DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12-154/S-023

Abbott Laboratories
200 Abbott Park Road, D-389, J45-2
Abbott Park, IL 60064-6157

Attention: Mary Amiryaghoobi
Regulatory Specialist
Hospital Products Division

Dear Ms. Amiryaghoobi:

Please refer to your supplemental new drug application dated December 11, 1996, received December 13, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ureaphil (urea for injection, USP).

We acknowledge receipt of your submission dated December 18, 1996, and October 31, 2001.

The supplemental new drug application provides for a revised "Pediatric Use" subsection of the PRECAUTIONS section of the package insert.

We have completed our review of this supplemental application, as amended, and it is approved effective on the date of this letter.

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 the respective 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 Victoria Kao, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
and Addiction 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/

Bob Rappaport

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