IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Public Citizen, Inc. 1600 20th Street, N.W. Washington, DC 20009 (202) 588-1000, Plaintiff, vs. Food and Drug Administration 5600 Fishers Lane Rockville, MD 20854 (301) 827-2410, Defendant.	)	C. A. No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff brings this action pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301- 394 (FDCA), and the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706 (APA), to compel the United States Food and Drug Administration (FDA) to act on Public Citizen's petition seeking a ban on the uniquely dangerous antidepressant drug Serzone. Serzone is the trade name for nefazodone, manufactured by Bristol-Myers Squibb Company. In March 2003, pursuant to 21 C.F.R. § 10.30, Public Citizen petitioned the FDA to withdraw marketing approval of Serzone, citing a mounting number of deaths and serious injuries from liver failure associated with Serzone use. Although more than one year has passed since Public Citizen filed its petition, Defendant

has neither granted nor denied the petition, and it has taken no action to remove Serzone from the market. Therefore, to protect public safety and prevent needless death and injury, Plaintiff seeks a declaration that Defendant has acted unlawfully by withholding action on Public Citizen's petition and an order requiring Defendant to act thereon.

PARTIES

2. Plaintiff Public Citizen is a national non-profit advocacy organization, headquartered in Washington, D.C., with approximately 160,000 members. Since its founding in 1971, Public Citizen has worked before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide-range of consumer protection issues. In particular, Public Citizen's Health Research Group (HRG) promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs, medical devices, doctors, hospitals, and occupational health. HRG works to ban or relabel unsafe or ineffective drugs, and publishes "Worst Pills, Best Pills News," a consumer guide to avoiding drug-induced death or illness, which has about 170,000 subscribers. Public Citizen and its members have been, and continue to be, injured by the failure of Defendant to act on Public Citizen's petition and to withdraw marketing approval of the dangerous drug Serzone. As long as Serzone remains on the market, Public Citizen's members are at risk of being prescribed Serzone and suffering severe liver injury as a result.

3. The Department of Health and Human Services (HHS) is the federal agency responsible for administration of the FDCA, 21 U.S.C. § 301 *et seq*. Defendant FDA is an agency within HHS. By delegation from HHS, FDA is responsible for administration of the

FDCA. 21 C.F.R. § 5.10. In particular, FDA is responsible for withdrawing approval of unsafe drugs. As set forth in more detail below, FDA has violated the law by failing to act on Public Citizen's petition seeking the withdrawal of marketing approval of Serzone.

JURISDICTION

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

5. Serzone is an antidepressant drug manufactured and marketed by the Bristol-Myers Squibb Company. The active ingredient in Serzone is nefazodone.

6. Serzone is a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug within the meaning of 21 U.S.C. § 321(p).

7. The FDCA, 28 U.S.C. § 355, prohibits the introduction into interstate commerce of any new drug without FDA approval.

8. The FDCA, 28 U.S.C. § 355(e), requires that the FDA withdraw approval of unsafe drugs.

9. Serzone was approved by the FDA on December 22, 1994. Since then, Serzone has been widely prescribed for the treatment of depression, with over 2.8 million prescriptions filled in the United States in 2002, the latest year for which data are available.

10. Liver toxicity associated with nefazodone has been observed since at least 1998. Since that time, reports of nefazodone-induced liver failure or other severe hepatic injuries have appeared repeatedly in the medical literature.

11. The FDA's Adverse Event Reports Database reports at least 94 liver injuries associated with the use of nefazodone, including 55 cases of liver failure (including 12 liver

transplants) and 20 deaths from liver toxicity between the time the drug was first marketed and May 2003. Because only a fraction of adverse reactions typically are reported to the FDA, the actual number of injuries and deaths attributable to nefazodone is certainly higher.

12. Defendant has acknowledged the risk of serious liver injury associated with Serzone use. In January 2002, the increasing number of serious adverse reaction reports relating to liver toxicity led the FDA to require additional warnings on the Serzone label. However, the FDA received more reports of Serzone-associated liver failure in the one year and five months after the warnings were strengthened than in the five previous years.

13. Serzone offers no advantage in efficacy over the existing drugs in its class or older antidepressants. Among drugs in its class, Serzone has unique and unpredictable toxicity. Serzone is unsafe because of its dangerous interactions with many other drugs, its non-linear blood levels (blood levels of Serzone increase more than expected because Serzone inhibits its own metabolism), the impossibility of predicting who is at risk for liver toxicity, the difficulty in monitoring those at risk, and the rapidity with which serious and irreversible liver damage can occur in Serzone users.

14. In January 2003, Bristol-Myers Squibb withdrew nefazodone from the European market.

15. On October 2, 2003, Bristol-Meyers Squibb announced that after "discussions" with the Canadian government, it was discontinuing sales of nefazodone in Canada effective November 27, 2003. In announcing the withdrawal of the drug, Bristol-Meyers Squibb acknowledged that the use of nefazodone is associated with liver failure. Bristol-Meyers Squibb further acknowledged that no risk factor has been identified "to predict patients

who will develop irreversible liver failure with nefazodone," and "no clinical strategy, such as routine liver function tests, could be identified to reduce the risk of liver failure."

16. Bristol-Myers Squibb has announced that it will withdraw nefazodone from the Australian and New Zealand markets by May 2004.

17. On March 6, 2003, pursuant to 21 C.F.R. § 10.30, Public Citizen filed a petition with the FDA, docket no. 03P-0090, urging that the FDA withdraw its approval of Serzone.

18. In support of its petition, Public Citizen cited numerous reports of nefazodone-associated liver toxicity in the medical literature and the FDA's own database, the actions taken in other countries, and other evidence of the dangers and lack of unique efficacy of Serzone.

19. Public Citizen's petition provides sufficient grounds for Defendant to begin the process of withdrawing approval of Serzone pursuant to the FDCA, 28 U.S.C. § 355(e).

20. On September 4, 2003, the FDA responded to Public Citizen's petition, indicating that the FDA had not yet reached a decision because the petition "raises complex issues requiring extensive review and analysis by FDA officials."

21. On October 29, 2003, Public Citizen submitted further information in support of its petition, noting the withdrawal of the drug in Canada because of its association with severe liver injury and the increase in reports of liver toxicity connected with Serzone use. Public Citizen reiterated its call for the FDA to remove Serzone from the market before more people are injured or killed.

22. To date, the FDA has not issued a decision on Public Citizen's petition, nor has it taken action to withdraw its approval of Serzone. FDA has failed to act despite Serzone's significant rate of severe liver injury and the availability of safer alternatives.

23. The considerable danger to public health occasioned by FDA's continuing approval of Serzone counsels in favor of expeditious action on Public Citizen's petition. The pace of FDA's decisional process is lagging unreasonably in light of the nature and extent of the public health interests prejudiced by FDA's delay. Without FDA action on Public Citizen's petition to ban Serzone, Public Citizen's members will continue to suffer injury or the threat of injury because they are at risk of being prescribed Serzone and suffering liver failure as a result.

CLAIMS FOR RELIEF

24. Defendant's failure to act on Public Citizen's petition constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

25. Defendant's failure to act on Public Citizen's petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court:

A. Declare unlawful Defendant's failure to act on Public Citizen's petition;

B. Order Defendant to issue a decision on Public Citizen's petition within 30 days of declaring Defendant's failure to act unlawful;

C. Award Plaintiff its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

Brian Wolfman
(DC Bar No. 427491)
Michael T. Kirkpatrick
(Texas State Bar No. 11531002)
(DC Bar application pending)

Public Citizen Litigation Group
1600 20th Street, N.W.
Washington, DC 20009
(202) 588-1000

Attorneys for Plaintiff

Dated: March 15, 2004