

021733 - Original Approval - Package. PDF

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Approval Package for:

APPLICATION NUMBER:

21-733

Trade Name: Cymbalta

Generic Name: Duloxetine hydrochloride delayed-release capsules

Sponsor: Lilly Research Laboratories

Approval Date: September 3, 2004

Indications: Provides for the use of Cymbalta (duloxetine hydrochloride) Delayed-release Capsules 20, 30, and 60 mg for the management of neuropathic pain associated with diabetic peripheral neuropathy.

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APPROVAL LETTER(S)

NDA 21-733

Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Attention: Gregory T. Brophy, Ph.D.
Director, U.S. Regulatory Affairs

Dear Dr. Brophy:

Please refer to your new drug application (NDA) dated March 2, 2004, received March 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cymbalta (duloxetine hydrochloride) Delayed-release Capsules 20, 30 and 60 mg.

We acknowledge receipt of your submissions dated May 5 and 11, June 2, July 1 and 26, and August 12 (2) and 30, 2004.

This new drug application provides for the use of CYMBALTA (duloxetine hydrochloride) Delayed-release Capsules 20, 30 and 60 mg for the management of neuropathic pain associated with diabetic peripheral neuropathy.

We have completed our review of this application, as amended, and 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 the package insert). As agreed, the immediate container and carton labeling should be revised to include the product name "Cymbalta (duloxetine hydrochloride) Delayed-release Capsules" at the time of your next printing. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-733.**" 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 indication.

We remind you of your postmarketing commitments, numbered 2 and 4, in the approval letter dated August 3, 2004 for NDA 21-427.

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 have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-427 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Lisa Malandro, Regulatory Project Manager, at (301)827-7416.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division Director
Division of Anesthetic, Critical Care
and Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport
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