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(54) **IMMUNITY ENHANCING SUPPLEMENTS FOR LUNG SUPPORT**

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(57) **ABSTRACT**

Supplement compositions designed to support healthy lung function and to help strengthen the immune system.

IMMUNITY ENHANCING SUPPLEMENTS FOR LUNG SUPPORT

BACKGROUND

[0001] The prior art regarding this invention arises from distinct areas not heretofore combined to create new and useful formula sets or new and useful improvements thereof regarding Immunity Enhancing Supplements for Lung Support.

[0002] This invention relates to the evolving science that several lung disorders are believed to be characterized by low glutathione levels. Glutathione is involved in numerous vital processes. Low glutathione levels have been implicated in inflammatory lung disorders and have been linked to abnormalities in the lung surfactant system and can cause abnormalities in the epithelial lining fluid. Reduced glutathione levels are a risk factor for chronic diseases[1]. Glutathione levels reduce naturally as we age; elderly people may then be at risk because of a decreased capacity to maintain many metabolic and detoxification reactions mediated by glutathione[2]. The key ingredient in this invention, N-Acetyl Cysteine, increases intercellular glutathione and has been shown to reduce the number of infectious bacteria in chronic bronchitis caused by smoking. N-Acetyl Cysteine is a better source of glutathione than taking glutathione itself because less than half of supplemental glutathione gets out of the digestive system and into the body. In addition, N-Acetyl Cysteine is a powerful antioxidant, antitoxin and immune support substance.

[0003] Albert M. Fleischner, Ph.D., has a doctorate in Pharmaceutical Chemistry from Rutgers University and has had over thirty years experience in the pharmaceutical industry with firms such as Schering-Plough Corporation, Roberts Pharmaceutical Corporation, Lehn & Fink Division of Sterling Drugs, Bradley Pharmaceutical Corporation, Amerchol Division of CPC and the Goen Group companies. He has a number of published papers and two previously granted patents and has several patents pending.

[0004] Not only do the lungs enable us to breathe, but in doing so they help the body eliminate waste gasses. When air is pulled in through the nose and mouth, it enters the trachea and moves down to the broncus, which divide into left and right bronchial tubes. These tubes carry air into the lungs where it is further divided into alveoli, little air sacs, which hold oxygen. As blood flows into the lungs through the capillaries, it brings with it carbon dioxide and other waste gasses. The carbon dioxide and waste gasses switch places with the oxygen as you breathe and the waste gasses are eliminated as you exhale. The oxygen is then distributed throughout the body.

SUMMARY

[0005] The invention discloses the formula sets that embody the invention of the supplement composition for increasing glutathione and antioxidant and antitoxin levels to achieve and maintain a healthy status. According to a Cornell University study, antioxidants seem to help protect lung function and may help prevent asthma, emphysema and chronic bronchitis. Specifically, in terms of lung function as measured by how much air the lungs could expel, the difference between people with above-average levels of all the major antioxidants and those with below-average levels is about equivalent to the difference between the lung function of nonsmokers versus those who've smoked a pack a day for 10 years.[3]

[0006] N-Acetyl Cysteine works to maintain glutathione and related antioxidant levels that normally decrease with stress, injury, exercise or age, while enhancing vitamin C's ability to support the immune system. This is particularly important since, as the body ages, the ability to digest and absorb protein is reduced over the years, resulting in shortages that lead to disease. Key groups that become oxidized are smokers, those deficient in antioxidants, those under stress and those who are aging. Oxidization makes us more susceptible to viral infection. Studies at the Louisville School of Medicine clearly show that glutathione possesses a unique ability to slow the aging process.[4]

[0007] Glutathione levels in the blood and tissues decrease with age[5]; higher glutathione levels are related to higher levels of physical health.[6] Exposure to glutathione can enhance our antioxidant defenses.[7] In a double-blind study, individuals with chronic bronchitis showed a significant reduction in the number of exacerbations of their illness.[8] Smokers have also benefited from taking N-Acetyl Cysteine[9]. In addition to helping break up mucus, N-Acetyl Cysteine may reduce the elevated bacterial counts that are often seen in the lungs of smokers with chronic bronchitis.[10] In another study, people with chronic bronchitis who took N-Acetyl Cysteine showed an improved ability to expectorate and a reduction in cough severity.[11] These benefits may result from N-Acetyl Cysteine's capacity to reduce the viscosity of sputum.[12]

[0008] N-Acetyl Cysteine has been shown to provide protection against free radicals as well as against a variety of toxic hazards such as: acrolein (found in barbecue and cigarette smoke and auto exhaust), bromobenzene, paraquat (a toxic herbicide) and the side effects of cyclophosphamide and adrimycin (anti-cancer drugs).[13] Diseases in which free radicals play a role include cancer, AIDS, cirrhosis and many others. According to a study at Stanford University, patients given N-Acetyl Cysteine daily for six weeks were roughly twice as likely to survive for two years as the subject that did not take N-Acetyl Cysteine.[14]

[0009] In reviewing approximately 200 published studies, there was overwhelming evidence that antioxidants are associated with reduced cancer incidence. Antioxidants neutralize free radicals, which are produced by normal metabolic activity. Without antioxidants, free radicals would damage cells and DNA and is a major factor in cancer and aging. Cigarette smoke contains oxidants as well as several precarcinogens. Metabolism of carcinogens and the steps of carcinogenesis are a balance between metabolic activation and detoxification, formation and scavenging of radicals and DNA damage and repair. This suggests that carcinogenic compounds can initiate tumor growth only when they saturate detoxification pathways. Glutathione plays a role in the detoxification of xenobiotics. N-Acetyl Cysteine has been shown to have important chemopreventive properties and may provide protection against different mutagens and carcinogens in different stages of carcinogenesis.[15] A study at Harvard Medical School found that while glutathione aids in the protection of all cells and membranes, it is especially able to enhance immune system cells, protecting against damage from radiation and helping to reduce the side effects of chemotherapy, x-rays and alcohol.

[0010] N-Acetyl Cysteine has reached the Phase III trial stage in chemoprevention in Europe and has been used in clinical practice there for more than 30 years. In large groups of patients with chronic obstructive lung disease, N-Acetyl Cysteine has been a safe agent with minor effects even when prescribed for a prolonged period.[16]

[0011] N-Acetyl Cysteine is an excellent mucolytic agent. It keeps the membranes of the respiratory system moist, thereby lessening the irritation of dry air, dust and pollutants. It also helps the immune system to do its job properly in the respiratory tract. A study conducted by the Departments of Pulmonology and Surgery at Maastricht University and at the Asthma Centre Homerheide, both in The Netherlands, found that altered glutamate metabolism is associated with reduced muscle glutathione levels in patients with emphysema.[17]

[0012] Science already knows that N-Acetyl Cysteine has demonstrated in clinical studies that it can help protect, prevent and repair damaged cells and DNA. This invention takes that information and embodies it in a new and useful set of formulae, disclosed herein.

[0013] We now discuss in detail the most preferred version, variants or embodiments of the invention. First, a few words on terminology. The claim term "a" includes one and more than one. The claim term "label" is used as defined in the Federal Food Drug & Cosmetic Act and the regulations promulgated thereunder. We now turn to discussing in great detail the best (or "preferred") versions (or "embodiments") of the invention.

[0014] The composition of each unit of the lung support supplement includes any combination of the specified range of the following ingredients:

Vitamin A (as retinyl palmitate)	1,000 IU–10,000 IU
Vitamin B_6 (as pyridoxine HCI)	1 mg–50 mg
N-Acetyl-cysteine	25 mg–500 mg
Deglychrrhizinated licorice root extract	25 mg–200 mg
Matricaria chamomile (flowering tops)	10 mg–150 mg
Slippery elm bark	10 mg–150 mg
Sarsaparilla	25 mg–100 mg
Astralagus root	10 mg–100 mg
Gotu kola leaf extract (10% asiaticosides)	10 mg–50 mg
Turmeric rhizome standardized extract (95% curcuminoids)	5 mg–20 mg

[0015] A representative formula for lung support supplement is as follows, one tablet contains:

Vitamin A (as retinyl palmitate)	1,250 IU
Vitamin B_6 (as pyridoxine HCI)	5 mg
N-Acetyl-cysteine	250 mg
Deglychrrhizinated licorice root extract	100 mg
Matricaria chamomile (flowering tops)	75 mg
Slippery elm bark	75 mg
Sarsaparilla root	50 mg
Astralagus root	25 mg
Gotu kola leaf extract (10% asiaticosides)	225 mg
Turmeric rhizome standardized extract (95% curcuminoids)	125 mg

[0016] The scientific rationale for the formulation is as follows:

[0017] Vitamin A maintains the cells that line the respiratory tract. It is vital for normal reproduction, growth and development. Vitamin A has also been shown to be crucial to the immune system, ultimately forming an important defense against diseases. It is an antioxidant that is necessary for new cell growth. Vitamin A deficiency has been associated with greater susceptibility to carcinogens and an increased risk of cancer. By strengthening the immune system, it increases resistance to infections, including colds, sore throats, flu, and bronchitis[18].

[0018] Vitamin B6, acting as a coenzyme, aids in immune system function and in antibody production. It plays a role in cancer immunity and aids in the prevention of arteriosclerosis[19].

[0019] N-Acetyl Cysteine is used for the reasons set forth above.

[0020] Deglycyrrhizinated licorice root soothes inflamed mucous membranes (demulcent effect) of the lungs and has expectorant properties[20]. It also has antiviral properties[21&22].

[0021] Chamomile is used to soothe respiratory tract inflammation[23]. It has been suggested that there is a stimulation of local prostaglandin synthesis, thus strengthening the protective mucosal barrier against ulceration[24].

[0022] The chief constituent of slippery elm bark is mucilage, which has demulcent, emollient and nutritive properties[25].

[0023] Sarsaparilla was used as an expectorant and cough remedy as early as 1738 in Europe; it then gained favor in the colonies. While its mode of action is obscure, it may aid in the absorption of other ingredients[26]. Sarsaparilla root protects against free radical harm from radiation exposure[27].

[0024] Astragalus root acts as a tonic to protect the immune system[28]. It is traditionally considered to benefit the body's resistance, reduce swelling and regenerate tissue. Modem uses include support for those suffering from the common cold, immune-deficiency related problems (including AIDS, cancer and tumors) and influenza; it is known to strengthen the body's defenses and is effective for chronic lung weakness[29].

[0025] Gotu kola leaf extract has been used to bring down a fever and to relieve colds and upper respiratory infections. Gotu kola has anti-inflammatory, anticonvulsant, antidepressant and analgesic properties[30]. Extracts have been found to promote wound healing[31]. This herb aids in the elimination of excess fluids and shrinks tissues[32].

[0026] Turmeric has anti-inflammatory and cytotoxic effects[33]. Regular dietary intake of turmeric provides effective antimutagen action and may be useful in chemoprevention[34]. In vitro and in vivo experiments have found that turmeric has antihepatotoxic and antibacterial effects[35]. The protective, antioxidant effects of turmeric and curcumin were greater than those of vitamins E and A[36].

[0027] Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to its fullest extent. The specific formulas are included as a preferred embodiment of the composition formula ranges, and not to further qualify the

description. Claim references to specific components include the component itself, as well as concentrates, metabolites, constituents, extracts or combinations of said ingredients.

I claim:

1. A composition of matter intended to support healthy lung function,

(a) said composition of matter containing (i) N-Acetyl Cysteine, and (ii) Vitamin A, and (iii) Vitamin B_6 and (iv) deglycyrrhizinated licorice root extract, and (v) matricaria chamomile (flowering tops), and (vi) slippery elm bark, and (vii) sarsaparilla root, and (viii) astragalus root, and (ix) gotu kola leaf extract (10% asiaticosides), and (x) turmeric rhizome standardized extract (95% curcuminoids).

(b) said composition of matter intended for ingestion in pill, capsule, tablet or liquid form; and

(c) said composition of matter not represented for use as a conventional food or as the sole item of a meal or diet; and

(d) said composition of matter labeled as a supplement for use in or by humans.

2. A composition of matter intended to support healthy lung function.

3. (a) said combination of matter containing (i) N-Acetyl Cysteine and (ii) additional dietary substances which support the primary ingredient's activities.

(b) same

(c) same

4. The supplement of claim wherein said ingredients are present in any combination thereof in the following approximate amounts:

Vitamin A (as retinyl palmitate)	1,000 IU–10,000 IU
Vitamin B_6 (as pyridoxine HCl)	1 mg–50 mg
N-Acetyl-cysteine	25 mg–500 mg
Deglychrrhizinated licorice root extract	25 mg–200 mg
Matricaria chamomile (flowering tops)	10 mg–150 mg
Slippery elm bark	10 mg–150 mg
Sarsaparilla	25 mg–100 mg
Astralagus root	10 mg–100 mg
Gotu kola leaf extract (10% asiaticosides)	10 mg–50 mg
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