DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-708/S- 017

Questcor Pharmaceuticals, Inc.
3260 Whipple Road
Union City, CA 94587

Attention: Steven Halladay, Ph.D.
Sr. Vice President, Clinical and Regulatory Affairs

Dear Dr. Halladay:

Please refer to your supplemental new drug application dated July 23, 2007, received July 26, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doral (quazepam) Tablets.

We also refer to your August 1, 2007 submission which clarifies the package insert format. This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the package insert and for the provision of a medication guide and is submitted in response to the Agency's supplement request letter dated March 5, 2007.

We completed our review of the supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 23, 2007.

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

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 Cathleen Michaloski, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director, Division of Neurology Products
Office of new Drugs 1
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/

Russell Katz

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