CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-549

Correspondence

Steven A. Aurecchia, M.D.
Director
Regulatory Affairs

Merck & Co., Inc.
BLA-20
P.O. Box 4
West Point PA 19486
Tel 484 344 4662
215 652 5000
Fax 484 344 2516
Email: steven_aurecchia@merck.com

March 21, 2003

MERCK
Research Laboratories

Robert Justice, M.D., Director
Division of Gastrointestinal & Coagulation
Drug Products, HFD-180, Room 6B-45
Office of Drug Evaluation III (CDER)

c/o Central Document Room
Food and Drug Administration
Center for Drug Evaluation and Research
12229 Wilkins Avenue
Rockville, MD 20852

Dear Dr. Justice:

NDA 21-549: EMEND® (Aprepitant) Capsules

Response To FDA Request for Information
(Phase IV Commitments)

Reference is made to the New Drug Application cited above for EMEND® submitted as an electronic archive on September 27, 2002. Reference is also made to teleconferences held March 19, 2003 and March 20, 2003 between members of the Gastrointestinal Drugs Review Division and representatives from Merck Research Laboratories (MRL), a Division of Merck & Co., Inc.. Additional reference is made to March 18, 2003 and March 20, 2003 facsimile communications from Dr. Steven A. Aurecchia, MRL, to Mr. Brian Strongin, FDA, containing proposed Phase IV commitments for EMEND to facilitate discussions during the aforementioned teleconferences.

With this letter, Merck agrees to the following Phase IV commitments:

Commitment #1:

Merck will obtain pharmacokinetic interaction data on a total of 10 patients reeeiving concomitant aprepitant and docetaxel (an IV chemotherapy CYP3A4 substrate), instead of the originally planned 20 patients (Protocol 051, Serial No. 242, IND [redacted]).

The proposed target timelines are as follows:

- **Completion of patient portion of study (N=10)** **4Q03**
- **Submission of Clinical Study Report** **2Q04**

Commitment #2:

Merck will conduct a drug interaction study to evaluate the effect of aprepitant on either vinorelbine or irinotecan.

The proposed target timeline is as follows:

- **Completion of patient portion of study** **4Q05**

Commitment #3:

Merck will conduct a drug interaction study in healthy subjects, including some who are CYP2D6 poor metabolizers, to evaluate the effect of aprepitant on dolasetron.

The proposed target timelines are as follows:

- **Draft Clinical Study Protocol to FDA** **4Q03**
- **Completion of patient portion of study** **2Q04**
- **Submission of Clinical Study Report** **4Q04**

Commitment #4:

Merck will initiate a risk management program as outlined in our submission dated March 18, 2003, to ensure that healthcare professionals are aware of EMEND for chemotherapy-induced nausea and vomiting and to identify and minimize potential for confusion with AMEN or VFEND. Merck will submit all medication error reports relating to tradename confusion, both potential and actual, that occur with EMEND for a period of one year following the date of approval. All actual and potential errors will be submitted as 15-day reports regardless of patient outcome. Merck agrees to evaluate these data with FDA and, if needed, to implement interventions to further minimize risk of medication errors.

Commitment #5:

Merck will submit to FDA a report on the assessment of the inhibitory properties of aprepitant on CYP2C8 and CYP2B6 *in vitro* in human liver microsomes.

The proposed target timeline is as follows:

- Submission of final report to FDA 2Q03

Commitment #6:

Merck commits to justify the use of [redacted] capsule formulation [redacted] method, including studies on the [redacted] for the nanoparticle capsule formulation. Accordingly, based on the data presented in the response, the dissolution specification will be reviewed and, if warranted, revised.

The proposed target timeline is as follows:

- Submission of information to FDA 2Q03

This submission is formatted as required in Title 21 paragraph 314.50 of the Code of Federal Regulations and is being submitted in accordance with the January 1999, Guidance for Industry– Providing Regulatory Submissions in Electronic Format – NDAs. As an attachment to this letter, Merck Research Laboratories (MRL), a Division of Merck & Co., Inc., is providing one Compact Disk (CD) which contains the amendment. All documents requiring signatures for certification are included as paper for archival purposes.

All of the information is contained on one CD and is not more than 100 MB. We have taken precautions to ensure that the contents of this CD are free of computer viruses (Norton Anti-Virus 7.5.1, Symantec Corp., 2000) and we authorize the use of anti-virus software, as appropriate.

A list of reviewers from the Division of Gastrointestinal & Coagulation Drug Products who should be provided access to this electronic submission on their desktops may be obtained by contacting Mr. Brian Strongin, Regulatory Project Manager, Division of Gastrointestinal & Coagulation Drug Products.

We consider the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

Questions concerning this submission should be directed to Steven A. Aurecchia, M.D. (484-344-4662) or, in my absence, to Michael C. Elia, Ph.D., DABT (484-344-3180).

Sincerely,

Dennis M. Eeb PA,
Steven A. Aurecchia, M.D.
Director
Regulatory Affairs

Enclosure: CD

Federal Express #1

Desk Copy: Mr. Brian Strongin, Regulatory Health Project Manager
HFD-180, Room 6B-45
Federal Express #2

Q:\BOOKER\Booker\NDA21549\ResponseToPhaseIV_21Mar2003.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Merck & Co., Inc.	21 MAR 2003
TELEPHONE NO. *(include Area Code)* 484-344-4662	FACSIMILE (FAX) *Number (include Area Code)* 484-344-2516
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: Sumneytown Pike, P.O. Box 4, BLA-20 West Point, PA 19486	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE Steven A. Aurecchia, M.D. Director, Regulatory Affairs

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 21-549

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
aprepitant	EMEND™

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(if any)*	CODE NAME *(if any)*
5-[[(2R,3S)-2-[(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)-4-morpholinyl]methyl]-1,2-dihydro-3H-1,2,4-triazol-3-one	MK-0869 (L-754030-004H)

DOSAGE FORM: Capsules	STRENGTHS: 80 mg, 125 mg	ROUTE OF ADMINISTRATION: Oral

(PROPOSED) INDICATION(S) FOR USE:
For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin.

APPLICATION INFORMATION

APPLICATION TYPE *(check one)*
☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one) ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION RESPONSE TO FDA REQUEST FOR INFORMATION (PHASE IV COMMITMENTS)

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT *(Rx)* ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED	THIS APPLICATION IS
1	☐ PAPER ☒ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
X	1. Index
	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CIFIR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601-2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or 0)(2)(A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (k)(3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. Financial Information (21 CFR Part 54)
	20. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contra i nd ications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Steven A. Aurecchia for	Steven A. Aurecchia, M.D., Director, Regulatory Affairs	21 MAR 2003

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
Sumneytown Pike, P.O. Box 4, BLA-20 West Point, PA 19486	(484) 344-4662

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549

Merck & Co., Inc.
Attention: Steven A. Aurecchia, M.D.
Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Aurecchia:

Please refer to the meeting between representatives of your firm and FDA on January 24, 2003. The purpose of the meeting was to discuss your draft background package for the March 6, 2003 Gastrointestinal Drugs Advisory Committee meeting.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call me at (301) 827-7473.

Sincerely,

/S/

{See appended electronic signature page}

Brian Strongin, R.Ph., M.B.A.
Regulatory Health Project Manager
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549

Merck & Co., Inc.
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Sanders:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: EMEND™ (aprepitant) Capsules

Review Priority Classification: (P) Priority

Date of Application: September 27, 2002

Date of Receipt: September 27, 2002

Our Reference Number: NDA 21-549

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 26, 2002 in accordance with 21 CFR 314.101(a). If we file the application, the user fee goal date will be March 27, 2003.

Under 21 CFR 314.102(c), you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the ultimate approvability of the application. Alternatively, you may choose to receive a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service/Courier/Overnight Mail:
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room, 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-7310.

Sincerely,

/S/

{See appended electronic signature page}

Brian Strongin, R.Ph., M.B.A.
Regulatory Health Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Brian Strongin
11/8/02 11:20:18 AM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549

Merck & Co., Inc.
Attention: Charlene G. Sanders, M.D., Director, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486-2850

Dear Dr. Sanders:

We refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emend® (aprepitant) Capsules.

Your October 17, 2002, request for formal dispute resolution, received on October 21, 2002, concerned acceptability of your proposed trade name for aprepitant, Emend®. The Division of Medical Errors and Technical Support and the Division of Gastrointestinal and Coagulation Drug Products had deemed Emend® unacceptable because of the possibility that it could be confused with the trade name, Amen. Amen is an approved drug product that is not currently marketed.

I have reviewed your appeal and documentation and find that the trade name Emend® is acceptable, provided you implement a post-marketing risk management program that is similar to the one you described on page 60 of your submission. The risk management program is intended to educate patients, prescribers, and pharmacists to avoid mix-ups and confusion between Emend® and Amen and to monitor prescribing and use of the drug to ensure that these drugs are not confused and used inappropriately. The program should include educational materials for patients, prescribers, and pharmacists that would highlight that Emend® should not be confused with Amen, proactive surveillance of reported adverse events to discern whether incorrect dispensing is occurring, proactive surveys of representative samples of providers and pharmacists regarding erroneous dispensing occurrences, and work with a computerized pharmacy information system to flag new prescriptions and alert pharmacists to similar product names to Emend. Please submit your risk management plan to the Division of Gastrointestinal and Coagulation Drug Products for review and comment prior to implementation.

If you have any questions, call Ms. Kim Colangelo, Formal Dispute Resolution Project Manager, at (301) 594-3937.

Sincerely,

/S/

{See appended electronic signature page}

Florence Houn, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Florence Houn
10/30/02 02:45:16 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549
IND [redacted]

Merck & Co., Inc.
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Sanders:

We refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for aprepitant capsules, and your investigational new drug application (IND) submitted under section 505(i) of the Act for the same product.

We acknowledge receipt on October 21, 2002, of your October 17, 2002, request for formal dispute resolution. Your request concerns the Division of Gastrointestinal and Coagulation Drug Products' decision to object to the proposed trademark (EMEND) for the above referenced product based upon a review performed by the Division of Medical Errors and Technical Support, Office of Drug Safety.

Pursuant to the CDER/CBER Guidance to Industry "Formal Dispute Resolution: Appeals Above the Division Level," we have thirty (30) calendar days from the receipt date of the formal request to respond to the appeal. Therefore, our response to this request is due on or before November 20, 2002.

This request for formal dispute resolution has been forwarded for review to Dr. Florence Houn, Director, Office of Drug Evaluation III. We will contact you should we have any questions or require additional information.

If you have any questions, please contact me at (301) 594-5479.

Sincerely,

/S/

(See appended electronic signature page)

Kim M. Colangelo
Formal Dispute Resolution Project Manager
Center for Drug Evaluation and Research

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/s/

Kim Colangelo
10/25/02 10:54:46 AM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND [redacted]

Merck Research Laboratories
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
P.O. Box 4; BLA-20
West Point, PA 19486-0004

Dear Dr. Sanders:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for MK-0869.

We also refer to your amendment dated February 15, 2002, containing a response to our January 29, 2002 letter containing comments regarding the proposed tradename, EMEND®.

We have completed the review of your submission and continue to find the proposed tradename, EMEND, unacceptable due to concerns regarding potential tradename confusion with the product AMEN. Despite differences in indication and dosing, the opportunity for errors to occur still exists due to the strong similarity in the proprietary names, particularly when the names are spoken. In addition, since the names sound so similar, practitioners may confuse the spellings of AMEN and EMEND when prescribing or receiving a verbal order. Although AMEN is no longer being manufactured, the trade name is still commonly found in numerous reference texts and resources (i.e., Micromedex Integrated Index Query, Facts and Comparisons). Consulting these references may perpetuate the tradename confusion.

If you have any questions, call Brian Strongin, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

/S/

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Victor Raczkowski
4/1/02 04:11:06 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND [redacted]

Merck Research Laboratories
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
P.O. Box 4; BLA-20
West Point, PA 19486-0004

Dear Dr. Sanders:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for MK-0869.

We also refer to your amendment dated October 19, 2000 (serial # 165), containing a request for review and comment on your proposed tradename, EMEND.

We have completed the review of your submission and find the proposed tradename unacceptable due to concerns regarding sound-alike and look-alike names that already exist in the U.S. marketplace including "Amen" and "Anu-med".

If you have any questions, call Brian Strongin, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

/S/

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Victor Raczkowski
1/29/02 02:04:14 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND [redacted]

Merck Research Laboratories
Attention: Charlene G. Sanders, M.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 4
BL, A-20
West Point, PA 19486-0004

Dear Dr. Sanders:

Please refer to the meeting between representatives of your firm and FDA on January 22, 2002. The purpose of the meeting was to obtain agreement with FDA on the proposed format for the MK-069 NDA.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call me at (301) 827-7310.

Sincerely,

/S/

{See appended electronic signature page}

Brian Strongin
Regulatory Health Project Manager
Division of Gastrointestinal &
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Meeting Minutes

OCT 20 2000

IND [redacted]

Merck Research Laboratories
Attention: Charlene G. Sanders, M.D.
P.O. Box 4, BL A-20
West Point, PA 19486

Dear Dr. Sanders:

Please refer to the meeting between representatives of your firm and FDA on September 21, 2000. The purpose of the meeting was to discuss and secure FDA concurrence with issues pertaining to the clinical program that will support the submission and claims made in the NDA for MK-0869.

A copy of our minutes of that meeting is enclosed. These minutes are the official minutes of the meeting. You are responsible for notifying us of any significant differences in understanding you may have regarding the meeting outcomes.

If you have any questions, contact me at (301) 827-7310.

Sincerely yours,

/S/ 10/20/00

Melodi McNeil
Regulatory Health Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment: Meeting Minutes

cc:
Archival IND [redacted]
HFD-180/division file
HFD-180/RPM/M. McNeil
HFD-180/H. Gallo-Torres
HFD-180/J. Choudary

Drafted by: hw/10/20/00
Initialed by: mm/10/20/00
Final: hw/10/20/00
filename: C:\DATA\CSO[redacted]MEETING.MIN.0MM

GENERAL CORRESPONDENCE (Minutes Sent)