DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-642

Nastech Pharmaceutical Company, Inc.
Attention: Gordon Brandt, MD
Executive Vice President of Science and Clinical Development
3450 Monte Villa Parkway
Bothell, WA 98027

Dear Dr. Brandt:

Please refer to your new drug application (NDA) dated December 26, 2003, received December 29, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Nascobal (cyancobalamin, USP) Nasal Spray for intranasal administration.

We acknowledge receipt of your submissions dated November 3, 12, and 28, and December 1, 2004, and January 20, 2005.

The December 1, 2004, submission constituted a complete response to our October 28, 2004, action letter.

This new drug application provides for the use of Nascobal (cyanocobalamin) Nasal Spray for maintenance of normal hematologic status in pernicious anemia patients.

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 (package insert submitted January 20, 2005, and the immediate container and carton labels submitted December 1, 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 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 21-642**." Approval of this submission by FDA is not required before the labeling is used.

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 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 Holly Wieland, Regulatory Project Manager at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

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
1/31/05 07:53:32 PM
for Dr. Orloff