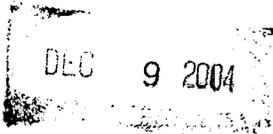




DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857



Beverly D. Crowley  
Regulatory Affairs Specialist  
Boehringer Ingelheim Vetmedica, Inc.  
15<sup>th</sup> and Oak  
P.O. Box 338  
Elwood, KS 66024

**Re: NADA 141-228  
Buscopan™ (N-butylscopolammonium bromide) Injectable Solution BI  
3701-4 5/04; BI 3701-3 5/04; 3701-6 5/04; BI 3701-2 5/04; BI 3701-5 5/04; and  
Buscopan Ad submitted 6/4/04**

Dear Ms. Crowley:

The Division of Surveillance (DOS) has reviewed promotional pieces listed above for Buscopan (N-butylscopolammonium bromide, 20 mg/mL) Injectable Solution submitted by Boehringer Ingelheim Vetmedica, Inc. (BIV) under cover of form FDA 2301. The materials contain statements that are false and misleading under the Federal Food, Drug, and Cosmetic Act (the Act). These violations are more fully discussed below. Additionally, the established name of the drug fails to appear in letters that are at least half as large as the letters comprising the proprietary name of the drug, as required by Section 502(n) of the Act.

#### **False or Misleading Statements**

According to the FDA-approved labeling (package insert, or PI) for the drug, Buscopan (N-butylscopolammonium bromide, 20 mg/mL) is an injectable solution to be administered intravenously indicated for the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions in horses. The **Precautions** section of the PI states (in pertinent part):

Administration of Buscopan results in heart rate elevation. Heart rate can not be used as a valid indicator of severity of pain for 30 minutes following IV injection.

The **Adverse Reactions** section of the PI states:

Transient tachycardia and decreased borborygmal sounds lasted approximately 30 minutes following administration. Transient pupillary dilation may also be observed.

The promotional pieces state:

- Will *not* disguise worsening of colic symptoms;
- Does Not Disguise Colic Symptoms;

- Buscopan provides fast relief of many types of colic without masking clinical signs;
- Buscopan relieves colic pain . . . without confusing the diagnostic picture; and
- veterinarians in other countries have reached for Buscopan . . . without masking clinical signs

As noted, Buscopan is associated with abnormal heart rate and abnormal borborygmal sounds. These clinical signs can mask or disguise symptoms of disease and delay diagnosis and treatment. Therefore, these claims are false or misleading. See section 502(a), (n) of the Act; 21 CFR 202.1(e)(1).

One of the promotional pieces contains a comparison chart titled Comparison of Selected Drugs Used in the Treatment of Equine Colic. This chart is false or misleading because it suggests the drug is better than has been demonstrated, 21 CFR 202.1(e)(6)(i), and because it suggests the drug is safer or more effective than another drug when it has not, to our knowledge, been demonstrated to be safer or more effective by substantial evidence or substantial clinical experience, 21 CFR 202.1(e)(6)(ii).

### **Conclusion and Requested Action**

As discussed above, the promotional pieces listed in the subject line of this letter violate the Act because they make false and misleading statements and because the drug's established name fails to appear in letters at least half as large as the letters comprising the proprietary name of the product.

DOS requests that Boehringer Ingelheim Vetmedica, Inc. immediately cease the dissemination of promotional pieces for Buscopan the same as or similar to those described above. Please submit a written response to this letter on or before January 10, 2004, describing your intent to comply with this request, listing all promotional materials for Buscopan the same or similar to the pieces described above, and explaining your plan for discontinuing use of such false and misleading statements. Please direct your response to me at the Food and Drug Administration, Division of Surveillance, HFV-216, 7519 Standish Place, Rockville, MD 20855. We remind you that only written communications are considered official.

The violations discussed in this letter are not necessarily an exhaustive list. It is your responsibility to ensure that your promotional materials for Buscopan comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.  
Team Leader  
Post-Approval Review Team, HFV-216  
Division of Surveillance  
Center for Veterinary Medicine