



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

NOV 22 2005

Mr. Nicolas Coudurier
Biocodex, Inc.
300 North Mill Street
P.O. Box 387
Creswell, Oregon 97426

Dear Mr. Coudurier:

This is to inform you that the notification, dated August 31, 2005 that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on September 8, 2005. Your notification concerns the substances that you call "*Saccharomyces boulardii*"¹ that you identify as a new dietary ingredient that you intend to market as a dietary supplement product called Florastor®.

According to your notification, "Florastor® will be sold in the U.S. as a capsule...or a sachet..., each containing live, freeze-dried lyophilized *S. boulardii* cells in powdered form. ... Each capsule or sachet of Florastor® contains 250 mg (5 billion live freeze dried lyophilized cells) of *S. boulardii*. ... The package labeling instructs consumers to take one capsule or sachet in the morning and one in the evening for a total of 2 units/day (500 mg/day)."

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 21 U.S.C. 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

¹ Your notification fails to correctly identify the botanical which is the subject of the notification. The notification erroneously uses the name "*Saccharomyces boulardii*" to describe what appears to be *Saccharomyces cerevisiae* Meyen ex E.C. Hansen var. *cerevisiae* (*S. cerevisiae*). Under the requirements of 21 CFR 190.6(b)(2) and of 21 CFR 101.4 (h) the Latin binomial name must be stated in accordance with the internationally accepted rules on botanical nomenclature.

information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

The substance that you call "*Saccharomyces boulardii*" may be excluded from the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)(B). "*Saccharomyces boulardii*" is an article authorized for investigation as a biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

Your notification states (page 2) that "*S. boulardii* containing products have been approved for sale by over 50 countries worldwide...as either a dietary supplement or an over the counter (OTC) drug." Because the information in your notification does not specify any references to support this statement, we are unable to determine whether the substance that you call "*Saccharomyces boulardii*" has been lawfully marketed as a dietary supplement or as a food. Please provide FDA with documented evidence that establishes the lawful marketing of the organism that you call "*Saccharomyces boulardii*" as a dietary supplement or a food. FDA will then complete its evaluation shortly and send you a response to your notification explaining FDA's decision about whether your product is a dietary supplement within the meaning of 21 U.S.C. 321(ff).

This letter is to alert you within the 75-day notification period that FDA has concerns about whether your product can lawfully be marketed as a dietary supplement. Please note that failure to respond to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342. 21 C.F.R.190.6(f).

Your notification will be kept confidential for 90 days after the filing date of September 8, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Dr. Linda Pellicore 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