DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 30 2007

Ms. Linda Duple
Director, North American Regulatory Affairs
Bimeda Inc.
2836 Dolliver Park Avenue
Lehigh, Iowa 50557

Dear Ms. Duple:

This responds to your November 27, 2007 e-mail to Dr. Neal Bataller, requesting a temporary waiver for Bimeda Inc. of Lehigh, Iowa to import 100mL vials of 200 mg/ml Injectable Iron Dextran product manufactured by Bimeda MTC Animal Health Inc. (Division of Cross Vetpharm Group) of Cambridge, Ontario, Canada for sale and use in the United States.

We have evaluated the situation as to the availability of an adequate supply of this medically necessary veterinary drug product, and we concur that there is a high probability that a shortage of Food and Drug Administration (FDA) approved product continues to exist. We are, therefore, by copy of this letter, not objecting to Bimeda Inc. temporarily importing and distributing this product from Bimeda MTC Animal Health Inc. through the end of May 2008 or until we have notified you that an adequate United States domestic manufactured supply is available. We suggest that import quantities be limited to amounts needed for short periods of time. When the legal American product again becomes available, we will allow you to deplete small amounts of stock.

We suggest you provide a copy of this letter to the FDA import monitor at whatever city is to be the port of entry for the importation of the product.

If you have any questions or need further assistance, please feed free to contact William Bargo, Consumer Safety Officer, at 240-276-9204.

Sincerely,

Neal Bataller, M.E., D.V.M.
Director, Division of Compliance (HFV-230)
Office of Surveillance and Compliance
Center for Veterinary Medicine