UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of GENERAL NUTRITION CORPORATION, a corporation, also trading as NATURAL SALES COMPANY, and DAVID B. SHAKARIAN, individually and as an officer of said corporation.	)	DOCKET NO. C-1517
In the Matter of GENERAL NUTRITION, INC. a corporation.	)	DOCKET NO. 9175

ORDER GRANTING IN PART AND DENYING IN PART REQUEST TO REOPEN THE PROCEEDING AND MODIFY CEASE AND DESIST ORDER IN DOCKET NO. C-1517 AND DENYING REQUEST TO REOPEN AND MODIFY CEASE AND DESIST ORDER IN DOCKET NO. 9175

On May 7, 1999, General Nutrition, Inc. ("GNC") filed a request to reopen the proceedings in Docket No. C-1517[1] and 9175[2], and to modify the orders issued by the Commission, pursuant to Section 5(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(b), and Section 2.51 of the Commission's Rules of Practice, 16 C.F.R. § 2.51.[3] The request was placed on the public record for 30 days for comment. No comments were filed. GNC also requests that the Commission seek the Department of Justice's assistance in asking a federal court to modify a 1994 consent decree[4] enjoining GNC from violating these two orders and from making deceptive claims for any hair loss product.

I. THE ORDERS AND THE DECREE

[1] 75 F.T.C. 529 (1969), *modified*, 77 F.T.C. 1458 (1970) ("1969 order").

[2] 111 F.T.C. 387 (1989) ("1989 order").

[3] Pursuant to Section 3.72(b)(3)(ii) of the Rules of Practice, 16 C.F.R. § 3.72(b)(3)(ii), these two administrative orders will terminate no sooner than April 28, 2014.

[4] Civil No. 94-686 (W.D. Pa. May 20, 1994).

The 1969 order applies to all food or drug preparations containing vitamins and/or minerals marketed by GNC and its "officers . . . agents, representatives and employees, directly or through any corporate or other device." Paragraph 1(a) prohibits GNC from claiming the use of any such preparation will be of benefit in the prevention, relief or treatment of any symptom unless: (1) the claim is expressly limited to a symptom caused by a deficiency of one or more of the vitamins or iron provided by the preparation; and (2) GNC discloses that the preparation will not prevent, treat, or relieve the symptom for the vast majority of persons suffering from such symptom; and that the presence of an iron or vitamin deficiency cannot be self-diagnosed and can be determined only by tests conducted under a physician's supervision. Paragraphs 1(b)-(h) prohibit GNC from making specific false claims involving the body's ability to store vitamins B and C, the treatment of iron deficiency, and the diagnosis of iron or vitamin deficiencies.

Paragraph 2 prohibits GNC from disseminating any advertisement of a product advertised for sale by reason of its vitamin and/or mineral content which lists or refers to an ingredient, except in the name of such product, the need for which in human nutrition has not been established, or an ingredient whose presence is without nutritional significance, unless the advertisement discloses that the presence of such ingredient is without nutritional significance. Paragraph 2 also prohibits GNC from misrepresenting that the need for an ingredient for human nutrition has been established. In addition, Paragraph 2 contains a safe harbor providing that any regulation by the FDA affirmatively permitting a claim of nutritional significance for a vitamin or mineral in a specified amount will be accepted as evidence that the presence of that amount of the specified nutrient has nutritional significance.

On August 19, 1993, Commission staff from the Bureau of Consumer Protection's Division of Enforcement issued an advisory opinion addressing the scope of Paragraph 1(a) of the 1969 order.[5] The staff's advisory opinion states that Paragraph 1(a) applies only to food and drug preparations containing vitamins and/or minerals for which claims are made, directly or by implication, that the vitamin[s] or mineral[s] present in such preparations will be of benefit in the prevention of tiredness, etc. Thus, as interpreted by Commission staff, Paragraph 1(a) does not apply to a product marketed as effective in preventing tiredness provided the benefit is attributed to an ingredient other than any vitamins or minerals also present in the product.

The 1989 order is considerably broader than the 1969 order. Part I of the 1989 order prohibits GNC from making certain false cancer-related claims for "Healthy Greens" (a food supplement made from vegetables and containing various nutrients) or any substantially similar product. Part II prohibits GNC from making false claims relating to scientific evidence with respect to any product's ability to cure, treat, prevent or reduce the risk of developing any disease. Part III prohibits GNC from making certain muscle building, fat or weight loss, and other health-related claims for any free form amino acid containing arginine, ornithine, tryptophane or a combination thereof. Part IV prohibits GNC from using the expression "Growth Hormone

[5] *See* Letter from Justin Dingfelder, Asst. Dir., Div. of Enforcement, Bureau of Consumer Protection, FTC, to Christopher Smith, Arent Fox Kintner Plotkin & Kahn.

Releaser" or any similar expression as a brand name or product description, unless such product stimulates the production or release of greater amounts of human growth hormone in users than in non-users and GNC has substantiation for the claim. Part V prohibits GNC from making any unsubstantiated representation: (1) concerning any product's ability to cure, treat, prevent or reduce the risk of developing any disease; (2) that any product assists a user to lose or control weight or fat or suppress appetite; (3) that any product expands, extends, or prolongs life or retards aging; or (4) that any product aids a user in achieving greater or faster muscular development, greater endurance, strength, power or stamina, or shorter exercise recovery time.[6] Like the 1969 order, Parts I through V of the 1989 order apply to GNC and its "officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device." Part VI required GNC to pay $600,000 to the American Diabetes Association, the American Cancer Society, and the American Heart Association. Parts VII to X require recordkeeping, notice of corporate status changes, the filing of a compliance report, and distribution of the order to GNC's divisions and distributors.

In 1994, the Commission brought an enforcement action against GNC alleging numerous violations of the 1969 and 1989 orders, as well as Sections 5(a) and 12 of the FTC Act. GNC settled the action by agreeing to pay a $2.4 million civil penalty and to the entry of an injunction prohibiting GNC and its "officers, agents, representatives and employees . . . directly or through any corporation, subsidiary, division, or other device" from violating the 1969 and 1989 orders. The injunction also prohibits false and unsubstantiated claims regarding the ability of any product or service to prevent, cure, relieve, reverse or reduce hair loss, or promote the growth of hair, where hair has already been lost. Paragraph 6 of the consent decree provides that: "In the event that either the 1989 or the 1970 Order [the 1969 order] is hereafter modified, defendant's compliance with such Order as so modified shall not be deemed a violation of this injunction."

II. STANDARD FOR REOPENING A FINAL ORDER

Section 5(b) of the FTC Act provides that the Commission shall reopen an order to consider whether it should be altered, modified, or set aside if the respondent makes "a satisfactory showing that changed conditions of law or fact" so require.[7] A satisfactory showing

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[6] Part V contains a "safe harbor" providing that GNC shall not be liable under this paragraph for any representation contained on a package label or package insert for a product that meets all of the following conditions: (1) the product is manufactured and distributed by a third party and is not manufactured or distributed exclusively for GNC; (2) the product is generally available at competing retail outlets; (3) the product is not identified with GNC and does not contain GNC's name or logo; (4) the product was not developed or manufactured at the instigation or with the assistance of GNC; and (5) the product representation is not otherwise advertised or promoted by GNC.

[7] Section 5(b), as amended in 1980, provides, in part:

> [T]he Commission may at any time . . . reopen and alter, modify, or set aside, in whole or

sufficient to require reopening is made when a request identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of the order inequitable or harmful to competition. *Louisiana Pacific Corp.,* Docket No. C-2956, Letter to John C. Hart (June 5, 1986) at 4.

Generally in determining whether to modify an order based on a *change in fact*, the Commission requires that the change be one that was unforeseeable.[8] In a dynamic economy, change is predictable and inevitable. But, the nature and type of change are not necessarily foreseeable. The Commission has recognized marketplace realities in evaluating whether petitions have demonstrated that a change was not reasonably foreseeable.

For example, in *Beneficial Corp.*, 108 F.T.C. 168, 171 (1986), the petitioners asked the Commission to reopen and modify a 1979 order addressing their marketing of tax return preparation services based on change in fact and law, and on public interest grounds. The petitioners argued, among other things, that their tax return preparing personnel were now required to undergo more extensive training compared to the training required at the time of the order's issuance. *Id.* at 171. The petitioners further argued that this constituted a change in fact warranting modification of Paragraph Six, which was an absolute prohibition against representations regarding the competence of the petitioners' tax return preparing personnel. The petitioners asked the Commission to modify Paragraph Six to prohibit them from "misrepresenting, in any manner, the competence or the ability of respondents' tax preparing personnel." *Id.* The Commission held that the petitioners had demonstrated a change in fact warranting modification of Paragraph Six of the order so that it would only prohibit misrepresentations of competence or ability.[9]

> in part any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require.

The 1980 amendment to Section 5(b) did not change the standard for order reopening and modification, but "codifie[d] existing Commission procedure by requiring the Commission to reopen an order if the specified showing is made," S. Rep. 96-500, 96th Cong., 2d Sess. 9-10 (1979), and the amendment added the requirement that the Commission act on petitions to reopen within 120 days of filing.

[8] *See Phillips Petroleum Co.,* 78 F.T.C. 1573, 1575 (1971) (modification not required for changes reasonably foreseeable at time of consent negotiations); *Pay Less Drugstores Northwest, Inc.*, Docket No. C-3039, Letter to H.B. Hummelt (Jan. 22, 1982) (changed conditions must be unforeseeable, create severe competitive hardship and eliminate dangers that the order sought to remedy) (unpublished); *see also United States v. Swift & Co.*, 286 U.S. 106, 119 (1932) ("clear showing" of changes that eliminate reasons for order or such that order causes unanticipated hardship).

[9] *See also Union Carbide Corp.,* 108 F.T.C. 184, 188 (1986)(petitioner's sale of welding products and gas welding apparatus operations warranted deletion of references to these product

In determining whether to modify an order based on a *change in law,* the Commission decides whether the change brings the order into conflict with existing law. *Union Carbide Corp.*, 108 F.T.C. 184, 186 (1986). In *Kroger Co.*, 113 F.T.C. 772, 775-76 (1990), the Commission modified the order to make it consistent with the amended Unavailability Rule, 16 C.F.R. § 424, in part based on changed conditions of law. In its petition, Kroger argued that it was in the position of violating the order by complying with the amended Rule or violating the amended Rule by complying with the order. *Id.* at 774. The Commission concluded that the amendments to the Rule brought the terms of the order into conflict with the Rule. *Id*. at 776. In *Bulova Watch Co.*, 102 F.T.C. 1834 (1983), the Commission found that the Supreme Court's ruling in *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 57-59 (1977), that non-price vertical restraints such as transshipment restrictions are not *per se* illegal, but instead should be evaluated pursuant to the rule of reason, constituted a change in law warranting deletion of the order's transshipment provisions. Thus, a change in law may warrant modification of an order if, because of a change in law, the order prohibits conduct that would or could be permissible absent the order (even if it is possible to comply with the order and the changed law simultaneously). A change in law need not result in a direct conflict to warrant reopening. In *ITT Continental Baking Co.*, 102 F.T.C. 1298 (1983), the Commission held that the passage of the Hart-Scott-Rodino Act constituted a change in law requiring an order modification because it overlapped with the order's disclosure requirements.

Section 5(b) also provides that the Commission may reopen and modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest so requires. The Commission recently reopened and modified an order on public interest grounds, because the reasons to modify the order outweighed the reasons to retain it as written. *Schnuck Markets, Inc.*, Docket No. C-3585 (June 2, 1998) (modifying prohibition on removal of equipment from supermarkets owned by respondent to allow respondent to make a specified charitable donation to a college of used equipment from a store closed for nearly three years). There, the Commission concluded that there was only a slight possibility that the original purpose of the prohibition -- to make it more likely that any supermarket closed by respondent would be reopened as a supermarket by someone else -- would be affected by the modification, and this possibility was outweighed by the possible detrimental impact on the respondent's public image and the public benefits to the college of retaining the prohibition. Id. at 3.

The language of Section 5(b) indicates that the requester has the burden of making "a satisfactory showing" of changed conditions to obtain reopening of the order. *See Gautreaux v. Pierce*, 535 F. Supp. 423, 426 (N.D. Ill. 1982) (requester must show "exceptional circumstances, new, changed or unforeseen at the time the decree was entered"). The legislative history also

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lines from the order on change in fact and public interest grounds); *General Mills Fun Group, Inc.*, 106 F.T.C. 607 (1985)(sale of the subsidiary that had engaged in violative conduct deemed a change in fact warranting modification); *Genstar Ltd.*, 104 F.T.C. 264 (1984)(increased capacity in the relevant market required reopening and modification of the order); *AHC Pharmcal*, 101 F.T.C. 40 (1983)(corrective advertising requirement deleted in part because of respondent's changed financial condition).

makes clear that the requester has the burden of showing, by means other than conclusory statements, why an order should be modified.[10]

If the Commission determines that the requester has made the necessary showing, the Commission must reopen the order to determine whether the modification is required and, if so, the nature and extent of the modification. The Commission is not required to reopen the order, however, if the requester fails to meet its burden of making the satisfactory showing of changed conditions required by the statute. The requester's burden is not a light one in view of the public interest in repose and finality of Commission orders.[11]

III. PETITIONER'S REQUEST AND ANALYSIS

GNC alleges that changes in law and fact, as well as public interest considerations, warrant reopening and modifying the orders and decree. GNC requests that the Commission modify the 1969 order by:

> (1) replacing Paragraph 1, which prohibits a number of specific claims and requires certain triggered disclosures, with a provision prohibiting GNC from making any unsubstantiated claim that the presence of any vitamin or mineral will prevent, relieve, or treat any symptom or that the presence of any vitamin or mineral deficiency can be self-diagnosed;
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> (2) deleting Paragraph 2, a disclosure requirement regarding the nutritional significance of certain food ingredients, and Paragraphs 3 and 4, two provisions that are no longer necessary in light of the proposed changes to Paragraph 1 and the deletion of Paragraph 2;
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> (3) adding "safe harbors" providing that nothing in the order shall prohibit GNC

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[10] The legislative history of amended Section 5(b), S. Rep. No. 96-500, 96th Cong., 2d Sess. 9-10 (1979), states:

> Unmeritorious, time-consuming and dilatory requests are not to be condoned. A mere facial demonstration of changed facts or circumstances is not sufficient . . . The Commission, to reemphasize, may properly decline to reopen an order if a request is merely conclusory or otherwise fails to set forth specific facts demonstrating in detail the nature of the changed conditions and the reasons why these changed conditions require the requested modification of the order.

[11] *See Federated Department Stores, Inc. v. Moitie*, 452 U.S. 394 (1981) (strong public interest considerations support repose and finality); *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 296 (1974) ("sound basis for . . . [not reopening] except in the most extraordinary circumstances"); *RSR Corp. v. FTC*, 656 F.2d 718, 721-22 (D.C. Cir. 1981) (applying *Bowman Transportation* standard to FTC order).

from making any representation: (a) that is specifically permitted in labeling by regulations promulgated by the Food and Drug Administration ("FDA") pursuant to the Nutritional Labeling and Education Act of 1990 or sections 303-304 of the Food and Drug Administration Modernization Act of 1997; or (b) that is permitted in labeling under any tentative final or final standard or monograph promulgated by the FDA, or under any new drug application approved by the FDA;

(4) adding three definitions and deleting two administrative provisions imposing one-time requirements that GNC distribute the order and file a compliance report; and

(5) dropping the individual respondent who is now deceased.

In addition, GNC requests that the Commission modify the 1969 and 1989 orders and seek modification of the 1994 consent decree to add a new provision limiting GNC's liability for the actions of its franchisees and licensees. This provision would require GNC to bind its franchisees and licensees contractually to comply with the respective order or decree, notify non-complying franchisees and licensees that they are violating the respective order or decree, and report non-complying franchisees and licensees to the FTC if they continue to violate the respective order or decree after receiving such notice. It would also provide that GNC's compliance with the new provision shall constitute an affirmative defense to any civil penalty action arising from the conduct of a franchisee or licensee provided GNC has not authorized, approved or ratified the conduct and has reported that conduct promptly to the FTC.

On August 30, 1999, GNC submitted a new proposed provision limiting its liability for the conduct of its franchisees and licensees. Unlike GNC's first proposed modification, this new provision would require GNC to monitor advertising of its franchisees and licensees. It would also provide that the affirmative defense is not available to GNC unless the company has "diligently pursued reasonable and appropriate remedies available under the franchise or license agreement and applicable state law to bring about the cessation of that conduct by the franchisee or licensee" in cases where the franchisee or licensee conduct constitutes a material or repeated violation of the order.

A. GNC's Proposed Modifications of the 1969 Order

1. GNC's Request and Rationale

GNC requests that the Commission modify the 1969 order by replacing it with the following language:

ORDER

For purposes of this order, the following definitions shall apply:

A. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

B. Unless otherwise specified, "respondent" shall mean General Nutrition, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.

C. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising of any food, dietary supplement, or drug containing any vitamin or mineral, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and as "dietary supplement" is defined in Section 201(ff) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(ff), in or affecting commerce, shall not make any representation, in any manner, expressly or by implication:

A. That the presence of any vitamin or mineral in any such food, dietary supplement, or drug will be of benefit in the prevention, relief or treatment of tiredness, listlessness, lack of normal appetite, "depleted" feeling, "run-down" feeling, easy fatigability or any other symptom; or

B. That the presence of any vitamin or mineral deficiency can be self-diagnosed;

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or to Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

III.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard or monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

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GNC asserts that the proposed modification would simplify the order and reconcile the scope of Paragraph 1 with staff's 1993 advisory opinion, and that the modification is warranted on public interest grounds. GNC maintains that Paragraph 1 as currently worded is ambiguous in that it does not precisely define the advertising claims that trigger the disclosure requirement. GNC relies on *Encyclopedia Britannica, Inc.* 111 F.T.C. 1 (1988), a case where the Commission reopened and modified the order on public interest grounds to effectively eliminate any conceivable ambiguity in a provision requiring verbal disclosures during telephone sales presentations by establishing a bright line standard to measure future compliance. GNC contends that it is impractical for it to make the lengthy disclosures required by Part 1(a), and that as a result, this provision operates in effect as a ban on the claims triggering the disclosure requirement.[12] GNC further maintains that it cannot rely on the 1993 staff advisory opinion described earlier because the staff's interpretation of the order may change in the future. GNC thus argues that there is an affirmative need to modify this provision to provide legal certainty regarding the scope of the provision.

GNC asserts that deletion of Paragraph 2 is warranted on public interest and change in law grounds. GNC relies on *Firestone Tire & Rubber Co.*, 114 F.T.C. 450 (1991), a case where the Commission reopened and set aside an order as to respondent Shell Oil Co. on change in law grounds. The Commission set aside the order as to Shell because the legal standard for liability relating to tying and nonprice vertical restraints had changed. GNC argues that the Paragraph 2 affirmative disclosure requirement no longer comports with the current state of Food and Drug Administration ("FDA") regulations pertaining to dietary supplements, and that it is contrary to the regulatory scheme for supplements created by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). GNC maintains that the parties intended Paragraph 2 to track the then-current FDA regulations concerning the labeling of products containing vitamins and minerals. At that

[12] As noted earlier, Paragraph 1(a) requires GNC to disclose that the preparation will not prevent, treat, or relieve the symptom for the vast majority of persons suffering from such symptom; and that the presence of an iron or vitamin deficiency cannot be self-diagnosed and can be determined only by tests conducted under a physician's supervision.

time, the FDA required labeling disclaimers for certain vitamin and mineral ingredients for which no need in human nutrition has been established. Because the FDA no longer requires such disclaimers, GNC contends the Commission should delete Paragraph 2. If the Commission does not delete Paragraph 2 as requested, GNC will be subject to disclosure requirements to which the rest of the supplement industry is no longer subject to as a result of DSHEA and the changes in FDA regulations.

GNC also argues that the disclosures required by Paragraph 2 conflict with disclosures required by DSHEA and could generate confusion. DSHEA requires the following disclaimer to appear in conjunction with claims of nutritional support: "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." GNC contends that the disclaimer required by Paragraph 2 (*i.e.*, this ingredient is without nutritional significance) conflicts with the DSHEA disclaimer. To illustrate this point, GNC offers a hypothetical example involving the FDA's proposal to permit the statement "to meet nutritional needs during pregnancy" on labeling for a supplement provided the statement can be properly substantiated. GNC asserts that it could have substantiation for this statement as to a particular vitamin or mineral, yet be unable to establish a need in human nutrition for the vitamin or mineral. If so, GNC contends, its advertising would confuse consumers by stating "Product X contains ingredient Y which helps meet nutritional needs during pregnancy" along with the DSHEA disclaimer and the Paragraph 2 disclaimer "this ingredient is without nutritional significance.[13]

GNC also argues that modifying Paragraph 2 would serve the public interest by enabling GNC to market products in accordance with DSHEA without risking a regulatory challenge from the FTC based on the Paragraph 2 disclosure requirement, and that GNC has therefore demonstrated an affirmative need to modify Paragraph 2. GNC maintains that the modification would also serve the public interest by preventing any potential confusion about the value of certain vitamins and minerals stemming from the Paragraph 2 disclosure requirement.

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[13] As explained in more detail below, GNC's argument lacks merit. If GNC can substantiate a claim that a particular vitamin or mineral helps meet nutritional needs during pregnancy and the FDA permits such a claim to be made, it arguably follows that a need for the vitamin or mineral in human nutrition has been established. If the need for a particular vitamin or mineral has been established, Paragraph 2 does not require GNC to make any disclosures in advertising for such vitamin or mineral. GNC would not have to disclose which symptoms, if any, are prevented, relieved or treated by the vitamin or mineral.

2. Analysis

GNC has demonstrated that changes in law and the public interest warrant reopening the 1969 order. Without modification, the 1969 order potentially could prohibit truthful advertising claims and require disclosure of inaccurate or irrelevant information to consumers.

a. Paragraph 1

The public interest warrants modification of Paragraph 1. Paragraph 1(a) of the 1969 order prohibits GNC from disseminating an advertisement claiming that the use of any food or drug preparation will be of benefit in the prevention, relief or treatment of any symptom unless: (1) the claim is expressly limited to a symptom caused by a deficiency of one or more of the vitamins or iron provided by the preparation; and (2) GNC makes certain disclosures. Theoretically, this provision as interpreted by Commission staff in 1993 could prohibit a truthful claim that a vitamin or iron prevents, relieves or treats a symptom (*e.g.*, a situation where there is evidence that taking more than the recommended daily allowance of a vitamin would help prevent, relieve, or treat a symptom). The modification sought by GNC would enable it to make any substantiated symptom prevention, relief or treatment claim for a vitamin or mineral, regardless of whether such symptom is related to a vitamin or mineral deficiency.

In addition, the substitute language would not require GNC to make the three lengthy disclosures required by Paragraph 1(a) of the order. GNC must make these disclosures if the triggering claim is for any vitamin or for iron. As a result, the order could require GNC to make irrelevant or even inaccurate disclosures. For example, if GNC advertised truthfully that a vitamin helps prevent a symptom other than fatigue, Paragraph 1(a)(1) of the order would require GNC to disclose that for the great majority of consumers the product will be of no benefit in the prevention of such symptom. This disclosure could be inaccurate. Such a claim would also trigger the requirement in Paragraph 1(a)(2) that GNC disclose that the presence of iron deficiency anemia or iron deficiency of any degree cannot be self-diagnosed and can be determined only by means of medical or laboratory tests conducted by or under the supervision of a physician. This disclosure could be irrelevant to the claim that triggers it. This claim would also trigger the requirement in Paragraph 1(a)(3) that GNC disclose that the presence of a deficiency of the B vitamins, or of any vitamin, cannot be self-diagnosed and can be determined only by means of medical or laboratory tests conducted by or under the supervision of a physician. This disclosure could be of dubious value to consumers considering supplementation.

Paragraph 1(a) of the order is even more problematic if one interprets it literally instead of interpreting it as the Commission staff did in its 1993 advisory opinion. Interpreted literally, Paragraph 1(a) would require GNC to make the disclosures described above in advertising for a product containing an ingredient that is effective in treating a symptom and one or more vitamins or iron for which no claim regarding the treatment of any symptom is made. It would make no sense to require GNC to make the Paragraph 1(a) disclosures in this context. For example, if GNC marketed a product containing an ingredient proven effective in treating nasal congestion plus vitamins or iron, there would be no reason to require a disclosure that the great majority of persons suffering from nasal congestion will not benefit from the product. This disclosure would

contradict the truthful claim being made for the product and could confuse consumers. Similarly, there would be no reason to require a disclosure that the presence of an iron or vitamin deficiency cannot be self-diagnosed and can be determined only through medical tests. This disclosure would be irrelevant to the efficacy claims being made for the product.

Paragraphs 1(b)-(h) of the order prohibit a number of specific claims relating to the body's ability to store any B Complex Vitamin or Vitamin C; the effectiveness of ingredients other than iron in treating iron deficiency anemia; vitamin or mineral deficiencies accompanying iron deficiency; and the ability of consumers to self-diagnose vitamin or iron deficiencies. These provisions could at some point prohibit truthful claims if, for example, scientific advances make it possible for consumers to self-diagnose deficiencies without the aid of a physician. The proposed modification of the order simplifies these provisions by replacing them with a substantiation requirement for symptom prevention, relief and treatment claims as well as claims that the presence of a vitamin or mineral deficiency can be self-diagnosed.

For these reasons, we conclude that the public interest warrants modification of Paragraph 1. The order as modified will require GNC to substantiate the relevant claims, but will no longer prohibit truthful claims nor require disclosure of inaccurate or irrelevant information.

b. Paragraph 2

GNC correctly asserts that FDA regulation of dietary supplements has changed substantially since 1970, the last time the Commission modified Paragraph 2. As a result of these changes in FDA regulation, Paragraph 2 requires GNC to make disclosures that other supplement companies need not make. Although it is not uncommon for companies under FTC order to be in this position, in this case Paragraph 2 was initially drafted to ensure that GNC's advertising contained the same disclosures required in labeling by the FDA.[14]

In 1970 FDA regulations required the labeling disclosure: "The need for X in human nutrition has not been established" for vitamin and mineral ingredients for which no minimum daily requirement had been established.[15] This appears to have been consistent with the prevailing scientific view that the benefits of supplements were limited to prevention of deficiencies. The

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[14] GNC's April 1970 Motion for Amendment to Order to Cease and Desist asserts that the "sole purpose . . . of Paragraph 2 of the Order was to bring any listing of ingredients in any advertisement predicated upon alleged vitamin or mineral efficacy into conformity with any listing of ingredients shown on the labels for the advertised products." The FTC staff's Answer to Respondents' Motion for Amendment to Order to Cease and Desist did not dispute this assertion. In 1970 the Commission modified the order by, among other things, adding a safe harbor providing that any FDA regulation permitting claims of nutritional significance of a vitamin or mineral in a specified amount will be accepted as evidence that the presence of that amount of the specified nutrient has nutritional significance.

[15] 21 C.F.R. §§ 125.3(a)(2), 125.4(a)(2) (1970).

enactment of DSHEA in 1994 reflected a broader view of the benefits of supplements. DSHEA explicitly permits statements of nutritional support[16] on supplement labeling regardless of whether the FDA has recognized the ingredient in question to be of significant nutritional value. FDA has revised its regulations to be consistent with DSHEA and no longer requires the nutritional significance disclaimer on food supplement labels.

In passing DSHEA in 1994, Congress stated that the "Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." Section 6 of DSHEA allows a statement for a dietary supplement to be made if:

> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
> (C) the statement contains, prominently displayed and in boldface type, the following: "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."

Section 7 of DSHEA provides that ingredients for which a recommendation for daily consumption has been established are listed first. Other ingredients are listed next. DSHEA requires listing such ingredients but does not require or prohibit disclosures regarding the absence of nutritional significance.

Subsequent to the enactment of DSHEA, the FDA modified its regulations in several respects. For example, FDA deleted 21 C.F.R. § 101.9(k)(5), a provision stating that a food is misbranded if its label or labeling represents, suggests, or implies that "the food has dietary properties when such properties are of no significant value or need in human nutrition," to eliminate any inconsistency between FDA regulations and Section 6 of DSHEA.

Paragraph 2 of the 1969 order is not directly inconsistent with DSHEA, given the latter's application to the FDA and not the FTC. However, Paragraph 2 is inconsistent with Congress' intent that the federal government not impose unreasonable limits on the provision of accurate information to consumers, because it could chill advertising permitted under the DSHEA. If GNC lists an ingredient, it must, unlike its competitors operating under amended FDA regulations,

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[16] A claim of "nutritional support" is a term used in DSHEA to describe a claim regarding an effect on the structure or function of the human body, as opposed to a claim about the prevention or cure of disease.

disclose that the presence of the ingredient is without nutritional significance unless the need for the ingredient has been established.

Accordingly, we conclude the passage of DSHEA and the evolution of FDA regulations constitute a change in law warranting modification of Paragraph 2. This provision was designed to track the FDA regulations in effect in 1970 so as to ensure that GNC's advertising set forth the same disclosures required on labels by FDA. The FDA disclosure requirements effective in 1970 no longer exist. Therefore, the law has changed in that companies marketing food supplements are no longer required to make these disclosures on their product labels.

In addition, public interest considerations support the modification sought by GNC. Paragraph 2 requires GNC to make advertising disclosures that its competitors need not make and that may in some instances confuse consumers regarding the value of certain nutrients. Deletion of Paragraph 2 would promote a level playing field in the supplement industry by eliminating disclosure requirements based on defunct FDA regulations and applicable only to GNC.

c. Other Issues

GNC proposes two FDA safe harbors commonly included in orders addressing claims for food and drug products. The NLEA safe harbor is standard, except that it also covers any representation for any product that is specifically permitted in labeling for such product by FDA regulations promulgated pursuant to Sections 303-304 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). Sections 303-304 of FDAMA permit advertisers to make health claims for their food products if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences. This safe harbor applies only to any claim that FDA has "specifically permitted" by promulgating a regulation permitting the claim pursuant to the NLEA or FDAMA. This safe harbor would not apply to a claim that FDA has permitted by taking no action with respect to the claim.

GNC also proposes to add three standard definitions of "competent and reliable scientific evidence," " the respondent," and "commerce"; and to delete two administrative provisions that imposed one-time obligations on GNC to distribute the order and file a compliance report. In addition, GNC proposes to drop the individual respondent who is now deceased.

Finally, GNC proposes to delete Paragraphs 3 and 4 of the order. Paragraph 3 prohibits the dissemination of advertisements containing statements which are inconsistent with any of the affirmative disclosures required by Paragraphs 1 or 2 of the order. This paragraph would serve no purpose after elimination of the disclosure requirements in Paragraphs 1 and 2. Paragraph 4 prohibits the dissemination of any advertisement which contains any of the representations prohibited by Paragraphs 1 and 2 or that fails to comply with the disclosure requirements in Paragraphs 1 and 2. This paragraph merely restates the prohibition on making claims prohibited by Paragraph 1 and requires compliance with disclosure requirements that will no longer exist.

The changes discussed above serve the public interest by simplifying the order, deleting

requirements already fulfilled by GNC or made obsolete by the death of the individual respondent, and conforming the order to modern practice.

B. GNC's Proposed Limitation of its Liability for the Conduct of Franchisees and Licensees

1. GNC's Request and Rationale

GNC also requests that the Commission reopen the 1969 and 1989 orders and add a new provision limiting its liability for the conduct of GNC franchisees and licensees. In addition, GNC requests that the Commission seek modification of the 1994 consent decree by adding an identical provision. GNC's petition proposes to add the following provision to each order and the decree:

> Respondent shall distribute a copy of this Order to each of its franchisees and licensees and shall contractually bind them to comply with the prohibitions and affirmative requirements of this Order;
>
> Respondent may satisfy this contractual requirement by incorporating such Order requirements into its Franchisee Operations Manual or license agreements with its licensees; and
>
> Respondent shall further make reasonable efforts to monitor its franchisees' and licensees' compliance with the Order provisions; respondent may satisfy this requirement by: (1) taking reasonable steps to notify promptly any franchisee or licensee that respondent determines is failing materially or repeatedly to comply with any Order provision that such franchisee or licensee is not in compliance with the Order provisions and that disciplinary action may result from such noncompliance; and (2) providing the Federal Trade Commission with the name and address of the franchisee or licensee and the nature of the noncompliance if the franchise or licensee fails to comply promptly with the relevant Order provision after being so notified;
>
> provided, however, that respondent's compliance with this Part shall constitute an affirmative defense to any civil penalty action arising from an act or practice of one of respondent's franchisees or licensees that violates this Order where respondent: (a) has not authorized, approved or ratified that conduct; and (b) has reported that conduct promptly to the Federal Trade Commission under this Part.

On August 30, 1999, GNC submitted a new proposed provision limiting its liability for the conduct of its franchisees and licensees and advised that this new provision replaces the provision set forth in the petition:

> Respondent shall distribute a copy of this Order to each of its franchisees and licensees; Respondent shall contractually bind its franchisees to comply with the requirements of this Order; Respondent shall contractually bind its licensees to comply with the Order as it

pertains to licensed products;

Respondent may satisfy this contractual requirement by incorporating such Order requirements into its Franchisee Operations Manual or license agreement with its licensees; and

Respondent shall further use its best efforts to obtain its franchisees' and licensees' compliance with this Order by doing the following:

(1) Respondent shall distribute a copy of this Order to each of its franchisees or licensees;

(2) Respondent shall review advertising and promotional materials submitted to it from its franchisees or licensees prior to dissemination and publication to determine compliance with the requirements of this Order;

(3) Respondent shall notify any franchisee or licensee in writing if any advertising or promotional material does not comply with the requirements of this Order and that it should not be disseminated or published;

(4) Respondent shall monitor franchisee and licensee advertising and where it finds advertising that has not been submitted to it and which it believes is not in compliance with the requirements of this Order, it will notify such franchisee or licensee in writing of its findings and that such advertising should be withdrawn;

(5) Respondent shall maintain separate files for each franchisee or licensee containing copies of any correspondence relating to any advertising and promotional materials with respect to the issues raised by this Order for a period of three (3) years; and

(6) Upon request, Respondent shall make these files available to the Commission staff for inspection and copying.

Provided, however, that Respondent's compliance with this Part shall constitute an affirmative defense to any civil penalty action arising from an act or practice of one of Respondent's franchisees or licensees that violates this Order where Respondent: (a) has not authorized, approved or ratified that conduct; (b) has reported that conduct promptly to the Federal Trade Commission under this Part; and (c) in cases where that franchisee's or licensee's conduct constitutes a material or repeated violation of the Order, has diligently pursued reasonable and appropriate remedies available under the franchise or license agreement and applicable state law to bring about a cessation of that conduct by the franchisee or licensee.

# # #

GNC asserts that this modification is warranted on public interest and change in fact grounds. To support its contention that the public interest warrants this modification, GNC relies

on *Tarra Hall Clothes, Inc.*, 115 F.T.C. 920 (1992), a case where the Commission reopened and modified the order on public interest grounds. The Commission modified a requirement that prohibited the importation of wool products unless the respondents filed a bond with the Secretary of the Treasury by limiting the scope of the bonding requirement to recycled wool products. The Commission held that the public interest may warrant a modification if intrinsic fairness dictates the modification.

GNC argues that the relief it seeks is consistent with the relief obtained by the respondents in *Tarra Hall*. GNC explains that, just as the *Tarra Hall* respondents did not seek the elimination of the bonding requirement, GNC does not seek to abdicate all responsibility for its franchisees' and licensees' conduct. Instead, GNC maintains, it only seeks to avoid liability for the unlawful conduct of franchisees and licensees if it has not authorized, approved or ratified the conduct and takes other actions as explained above.

GNC contends that it has demonstrated an affirmative need to modify the orders and decree in this way so as to prevent the imposition of strict liability for the acts of its franchisees and licensees. GNC asserts that it has over 1,200 domestic franchises, and plans to add an additional 240 franchises during the current fiscal year. GNC also asserts that it has established a strategic alliance with Rite Aid Corporation in which Rite Aid as a licensee is expected to open GNC stores inside 1,500 Rite Aid locations during the next three years. GNC claims that it cannot exercise sufficient control over these franchises and licensees to ensure compliance with the orders and decree. Thus, GNC maintains, fairness dictates that it should not be strictly liable for the acts of its franchisees and licensees.

GNC also contends that it is unreasonable to hold it liable for the acts of its franchisees and licensees because they are not its agents. GNC argues that it does not exert sufficient control over the day-to-day operations of the franchisees and licensees to establish an agency relationship. GNC submitted a copy of its standard franchise agreement and cites several court cases addressing whether an agency relationship exists.

GNC also argues that the Commission has reopened and modified orders on public interest grounds to bring them into conformity with Commission policy. In *Schnuck Markets*, GNC notes, the Commission modified the order to convert the prior approval requirement into a prior notice requirement, to make the order consistent with the Commission's *Statement of Federal Trade Commission Policy Concerning Prior Approval and Prior Notice Provisions*. GNC contends that the Commission has also set aside or modified several orders prohibiting price restrictions in cooperative advertising programs to bring the orders into conformity with the Commission's change in policy regarding the legal standard applied to such restrictions.

In this respect, GNC asserts that the modification it seeks is consistent with current Commission policy as expressed by a number of existing Commission orders against respondents that market products or services through a franchise system. GNC cites a number of recent orders containing provisions purportedly similar to the one it seeks. GNC also maintains that the modification would serve the public interest by clarifying the orders and the decree, none of which mention franchises. As a result, GNC argues, it must conduct its business in regulatory uncertainty.

The addition of the requested provision would clarify GNC's exposure under the order and be consistent with Commission policy as expressed in other Commission orders.

Finally, GNC maintains that the initiation and enormous expansion of its franchise operations constitute a change in fact warranting the requested modifications. GNC asserts that it could not have foreseen the initiation and expansion of its franchise operations at the time it agreed to the issuance of the 1969 and 1989 orders. GNC states that it did not initiate its franchise operations until mid-1988, over a year after GNC executed the consent agreement leading to the 1989 order. Although GNC's franchise operations existed when it agreed to the 1994 consent decree, GNC claims that it raised but did not press the franchise issue because both it and Commission staff agreed that the franchise issue would be more appropriately addressed for the two orders and the decree collectively at some future time.[17]

2. Analysis

GNC has not demonstrated that the public interest or changes in fact warrant reopening and modification of the two orders or the decree by adding a provision limiting GNC's liability for the conduct of its franchisees and licensees.

[17] In 1994 Commission staff reviewed a draft order modification petition similar to the one currently pending before the Commission. At that time Commission staff advised GNC in writing that it could not support GNC's petition, concluding among other things that GNC would be liable for the acts of its franchisees.

a. There Are No Public Interest Grounds for Modifying the Orders or Decree

GNC maintains that public interest considerations warrant modification of the orders by addition of an affirmative-defense provision that protects GNC from liability for order violations, based on the actions of its franchisees and licensees, as long as GNC engages in specified types of monitoring of those entities. In support of this contention, GNC advances four arguments: (1) it would be unfair for the Commission to hold GNC strictly liable for the transgressions of its franchisees and licensees, because of the reduced control GNC exercises over those entities in comparison with its company-owned stores; (2) it would be unreasonable for GNC to be liable for the actions of its franchisees and licensees since no agency relationship exists between GNC and those entities; (3) provisions similar to the ones that GNC seeks appear in other Commission orders against companies that operate through franchisees or licensees, establishing a Commission policy favoring such provisions; (4) the requested modifications would clarify the terms of the orders. We find these arguments unpersuasive.[18]

(1) No Inequity Would Result from Any Determination that GNC Is Liable for Order Violations Based on Actions of Its Franchisees or Licensees

GNC's first argument misconceives the import of the absence from the orders of any provision relating to GNC's potential liability for the actions of its franchisees or licensees. The premise of GNC's argument is that, by their silence on this subject, the orders make it "strictly liable for its franchisees' and licensees' Order violations." That is a misreading of the orders. The orders, with minor variations in wording, impose compliance obligations upon GNC and its "officers, . . . agents, representatives and employees, directly or through any corporate or other device." Insofar as such language renders GNC liable for the acts of its franchisees and licensees, it simply reflects the well-established principle that a respondent may, where the public interest requires, be held liable under the FTC Act for violations committed by its agents or other similarly related entities or individuals, even where the respondent alleges that it cannot control or prevent those violations. The issue of GNC's liability for the actions of its franchisees and licensees is one that cannot be resolved in the abstract, but would depend on the particular facts and circumstances giving rise to a civil penalty action.[19] Therefore, contrary to the premise of GNC's

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[18] GNC also seeks to derive support for its position from *Tarra Hall Clothes, Inc.*, 115 F.T.C. 920 (1992), a case where the Commission reopened and modified the order on public interest grounds. The only point of similarity between *Tarra Hall* and the present matter is that in the former the respondent sought, and in the latter GNC seeks, what GNC describes as "a limitation, not an elimination" of an existing order requirement. The unexceptional proposition that the Commission may sometimes agree to a limited modification of an order does nothing to advance GNC's argument.

[19] We note that Commission staff have previously advised GNC of their view that GNC is in fact liable for the acts of its franchisees. *See supra* note 17. The question whether GNC may be

argument, the orders in their present form do not make GNC "strictly liable" for any order violations committed by its franchisees or licensees.

To the extent that GNC views its potential liability for the actions of its franchisees and licensees as "unfair," its disagreement is not with anything contained in the orders, which are silent on this point, but rather with the law of vicarious liability. GNC's argument therefore presents no grounds for modifying the orders.

(2) GNC's Contention that It Is Not in an Agency Relationship with Its Franchisees and Licensees Is of No Relevance

GNC's argument that the degree of its control over its franchisees and licensees is insufficient to establish an agency relationship under common law, whether correct or not, does not supply any basis for modifying the orders. As noted above, the orders are silent on this point. GNC's disagreement with the law of vicarious liability cannot justify any modification of the orders.

(3) There Is No Commission Policy Favoring Inclusion in Orders of the Provisions that GNC Seeks

GNC cites several Commission orders that contain provisions similar to the modification it proposes for its own orders, and argues that its orders should be modified to bring them into conformity with what it characterizes as "Commission policy." There is no such policy. While pointing to four[20] Commission orders that contain an affirmative defense provision of the sort GNC

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held to have violated the orders by virtue of the actions of its franchisees and licensees is, of course, ultimately one for the courts to decide. In deciding such an issue, the courts may consider, for example, the extent to which the violative actions appear to be authorized by the respondent and the nature of the benefit, if any, the respondent may derive from those actions. *See, e.g.*, *Goodman v. FTC*, 244 F.2d 584, 593 (9th Cir. 1957) (salesmen who worked for the respondent as independent contractors appeared to be the respondent's authorized agents, "so far as the public was concerned"); *Standard Distributors, Inc. v. FTC*, 211 F.2d 7, 12-13 (2d Cir. 1954) (despite respondent's "honest" efforts to detect and prevent its salesmen from making certain misrepresentations, "they made were at least within the apparent scope of their authority and part of the inducement by which were made sales that inured to the benefit of the corporate petitioner. Unsuccessful efforts by the principal to prevent such misrepresentations by agents will not put the principal beyond the reach of the [FTC] Act.").

[20] GNC cites six Commission orders that it claims "contain language substantially similar to that requested by GNC." But only four of those orders include an affirmative-defense provision. *See Diet Workshop, Inc.*, 121 F.T.C. 726 (1996); *Formu-3 Int'l, Inc.*, 119 F.T.C. 449 (1995); *Diet Center, Inc.*, 116 F.T.C. 1453 (1993); and *Physicians Weight Loss Centers, Inc.*, 116 F.T.C. 1484 (1993). The other two orders require the respondents to monitor their franchisees' and licensees' compliance with the orders, but do not offer any affirmative defense to civil penalty

seeks, GNC ignores the vastly greater number of orders that, like its own, are silent as to the respondent's responsibility for the actions of its franchisees and licensees.[21] The orders that GNC cites are unusual, in that they limit the application of the law of vicarious liability that the Commission would otherwise apply if it sought to hold GNC liable for the actions of its franchisees and licensees.[22] While a divergence from the ordinary rules of liability may be appropriate in limited circumstances, it is not Commission policy to insulate respondents from liability in this way,[23] nor has GNC demonstrated why such a divergence would be warranted here.

(4) No Clarification of the Orders Is Required

As noted above, the orders' silence concerning GNC's liability for actions of its franchisees and licensees that violate the orders means that the existing law of vicarious liability under the FTC Act will determine whether GNC is liable for such actions. The orders therefore do not give rise to any lack of clarity beyond that which necessarily exists with respect to application of a legal standard that depends upon the factual circumstances presented.

b. There Is No Change in Fact Warranting Modification of the Orders or Decree

GNC reports that its sales network now consists of about 3,700 stores, of which over 1,200 are operated by franchises. GNC's petition asserts that it plans to add an additional 240

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liability based on actions of those franchisees and licensees. *See Jenny Craig, Inc.*, Docket No. 9260 (Feb. 27, 1998); *Beverly Hills Weight Loss Clinics Int'l, Inc.*, 118 F.T.C. 213 (1994). *Weight Watchers Int'l, Inc.*, Docket No. 9261 (Dec. 24, 1997), upon which GNC further relies, likewise contains no affirmative defense provision.

[21] *See, e.g.*, *Sun Co.*, 115 F.T.C. 560 (1992); *Unocal Corp.*, 117 F.T.C. 500 (1994). Although respondents in both of these cases market gasoline through franchise operations, the cited orders do not include the kind of "affirmative defense" provision that GNC seeks here.

[22] Furthermore, the affirmative defense that GNC seeks could also have the peculiar result of insulating GNC from liability based on actions by its franchisees or licensees that violate the orders, while GNC would remain liable for those entities' violations of Section 5 of the FTC Act that happen to fall outside the terms of the order.

[23] In approving a relatively recent consent order, the members of the Commission expressed their views that self-imposed limitations on the Commission's exercise of its prosecutorial discretion are highly disfavored. *See Civic Development Group, Inc.*, C-3810, Concurring Statement of Chairman Robert Pitofsky and Commissioner Sheila F. Anthony and Concurring Statement of Commissioner Mozelle W. Thompson (March 18, 1998).

franchises during the current fiscal year. In addition, during the next three years, GNC plans to add 1,500 stores operated by Rite Aid as a licensee.

Neither the creation and expansion of its franchise operation nor the Rite Aid licensing arrangement constitutes a change in fact warranting modification of the orders or the decree. The likelihood that GNC would operate through franchisees and licensees was reasonably foreseeable at the time GNC agreed to the 1989 order, and its operation through franchisees was actually known at the time GNC agreed to the entry of the 1994 decree. GNC argues that it did not open its first franchise store until mid-1988, nearly a year and a half after it executed the consent agreement that gave rise to the 1989 order. The consent agreement was executed on February 2, 1987, and was provisionally approved and placed on the public record on June 13, 1988. If GNC opened its first franchise store in mid-1988, it seems unlikely that GNC could not have reasonably foreseen the creation of the franchise operation in early 1987, especially when competitors such as Great Earth International[24] were marketing their products through franchises. In addition, GNC had the opportunity to seek revisions to the proposed order while the consent agreement was subject to public comment from June to August 1988. GNC did not take this opportunity to ask the Commission to include a provision limiting its liability for the conduct of franchisees and licensees, even though GNC opened its first franchise store in mid-1988, and must have contemplated and planned this development for some period of time in advance.

IV. CONCLUSION

The Commission concludes that the 1969 order should be reopened and modified as described above. The Commission further finds that GNC has not established any grounds, predicated on the public interest or change in fact, for modifying the 1969 or 1989 orders by adding a provision limiting GNC's liability for order violations on the part of its franchisees and licensees. The Commission accordingly concludes that the 1969 and 1989 orders should not be reopened and modified with respect to the requested limitation on liability, and that there are no grounds for assisting GNC to seek court modification of the 1994 consent decree.

It is therefore ordered, That the proceeding is hereby reopened and the order issued on April 4, 1969, and previously modified on November 4, 1970, is hereby modified to read as follows:

[24] *See Great Earth Int'l, Inc.*, 110 F.T.C. 188 (1988).

ORDER

For purposes of this order, the following definitions shall apply:

A. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

B. Unless otherwise specified, "respondent" shall mean General Nutrition, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.

C. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising of any food, dietary supplement, or drug containing any vitamin or mineral, as “food” and “drug” are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and as “dietary supplement” is defined in Section 201(ff) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(ff), in or affecting commerce, shall not make any representation, in any manner, expressly or by implication:

A. That the presence of any vitamin or mineral in any such food, dietary supplement, or drug will be of benefit in the prevention, relief or treatment of tiredness, listlessness, lack of normal appetite, “depleted” feeling, “run-down” feeling, easy fatigability or any other symptom; or

B. That the presence of any vitamin or mineral deficiency can be self-diagnosed;

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or to Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

III.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard or monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

By the Commission.

Donald S. Clark
Secretary

ISSUED: January 31, 2000