



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-748/S-005

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 December 16, 2008, received December 17, 2008, submitted under section 505(b) pursuant to section of the Federal Food, Drug, and Cosmetic Act for Glumetza (metformin HCl) Extended-Release Tablets, 500 mg and 1000 mg.

We acknowledge receipt of your submission dated February 20, 24 and 25, 2009.

This "Changes Being Effected" supplemental new drug application provides for editorial changes to the package insert. These changes are considered annual reportable changes as per CFR 314.70(c)(7)(d)(2)(x).

We have 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. We note that this submission included content of labeling in structured product labeling (SPL) format.

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
Suite 12B05
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).

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

Enclosure: package insert

**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
6/16/2009 03:50:25 PM