DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-976/S-006
NDA 21-160/S-001

Nabi Biopharmaceuticals
Attention: Lewis Pollack, Ph.D.
Senior Director, Regulatory Affairs
12280 Wilkins Avenue
Rockville, MD 20852

Dear Dr. Pollack:

Please refer to your supplemental new drug application dated and received August 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PhosLo (calcium acetate) Tablets (NDA 19-976), and PhosLo (calcium acetate) Gelcaps and Capsules (NDA 21-160).

These "Changes Being Effected" supplemental new drug applications provide for a name change from Braintree Laboratories to Nabi Biopharmaceuticals, and a new NDC code number.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 8, 2003.

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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

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/

David Orloff

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