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MANDATORY PRINTING OF BOXED WARNING ON ALL PHENYLPROPANOLAMINE (PPA) CONTAINING PRODUCTS (OTC AND RX)

In the interest of public health and safety, all packaging and information materials (labels, inserts, drug literatures, patient information leaflet, etc.) should contain prominent boxed warning that is easily read and understood, informing the consumer of the risks associated with using PPA. It should be emphasized that patients with the following health conditions should be careful in taking PPA: 1) High blood pressure, 2) toxic goiter, 3) benign prostatic hypertrophy, 4) heart rate irregularity, 5) glaucoma and 6) if taking antidepressants. Patients with heart disease and uncontrolled/untreated high blood pressure should consult the doctor prior to taking PPA.

- For capsules/tablets in blister/strip foils, boxed warning should be printed on the box in the side panel.

- For preparations packaged in a bottle, boxed warning should be printed on the immediate label and the box.

- All products whether classified as OTC or Rx should include the patient information leaflet.

All concerned drug manufacturers/traders/importers/distributors are required to submit corrected materials to Product Services Division within three (3) months on or before June 15, 2003. As an interim measure, companies that have existing printed materials without the warning are required to provide stick-on warnings immediately. Exhaustion of existing materials will be allowed until the end of the year, December 2003.

For your information and guidance.

Adopted: 17 March 2003

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