



POSITION STATEMENT

FDA Seeks Clarity on Complementary & Alternative Products: Misinterpretation of DRAFT GUIDANCE Causes Unwarranted Concerns; DSHEA is Safe

Background

Earlier this year, the Food and Drug Administration (FDA) released a *Draft Guidance for Industry on Complementary and Alternative Medicine (CAM) Products and Their Regulation by FDA*. As a result of a few typographical errors and some confusion over the comment deadline, FDA extended the comment period to May 29, 2007. In addition, there has been some misinformation and confusion about the purpose and effect of this Draft Guidance. While CRN has expressed concerns about specific items in the Draft Guidance, it is important to understand what this document is and how it would be used by the agency.

What is an FDA Guidance?

This document, as with any Guidance issued by FDA, is intended to provide the public with FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public, as FDA has acknowledged. Nor can a Guidance document change the law or supersede either court cases or statutory pronouncements on dietary supplements; it merely explains FDA interpretation of the law and provides indications of how the agency might implement it. FDA issues such documents as "Draft" in order to obtain public comments and to revise the material where questions or concerns have been raised before a "Final" version is released.

Under DSHEA, supplements are a category of foods

This Draft Guidance underscores that under DSHEA, dietary supplements are a category of foods—something that has always been the case and that CRN strongly supports. In its most recent notice extending the deadline for comments, the FDA addresses the confusion created by the Draft Guidance, saying "... we want consumers and CAM practitioners to understand that the draft guidance does not contain or propose any new regulatory requirements for any complementary and alternative medicine product marketed in the United States..." CRN agrees.

Concerns

There are, however, some concerns with the Draft Guidance. One issue is that the Draft Guidance does not discuss or acknowledge FDA-approved health claims and qualified health claims, and thus creates a misimpression that any mention of disease associated with a food or supplement automatically makes that product a drug. While that omission does not—and cannot—change DSHEA or FDA's regulations, it could confuse lay readers of the Guidance by failing to point out permissible health claims for dietary supplements. Similarly, a lay reader of the Draft Guidance could receive the impression that the bacteria used in probiotics could make products like yogurt, currently regulated as food, into biologic products subject to the Public Health Service Act (PHSA). Probiotics should be regulated as food as long as the intended use is not to treat, cure, prevent or mitigate a disease condition. CRN addresses both of these issues in depth in its comments (available on CRN's website: www.crnusa.org/pdf/CRN_CAMguidance_comments0407.pdf.)

Draft Guidance won't overturn years of appropriate regulation

CRN encourages interested companies to provide their views on the Draft Guidance to FDA, but cautions against the "call to arms" among industry that this Draft Guidance could overturn fourteen years of appropriate regulation under DSHEA, or make supplements into "drugs." That simply is not the case.