



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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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:

I am writing to apprise you of the status of FDA's response to the court's referral of the above referenced action. This follows our letter dated March 19, 2003 accepting such referral.

As you may recall, the referral involves FDA's assessment of whether labeling changes and other warnings for Vioxx (rofecoxib) and Celebrex (celecoxib) are warranted due to cardiovascular risk associated with these drugs; whether the manufacturers of Vioxx and Celebrex should be required to alert users of these drugs as to the "serious health dangers and risks as compared to more traditional pain relief medication used to treat similar conditions;" and whether the manufacturers of Vioxx and Celebrex should be required to establish a medical monitoring program for users of these drugs.

There are significant studies that are pertinent to these issues that are currently underway. We believe that the results of these studies will greatly inform the issues referred to FDA by the court. As a consequence, I anticipate that our review of the study data and preparation of a response will be completed in the third quarter of 2004, and we will provide our response in writing at that time. Should our response take longer than anticipated, we will apprise you of the status in writing. Thank you for your kind attention.

Sincerely yours,

William K. Hubbard
Associate Commissioner
for Policy and Planning

02N-0471

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The Honorable Sterling Johnson, Jr.

cc: Clerk of the Court, Civil Desk
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