UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of
Regulations on Statements Made for Dietary Supplements
Concerning the Effect of the Product on the Structure or
Function of the Body; Proposed Rule

[Docket No. 98N - 0044]

Comments of the Staff of the
Bureau of Consumer Protection

function of the body (structure/function claim), and thus be permitted in labeling. The proposed rule also establishes criteria for determining when a label statement would be considered a claim about a supplement's ability to diagnose, cure, mitigate, treat, or prevent disease (disease claim), and thus be prohibited in labeling. Because the Federal Trade Commission (FTC) has jurisdiction over claims made in supplement advertising, the staff of the FTC's Bureau of Consumer Protection is submitting this comment on an issue that is central to both agencies' treatment of dietary supplements: the requirement that claims for dietary supplements be substantiated.

II. BACKGROUND

The FTC and FDA have complementary jurisdiction to address the marketing of dietary supplements. Under the terms of a liaison agreement governing the division of responsibilities between the two agencies, the FTC has primary responsibility for advertising and FDA has primary responsibility for labeling.(1) Their shared jurisdiction means that the two agencies coordinate closely to ensure that their actions are consistent to the fullest extent feasible given the statutory authority of each.

The regulation of supplement labeling claims by FDA is governed by the Dietary Supplement Health and Education Act of 1994 (DSHEA).(2) Under Section 6 of DSHEA, codified as Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDCA), structure/function claims are permitted in dietary supplement labeling without prior authorization by FDA, provided the manufacturer has substantiation for the claims and complies with certain notification and disclaimer requirements.(3)

Claims made in supplement advertising are addressed primarily under the Federal Trade Commission Act (FTC Act). Section 5 of the FTC Act broadly prohibits deceptive and unfair acts or practices in or affecting commerce,(4) including deceptive advertising. In addition, supplement advertising falls under Sections 12 and 15 of the FTC Act.

These two sections prohibit false advertisements of foods, drugs, devices, services and cosmetics, which are defined as advertisements that are misleading in a material respect.(5) The FTC has developed a legal framework for assessing advertising claims pursuant to these provisions. This framework, set out in the FTC's Deception Policy Statement and its Substantiation Policy Statement,(6) can be distilled into two fundamental legal principles: 1) advertising must be truthful and not misleading; and 2) advertisers must have substantiation for all objective claims before the claims are disseminated.(7)

III. SUBSTANTIATION OF STRUCTURE/FUNCTION CLAIMS

Under Section 403(r)(6) of the FDCA,3(t)2(h)10

The FTC's application of this standard shares many similarities with the Supplement Commission Report's proposal for "scientifically valid evidence." Consistent with the Supplement Commission's guidance, the FTC considers all forms of research when evaluating substantiation. As a general matter, the FTC considers well-controlled human clinical studies to be the most reliable form of evidence, but also takes into account other forms of research, including epidemiologic evidence, animal and in vitro studies in appropriate circumstances.(20) Like the Supplement

7. While the majority of advertising cases are brought pursuant to the FTC's deception authority, the agency can also challenge advertising under its unfairness jurisdiction. An unfair practice is one that causes, or is likely to cause, substantial injury to consumers, which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. 15 U.S.C. § 45 (n).

8. 21 U.S.C. § 343(r)(6)(B).

9. The current rule implementing the notification procedures for structure/function claims, includes the provision that the firm must certify that it has "substantiation that the statement is truthful and not misleading." 21 C.F.R. § 101.93 (a)(3).

10. 21 C.F.R. § 101.93 (f) (proposed). The new provision on structure/function claims merely states that dietary supplement labels may bear such claims "subject to the requirements of this section."

11. Staff suggests including an explicit reference to the substantiation requirement in proposed Section 101.93(f).

12. Report of the Commission on Diet

21. In its Food Policy Statement, for example, the FTC provided that, when a claim is based on science that is inconsistent with the larger body of evidence, it is likely to be misleading, even if qualified. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28388, 28393-94 (June 1, 1994).

22. FDA's notice states, "The Commission Report includes guidance on what quantity and quality of evidence should be used to substantiate claims made under section 403(r)(6) of the act.... The agency agrees with the guidance." Dietary Supplements; Comments on Report of the Commission on Dietary Supplement Labels, 63 Fed. Reg. 23633, 23635 (April 29, 1998).