



## Addendum

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### Pre Market Notification for "Absolbotani"

Submitted By: This Addendum is being submitted by the Center for Lifestyle Disease, PO Box 1487, Surprise, AZ 85378. Person of contact is Mitchell L. Tate, CEO. The contact information is 623-776-3285 phone/fax and email is [mitchelltate@cox.net](mailto:mitchelltate@cox.net).

**Description of Dietary Supplements:** The Ordinary Condition of Use for Absolbotani is to be in dietary supplements in conjunction with anti-oxidants or without other antioxidants, seeking to aid the body's immune system.

The Initial Product to be released will be a ready to drink (RTD) liquid drops in a 1oz (30 ml) dropper bottle where Absolbotani will be mixed with orange juice or artificially flavored orange liquid, that decision hasn't been finalized yet, and ascorbic acid and salt. The directions for use on the product will indicate the following: It can be taken two 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.

Adult Serving: 18 drops Number of Servings per bottle: 12 servings

Children & Under 100 lbs: 12 drops

Toddlers Under 2 years: 4-7 drops

Directions: Shake bottle gently and Drop appropriate number of drops directly into the mouth or into juice or water and swallow. Repeat 3-4 times per day until bottle is empty. It is important to check with your health care provider before taking dietary supplements.

**Note:** The direction to shake is not related to the distribution of the Absolbotani portion of the formula. It is for even distribution of the artificial orange powder used as flavoring agent. The Absolbotani stays suspended in the liquid evenly after initial mixture. Absolbotani has natural surfactant properties.

The **Level of Ingredient** of Absolbotani in the above supplement is .015 ml per 30 ml bottle (.05%). This is the total amount of Absolbotani the consumer would receive upon having used the entire bottle (12 doses). This is the total amount of Absolbotani a child would encounter if for some reason they consumed the entire

bottle at one time. There would be no need for poison control intervention and there would be no adverse affect experienced by the child.

**Frequency of Use:** On average adults would use the product (complete 12 doses) once to twice monthly. During winter months, the frequency of use may double or triple in a month's time. If the complete 12 doses were to be taken by an adult 12 times in one month, the consumer will have had .18 ml of Absolbotani in total. This amount of Absolbotani is completely safe, however, it is unlikely that the same person would take the full 12 doses of the product 12 times in one month. We just wanted to show that if someone does, it is safe to do so.

**General Use** of Absolbotani would never occur in concentrations greater than .2% of any product but most commonly would be present in concentrations of .05% or less.

**References to Mass Balance Test:** The mass balance test \_\_\_\_\_ gives the complete breakdown of each of the chemical constituents found in the final extract known as Absolbotani, referred to in the test as Absolute Fx Liquid. Each of the chemicals listed were checked against all Federal toxicology data bases and there are no indications of toxicity for any of these chemicals.

With the known information about the safety of the plants used and plant extracts from these plants, combined with the chemical analysis also indicating nothing present that could be considered unsafe, we propose that it is reasonable to believe that the Absolbotani extract is safe as a new dietary ingredient. We respectfully submit this addendum to our Pre Market Notification for NDI.

Respectfully,



Mitchell L. Tate  
CEO