

Memorandum

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Date: OCT 07 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Ubiquinol

Firm: Kaneka Corporation

Date Received by FDA: May 5, 2005

90-Day Date: _____

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

19955-0316

LET 12



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

OCT - 7 2005

David H. Bechtel, Ph.D., DABT
Managing Director and Senior Scientific Consultant
Cantox U.S., Inc.
1011 U.S. Highway 22, Suite 200
Bridgewater, NJ 08807

Dear Dr. Bechtel:

This is in further response to the April 28, 2005,¹ new dietary ingredient notification for "ubiquinol" or "KANEKA QH™" submitted by you on behalf of your client, Kaneka Corporation.

According to the notification you intend to market your new dietary ingredient "ubiquinol" in softgel capsule form. The notification states that "each serving of the dietary supplement will contain 50 mg of KANEKA QH™. Consumption of up to 6 servings per day will be suggested or recommended in the label directions."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

¹ May 5, 2005 is the date FDA received and filed the notice submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)). Additional information was dated June 20, 2005, and was received by the Agency on June 21, 2005.

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In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

This letter supercedes FDA's letter dated July 19, 2005.

This letter will be placed on public display at FDA's Division of Docket Management Branch in docket number 95S-0316 and will be appended to Report 283.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,



for

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition