DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-316/SLR-016 **CBE-30-SUPPLEMENT**

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 August 10, 2000, received August 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxilan, (Ioxilan) Injection 300 mgI/mL and 350 mgI/mL.

We acknowledge receipt of your submission dated November 25, 2002.

Your submission of November 25, 2002, constituted a complete response to our June 20, 2002, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for labeling change of the adverse events from postmarketing surveillance.

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 and with the minor editorial revisions listed below.

> "Additional adverse events reported in postmarketing surveillance with the use of Oxilan Injection include: brochospasm."

Please submit the final printed labeling (FPL) electronically 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. Please individually mount ten of the copies on heavy-weight paper or similar material.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-7498.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and Radiopharmaceutical Drug Products
Office of Drug Evaluation III
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/

Patricia Love

1/6/03 04:11:00 PM