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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J. COOKE

Food and Drug Administration

[Docket No. 2003N-0324]

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Certain Antibiotic New Animal Drug Products and Use Combinations Subject to Listings in the New Animal Drug Regulations; Drug Efficacy Study Implementation; Notice of Opportunity for Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of opportunity for hearing that published in the **Federal Register** on August 8, 2003 (68 FR 47332). FDA is correcting a product name used by the current sponsor of NADA 141-137, the FR citation for a Drug Efficacy Study Implementation Program finding of effectiveness, and the column headings of six tables. These corrections are being made to improve the accuracy of the **Federal Register**. This notice also extends the deadline for parties who have requested a hearing to submit data and analysis upon which their request for a hearing relies. Other interested persons may submit comments on the notice of opportunity for hearing (NOOH) before the deadline.

DATES: Submit all written data and analysis upon which a request for a hearing relies and other written comments by November 6, 2003.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-1), 7519 Standish Pl., Rockville, MD 20855, 301-827-2954, e-mail: abeaulie@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of August 8, 2003 (68 FR 47332), FDA announced the effective conditions of use for some of the drug products and use combinations subject to the listings in §§ 510.515 and/or 558.15 (21 CFR 510.515 and/or 558.15), and proposed to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. The Center for Veterinary Medicine (CVM) also provided an opportunity for hearing for applications proposed to be withdrawn. Interested persons were given until September 8, 2003, to submit written appearances and requests for a hearing; until October 7, 2003, to submit data and analysis upon which a request for a hearing relies; and until November 6, 2003, to submit supplemental NADAs. After publication of the NOOH, several errors were found by CVM and others. CVM is correcting these errors, but does not believe that these corrections alter the underlying basis of the NOOH.

II. Corrections

In FR Doc. 03-20241, published August 8, 2003 (68 FR 47332), the following corrections are made:

1. On page 47333, in the third column, under "*A. Bacitracin Methylene Disalicylate Single-Ingredient Type A Medicated Articles*," the trade name following NADA 141-137, "FORTRACIN", is corrected to read "PENNITRACIN".

2. On pages 47335 in tables 2, 3, and 4, and on page 47336 in table 5, in the table heading "Oxytetracycline" is corrected to read

“Oxytetracycline¹” with a footnote added to read “¹Expressed in terms of an equivalent amount of oxytetracycline hydrochloride” and “Neomycin” is corrected to read “Neomycin Sulfate”.

3. On pages 47335 in tables 2, 3, and 4, and on page 47336 in table 5 in the first column heading “Oxytetracycline” is corrected to read “Oxytetracycline¹” and “neomycin” is corrected to read “neomycin sulfate”.

4. On page 47336, in the first column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 98–371 “NICARBAZIN (nicarbazine), PENICILLIN G PROCAINE (procaine penicillin), and 3-NITRO (roxarsone)” is corrected to read “nicarbazine, procaine penicillin, and roxarsone”.

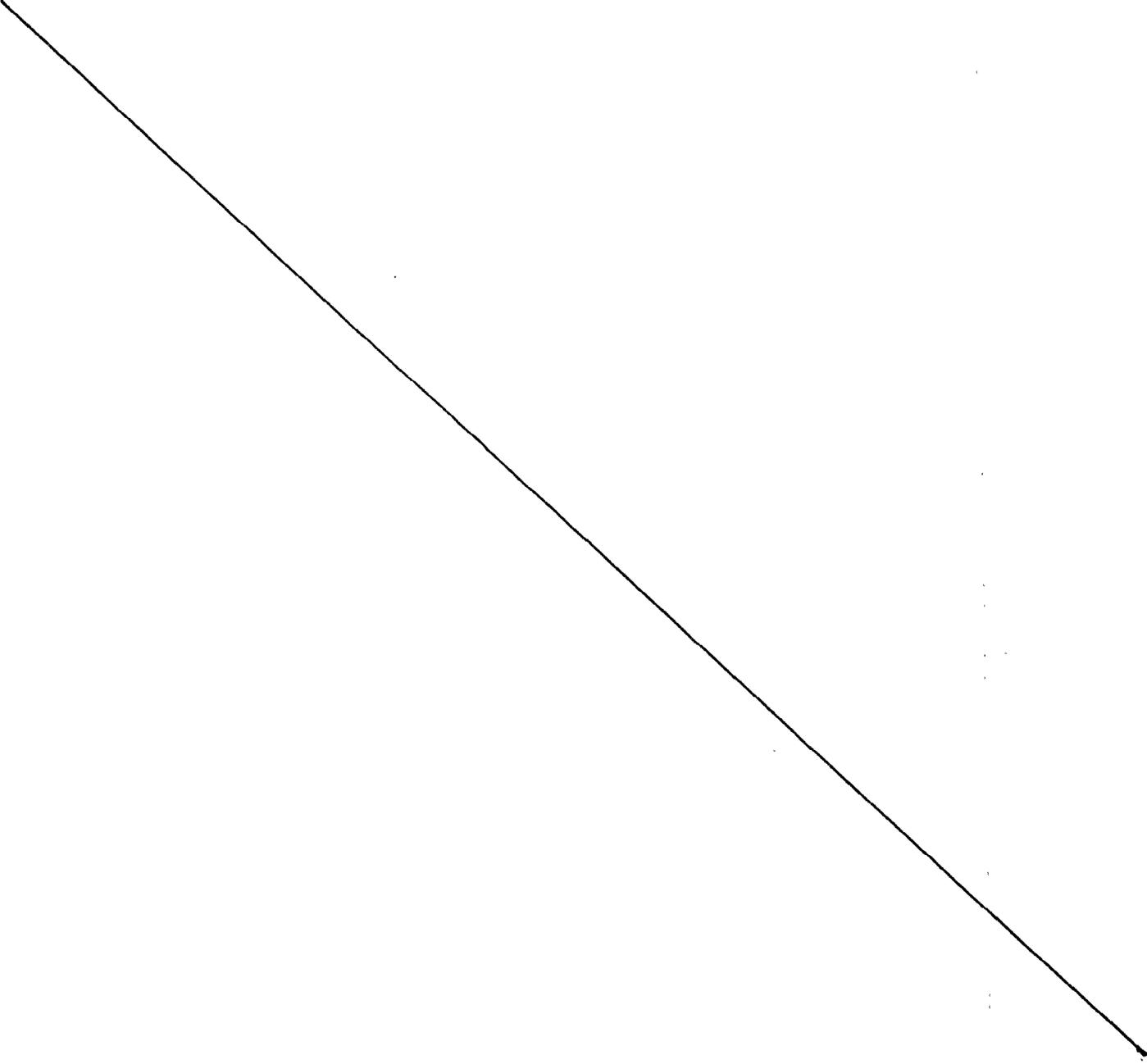
5. On page 47336, in the first column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 98–374 “NICARBAZIN (nicarbazine) and PENICILLIN G PROCAINE (procaine penicillin)” is corrected to read “nicarbazine and procaine penicillin”.

6. On page 47336, in the second column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 100–853 “NICARBAZIN (nicarbazine), BACIFERM (BMD), and 3-NITRO (roxarsone)” is corrected to read “nicarbazine, bacitracin methylene disalicylate, and roxarsone”.

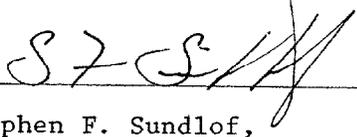
7. On page 47336, in the third column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” in the fourth line, “bacitracin zinc” is corrected to read “bacitracin methylene disalicylate”.

8. On page 47336, in the third column, in the eighth and ninth lines, "35 FR 12490, August 5, 1970 (bacitracin zinc)" is corrected to read "35 FR 11531, July 17, 1970, as corrected by 35 FR 15408, October 2, 1970 (bacitracin methylene disalicylate)".

9. On page 47337 in table 6, and on page 47338 in table 7, in the first three column headings "Type A article in g/ton" is corrected to read "Drug in g/ton".



Dated: 10/1/03
October 1, 2003.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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