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U.S. Human Health
P.O. Box 4
West Point PA 19486-0004

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prot



TO: Christa Defusco
Regulatory Coordination-BLA 10

FROM: Kathy Kelley Carbone, RN, MSN
Regulatory Operations, CDP
HM-101
(215) 328-2254

DATE: March 5, 1999

**SUBJECT: Final Protocol and Signature Pages for Protocol #102-00/COX472/
Advantage**

Attached is the final protocol and signature pages for the protocol 102-00 / COX472:
“ A Randomized, Double Blind, Multicenter Study to Evaluate the Tolerability and Effectiveness of Rofecoxib (MK-0966) 25mg q.d. vs. Naproxen 500mg b.i.d. in Patients with Osteoarthritis”, for your submission to the FDA. The original versions are filed in Regulatory Information Clinical Development (RICD). Additionally, I have enclosed the Transfer of Obligations to CRO Worksheet and memo, as we are using the CRO PPD Pharmaco, Morrisville North Carolina to assist us with this trial. Please call me if you need further information.

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Persons forbidden by Order of
the United States District Court of
Southern District of Illinois*

LEH 8040576

LEH8040576

Protocol Approval Form - Clinical Development Programs (CDP)

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COMPLETE TITLE OF PROTOCOL: A Randomized, Double Blind, Multi-Center Study to Evaluate the Tolerability and Effectiveness of Rofecoxib (MK-0966) 25 mg q.d. vs. Naproxen 500 mg b.i.d. in Patients with Osteoarthritis.

STUDY DRUG MK-0966 STUDY NUMBER COX472

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- **TYPE OF STUDY:** MERCK IND INVESTIGATOR IND CRO-IND NON-IND
- **PHASE OF STUDY:** PHASE I PHASE II PHASE IIIB PHASE IV PHASE V
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Clinical MPC	Carol Skalky / Daryl Najarian	<i>Carol Skalky</i> 2/12/99
	Kathy Carbone	<i>Kathy Carbone</i> 2/12/99
Regulatory MPC	Adam Polis	<i>Adam Polis</i> 2/12/99
Project Statistician Assoc. Director, Biostatistics	Thomas Dobbins, Ph.D.	<i>Thomas Dobbins</i> 2/20/99
	Iris Latorre	<i>Iris Latorre</i> 1/1
PR&D Drug Supply Coordinator	Alan Nies, M.D.	<i>Alan Nies</i> 1/1
Project Team Chair, MRL	Robert Silverman, M.D., PhD.	<i>Robert Silverman</i> 1/1
Regulatory Liaison, MRL	George Williams, PhD	<i>George Williams</i> 1/1
Director, Biostatistics, MRL	Joanne Lahner	<i>Joanne Lahner</i> 1/1
Office of Counsel	Charlotte Mc Kines	<i>Charlotte Mc Kines</i> 1/1
Marketing Liaison	<i>if applicable</i>	<i>1/1</i>
* Director, WPS&E	Glenn Gormley, M.D., Ph.D.	<i>Glenn Gormley</i> 1/1
Vice President, Clinical Development		<i>1/1</i>

• **PROJECT CODE INFORMATION:** (To be completed by CDP)
 COMPOUND MK-0966 ROUTE ADMIN. 1 FORMULATION 10
 TARGET CLASS ANTI-INFLAMMATORY DISEASE OSTEOARTHRITIS ORGAN SYSTEM 20
 COMPASSIONATE USE (YES or NO) NO RELEASE PACKAGE TABLETS

• **TO BE COMPLETED BY REGULATORY COORDINATION (BL):**
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STUDY DRUG MK-0966 STUDY NUMBER COX472

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	Carol Skalky / Daryl Najarian	<i>Carol Skalky</i> 2/12/99 <i>Daryl Najarian</i> 2/10/99
Clinical MPC	Kathy Carbone	<i>Kathy Carbone</i> 2/12/99
	Adam Polis	<i>Adam Polis</i> 2/16/99
Regulatory MPC	Thomas Dobbins, Ph.D.	1/1
	Iris Latorre, Pharm.D.	<i>Iris Latorre</i> Feb 11 1999
PR&D Drug Supply Coordinator	Alan Nies, M.D.	1/1
Project Team Chair, MRL	Robert Silverman, M.D., PhD.	1/1
Regulatory Liaison, MRL	George Williams, PhD	1/1
Director, Biostatistics, MRL	Joanne Lahner	1/1
Office of Counsel	Charlotte Mc Kines	1/1
Marketing Liaison	<i>if applicable</i>	1/1
* Director, WPS&E	Glenn Gormley, M.D., Ph.D.	1/1
Vice President, Clinical Development		

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Regulatory MPC	Thomas Dobbins, Ph.D.	_____/____/____
	Iris Latorre	_____/____/____
PR&D Drug Supply Coordinator	Alan Nies, M.D.	<i>Alan Nies</i> 2/15/99
Project Team Chair, MRL	Robert Silverman, M.D., Ph.D.	_____/____/____
Regulatory Liaison, MRL	George Williams, Ph.D.	_____/____/____
Director, Biostatistics, MRL	Joanne Lahner	_____/____/____
Office of Counsel	Charlotte Mc Kines	_____/____/____
Marketing Liaison	<i>if applicable</i>	_____/____/____
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Vice President, Clinical Development		

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STUDY DRUG MK-0966 STUDY NUMBER COX472

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	Iris Latorre	1/1
PR&D Drug Supply Coordinator	Alan Nies, M.D.	1/1
Project Team Chair, MRL	Robert Silverman, M.D., Ph.D.	<i>Eric Boyd for RS</i> 2/17/99
Regulatory Liaison, MRL	George Williams, PhD	1/1
Director, Biostatistics, MRL	Joanne Lahner	1/1
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• **TO BE COMPLETED BY REGULATORY COORDINATION (3L):**
 IND NO (if applicable) 76-004 PROTOCOL NO 762-00 DATE 2-17-99
 STUDY DRUG _____ STUDY NUMBER _____

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Director, Biostatistics, MRL	George Williams, PhD	<i>George W. Williams</i> 2/12/99
Office of Counsel	Joanne Lahner	1/1
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Director, Biostatistics, MRL	Joanne Lahner	<i>Joanne Lahner</i> 2/19/99
Office of Counsel	Charlotte Mc Kines	_____/____/____
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* Director, WPS&E	Glenn Gormley, M.D., Ph.D.	_____/____/____
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See comments. Also, note that a single study will probably not be suitable in promotion.

Revised 01/11/99

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* Director, WPS&E	Glenn Gormley, M.D., Ph.D.	_____/_____/_____
Vice President, Clinical Development		_____/_____/_____

Completed, Discussed as Unrestricted
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