CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-667

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-677

Nutritional Restart Pharmaceutical, L.P.
c/o Cato Research
200 Westpark Corporate Center
4364 South Alston Avenue
Durham, NC 27713

Dear Ms. Sutton:

Please refer to your new drug application (NDA) dated August 8, 2003, received August 11, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for NutreStore™ (L-glutamine powder for oral solution).

We acknowledge receipt of your submissions dated October 14, 2003, December 5, 2003, December 8, 2003, January 29, 2004, February 18, 2004 and May 13, 2004.

This new drug application provides for the use of NutreStore™ (L-glutamine powder for oral solution) for treatment of short bowel syndrome in patients receiving specialized nutritional support when used in conjunction with a recombinant human growth hormone that is approved for this indication.

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) and the submitted labeling (package insert submitted June 9, 2004, immediate container and carton labels submitted June 7, 2004). 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 an electronic version of the FPL (package insert and immediate container and carton labels) 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-667**." Approval of this submission by FDA is not required before the labeling is used.

We recommend you develop a patient package insert (PPI) and to submit the PPI within 30 days of this letter. The PPI should be submitted as a labeling supplement to this Division.

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 are waiving 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 have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Tanya Clayton, B.S., Regulatory Project Manager, at (301) 827-4005.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Deputy Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure