

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ALPHARMA INC.,

Plaintiff,

Civil Action No. 8:03-cv-01406-PJM

v.

MARK B. MCCLELLAN, M.D.)
PH.D., COMMISSIONER OF)
FOOD AND DRUGS, FOOD)
AND DRUG ADMINISTRATION)

and

FOOD AND DRUG)
ADMINISTRATION,)
)
Defendants.)

STIPULATION AND ORDER OF DISMISSAL

WHEREAS, Alparma Inc. ("Alparma") has sued Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs, and the Food and Drug Administration "FDA" for declaratory judgment and injunctive relief alleging that the FDA has not approved certain claims being made for Pennitracin MD, a bacitracin methylene disalicylate product of PennField Oil Co. "PennField" ; and

WHEREAS, FDA addressed the matter of PennField's claims when it published in the Federal Register on August 8, 2003, a Notice of Opportunity for Hearing, 68 Fed. Reg. 47332 (Aug. 8, 2003); and a Notice of Proposed Rulemaking, 68 Fed. Reg. 47272 (Aug. 8, 2003); and

WHEREAS Alpharma does not agree with all of the conclusions stated by FDA in the Notice of Opportunity for Hearing, 68 Fed Reg. 47332 (Aug. 8, 2003); and

WHEREAS, Alpharma and FDA ("the parties") wish to resolve this matter without any admission or finding of liability or wrongdoing;

THEREFORE, it is AGREED AND STIPULATED between the parties and the COURT SO FINDS:

A. FDA has stated in the Federal Register that PennField is transitionally approved to make the following claims for its bacitracin methylene disalicylate Type A medicated article for use in animal feed (see 41 Fed. Reg. 8282 (Feb. 25, 1976)):

1. 4 to 50 grams/ton Chickens: For growth promotion and feed efficiency.
2. 4 to 50 grams/ton Turkeys: For growth promotion and feed efficiency.
3. 4 to 50 grams/ton Pheasants: For growth promotion and feed efficiency.
4. 5 to 20 grams/ton Quail not over 5 weeks of age: For growth promotion and feed efficiency.
5. 10 to 50 grams/ton Swine: For growth promotion and feed efficiency.
6. 10 to 50 grams/ton Chickens: maintaining or increasing egg production.
7. 50 to 100 grams/ton Chickens: prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).
8. 50 to 100 grams/ton Swine: aid in prevention of bacterial swine enteritis

9. 50 to 100 grams/ton Turkeys: prevention of infectious sinusitis, blue comb (mud fever).
10. 100 grams/ton Chickens: maintaining or increasing hatchability of eggs.
11. 100 grams/ton Chickens: during times of stress, prevention of diseases named in former section 121.252, caused by organisms susceptible to bacitracin.
12. 100 grams/ton Chickens: prevention of early mortality of chicks due to susceptible organisms.
13. 100 grams/ton Swine; treatment of bacterial swine enteritis.
14. 100 to 200 grams/ton Chickens: treatment of chronic respiratory disease (air-sac infection); ; comb (nonspecific infectious enteritis).
15. 100 to 200 grams/ton Turkeys: treatment of infectious sinusitis, blue comb (mud fever).
16. 70 milligrams/head/day Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.
17. 250 milligrams/head/day Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses; and

B. Since the transitional approval that FDA states exists as described in paragraph A, FDA has not published in the Federal Register any approval notice pursuant to 21 U.S.C. § 360b(i) for PennField or its predecessors for a bacitracin methylene disalicylate Type A medicated article for use in animal feed; and

C. FDA has no record that PennField has applied for or is approved to make the following claims for its bacitracin methylene disalicylate product:

1. 50 grams/ton Broiler chickens: As an aid in prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate;
2. 100-200 grams/ton Broiler chickens: As an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate. CAUTION: To control a necrotic enteritis outbreak, start medication at the first clinical signs of the disease. The dosage range permitted provides for different levels based on severity of the disease. Consult a poultry diagnostic laboratory or pathologist to determine the diagnosis and advice regarding the optimal level of drug. Administer continuously for 5 to 7 days or as long as clinical signs persist, and then reduce medication to prevention level (50 grams per ton);
3. 10-25 grams/ton Laying hens: For increased egg production and improved feed efficiency during the first seven months of production;
4. 200 grams/ton Growing turkeys: As an aid in control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylene disalicylate. Feed continuously as the sole ration;
5. 250 grams/ton Growing/finishing swine: For control of swine dysentery (bloody Scours) associated with *Treponema hyodysenteriae* in pigs up to 250 lbs body weight. Feed 250 grams per ton of complete feed on premises with history of swine dysentery, but where signs of disease have not yet occurred or following an approved treatment of the disease condition. The 250 grams per ton level 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 not satisfactory. Feed containing an approved level of bacitracin methylene disalicylate should be feed (sic) as the sole ration;
6. 250 grams/ton Pregnant sows: For control of clostridial enteritis caused by *C. perfringens* in suckling pigs when fed to sows from 14 days before through 21 days after farrowing on premises with a

history of clostridial scours. CAUTION: Diagnosis should be confirmed by a veterinarian when results are not satisfactory. Feed containing an approved level of bacitracin methylene disalicylate should be feed (sic) as the sole ration; and

7. 200 grams/ton Quail: For prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate. Feed continuously as sole ration.

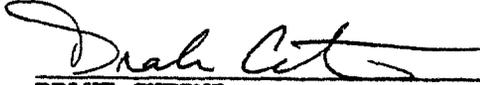
See Alpharma's Complaint, Exh. B.

It is FURTHER AGREED AND STIPULATED, pursuant to Federal Rule of Civil Procedure 41(a)(2), that this case be dismissed with prejudice, and each party shall bear its own costs and fees upon the entry of this Order.


DOUGLAS J. BEHR, Md. Federal
Bar No. 013506
JOHN B. DUBECK, to be admitted
pro hac vice
FREDERICK A. STEARNS,
admitted pro hac vice
LYNN LORIS OWENS,
admitted pro hac vice
Keller and Heckman LLP
1001 G Street, N.W.
Washington, D.C. 20001

Counsel for Plaintiff Alpharma


TARRA DESHIELDS
Assistant U.S. Attorney
6625 U.S. Courthouse
101 West Lombard Street
Baltimore, Maryland 21201-2692
Telephone: (410) 209-4841
Facsimile: (410) 962-2310


DRAKE CUTINI
Trial Attorney
Office of Consumer Litigation
Department of Justice
P.O. Box 386
Washington, DC 20044
Telephone: (202) 307-0044
Facsimile: (202) 514-8742

OF COUNSEL:

ALEX M. AZAR II
General Counsel
Department of Health and
Human Services

DANIEL E. TROY
Chief Counsel
Food and Drug Administration

BARBARA J. ALKALAY
Associate Chief Counsel
for Enforcement
Food and Drug Administration
Rockville, Maryland 20857

Counsel for Defendants Mark
B. McClellan, M.D., Ph.D., and
Food and Drug Administration

BASED ON the stipulations and findings set out above, it is this
___ day of _____, 2003, ORDERED, pursuant to Federal
Rule of Civil Procedure 41(a)(2), that this case is dismissed
with prejudice, and each party shall bear its own costs and fees
upon the entry of this Order

Peter J. Messitte
United States District Court Judge