DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-453/S-014

Teva Global Respiratory Research, LLC
Attention: Steven M. Viti, Ph.D., MBA
Senior Director, Global Respiratory Regulatory Affairs
50 NW 176 Street
Miami, FL 33169

Dear Dr. Viti:

Please refer to your supplemental new drug application dated November 5, 2008, received November 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proglycem® (diazoxide USP) Suspension.

We acknowledge receipt of your submission dated December 8, 2008.

This "Prior Approval" supplemental new drug application provides for the following:

1. Transfer of the drug product manufacturing, packaging, and analytical testing from the current site in Miami, FL to the Sellersville, PA site.
2. Change in supplier for two inactive ingredients.
3. Application of USP General Chapter <467> Residual Solvent using Option 2.
4. Change in closure from **(b) (4)**

5. The addition of Release and Stability Specifications.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on November 5, 2008.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 17-453/S-014**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Melissa Fratine, Regulatory Project Manager, at (301) 796-4231.

Sincerely,

{See appended electronic signature page}

Eric P. Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

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

/s/

Eric Duffy

12/17/2008 05:28:32 PM