FDA Background

The Safety of Phenylpropanolamine Hydrochloride (PPA) used in OTC Weight Control and Nasal Decongestant Drug Products

NDAC
October 19, 2000

On October 19, 2000, the Non-Prescription Drug Advisory Committee will meet to discuss the results of the Hemorrhagic Stroke Project (HSP) which was conducted by investigators at Yale University School of Medicine. As part of the background of this meeting, the FDA is providing the committee members and invited consultants with the attached reviews, prepared by FDA's Division of Drug Risk Assessment I (Office of Post-Marketing Drug Risk Assessment) and Quantitative Methods Research Staff. The reviews analyze the HSP findings and other information available to FDA, and describe the conclusions reached by these reviewers and their recommendations regarding possible regulatory actions. The conclusions and recommendations expressed in these reviews are the opinions of the reviewers and do not, at this time, represent final Agency conclusions. The Agency will consider all available information, including the information reported and advice received at the Advisory Committee meeting, before any final Agency conclusions and regulatory decisions are made on the issues before the committee.

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