



JUN 20 2006

Food and Drug Administration  
College Park, Maryland 20740**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Gary M. Rodkin  
ConAgra Foods, Inc.  
One ConAgra Drive  
Omaha, Nebraska 68102

Ref. No. CL-06-HFS-810-224

Dear Mr. Rodkin:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.culturelle.com> and has determined that the product "Culturelle" is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

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

**Culturelle**

"Following are some of the conditions in which *Lactobacillus GG* has been clinically shown to help:

- Antibiotic associated diarrhea ...
- Viral diarrhea
- Clostridium difficile (C. diff) diarrhea
- Vaginal infections

Reduction of upper respiratory infections in patients with cystic fibrosis"

- "Press Release: Colon Cancer
- Press Release: Flu"

Examples of some of the claims observed on your "Success Stories" page include:

"My son was diagnosed with Crohns Disease at age 4 and he tried so many different medications that didn't work and if they did work they only alleviated the symptoms not repairing any of the damage done to his intestines. My son has been taking Culturelle for 2 years now and is seven; his disease is under control with a medication and Culturelle. He has a colonoscopy every year and the doctors at the Children's Hospital he goes to, have commented that some of the ulcers in his intestines have actually healed and that they feel the medication he is taking is stopping the growth of more and that the lactobacillus is promoting healthy healing of the damage that has been done over the last few years."

"I have had Irritable Bowel Syndrome for forty years. Within two weeks of taking Culturelle, my pain and diarrhea have not returned in the two years I have taken Culturelle."

"About 3 years ago, I was diagnosed with Collagenous Colitis. After going through several rounds of medication as prescribed by my GI, I heard about Culturelle from a website support group. Since I have been taking one Culturelle per day, my condition has significantly improved."

"Our son has Down syndrome and was born with Hirschprung's disease also. This disease has caused him intense stomach pain all his life (11 years). ... I went to his doctor feeling at wits end when he recommended trying "Culturelle" for my son's disease. Within 1 week time our son had no gas pain in his stomach and his stools changed for the better."

“I have had Irritable Bowel Syndrome for many years. Neither Lomotil nor Imodium gave me significant relief. After Lotronex (a great help) was removed from the market I was again suffering from frequent diarrhea. ... Now my attacks of diarrhea are greatly minimized ...”

“[M]y problem [is] not being able to take antibiotics without suffering from contracting the intestinal bacterial infection called clostridium difficile (c. diff.). ... I have taken antibiotics since I started using Culturelle and thankfully I have not contracted c. diff since! I use it on a daily basis to control IBS as well. I tell everyone who needs to use antibiotics for any reason to be sure to take Culturelle as well to promote a healthy intestinal flora!”

“I was diagnosed with Ulcerated Colitis some time ago. I was constantly taking one antacid or another. I constantly experienced some disorder of the stomach or intestines UNTIL Culturelle. ... Now, I am reordering because it made such a difference in the function of my digestive tract. I was not feeling bloated, or having heartburn or indigestion. ... Getting rid of gas was something I could hardly ever do. I was taking a second prescription of anti-biotics and can you believe it, NO YEAST INFECTIONS from the anti-biotics. ... I have been out of my Culturelle for almost a week now, and the symptoms are returning.”

“I’ve been suffering from IBS for a few years now. Over time, my symptoms have gotten progressively worse. ... Since starting a regular dosage of Culturelle, my symptoms have all but disappeared!”

“I was diagnosed a year ago with a lung disease called mycobacterium avium complex. I was prescribed very large doses of antibiotics and anti-bacterials to be taken for two years. I started taking Culturelle with my first dose of medications. I have never had any gastrointestinal effects and the doctors are amazed.”

“I was having kidney infections every three months. I have been on Culturelle for 2-1/2 years and have not had 1 kidney infection.”

“I had been through a run of 8 weeks of Cipro for a particular problem. My physician did not warn me of the potential intestinal problems. I only knew that my sides were hurting tremendously toward the end of the treatment and eventually went through an IVP in order to check for kidney problems. ... After the second day of use I found that there was a notable bubbling in my intestines (this is the first good action in a long time there). Following a serious stool test, I realized that the problem was clearing finally!”

“Our daughter contracted C. Difficile at 5 months of age. ... She has the severe toxin which recurs in her every few weeks and makes her very sick. During the last bout of C. Difficile, once her medication was finished, she started being symptomatic once again (this is common for her). Thankfully, we started Culturelle at this point and her symptoms reversed! She has been symptom free for 2 1/2 months now!!”

“I have had belching and heartburn problems almost everyday for about 2 years now. ... [M]y stomach was a little inflamed due to extra acid production. The only thing that was working was the prescription Famotidine. But it has side effects I didn't want to have to take it for the rest of my life, it costs \$300 to fill, and I still felt like I was not always digesting my food properly. So, my Step Father sent me a pack of Culturelle. ... [W]ithin 2 - 3 days it cleared up my heartburn. ... For 2 weeks now all my symptoms have disappeared.”

“After Esophageal cancer, I had a terrible time with diarrhea. After 1 1/2 years, my Gastroenterologist suggested Culturelle. ... It worked. After a few weeks, my system was returning to normal.”

“I had a case of Prostatitis a little over a year ago. I was treated with antibiotics for over a month. The course of Cipro effectively treated the infection, but caused an intestinal infection. Culturelle was prescribed by my Doctor to repopulate my intestinal tract with beneficial bacteria. If not for Culturelle, I'm convinced that I would still be suffering.”

Your product, Culturelle, is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for their intended purposes. Thus, Culturelle is misbranded under section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. 352(f)(1)].

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met.

However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

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.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Linda J. Webb, Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Robert J. Moore, Ph.D.  
Team Leader, Compliance and Enforcement  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition