



NDA 17-453/S-010

IVAX Research, Inc.  
Attention: Steven M. Viti, Ph.D.  
Director, Regulatory Affairs  
4400 Biscayne Blvd.  
Miami, FL 33137

Dear Dr. Viti:

Please refer to your supplemental new drug application dated July 22, 2003, received July 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proglycem (diazoxide) suspension.

We acknowledge receipt of your submissions dated July 23, and November 20, 2003, and January 14 and 16, 2004.

Your submission of November 20, 2003, provided a response to our October 30, 2003, additional information request letter.

(b)(4)----- for (1) (b)(4)-----  
----- (2) a drug product manufacturing site transfer to  
-----) the addition of (b alternate control sites.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels submitted on November 20, 2003).

Please submit the 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-453/S-010." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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, HFD-410  
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).

We request that information on anti-microbial agent be included in the next annual report:

In accordance with USP <1225>, method <341> Anti-Microbial Agent - Contents does not require validation for accuracy and reliability, but should be verified for suitability under actual conditions of use with the drug product. An example chromatogram with each peak of interest labeled, to verify specificity, should be submitted in the next annual report.

If you have any questions, call Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.  
Director  
Division of Metabolic  
and Endocrine Drug products, HFD-510  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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David Orloff

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