

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH ADVISORY

SUBJECT: SAFETY OF PHENYLPROPANOLAMINE

November 6, 2000

The Food and Drug Administration (FDA) is issuing a public health advisory concerning phenylpropanolamine hydrochloride. This drug is widely used as a nasal decongestant (in over-the-counter and prescription drug products) and for weight control (in over-the-counter drug products). FDA is taking steps to remove phenylpropanolamine from all drug products and has requested that all drug companies discontinue marketing products containing phenylpropanolamine.

Phenylpropanolamine has been marketed for many years. A recent study reported that taking phenylpropanolamine increases the risk of hemorrhagic stroke (bleeding into the brain or into tissue surrounding the brain) in women. Men may also be at risk. Although the risk of hemorrhagic stroke is very low, FDA recommends that consumers not use any products that contain phenylpropanolamine.

FDA's Nonprescription Drugs Advisory Committee (NDAC) recently discussed this study and other information on phenylpropanolamine. NDAC determined that there is an association between phenylpropanolamine and hemorrhagic stroke and recommended that phenylpropanolamine not be considered safe for over-the-counter use.

Although this risk of hemorrhagic stroke is very low, FDA has significant concerns because of the seriousness of a stroke and the inability to predict who is at risk. FDA does not consider the conditions for which phenylpropanolamine is used (over-the-counter or by prescription) as justifying the risk of this serious event. Other products are available for use.

In the meantime, consumers can identify over-the-counter cough-cold, nasal decongestant, and weight control products containing this ingredient by looking for "phenylpropanolamine" in the list of active ingredients on the label. Consumers can check with their health care provider or pharmacist to see whether their prescription cough-cold or nasal decongestant product contains phenylpropanolamine. We advise consumers to discuss alternative over-the-counter and prescription products with their health care providers or pharmacists.

1976 N-0052N

M I

Information about the history of phenylpropanolamine, the Public Health Advisory, and the stroke study results can be found on the FDA website at:

<http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3647b1.htm>

####