Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

Exhibit

E



DEPARTMENT OF HEALTH & HUMAN SERVICES

REC'D NOV 20 1998

Public Health Service

NOV 2

Food and Drug Administration
Rockville MD 20857

NADA 141-130 A0000

• Sondra C. Flick
Director Regulatory Affairs
ALPHARMA Inc.
Animal Health Division
One Executive Drive
Fort Lee, New Jersey 07024

Cc: NADA 141-130
S. Flick
D. Rupp
J. Skinner
L. Muir

Dear Ms. Flick:

This letter will confirm receipt of your certification letter dated October 8, 1998, sent to CVM in response to my letter of July 29, 1998. The letter related to the combination of zoalene and bacitracin methylene disalicylate which is the subject of NADA 141-130.

In accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 141-130 which provides for a Type A Medicated Article, zoalene (0.004% to 0.0125%) and bacitracin methylene disalicylate (4 to 50 grams per ton), for use for the indications and under the conditions of use specified in the labeling attached to your letter.

The agency will begin the work of codifying the approval via publication in the Federal Register. This task most likely will be accomplished as part of an action affecting a number of products currently listed in 21 CFR 558.15. We will make every effort to bring this process to a conclusion as rapidly as possible given resource constraints and public health priorities. In the meantime, you may rely on this letter to verify the approved status of NADA 141-130.

If you have any questions concerning the agency's position regarding this NADA and the subject products, please do not hesitate to call me.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine



**FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE
FACSIMILE TRANSMISSION RECORD**

DATE: MONDAY, NOVEMBER 16, 1998	TIME: 9:45:11 AM
TO: (NAME, ORGANIZATION, CITY AND STATE) MS. SONDR A. FLICK DIRECTOR, R.A. ALPHARMA, INC.	FROM: (NAME, ORGANIZATION, CITY AND STATE) DR. DIANNE MCRAE IRMA M. CARPENTER APPLICATIONS EXAMINER HFV-102
FAX (201) 947-3879	DHHS/FDA/CVM/ONADE?HFV-100 TEL. (301) 694-1620 FAX (301) 694-2297
TEL (201) 947-7774	METRO PARK NORTH II 7500 STANDISH PLACE. ROCKVILLE MD 20855

(Telephone 301-594-1620 immediately if re-transmission is necessary)

NOTE: Faxing 4 Original letters for the Ns-141130, 141131, 141132 and 100853.

Number of pages including cover sheet: 5 pages

CVM/ONADE FAX NUMBER (301) 594-2297



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 2 1998

Food and Drug Administration
Rockville MD 20857

NADA 141-131 A0000

Sondra C. Flick
Director Regulatory Affairs
ALPHARMA Inc.
Animal Health Division
One Executive Drive
Fort Lee, New Jersey 07024

Dear Ms. Flick:

This letter will confirm receipt of your certification letter dated October 8, 1998, sent to CVM in response to my letter of July 29, 1998. The letter related to the combination of zoalene, bacitracin methylene disalicylate and roxarsone which is the subject of NADA 141-131.

In accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 141-131 which provides for a Type A Medicated Article, zoalene (0.004-0.0125%) with bacitracin methylene disalicylate (BMD) (4 to 50 grams per ton) and roxarsone 22.7 to 45.4 grams per ton for use for the indications and under the conditions of use specified in the labeling attached to your letter.

The agency will begin the work of codifying the approval via publication in the Federal Register. This task most likely will be accomplished as part of an action affecting a number of products currently listed in 21 CFR 558.15. We will make every effort to bring this process to a conclusion as rapidly as possible given resource constraints and public health priorities. In the meantime, you may rely on this letter to verify the approved status of NADA 141-131.

If you have any questions concerning the agency's position regarding this NADA and the subject products, please do not hesitate to call me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S7 SJA".

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

U Gray

Stephen F. Sundlof, D.V.M. Ph.D.
Director, Center for Veterinary Medicine



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 12 1998

NADA 141-132 A0000

Sondra C. Flick
Director Regulatory Affairs
ALPHARMA Inc.
Animal Health Division
One Executive Drive
Fort Lee, NJ 07024

Dear Ms. Flick:

This letter will confirm receipt of your certification letter dated October 8, 1998, sent to CVM in response to my letter of July 29, 1998. The letter related to the combination of nitarsons and bacitracin zinc which is the subject of NADA 141-132.

In accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 141-132 which provides for a Type A Medicated Article, nitarsons (0.01875%) and bacitracin zinc (4 to 50 g/ton) for use for the indications and under the conditions of use specified in the labeling attached to your letter.

The agency will begin the work of codifying the approval via publication in the Federal Register. This task most likely will be accomplished as part of an action affecting a number of products currently listed in 21 CFR 558.15. We will make every effort to bring this process to a conclusion as rapidly as possible given resource constraints and public health priorities. In the meantime, you may rely on this letter to verify the approved status of NADA 141-132.

If you have any questions concerning the agency's position regarding this NADA and the subject products, please do not hesitate to call me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S F Sundlof".

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 12 1998

NADA 100-853 A0000

- James H. Schafer
Consultant to the Veterinary
Pharmaceutical Industry
800 Helena Court
Ft. Collins, Colorado 80524

Dear Dr. Schafer:

This letter will confirm receipt of your certification letter dated October 23, 1998, sent to CVM in response to my letter of July 29, 1998, addressed to Mr. Erick G. Wolf of Koffolk, Inc. The letter related to the combination of nicarbazin, bacitracin (BMD) and roxarsone which is the subject of NADA 100-853.

In accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 100-853 which provides for a Type A Medicated Article, nicarbazin (0.01%-0.02%) and bacitracin methylene disalicylate (4 to 50 g/ton) and roxarsone (22.7 to 45.4 g/ton) for use for the indications and under the conditions of use specified in the labeling attached to your letter.

The agency will begin the work of codifying the approval via publication in the Federal Register. This task most likely will be accomplished as part of an action affecting a number of products currently listed in 21 CFR 558.15. We will make every effort to bring this process to a conclusion as rapidly as possible given resource constraints and public health priorities. In the meantime, you may rely on this letter to verify the approved status of NADA 100-853.

If you have any questions concerning the agency's position regarding this NADA and the subject products, please do not hesitate to call me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S F Sundlof".

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

RECEIPT FOR PAYMENT
UNITED STATES DISTRICT COURT
for the

DISTRICT OF MARYLAND
GREENSBELT, MARYLAND, MD

0000000

RECEIVED FROM:
WALTER ANN TELEPHON

Case Number:

VIA-MS 1400

File No:

Party ID:
Funder Types: CHECK

91-004700 100.00

LIVEL 11100-006900
4.00

Remarks: Check No: 54527
03-510000 100.00

Civil Filing 510000
1.00

Remarks:

Subtotal: 1100.00

Receipt Total: 1100.00

* Checks and drafts are accepted
subject to collections and full
credit will only be given when
the check or draft has been
accepted by the financial
institution on which it was drawn.

Date: 5/11/81
Clerk: JT