**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-744/S-013

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

Dear Ms. Welton:

Please refer to your supplemental new drug application submitted on November 13, 2008, received on November 14, 2008, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

| NDA Number | Supplement Number | Drug Product |
|---|---|---|
| 21-744 | 013 | Proquin XR (ciprofloxacin HCl extended-release) Tablets, 500 mg |

We acknowledge your submission of February 3, 2009.

This supplemental new drug application provides for various chemistry-related revisions throughout the content of labeling for the package insert.

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 label text, and provides for the following revisions in the package insert (additions are noted with double underline and deletions are noted with ~~cross-through~~):

1. The last paragraph of the **DESCRIPTION** section of the labeling has been revised as follows:

   Proquin XR is available as 500 mg (ciprofloxacin equivalent) tablets, utilizing Acuform™ delivery technology. Proquin XT tablets are blue-film-coated and oval-shaped. The inactive ingredients are povidone, magnesium stearate, polyethylene oxide, and film coating (Opadry® Blue).

2. The **HOW SUPPLIED** section has been revised to remove the 50-count bottle package that is no longer distributed as follows:

   Proquin XR is available as blue film-coated tablets containing 500 mg ciprofloxacin. The tablet is debossed with "500" on one side and "DMI" on the other side.

| Package | Strength | NDC Code |
|---|---|---|
| Bottles of 30 | 500 mg | 13913-001-30 |
| ~~Bottles of 50~~ | ~~500 mg~~ | ~~13913-001-50~~ |
| Blister Packs of 3 | 500 mg | 13913-001-03 |

Store Proquin XR at 25 $^{o}$C (77 $^{o}$F); excursion permitted to 15-30 $^{o}$C (59-86 $^{o}$F) [see USP Controlled Room Temperature]

3. The spelling of povidone has been corrected.

4. Minor editorial revisions were made throughout the package insert.

## CONTENT OF LABELING

On February 3, 2009, we note that you have submitted the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). That version was transmitted to the National Library of Medicine for public dissemination.

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in SPL format to include the changes approved in this application. Marketing the product with final printed labeling that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We request that the revised labeling for the package inserts approved today be available on your website within 10 days of receipt of this letter and that the revised labeling be reflected in the next printing of the labeling. While you may use labeling already printed as of the date of this letter until August 14, 2009, after that date we request that the revised labeling accompany any newly shipped product.

Failure to make these changes promptly could make your product misbranded under Sections 201(n) and 502(a) of the FDCA.

## LETTERS TO HEALTH CARE PROFESSIONALS

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, call Rebecca D. McKinnon, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

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/s/

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Renata Albrecht

5/7/2009 09:31:45 AM