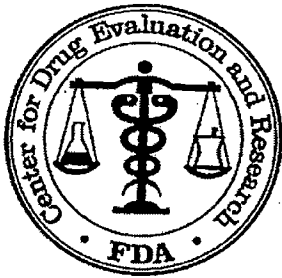


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-995

STATISTICAL REVIEW(S)



STATISTICAL REVIEW AND EVALUATION

Biometrics Division: VI

NDA No.:	21-995
SERIAL NO.:	Amendment
DATE RECEIVED BY THE CENTER:	September 21, 2006
DRUG NAME:	MK-0431
DOSAGE FORM:	Tablets
SPONSOR:	Merck Inc.
DOCUMENTS REVIEWED:	Electronic Copy Dated September 19, 2006
NAMES OF STATISTICAL REVIEWERS:	Yi Tsong, Ph.D. Meiyu Shen, Ph.D. Jinglin Zhong, Ph.D.
NAME OF CHEMISTRY REVIEWER:	Shah, Vibhakar J, Ph.D. Christine Moore, Ph.D.

Yi Tsong, Ph.D.
Deputy Director

Meiyu Shen, Ph.D., Mathematical Statistician

Jinglin Zhong, Ph.D., Mathematical Statistician

Concur:

Stella G. Machado
Director, DBVI

Distribution: NDA 21-995
OBVI/Y. Tsong, Ph.D.
OBVI/S.Machado Ph.D.
OB/Bob O'Neil, Ph.. D.
OB/ Patrician, Lillian, MS

Statistical Review of NDA21-995, 10/11/2006

ONDQA/DPE/ Shah, Vibhakar J, Ph.D.
ONDQA/DPE/ Christine Moore, Ph.D.

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5 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

Withheld Track Number: Statistical- 1

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MeiYu Shen
10/11/2006 02:42:02 PM
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