Naming Names – Propecia approval process, who is responsible.

Robert E. Silverman, M.D., Ph. D.

Submitted the NDA 20-788

Senior Director, Regulatory Affairs, Merck Research Laboratories
P.O. Box 4, BLA-20
West Point, PA 19486-0004
http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_APPROV.PDF (Dec 19, 1997)

Pharmacology review, Dec 2, 1997

Note: Page 15 of 16 is marked "Redacted, trade secret and/or confidential commercial information"
http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_PHARMR.PDF
Javier Avalos, Ph. D.
Toxicologist

Statistical Review and Eval Dec 11, 1997

Hon-Sum Ko, M.D. (Medical Officer)
http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_STATR.PDF

Clinical Pharmacology and Biopharmaceutics Review Oct 22, 1997

Kofi A. Kumi, Ph. D.
http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_BIOPHARMR.PDF

Administrative Documents Feb 3, 1997

Note: Next to last page regarding Recommended Changes to Propecia Label states: "Redacted, 1 page of trade secret and/or confidential commercial information"
Mary Jean Kozma-Fornaro
Supervisor, Project Manager
Division of Dermatologic and Dental Drug Products at CDER
http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_ADMINDOCS.PDF

Correspondence, December 20, 1996

JBaronathan K. Wilkin, M.D.
Director of Topical Drug Products, FDA

http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20788_PROPECIA%20TABLETS,%201MG_CORRES.PDF

Serious Adverse Experiences were reported in the studies. Merck knew about this in 1997, then proceeds to downplay the importance of the adverse events in the very next paragraph, and then lays claim that this information is "Confidential" and not to be make public!

Additionally, serious adverse experiences (AEs) reported from ongoing Male Pattern Hair Loss studies through January 15, 1997 are provided.

Based on the data for the additional 6-month reporting period in this SUR from the five Male Pattern Hair Loss studies, there is no evidence to suggest that there is an increased incidence of AEs with greater duration of therapy. Thus, the safety data for finasteride presented in this SUR support the overall favorable safety and tolerability profile of finasteride presented in the original NDA and in the proposed product label.

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.

Names of the NDA reviewers

The reviewers from the Division of Dermatologic and Dental Drug Products (DDDDP) and Division of Scientific Investigation (DSI) who should be provided access to the electronic submission from their desktops are as follows:

Ms. Robin Anderson	Project Manager	DDDDP	CRP2 N240	301-827-2042
Dr. Javier Avalos	Pharmtox.	DDDDP	CRP2 N221	301-827-2024
Dr. Jose Carreras	Clinical Audit	DSI	MPN1 119	301-594-1032
Dr. Valeria Freidlin	Biostatistics	DDDDP	CRP2 N250	301-827-2081
Dr. Joel S. Hathaway	Chemistry	DDDDP	CRP2 N237	301-827-2040
Dr. Barbara Hill	Pharmatox.	DDDDP	CRP2 N223	301-827-2069
Dr. Hon Ko	Medical	DDDDP	CRP2 N223	301-827-2022
Mr. Rodney Smith	Computer Resources	DDDDP	PKLN 8B45	301-827-3276