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February 1, 2007

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

Re: OTC Monograph for Nasal Decongestant Drug Products; Docket 76N-052N

Dear Sir or Madam:

Reference is made to a recent series of communications between Representative Waxman and the FDA on the efficacy of 10 mg phenylephrine. As a result of these communications, a task group of the Consumer Healthcare Products Association (CHPA) obtained copies of all studies cited in the bibliography of the phenylephrine section of the 1976 OTC Review panel report on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products. In addition, a literature search for additional studies investigating phenylephrine's efficacy was conducted. A review of all data obtained led to the conclusion that a meta-analysis of a set of studies would be feasible and would make a meaningful contribution to the discussion regarding the efficacy of phenylephrine. The CHPA Phenylephrine Task Group carried out this meta-analysis and CHPA is herewith submitting the report to the Docket 76N-052N, OTC Monograph for Nasal Decongestant Drug Products. Two expert biostatisticians, Michael Stoto, Ph.D., of Georgetown University, and Dallas Johnson, Ph.D., of Kansas State University, reviewed the meta-analysis. Their reports are also herewith submitted to the docket.¹

The results of the meta-analysis support the Agency's opinion that phenylephrine at a dose of 10 mg is an effective oral nasal decongestant.

Sincerely,

Heinrich Schneider, Dr. Med.
Vice President, Regulatory and Scientific Affairs

cc: Dr. Charles Ganley, Office of Nonprescription Products

¹ All attachments are releasable.

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Enclosures:

- (1) Consumer Healthcare Products Association (CHPA) Phenylephrine Task Group, "Efficacy Meta-Analysis of Single-Dose 10 mg Phenylephrine vs. Placebo in Adults With Acute Nasal Congestion Due to Common Cold", Final Report; January 30, 2007 
- (2) Memorandum to Heinz Schneider from Michael Stoto, "Phenylephrine meta-analysis", January 27, 2007 
- (3) Letter to Heinz Schneider from Dallas E. Johnson; January 18, 2007 

HS/mm