

09 November 2003

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

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;

**Chocolate Smooth Move® Herbal Dietary Supplement**, containing 1,080 mg of senna leaf (*Sennae folium Ph.Eur.*) and 920 mg of a proprietary blend composed of, in order of predominance, roasted breadnut seed (*Brosimum alicatrum Sw.*), licorice root (*Glycyrrhiza glabra L.*), cocoa seed dry extract (*Theobroma cacao L.*) and roasted carob pod (*Ceratonia siliqua L.*): "Stimulant Laxative," "Relief of Occasional Constipation," "Chocolate Smooth Move will Generally Produce Bowel Movements in 8 to 12 Hours."

**DIRECTIONS:** Pour 8 oz freshly boiled water over a teabag in a cup. Cover cup and steep 10-15 minutes. Gently squeeze the tea bag to release the remaining extract. Adults and children 12 years and over: Drink 1 cup preferably at bedtime. Not to exceed 3 cups in 24 hours. Children 6-12 years: Drink ½ cup preferably at bedtime. Not to exceed 1 cup in 24 hours. Children 2-6 years: Drink ¼ to ½ cup preferably at bedtime. Children under 2 years: Consult a doctor.  
**CONTRAINDICATIONS:** Ileus, acute intestinal inflammation (e.g. Crohn's disease, ulcerative colitis), appendicitis, abdominal pain of unknown origin, severe dehydration states with water and electrolyte depletion.  
**NOTICE:** This product contains senna leaf. Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain because senna leaf may worsen these conditions and be harmful to your health. Consult your physician if you have frequent diarrhea or if you are pregnant, nursing, taking medication, or have a medical condition.

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.

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Yours truly,



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



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