



NDA 21-744/S-002

Esprit Pharma, Inc.
Attn: Richard J. Brown, M.D.
Vice President, Regulatory Affairs
Two Tower Center Blvd.
East Brunswick, NJ 08816

Dear Dr. Brown:

Please refer to your supplemental new drug application dated February 16, 2006, received February 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proquin XR (ciprofloxacin HCl extended-release) Tablets, 500 mg.

We acknowledge receipt of your submission dated April 10, 2006.

This “Changes Being Effected” supplemental new drug application provides for (1) marketing the three-tablet blister pack, previously approved as a physician package, and a package of 30 tablets in the approved 120-cd^{(b) (4)} bottle; (2) extension of the expiry date of the drug product in^{(b) (4)} bottles from 24 months to 36 months; and (3) the following changes to the package insert (inserted text is double underlined and deleted text is ~~crossed-out~~):

1. Additional information was added to the **HOW SUPPLIED** section of the package insert as follows:

HOW SUPPLIED

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
<u>Bottles of 30</u>	<u>500 mg</u>	<u>15456-001-30</u>
<u>Bottles of 50</u>	<u>500 mg</u>	<u>13913-001-50</u>
<u>Blister Packs of 3</u>	<u>500 mg</u>	<u>15456-001-03</u>

Store Proquin XR at 25 °C (77 °F); excursion permitted to 15-30 °C (59-86 °F)

2. The following information in the **PATIENT PACKAGE INSERT** was revised as follows:

~~1-866-230-0375~~~~800-206-2945~~ and ~~www.P~~proquinxr.com

What are the ingredients in Proquin XR?

Active Ingredient: ciprofloxacin hydrochloride

Inactive Ingredients: film coating, magnesium stearate, polyethylene oxide, and povidone

Rx Only

Proquin® is a registered trademark of Depomed, Inc.

© 2005 Depomed, Inc.

Distributed by:

Esprit Pharma

East Brunswick, NJ 08816

Proquin® XR is manufactured for:

Depomed, Inc.

1360 O'Brien Drive

Menlo Park, CA 94025-1436

Rx Only

~~©2005 Depomed, Inc.~~

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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 21-744/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

Submit revised 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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