



INTEMEDICA™, LLC

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29 March 2005

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

RECEIVED
MAY 19 2005
BY: _____

This letter is in response to a letter from you dated May 5, 2005 in response to a letter from me dated March 29, 2005 to the Food and Drug Administration pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (the Act). In your letter you state that the following products do not meet the requirements of 21 U.S.C. 343(r)(6): Supporter Constipation Herbal, Supporter Diarrhea Herbal, and Supporter Irritable Bowel Herbal.

In response to this, we have changed the names to Large Bowel Deficiency Herbal, Large Bowel Excess Herbal and Bowel Tension Herbal. To date, bottles have been sold to only one source. We have informed this source that the previous names must be removed immediately from the bottles. As this source is a physician, the physician has indicated that they will remove the name from the label and cover it with a label of their own in accordance with the new names above. InteMedica will not market the previous named bottles to any other sources.

I hope that this satisfies the requirements under the Act and trust that you will let me know if any further action is required. At InteMedica, we are extremely concerned about following every rule and regulation and apologize that our interpretation of the Act was not congruent with yours.

Respectfully yours,

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

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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