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AUG 11 2005

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

Dear Mr. Sadler:

This is in response to your letters of July 8, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). You submitted one letter for a product named "Just for Kids Organic Cold Care."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product (i.e., the inclusion of the common cold in the product name) suggests that it is intended to treat, prevent, or mitigate disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Your submissions also state that you are marketing the products "Just for Kids Organic Throat Coat," Herba Tussin Herbal Syrup," and Throat Coat Herbal Syrup." The products are described, variously, as "cough syrup" and "soothing and cooling," and being intended to coat and/or soothe the throat and/or sore throats.

These products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. We explain the basis for our opinion below.

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The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is applied externally to the skin is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, products that are intended to have their intended effect prior to ingestion (i.e., in the throat prior to swallowing) are not subject to regulation as dietary supplements because they are not "intended for ingestion." Furthermore, they appear to be drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body. They also appear to be drugs under 21 U.S.C. 321(g)(1)(B) because they appear to be intended to treat, cure, prevent, or mitigate diseases that result in sore throats and coughs.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA-240

01 July 2005

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

JUL 26 2005

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;

Throat Coat® Herbal Syrup Herbal Dietary Supplement, containing 6.2 g of an aqueous extract (1:5) of a proprietary mixture (in order of predominance) of licorice root (*Glycyrrhiza glabra* L.), wild cherry bark (*Prunus serotina* EHRH.), organic bitter fennel fruit (*Foeniculum vulgare* MILL. ssp. *vulgare* var. *vulgare*), organic cinnamon bark (*Cinnamomum* spp.), organic sweet orange peel (*Citrus sinensis* (L.) OSBECK), slippery elm bark (*Ulmus rubra* MUHL.), organic marshmallow root (*Althaea officinalis* L.), and dry extract (8:1) of Chinese licorice root (*Glycyrrhiza uralensis* FISCH. ex DC.): "Soothes Sore Throats."

Other ingredients: Kosher vegetable glycerin, organic honey, purified water, organic peppermint leaf essential oil.

Directions: Shake well before using. Adults and children 12 and over: 1 tablespoonful every 2 hours. Children 6-12 years: 1/3-1/2 adult serving. Children 3-6 years: 1/4-1/3 adult serving. Children under 3: consult a doctor.

Cautions: If sore throat is severe, accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your doctor promptly.

Contraindications: Do not use if you are pregnant or breastfeeding.

Other Information: Refrigerate after opening. Do not use if tamper-evident seal is broken or missing.

05-4538

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,

A handwritten signature in black ink, appearing to read 'Drake Sadler', with a long horizontal flourish extending to the right.

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

01 July 2005

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

JUL 26 2005

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;

Herba Tussin® Herbal Syrup Herbal Dietary Supplement, containing 6.2 g of an aqueous extract (1:5) of a proprietary mixture (in order of predominance) of organic spearmint leaf (*Mentha spicata* L.), eucalyptus leaf (*Eucalyptus globulus* LABILL.), licorice root (*Glycyrrhiza glabra* L.), slippery elm bark (*Ulmus rubra* MUHL.), wild cherry bark (*Prunus serotina* EHRH.), organic West Indian lemongrass leaf (*Cymbopogon citratus* (DC. ex NEES) STAPF), elecampane rhizome (*Inula helenium* L.), organic lemon peel (*Citrus × limon* (L.) OSBECK), organic stevia leaf (*Stevia rebaudiana* (BERTONI) BERTONI), organic lemon myrtle leaf (*Backhousia citriodora* F. MUELL.), and organic marshmallow root (*Althaea officinalis* L.): **“Soothing and Cooling,” “Cough Syrup,” “A Traditional Herbal Cough and Bronchial Formula That Supports the Respiratory System.”**

Other ingredients: Kosher vegetable glycerin, organic honey, purified water, organic peppermint leaf essential oil.

Directions: Shake well before using. Adults and children 12 and over: 1 tablespoonful every 2 hours. Children 6-12 years: 1/3-1/2 adult serving. Children 3-6 years: 1/4-1/3 adult serving. Children under 3: consult a doctor.
Cautions: A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor. Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
Contraindications: Do not use if you are pregnant or breastfeeding.
Other Information: Refrigerate after opening. Do not use if tamper-evident seal is broken or missing.

05-4538

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,

A handwritten signature in black ink, appearing to read "D Sadler", with a long horizontal line extending to the right.

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

08 July 2005

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

JUL 26 2005

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;

Just for Kids Organic Throat Coat® Herbal Dietary Supplement, containing 1,500 mg of a proprietary blend of, in order of predominance, organic marshmallow root (*Althaea officinalis* L.), organic sage leaf (*Salvia officinalis* L.), organic calendula flower (*Calendula officinalis* L.), organic licorice root (*Glycyrrhiza glabra* L.), organic cinnamon bark (*Cinnamomum* spp.), and wild cherry bark (*Prunus serotina* EHRH.): "Supports Throat Health."

Contraindications: Do not use if your child has known allergies to plants of the Asteraceae (daisy) family such as calendula, chamomile, echinacea, or yarrow.

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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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;

Just for Kids Organic Cold Care Herbal Dietary Supplement, containing 1,500 mg of a proprietary blend of, in order of predominance, organic European elder flower (*Sambucus nigra* L.), organic linden flower (*Tilia cordata* L.), organic chamomile flower (*Matricaria recutita* L.), and organic peppermint leaf (*Mentha x piperita* L.): "Winter Season Tea."

Contraindications: Do not use if your child has known allergies to plants of the Asteraceae (daisy) family such as calendula, chamomile, echinacea, or yarrow. Consult a pediatrician prior to use if your child has gallstones, gallbladder or bile-duct obstruction, hiatal hernia, or acid reflux.

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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05-4538