DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-722/S-004

Nastech Pharmaceutical Co.
Attention: Peter C. Aprile, R.Ph.
Senior Director, Regulatory and Quality Affairs
Corporate Headquarters
45 Adams Avenue
Hauppauge, NY 11788

Dear Mr. Aprile:

Please refer to your supplemental new drug application dated December 20, 2001, received December 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nascobal (cyanocobalamin, USP) Gel for Intranasal Administration.

We acknowledge receipt of your submission dated February 2, 2002.

This supplemental new drug application provides for revision of the INDICATIONS AND USAGE section of the package insert to add HIV infection, AIDS, and Crohn's disease to the list of conditions which could result in Vitamin B12 deficiency and for which Nascobal would be indicated.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted February 2, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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 19-722/S-004." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care

Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

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

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

/s/

Kati Johnson

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