DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-284

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Stiles:

Please refer to your new drug application (NDA) dated November 28, 2000, received November 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ritalin® LA (methylphenidate hydrochloride) Extended-release Capsules.

We acknowledge receipt of your submissions dated October 18 and December 6, 2001; February 28, March 21 (juvenile animal study), April 16, May 6, 13 and 23, 2002. Your submission of December 6, 2001 constituted a complete response to our October 1, 2001 action letter.

This new drug application provides for the use of Ritalin® LA (methylphenidate hydrochloride) Extended-release Capsules for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) for children aged 6 to 12.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). 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 the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). 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. 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 NDA 21-284." Approval of this submission by FDA is not required before the labeling is used.

The following agreed upon dissolution specifications have been approved for all strengths of Ritalin® LA Extended-release Capsules:

Table 1 Dissolution Method and Specifications

Parameter	Description
Apparatus type:	USP Apparatus I (basket)
Media:	Medium I: Medium II:
Volume (ml):	500 ml for both medium I and medium II
Temperature	
Speed of rotation (rpm):	
Sample times (hours):	
Specifications (% of Label Claim)	(b)(4)
Acceptance criteria for 2 – 10 hours	As per USP XXIV – NF 19 <724> Drug Release Acceptance Table 1

We have approved an expiration date of two years for this drug product.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated.

Please be advised that, as of April 1, 1999, 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 (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please call Ms. Anna Marie H. Weikel, R.Ph., Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz
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