

10 February 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS, 8.00)  
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;

**Breathe Easy<sup>®</sup>** Herbal Dietary Supplement containing 300 mg Licorice root Ph.Eur. (*Glycyrrhiza glabra* L.), 285 mg Eucalyptus leaf Ph.Eur. (*Eucalyptus globulus* LABILL.), 255 mg Bitter Fennel fruit Ph.Eur. (*Foeniculum vulgare* MILLER, ssp. *vulgare*, var. *vulgare*) 120 mg Bi Yan Pian\* dry aqueous extract 8:1 (w/w), and 540 mg of a proprietary blend containing, in order of predominance, Peppermint leaf Ph.Eur. (*Mentha x piperita* L.), Calendula flower Ph.Eur. (*Calendula officinalis* L.), Pleurisy root BHP (*Asclepias tuberosa* L.) and Ginger rhizome Ph.Eur. (*Zingiber officinale* ROSCOE): **“Promotes Respiratory Health,” “A Traditional Formula for the Nasal Passages,”** and **“Beneficial for Upper Respiratory Tract Health.”**

\* Bi Yan Pian dry aqueous extract 8:1 (w/w) contains dried extractive of the following botanicals in order of predominance: Xanthium fruit (*Xanthium sibiricum* PATRIN ex WIDDER), Magnolia flower (*Magnolia officinalis* REHDER & E.H. WILSON), Siler root (*Saposhnikovia divaricata* (TURCZ.) SCHISCHK.), Forsythia fruit (*Forsythia suspensa* (THUNB.) VAHL), Wild chrysanthemum flower (*Chrysanthemum indicum* L.), Schisandra fruit (*Schisandra chinensis* (TURCZ.) BAILL.), Platycodon root (*Platycodon grandiflorum* (JACQ.) A. DC.), Fragrant angelica root (*Angelica dahurica* (FISCH. ex HOFFM.) BENTH. & HOOK. F. ex FRANCH & SAV.), Anemarrhena rhizome (*Anemarrhena asphodeloides* BUNGE), Schizonepeta herb (*Nepeta tenuifolia* BENTH.), and Chinese licorice root (*Glycyrrhiza uralensis* FISCH. ex DC.)

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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