



NDA 21-748/S-002

DepoMed, Inc.
Attention: Jeffrey Miller
VP, Regulatory Affairs & QA
1360 O'Brien Drive
Menlo Park, CA 94025-1436

Dear Mr. Miller:

Please refer to your supplemental new drug application dated July 6, 2006, received July 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glumetza™ (metformin HCl) Extended-Release Tablets, 500 mg and 1000 mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **CONTRAINDICATIONS** and **HOW SUPPLIED** sections of the package insert.

We completed our review of this application. 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 attached labeling (text for the package insert) dated July 6, 2006.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-748/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

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 20857

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, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
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/

Mary Parks
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