



July 18, 2006

## **FDA Pre Market Notification for "Absolbotani"**

**Submitted By:** This Pre Market Notification is being submitted by the Center for Lifestyle Disease with the mailing address of P.O. Box 1487, Surprise, AZ 85378. Person of contact is Mitchell L. Tate, Chief Executive Officer of the company. The contact information is 623-776-3285 Phone/fax and email address is [mitchelltate@cox.net](mailto:mitchelltate@cox.net).

**New Dietary Ingredient:** The name of the new dietary ingredient is Absolbotani, a name chosen by the company and is not reflective of the substrates used to produce the new ingredient. Previous nomenclature used by the company in various tests have been Absolute Solution and Absolute Fx, but in each case represented the exact same chemical structure as indicated in the enclosed mass balance test. Absolbotani is a Trade Secret Protected formulation, a liquid extract, and as such the actual combination of ingredients is a trade secret and will be protected as such. Absolbotani is made by combining a proprietary aqueous extract and a proprietary alcohol extract from 3 different plants. This formula is made from dietary ingredients that were known and sold as dietary ingredients prior to October 15, 1994 and therefore normally may not need pre market notification. However, since the Center for Lifestyle Disease is seeking approval from the Office of Nutritional Products, Labeling and Dietary Supplements, FDA for a special allowance identifying this ingredient on labels of products for which it is an ingredient, we have elected to submit this pre market notification to provide evidence that this ingredient is reasonably expected to be safe. Only those companies having a legal license issued by the Center for Lifestyle Disease may use this ingredient or list it on a label as an ingredient.

In lieu of disclosing the three plant extracts used in the formulation, we will submit Attachment A-1, which is a mass balance test performed by an independent laboratory showing the chemical structure with associated CAS numbers of the final liquid extract we call Absolbotani. We do this because there is no official chemical name yet established for Absolbotani and when or if it is done, it would be too lengthy to include on product labels, and we want to be excluded from listing the actual plants on the labels due to the Trade Secret Protection we are enlisting. The Center for Lifestyle Disease deems the mass balance test, Attachment A-1, to be confidential information and it does provide sufficient evidence that the Absolbotani extract is reasonably expected to be safe. None of the chemicals listed show up on the federal chemical toxicity databases as potential or known toxic substances.

As the preamble to Attachment A-1 explains in more detail, Absolbotani will not be expected be found in any dietary supplement in greater concentration than 1:500 dilution and most often not more concentrated than 1:2000-1:5000.

**Description of Dietary Supplements:** The first dietary supplement expected to be released after the 75 day waiting period, will be a 1 oz. liquid drops with natural or artificial orange flavor, vitamin C, sweetener, mild saline and Absolbotani. There will be 1 part Absolbotani to 2000 parts the remaining ingredients or .05% presence of Absolbotani. The exact percentages of these ingredients are also deemed confidential and trade secret protected. We would like to reference this ingredient's presence on the label as "Absolbotani (proprietary botanical extract) and list the percentage in which it is present."

**The conditions of use** as stated on the label will be: "It can be taken 2 ways: at the first sign of your body's immune system fighting an attack from germs, or before entering crowded environments, like airplanes, offices and schools." This is based upon the combination of orange or other citrus products as the primary ingredient in the formula combined with Absolbotani and the other ingredients.

There is no historical use of the Absolbotani ingredient being used since it is a new and trade secret protected formulation, and is an original formulation from the Center for Lifestyle Disease. However, again, we site the mass balance test as evidence that it is reasonably expected to be safe. In addition to this, one of the plant extracts used in the Absolbotani formulation is on the FDA GRAS list.

In addition to this, preliminary safety and toxicity tests have been performed on Absolbotani (referenced in these tests as Absolute Fx Liquid) which indicates that it is safe and non-toxic. The summary page is page number seven in each of the reports. These tests were done at DuPont's Haskel Laboratories and are identified within this notice collectively as Attachment B-1. In summary, these tests were dermal, eye irritation and oral toxicity tests. Also, a use dilution test was done showing that there are some dermal sensitivity and other irritations that occur at concentration levels higher than 1%. This test would also indicate that at much less concentrated levels, such as the .05% as in the new product to be released, it is reasonable to assume that it will be safe.

We are also attaching our request for special allowance from your Office of Nutritional Products, Labeling and Dietary Supplements as Attachment C-1.

**Discussion:** Since it is reasonable to assume that the new dietary ingredient known as Absolbotani is safe based upon the evidence provided, and since we have provided the chemical structure of the extract solution with CAS #, we feel this information properly identifies the extract chemically for the purposes of

evaluating safety and therefore revealing the trade secret protected plant combination would not be necessary. We would also like to call your attention to the fact that Absolbotani will commonly be present in various end product dietary supplements and food products in dilutions of 1:2000 or higher. There is no evidence anywhere in the scientific literature indicating that any of the chemicals listed on the mass balance test to have any possible safety issues whatsoever at those extended dilution levels. We feel that the evidence is overwhelming in showing that there is reason to believe Absolbotani is safe as a new dietary ingredient. We respectfully submit this pre market notification in preparation for Absolbotani being used as a new dietary ingredient after the 75 day period.

Sincerely,



Mitchell L. Tate  
CEO

Enclosures: