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April 19, 2000

BY HAND DELIVERY

Re: Docket OON-0598: Implementing the Pearson Court Decision

Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville MD 20852  
Attention: Docket No. OON-0598

Dear Sir or Madam:

On behalf of our client, Symbiotics, Inc. (Symbiotics), a marketer of bovine colostrum intended, among other things, for use as a dietary supplement, we submit the following comment.

Our comment is directed to the narrow issue of health claims made in labeling materials directed to physicians and pharmacists. With increased use of dietary supplements by consumers, physicians and pharmacists are receiving a vastly increased volume of questions about them from their patients. In addition, many physicians and pharmacists are becoming increasingly interested in incorporating dietary supplements into their practices. However, due to competing claims for the physician's and pharmacist's time and resources, the physician and pharmacist may not have the time to perform a thorough search of the scientific literature each time a new dietary supplement is brought to his attention by a patient. When faced with a query about a particular supplement, the physician and pharmacist may know little or nothing about it, including known side effects or contraindications with prescription drugs he or she has prescribed for the patient. By contrast, marketers of dietary supplements know a lot about their products, including the support or lack thereof of their benefits existing in the scientific literature. Marketers of dietary supplements have strong incentives to educate physicians and pharmacists about the benefits of their products. Yet current FDA policy makes no distinction between making health claims to physicians and pharmacists and making them to ordinary consumers.

This makes no sense and insults the intelligence of physicians and pharmacists. As we explain below, permitting health claims to be made in labeling materials prominently and specifically directed to physicians and pharmacists so long as they are accompanied by full cites (and/or abstracts) to peer reviewed scientific literature supporting each claim would be an effective way to enhance the physician's

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and pharmacist's ability to meaningfully screen existing scientific literature while reducing the physicians' and pharmacists' search costs and time. By better educating learned intermediaries, patient care is likely to be improved and patient safety enhanced, while the chances of consumer deception are kept to little or nothing.

**I. HEALTH CLAIMS SHOULD BE ABLE TO BE MADE TO PHYSICIANS ABOUT DIETARY SUPPLEMENTS, ABSENT SIGNIFICANT SCIENTIFIC AGREEMENT**

Physicians and pharmacists do not need to be shielded from health claims about which there is no significant scientific agreement, however that term is defined by FDA. Of all consumers of labeling for dietary supplements, physicians and pharmacists are the least likely to be deceived by health claims made in the labeling of a dietary supplement, so long as they can readily and independently verify the basis or lack thereof for the claim. Unlike most consumers, physicians and pharmacists have been trained to evaluate scientific evidence critically, including in vitro and clinical studies. Physicians and pharmacists are fully familiar with concepts such as selection bias, statistical significance and the many other factors which positively or adversely affect the weight that should be accorded to a study.

We recommend that FDA determine that it is permissible to make any health claim to physicians and pharmacists in labeling for a dietary supplement, so long as the labeling cites scientific support for each such claim, either by providing a citation to a peer reviewed article or by providing the title and at least the full, unedited abstract of the article. FDA should further require that the citations provided represent a balanced view of the scientific support for the claim at the time the labeling was prepared. Known side effects and contraindications should also be disclosed in the labeling materials, to the extent they are known.

Providing the citations will give the physician and pharmacists ready access to scientific literature supporting the claim. If the abstracts do not provide the physician and pharmacists with enough evidence to determine whether they are sufficiently supportive of the claim, the physician or pharmacist can use the citations to access the full articles. Based upon the citations, he or she can either use the cited references in the full article to do further research, or do an independent search of the scientific literature on the subject. Based upon the results of the research, the physician and pharmacist can then make up his or her mind about what to say to a patient who asks him or her about whether to take a particular dietary supplement.

By permitting health claims to be made to physicians and pharmacists about which there may or may not be significant scientific agreement, yet at the same time providing them with easy access into the scientific literature supporting such claims, FDA will make physicians and pharmacists better educated learned intermediaries

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who are likely to improve patient care. Instead of putting a physician and pharmacist pressed for time in a situation where, in response to a query from a patient about the benefit of taking a dietary supplement, he or she either knows nothing about it or very little, the physician and pharmacist would be able to provide the consumer with an intelligent assessment of its benefits and detriments including any known side effects or contraindications with any medications he or she has prescribed. Such a determination will not only enhance public health but also improve patient safety.

## **II. HEALTH CLAIMS TO PHYSICIANS AND PHARMACISTS NEED MINIMAL QUALIFICATION**

Because physicians and pharmacists have been trained to evaluate health claims, they need only minimal qualification when made to physicians and pharmacists. However, in addition to the recommendations made in Part I, the FDA also might want to require that the labeling prominently disclose that the labeling material intended for physician's and pharmacist's, and the subject of this comment, is intended solely for the use of physicians and pharmacists so that the labeling material is not directed to consumers who may be less qualified than the physicians and pharmacists to evaluate the validity of the claim. In addition, all claims would be qualified by the legend set forth in Section 403(2)(C) of the Federal Food Drug and Cosmetic Act: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

## **III. HEALTH CLAIMS TO PHYSICIANS AND PHARMACISTS SHOULD BE PERMITTED ABOUT MITIGATION OR TREATMENT OF AN EXISTING DISEASE**

Physicians and pharmacists have been trained to evaluate products which mitigate or treat existing diseases, including prescription drugs and medical devices. Due to their training, they will be able to evaluate any health claims made about the mitigation or treatment of existing diseases, so long as they are given the basic research tools to evaluate them at the time the claim is made, specifically, the title to peer reviewed scientific support for the claim and/or the full abstract. In the case of physicians and pharmacists, there is no reason to draw an artificial line between whether claims about reducing the risk of a disease should be permitted vis-à-vis claims about mitigation or treatment of an existing disease. Permitting physicians and pharmacists easy access to the scientific literature is likely to better prepare them to answer patient inquiries about particular dietary supplements more thoroughly and intelligently. In turn, a more convincing physician and pharmacist presentation on the benefits or detriments of taking a supplement is likely to enable consumers to make a more intelligent decision about whether or not to take a particular dietary supplement.

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The net result should be improved patient care and enhanced patient safety, with a minimal possibility of deception of ultimate consumers.

For the above reasons, we urge the FDA adopt our recommendations.

Kind regards

A handwritten signature in cursive script that reads "Jill B. Deal". The signature is written in black ink and is positioned below the typed name.

Jill B. Deal

JBD/bls

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