

JAN 14 1997

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Mr. Randall P. Wisegarver
President
Pacific BioLogic
108 Camino Pablo
Orinda, California 94563

Dear Mr. Wisegarver:

This is in response to your letter to the Food and Drug Administration (FDA) dated November 11, 1996, in which you submitted revised text for a product brochure that describes the intended use of a number of dietary supplements that your firm intends to market.

Based on the information you submitted, we have no further comment on "RESIST 2" and "COLD FREE 1 PLUS".

In our letter to you dated March 6, 1996, we explained that section 403(r)(6) of the act makes clear that a claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases may not be made under the authority of that section. Certain statements contained in the text you submitted suggest that RESIST and PRE COLD PLUS are intended for one of these purposes. RESIST is promoted for use in "conditions characterized by suppressed or compromised immune functional include: HIV infection, Epstein-Barr and Chronic Fatigue Syndrome. Some physicians are now beginning to believe that Cancer is also related to immune function." In addition, the text refers potential users of the product to a book entitled "Immune Power - A Comprehensive Treatment Program for HIV." The product PRE COLD PLUS is promoted to optimize immune function "when the seasons are changing or during the winter months," but then goes on to state that "the body is best able to combat the woes of the cold and flu season when immune function is optimal." This latter claim suggests that the intended use of this product is to treat, prevent or mitigate the symptoms of colds and flu.

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These claims on the label or in the labeling of your products evidence that these products are intended to prevent, cure, treat, or mitigate disease and that the products are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855. Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals

cc:

HFA-224 (w/incoming)

HFD-310

HFR-PA140

HFS-22 (CCO)

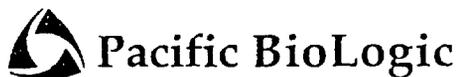
HFS-450 (r/f)

HFS-456 (r/f, Moore w/cpy incoming)

r/d:HFS-456:RJMoore:12/20/96

Init:GCF-1:PDerfler:1/8/97

f/t:HFS-456:RJMoore:rjm:1/8/97:DocName:50284.OSN:Disc20



Rec'd 12/19/96

11/15/96

Dr. Elizabeth Yetley
Division/Office of Special Nutritionals - [HFS-450]
Food & Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Dr. Yetley,

After consideration of the feedback we received from your office we are proposing the following changes to our Product Guide per Robert Moore's concerns with four of our product descriptions. One of the factors we considered when making these changes was to notice that Mr. Moore may have interpreted certain terms as physical terms rather than the metaphysical terms intended. Many of our products are used in the Chinese community and require us to refer to concepts familiar to these individuals. In the Chinese culture certain terms, when applied to nutrition or health, refer to the Chinese concept of "spiritual balancing" rather than an actual physical manifestation.

The specific terms at issue are the words "heat" and "clearing". Mr. Moore objected to the use of the word "heat" apparently assuming that this word referred to temperature - either within the body or ambient air temperature. However, in the Chinese culture the word "heat", in this context refers to a condition of excessive spiritual and emotional intensity. The closest English definition of this same phenomenon would be the term "anger" which is a very rough translation. The Chinese feel that diet can affect the balance of their spiritual energies, and often recommend supplementation with herbs and other dietary changes to "balance" their spiritual energies. In the case of "heat" they use certain herbs along with large amounts of green vegetables and other "cool" foods to accomplish this.

Similarly, the Chinese use the word "clear" or "clearing" to refer to dietary strategies designed to balance "heat". In this context certain herbs and foods which are considered "clearing" (the Chinese categorize all foods into hot/cold, dry/wet tonic/clearing etc.) are consumed to "clear excess heat" etc. and balance the diet. Below are rewritten drafts of the sections noted by Mr. Moore. We have attempted to modify the copy so it is clear that these particular words are meant to refer to the Chinese metaphysical definition. These definitions are denoted as "TCM". We have also rewritten sections to better address the role of diet and lifestyle factors when discussing a particular dietary program.

RESIST

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms.

Resist is a very versatile tonic and is considered slightly "sweet and warm" (as defined by TCM). It can be used by a wide variety of individuals in different states of health. Most professionals use Resist when creating programs which are intended to balance the diet when strengthening the body and its own defense mechanisms. Immune function can be suppressed or compromised through poor nutrition

or malabsorption of nutrients. Other factors can also effect immune function - particularly those that negatively impact bone marrow and the production of white blood cells. Many drugs and chemicals have been shown to have this effect, particularly chemotherapy agents and many of the popular anti-viral drugs. Some examples of conditions which are characterized by suppressed or compromised immune functional include: HIV infection, Epstein-Barr and Chronic Fatigue Syndrome. Some physicians are now beginning to believe that Cancer is also related to immune function. Even people who do not have any of the above mentioned conditions can experience poor immune function through dietary deficiencies or other lifestyle factors such as excessive physical and emotional stress. For more information on using Resist to supplement dietary and lifestyle programs read Dr. Jon Kaiser's book "Immune Power - A Comprehensive Treatment Program for HIV", published by St. Martins Press. Dr. Kaiser's book goes into considerable detail on how dietary and lifestyle changes may effect immune function.

Recommendations: Resist is best used in conjunction with Resist 2 in daily rotation. Reduce or discontinue use of Resist during flare-ups of symptoms or during illnesses such as colds and flu.

RESIST 2

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms. Specifically intended to be used in rotation with Resist to provide a more comprehensive program.

Unique combination of potent western and Chinese herbs in a TCM format. This balanced formula is designed especially to be used and rotated with Resist to provide dietary support when the total program is intended to have "clearing" (as defined by TCM) properties without compromising the tonic effects of the program.

Suggested use: Under normal conditions use 2-3 capsules per night while using Resist during the morning and afternoon. Under more challenging conditions most professionals prefer to use 3-4 capsules of Resist 2 at night and in the afternoon while still using Resist in the morning. For the most challenging conditions Resist 2 may be used by itself - 3-4 capsules 3 times per day.

PRE COLD PLUS

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms.

Pre Cold Plus is a unique design which is considered to be a mild tonic but also contains significant clearing components (as defined by TCM). It is intended to be used to supplement the diet when following total dietary and lifestyle programs which are intended to build the body's own defense mechanisms when the seasons are changing or during the winter months. Proper nutrition is a key component of insuring the best immune function. The body is best able to combat the woes of the cold and flu season when immune function is optimal. Highly concentrated.

Suggested use: 2-6 capsules, 3-4 times a day. Use as early as possible when desiring extra dietary support during the cold and flu season. If greater dietary support is needed then Cold Free 1 Plus may be preferred after the first 48 hours.

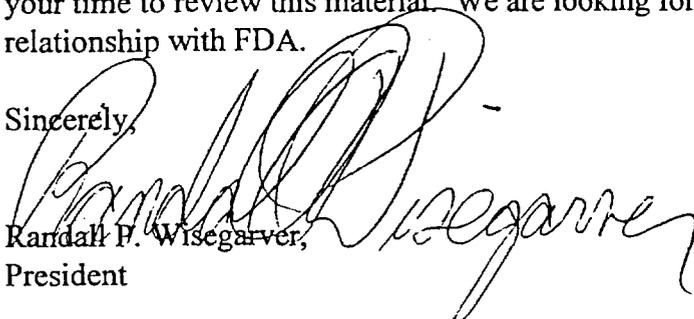
Cold Free 1 Plus

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms.

Cold Free 1 Plus is a powerful clearing formula (as defined by TCM) which is designed to be used in place of Pre Cold Plus when extra dietary support is desired during the changing of the seasons and during winter. Its basic design is somewhat similar to the Chinese patent formula Yin Chiao, but Cold Free 1 Plus has a much stronger clearing component (as defined by TCM), and is many times more concentrated.

We expect that these changes will sufficiently address your concerns while still accurately communicating the proper use of our products. We are looking forward to your feedback and will send you a changeover schedule for these revisions shortly after receiving your approval. Thank you for your time to review this material. We are looking forward to continuing a strong and healthy relationship with FDA.

Sincerely,



Randall F. Wisegarver,
President

RW/pc.230

cc: Robert Moore, FDA