

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA**

<b>In re: VIOXX</b>	)	
<b>PRODUCTS LIABILITY LITIGATION</b>	)	<b>MDL NO. 1657</b>
	)	
<b>THIS DOCUMENT RELATES TO ALL</b>	)	<b>SECTION: L</b>
<b>CASES</b>	)	<b>JUDGE FALLON</b>
	)	
	)	

**PRE-TRIAL ORDER NO. 22:  
(MOTIONS TO COMPEL FOREIGN VIOXX INFORMATION  
AND INFORMATION CONCERNING ARCOXIA)**

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This matter comes before the Court on two motions filed by the Plaintiffs’ Steering Committee (“PSC”)—a motion to compel foreign information concerning VIOXX and a motion to compel information concerning the medicine ARCOXIA. The Defendant’s Steering Committee (“DSC”) filed oppositions to both motions. The Court conferred with counsel for the parties, and they have advised the Court that they have resolved the disputes raised by these motions without waiving their rights to seek or oppose additional information covered by the motions. Accordingly, the Court will enter the following Order that embodies the agreement between the PSC and DSC:

IT IS ORDERED, that:

FOREIGN VIOXX INFORMATION

1. Merck shall produce Merck Frosst documents (including, without limitation, e-mails, correspondence, notes, etc.) concerning VIOXX science and research and development located following a duly diligent search of files of employees of Merck Frosst. The phrase “VIOXX science and research and development” is intended to include, without limitation,

(a) VIOXX pre-clinical studies, (b) VIOXX research and development, and (c) VIOXX patent applications and patents.

2. Merck shall produce the reports of all VIOXX pre-clinical studies conducted in the United Kingdom and France. These have been identified as reports: TT #95-4273; TT #95-601-0; TT #96-604-0; TT #96-606-0; TT #95-610-0; TT #95-611-0; TT #95-614-0; TT #95-615-0; and TT #95-617-0.
3. Merck will produce from its Regulatory Affairs, International department in the U.S. the transcripts of hearings of (if any), and submissions and communications by and between Merck and: (a) the Medicines and Healthcare Products Regulatory Agency (“MHRA”) of the United Kingdom (formerly known as the Medicines Control Agency); (2) Health Canada; and (3) the European Medicines Agency (“EMA”) and the Committee for Medicinal Products for Human Use (“CHMP”) of the European Union. The Regulatory Affairs, International department is responsible for coordinating regulatory filings for marketing approval and other registration activities including the coordination of communications with regulatory agencies outside the United States.
4. Merck shall produce from its Regulatory Affairs, International department in the U.S. the final and draft VIOXX labeling submitted to or received from: (a) the MHRA; (2) Health Canada; and (3) the EMA and the CHMP, together with documentation of the various iterations of labeling over time.
5. Merck shall produce documents sufficient to show the membership and meetings of the Worldwide Arthritis Advisory Board and shall also produce a set of the VIOXX presentations, agendas, and minutes of that Board.

## ARCOXIA

1. Merck shall provide a response to Interrogatory #48 in a similar form to its response to Interrogatory # 40.
2. Merck shall produce the ARCOXIA clinical study reports (“CSRs”), including non-electronic appendices thereto, and a set of the ARCOXIA protocols, clinical investigator brochures, and forms of informed consents. Nothing in this order shall require Merck to produce any information regarding any ongoing study of ARCOXIA for which no unblinded interim analyses presently exist except for the protocols, clinical investigator brochures, and forms of informed consents. Merck will produce the CSRs for the ongoing studies within thirty days after their completion, which the parties understand will occur after the studies themselves are complete. Merck shall, within thirty days of this order, unredact the information regarding ARCOXIA described in subparagraphs and below from the documents it has previously produced and shall not redact such information from the documents it produces in the future.
  - a. Information pertaining to study plans, study design, and study results for ARCOXIA-related studies.
  - b. ARCOXIA-related safety data analyses, safety results, comparisons of safety data, and discussions of safety data.
3. Merck shall produce a set of the ARCOXIA presentations, agendas, and minutes of the Worldwide Arthritis Advisory Board.

TIMING

1. Merck shall produce the documents specified herein on a rolling basis with production to start on or before November 18, 2005.

Houston, Texas, this 2<sup>nd</sup> day of November, 2005

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ELDON E. FALLON  
JUDGE, U.S. DISTRICT COURT