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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

MAR - 1 2005

WARNING LETTER

Certified Mail
Return Receipt Requested

USA Chemicals, Inc
P.O. Box 4195
Cordova, TN 38088

Perry M. Belcher Companies
P.O. Box 3795
Cordova, TN 38088-3795

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses' http://www.schmedica.com, http://www.welatonin.com, http://www.tanningpillsplus.com and http://www.veinocal.com and has determined that your products "Welatonin™," "Digestrin™," "Veinocal™," "Chiterex™," "Goutin™", and "Cantharex™" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Welatonin™

- "Defeat Depression COLD TURKEY! in a Matter of DAYS without Mind Altering Drugs like Prozac!
- "Welatonin™ is a state of the art solution that alleviates unwanted feelings of despair and depression."

Digestrin™

- "There is an answer to ending your IBS [irritable bowel syndrome].... [T]here is an answer, Digestrin..."
- "Eliminate IBS Forever in Less than 72 Hours. Stop Diarrhea ...."
- "You will no longer have to deal with gas, diarrhea, or constipation."

Veinocal™

- "Make 94.6% of ...Varicose Veins Disappear Like Magic in Days!"

Chitorex™

- "[R]esearchers found that four weeks of chitosan [an ingredient in Chitorex] reduced total blood cholesterol ..."

Goutin™

- "[E]liminated severe gout pain."
- "Goutin™ is a 100% guaranteed solution to complete[sic] alleviate the pain and difficulty associated with gout.
- "Goutin™ has been shown to relieve the pain and dissolve the crystals that are the cause of gout."
- The name of the product "Goutin" is itself a disease claim because the term "gout" in the name implies that the product is intended to cure, mitigate, treat or prevent the disease. See 21 CFR 101.93(g)(2)(iv)(A).

Canthorex™

- "The use of Canthaxanthin may decrease one's chances of getting skin cancer."

FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, these products may also be "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are safe and effective.

Even if your products did not bear disease claims that cause them to be drugs, as dietary supplements, they are misbranded. Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. The manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling must have substantiation that the claim is truthful and not misleading [21 U.S.C. § 343(r)(6)(B)].

The labeling of your product "Chitorex™" bear structure/function claims about these products and their ingredients, including the following:

- "Chitorex™ is a "MECHANICAL" weight loss aid that absorbs 2000X it's weight in fat and converts it to a non-digestible gel that not only eliminates the fat but makes you feel full for hours."

We have reviewed these claims and have concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your products to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act [21 U.S.C. §§ 343(a)(1), (r)(6)(B)].

In addition, the products Digestrin™, Goutin™, Liporex™, Chitorex™, Zetacap™, and Welatonin™ are misbranded under section 403(a)(1) of the Act in that its labeling is false or misleading [21 U.S.C. § 343(a)(1)]. The products contain the following claims:

"Q: Is [Welatonin, Zetacap, Goutin, Digestrin, Chitorex, Lipex] approved by FDA?" "A: The ingredients [in Welatonin, Zetacap, Goutin, Digestrin, Chitorex, Lipex] have been given

"GRASE" status by the US Food and Drug Administration (FDA) 'Generally recognized as safe and effective' ...."

These statements are false and misleading and misbrand the products Digestrin™, Goutin™, Liporex™, Chitorex™, Zetacap™, and Welatonin™ under 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] because they state that the ingredients contained in these products are generally recognized as safe and effective when, in fact, they are not. Furthermore, they imply that FDA reviews and approves dietary supplement products and/or their ingredients. In fact, FDA does not approve dietary supplements or their ingredients.

Canthorex Product

Even if the labeling for Canthorex did not contain claims which cause it to be a drug, the product is an adulterated cosmetic. Your Internet web site promotes this product for coloring the skin. The Act defines the term "cosmetic" at section 201(i)(1) to include articles intended to be introduced into the human body for altering appearance [21 U.S.C. § 321(i)(1)]. Even though your web site states that Canthorex™ capsules "are not sold as tanning pills", and are instead "sold as a skin care supplement" the following web site statements establish that Canthorex is intended for use to alter the skin color to simulate a suntan:

- "Canthaxanthin [an ingredient in Canthorex] Colors the Skin."
- "[T]an from the inside to achieve all-over even tan that tanning booths do not produce. Canthorex™ provides you with this even skin tone and helps to make your tan appear more natural."
- "With Canthorex™ your skin is bronzed from the inside out so your skin looks sun-kissed all year long ...."
- "Anyone can use Canthorex.... [Y]ou can have beautiful beachworthy skin year round...."

The above claims and similar oral statements made on the web site's voice-over establish that the Canthorex you are currently marketing on your web site is intended to impart color to the skin, thus making it a cosmetic product.

The Act defines the term "color additive" at section 201(t)(1)(B) as a material which, when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color thereto [21 U.S.C. § 321(t)(1)(B)]. Canthaxanthin is a color additive. Color additives are deemed to be unsafe unless they are used in accordance with a color additive regulation that specifies the conditions under which the color additive may be safely used, including the purposes for which it may be used and the product category or categories to which it may be added [section 721(a) of the Act; 21 U.S.C. § 379e(a)].

There is no color additive regulation currently allowing for the use of Canthaxanthin to impart color to the skin or, for that matter, for the use of Canthaxanthin in a cosmetic product for any purpose.

Based on the above, the Canthaxanthin product you are marketing on your web site is adulterated under section 601(e) of the Act [21 U.S.C. § 361(e)], in that it bears or contains a color additive, namely Canthaxanthin, which is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. § 379e(a)].

In addition Canthorex is a misbranded cosmetic under section 602(a) of the Act in that its labeling is false or misleading [21 U.S.C. § 362(a)]. We call your attention to the following web site exchange, under common questions:

> "Q: Is Canthorex™ FDA approved?
> A: The ingredients have been given 'GRASE' status by the US Food and drug Administration (FDA) 'Generally recognized as safe and effective."

This statement misbrands the product because it states that ingredients in Canthorex are generally recognized as safe and effective when, in fact, they are not. Furthermore, This exchange implies FDA approval (and safety) when, as we have pointed out above, this is an unsafe use of the color additive, canthaxanthin

It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food (including a dietary supplement) or cosmetic that is adulterated or misbranded [21 U.S.C. § 331(a)].

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur.

If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be addressed to Compliance Officer Kristen L. Moe, 5100 Paint Branch Parkway, HFS-607, College Park, Maryland, 20740-3835.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition