

Michael C. Elia, Ph.D., DABT  
Director  
Regulatory Affairs

Merck & Co., Inc.  
BLA-20  
P.O. Box 4  
West Point PA 19486  
Tel 484 344 3180  
215 652 5000  
Fax 484 344 2516  
Email: michael\_elia@merck.com

**These copies are  
OFFICIAL FDA Copies  
not desk copies**

December 18, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room. 1061  
Rockville, MD 20852



Dear Sir or Madam:

**DOCKET NO. 01N-0496  
WRITTEN REQUEST TO PARTICIPATE IN PATIENT PROFILE VIEWER PILOT  
PROJECT**

Pursuant to the Federal Register Notice published on Wednesday, December 5, 2001, Merck & Co., Inc. hereby submits to Docket No. 01N-0496 a Written Request to participate in the FDA's pilot project on the Patient Profile Viewer. Merck & Co., Inc has provided Case Report Tabulations (CRTs) to the FDA in accordance with the guidance "Providing Regulatory Submissions in Electronic Format - NDAs" for 64 submissions. A total of 5,082 SAS Transport files have been submitted representing 23 gigabytes of information.

In addition, Merck & Co., Inc. is an active member of the CDISC Submission Data Standards group that defined the standards proposed to be utilized during the pilot exercise. Merck & Co., Inc has been involved with CDISC since its inception as both a Board member and with membership on several of the working groups. We feel that this experience with both electronic submissions and the CDISC standards would make Merck & Co., Inc. an excellent contributor to the pilot.

Anita Zubak, Associate Director, Clinical Trial System Standards, Merck & Co., Inc. (anita\_zubak@merck.com, 484-344-3324) would be the primary contact person for the pilot project.

Thank you for your consideration of this request. If you have any questions or need additional information, please contact Michael C. Elia, PhD, DABT (484-344-3180) or, in my absence, Bonnie J. Goldmann, MD, (484-344-2383).

Sincerely,

A handwritten signature in black ink that reads 'M.C. Elia'.

Michael C. Elia, PhD, DABT  
Director, Regulatory Affairs

Federal Express #1

cc: R. Levin, Center for Drug Evaluation and Research (HFD-001)  
Food and Drug Administration  
5600 Fishers Lane, Rockville, MD 20857  
Tel. 301-594-5411, e-mail: levinr@cder.fda.gov.  
Federal Express #2

Q:Booker/SAStransport/FDADocketNo01N0496

**01N-0496**

**APE 1**

Express

These copy  
OFFICIAL FD  
desk cc  
These copy  
OFFICIAL FD  
desk cc

Align to

BLUE BELL PUBLISHING CENTER  
MERCK & COMPANY, INC  
BUILDING 5 EAST, BLA-11  
BLUE BELL PA 19422  
(484)344-2218

SHIP DATE: 19DEC01  
ACC# 180687319

ACTUAL WGT: 1 LBS SCALE

TO: DOCKETS MANAGEMENT BRANCH  
FDA  
HFA-305 RM. 1061  
5630 FISHERS LANE  
ROCKVILLE MD 20852

4957 8112 5412

FedEx

REF: 57834.7745.040

PRIORITY OVERNIGHT THU

CAD# 0088786 19DEC01

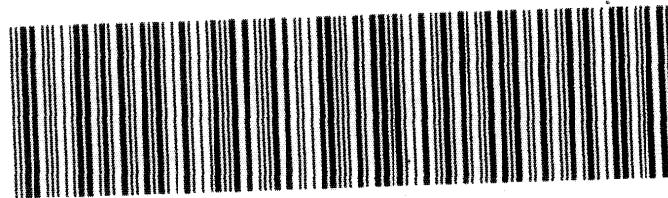
Deliver by:  
20DEC01

TRK# 4957 8112 5412 Form 0201

IAD

20852 -MD-US

ZM GAIA



153077  
MIT 08/01  
AA

The World On Time<sup>®</sup>

Envelope