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November 12, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Correction to November 6, 2003 Submission to Docket No. 2003N-0324

To Whom it May Concern:

Please find attached 2 copies of each of two signed pages by Dr. Donald Gable. These pages are to replace the current signature pages on Dr. Gable's declarations which Pennfield Oil Company/Pennfield Animal Health submitted in support of the requests for hearing for NADA 141-137 (bacitracin MD) and NADA 138-939 (neomycin/oxytetracycline). Both the redacted and unredacted versions of the declarations should contain this replaced signature page.

Sincerely,

Todd A. Harrison
Counsel to Pennfield Oil Company/
Pennfield Animal Health

2003N-0324 CR 1

addressed the approval status of only the single ingredient product...." While I believe the reference to the November 17, 1998 letter to be in error (as I attached no labels to the November 17, 1998 letter), I believe this letter provides additional evidence that FDA continued to recognize the full legal approval status of NADA 141-137 after the 1998 certification process for all the claims, species, and indications for use approved as part of the DESI review process and those subsequently approved, too. I particularly hold this belief since this June 24, 2002 letter specifically references the March 12, 2002 letter to which current product labeling was attached, and because the Agency had before it a complete administrative record of the approval of this bacitracin MD product. This June 24, 2002 letter confirms that the administrative record for the approval of this product contained all of the claims now in dispute by the Agency.

47. Extensive scientific literature exists with respect to the claims for bacitracin MD as listed in Exhibit 14.

48. Based on the DESI review process findings, the applicable FR notices, my belief of what is in the administrative file for NADA 141-137, the long history of the product's use, and the scientific literature, I am of the opinion that the totality of the evidence indicates that Pennfield's Pennitracin product is effective for the species, uses, and indications for use listed in 21 C.F.R. §§ 558.15 and 558.76.

49. From the totality of the evidence before me, it is clear that FDA has determined that the bacitracin MD product that is the subject of NADA 141-137 is approved for the species, uses, and indications for use listed in 21 C.F.R. §§ 558.15 and 558.76 that were approved as part of DESI and subsequently.

50. It is further clear to me that the Pennfield product could be approved for these claims under GADPTRA.

Donald A. Gable

Donald A. Gable, DVM
Consultant, Pharmaceutical Regulatory Affairs
St. Joseph, Missouri

NADA 141-137

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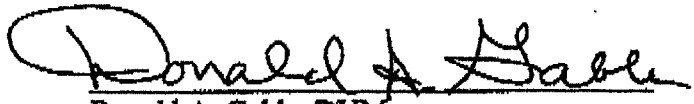

Donald A. Gable, DVM
Consultant, Pharmaceutical Regulatory Affairs
St. Joseph, Missouri

NADA 141-137

35. Extensive scientific literature exists with respect to both neo and oxy, and that literature is being submitted. That literature is consistent with my discussion above.

36. In the NOOH for NEO-OXY, the prior Federal Register notices covering § 558.15, and the other Federal Register and DESI notices covering the numerous combination dosage form products containing neo and oxy, the multiple indications and species, there is no basis for differentiating among the 1:1 and 2:1 ratios.

37. Based on my review of the DESI review process findings, the applicable FR notices, my belief of what is in the administrative file for NADA 138-939, the long history of the products' use as a dosage form and in animal feed, data in FDA's files that must now be made publicly available for review, I am of the opinion that the totality of the evidence meets the definition of "substantial evidence" as set forth in 21 C.F.R. § 514.4(a). Pennfield's NEO-OXY products "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" for the species, uses, and indications that there is no evidence of interference with indications for use listed in 21 C.F.R. § 558.15 and in the August 8, 2003 NOOH.

Donald A. Gable

Donald A. Gable, DVM
Consultant, Pharmaceutical Regulatory Affairs
St. Joseph, Missouri

NADA 138-939

35. Extensive scientific literature exists with respect to both neo and oxy, and that literature is being submitted. That literature is consistent with my discussion above.

36. In the NOOH for NEO-OXY, the prior Federal Register notices covering § 558.15, and the other Federal Register and DESI notices covering the numerous combination dosage form products containing neo and oxy, the multiple indications and species, there is no basis for differentiating among the 1:1 and 2:1 ratios.

37. Based on my review of the DESI review process findings, the applicable FR notices, my belief of what is in the administrative file for NADA 138-939, the long history of the products' use as a dosage form and in animal feed, data in FDA's files that must now be made publicly available for review, I am of the opinion that the totality of the evidence meets the definition of "substantial evidence" as set forth in 21 C.F.R. § 514.4(a). Pennfield's NEO-OXY products "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" for the species, uses, and indications that there is no evidence of interference with indications for use listed in 21 C.F.R. § 558.15 and in the August 8, 2003 NOOH.

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NADA 138-939