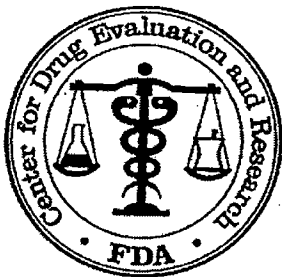


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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'Neill, 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.

**APPEARS THIS WAY
ON ORIGINAL**

**APPEARS THIS WAY
ON ORIGINAL**

5 Page(s) Withheld

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

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

Withheld Track Number: Statistical- /

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

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

Yi Tsong
10/12/2006 11:07:18 AM
BIOMETRICS

Jinglin Zhong
10/12/2006 02:54:03 PM
BIOMETRICS



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.