DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-708\S-014

Wallace Laboratories
Attention: Ana M. Fontana
Vice President, Drug Regulatory Affairs
Half Acre Road/P.O. Box 1001
Cranbury, NJ 08512-0181

Dear Ms. Fontana:

Please refer to your supplemental new drug application dated August 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doral® (quazepam) Tablets.

We acknowledge receipt of your submission dated March 15, 2002. Your submission of March 15, 2002 constituted a complete response to our September 25, 2001 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application proposes to include a Geriatric Use subsection to the PRECAUTIONS section of product labeling.

We have completed the review of this supplemental application, 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 March 15, 2002/Label code IN-9000-05). Accordingly, this supplemental application is approved on the date of this letter.

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 Ms. Melaine Shin, R.Ph., Regulatory Management Officer, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation ODE I
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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