DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-279/S-008

Questcor Pharmaceuticals, Inc.
Attention: Jonathan Goldsmith, M.D.
V.P. Clinical Research and Regulatory Affairs
26118 Research Road
Hayward, CA 94545

Dear Dr. Goldsmith:

Please refer to your supplemental new drug application dated December 16, 1998, received December 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glofil-125.

We acknowledge receipt of your submission dated December 16, 1998.

This "Changes Being Effected" supplemental new drug application provides for a revision to the **CONTRAINDICATIONS** section of the label. This section was revised to read as follows:

CONTRAINDICATIONS

"Glofil-125 should not be administered via a central venous line."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted December 16, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Tia Harper-Velazquez, Pharm.D., Project Manager, at (301) 827-7510.

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

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