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XETAPHARM™
Natural Preventive Healthcare

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May 24, 1996

Dr. Elizabeth A. Yetley, Director
Office of Special Nutritionals HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, N.W.
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given persuant to the requirements of Section 403(r)(6) (21 U.S.C. 343 (r)(6)) of the Federal Food, Drug and Cosmetic Act of Statements of nutritional support which have been made on the label and in the labeling in connection with the marketing of the dietary supplement Melatonin 1 mg with Vitamin B-6 1 mg tablet. Melatonin 1 mg with Vitamin B-6 1 mg tablet will be first marketed with these statement of nutritional support on June 17, 1996. The statements of nutritional support are as follows:

Label:

DIRECTIONS: For restoring normal sleep in individuals whose natural melatonin has been altered, take 1 tablet at bedtime, or as directed by your health care professional.

WARNINGS: TAKE ONLY ONE TABLET PER DAY. NOT FOR CHILDREN UNDER 18. DO NOT USE IF PREGNANT OR NURSING, OR IF TRYING TO CONCEIVE (BOTH MEN AND WOMEN). FOR RELIEF OF OCCASIONAL SLEEPLESSNESS. IF SLEEPLESSNESS PERSISTS CONTINUOUSLY FOR MORE THAN 2 WEEKS, CONSULT YOUR DOCTOR. DO NOT TAKE THIS PRODUCT IF YOU ARE TAKING SEDATIVES OR TRANQUILIZERS OR UNDER MEDICATION WITHOUT CONSULTING YOUR DOCTOR (SEE ENCLOSED INSERT).*

Melatonin helps regulate your sleep cycle, resulting in quality sleep. This is especially useful for travelers and shift workers. This product is also an excellent source of Vitamin B-6 which is needed for your body's natural ability to produce melatonin.*

*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

A Label copy is attached.

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GOLD LEAF

Labeling:

MELATONIN
with Vitamin B-6
Dietary Supplement

Dietary Supplement:*

Melatonin: Melatonin is produced by the tiny pineal gland situated at the center of the brain. The pineal gland's production of melatonin varies both with the time of day, and with age. Production of melatonin is dramatically increased during the night time hours and decreases during the day.

The fact that the light cycle affects melatonin production led to the belief that night time production of melatonin is an important factor in producing sleep.

Experimentation began about 5 years ago, with findings that administration of melatonin does indeed bring about sleep. The effect has been seen during the day (1), the evening (2) and in the elderly (3). There is a good basis to claim that melatonin helps regulate the onset and quality of sleep. This is particularly useful for those who have their light patterns disrupted; shift workers, travelers across time zones, and individuals who have difficulty adjusting to seasonal changes in day/night length.

Vitamin B-6: Vitamin B-6 is a traditional vitamin, so is allowed in dietary supplements. Vitamin B-6 is required for normal biochemical production of melatonin from tryptophan (4,5). It can therefore be stated that Vitamin B-6 is required to maintain the body's natural ability to produce melatonin. This statement would be supported by a product which delivers a significant nutritional amount of Vitamin B-6, i.e. containing at least 10% of the Recommended Daily Intake per serving.

Safety:*

The dose range in the earliest study (1) on melatonin and sleep was 0.1 mg to 10 mg. The most effective dose was 1 mg. The 10 mg dose was less effective. The later study (2) by this group indicated that the dosages of 0.3 mg and 1 mg were equally effective.

We recommend that a melatonin product for use as a sleep aid contain **no more than 1 mg per dose.** This is an effective dose, and there is no reason to exceed it.

Vitamin B-6 is quite safe, with toxicity noted only after prolonged intake at many times the Reference Daily Intake (6).

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A Labeling copy is attached.

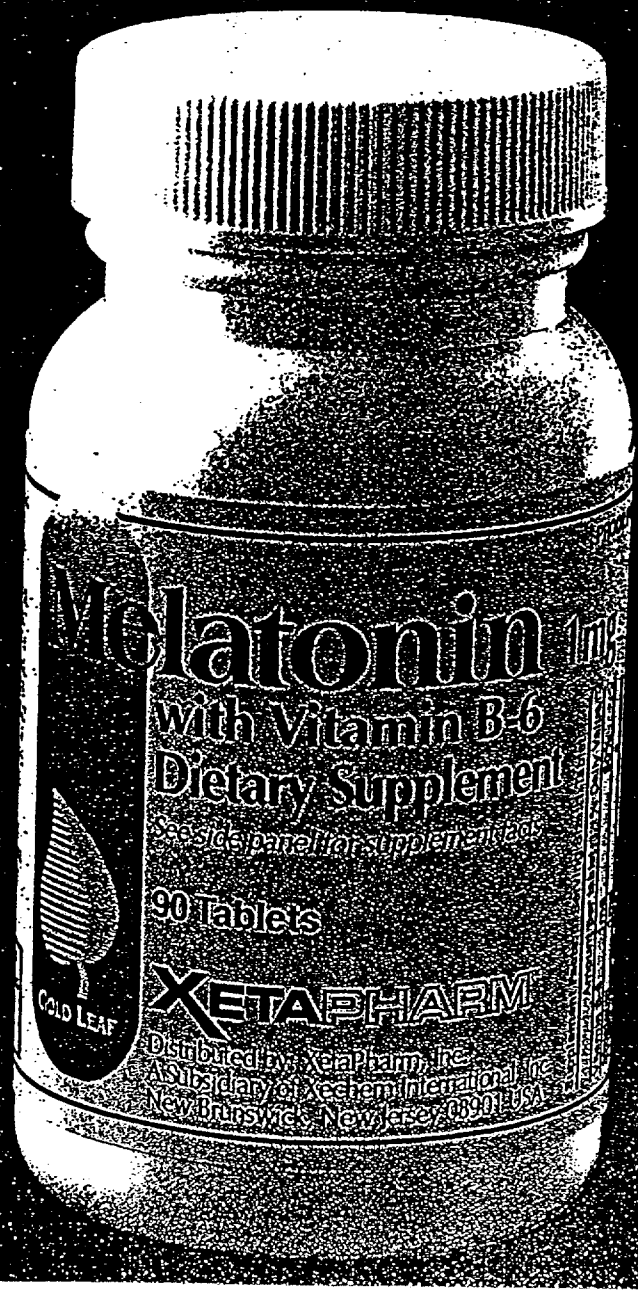
Very truly yours,
XetaPharm, Inc.
A subsidiary of
Xechem, International Inc.

RCPandey.

Ramesh Chandre Pandey, Ph.D.
President and CEO

XETAPHARM

GOLD LEAF

Introducing Melatonin with Vitamin B-6 Dietary Supplement

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Where Higher Standards are Standard Practice