UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN)
HEALTH RESEARCH GROUP,)
1600 20th Street, NW)
Washington, DC 20009,)
)
Plaintiff,) Case No. _____
)
v.)
)
FOOD AND DRUG)
ADMINISTRATION,)
5600 Fishers Lane)
Rockville, MD 20857,)
)
Defendant.)
_____)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action is brought under the Freedom of Information Act, 5 U.S.C. ' 552 ("FOIA"), to compel the production of a complete, unredacted copy of the medical reviews prepared by the Food and Drug Administration ("FDA") concerning the drug valdecoxib (Bextra).

2. This Court has jurisdiction under 28 U.S.C. ' 1331 and 5 U.S.C. ' 552(a)(4)(B).

3. Plaintiff Public Citizen Health Research Group ("HRG") is an arm of Public Citizen, Inc., a non-profit consumer advocacy organization. HRG works to promote consumer health and safety and is the requester of the withheld records.

4. Defendant FDA is an agency of the United States. The FDA has possession of and control over the records that Plaintiff seeks.

5. On January 15, 2001, G.D. Searle & Co. ("Searle") submitted to the FDA a new drug application seeking approval to market the drug valdecoxib for four indications: primary dysmenorrhea (menstrual pain), osteoarthritis, adult rheumatoid arthritis, and acute pain.

6. On November 16, 2001, the FDA approved valdecoxib for use in treating primary dysmenorrhea, osteoarthritis, and adult rheumatoid arthritis, but disapproved it for use in treating acute pain.

7. After approving a new drug application, the FDA's practice is to post on its web site a copy of what the agency calls the "approval package." An approval package typically contains the approval letter, printed labeling, and reviews by the FDA's medical officer, pharmacologist, and chemist, among other information.

8. In a letter to the FDA dated December 6, 2001, Plaintiff requested a copy of the "Original Approval Package for Valdecoxib (Bextra); NDA 21-341."

9. Upon information and belief, in early 2002, the FDA posted on its web site a complete copy of the approval package for valdecoxib. A few days later, at the request of Searle, the FDA took the information off its web site.

10. Plaintiff did not look for the approval package on the FDA's website during the period when, on information and belief, the records were on the FDA's website.

11. Sometime later, the FDA re-posted the approval package for valdecoxib on its web site. However, the FDA redacted from the approval package information about the drug's safety and efficacy in treating acute pain. Some of the redacted material was replaced with a statement that it "[has] been removed because it contains trade secret and/or confidential information that is not disclosable."

12. By letter dated April 2, 2003, Plaintiff requested "[a]n un-redacted copy of the Medical Reviews for the drug valdecoxib (Bextra; NDA 21-341) now posted on the FDA's web site."

13. The FDA has not responded substantively to Plaintiff's April 2, 2003 FOIA request.

14. The FDA has not made the requested material available to Plaintiff.

CAUSE OF ACTION
(FOIA)

15. Plaintiff adopts by reference the allegations in paragraphs 3 through 14, above.

16. Plaintiff has a statutory right under FOIA to the records it seeks, and no legal basis exists for Defendant's refusal to disclose them to Plaintiff.

WHEREFORE, Plaintiff prays that this Court:

(A) Declare that Defendant's withholding of the requested records is unlawful under FOIA;

(B) Order Defendant to make the requested material available to Plaintiff;

(C) Award plaintiff its costs and reasonable attorneys' fees pursuant to 5 U.S.C. ' 552(a)(4)(e); and

(D) Grant such other relief as this Court may deem just and proper.

Dated: February 26, 2004

Respectfully submitted,

_____

Allison M. Zieve
(D.C. Bar No. 424786)
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(admitted to CT bar, application for admission to DC bar pending)
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