DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 3, 2000

Dear CEO or President:

This letter concerns drug products containing phenylpropanolamine and its salts marketed by prescription or over-the-counter (OTC), which are now or have previously been manufactured, relabeled, repacked, or distributed by your firm. Phenylpropanolamine is currently available by prescription and OTC as a nasal decongestant, and OTC for weight control. Your firm is receiving this letter based on information in the Food and Drug Administration's (FDA) Drug Listing System or because you have a new drug application (NDA) or abbreviated new drug application (ANDA) for a product containing phenylpropanolamine.

This letter is to inform you of recent developments relating to phenylpropanolamine. Earlier this year, FDA received a report entitled "Phenylpropanolamine & Risk of Hemorrhagic Stroke: Final Report of the Hemorrhagic Stroke Project" from scientists at Yale University School of Medicine. This report, which is on display in Docket No. 81N-0022 in the FDA Dockets Management Branch, states that the data suggest that phenylpropanolamine increases the risk for hemorrhagic stroke.

On October 19, 2000, the Agency's Nonprescription Drugs Advisory Committee (NDAC) discussed this report and other information on phenylpropanolamine. NDAC determined that there is an association between phenylpropanolamine and hemorrhagic stroke and recommended that phenylpropanolamine not be considered generally recognized as safe for OTC use as a nasal decongestant or for weight control. 1

Based on these recent developments, FDA intends to initiate rulemaking to classify phenylpropanolamine as nonmonograph (not generally recognized as safe and effective) for OTC use. Based on the recent research findings, FDA also has significant concerns about the continued use of phenylpropanolamine in prescription drug products. FDA also intends to take action to remove phenylpropanolamine from prescription drug products. FDA plans to issue a Public Health Advisory on phenylpropanolamine to alert consumers and health professionals about the report.

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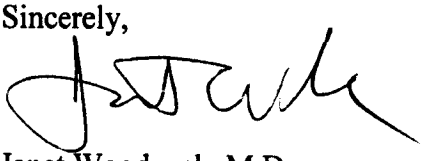
1 In the mid-1970s, phenylpropanolamine was classified as Category I (safe and effective) by two OTC drug advisory review panels. The Cough-Cold Panel's recommendations on phenylpropanolamine as a nasal decongestant appeared in the FEDERAL REGISTER of September 9, 1976 (41 FR 38312) and the Miscellaneous Internal Panel's recommendations for weight control use appeared on February 26, 1982 (47 FR 8466). However, FDA deferred its classification of phenylpropanolamine because of subsequent safety issues that were raised, pending completion of additional studies.

FDA also believes that, as an interim measure to protect the public health, you should voluntarily discontinue marketing any drug products containing phenylpropanolamine. If applicable, you may reformulate such products to remove the phenylpropanolamine ingredient.

If you have any questions or want additional information, including information about options for reformulating products that contain phenylpropanolamine, please contact Jerry Rachanow or Robert Sherman at 301-827-2241.

Your cooperation and prompt attention to this matter will be appreciated.

Sincerely,



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