DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-748/S-008 **SUPPLEMENT APPROVAL**

DepoMed, Inc.
Attention: Hayley Welton, RAC
Associate Director, Regulatory Affairs
1360 O'Brien Drive
Menlo Park, CA 94025-1436

Dear Ms. Welton:

Please refer to your supplemental new drug application dated May 28, 2009, received June 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Glumetza (metformin HCl) Extended-Release Tablets, 500 mg and 1000 mg.

This "Changes Being Effected" supplemental new drug application provides for the following labeling revisions to the immediate container (bottle) labels: 1) patent information, 2) label part numbers, and 3) the FDA statement and phone number for reporting side-effects.

We have completed our review of this application. This application is **approved**, effective on the date of this letter.

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, please call Ms. Jena Weber, Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
a. 1000 mg, 90 ct. bottle label
b. 1000 mg, 7 ct. bottle label
c. 500 mg, 100 ct. bottle label

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21748	SUPPL-8	DEPOMED INC	GLUMETZA(METFORMIN HCL)500/1000MG ER TAB

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/s/

MARY H PARKS
02/25/2010