

01 July 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Food and Drug Administration
200 C Street SW
Washington, DC 20204

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To whom it may concern,

Pursuant to 21 CFR 101.93 (a) (2), Traditional Medicinals, Inc., 4515 Ross Road, Sebastopol, California 95472 hereby notifies the FDA that it is making the following statements covered by the referenced regulation for its;

Echinacea Plus® Herbal Pastilles Herbal Dietary Supplement, containing 88.5 mg of dried, fresh pressed juice of echinacea purpurea herb (*Echinacea purpurea* (L.) MOENCH) and 250 mg of an aqueous-ethanolic extract (5-7 : 1) of a proprietary blend (in order of predominance) of organic echinacea purpurea flowering tops (*Echinacea purpurea* (L.) MOENCH), organic West Indian lemongrass leaf (*Cymbopogon citratus* (DC. ex NEES) STAPF), organic spearmint leaf (*Mentha spicata* L.), dry extract (6:1) of echinacea purpurea root (*Echinacea purpurea* (L.) MOENCH), and organic echinacea angustifolia flowering tops (*Echinacea angustifolia* DC.): "Supports the Immune System."

Other ingredients: Organic gum arabic, organic raw cane sugar, organic maltose syrup, honey, spearmint leaf essential oil, lemongrass leaf essential oil, natural vegetable and beeswax glaze.

Directions: For adults and children 2 to 12 years of age: Allow 1 pastille to dissolve slowly in the mouth, 5-6 times daily or as directed by your healthcare provider. Do not chew. Children under 2 years of age: consult a doctor.

Cautions: Consult a health care provider use if you have rheumatoid arthritis, an autoimmune disorder or a progressive systemic disease such tuberculosis, leucosis, collagenosis, multiple sclerosis, AIDS or HIV infections. Consult a health care provider prior to use if you are taking immunosuppressants, or if symptoms persist.

Contraindications: Do not use if you are pregnant or breastfeeding. Do not use if you have an allergy to Asteraceae/Compositae (the daisy family) plants.

Other Information: Tamper-evident: each pastille is individually enclosed in a sealed, imprinted blister. Do not use if the blister unit is open or torn.

The undersigned certifies that the information contained in this notice is complete and accurate and that Traditional Medicinals, Inc. has substantiation that the statement is truthful and not misleading.

Yours truly,



Drake Sadler, CEO
Traditional Medicinals, Inc.
4515 Ross Road
Sebastopol, California 95472

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