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be included in the Priority Section of the List. The fulfillment of a prioritization criterion for finasteride is discussed below.

- **Finasteride, 1 mg is an agent which is approved for the treatment of androgenetic alopecia in males, an indication for which additional therapeutic options for the pediatric population are needed.**

A need for therapy for androgenetic alopecia in the male adolescent-Pediatric population

No therapy is currently approved for the treatment of androgenetic alopecia in adolescent males.

In genetically predisposed individuals, an androgen-induced decline in scalp hair density generally begins during adolescence and progresses with age. The estimated prevalence of androgenetic alopecia in men increases with age, ranging from 12-26% in those 18-29 years of age to 43-50% in those 40-49 years of age [1-3]. There are very limited published data on the prevalence of early onset androgenetic alopecia; i.e., androgenetic alopecia occurring in adolescent men aged 15-17 years. In his series, Hamilton reported one case of androgenetic alopecia (male pattern Type IV) among eighteen males 15-19 years old, but the age distribution of the sample and the age of the affected individual were not reported [1]. However, it is widely acknowledged by practicing dermatologists that adolescents with this type of early onset, or premature, androgenetic alopecia comprise a part of their practice.

Androgenetic alopecia has been shown to have a significant impact on many men [4-6]. Adolescence is well known to be a time of upheaval; for the individual, it involves establishing a sense of identity and a preoccupation with how he is viewed by others. Like acne, which, due to its cosmetic impact, can contribute to decreased self image in adolescents [7], androgenetic alopecia has also been shown in some men to lead to decreased body image satisfaction, increased preoccupation, and stress and distress, leading to coping efforts to maintain body image integrity [8]. Scalp hair loss, which is less common than acne in this sensitive population, may thus be especially distressing. For example, it has been demonstrated that some adolescents with cancer who experience hair loss as a result of chemotherapy restrict themselves in social interactions with peers due to the alteration in their self-image and not due to the primary diagnosis of cancer [9]. Adolescents with significant androgenetic alopecia who, by definition, have early onset of the condition, may feel stigmatized as looking far older than their age and thus suffer with a loss of self-image during this sensitive time when adult identity is being formed. The potential impact on the adolescent has underscored the need for a treatment for adolescents who suffer from androgenetic alopecia with early onset, and this need has been well-documented in other pathologies involving scalp hair loss, such as alopecia arcata, by practitioners caring for these patients [10,11].

Thus, a clear rationale, based on patient need, exists to offer therapy for adolescents seeking treatment for early onset androgenetic alopecia. For adult men with androgenetic alopecia, finasteride (1 mg) has been demonstrated to be a safe and effective treatment. The pediatric population in need of a therapy option is comprised of males in late adolescence, i.e., males

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between the ages of 15 and 17 who have documented sexual maturation and growth as demonstrated by Tanner stage and bone age. Pediatric studies are proposed solely for this patient population, based on the need for these individuals to have a therapeutic option and the safety profile of finasteride demonstrated in adults.

Safety Issues Specific to the Study Population

No significant safety issues specific to the sexually mature male adolescent pediatric population

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The undersigned, on behalf of Merck & Co., Inc., submits this petition under section 505A (c) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to request the Commissioner of Food and Drugs to add finasteride, 1 mg (Merck Research Laboratories' PROPECIA™) to the priority section (Pediatric Priority List of Drugs Regulated by the Center for Drug Evaluation and Research) of the "List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population" ("the List") (Docket 98N-0056, dated May 20, 1998).

A. Action Requested

This petition requests the Commissioner to 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".

B. Statement of Grounds

... 1999 ... Food and Drug Administration approved PROPECIA™ for the

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D. Economic Impact

This information will be submitted only when requested by the Commissioner following review of the petition. See 21 CFR § 10.30(b).

E. Certification

The undersigned certifies that, to the best of her knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

We consider the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

Sincerely yours,

Tamra L. Goodrow
Tamra L. Goodrow, Ph.D.
Associate Director
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TLG/ped

Enclosures: References

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REFERENCES*

1. Hamilton JB. Patterned loss of hair in man: types and incidence. *Ann NY Acad Sci* 1951; 53:708-28
2. Norwood OT. Male pattern baldness: classification and incidence. *South Med J* 1975; 68 (11):1359-65
3. Olsen EA. Androgenetic alopecia. In: Olsen EA, ed. *Disorders of hair growth: diagnosis and treatment*. New York: McGraw-Hill, Inc., 1994:257-83.
4. Cash TF, Price VH, Savin RC. Psychological effects of androgenetic alopecia on women: comparisons with balding men and with female control subjects. *J Am Acad Dermatol* 1993;29(4):568-75.
5. Patzer GL. Psychologic and sociologic dimensions of hair: An aspect of the physical attractiveness phenomenon. In: DeVillez RL, Griggs LMP, Freeman B, eds. *Clinics in dermatology*. 6th ed. Philadelphia: J.B. Lippincott, 1988:93-101.
6. Cash TF. The psychosocial consequences of androgenetic alopecia: a review of the research literature. *Br J Dermatol* 1999;141:398-405.
7. Krowchuck DP, Stancin T, Keskinen R, Walker R, Bass J, and Anglin T. The psychosocial effects of acne. *Pediatric Dermatology* 1991; 8(4):332-337.
8. Cash TF. Losing hair, losing points?: The effects of male pattern baldness on social impression formation. *J App Social Psy* 1990;20(2):154-67.
9. Hinds P. Quality of life in children and adolescents with cancer. *Seminars in Oncology Nursing* 1990; 6(4): 285-291.
10. Sahn EE. Alopecia areata in childhood. *Seminars in Dermatology* 1995;14 (1) :1-14.
11. Beard HO. Social and psychological implications of alopecia areata. *J Am-Acad-Dermatol* 1986;14 (4): 697-700.

*References available upon request