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\*NOT ADMITTED IN DC

February 15, 2001

**BY FACSIMILE/CONFIRMATION COPY BY MAIL**

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: 00P-1600/CP1 - Suitability Petition to File an ANADA for an Ivermectin  
Product for Oral Use in Horses (Iverdex® Equine)**

To Whom It May Concern:

This is an addendum to the cover letter (corrections to the above Re: line) for the Letter of Clarification originally dated February 13, 2001, on behalf of our client, Royer Biomedical, Inc. ("Royer", formerly known as Buford Biomedical, Inc.).

If you have any questions about this Letter of Clarification, please contact my colleague, Brian J. Malkin, or me at 202-737-5600.

Sincerely,

*Brian J. Malkin for*  
Frank J. Sasinowski

*Brian J. Malkin*  
Brian J. Malkin

FJS/BJM/dng  
Enclosure

00P-1600

CRI

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Dockets Management Branch (HFA-305)  
February 13, 2001  
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HYMAN, PHELPS & MCNAMARA, P.C.

cc: Lonnie Luther (HFV-102)  
Sam Hansard, II (HFV-102)  
Center for Veterinary Medicine  
Food and Drug Administration

Dr. Garfield Royer  
Royer Biomedical, Inc.

Dr. Gerald Guest  
Consultant to Royer Biomedical, Inc.

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February 13, 2001

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Rockville, Maryland 20852

**Re: 00P-1600/CP1 - Suitability Petition to File an ANADA for an Ivermectin  
Product for Oral Use in Horses (Iverdex<sup>®</sup> Equine)**

To Whom It May Concern:

On behalf of our client, Royer Biomedical, Inc. ("Royer", formerly known as Buford Biomedical, Inc.), we are filing the attached Letter of Clarification to the above-referenced petition (dated November 1, 2001) as indicated in our February 2, 2001 letter to the file. This Letter of Clarification presents in writing information that was presented or discussed during the Royer meeting with the Center for Veterinary Medicine ("CVM") on January 25, 2001, and includes publicly available information regarding case precedent in CVM, and should not present new information requiring additional notice and comment.

If you have any questions about this Letter of Clarification, please contact my colleague, Brian J. Malkin, or me at 202-737-5600.

Sincerely,

*Brian J. Malkin for*  
Frank J. Sasinowski

*Brian J. Malkin*  
Brian J. Malkin

Dockets Management Branch (HFA-305)  
February 13, 2001  
Page 2

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