

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-658/S-012

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-658 / S012

GlaxoSmithKline Corporation
Attention: Leslie C. Rogers, M.D.
Sr. Director, Regulatory Affairs, Neurology
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Rogers:

Please refer to your supplemental new drug application dated December 9, 2002, received December 10, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Requip (ropinirole hydrochloride) Tablets.

This "Changes Being Effected" supplemental new drug application provides labeling changes to the sample starter pack for Requip Tablets in order to strengthen instructions about dosage and administration.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the December 9, 2002 submitted labeling text.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-658/S-012. Approval of this submission by FDA is not required before the labeling is used.

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

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, HFD-410
FDA
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 Teresa Wheelous, R.Ph., Senior Regulatory Project Manager, at (301) 594-2850.

Sincerely,

Russell Katz, MD
Director
Division of Neuropharmacological Drug Products
Office of Evaluation I
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

**This is a representation of an electronic record that was signed electronically and
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/s/

Russell Katz
6/19/03 07:56:09 AM

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