DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-202/S-021

Novartis Pharmaceuticals Corporation
Attention: Donna M. Vivelo
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Vivelo:

Please refer to your supplemental new drug application dated December 3, 2002, received December 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytadren® (aminoglutethimide) Tablets, USP.

We acknowledge receipt of your submissions dated March 17, and April 2, 2003, containing revised labeling.

This supplemental new drug application proposed to add a **Geriatric Use** subsection to the **PRECAUTIONS** section of the package insert to comply with 21 CFR 201.57(f)(10).

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

The final printed labeling (FPL) must be identical to the draft package insert submitted on April 2, 2003, and must be formatted in accordance with the requirements of 21 CFR 201.57

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 18-202/S-021." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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, 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 and Research

Enclosure: package insert (final draft submitted on April 2, 2003).

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

/s/

David Orloff

5/7/03 06:46:05 PM