



Rec'd 12/7/06  
jfb

MEMORANDUM OF TELECONFERENCE

Date: December 5, 2006

Re: Docket No. 1976N-0052N, Comment No. CP19  
Docket No. 1981N-0022, Comment No. CP20

Between: Office of Nonprescription Products, Division of Nonprescription Regulation Development

Walter Ellenberg, Ph.D., Regulatory Project Management Officer  
Robert L. Sherman, Review Biologist, IDS

and:

Walter N. Kernan, M.D.  
Professor of Medicine  
Yale University School of Medicine

Subject: Citizen Petition to Withdraw the Tentative Final Monograph on OTC Drug Products  
Containing Phenylpropanolamine

On November 20, 2006, representatives of FDA's Office of Nonprescription Products spoke with Walter N. Kernan, M.D. of Yale University School of Medicine, regarding a Citizen Petition submitted on behalf of Wyeth Consumer Healthcare. The Citizen Petition requests that FDA withdraw the Tentative Final Monograph (TFM) for OTC Nasal Decongestant and Weight Control Drug Products Containing Phenylpropanolamine (PPA). The TFM is based on a body of evidence, including the Yale Hemorrhagic Stroke Project study (HSP), showing that PPA used in OTC drug products is associated with an increased risk of hemorrhagic stroke. Dr. Kernan was one of the principle investigators of the HSP.

Dr. Kernan was informed that the Citizen Petition was submitted to FDA, and that the petition questioned the validity of the HSP, contending that the study had design, conduct, and analyses flaws. The petition also contended that, based on the HSP, FDA had drawn unsupportable conclusions on the safety of PPA.

Dr. Kernan was offered the opportunity to respond to the petition's specific challenges to the results of the HSP. The fact that FDA was merely offering the opportunity for the Yale investigators to respond in a public forum, rather than requesting a response, was stressed.

Dr. Kernan stated that he was unaware of the Citizen Petition and thanked FDA for bringing it to his attention. He stated that the HSP investigators would submit a response.

Walter Ellenberg

Walter Ellenberg 12/5/06

Robert L. Sherman

Robert L. Sherman 12/5/06

1981N-0022

MT 11

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: DEC 7 2006

FROM: Acting Director  
Division of Nonprescription Regulation Development

SUBJECT: Material for Docket No. 1976 N-0052 N,  
1981 N-0022

TO: Division of Docket Management, HFA-305

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment No. CP19  
CP20

  
Susan S. Johnson, Ph.D.

Attachment