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December 16, 2002

By Express Mail

The Honorable Lester M. Crawford, Jr.
Deputy Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Room 1471, HF-1
Rockville, Maryland 20857

Re: *Alex Cain, et al v. Merck & Co., Inc. et al.*,
Docket No. CV-01-3411(SJ)
United States District Court
Eastern District of New York/FDA Docket 02N-0471

Dear Commissioner Crawford:

We represent Pharmacia Corporation and write in response to the letter dated October 14, 2002 addressed to you from David A. Barrett, plaintiff's counsel in the above lawsuit. We respectfully submit that the FDA should reject Mr. Barrett's request that the defendants be ordered to "locate and notify" all persons who have ever taken Celebrex[®] or Vioxx of alleged "serious health dangers," and provide revised warnings. The FDA has already conducted a thorough review of the relevant studies, and approved new labeling for Celebrex[®] and Vioxx earlier this year. The allegations of plaintiffs' complaint provide no basis for further action.

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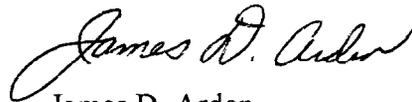
The complaint which forms the basis for Mr. Barrett's request was filed in May 2001 and seeks to certify a consumer fraud class action, while disclaiming any personal injury damages from the use of Celebrex[®] and Vioxx. Plaintiffs' complaint sought "injunctive relief" in the form of court-ordered changes in the labeling for these prescription drugs. (Am. Complaint, paras. 65, 68(b).) However, plaintiffs' complaint did not disclose that a comprehensive review of these drugs was already well under way by the FDA Arthritis Advisory Committee, though it noted that studies had been "recently presented to the Food & Drug Administration." Plaintiffs may not have been aware of the scope and manner of review, as their suit was hastily filed after allegations appeared in media reports about certain information contained in Merck's VIGOR study.

On September 21, 2001, defendants served a motion to dismiss the request for injunctive relief in view of the FDA's jurisdiction and its expertise with respect to prescription drugs and accompanying labeling. Plaintiffs opposed the motion. Defendants filed a further brief on November 28, 2001, noting "that the issue of drug warnings requires the FDA's specialized expertise and is within its primary jurisdiction, and that the FDA is in fact considering the very matter at issue." (emphasis added). The Court granted the motion by order dated August 19, 2002, a copy of which was included with Mr. Barrett's letter. In the order (at 7), the Court found: "Plaintiffs are essentially asking this Court to determine that the findings of the VIGOR study warrant a change in the labeling and package inserts included with Vioxx and Celebrex. The FDA, not this Court, has the relevant expertise to make such a determination."

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After the motion was submitted, the FDA's Advisory Committee fully evaluated the studies regarding the prescription drugs at issue. Thereafter, the FDA approved new labeling for Celebrex[®] on June 7, 2002, and for Vioxx on April 16, 2002. Plaintiffs have not submitted or cited any evidence that has not been considered by the FDA, let alone any evidence that would warrant further changes to the labeling.

Very truly yours,



James D. Arden

JDA:en

cc: The Honorable Sterling Johnson, Jr.
Theodore V.H. Mayer, Esq.
David A. Barrett, Esq.
Steven Glickstein, Esq.
FDA Dockets Management Branch