DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-066/S-011 and S-013

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: Rita Wittich
Vice President, Regulatory Strategy

Dear Ms. Wittich:

Please refer to your supplemental new drug application (S-013) dated February 19, 2002, received February 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unisom Sleep Tabs (25 mg doxylamine succinate tablets).

This "Changes Being Effected" supplemental new drug application provides new labeling for two additional package sizes (40- and 64-count) and revised labeling for four package sizes (8-, 16-, 32-, and 48-count).

We also refer to your supplemental new drug application (S-011) dated July 24, 2000, received July 25, 2000, that proposed new labeling for the 8-, 16-, 32-, and 48-count package sizes, and to our April 11, 2001, letter for this application. Your responses to the deficiencies cited in this letter were incorporated into the labeling submitted in supplemental application S-013. Therefore, the labeling proposed in supplement S-013 supercedes the proposed labeling submitted in supplement S-011.

We have completed the review of supplemental application S-013 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 submitted final printed labeling (immediate container and carton labels for all package sizes noted above submitted February 19, 2002). Accordingly, the supplemental application S-013 is approved effective on the date of this letter.

Supplemental application S-011 is hereby administratively closed and will be retained in our files.

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

Please submit one market package of the drug product when it is available.

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 Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Linda Katz

5/30/02 01:31:53 PM