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Before the
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

In Re: Petition for a Rule Authorizing Issuance of Advisory Opinions Concerning Dietary Supplement Structure/Function Claim Advertising or, in the Alternative, Defining the Criteria FTC Uses to Evaluate Scientific Evidence Required in Support of Dietary Supplement Structure/Function Claim Advertising	)	Docket No. P002501

PETITION FOR RULEMAKING

Dr. Julian M. Whitaker; Pure Encapsulations, Inc.; Imagenetix, Inc.; and XCEL Medical Pharmacy, Ltd. (collectively, "Joint Petitioners"), by counsel and pursuant to 16 C.F.R. § 1.9 and Section 18 of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 57(a)(1)(B), hereby petition the Federal Trade Commission ("FTC") to promulgate a rule for the issuance of advisory opinions concerning whether an advertiser's scientific corroboration for planned structure/function claim advertising[1] constitutes "competent and reliable scientific evidence" needed to substantiate the claims. In the alternative, the Joint Petitioners petition FTC to promulgate a rule that will make explicit the principles which guide agency action when it evaluates the sufficiency of scientific evidence in support of dietary supplement structure/function claim advertising.

[1] The term "structure/function claim advertising" is meant to refer to those statements which appear in advertising that satisfy the definition of such claims contained in 21 U.S.C. § 343(r):

> [a] statement [that] 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.

DESCRIPTION OF THE PARTIES

Dr. Julian M. Whitaker. Julian M. Whitaker, M.D. is a physician licensed to practice medicine in the states of California and Washington. He graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the Whitaker Wellness Institute in Newport Beach, California. He is the author of five books: ***Reversing Heart Disease*** (1985), ***Reversing Diabetes*** (1987), ***Reversing Health Risk*** (1989), ***Natural Healing*** (1994), and ***What Your Doctor Won't Tell You About Bypass*** (1995). Since August of 1991 he has been the editor of ***Health & Healing***, currently the nation's largest single editor health newsletter. In 1996, ***Health & Healing*** had over 500,000 subscribers. Dr. Whitaker sells and promotes the sale of his own brand of dietary supplements. He receives royalties from the distribution and sale of several dietary supplements based on formulas he develops and licenses.

Dr. Whitaker would disseminate print advertising containing the following structure/function claims in association with his sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits A-C) will be regarded by FTC as competent and reliable.

Product Description

Omega-3 Fatty Acid (EPA (360 mg per serving) and DHA (240 mg per serving))

Health Benefit Advertising Claim

Consumption of omega-3 fatty acids supports and promotes cardiovascular health.

Product Description

Saw Palmetto (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary function.

Product Description

Folic Acid (800 mcg per serving), Vitamin B6 (25 mcg per serving) and Vitamin B12 (100mcg per serving)

Health Benefit Advertising Claim

Folic Acid when taken in combination with Vitamin B6 and Vitamin B12 supports vascular health.

Pure Encapsulations, Inc. Pure Encapsulations, Inc. (Pure) is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling over 250 pharmaceutical grade dietary supplements for human and companion animal consumption.

Pure Encapsulations, Inc. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits A, B and D) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto Plus (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary flow.

Product Description

Vitamin E (400 I.U. per serving)

Health Benefit Advertising Claim

As a part of a healthy diet low in saturated fat and cholesterol 400 IU/day of Vitamin E promotes cardiovascular health.

Product Description

EPA/DHA (1000 mg per serving)
Flax/Borage Oil (600 mg per serving)

Health Benefit Advertising Claim

Consumption of omega-3 fatty acids as found in our EPA/DHA and Flax/Borage Oil supplement products promote cardiovascular health.

Imagenetix, Inc. Imagenetix, Inc. (Imagenetix) is a California corporation engaged in the business of manufacturing, distributing, and selling multiple pharmaceutical grade dietary supplements for human consumption.

Imagenetix, Inc. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits B, C, and D) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary flow.

Product Description

Vitamin E (50 I.U. per serving)

Health Benefit Advertising Claim

As a part of a healthy diet low in saturated fat and cholesterol, Vitamin E supports cardiovascular health.

Product Description

Folic Acid (400 mcg per serving), Vitamin B6 (10 mg per serving), and Vitamin B12 (50 mg per serving)

Health Benefit Advertising Claim

Folic acid when taken in combination with vitamin B6 and Vitamin B12 supports vascular health.

XCEL Medical Pharmacy, Ltd. XCEL Medical Pharmacy, LTD d/b/a XCEL Health Care (XCEL) is a California corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human consumption. XCEL Medical Pharmacy, Ltd. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibit B, D, and E) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto (325 mg per serving)

Health Benefit Advertising Claim

Our saw palmetto product includes high quality saw palmetto and is formulated to promote prostate health and support healthy urine flow in men.

Product Description

Vitamin E (400 I.U. per serving)

Health Benefit Advertising Claim

XCEL's Vitamin E dietary supplement contains a-tocopherol and dl-a-tocopherol. This Vitamin E dietary supplement supports cardiovascular health especially when taken as part of a healthy diet low in saturated fat and cholesterol.

Product Description

Antioxidant Vitamin (vitamin A (7,500 I.U. per serving), vitamin C (70 mg per serving), vitamin E (100 mg per serving))

Health Benefit Advertising Claim

XCEL's dietary supplement contains antioxidant vitamins that are formulated to promote cellular structure integrity.

II. THE PROBLEMATIC AGENCY PRACTICE AT ISSUE

The FTC deems a structure/function claim ad deceptive unless it is supported by "competent and reliable scientific evidence." *See, e.g., In the Matter of Western Direct Marketing Group*, 1998 FTC LEXUS 78, (July 28, 1998); *In the Matter of Amerifit*, 123 F.T.C 1454, (1997); *In the Matter of Kave Elahie d/b/a MEK International*, 124 F.T.C. 407 (1997); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); *In the Matter of Nature's Bounty* 130 F.T.C. 206 (July 21, 1995). In *Thompson Medical Company v. Federal Trade Commission*, the FTC made clear in connection with health claim advertising[2] for drugs (and, presumably, the precedent applies equally well to health claim advertising for dietary supplements) that two well-designed double blind placebo controlled clinical trials are the minimum acceptable corroboration for a claim. 104 F.T.C. 648 (1986), *affirmed*, 791 F.2d 189 (D.C. Cir. 1986), *see also American Home*

[2] The term "health claim advertising" is meant to refer to that advertising which contains "health claims" as that term is understood by the Food and Drug Administration, namely: a "claim . . . that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." As used herein the term "health claim advertising" is distinguishable from "structure/function claim advertising" in that the latter—with the exception of classic nutrient deficiency diseases—associates a nutrient with a body structure or function without reference to a disease or disease condition.

Product Corp., *98* F.T.C. 136 (1981), *modified*, 696 F.2d 681 (3rd Cir. 1983). The lack of a comparable, clear definition for "competent and reliable scientific evidence" as it applies to dietary supplement structure/function claim advertising makes it impossible for the Joint Petitioners to discern what level, degree, quality, quantity, and kind of scientific evidence FTC will consider necessary and sufficient support for any dietary supplement structure/function claim ad. To date, although FTC's Bureau of Consumer Protection issued "Dietary Supplements: An Advertising Guide for Industry" in 1998, that otherwise helpful document does not provide necessarily specific guidance on the level, degree, quality, quantity, and kind of scientific evidence FTC expects to corroborate structure/function claim advertising that the Joint Petitioners must have to discern what FTC expects of them.

Incapable of discerning from FTC precedent what principles guide the agency in making its determinations on the corroborative sufficiency of science supporting dietary supplement structure/function claim advertising, and in light of Commissioner Sheila Anthony's order compelling greater FTC enforcement of its laws and policies against deceptive advertising in the dietary supplement marketplace (see Exhibit F), the Joint Petitioners dare not use the structure/function claim advertising listed above for fear that FTC will second-guess the sufficiency of the science they possess corroborating the claims. Furthermore, the Joint Petitioners cannot otherwise ascertain FTC's position in advance of advertising because FTC has no procedure for rendering advisory opinions as to whether a proposed structure/function claim advertisement is deceptive. Moreover, they cannot determine how best to qualify the claims to address, e.g., any concerns FTC may have about the extent to which the science provides suggestive, rather than

conclusive, evidence of the claimed health benefits. Lacking legally sufficient guidance, the Joint Petitioners now engage in self-censorship because they cannot discern what, if any, meaningful definition or distinguishing principle FTC applies to determine whether structure/function claim advertising is backed by "competent and reliable scientific evidence."

The FTC has never revealed precisely what objective criteria it uses to evaluate scientific evidence submitted to it in response to access letters and civil investigative demands that call into question scientific corroboration for dietary supplement structure/function claim advertising. In its dietary supplement claim decisions and in its consent agreements concerning those claims, the FTC does not explain the content of the staff's scientific evaluations and never reveals the content of the scientific evaluations supplied to it by independent reviewers, thereby denying relevant insight into the process that determines the advertiser's fate. In short, FTC's criteria for evaluating dietary supplement structure/function claims and its weighing of those criteria are hidden from advertisers. Consequently, neither the Joint Petitioners nor any other regulatee can discern, with confidence, in advance of advertising what science will prove adequate to satisfy FTC.[3] The Joint Petitioners thus perceive inherent risk of adverse regulatory action in undertaking advertising of this kind.

The need for definition is particularly essential in the area of structure/function claim advertising because dietary supplements, unlike pharmaceutical drugs, yield substantially less revenue per unit sold than do drug products. In addition most dietary

[3] This problem is compounded by the fact that agency staff attorneys routinely advise that the level of scientific evidence needed to support a structure/function claim ad is generally less than that required to support a health claim ad. In public presentations, FTC representatives have indicated that structure/function claim ads may not need to be supported by two or more double blind placebo controlled

supplements cannot be patented, unlike drugs, and thus do not enjoy monopoly rents needed to finance costly intervention trials. Double blind placebo controlled clinical trials for drug products frequently require expenditures of several hundred million dollars to establish, to FDA's satisfaction, the safety and efficacy of a drug. As a consequence of the foregoing market realities, almost all dietary supplement companies depend upon publicly available scientific evidence, and not commissioned clinical trials, to corroborate structure/function claim advertising.

In the absence of principles to guide them, the Joint Petitioners are entirely at a loss to know whether, if ever, the scientific evidence they possess will satisfy FTC's substantively undefined standard for structure/function claim advertising.

FTC defines "competent and reliable scientific evidence" as:

> Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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.

See, e.g., In the Matter of Western Direct Marketing Group, 1998 FTC LEXUS 78, (July 28, 1998); *In the Matter of Amerifit*, 123 F.T.C 1454, (1997); *In the Matter of Kave Elahie d/b/a MEK International*, 124 F.T.C. 407 (1997); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); and *In the Matter of Nature's Bounty* 130 F.T.C. 206 (July 21, 1995).

In the context of health claims for drug products and, to some extent, of health claims for dietary supplements, FTC appears to rely upon *Thompson Medical*, 104 F.T.C. 648 (1986), which indicates that two well designed clinical trials will often suffice. No comparable criteria exist in the precedent for dietary supplement structure/function claim ads. The agency's lack of definition for adequate corroboration for dietary supplement

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clinical trials, as is the case under *Thompson Medical*, 104 F.T.C. 648 (1986) for health claims on drug products.

structure/function claim ads begs several questions, the answers for which are essential requisites to an advertiser's comprehension of the requirements imposed by this agency:

(1) What nature, quality, and quantity of tests, analyses, research, studies, or other evidence (collectively "scientific evidence") does FTC require to support a claim? (e.g., Will animal studies suffice or must there be human clinical trials? Will one study suffice or must there be a dozen or more? Will studies on an active ingredient in a product be sufficient or must all ingredients of the product be evaluated? Will studies by independent individuals and entities on the same ingredient used in a product suffice or must the product itself be tested? Are studies in peer-reviewed scientific journals preferred over unpublished clinical trials?)

(2) Upon the expertise of how many professionals in the relevant area must the scientific evidence be based? (e.g., Will two concurring professionals suffice? Will agreement among some minority of professionals in the field suffice or must there be a consensus among all professionals in the relevant area?)

(3) What criteria does FTC employ to determine whether a test, analysis, research, study or other evidence has been conducted and evaluated in an objective manner?

(4) What criteria does FTC employ to determine whether a test, analysis, research, study or other evidence is well-designed?

(5) What criteria does FTC employ to determine whether a person is qualified to conduct and evaluate scientific evidence?

(6) What criteria does FTC employ to determine whether procedures in testing used are generally accepted in the profession to yield accurate and reliable results?

(7) What factors does FTC take into account to determine whether scientific evidence is accurate?

(8) What factors does FTC take into account to determine whether scientific evidence yields reliable results? To what extent must a study otherwise acceptable to FTC be the subject of redundant scientific studies to be deemed "reliable"?

Without answers to the foregoing questions regulatees, including the Joint Petitioners, simply cannot discern what nature, degree, quality, and quantity of scientific evidence they must possess to satisfy FTC. The Joint Petitioners note that FTC

frequently disagrees with regulatees concerning whether the science they have marshaled in support of claims is "competent and reliable." *See, e.g., In the Matter of Schering Corporation*, 118 F.T.C. 1030 (1994); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); and *In the Matter of Nature's Bounty* 130 F.T.C. 206 (1995).

In 1998, the FTC's Bureau of Consumer Protection published "Dietary Supplements: An Advertising Guide for Industry." While that guidance informs the industry of the need to have substantiation for a claim (pages 8 to 17 therein), it does not do more than recite general considerations advertisers should take into account when developing ads (e.g., the need to evaluate the level of support for a claim, the amount and type of supportive evidence, the quality of the evidence, the totality of the evidence, and the relevance of the evidence to a specific claim). Taking those considerations into account, the prospective advertiser must still be, as indeed the Joint Petitioners are, at a loss to understand precisely what level, degree, quality, quantity, and kind of science FTC expects to be present in advance of structure/function claim advertising.

I. THE STATUTORY AND CONSTITUTIONAL INFIRMITIES OF FTC'S CURRENT PRACTICE AND ITS ADVERSE IMPACT ON THE JOINT COMMENTERS

The FTC's failure to define the criteria it uses to evaluate dietary supplement structure/function claim advertising either case by case, by a separate rule, or by issuance of advisory opinions violates the Administrative Procedure Act's ("APA") prohibition on arbitrary and capricious agency action; the First Amendment's commercial speech standard; and the Fifth Amendment's void for vagueness standard. Accordingly, by failing to define explicitly the criteria it employs the FTC not only deprives the Joint Petitioners of their statutory right to rules that are neither arbitrary nor capricious but also

of their First and Fifth Amendment rights. The violation of the statute and the deprivation of constitutional rights are themselves palpable harms. They are not the only harms, however, that the agency's current practice imposes on the Joint Petitioners. The Joint Petitioners are forced to suffer economic losses equal to the sales that would be derived from purchases attendant to the above-referenced claims that they are not able to make for fear of adverse FTC action.

A. FTC'S CURRENT PRACTICE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

FTC's failure to define either by rule or case by case (including through advisory opinions) the criteria it employs in assessing whether scientific evidence supporting a dietary supplement structure/function claim is competent and reliable violates the Administrative Procedure Act's ("APA") prohibition against arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A) (1994). See *Pearson v. Shalala*, 164 F.3d 650, (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (1999) ("It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved," *citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[T]he agency must . . . articulate a satisfactory explanation for its action . . . ."). Indeed, in assessing the FDA's refusal to define the criteria it employs in applying its health claims standard, the Court of Appeals for the D.C. Circuit reasoned that "[t]o refuse to define the criteria . . . is equivalent to simply saying no without explanation" and cannot withstand scrutiny under the APA. *Pearson*, 164 at 660.

B. THE FTC'S CURRENT PRACTICE VIOLATES THE FIRST AMENDMENT

Dietary supplement structure/function claim advertising is protected by the First Amendment to the United States Constitution as commercial speech so long as it is not inherently misleading. *See Bolger v. Youngs Drugs Products, Corp.*,463 U.S. 60, 67-68 (1983); *Rubin v. Coors Brewing Company*, 514 U.S. 476 (1995). Under the First Amendment commercial speech standard, only inherently misleading claims may be suppressed outright. By contrast, potentially misleading claims must be permitted with reasonable disclaimers designed to eliminate the misleading connotation. *See In re RMJ*, 455 U.S. 191, 203 (1982); *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 144-46; *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 99-111 (1990).

The claims here in issue are ones for which scientific evidence provides support. Thus, they convey information. They therefore cannot be inherently misleading but must either be nonmisleading or potentially misleading. While the Joint Petitioners believe them to be the former, FTC may think them the latter, depending upon how it evaluates the scientific evidence supporting them. If it found them potentially misleading, its constitutional remedy would be to compel use of appropriate disclaimers, not to suppress the claims. *In re R. M. J.*, 455 U.S. 191 (1982). The issue is whether the scientific evidence supporting the claim rises to the level of "competent and reliable scientific evidence" sufficient to satisfy FTC that the claim is not deceptive. That standard must be defined by this agency in a manner consistent with existing First Amendment precedent which would not allow suppression or punishment of parties who communicate potentially misleading claims; rather, such claims may only be required to carry

corrective disclaimers. *Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206; *Shapero*, 486 U.S. at 478.

In the absence of clear criteria for discerning whether a dietary supplement structure/function claim is backed by competent and reliable scientific evidence and in the absence of any system for providing FTC advisory opinions on proposed claims, the Joint Petitioners cannot reasonably anticipate whether FTC will agree with them that their science is adequate support for a claim and cannot know whether any particular disclaimer could eliminate FTC concerns that would otherwise arise. They thus refrain from communicating the structure/function information above for fear that doing so will subject them to adverse regulatory action.

Indeed, when FTC calls into question the scientific support for a claim, it commences a process that imposes significant costs on the advertiser (legal fees, search costs, revised marketing and advertising costs) including on those, such as the Joint Petitioners, who possess science they reasonably believe corroborates their claims. In the first instance, agency officials issue either an access letter or a civil investigative demand (requesting or compelling the production of all corroborative science possessed by the advertiser). Then the information is evaluated but the agency does not disclose the criteria used for the evaluation and does not disclose the scientists who have advised it, the scientific reports it receives from those scientists, or even the precise content of, or reasons for its scientific findings. Thereafter, if the agency's undisclosed evaluation yields a determination that the scientific evidence is not "competent and reliable," it sends the advertiser a draft complaint and consent agreement stating that proposition in a conclusory manner. It thereby commences the first step in its prosecution of the

advertiser. The complaint and consent agreement do not reveal the agency's evaluation or the criteria used to assess the ads but include conclusory charges of statutory violations based on a purported lack of "competent and reliable scientific evidence," defined only as quoted above. In the absence of clear criteria that conform with the requirements of the First Amendment, these regulatory acts impose upon those who would communicate dietary supplement structure/function claims significant and unconstitutional burdens of a financial and regulatory nature. FTC causes those burdens to be imposed regardless of whether the speech in issue is inherently misleading or potentially misleading. If the agency's criteria were revealed and adequately defined, and if those criteria comported with the requirements of the First Amendment, the Joint Petitioners would be able to discern the circumstances in which FTC would regard their dietary supplement structure/function claims as adequately supported and the circumstances in which otherwise inadequately supported ads could be rendered unobjectionable through use of appropriate disclaimers. The Joint Petitioners are not able to discern those circumstances given current precedent.

Thus, in the absence of defined criteria, the agency's entire system for evaluating dietary supplement structure/function claim advertising violates the First Amendment's commercial speech standard. Accordingly, to avoid further violation of the First Amendment, FTC must explain with particularity the criteria it uses in evaluating dietary supplement structure/function claims or, in the alternative, authorize the issuance of advisory opinions to guide the Joint Petitioners and all regulatees on a case by case basis. The agency's criteria must distinguish potentially from inherently misleading claims and must permit use of disclaimers in association with potentially misleading claims as an

alternative to outright suppression. Finally, the comparative weight of its evaluative criteria must be explained either case by case or in a general rule.

C. THE FTC'S CURRENT PRACTICE VIOLATES THE FIFTH AMENDMENT

Under the Fifth Amendment, a law is unconstitutionally vague if it does not provide regulatees with sufficient information to discern how to conform their conduct to the requirements of the law. *See, Grayned v. Rockford*, 408 U.S. 105 (1972) and *Zauderer v. Ohio*, 471 U.S. 626 (1985). The absence of defined criteria creates just such a constitutional violation. The Joint Commenters are effectively deprived of their liberty and property rights in their chosen commercial speech and advertising because they cannot discern through the exercise of reason what FTC will and will not accept as scientific corroboration for a dietary supplement structure/function claim, and thus, must refrain from advertising *ab initio* to avoid the risk of law violation.

II. THE PROPOSED RULE

The Joint Petitioners respectfully request that the FTC promulgate a proposed rule that will either (1) authorize the issuance of advisory opinions concerning whether dietary supplement structure/function claim advertising satisfies its competent and reliable scientific evidence requirement or (2) make express all of the criteria that it applies to evaluating scientific evidence under its "competent and reliable scientific evidence" standard for dietary supplement structure/function claim advertising, elucidating the nature, degree, quality, quantity, and kind of scientific corroboration it expects in support of dietary supplement structure/function claim advertising. In particular, if the agency chooses the second option, the Joint Petitioners ask that it promulgate a proposed rule that will articulate all criteria used by FTC to evaluate

scientific evidence, define the comparative weight of each criterion, and explain the principles that guide the agency in reaching decisions as to whether scientific evidence corroborates a dietary supplement structure/function advertising claim. In addition, the Joint Petitioners ask the agency to explain when and how disclaimers may be appropriately used to correct potentially misleading speech.

III. THE COSTS OF UNDERTAKING THE PROPOSED RULE

The costs of undertaking the proposed rule are entirely administrative and are minimal. Moreover, as explained above, commencement of the proposed rulemaking is a statutory and constitutional imperative. The ultimate costs associated with enforcing the proposed rule will likely be less than those associated with enforcing the current rule because regulatees informed of the criteria the agency employs to assess "competent and reliable scientific evidence" for structure/function claims will be able, for the first time, to determine whether the scientific evidence they possess for a claim is sufficient corroboration for the claim. In turn, the agency should experience a reduction in the need to prosecute cases of this kind because the regulated class will perceive the principles that guide agency action.

IV. CONCLUSION

For the foregoing reasons, the Joint Petitioners respectfully request that the FTC Commence a rulemaking to adopt the rule proposed herein. Because First and Fifth Amendment constitutional violations are present, the Joint Petitioners respectfully request

that the agency expedite action on this petition.

Sincerely,

DR. JULIAN M. WHITAKER;
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XCEL MEDICAL PHARMACY, LTD.,

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Dated: December 20, 1999