

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-645**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-645

Ucyclyd Pharma, a wholly owned subsidiary of Medicis Pharmaceutical Corp.  
Attention: R. Todd Plott, M.D.  
Vice President, Clinical Research and Regulatory Affairs  
8125 North Hayden Road  
Scottsdale, AZ 85258

Dear Dr. Plott:

Please refer to your new drug application (NDA) dated August 9, 2004, received August 10, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ammonul (sodium phenylacetate and sodium benzoate) Injection, 10% / 10%.

We acknowledge receipt of your submissions dated August 16, October 8, and 11, November 9, December 9, and 20, 2004 and January 5(2), 17, 20, 21, 24, and 28, and February 4, and 10, 2005.

This new drug application provides for the use of Ammonul (sodium phenylacetate and sodium benzoate) Injection, 10% / 10% as adjunctive therapy in the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle.

We completed our review of this application, as amended. 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, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Submit the content of labeling in electronic format as described in 21 CFR 314.50(1)(5) and in the format described at the following website: <http://www.fda.gov/oc/datacouncil/spl.html>. For administrative purposes, designate this submission "**FPL for approved NDA 20-645.**" Approval of this submission by FDA is not required before the labeling is used.

All communications regarding this application that contain electronic media or a combination of electronic and paper media should be addressed as follows:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Rd.  
Beltsville, Md. 20705-1266

Paper communications regarding this application that **DO NOT** contain electronic media should be addressed as follows:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolic and Endocrine Drug Products, HFD-510  
Attention: Division Document Room, 8B45  
5600 Fishers Lane  
Rockville, Maryland 20857

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 note that you have fulfilled the pediatric study requirement for this application.

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

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 Pat Madara, Regulatory Project Manager at (301) 827-6416.

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

Enclosures: package insert, immediate container label, carton label