

OIP FE J151
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DEMARK OFFICE

Exhibit 7

December 27, 2000

Dr. Melanie R. Berson
Director, Division of Therapeutic Drugs for Non-Food Animals
HFV-110, Room N301
FDA, Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855



4249-105 Piedmont Parkway
Greensboro, NC 27410

Office: 336-852-4040

Fax: 336-852-3540

Dear Dr. Berson:

Re: Diclofenac Liposomal Cream- New Animal Drug Application (NADA)

Enclosed please find our New Animal Drug Application (NADA) for Diclofenac Liposomal Cream. The data for this NADA were gathered under INAD number 10-294.

We have addressed all the issues raised in your review letters. The CVM comments and our responses are contained in the applicable sections of the NADA.

The following technical sections are included in this submission:

Technical Section	Studies/Information
Identification	Section 1 - Identification
Table of Contents and Summary	Section 2 - Table of Contents and Summary
Labeling	Section 3 - Labeling
Components and Composition	Section 4 - Components and Composition
Manufacturing Methods and Controls.	Section 5 - Manufacturing Methods, Facilities and Controls
Samples	Section 6 - Samples
Analytical Methods for Residues	Section 7 - Analytical Methods for Residues
Evidence to Establish Safety and Effectiveness	Section 8 - Evidence to Establish Safety and Effectiveness
Good Laboratory Practice Compliance	Section 9 - Good Laboratory Practice Compliance
Environmental Assessment	Section 10 - Environmental Assessment
Freedom of Information Summary	Section 11 - Freedom of Information Summary
Other	Section 12 - Confidentiality of Data and Information in a New Drug Application

Enclosed please find two (2) volumes, for your review and comment. Three (3) copies of each volume are enclosed and are labeled as follows:

Volume ___ of 2
SURPASS™
(Diclofenac 1% Liposomal Cream)

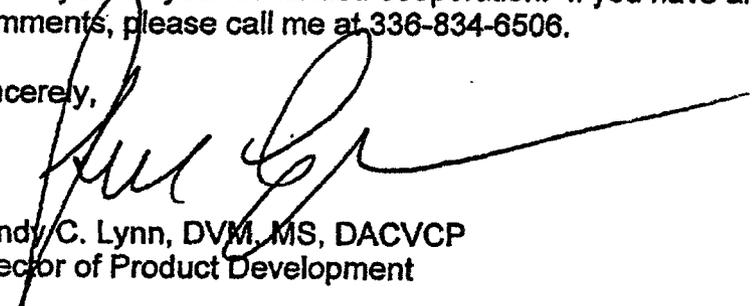
Complete NADA

<u>NADA:</u>	
<u>Date:</u>	December 27, 2000
<u>Dosage Form:</u>	1% Liposomal Cream
<u>Route:</u>	Topical
<u>Species:</u>	Equine
<u>Indications:</u>	Relief of lameness in horses.
<u>Contents:</u>	Sections 1-12 (Complete NADA)
<u>Sponsor:</u>	Blue Ridge Pharmaceuticals, Inc. 4249-105 Piedmont Parkway Greensboro, NC 27410

In addition to the paper documents, we have enclosed a compact disc that contains computer files that support Sections 3, 5, 8 and 11 of this NADA. We also enclose four video-tapes of equine gastroscopy and necropsy that support Section 8a of the application.

Thank you for your continued cooperation. If you have any questions or comments, please call me at 336-834-6506.

Sincerely,



Randy C. Lynn, DVM, MS, DACVCP
Director of Product Development

Enclosures

CC: FDA Atlanta Office