

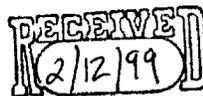


Melaleuca, Inc.

3910 South Yellowstone Hwy
Idaho Falls, Idaho 83402-6003
208.522-0700

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February 5, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: 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, Melaleuca, Inc., notifies FDA that it has begun using the following statements:

Optimal support for your body's immune system

One-of-a-kind formula maintains the strength of your body's defenses

Clinical studies show: Adults and children taking echinacea demonstrate stronger immune systems

Protect your whole family

In studies with adults and children, these natural extracts proved effective in supporting the immune system

Need more defense power? Activate your immune system

Take Activate Immune Complex when your immune system needs a boost

Works best when taken at the first sign your immune system needs support

When you feel your defenses need a boost, supercharge your immune system by taking one capsule three times daily

Use for up to three weeks at a time to keep your defenses strong

All-natural ingredients shown effective for both adults and children -- with virtually no reported side effects

Activate Immune Complex: Maintaining your defenses

Activate Immune Complex is an exclusive combination of extracts and vitamins that have all shown, in scientific studies, to help support the body's own defense mechanism: the immune system.

Formulated to help strengthen the immune system.

Echinacea: Promotes T cell and macrophage activity and increases the number of granulocytes. Clinical studies show: Adults and children that take Echinacea purpurea (the species of echinacea included in Activate Immune Complex) demonstrate stronger immune systems.

Astragalus: Studies have found that the root of this natural supplement increases macrophage and T cell activity and enhances the antibody response.

Arabinogalactan: A natural compound found in Western Larch trees that has been found to activate macrophages.

Vitamin C, E and Folic Acid: Found to help positively affect the immune system and to enhance white blood cell response.

Selenium and Zinc: Crucial to the development of white blood cells.

These ingredients combine to give the body the tools it needs to maintain a strong immune system.

In a world where our defenses are constantly being stressed, Activate Immune Complex can help support, rejuvenate, and refresh the immune system . . . so you can stay well, stay active, and be there for the important things in your life.

Activate Immune Complex is a unique combination of natural botanical extracts, vitamins and minerals that have shown, in reliable scientific studies, to help strengthen the immune system. Echinacea, also known as the purple coneflower, has appeared in over 300 scientific journals with relation to its immune-boosting effects. Clinical studies have shown that astragalus, a Chinese plant, has the ability to stimulate the immune system, and pure arabinogalactan (a specific compound found in Western Larch trees) has also been found to have a significant positive effect on the body's natural defenses. These extracts, in an exclusive combination with key vitamins and minerals, make Activate Immune Complex a powerful stimulant to the immune system, helping it to optimally defend the health of the body.

Echinacea: Supporting the Immune System

Activate Immune Complex has three different extracts that work together to strengthen the immune system.

Recent clinical studies have shown this plant [echinacea] to be a tried-and-true supporter of the immune system. For example, in one study of 180 patients, some were given an extract of echinacea purpurea (the species of echinacea most often used in the studies), while some were given a placebo (dummy pill). Those taking 900 mg of echinacea purpurea (the same amount and type as that used in a daily dose of Activate Immune Complex) demonstrated significantly stronger immune systems than those on the placebo.

Scientists have found that echinacea promotes T cell and macrophage activity, encourages antibody binding, and increases the number of a specific type of granulocytes. Echinacea has also shown to enhance the natural killer cells and to activate complement.

Astragalus: Maintaining the body's defenses

A traditional Chinese remedy, the root of the *Astragalus membranaceus* has shown in clinical studies to increase macrophage, T cell and natural killer cell activity as well as to enhance antibody response. Used in food supplements in China, herb specialists have referred to astragalus as an "adaptogen," or a type of natural substance that helps the body maintain its normal balance of health and wholeness.

The Chinese have used it [astragalus] for centuries to strengthen the *Wei Ch'i*, or "defensive energy," as they call the immune system.

Found in the bottom portion of this tree, arabinogalactan is a pure, renewable resource that has been discovered to help strengthen the immune system. In fact, arabinogalactan has demonstrated many talents, one of the most prominent being its effect on the body's defenses. For example, several studies showed that it enhanced the killing ability of natural killer cells and activated macrophages.

Though all vitamins and minerals are necessary to maintain a strong immune system, certain nutrients have demonstrated a unique powerful effect. The first of these is vitamin C, which enhances white blood cell response and function. A common partner with vitamin C, vitamin E has also shown strong immune-enhancing properties, and supplementation with vitamin E has been found to help positively effect the immune system.

In addition, studies have found that folic acid, a B vitamin, is necessary for proper immune function. Minerals like zinc and selenium, as well, are crucial to the development of white blood cells. Activate Immune Complex contains all of these nutrients in significant amounts to help the immune system to operate at its

maximum level.

When you're feeling like you need a little boost, take Activate Immune Complex, and activate your body's natural defenses.

Echinacea: Clinical studies show it helps maintain the immune system

Astragalus: Enhances antibody response

Arabinogalactan: Increases activity of natural killer cells and macrophages

Vitamin C: Enhances white blood cell function

Vitamin E: Has strong immune enhancing properties

Folic Acid: Necessary for proper immune function

Zinc & Selenium: Crucial to the development of white blood cells

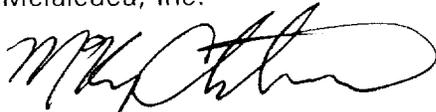
Activate Immune Complex helps supercharge your immune system with a daily dose (3 capsules) of 900 mg of Echinacea purpurea combined with standardized Astragalus herb extract, pure Arabinogalactan, key vitamins and minerals in an exclusive formula that offers quick and powerful support to your immune system.

These statements contain the statutory disclaimer. The name of the dietary supplement is Activate Immune Complex™, and the relevant dietary ingredients are Echinacea purpurea, Arabinogalactan, Astragalus membranaceus, Vitamin C, Vitamin E, Folic Acid, Zinc and Selenium.

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

Very truly yours,

Melaleuca, Inc.



McKay Christensen
Chief Operating Officer