DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-744

Depomed, Inc.
Attention: Bret Berner, Ph. D.
Vice President, Product Development
1360 O'Brien Drive
Menlo Park, CA 94025-1436

Dear Dr. Berner:

Please refer to your new drug application (NDA) dated July 18, 2004, received July 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proquin® XR (ciprofloxacin hydrochloride) Extended-Release Tablets, 500 mg.

We acknowledge receipt of your submissions dated:

August 18, 2004	December 22, 2004	February 17, 2005	May 16, 2005
November 11, 2004	January 24, 2005	February 24, 2005	May 18, 2005
November 23, 2004	February 9, 2005	April 21, 2005	May 19, 2005

This new drug application provides for the use of Proquin® XR (ciprofloxacin hydrochloride) Extended-Release Tablets, 500 mg for the treatment of uncomplicated urinary tract infections (acute cystitis) caused by *Escherichia coli and Klebsiella pneumoniae*.

We completed our review of this application, as amended. It 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 enclosed labeling (text for package insert and patient package insert) and submitted labeling (immediate container and carton labels submitted May 18, 2005). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: ***Providing Regulatory Submissions in Electronic Format - NDAs*** (January 1999) and ***Providing Regulatory Submissions in Electronic Format – Content of Labeling*** (February 2004). The guidances specify that labeling to be submitted

in *pdf* format. To assist in our review of the FPL and future submission, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, this submission should be designated "**FPL for approved NDA 21-744**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated May 19, 2005:

1. Bacterial Susceptibility Study

   Conduct a multi-center, in vitro surveillance study of *E. coli* isolates from community-acquired uncomplicated urinary tract infections to evaluate the baseline and current emergence of resistance to Proquin® XR for the first two years after initial marketing in the U.S.

Protocol Submission:	January 1, 2006
Study Start:	July 1, 2006
Final Report Submission:	December 31, 2008

2. Proquin® XR Usage Pattern

   Monitor and obtain data on the usage pattern of Proquin® XR for the first two years after initial marketing in the U.S. Include information such as patient demographics, setting of practice, indication for use, and treatment regimen prescribed. Submit these data as an annual update with the submission dates being no later than May 19, 2006 and May 19, 2007.

The Division anticipates discussing the details of the above studies at your earliest convenience.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol," "Postmarketing Study Final Report," or "Postmarketing Study Correspondence."**

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 this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Yon Yu, Pharm D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office Drug Evaluation IV
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/

Renata Albrecht
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NDA 21-744