



JAN 24 1997

Mr. Craig Kaplan
Phoenician Herbals, Inc.
7655 East Evans, Suite #2
Scottsdale, Arizona 85260

Dear Mr. Kaplan:

This is in response to your letter of October 30, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Section 403(r)(6) of the act has no application to your products since they are conventional foods and not dietary supplements. Your submission states that you are making the following statements for your products:

Male Potency Tea

Ginkgo - is known to improve arterial erectile dysfunction.

Digestion Tea

Papaya - used for an upset stomach since it contains all the enzymes necessary for digestion of food, thereby relieving a "sour" stomach and gas.

Ginger - sparks up the digestive system and is used for abdominal and intestinal pain and cramping.

Peppermint - is a digestive aid that stimulates production of digestive juices and relieves the pressure of after meal gas and bloat.

Fenugreek - is helpful for calming an inflamed gastrointestinal system and is especially good for those who ingest large quantities of dairy products.

Caraway - is useful for relieving digestive problems.

Fennel - is a digestive aid that helps to eliminate intestinal gas.

Anise - improves the digestive system by breaking up mucous blockage and helps ward off fermentation and gas in the digestive tract.

Star anise - activates the digestive system, eases digestive disturbances and relieves abdominal pain.

Cumin - is beneficial to the digestive system due to its astringency and antibacterial effects.

Detox Tea

Red clover - acts as a blood purifier; also a remedy for nervous exhaustion by calming the nerves.

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Licorice - helps protect the bodies detoxification plant, our liver, from disease.

Burdock - cleanses and eliminates long term impurities from the blood. Has the ability to neutralize most poisons, relieving both kidneys and lymphatic systems.

Dandelion - regarded by herbalist's as one of the best herbs for building up the blood and for helping with anemia.

Yellow dock - is used to combat liver disease and gall bladder problems.

Cascara sagrada - sparks up a sluggish colon that is chronically constipated by improving the flow of secretions from the stomach, liver, and pancreas.

Cold Care Tea

Ginger - is found to be useful in the early stages of the common cold and influenza.

Peppermint - is known for its antiviral, antibacterial, antiseptic and antimicrobial attributes and is one of the oldest household remedies today.

Lemon grass - has stringent properties which help dry up mucous discharge.

Yarrow - is very helpful for colds and fever when drunk as a hot tea since it normally raises body temperature and opens the skin's pores, thereby stimulating free perspiration and elimination of impurities.

Marshmallow - is a very valuable and unique plant that provides us with a mucilaginous, calcium rich herb which soothes mucous membranes such as the lungs

Horehound - works as a throat remedy and also as an expectorant.

Sleep Tea

Valerian - is a proven sedative that acts to calm the nerves.

Lemon balm - is known for calming frayed nerves since it acts as a mild sedative.

Passion vine - is effective in relieving restlessness and insomnia

Hops - is a reliever of insomnia due to its fast acting sedating, calming, and soothing effect on the nerves

Oatstraw - is a beneficial toner for the entire system and helps combat insomnia.

Catnip - promotes a deep sleep and helps alleviate restlessness, colic and even pain.

The statements that you are making for your products suggest that they are intended to mitigate, treat, or cure diseases. These claims suggest that these products are intended for other than food use within the meaning of section 201(g) of the act and that they are subject to regulation under the drug provisions of the act. Furthermore, it appears that these products are intended for drug use within the meaning of section 201(g)(1)(B) of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish

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Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

**James T. Tanner
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition**

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

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