DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 16 2000

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Tamra L. Goodrow, Ph.D.
Associate Director
Regulatory Affairs
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486

Re: Docket Nos. 00P-0110/CP1 and 98N-0056

Dear Dr. Goodrow:

This letter responds to your citizen petition dated December 9, 1999, requesting that the Food and Drug Administration (FDA) add finasteride to the priority section of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and determined that finasteride is not approved for any indication that occurs in the pediatric population. Therefore, finasteride does not qualify for inclusion on the list.

Finasteride is indicated for the treatment of male pattern hair loss (androgenetic alopecia) in men 18 years old and older. As stated in finasteride's labeling, efficacy in bitemporal recession has not been established. Finasteride is also indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for surgery including transurethral resection of the prostate and prostatectomy. FDA has no evidence that these indications occur in the pediatric population.

You suggest that androgenetic alopecia can occur in men younger than 18 years old. However, the references you submitted show only that bitemporal recession, not androgenetic alopecia, *may* occur in men younger than 18 years old. Since the indications for which finasteride is approved, androgenetic alopecia and BPH, do not occur in the pediatric population, finasteride is not included on the list.

Although finasteride may have some other use in the pediatric population, FDA notes that finasteride's labeling states that it is not indicated for use in pediatric patients. Finasteride inhibits Type II 5(alpha)-reductase, which metabolizes testosterone to the potent androgen 5(alpha)-dihydrotestosterone. FDA is concerned that use of finasteride by pediatric patients may pose long-term safety risks regarding growth, development, and sexual function. Any proposed use in the pediatric population would, of course, need to account for these safety concerns.

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Accordingly, your petition is denied. We appreciate your interest in conducting pediatric studies, and hope that there are pediatric indications for other products for which you will conduct studies.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research