



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAR 19 2003

The Honorable Sterling Johnson, Jr.  
United States District Court  
Eastern District of New York  
225 Cadman Plaza East  
Brooklyn, NY 11201

Re: Civil Action No. CV-01-3441 (SJ)  
FDA Docket No. 02N-0471/CO1

Dear Judge Johnson:

Pursuant to the court's Memorandum and Order filed August 21, 2002 in the case of Alex Cain, et al v. Merck & Co., Inc., et al, which was submitted to us by the plaintiff via letter dated October 14, 2002, the United States Food and Drug Administration hereby accepts, in accordance with 21 CFR §§10.25 (c) and 10.60(b), referral of the following issues described by the court.

Whether labeling changes and other warnings for Vioxx (rofecoxib) and Celebrex (celecoxib) are warranted due to findings of the Vioxx Gastrointestinal Outcomes Research ("VIGOR") study that indicate cardiovascular risk associated with these drugs (Order at 4-5);

Whether the manufacturers of Vioxx and Celebrex should be required to alert users of these drugs as to the "serious health dangers and risks of [Vioxx and Celebrex] as compared to more traditional pain relief medication used to treat similar conditions" (Order at 4 quoting Pls. Opp'n Mem. at 7); and

Whether the manufacturers of Vioxx and Celebrex should be required to establish a medical monitoring program for users of these drugs (Order at 4).

We anticipate that our review of this matter will be completed in 4-6 months, although other agency priorities or new information may cause delay of our review. Should the

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review time appear as if it will take substantially longer than 6 months, we will apprise you of the status in writing. Thank you for recognizing FDA's expertise and referring this matter under the doctrine of primary jurisdiction.

Sincerely yours,



William K. Hubbard  
Associate Commissioner  
for Policy and Planning

cc: Clerk of the Court, Civil Desk  
United States District Court  
Eastern District of New York  
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