EXHIBIT N

TO DECLARATION OF
JENNIFER A. SORENSON

FDA Letters to Drug Sponsors (2004)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 26 2004

Carol A. Wrenn
President, Animal Health Division
Alpharma Inc.
One Executive Drive
Fort Lee, New Jersey 07027-1298

Dear Ms. Wrenn:

As you are aware, the Center for Veterinary Medicine was charged with examining previously approved antimicrobial products as a result of an amendment to the FY 2001 appropriations sponsored by U.S. Representative Sherrod Brown. As part of that effort, we have completed our review of the administrative file for your Penicillin 100 (penicillin G procaine 50, Type A Medicated Article, NADA 046-666).

Our review included an examination of the correspondence contained in, data submitted to, and master files referenced in, the administrative file. We conducted a qualitative risk assessment in light of the Center's recently published Guidance for Industry #152 entitled, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern," using the information contained in the records.

We are taking this opportunity to provide you with a summary of our findings:

- The codified indications are: ""For increased rate of weight gain and improved feed efficiency."

- §558.15 studies were conducted in swine and chickens. Originally the company participated in the AHI effort and sought subtherapeutic indication. Then the original sponsor withdrew from AHI and sought therapeutic indication.

- CVM reviewed the studies and concluded that they had met the *Salmonella* shedding requirements under §558.15, but that there were still questions about the observed increases in resistant *Salmonella* and *E. coli.* Insufficient information to address GFI #152.

- CVM concluded numerous times that efficacy data were insufficient for the therapeutic claims.

- The NADA was DESI finalized on April 10, 1998 for the subtherapeutic indications.

- CVM's proposal to withdraw penicillin premixes remains pending. 42 FR 43,770. Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

The administrative record does not contain sufficient information to alleviate the Center's concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance. We used only that information on penicillin contained in your administrative file to evaluate your product. Where information on your specific product was lacking, we generally took a conservative approach and assessed the risk as high. The outcome of the qualitative risk assessment conducted according to Guidance #152 is that the product is considered Category 1. Production claims for increased rate of weight gain and improved feed efficiency are not considered appropriate for Category 1 or 2 products under Guidance #152.

The Center for Veterinary Medicine would like to invite you to meet with us and discuss our findings. Please contact my office as soon as possible to arrange this. If you have any questions please contact Dr. Linda Tollefson, Deputy Director at 301-827-2950.

Sincerely yours,

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

cc: NADA 046-666
Director, Office of New Animal Drug Evaluation
Division Director, Human Food Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Rockville MD 20857

MAY 26 2004

Carol A. Wrenn
President, Animal Health Division
Alpharma Inc.
One Executive Drive
Fort Lee, New Jersey 07027-1298

Dear Ms. Wrenn:

As you are aware, the Center for Veterinary Medicine was charged with examining previously approved antimicrobial products as a result of an amendment to the FY 2001 appropriations sponsored by U.S. Representative Sherrod Brown. As part of that effort, we have completed our review of the administrative file for your Aureo S-P250® (NADA 035-688); CSP™ 250 (NADA 039-077); and –Chlorachel™ 250 (NADA 091-668).

Our review included an examination of the correspondence contained in, data submitted to, and master files referenced in, the administrative file. We conducted a qualitative risk assessment in light of the Center's recently published Guidance for Industry #152 entitled, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern," using the information contained in the records.

We are taking this opportunity to provide you with a summary of our findings:

Aureo S-P250® (NADA 035-688)

- The product is a Type A medicated article intended to produce a Type C medicated feed consisting of 100 grams of chlortetracycline, 50 grams of procaine penicillin, and 100 grams of sulfamethazine per ton of feed.

- The codified indication is: "for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery), prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

- Protocols and data to address 21 CFR 135.109/558.15 were submitted. The requirements of 21 CFR 558.15 were not met.

- CVM's proposal to withdraw Aureo S-P250® remains pending. 42 FR 43,770, Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

CSP™ 250 (NADA 039-077)

- The product is a Type A medicated article intended to produce a Type C medicated feed consisting of 100 grams of chlortetracycline, 50 grams of procaine penicillin, and 100 grams of sulfathiazole per ton of feed.

- The codified indication is: "for reduction of the incidence of cervical abscesses; treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by ***Salmonella choleraesuis*** and vibrionic dysentery), maintenance of weight gains in the presence of atrophic rhinitis; swine 10 lbs of body weight to 6 weeks post weaning: increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks post weaning: increased rate of weight gain." (21 CFR 558.155).

- Protocols and data to address 21 CFR 135.109/558.15 were submitted. The requirements of 21 CFR 558.15 were not met.

- CVM's proposal to withdraw CSP™ 250 remains pending. 42 FR 43,770, Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

Chlorachel™ 250 (NADA 091-668)

- The product is a Type A medicated article intended to produce a Type C medicated feed consisting of 100 grams of chlortetracycline, 50 grams of penicillin and 100 grams of sulfamethazine.

- The codified indication is: "It is administered to swine in a Type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by ***Salmonella choleraesuis*** and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds." (21 CFR 558.145).

- Protocols and data to address 21 CFR 135.109/558.15 were submitted. The requirements of 21 CFR 558.15 were not met.

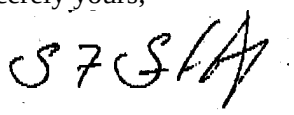
- CVM's proposal to withdraw Chlorachel™ 250 remains pending. 42 FR 43,770, Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

The administrative record does not contain sufficient information to alleviate the Center's concern about the use of these products and their possible role in the emergence and dissemination of antimicrobial resistance. We used only that information on penicillin, tetracycline, sulfathiazole, and sulfamethazine contained in your administrative files to evaluate your products. Where information on your specific products was lacking, we generally took a

conservative approach and assessed the risk as high. The outcome of the qualitative risk assessment conducted according to Guidance #152 is that the product is considered Category 1. Production claims for weight gain, maintenance of weight gains in the presence of atrophic rhinitis and for growth promotion and increased feed efficiency in swine are not considered appropriate for Category 1 or 2 products under Guidance #152.

The Center for Veterinary Medicine would like to invite you to meet with us and discuss our findings. Please contact my office as soon as possible to arrange this. If you have any questions please contact Dr. Linda Tollefson, Deputy Director at 301-827-2950.

Sincerely yours,



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

cc: NADA 035-688
NADA 039-077
NADA 091-668
Director, Office of New Animal Drug Evaluation
Division Director, Human Food Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 26 2004

Gregory P. Bergt
Director, Regulatory Affairs
Pennfield Oil Company
14040 Industrial Road
Omaha, NE 68144

Dear Mr. Bergt:

As you are aware, the Center for Veterinary Medicine was charged with examining previously approved antimicrobial products as a result of an amendment to the FY 2001 appropriations sponsored by U.S. Representative Sherrod Brown. As part of that effort, we have completed our review of the administrative file for your Pennchlor SP 250 and Pennchlor SP 500 (NADA 138-934).

Our review included an examination of the correspondence contained in, data submitted to, and master files referenced in, the administrative file. We conducted a qualitative risk assessment in light of the Center's recently published Guidance for Industry #152 entitled, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern," using the information contained in the records.

We are taking this opportunity to provide you with a summary of our findings:

- Both products are Type A medicated articles intended to produce a Type C medicated feed consisting of 100 grams of chlortetracycline, 50 grams of penicillin and 100 grams of sulfamethazine.

- The codified indication is: "It is administered to swine in a Type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds." (21 CFR 558.145).

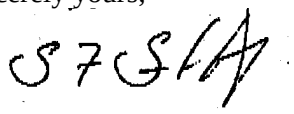
- Protocols and data to address 21 CFR 135.109/558.15 were submitted. The requirements of 21 CFR 558.15 were not met.

- CVM's proposal to withdraw penicillin premixes remains pending. 42 FR 43,770, Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

The administrative record does not contain sufficient information to alleviate the Center's concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance. We used only that information on penicillin, tetracycline, and sulfamethazine contained in your administrative file to evaluate your product. Where information on your specific product was lacking, we generally took a conservative approach and assessed the risk as high. The outcome of the qualitative risk assessment conducted according to Guidance #152 is that the product is considered Category 1. Production claims for maintenance of weight gains in the presence of atrophic rhinitis and for growth promotion and increased feed efficiency are not considered appropriate for Category 1 or 2 products under Guidance #152.

The Center for Veterinary Medicine would like to invite you to meet with us and discuss our findings. Please contact my office as soon as possible to arrange this. If you have any questions please contact Dr. Linda Tollefson, Deputy Director at 301-827-2950.

Sincerely yours,



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

cc: NADA 138-934
Director, Office of New Animal Drug Evaluation
Division Director, Human Food Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 26 2004

Norma A. Buckart
Manager, Regulatory Affairs
Phibro Animal Health
710 Rt. 46 East
Suite 401
Fairfield, NJ 07004

Dear Ms. Buckart:

As you are aware, the Center for Veterinary Medicine was charged with examining previously approved antimicrobial products as a result of an amendment to the FY 2001 appropriations sponsored by U.S. Representative Sherrod Brown. As part of that effort, we have completed our review of the administrative file for your Penicillin G Procaine 50% (Type A Medicated Article, NADA 46-668).

Our review included an examination of the correspondence contained in, data submitted to, and master files referenced in, the administrative file. We conducted a qualitative risk assessment in light of the Center's recently published Guidance for Industry #152 entitled, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern," using the information contained in the records.

We are taking this opportunity to provide you with a summary of our findings:

- The codified indications are: "For increased rate of weight gain and improved feed efficiency."
- No data were found to address 21 CFR 558.15 or GFI #152.
- CVM's proposal to withdraw penicillin premixes remains pending. 42 FR 43,770, Aug. 30, 1977 and 42 FR 56,264, Oct. 21, 1977.

The administrative record does not contain sufficient information to alleviate the Center's concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance. We used only that information on penicillin contained in your administrative file to evaluate your product. Where information on your specific product was lacking, we generally took a conservative approach and assessed the risk as high. The outcome of the qualitative risk assessment conducted according to Guidance #152 is that the product is considered Category 1. Production claims for increased rate of weight gain and improved feed efficiency are not considered appropriate for Category 1 or 2 products under Guidance #152.

The Center for Veterinary Medicine would like to invite you to meet with us and discuss our findings. Please contact my office as soon as possible to arrange this. If you have any questions please contact Dr. Linda Tollefson, Deputy Director at 301-827-2950.

Sincerely yours,

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

cc: NADA 046-668
Director, Office of New Animal Drug Evaluation
Division Director, Human Food Safety