



February 28, 2005

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

Re: Docket 2004N-0545 – Nonclinical and Clinical Datasets; Notice of Pilot Project

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate strategy — to discover new medicines through breakthrough research — encourages us to spend nearly \$3 billion annually on worldwide Research and Development (R&D). Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

Merck Research Laboratories (MRL), Merck's research division, is one of the leading U.S. biomedical research organizations. MRL tests many compounds as potential drug candidates through comprehensive, state-of-the-art R&D programs. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. In the course of developing products to treat and prevent a variety of diseases, Merck scientists regularly address issues affected by the draft guidance (hereafter referred to as the Guidance). Therefore, we are well qualified to comment on this guidance.

MRL is pleased to submit its request to participate in the CBER pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal and human data submitted to the FDA. The following MRL staff would represent the company during this pilot project: Kathleen A. Giordano and Rob Sarate of Worldwide Clinical Data Management Operations; and Mark Moroz and Mary Jo Brucker of Safety Assessment (Preclinical). Ms. Giordano and Mr. Sarate are active members of the Clinical Data Interchange Standards Consortium, Submission Data Standards Team and have successfully participated in two 2 previous pilots utilizing SAS Transport Files. Mr. Moroz and Ms. Brucker currently participate in the SEND pilot which is attributing the Reproductive Toxicology domain (Nonclinical). Ms. Brucker has successfully participated in the SEND pilot for the Toxicology domain (Nonclinical) and the Carcinogenicity domain (Nonclinical) utilizing SAS Transport Files. We believe that our experience in working with CDISC and SEND makes us an attractive partner for FDA's pilot project.

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We welcome the opportunity to work with the FDA on this important initiative. If you have any questions related to the information provided above, please feel free to contact me at (301) 941-1402.

Sincerely,

Taryn Nogalshi-Salle
Brian Mayhew
U.S. Regulatory Policy *fa*