



Shaklee Corporation

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Office of Special Nutritionals (HFS-450) 1861 '98 AUG 21 P12:47
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation notifies FDA that it has begun using the following statements:

- For daily colon care.
- Optiflora Daily Colon Care System promotes colon health by supporting the growth of healthy microflora naturally found in the colon. This prebiotic delivers FOS and Inulin, along with mixed tocopherols, which have gamma-tocopherol, a nutrient associated with colon health.
- Shaklee prebiotic is a pleasant-tasting drink mix that contains three grams of dietary fiber and features nutrients which selectively feed the friendly bacteria.
- Research shows that regular dietary intake of beneficial microflora must be maintained to experience the beneficial effects.
- Fructooligosaccharides (FOS)—a family of short-chain carbohydrates that deliver an immediate food source to nourish friendly microflora.
- Inulin—long-chain carbohydrate provides nutrients for beneficial microflora.
- Optiflora™ is a unique, two-product system that supplies both beneficial bacteria (probiotics) and the nutrients they need to thrive (prebiotics) to provide complete dietary support for the normal, healthy balance of intestinal microflora.

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- Research has shown that supplementing with prebiotics can significantly increase populations of beneficial microflora.
- Probiotics are supplemental populations of the “friendly bacteria” residing in the colon which help to maintain healthy intestinal microbial balance. The term probiotics was first used to refer to live microorganisms in supplement form that were fed to farm animals to stimulate growth and to improve resistance to stress. The term literally means “healthful for life,” and today, probiotics has a broader definition: a live microbial supplement which beneficially affects the host by improving its microbial balance.
- Optiflora™ offers a safe and natural way to supplement the diet with beneficial microorganisms naturally found in the gastrointestinal tract.
- These two supplemental components work together to help beneficial bacteria flourish in your intestinal tract to support whole body health.
- The unique combination of ingredients in Optiflora™ provide gentle, natural dietary support for the body’s natural ability to maintain a normal, healthy balance of intestinal microorganisms.

which contain the statutory statement, on labels and in labeling the following product(s):

Shaklee Optiflora™ Prebiotic Dietary Supplement
Shaklee Optiflora™ Probiotic Dietary Supplement.

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,



Christopher Jensen, MS, RD
Director, Health Sciences