To: Silber, Cynthia[cynthia_silber@merck.com]
From: Alberts, Christine M.
Sent: Wed 4/6/2011 11:20:59 AM
Importance: Normal
Subject: Persistent Sexual Dysfunction.search criteria.doc
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For your review.
thanks

Persistent Sexual Dysfunction DRAFT

The Worldwide Adverse Experience System (WAES) database was searched for spontaneous reports of sexual dysfunction received from health care providers (including regulatory agencies) and consumers in patients on therapy with finasteride 1 mg and 0.2 mg tablet (PROPECIA) from market introduction (11-Sep-1998) to 31-Dec-2010. MedDRA preferred terms searched included: anorgasmia, disturbance in sexual arousal, libido decreased, loss of libido, male orgasmic disorder, orgasm abnormal, erectile dysfunction, male sexual dysfunction, organic erectile dysfunction, and sexual dysfunction.

To identify cases that may represent persistent sexual dysfunction the MAH reviewed the reports with an outcome of *not recovered* in whom finasteride therapy was *discontinued*. A total of 446 spontaneous reports meeting this criteria were identified {add ref man #}.

It should be noted that in the majority of the reports the information was provided shortly after the onset of the adverse experience and despite attempts to obtain follow up information, in accordance with the MAH's standard procedures to obtain follow up, no further information was provided. Thus outcome information is limited to what was provided at the time of the report and in most instances long term outcome data is not available.