

12-27-01

NADA 141-067

Michael J. Hensley, MD  
Acting Vice President Regulatory & Technical Services  
• Biopure Corporation  
11 Hurley Street  
Cambridge, MA 02141  
USA

Dear Dr. Hensley:

This is in reference to your Drug Experience Reports dated June 28, July 6, and August 24, 2001, for Oxyglobin (Hemoglobin Glutamer) Solution, NADA 141-067. The submissions include several promotional pieces which are determined to be promotional labeling as described under 21 CFR 202.1(i)(2).

Specifically, we note that the newsletters titled "Biopure Progress" (MMCS146) and "Oxyglobin Courier" (MMCS120 vol.11 and MMCS120 vol.12) provide the same case of the month report in all of these labeling pieces. The case report discusses all the benefits of Oxyglobin, but does not mention any side effects, warnings, contraindications, or precautions that may be associated with the use of this product. The promotional labeling is required to provide both the risks and benefits information in the same language and emphasis as it is provided in the approved labeling (21 CFR 201.105(d)(1)).

We request that you discontinue using these promotional items immediately and revise the future promotional materials to include both the risk and benefit information in the text of the labeling pieces as required by 21 CFR Part 201.105(d)(1). We request that you give due consideration and attention to your company's promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301)827-6642.

Sincerely yours,

Mohammad I. Sharar, D.V.M., M.Sc.  
Team Leader, Marketed Product Scientific  
and Regulatory Review Team II, HFV-216  
Division of Surveillance  
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