



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

4282 '00 MAY 25 P2:01

MAY 19 2000

Ms. Jessica L. Johnston
Director of Scientific Affairs
Symbiotics, Inc.
2301 W. Highway 89A
Suite 107
Sedona, Arizona 86336

Dear Ms. Johnston:

This is in response to your letter of April 28, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Symbiotics, Inc. is making the following claims, among others, for the product **New Life Colostrum**:

“...enhance skin and muscle rejuvenation due to injuries.”

“New Life Colostrum contains titers of the following antibodies: *Escherichia coli*, *Escherichia coli* 0157:H7, *Candida albicans*, *Haemophilus* [sic] *influenzae*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Streptococcus mutans*, *Streptococcus agalactiae*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Staphylococcus aureus* [sic], *Staphylococcus epidermidis*, *Klebsiella pneumoniae*, *Helicobacter pylori*, *Listeria monocytogenes*, *Yersinia enterocolitica*, *Campylobacter jejuni*, *Bacillus cereus*, *Propionibacterium acnes*, *Shigella flexneri*, Rotavirus, and *Cryptosporidium*.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure or mitigate disease, namely injuries and infectious diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-811:rjm:5/17/00:docname:003107.adv:disc47



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April 28, 2000

U.S. Food and Drug Administration
(HF-40)
5630 Fishers Lane
Rockville, MD 20857

Dear Sir or Madam,

On behalf of Symbiotics, Inc. (Symbiotics), a marketer of bovine colostrum, intended, among other things, for use as a dietary supplement, I submit to you a list of the supplement claims used in our labeling and advertising material for your records. This letter notifies the Food and Drug Administration about our intent to use these claims.

1. New Life Colostrum may help support immune function.
2. New Life Colostrum may help increase lean body mass.
3. New Life Colostrum may help increase vitality and stamina.
4. New Life Colostrum may enhance skin and muscle rejuvenation due to injuries.
5. New Life Colostrum helps maintain healthy intestinal flora.
6. New Life Colostrum helps increase the bioavailability and absorption of nutrients in the gut.
7. New Life Colostrum contains titers of the following antibodies:
Escherichia coli, Escherichia coli 0157:H7, Candida albicans, Haemophilus influenzae, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus mutans, Streptococcus agalactiae, Salmonella enteritidis, Salmonella typhimurium, Staphylococcus aureus, Staphylococcus epidermidis, Klebsiella pneumoniae, Helicobacter pylori, Listeria monocytogenes, Yersinia enterocolitica, Campylobacter jejuni, Bacillus cereus, Propionibacterium acnes, Shigella flexneri, Rotavirus, and Cryptosporidium.

Further, each claim listed above is accompanied by an asterisk, which references a disclaimer that informs the consumer that results may vary, and that these statements are not evaluated by the Food and Drug Administration, nor are these products intended to diagnose, treat, cure or prevent any disease.

Please contact me at your convenience if there are any questions. Thank you for your time.

Sincerely,

Jessica L. Johnston, MS
Director of Scientific Affairs