FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

QUESTIONS TO ADVISORY COMMITTEE

DECEMBER 14, 2007

1. The many studies discussed today, in which the efficacy of oral phenylephrine hydrochloride (PEH) as a nasal decongestant was assessed, differ in many ways. For example:

- Patient inclusion criteria (healthy subjects or subjects with common cold, upper respiratory tract infection, acute rhinitis, or seasonal allergic rhinitis)
- Congestion model (naturally occurring, induced by exposure to pollen in an environmental exposure unit)
- Endpoints (objective reduction in nasal airway resistant (NAR), subjective improvement in symptom scores)
- Dose (10 mg, 25 mg), dosing interval, and endpoint assessment interval

In addition, the studies have been considered in several different groupings (studies evaluated by the Advisory Panel and discussed in the ANPR, CP meta-analysis, CHPA meta-analysis).

The agency would like the NDAC to discuss which aspects of the data, if any, that it finds supportive of the effectiveness of PEH for the symptomatic treatment of nasal congestion due to the common cold or upper respiratory allergies.

2. The following four statements represent alternative summary assessments of the data presented for PEH. Please consider each statement and vote (yes or no) on whether it represents your conclusions about the data.

a. PEH in a 10 mg immediate release formulation is effective when dosed every 4 hours for the symptomatic treatment of nasal congestion. No additional studies are needed. (Vote: yes or no)
b. PEH in a 10 mg immediate release formulation is effective. Additional study is needed to identify an appropriate dosing interval for this dose. (Vote: yes or no)
c. PEH in a 10 mg immediate release formulation is at the lower end of the dose response range. Additional studies are needed to assess the efficacy of higher doses (e.g., 25 mg) and determine appropriate dosing intervals. (Vote: yes or no)
d. There are no data to support the efficacy of PEH in a 10 mg immediate release formulation. Additional studies are needed to assess the efficacy of higher doses (e.g., 25 mg) and determine an appropriate dosing interval. (Vote: yes or no)

3. Based on the data presented, do you recommend that there be additional study of the effects that formulation (e.g., extended release) may have on the bioavailability and performance of phenylephrine? (Vote: yes or no)