October 19, 2000
Nonprescription Drugs Advisory Committee
Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, 2 Montgomery Avenue, Gaithersburg, MD

Safety Issues of Phenylpropanolamine (PPA) in Over-the-Counter Drug Products

Questions Related to the Results and Interpretation of the Hemorrhagic Stroke Project (HSP)

A. Do the results from the HSP study suggest that PPA is safe from risk of hemorrhagic stroke in subjects 18 – 49 years of age OR do the results suggest that there is an association between PPA and hemorrhagic stroke in subjects 18 – 49 years of age:
   1. across the entire study population?
   2. with the first dose of PPA?
   3. in subjects using PPA as an appetite supressant?
   4. in subjects using PPA as a decongestant?
   5. as a function of dose?

      a) In addressing these questions, please discuss any strengths or limitations in the design and/or conduct of the HSP that may affect the interpretation of data.
      b) Is there a consistency or lack of consistency in the results?

B. Does the HSP provide information on which populations may be at greater or lesser risk?

Questions Related to the Availability of PPA in the OTC Market.

C. There is a body of data collected over the years that has suggested a possible association between PPA use and hemorrhagic stroke. Taking all currently available information into account, do the data support the conclusion that:
   1. there is not an association between PPA use and hemorrhagic stroke?
   2. there is an association between PPA use and hemorrhagic stroke?
   3. the association still remains uncertain because of insufficient information?

D. Considering your answer to question C, can PPA be considered to be generally recognized as safe for use as:
   1. a decongestant ?
   2. an appetite suppressant?

      a) When answering this question, please address whether dose is an important consideration.

E. Does the Committee have any additional recommendations (e.g., further studies)?