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JAN 12 2006

Mr. Mo Kang, MBA, MS  
Senior Scientist  
New Product Development Department  
Sedona Laboratories, Inc.  
211 Jennifer Drive  
Cottonwood, Arizona 86326

Dear Mr. Kang:

This is in response to your letter of December 23, 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 Sedona Laboratories, Inc. is making the following claim, among others, for the product **iFlora™ YC-7**:

“Helps balance normal vaginal and intestinal microflora after antibiotic use.”

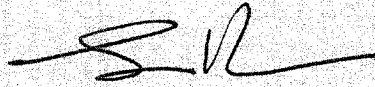
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. 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 20852.

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Please contact us if we may be of further assistance.

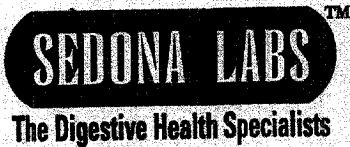
Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish 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

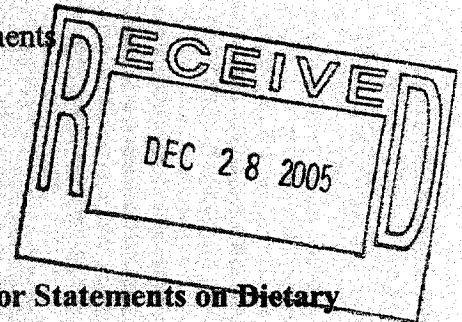
**Copies:**

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-PA240



December 23, 2005

The Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutrition Programs and Labeling (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740



**Title: New Product - Food Labeling; Notification Procedures for Statements on Dietary Supplements**

To Whom It May Concern:

We launched a new product in December, 2005. We are going to sell it with the name of iFlora™ YC-7 (please refer to the attached label):

The new product has the following ingredients:

- Proprietary Probiotic Blend 145 mg / V-caps
  1. *Lactobacillus casei*
  2. *Lactobacillus rhamnosus*
  3. *Streptococcus thermophilus*
  4. *Lactobacillus acidophilus*
  5. *Bifidobacterium lactis*
  6. *Lactobacillus plantarum*
  7. *Lactobacillus bulgaricus*

The main ingredient of the product are probiotics, which are widely used in US dietary supplements. Many published articles suggest that probiotics may potentially help maintain women's vaginal and intestinal health (please refer to the attached research articles).

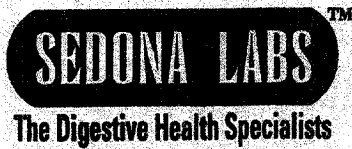
Here is the list of the attached for more information.

1. The New Product Label
2. Published Article about the efficacy of probiotics (*Lactobacillus casei*, *Lactobacillus rhamnosus*, *Streptococcus thermophilus*, *Lactobacillus acidophilus*, *Bifidobacterium lactis*, *Lactobacillus plantarum*, and *Lactobacillus bulgaricus*)

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**Sedona Labs, Inc.**  
211 Jennifer Drive • Cottonwood, AZ 86326  
tel: (888) 816-8804 • fax: (866) 887-8489  
www.sedonalabs.com

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I certify that all of the information and the attached data presented in this notice are accurate and truthful. If I can be of any assistance, please contact me at [mokang@sedonalabs.com](mailto:mokang@sedonalabs.com) or 1-800-914-6311.

Sincerely yours,

Mo Kang, MBA, MS  
Senior Scientist  
New Product Development Department  
Sedona Laboratories, Inc.

*cc: W. Nist*

**Sedona Labs, Inc.**  
211 Jennifer Drive • Cottonwood, AZ 86326  
tel: (888) 816-8804 • fax: (866) 887-8489  
[www.sedonalabs.com](http://www.sedonalabs.com)

**Supplement Facts**Serving Size: 2 Capsules  
Servings per Container: 30

Each Serving Contains:	%DV
Proprietary probiotic blend	145mg
Lactobacillus casei	*
Lactobacillus rhamnosus	*
Streptococcus thermophilus	*
Lactobacillus acidophilus	*
Bifidobacterium lactis	*
Lactobacillus plantarum	*
Lactobacillus bulgaricus	*

\*Daily value not established  
Other Ingredients: Rice maltodextrin, magnesium stearateSedona Labs  
211 Jewell Lane, Cottonwood AZ 86326  
555-816-8804  
www.sedonalabspro.com

\*\*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Made in USA

PROFESSIONAL USE ONLY

DIETARY SUPPLEMENT

SEDONA LABS  
SINCE 1987**iFlora™  
YC-7**

- 7 Specific Strains
- 15 Billion Cells/Capsule
- Dairy Free
- Shelf Stable

60 Vegetarian Capsules

**iFlora™ YC-7** is formulated using the most researched probiotic strains selected for women's vaginal and intestinal health.\*\* We use the patented cellular matrix stabilization process for temperature stability. All YC-7 strains are acid and bile resistant, and guarantee 15 billion viable cells per capsule at time of manufacture.

**Benefits:** Helps balance normal vaginal and intestinal microflora after antibiotic use. Promotes normal bowel regularity and digestion.\*\*

**Suggested Use:** Take 2 capsules daily for first week, then one daily for the second week. Repeat pattern for six weeks. Many professionals recommend taking with food.

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