DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-744/S-007
NDA 21-744/S-010

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 New Drug Application (NDA) for Proquin® XR (ciprofloxacin HCl extended-release) Tablets, 500 mg.

A. Approval of Labeling Supplement NDA 21-744/S-007

Please also refer to your supplemental new drug application dated October 8, 2007, received October 9, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

We acknowledge receipt of your submissions dated April 17, October 8, and October 16, 2008.

Your submission of April 17, 2008 constituted a complete response to our March 13, 2008 action letter.

This supplemental new drug application provides for a single tablet blister pack configuration as an alternative to the currently approved three-tablet configuration of your physician sample package and for the following information added to the labeling for Proquin® XR:

1. The following statement was added to the physician sample blister package (1-tablet configuration) outer carton label and blister foil label:

   This sample contains only one dose for the first day of treatment with Proquin XR. Your complete treatment is for 3 daily doses. You must fill a prescription for the remaining two daily doses before your next scheduled dose.

2. The following text was added to the Medication Guide section of the package insert between the "**What should I tell my healthcare provider before taking Proquin® XR**" subsection and "**How should I take Proquin® XR**" subsection:

   "What if I receive a sample of Proquin® XR from my healthcare provider? This sample contains only one dose for the first day of treatment with of Proquin® XR and is not a complete treatment. To treat your bladder infection, you must take all 3 daily doses of Proquin® XR. You must fill a prescription from your healthcare provider for the remaining two daily doses before your next scheduled dose. Take all of your doses as prescribed by your healthcare provider,

even if you are feeling better after the first dose. If you stop taking Proquin® XR before all of your doses are complete, Proquin® XR may not cure your bladder infection. It is not known if Proquin® XR will treat infections other than bladder infections. See also **How should I take Proquin® XR?"**

B. Approval of Labeling Supplement NDA 21-744/S-010

Please refer to your supplemental new drug application dated October 8, 2008, received October 14, 2008, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

We acknowledge receipt of your submission dated October 16, 2008.

This supplemental new drug application provides for the addition of the statement, "ENCLOSED MEDICATION GUIDE IS TO BE DISPENSED TO PATIENT," on the outer carton label to notify dispensers that a Medication Guide is to be dispensed with the product.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon label text.

CONTENT OF LABELING

As soon as possible, but no later than one month from the date of this letter, please submit 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 and carton/container labels). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 21-744/S-007 and NDA 21-744/S-010**."

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in SPL format to include the changes approved in these applications.

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 insert and carton/container labels 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 January 3, 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.

ADVERTISTING

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 the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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. Saville, 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

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

/s/

Renata Albrecht

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