



May 2, 2007

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

RE: Docket No. 2006D-0480, Request for Comment on Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration

The Council for Responsible Nutrition (CRN) appreciates the opportunity to provide FDA with comments regarding the recently issued *Draft Guidance for Industry on Complementary and Alternative Medicine (CAM) Products and Their Regulation by FDA*. CRN recognizes that this Guidance is intended not to provide any new information or to announce any change in FDA's views toward the regulation of these products, but rather it is intended to be a comprehensive review of the laws and regulations governing CAM products.

CRN applauds FDA for issuing this important guidance which should provide clarity around the regulation of CAM products, and reinforce the fact that the respective industries that provide these products are appropriately regulated by the Agency. However, we do have concerns about the Draft Guidance as published, particularly with respect to the discussion of the definitions of "drugs" and "dietary supplements"; certain examples of CAM products that would be regulated as dietary supplements pursuant to the Guidance; and the omission of other examples that would help to further clarify the proper regulation of these products based on their intended uses. As a result, the Draft Guidance creates the misimpression that certain CAM products that are properly regulated as dietary supplements should be regulated as drugs.

The Draft Guidance reiterates the intent of the Dietary Supplement Health and Education Act of 1994 (DSHEA) which called for the regulation of dietary supplements as a category of foods, a position that CRN strongly supports. Dietary supplements have always been regulated

as a category of foods and should continue to be regulated as such. We are pleased to see the Agency publicly acknowledge this fact in its guidance documents.

However, CRN has concerns regarding the definition of “drug” or “new drug” put forth in the Draft Guidance. On page 7 of the Guidance, the document defines a “drug” under the Federal Food, Drug, and Cosmetic Act (FD&CA), but does not quote all the relevant portions of the drug definition that exclude dietary supplements from that term. Omitted is the qualifying language stating that a food or a dietary supplement for which an FDA-approved health claim or a structure/function claim is made under section 403(r) is not a drug solely because the label or labeling contains such a statement. Further, on page 8 of the document there is a description of conditions under which an herbal product that is intended to treat arthritis would be a drug or possibly a new drug. At the end of that paragraph, to place the example in proper context, CRN recommends adding a statement such as: "Alternatively, if the herbal product is not intended to treat arthritis but instead contains a dietary ingredient and makes a claim that it is intended to support healthy joints, it would be considered a dietary supplement bearing a structure/function statement. Similarly, if a dietary supplement includes a dietary ingredient that is the subject of an approved health claim that the ingredient reduces the risk of developing arthritis, such a product would be considered a dietary supplement bearing an approved health claim."

Likewise, the section of the Draft Guidance discussing dietary supplements does not acknowledge FDA-approved health claims and qualified health claims. Under the FD&CA, the use of claims that either state or imply treatment of a disease or condition establishes that product as a drug. However, the Nutrition Education and Food Labeling Act of 1990 (NLEA) and subsequent court decisions have permitted claims for dietary supplements that describe a nutrient or food and a disease relationship (specifically disease risk reduction). The otherwise helpful example of “cranberry tablets” provided in the Draft Guidance lacks this distinction and should be revised to reflect the possibility of a health claim or qualified health claim. CRN recommends that the final sentence be modified and expanded to read: "The cranberry tablets could be labeled for use in '*reducing the risk of* urinary tract infection' only if FDA approved a health claim or permitted a qualified health claim for this use. Labeling the cranberry tablets for use to '*treat* urinary tract infections' would cause them to be regulated as drugs."

Regarding probiotic products (page 13) the Draft Guidance supposes that “the bacteria used in a probiotic product could make the product a ‘biologic product’ subject to the Public Health Service (PHS) Act”. CRN respectfully disagrees with this characterization of the law, and believes instead that due to their presence in conventional foods, such as yogurt, probiotics are properly regulated under the FD&CA as a component of food. In support of this position, CRN directs the Agency’s attention to the 2002 report of a Joint FAO/WHO Working Group entitled “Guidelines for the Evaluation of Probiotics in Food” (<http://www.fda.gov/ohrms/dockets/dockets/95s0316/95s-0316-rpt0282-tab-03-ref-19-joint-faowho-vol219.pdf>). These Guidelines recognize bacteria-based probiotics as food, and provide specific recommendations on classification and testing to ensure their safe use as foods.

21 CFR 600.3 (h) states in part that a "Biological product means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man: (1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa." By this definition, a probiotic would be considered a “biologic product” only if it potentially caused an infectious disease and at the same time it was used to prevent, treat or cure a disease. However, this does not characterize probiotic products in the form of conventional foods or dietary supplements which have many important uses, none of which are intended to prevent, treat or cure a disease. Therefore this example may have the potential to mislead, rather than enlighten readers as to the regulation of these products. To surmise that a probiotic product marketed as a food or dietary supplement might be a “biologic product” would suggest that yogurt, which contains active cultures, might be regulated as a “biologic product” as well. Doing so may confuse rather than clarify the issue, and may not be in the best interest of public health, as people consume yogurt as a conventional food for many reasons. CRN believes the suggestion that probiotics used as foods, including dietary supplements, would instead be regulated as biologic products, mischaracterizes the law and current regulation. We recommend the Agency consider removing this example from the Draft Guidance or modifying it as described below.

That paragraph should be modified to indicate what conditions would make the product a "biological product," such as not already having been approved for use in food or not being a

legitimate dietary ingredient. CRN recommends a modification to the final sentence of the paragraph to read: "For example, while many specific strains of bacteria are legitimately used in food and in dietary supplements to aid in maintaining a healthy gastrointestinal tract and good digestive health, under other conditions of use, the bacteria used in a probiotic product could cause it to be considered a "biological product" subject to the PHS Act. This would be the case if the probiotic has the potential for causing disease and thus is not considered safe for use in food or dietary supplements, or if it is labeled for therapeutic (drug) uses."

Once again, CRN appreciates the opportunity to comment on this valuable Draft Guidance. We hope the Agency finds these comments both supportive and constructive and that they will be given ample consideration in the drafting of the final guidance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrew Shao', with a long horizontal flourish extending to the right.

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