



NDA 12-911/S-023

Novartis Pharmaceuticals Corporation
Attention: Donna M. Vivelo
Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936

Dear Ms. Vivelo:

Please refer to your supplemental new drug application dated February 25, 2004, received February 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metopirone® (metyrapone USP) Capsules, 250 mg.

This supplemental new drug application proposes to add the following paragraph to the new **Geriatric Use** subsection, of the **PRECAUTIONS** section, of the package insert:

Clinical studies of Metopirone did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

We completed our review of this application. 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 (package insert submitted April 28, 2004).

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement "NDA 12-911/S-023." Approval of this submission by FDA is not required before the labeling is used.

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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.

Director

Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II Center for Drug Evaluation

Enclosure (package insert text)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Mary Parks
5/7/04 03:10:04 PM
for Dr. Orloff