



FEB 16 2006

Novartis Consumer Health, Inc.
Attention: Rich Cuprys
Global Head, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Docket No.: 77N-0094
CP15

Dear Cuprys:

Please refer to the teleconference between representatives of your firm and the FDA on January 19, 2006. The purpose of the meeting was to inform FDA of the transfer of ownership of the July 30, 2001 Citizen Petition, submitted by Bristol-Myers Squibb, to Novartis Consumer Health, Inc.

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 Walter Ellenberg, Ph.D., Sr. Regulatory Project Manager, at (301) 796-0885.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Johnson".

Susan Johnson, Ph.D.
Associate Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

MINUTES OF A TELECONFERENCE
January 19, 2006

Meeting Type: Teleconference

Docket No.: Docket 77N-0094

Subject: The transfer of ownership of a Citizen Petition from Bristol-Myers Squibb to Novartis Consumer Health, Inc.

Project Manager: Walter J. Ellenberg, Ph.D.

FDA Participants:
Center for Drug Evaluation and Research (CDER)

Susan Johnson, Ph.D., Associate Director, Office of Nonprescription Products (ONP)

Marina Chang, RPh., Interdisciplinary Scientist, Team Leader, ONP

Michael Benson, RPh. J.D., Regulatory Review Pharmacist, ONP

Walter Ellenberg, Ph.D., Sr. Regulatory Project Manager, ONP

Novartis Consumer Health Inc.

Lutz Hegeman, MD., Head, Clinical Research and Data Management

Phyllis Schumann, Head, R&D Operations / Excedrin R&D Lead

Jean Battikha, Director, Biostatistics

Rich Cuprys, Global Head, Regulatory Affairs

Background:

On July 30, 2001, Bristol-Myers Squibb submitted a Citizen Petition to the FDA regarding the use of 130 mg caffeine as an over-the-counter analgesic adjuvant.

On January 19, 2006, the Agency participated in a teleconference at the request of Novartis Consumer Health Inc. The purpose of this teleconference was to provide representatives of Novartis Consumer Health (NCH) the opportunity to introduce themselves as the new owners of the 2001 Bristol-Myers petition. During the brief teleconference, NCH officially informed FDA that they had assumed ownership of the petition from Bristol-Myers Squibb as of September 2005. Based on this acquisition, all rights to the data were transferred to NCH.

NCH informed ONP that all future correspondence to this petition should be directed to NCH. NCH was told that this petition is currently under review. NCH requested that if ONP's review findings were "not in favor" of the petition, NCH would like to have a meeting with ONP prior to issuance of our response.

NCH was told that any specific information about the status of our review or findings would need to be conveyed in a public forum. It was agreed that no meeting would be planned at this time.