DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-316/S-021

Guerbet LLC
Attention: John Warner
Compliance Manager
1185 West 2nd Street
Bloomington, IN 47403-2160

Dear Mr. Warner:

Please refer to your supplemental new drug application dated April 7, 2006, received April 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxilan (Ioxilan Injection) 300mgI/mL and 350 mgI/mL.

We acknowledge receipt of your submissions dated August 2, 18 and October 10, 2006.

This supplemental new drug application provides for a new presentation of Oxilan in 500mL type I clear glass vials intended for use as a Pharmacy Bulk Package.

Your submission of August 18, 2006 constituted a complete response to our August 9, 2006 action letter.

This supplemental new drug application provides for a new presentation of Oxilan in 500mL type I clear glass vials intended for use as a Pharmacy Bulk Package.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted October 10, 2006, immediate container and carton labels submitted October 10, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-316/S-021**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Renee C. Tyson, Regulatory Project Manager, at (301) 796-1476.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

George Mills
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