

MEMORANDUM OF TELEPHONE CONVERSATION

Date: May 1, 2002 9 37 4 '02 MAY -3 P1:22

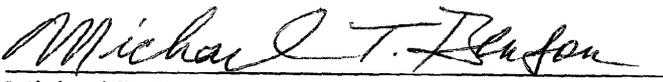
BETWEEN: JoAnn Robinett
Director; Regulatory Affairs
Bayer Corporation
973-254-5000

and Michael T. Benson
Regulatory Review Pharmacist (HFD-560)

Subject: Phenylephrine Bitartrate Citizen Petition CP18, Docket No. 76N-052N

Bayer Corp. submitted a citizen petition to amend the final monograph for OTC nasal decongestants to include phenylephrine bitartrate as an active ingredient.

I called Ms. Robinett to tell her that if phenylephrine bitartrate becomes approved for inclusion in the OTC nasal decongestant monograph, the ingredient will need a compendial monograph. I advised her that to decrease potential delay time between the approval processes for the OTC and compendial monographs, Bayer should begin working on obtaining a compendial monograph for the ingredient by submitting necessary information to the United States Pharmacopeia. She wholeheartedly agreed and thanked me for the advice. Our conversation concluded cordially.


Michael T. Benson

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