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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
San Francisco Division

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

WELLNESS SUPPORT NETWORK, INC., a corporation, ROBERT HELD, individually and as an officer of Wellness Support Network, Inc., and ROBYN HELD, individually and as an officer of Wellness Support Network, Inc.,

Defendants.

Case No. 3:10-cv-04879-JCS

OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FTC'S FIRST AMENDED COMPLAINT [Fed. R. Civ. Pro. 12(b)(6)]

Hearing Date: September 16, 2011
Time: 9:30 a.m.
Courtroom G, 15th Floor

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I. INTRODUCTION

Second verse, same as the first. Plaintiff's First Amended Complaint (Dkt. #27) charges Defendants with violating Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52, in connection with the marketing of products that purportedly treat or prevent diabetes. Defendants have moved to dismiss the *First Amended Complaint* on grounds different from those asserted in their first motion to dismiss. *Motion to Dismiss First Amended Complaint* (Dkt. #30, "2d Mot. Dismiss"). Defendants' motion is ill-founded. It misapprehends the standard for a Rule 12(b)(6) motion; ignores decades of relevant case law interpreting the statutes at issue here; brazenly asserts a constitutional right to deceptive advertising; and rests on the irrelevant premise that Defendants' products qualify as "medical foods" under a statutory scheme not applicable here. The Federal Trade Commission ("FTC" or "Commission") respectfully requests that the Court deny Defendants' attack on the First Amended Complaint in its entirety.

II. STATEMENT OF ISSUES PURSUANT TO LOCAL RULE 7-4

A. For purposes of analyzing a Rule 12(b)(6) motion, Plaintiff's factual allegations must be taken as true.

B. The FTC Act applies to Defendants' deceptive advertising.

C. Deceptive advertising is not a constitutional right.

D. The Administrative Procedure Act does not bar the FTC from challenging Defendants' deceptive advertising.

III. ARGUMENT

A. For purposes of analyzing a Rule 12(b)(6) motion, Plaintiff's factual allegations must be taken as true.

The Court has previously set forth in this matter the standards that apply to a Rule 12(b)(6) motion:

> A complaint may be dismissed for failure to state a claim for which relief can be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 12(b)(6). "The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint." *N. Star Int'l v. Ariz. Corp. Comm'n,* 720 F.2d 578, 581 (9th Cir. 1983).***
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> In ruling on a motion to dismiss under Rule 12, the court analyzes the complaint and *takes "all allegations of material fact as true and construe(s) them in the light[] most favorable to the nonmoving party." Parks Sch. of Bus. v. Symington,* 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal may be based on a lack of a cognizable legal theory or on the absence of facts that would support a valid theory. *Balistreri v. Pacifica Police Dep't,* 901 F.2d 696, 699 (9th Cir. 1990).

Order Granting in Part and Denying in Part Motion to Dismiss ("Order on Mot. Dismiss"), p. 9 (emphasis added).[1] Analyzing the FTC's original Complaint,

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[1] The FTC set forth the facts and legal theories underpinning its original Complaint in its *Opposition to Defendants' Motion to Dismiss Complaint* (Dkt. #18, *"Opp. to Mot. Dismiss"),* pp. 3-6. The facts contained in

this Court found that it properly alleged an action against corporate defendant Wellness Support Network and individual defendant Robert Held under Sections 5(a) and 12 of the FTC Act. *Id.* at 14-15.[2]

Motions to dismiss thus test the sufficiency of the complaint; they are not appropriate vehicles for resolving disputed evidentiary contentions. Nonetheless, Defendants raise challenges to the Complaint that are to the extent they are even relevant premature attempts to litigate the factual merits of the case. First, Defendants argue that, because they believe their own products fit the definition of "medical foods" under a variety of statutes and regulations applicable to the Food and Drug Administration ("FDA"), Sections 5(a) and 12 of the FTC Act do not apply to them. *2d Mot. Dismiss*, pp. 3-4. Defendants later claim that, because they believe their own products are not "drugs," as defined by the FDA, Defendants could not possibly have made false or unsubstantiated claims in the advertising of those products. *2d Mot. Dismiss*, pp. 9-10.

While legally unsupported, as discussed *infra,* the most basic infirmity with Defendants' arguments is that they are *factual* in nature. In deciding a Rule 12(b)(6) motion, the Court must take all allegations in the First Amended Complaint as true, construing those facts in the light most favorable to the FTC's position. *Parks Sch. of Bus. v. Symington,* 51 F.3d at 1484. This means that, for

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the First Amended Complaint are not materially different, and the legal theories are unchanged, so they are not further detailed here.

[2] The Court dismissed the FTC's allegations as to individual defendant Robyn Held with leave to amend. The FTC's *First Amended Complaint* adds additional detail on Robyn Held's involvement in Wellness Support Network and its deceptive practices. *See First Amended Complaint,* ¶¶ 7-8, p. 3.

the purposes of this motion, the Court should accept as true the FTC's factual allegation that the products sold by defendants are "foods" or "drugs" as defined in Sections 15(b) and (c) of the FTC Act. *See First Amended Complaint*, ¶¶ 22-23, p. 9. Defendants' contention that their products are "medical foods" is simply a contradiction of the FTC's factual contentions and thus cannot serve as a basis for granting a motion to dismiss.

Likewise, Defendants may believe that their products are not "drugs" and therefore advertising for those products cannot violate Sections 5(a) or 12 of the FTC Act, but it is the FTC's factual allegation that Defendants' products are "foods" or "drugs" under Sections 15(b) and (c) that governs here. Thus Defendants' argument that "because *Pantron I* [3] is both *factually* and legally distinguishable from this case, it cannot govern the Defendants' advertising practices" is inappropriate for the same reason. *2d Mot. Dismiss,* p. 9 (emphasis added). As for Defendants' argument that the legal standards enunciated in *Pantron I* cannot apply here, this Court has already held that they do:

> An advertisement is deceptive and misleading under Sections 5 and 12 of the FTC Act where 1) there is a representation, omission or practice that 2) is likely to mislead consumers acting reasonably under the circumstances, and 3) the representation, omission or practice was material. *FTC v. Pantron I Corp.,* 33 F.3d 1088, 1095 (9th Cir. 1994) (citing *In re Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 163-64 (1984)).

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[3] *FTC v. Pantron I Corp.,* 33 F.3d 1088 (9th Cir. 1994) (holding that claims that are false or that lack adequate substantiation are deceptive and violate Sections 5(a) and 12 of the FTC Act).

Order on Mot. Dismiss, pp. 10-11.[4] Defendants' motion should be denied on the grounds that its factual arguments are improper.[5]

B. The FTC Act applies to Defendants' deceptive advertising.

Defendants base virtually their entire Second Motion to Dismiss on the premise that their products are "medical foods." As such, they argue that advertising for their products is not currently covered by the FTC Act. This argument fails for two simple reasons. First, as noted above, the question of whether Defendants' products are medical foods is a factual one, not appropriately dealt with in a 12(b)(6) motion. Second, it is simply irrelevant whether Defendants' products are medical foods; they would still be covered by the FTC Act.

As noted by this Court, Section 5(a) of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C.

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[4] Despite Defendants' assertions to the contrary, *see* 2d Mot. Dismiss, p. 10, *Pantron I* remains good law. The Ninth Circuit continues to use its formulations for what constitutes a violation of Sections 5(a) and 12 of the FTC Act and how liability is created thereby. *See, e.g., FTC v. Cyberspace.com, LLC,* 453 F.3d 1196, 1199-1200, 1201-02 (9th Cir. 2006); *FTC v. Stefanchik,* 559 F.3d 924, 931 (9th Cir. 2009).

[5] Defendants' citation to *FDA v. Brown & Williamson,* 529 U.S. 120, 139 (2000) is inapposite. *2d Mot. Dismiss*, p. 10. "[T]his is an era of overlapping agency jurisdiction under different statutory mandates." *FTC v. Texaco, Inc.,* 555 F.2d 862, 881 (D.C. Cir.), cert. denied, 431 U.S. 974 (1977); *see also Thompson Medical Co. v. FTC,* 791 F.2d 189, 192 (D.C. Cir. 1986), *cert. denied,* 479 U.S. 1086 (1987); S. Rep. No. 1464, 85th Cong. 2d Sess. 4 (1958) (concurrent jurisdiction by two federal agencies, in that case the FTC and the Department of Agriculture, "is a common aspect of our regulatory system"). Indeed, the Supreme Court has long held that the same issues may be addressed and the same parties may be proceeded against simultaneously by more than one agency. *See, e.g., FTC v. Cement Institute,* 333 U.S. 683, 694 (1948).

§ 45(a). *Order on Mot. Dismiss*, p. 10. The FTC's jurisdiction under Section 5 of the FTC Act is very broad, covering nearly all products and services. There are only a handful of exceptions, which are stated in the statute. None of these exceptions applies to Defendants' products, nor have defendants cited to any. Neither do Defendants cite to any FTC case law that suggests that medical foods should be treated any differently under Section 5 than any other product.

In addition to Section 5, this action is brought under Section 12 of the FTC Act, 15 U.S.C. § 52. Section 12 prohibits dissemination of false advertisements in or affecting commerce for the purposes of inducing, or which are likely to induce, the purchase of food, drugs, devices, services, or cosmetics. 15 U.S.C. § 52(a). Such dissemination is itself an unfair or deceptive act under Section 5. 15 U.S.C. 52(b). The First Amended Complaint alleges that Defendants' products are either "foods" or "drugs" for purposes of Section 12, and describes in detail how Defendants have violated Sections 5 and 12 of the FTC Act. Taken as true, as these allegations must be for purposes of analyzing a motion to dismiss, the FTC Act clearly applies to Defendants' products.

Notwithstanding these facts, Defendants argue that the FTC seeks to measure Defendants' advertising against a legal standard that is meant only for dietary supplements, not for medical foods. *2d Mot. Dismiss*, pp. 3-4. This is incorrect. First, there is no FTC "dietary supplement" standard. There *is* a document entitled "*Dietary Supplements: An Advertising Guide for Industry*."[6] Its purpose is to provide *guidance* to the industry relating to the advertising of such products. This document may not have the force of law itself, but it describes in plain English the legal standards that do apply to the advertising of dietary supplements standards which apply to most other products and services

[6] Available at: *http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry.pdf*

as well.[7] Those standards, which require advertising claims to be truthful and not misleading, as well as supported by a reasonable basis, are not mere agency pronouncements. They have been enshrined in case law over decades by federal courts throughout the United States,[8] including this one. It is these standards which the Commission has asked the Court to use to protect consumers from Defendants' deceptive advertising.

In arguing that the FTC Act does not apply to them, Defendants do not cite to relevant FTC rules, statutes, or case law. Instead, they describe a number of statutes, regulations, and guidance documents which relate to the Food and Drug Administration. *2d Mot. Dismiss*, pp. 3-4. In attempting to show that their products are medical foods, Defendants discuss the differences between the FDA's treatment of medical foods and its treatment of foods, drugs, and dietary supplements; whether Defendants' products need to undergo premarket review or approval by FDA; and whether Defendants' products need to be registered with the FDA. *Id.*

The Plaintiff in this action, however, is not the FDA. Nor is the FTC

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[7] Discussed in more detail *infra*.

[8] For the widespread use of the reasonable basis or substantiation standard *see, e.g.*, *Daniel Chapter One v. FTC,* 2010 U.S. App. LEXIS 25496, at *2-3 (D.C. Cir. 2010), *cert. denied*, 2011 U.S. LEXIS 3931 (U.S. 2011); *Pantron I,* 33 F. 3d at 1096; *FTC v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1079 (N.D. Cal. 2009); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Georgia 2008); *FTC v. Natural Solution, Inc.,* 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. 2007), *10-12 (relying on *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. III. 1998).

For the widespread use of the deception standard *see, e.g., FTC v. Stefanchik,* 559 F.3d 924, 928 (9th Cir. 2009); *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1188-89; *FTC v. Cyberspace.com, LLC,* 453 F.3d 1196, 1199-1200 (9th Cir. 2006); *Pantron I*, 33 F. 3d at 1095.

attempting to apply any statute or regulation enforced by the FDA. Plaintiff is enforcing the FTC Act. How the FDA may or may not treat "medical foods" is irrelevant *on its face*.[9]

C. Deceptive advertising is not a constitutional right.

Defendants contend that the FTC's challenge to their deceptive advertising violates their commercial speech rights under the First Amendment. *2d Mot. Dismiss*, pp. 5-6, 10. Defendants are incorrect; deceptive advertising is not a constitutional right.

Defendants' argument rests on the erroneous premise that in evaluating their First Amendment claims, the Court should apply the three-part test articulated by the Supreme Court in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n,* 447 U.S. 557 (1980). In *Central Hudson,* the Supreme Court addressed the question whether a prophylactic regulation against utilities that limits or prohibits an entire class of protected commercial speech could pass constitutional muster. The Court held that the challenged ban on advertising by utilities violated the utilities' First Amendment rights because it was more extensive than necessary to advance the state's legitimate interests in energy conservation, and because the utilities' advertising was not misleading or unlawful. *Central Hudson,* 447 U.S. at 566; *cf. Mainstream Mktg. Servs. v.*

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[9] As stated above, a 12(b)(6) motion is not the place for factual disputes. Nevertheless, in attempting to prove their products are medical foods, Defendants have larded their brief with references to FDA documents that relate to medical foods. Defendants' use of FDA documents for this purpose constrains Plaintiff to point out two FDA documents Defendants have failed to mention: warning letters informing the Defendants that their advertising claims render the Diabetic Pack product an unapproved *drug*. *See* attached *Declaration of Craig Kauffman*.

FTC, 358 F.3d 1228, 1237 (10th Cir. 2004) (applying *Central Hudson* to FTC regulation prohibiting commercial calls to consumers in "do-not-call" registry).

By contrast to *Central Hudson,* this case does not involve a prior restraint or regulation of protected commercial speech.[10] This case involves a different question: Namely, whether the claims conveyed in Defendants' ads were deceptive and are therefore not entitled to any protection under the First Amendment. Deceptive commercial speech is entitled to no protection under the First Amendment. *Daniel Chapter One v. FTC,* 2010 U.S. App. LEXIS 25496, *4 (D.C. Cir. 2010), *cert. denied*, 2011 U.S. LEXIS 3931 (U.S. 2011); *Florida Bar v. Went For It, Inc.,* 515 U.S. 618, 623-34, (1995) ("Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading."); *Central Hudson,* 447 U.S. at 566.

The First Amended Complaint properly alleges that Defendants made false or unsubstantiated claims in the advertising for their products. *See First*

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[10] Defendants' reliance on *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) is misplaced. See *2d Mot. Dismiss*, pp. 5-6. That case involved a challenge to an FDA regulation that imposed a blanket prohibition on making health claims for dietary supplements unless there was significant scientific agreement among experts regarding the accuracy of the claim. Id. at 651. The principal issue in *Pearson* was whether a claim lacking scientific agreement could be barred on the ground that it was "potentially misleading." Id. at 655. That is, the FDA argued that its rule should be free from First Amendment scrutiny because some of the health claims to which the regulation applied might be deceptive, even though others would not be. The Court rejected that argument and therefore conducted a First Amendment analysis of the rule's restrictions under the three-part test set forth in *Central Hudson*. Id. at 655-56. The situation here is different. The Commission has alleged that defendants' advertisements were actually (not potentially) deceptive. If these allegations are established, then the advertising is entitled to no First Amendment protection at all.

Amended Complaint, ¶¶ 24-27, pp. 9-10. Both statements that are false and those that lack adequate substantiation constitute deceptive acts or practices under the FTC Act in the Ninth Circuit. *See Pantron I,* 33 F.3d at 1095-96. This Court will ultimately decide whether the challenged representations are deceptive, but for purposes of a motion to dismiss, the Court must assume the representations are false or lack substantiation, as alleged. As false and unsubstantiated claims are considered deceptive under relevant Ninth Circuit law, *see id.,* Defendants' representations are entitled to no constitutional protection and the First Amended Complaint must stand.

Defendants' commercial speech rights are not infringed by this proceeding. If the Court finds that the Defendants' advertising claims are false or unsubstantiated, then there is no constitutional violation because the First Amendment does not protect false or misleading commercial speech, and an order prohibiting such speech is an appropriate remedy. See *Zauderer v. Office of Disciplinary Counsel,* 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."); *In re R. M. J.,* 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely."); *Central Hudson,* 447 U.S. at 563-64 ("The government may ban forms of communication more likely to deceive the public than to inform it."); *Bristol-Myers Co. v. FTC,* 738 F.2d 554, 562 (2d Cir. 1984) ("deceptive advertising enjoys no constitutional protection") (citation omitted).[11]

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[11] Defendants also claim that the First Amended Complaint "fails to even consider the disclaimers" made in their advertising and that this "amounts to a constitutional violation." *2d Mot. Dismiss*, p. 6. This is perplexing, as Defendants themselves note that the First Amended Complaint attaches examples of their disclaimers. *See 2d Mot. Dismiss,* p. 6. Furthermore, it is well (continued...)

D. The Administrative Procedure Act does not prevent the FTC from challenging Defendants' deceptive advertising.

By basing part of their second Motion to Dismiss on the Administrative Procedure Act, 5 U.S.C. § 553 *et seq.* ("APA"), Defendants are essentially arguing that the APA serves as an absolute bar to this enforcement action. *See 2d Mot. Dismiss*, pp. 6-8. To make this argument, however, Defendants must take the position that the legal standards which apply here, requiring that Defendants' advertising claims be truthful and adequately substantiated, are new. *Id.* at 7-8. This borders on the frivolous. The FTC is in no way seeking to extend the law in this case, only to enforce the law which has always applied to Defendants' advertising. Furthermore, even if the FTC were attempting to change the law or adopt "new rules of widespread application," the agency could clearly do so, as the FTC's action here is not an attempt to circumvent a pending rulemaking under the APA.

1. The FTC is not attempting to create a new standard.

The FTC is not attempting to create a new rule by suing Defendants for their deceptive advertising. The supposedly "new" legal standards Defendants cite to have been used by courts in the Ninth Circuit for decades. The leading case in this Circuit, as Defendants correctly surmise,[12] is *Pantron I,* which held that there are at least two theories under which the FTC can demonstrate that

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[11](...continued)
established that "a disclaimer does not automatically exonerate deceptive activities." *FTC v. Gill,* 71 F. Supp. 2d 1030, 1044 (C.D. Cal. 1999), *aff'd,* 265 F.3d 944 (9th Cir. 2001). The mere existence of disclaimers in Defendants' advertising here does not insulate that advertising from challenge under the FTC Act.

[12] *See 2d Mot. Dismiss*, pp. 9-10.

Defendants have misled consumers in violation of Sections 5 and 12 of the FTC Act. *Pantron I,* 33 F.3d at 1096. First, the FTC can use a "falsity" theory, under which the Commission must prove that the express or implied messages conveyed by the advertisements are false. *Id.* The FTC can also use a "reasonable basis" theory, under which the FTC must show that Defendants lacked a "reasonable basis" also known as "substantiation" for their claims. *See id*.

Under the "reasonable basis" theory, advertising claims must be substantiated by competent and reliable evidence. *Id.* Health claims, however, must be substantiated by competent and reliable *scientific* evidence. *See, e.g.*, *FTC v. Natural Solution, Inc.,* 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. Aug. 7, 2007), *10-12 (quoting *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006), *aff'd* 512 F. 3d 858 (7th Cir. 2008)); *FTC v. Nat'l Urological Group,* 645 F. Supp. 2d 1167, 1190 (N.D. Georgia 2008); *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d 285, 299 (D. Mass. 2008). This standard has been applied in numerous cases finding that advertisements making health claims without a reasonable basis substantiating those claims were deceptive. *See, e.g., Natural Solution,* 2007 U.S. Dist. LEXIS 60783 at *16-17; *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. III. 1998); *QT,* 448 F. Supp. 2d at 961.

As noted above, the First Amended Complaint properly alleges that Defendants' products are "foods" or "drugs" for purposes of Section 12 of the FTC Act, and that violations of Section 12 are also violations of Section 5. The FTC has also properly alleged that Defendants' advertising claims for their products were false or unsubstantiated at the time they were made. The requirement that substantiation include competent and reliable scientific evidence applies not only to "dietary supplements," but to health claims *generally*. It does not matter whether those health claims are about dietary

supplements,[13] drugs,[14] metal bracelets with purported healing powers,[15] or, as in this case, about a combination of pills touted as a "diabetes breakthrough."[16] Regardless of the product, the standard for health claims is the same, and the application of this standard to Defendants' advertising is neither new nor elusive.

Defendants make much of the fact that the FTC referred to "guidance documents" in its opposition to Defendants' First Motion to Dismiss. *See 2d Mot. Opp*., pp. 2, 4, 8-9. From this reference, Defendants argue that the Commission is trying to improperly give its guidance documents the force of law. The Defendants are simply wrong. The Commission never suggested that guidance documents, *in and of themselves*, have the force of law. *See FTC Opposition to Motion to Dismiss* (Dkt. #18), pp. 8-9. The relevant law here is, and always has been, those Ninth Circuit decisions applying the FTC Act.[17] The FTC's guidance documents, including those cited in this case, describe the state of FTC law as it currently exists something Defendants previously claimed they did not understand. *See Defendants' Motion to Dismiss* (Dkt. #9), p. 6, n.1.

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[13] *Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783.

[14] *Pantron I Corp.*, 33 F.3d at 1105.

[15] *QT, Inc.*, 448 F. Supp. 2d at 961 (N.D. Ill. 2006).

[16] *First Amended Complaint*, ¶ 20.

[17] Defendants also argue that Commission policy statements that were not promulgated under the APA do not warrant *"Chevron* deference," citing *Christensen v. Harris County*, 529 U.S. 576 (2000). *2d Mot. Dismiss*, p. 8. *Chevron* deference, which refers to the level of deference a court will show an agency's interpretation of its own statute, is a red herring. The FTC has not asked for *Chevron* deference here. This and the FTC's prior pleadings cite to cases in which *courts* have taken up the FTC's recommended deception and substantiation standards and made them their own.

2. Even assuming the Commission were advancing a new legal principle in this case, it is free to do so.

Notwithstanding Defendants' claims to the contrary, *see 2d Mot. Dismiss*, pp. 6-8, administrative agencies are generally free to announce new principles of law during adjudication. In *SEC v. Chenery Corp*., 332 U.S. 194, 200-03 (1947) (*"Chenery II")*, the Supreme Court rejected the argument that a federal administrative agency must employ rulemaking rather than adjudication when articulating new legal standards. As the Court said, "[t]here is ... a very definite place for the case-by-case evolution of statutory standards. And the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *See also NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 290-95 (1974) (agencies are "not precluded from announcing new principles in an adjudicative proceeding and...the choice between rulemaking and adjudication lies in the first instance within the [agency's] discretion" 416 at 294); *NLRB v. Wyman-Gordon*, 394 U.S. 759, 765-66, 772 (1969).[18]

The Ninth Circuit has found only two narrow circumstances in which an

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[18] Defendants cite *Wyman-Gordon* for the flat proposition that the FTC cannot develop rules through adjudication. *See 2d Mot. Dismiss,* pp. 7-8. *Wyman-Gordon* does not so hold. The Court of Appeals in *Wyman-Gordon* had held that an order of the National Labor Relations Board was invalid because it was based on a rule laid down in adjudication and not rule-making under the APA. The Supreme Court reversed. While a plurality of the Court criticized the NLRB's use of adjudicatory proceedings to announce rules only applicable prospectively, they made clear that *there was no impediment to agency adjudications that establish new precedent applicable to the parties in the case at hand*. *Id.* at 765-66. Three justices concurred in the result, and reiterated the holding in *Chenery II:* "the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *Chenery II,* 332 U.S. at 203.

agency cannot articulate new principles through adjudication: (1) if doing so would amount to an abuse of discretion; or (2) if doing so would circumvent APA requirements. *Union Flights, Inc. v. Administrator, Federal Aviation Admin.*, 957 F.2d 685, 688 (9th Cir. 1992) (citing *Bell*, 416 U.S. at 294). As noted above, the Commission is not announcing new principles in this case. Even if it were, however, it is neither abusing its discretion nor circumventing the APA. We now address the applicability of these exceptions to this case.

a. The FTC is not abusing its discretion.

The first exception, where announcing new principles through adjudication constitutes an abuse of discretion, applies when the agency suddenly changes its direction and that change also results in a unique hardship for those who relied on past policy. *Union Flights,* 957 F.2d at 688. This is obviously not the case here, as the Commission has consistently filed enforcement actions against companies who make false or unsubstantiated health claims. In fact, the courts' willingness over the years to apply both the deception and substantiation standards to a wide variety of products should have put defendants on notice that their products, whether medical foods or not, would be treated no differently. Defendants notably make no claim in their second Motion to Dismiss that they relied on any Commission policy to their detriment. As such, they cannot argue that the FTC has abused its discretion in violation of the APA.

b. The FTC is not attempting to circumvent the APA through adjudication.

The second narrow exception to agency adjudication arises when an agency uses adjudication as a way to circumvent the APA. *See Wyman-Gordon*, 394 U.S. at 764; *Anaheim, Riverside, Banning, Colton & Azusa v. Federal Energy Regulatory Com.*, 723 F.2d 656, 659 (9th Cir. 1984); *Montgomery Ward & Co. v. FTC*, 691 F.2d 1322 (9th Cir. 1982); *Patel v. INS*, 638 F.2d 1199 (9th Cir. 1980). Courts have clarified and limited this exception, applying it only when an agency uses adjudication as a means to either amend a recently adopted rule or to bypass or supplant a pending rulemaking. *Union Flights, Inc.* 957 F.2d at 688; *Anaheim*, 723 F.2d at 656. Here, neither of these situations arises: There is no recently adopted rule the agency is attempting to amend, nor is there any pending rulemaking regarding matters arising in this case.

Nonetheless, Defendants argue, citing *Ford Motor Co. v. FTC*, 673 F.2d 1008 (9th Cir. 1981), that the First Amended Complaint must be dismissed because, by bringing this enforcement action, the FTC is attempting to establish a new rule of widespread application. *2d Mot. Dismiss*, p. 7. In *Ford,* the Court barred an FTC action seeking a change to substantive law on the ground that a then-pending rulemaking would accomplish the same goal. Beyond the fact that the FTC is clearly not seeking to establish a new rule here, over the past three decades the Ninth Circuit has essentially limited *Ford* to its facts. *See Anaheim,* 723 F.2d at 659 (agency use of adjudication was not improper attempt to circumvent APA's rulemaking procedures; *Ford* inapplicable because the agency was not using adjudication to "supplant" a pending rulemaking); *Union Flights, Inc.* 957 F.2d at 688 (*Ford* inapplicable because agency did not use adjudication to "bypass" pending rulemaking); *see also Weight Watchers v. FTC*, 830 F. Supp. 2d 539, 542 (W.D. Wash. 1993), *aff'd* in part and *rev'd* in

part on other grounds, 47 F. 3d 990 (9th Cir. 1994) (rejecting a *Ford*-based challenge by individual weight loss providers to the Commission's case-by-case approach to an industry-wide problem, even though the remedy requested by the FTC was new; "[s]ubsequent Ninth Circuit law ... has limited the holding of *Ford*.").

In this case, not only is there no new principle of law being advanced, even if there were, the limited *Ford* exception would not apply. Defendants' reliance on *Ford* is unavailing.

IV. CONCLUSION

This lawsuit is brought to protect consumers from Defendants' false and unsubstantiated advertising. Notwithstanding Defendants' contentions, the FTC Act does apply to Defendants' advertising; there is no procedural bar to this lawsuit; and Defendants' deceptive advertising deserves no constitutional protection. For these reasons, the Federal Trade Commission respectfully asks the Court to deny Defendants' Motion to Dismiss the First Amended Complaint.

Respectfully submitted,

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