



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 18 2000

NADA 141-067

Christine L.E. Regan
Associate Director, Regulatory Affairs
Biopure Corporation
11 Hurley Street
Cambridge, MA 02141

Dear Ms. Regan:

We refer to your submission dated June 30, 2000, for Oxyglobin, NADA 141-067. The submission includes a Sales Flip Book - Additional, coded MMCS124, a sales Newsletter, coded MMCS120 Vol.5, and a Sales flyer designated as MMCS125. The submitted material constitute labeling as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act and its attendant regulations, 21 CFR 202.1(1)(2).

The promotional pieces are deemed to be false, lacking in fair balance or otherwise misleading in that they fail to include the full prescribing information as required under 21 CFR 201.105(d)(1) and (2). Consequently, the violative promotional material causes your product to be misbranded under 502(f)(1) of the Act.

We request that you stop using this violative promotional material **immediately**. If you wish to use this material in the future, it must be revised to include the required full disclosure information - essentially the reproduction of the approved package insert.

Please inform us of your intentions within 30 days of the date of this letter. We also like to remind you of our June 26, 2000 letter which addresses similar promotional violations. Your response to that letter is due on or by July 26, 2000. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine