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May 22, 2001

Dockets Management Branch (HFA 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Guidance on Applying the Structure/Function Rule: Request for Comments

Dear Sir or Madam:

We are responding to your request for comments in the Federal Register (66 FR 11172, Feb. 22, 2001) on behalf of a client which markets bovine colostrum as a dietary supplement.

We support FDA's intent to issue a guidance document (Guidance) setting forth permissible structure/function claims that can be made for dietary supplements under FDA's Regulations on Statements Made for Dietary Supplements Concerning the Effect on the Structure or Function of the Body; Final Rule, 65 FR 999 (Jan. 6, 2000). The Structure/Function Rule created a substantial amount of commercial uncertainty by not providing enough examples of where FDA would draw the line between a permissible structure/function claim under the Structure/Function Rule and an impermissible drug or disease claim under Section 505(b)(1) of the Federal Food Drug and Cosmetic Act for different types of dietary supplements, including bovine colostrum. Guidance is urgently needed to give marketers of dietary supplements a "safe harbor" to rely upon when they are making claims for particular types of products. Such a Guidance would also be useful to consumers who could consult it to determine whether a specific claim being made for a dietary supplement is a permissible claim.

The Guidance should make it clear that any person or entity making any of the claims set forth in the Guidance for a particular product will not be subject to any Agency enforcement action if such action would only be taken based on a claim permitted by the Guidance.

In addition, due to the Federal Trade Commission's (FTC) jurisdiction over advertising claims of dietary supplements, the FDA should enter into an interagency agreement with the FTC that binds the FTC not to take any enforcement actions pursuant to Section 5 of the Federal Trade Commission Act against any person or entity making claims for a particular dietary supplement which would be permissible under the Guidance.

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Finally, we believe that, the FDA should approve use of the following claims in its Guidance for bovine colostrum intended for use as a dietary supplement:

--Helps maintain/support a healthy immune system.

--Helps maintain/support a properly balanced immune system.

--A properly functioning human gut has "good" and "bad" bacteria in it. Helps keep the "good" and "bad" bacteria properly balanced.

--When you travel to new places you may face new types of bacteria. Helps your digestive system combat/process bacteria and other pathogens it has never met before.

--Helps your digestive system adjust to a new climate/environment.

--Helps maintain/support a healthy gut.

--Helps your digestive system keep the "good" and "bad" bacteria in balance.

--Helps maintain/support normal blood glucose levels.

--Provides digestive support when you are taking drugs that may adversely affect your digestive system/gut.

--Enhances mood under stress.

--Helps maintain/support a healthy environment in your mouth.

--Helps maintain/support normal kidney function.

--Builds lean muscle.

--Increases vitality and stamina.

--Helps maintain/support normal growth of bone and tissue.

--Helps maintain/support the normal healing process for burns.

--In a pilot open and uncontrolled study, bovine colostrum was found to be safe and free from any side effects and at least transitorily efficient in treating

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the diarrhea of most of the HIV patients participating in the trial, including those with Cryptosporidiosis.<sup>1</sup>

--A small placebo-controlled double-blind study (27 patients) found that bovine colostrum is well tolerated and diminished the frequency of loose stools in children with *E. coli* associated diarrhea.<sup>2</sup>

--Contains bovine antibodies for the following pathogens: *Candida albicans*, *helicobacter pylori*, *streptococcus agalactiae*; *propionibacterium acnes*, *salmonella enteritidis*, *haemophilus influenzae*, *campylobacter jejuni*, *yersinia enterocolitica*, *escherichia coli*, *escherichia coli O157*; H7 *listeria monocytogenes*, *streptococcus pneumoniae*, *staphylococcus aureus*, *streptococcus pyogenes*, *klebsiella pneumoniae*, *salmonella typhimurium*.<sup>3</sup>  
[Some of these may differ from human antibodies.]

Very truly yours,



Jill B. Deal

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<sup>1</sup> Rump JA, Arndt R; Arnold A; Bendick C; Dichtelmüller H; Franke M; Helm EB; Jäger H; Kampmann B; Kolb P; et al, "Treatment of Diarrhoea in Human Immunodeficiency Virus-Infected Patients with Immunoglobulins from Bovine Colostrum, Clin. Investig. 588-94 (1992 July); Article available on request.

<sup>2</sup> Huppertz HA, Rutkowski S, Busch DH, Eesebit R, Lissner R, Karch H, "Bovine Colostrum Ameliorates Diarrhea in Infection with Diarrheagenic *Escherichia coli*, Shiga Toxin-Producing *E. Coli* and *E. Coli* Expressing Intimin and Hemolysin, *Journal of Pediatric Gastroenterology and Nutrition* 29: 452-456 (October 1999); Article available on request.

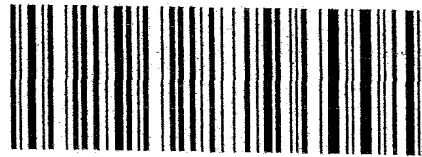
<sup>3</sup> Claims as to antibodies for a particular pathogen would only be made based on results of ELISA tests for that batch of bovine colostrum.

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PLACE STICKER AT TOP OF ENVELOPE  
TO THE RIGHT OF RETURN ADDRESS  
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**CERTIFIED MAIL**



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