



MAY - 5 2005

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W. John Diamond, M.D.
Chief Medical Officer
InteMedica, LLC
9436 Double R Boulevard
Suite B
Reno, Nevada 89521

Dear Dr. Diamond:

This is in response to your letter of March 29, 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)). Your submission states that InteMedica, LLC is making claims for three products through their product names, namely, Supporter Constipation Herbal, Supporter Diarrhea Herbal, and Supporter Irritable Bowel Herbal.

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 statements that you are making for these products, through inclusion of the terms "constipation," "diarrhea," and "irritable bowel" in the product names, suggest that they are intended to treat, prevent, or mitigate diseases, namely constipation, diarrhea, and irritable bowel syndrome. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

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Please contact us if we may be of further assistance.

Sincerely yours,



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, Denver District Office, Office of Compliance, HFR-SW240



INTEMEDICA™,LLC

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29 March 2005

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Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration,
5100 Paint Branch Pkwy
College Park, MD 20740

Pursuant to the requirements of section 403(r)(6)(21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, InteMedica, LLC provides notification for statements on dietary supplements as follows:

Address of Distributor:
InteMedica, LLC
9436 Double R Blvd., Suite B
Reno, NV 89521

INTEMEDICA BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
Supporter Constipation Herbal	Rehmannia Unprocessed Root Tuber (Sheng Di Huang), Chinese Rhubarb Root and Rhizome (Da Huang), Bitter Orange Young Fruit (Zhi Shi), Flax Seed (Linum usitatissimum) (Hu Ma Ren), Peach Seed (Tao Ren), Sickle-pod Senna Seed (Jue Ming Zi), Dong Quai Root (Dang Gui), Japanese Bush Cherry Seed (Yu Li Ren), Costus Root (Mu Xiang), Apricot Seed (Xing Ren), Fo-Ti Dried Root Tuber (He Shou Wu), Chinese Amomum Fruit (Sha Ren)	Supporter Constipation Herbal is a herbal formulation designed to support healthy bowel function.
Supporter Diarrhea Herbal	Fragrant Angelica Root (Bai Zhi), Dolichos Seed (Semen Dolichoris Album) (Bai Bian Dou), Poria Sclerotium (Fu Ling), Ginger Dried Rhizome (Gan Jiang), Chinese Giant Hyssop Aboveground Parts (Huo Xiang), Bai-Zhu Atractylodes Rhizome (Bai Zhu), Magnolia Bark (Hou Po), Platycodon Root (Jie Geng), Tangerine Dried Rind of Mature Fruit (Chen Pi), Chinese Skullcap Root (Huang Qin), Perilla Leaf (Zi Su Ye), Sacred Lotus Seed (Lian Zi), Chinese Honey Baked Licorice Root (Glycyrrhiza uralensis) (Zhi Gan Cao), Jujube Fruit (Da Zao)	Supporter Diarrhea Herbal is a herbal formulation designed to support healthy bowel function.

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Supporter Indigestion Herbal	Codonopsis Root (Dang Shen), Chinese Yam Rhizome (Shan Yao), Bai-Zhu Atractylodes Rhizome (Bai Zhu), Ginger Fresh Rhizome (Sheng Jiang), Poria Sclerotium (Fu Ling), Astragalus Root (Huang Qi), Pseudostellaria Root Tuber (Tai Zi Shen), Costus Root (Mu Xiang), Dolichos Seed (Semen Dolichoris Album) (Bai Bian Dou), Bitter Orange Mature Fruit (Zhi Ke), Chinese Amomum Fruit (Sha Ren), Magnolia Bark (Hou Po), Jujube Fruit (Da Zao), Chinese Giant Hyssop Aboveground Parts (Huo Xiang), Tangerine Dried Rind of Mature Fruit (Chen Pi), Perilla Leaf (Zi Su Ye), Chinese Honey Baked Licorice Root (Glycyrrhiza uralensis) (Zhi Gan Cao)	Supporter Indigestion Herbal is a herbal formulation designed to support a healthy digestive system
Supporter Irritable Bowel Herbal	Yin-Chen Wormwood Young Shoot (Yin Chen), Bai-Zhu Atractylodes Rhizome (Bai Zhu), Schisandra Fruit (Wu Wei Zi), Job's Tears Seed (Yi Yi Ren), Codonopsis Root (Dang Shen), Magnolia Bark (Hou Po), Poria Sclerotium (Fu Ling), Bupleurum Root (Chai Hu), Phellodendron Bark (Huang Bai), Chinese Giant Hyssop Aboveground Parts (Huo Xiang), Ginger Prepared Rhizome (Pao Jiang), Chinese Honey Baked Licorice Root (Glycyrrhiza uralensis) (Zhi Gan Cao), Chinese Ash Stem Bark (Qin Pi), Chinese Pulsatilla Root (Bai Tou Weng), Costus Root (Mu Xiang), Chinese Peony Root without Bark (Bai Shao Yao), Coptis Rhizome (Huang Lian), Siler Root (Fang Feng), Tangerine Dried Rind of Mature Fruit (Chen Pi), Fragrant Angelica Root (Bai Zhi)	Supporter Irritable Bowel Herbal is a herbal formulation designed to support a healthy bowel.
Supporter Soothing Bowel Herbal	Chinese Peony Root without Bark (Bai Shao Yao), Ligusticum Wallichii Rhizome (Chuan Xiong), Bupleurum Root (Chai Hu), Bitter Orange Mature Fruit (Zhi Ke), Poria Sclerotium (Fu Ling), Corydalis Yanhusuo Tuber (Yan Hu Suo), Chinese Salvia Root and Rhizome (Dan Shen), Tangerine Dried Rind of Mature Fruit (Chen Pi), Jujube Seeds (Suan Zao Ren), Pseudostellaria Root Tuber (Tai Zi Shen), Chinese Honey Baked Licorice Root (Glycyrrhiza uralensis) (Zhi Gan Cao)	Supporter Soothing Bowel Herbal is a herbal formulation designed to support a healthy bowel.

THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE AND THAT INTEMEDICA, LLC HAS SUBSTANTIATION THAT THE STATEMENTS CONTAINED HEREIN ARE TRUTHFUL AND NOT MISLEADING.

Respectfully yours,



W. John Diamond, MD
 Chief Medical Officer
 InteMedica, LLC