

The following warning statement would appear on the principal display panel of the product:

WARNING: *Contains ephedrine alkaloids. Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids.* Not for pregnant or breast-feeding women or persons under 18. Risk of injury can increase with dose or if used during strenuous exercise or with other products containing stimulants (including caffeine). Do not use with certain medications or if you have certain health conditions. Stop use and contact a doctor if side effects occur. See more information [...].

The following additional information would appear on the outer product label or in product labeling that is an integral part of the outer product packaging such that this information may be read at point of purchase (For example, this information could be contained in the outer information panel, riser backing, panel extension, outsert, etc.):

This product contains ephedrine alkaloids, which can have potentially dangerous effects on the heart and central nervous system.

Do not use with

- ✓ a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping a MAOI drug;
- ✓ certain drugs for depression, psychiatric, or emotional conditions;
- ✓ drugs for Parkinson's disease;
- ✓ drugs for obesity or weight control;
- ✓ methyl dopa.

Contact a doctor before using this product if you have or ever had

- ✓ heart disease, high blood pressure, thyroid disease, seizure, diabetes, depression, other mental, emotional or behavioral conditions, glaucoma, or difficulty urinating due to prostate enlargement.

Stop use and contact a doctor immediately if these side-effects occur

- ✓ dizziness, severe headache, rapid and/or irregular heartbeat, chest pain, shortness of breath, nausea, loss of consciousness, or changes in emotions or behavior (such as depression, hallucinations or severe mood swings).

Your risks of serious side-effects from this product can increase

- ✓ with increased dose, frequency, or duration of use;
- ✓ if you take it with other dietary supplements containing ephedrine alkaloids (such as ephedra, ma huang, *Sida cordifolia*);
- ✓ if you take it with additional products containing stimulants, such as caffeinated beverages and foods (including dietary supplements containing guarana, kola nut, mate, yohimbine/yohimbe, *Citrus aurantium*);
- ✓ if you take it with medications containing synephrine, phenylephrine, ephedrine, pseudoephedrine, or phenylpropanolamine;
- ✓ if you use it before or during strenuous exercise.

FDA also intends to consider, to the extent possible, whether in light of current information FDA should determine that dietary supplements

containing ephedrine alkaloids present a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling,

or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use" (see 21 U.S.C. 342(f)(1)(A)). Furthermore, FDA