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September 13, 2002

VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Docket No. 02N-0209**

**Request for Comment on First Amendment Issues  
67 Fed. Reg. 34942, May 16, 2002**

Dear Sir or Madam:

These comments are submitted on behalf of Metagenics Inc., (“Metagenics”) of San Clemente, California, pursuant to the FDA’s “Request for Comment on First Amendment Issues” published in the Federal Register of May 16, 2002 (67 Fed. Reg. 34942). Metagenics is a manufacturer and supplier of high quality dietary supplements providing numerous health benefits for consumers. The Company markets its products under its own name, as well as under the Ethical Nutrients, Unipor, and MetaBotanica brand names.

Metagenics respectfully submits that the time has long since past for the Food and Drug Administration (the “FDA”) to begin consideration of the impact of the First Amendment on its efforts to suppress the communication of truthful and non-misleading health related information to the American public. Over the past four years, the federal courts have repeatedly found that the Agency’s efforts to prevent the dissemination of such information violate fundamental constitutional principles. In the face of such legal precedent, it is surprising and entirely inexcusable that the FDA has not made a single attempt to comply with the requirements of the First Amendment, its current request for comments notwithstanding. This is not to say that the FDA has remained silent on the interrelationship between its regulations and the U.S. Constitution. On the contrary, the FDA has actively refused to waiver on the First Amendment

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issue, litigating all claims as they arise to the fullest extent possible. The FDA even stated in its request for comments on the First Amendment that it will continue, “to defend the act against any constitutional challenges,” as it did unsuccessfully in Thompson v. Western States Medical Center, 122 S. Ct. 1497, 2002 U.S. LEXIS 3035 (2002). Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942, 34,943 (May 16, 2002).

The FDA’s continuing suppression of speech, not only violates the First Amendment of the Constitution, but is also contrary to the public health as it restricts the free flow of truthful and non-misleading information regarding scientific discovery and innovation. Such suppression of speech harms consumers by keeping them apart from the information they need to make intelligent and informed health care choices. The FDA has taken the unsupportable position, and seeks to gather public support and sympathy regarding that position, that the governing body of First Amendment law striking down many of the FDA’s regulations not only has “thwarted actions FDA has wished to pursue, however beneficial as matters of public policy, but they [governing body of First Amendment law] may threaten to diminish the overall legal credibility necessary for FDA to sustain its authority to accomplish its important public health duties.” *Id.* at 34,943. This contention is entirely without merit.

#### First Amendment Commercial Speech Analysis

In analyzing the constitutionality of the government’s regulation and/or suppression of truthful and non-misleading health related speech by the food, drug or dietary supplement industry, the dissemination of which the courts have unanimously treated as commercial speech, the four part commercial speech analysis as articulated by the Supreme Court in Central Hudson Gas & Electric Corp., v. Public Service Commission of New York, 447 U.S. 557 (1980), is applied.

Under Central Hudson, the court must perform the following analysis:

- (1) It must first determine whether the speech at issue is unlawful, false or inherently misleading;
- (2) If the speech is lawful, truthful and non-misleading, the government must then demonstrate a substantial interest in regulating the speech;
- (3) Next, the regulation in question must directly advance the government’s named substantial interest; and
- (4) Finally, the regulation must burden no more speech than necessary.

See *Id.*, Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81, 84 (1999).

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Application of Governing First Amendment Case Law to the Food and Drug Administration's Regulations, Guidances, Policies and Practices

The critical application of the Central Hudson commercial speech analysis to evaluate the FDA's regulation and/or suppression of speech was performed by the court in Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (1998) in 1998. Washington Legal Foundation involved the FDA's unconstitutional regulation of the dissemination of third party scientific literature regarding off label prescription drug uses. This case was followed by Pearson v. Shalala, 164 F. 3d 650 (D.C. Cir. 1999), in January 1999, which involved the unconstitutional regulation of health claims on dietary supplements. In July of 1999, Washington Legal Foundation was involved in an additional lawsuit involving the same speech as in Washington Legal Foundation v. Friedman, however in this case the court expanded the scope of its previous order to reflect the determination that the FDAMA and its implementing regulations, as opposed to only the FDA's Guidance Documents, are unconstitutional. Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (1999). These decisions were followed the Supreme Court's decision in Thompson v. Western States Medical Center, 122 S. Ct. 1497, 2002 U.S. LEXIS 3035 (2002), in April 2002, whereby the FDA was held to be unconstitutionally restricting advertising of drug compounding services. In each of these decisions, the court found that FDA's actions and/or regulations unconstitutionally violated the First Amendment. Contrary to the FDA's position regarding the overall effect of these decisions, they do not diminish the overall legal credibility necessary for FDA to sustain its authority to accomplish its important public health duties. In fact, public health is actually best served by the free flow of truthful non-misleading information permitted under the First Amendment. It was this exchange of information that Thomas Jefferson referred to as "The Marketplace of Ideas" and which has become a cornerstone of American Society. Whether or not the government had at least one substantial interest in regulating the speech involved in each of these cases, the courts found that such interests (whether valid or not) were not directly advanced by the FDA's actions/regulations contested in those matters nor were they accomplished by the least restrictive means available. As long as the government's interest in regulating commercial speech is substantial, the determination of which is no longer a foregone conclusion, the FDA has the affirmative duty to tailor its regulations, guidances, policies and practices so as to not unduly restrict commercial speech.

The Food and Drug Administration's Actions in  
Light of Governing First Amendment Law

It is painfully clear that the FDA, by its apparent unwillingness or mere sluggishness to modify its regulations, guidances, policies and practices, has not given the courts' recent First Amendment decisions the respect that they most certainly deserve. It is also clear, in hindsight,

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that prior to Washington Legal Foundation v. Friedman, the FDA must not have given the First Amendment much thought as it created food and drug policy and as it implemented its regulations. The growing body of case law regarding the preservation of commercial speech must change this attitude. The Supreme Court, in Western States, stated the government's past regard for the First Amendment in promulgating its regulations the best by saying, "If the First Amendment means anything, it means that regulating speech must be a last – not first – resort. Yet here it seems to have been the first strategy the Government thought to try." Western States, 122 S. Ct. 1497, 2002 U.S. LEXIS 3035 at \*31 (2002).

It should be noted that the FDA's policy to continue, "to defend the act against any constitutional challenges," as it did in Western States, even if there exists no justifications for their regulatory actions, may arguably be, in of itself, an unconstitutional burden on free speech. As Justice O'Connor for the Supreme Court in Western States ruled, "it is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" Western States, 122 S. Ct. 1497, 2002 U.S. LEXIS 3035 at \*31 (2002) citing Edenfield v. Fane, 507 U.S. 761, 770 (1993) (quoting Bolger v. Youngs Drug Products Corp., 463 U.S. 60 (1983)). As many of the FDA's current regulations, policies, guidances and practices impose unconstitutional restrictions on speech, the FDA's intentional delay in complying with the governing First Amendment case law as well as its intentional failure to conform its regulations, policies, guidances and practices to such laws without justification, as in this case, may be unconstitutional.

Metagenics' Request for the Food and Drug Administration to  
Act Promptly and Amend its Regulations, Guidances, Policies and  
Practices to Comply with the Governing First Amendment Case Law

Metagenics is certain that the governing body of First Amendment case law that has been developed will continue to grow and will eventually encompass and, in turn, invalidate FDA's regulations that unconstitutionally burden free speech. It is therefore incumbent on the FDA to act promptly and amend its regulations, guidances, policies and practices to comply with the governing First Amendment case law. To do otherwise would not only be a continuing violation of the First Amendment of the Constitution of the United States, but would also impose a severe financial burden on the United States taxpayers, would unnecessarily clog the court system wasting judicial resources and would deplete the FDA's self-described scarce resources.<sup>1</sup>

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<sup>1</sup> Metagenics respectfully submits that the FDA would better serve the public by expending its "scarce" resources on the promulgation of good manufacturing practices for dietary supplement manufacturers and undertaking legitimate enforcement activities against rogue companies that believe that they can safely market misbranded and/or adulterated dietary supplements without fear of FDA action.

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Metagenics' Assessment on the Current State of the Food and Drug Administration's Regulations, Guidances, Policies and Practices in Light of Governing First Amendment Law relating to Commercial Speech

A. Introduction.

Metagenics believes that to ensure that the FDA's regulations, guidances, policies and practices comply with governing First Amendment case law, that the communication of truthful and non-misleading information in the form of published or non published abstracts, articles, books or other publications regarding dietary supplement products or the ingredients contained therein which document research results and scientific evidence and discoveries to accredited health care professionals and to the consumer, should not be suppressed or regulated in any significant way. However, Metagenics acknowledges that because the FDA's interest in protecting consumers, who likely lack the same knowledge or sophistication as accredited health care professionals to be able to accurately assess scientific literature received, may be greater than its interest in protecting accredited health care professionals, the standards in judging speech directed towards both groups should be different.

B. Communication Directed to Consumers.

Metagenics believes that communication to the public regarding published articles or books documenting research results and scientific discoveries should not be limited in any way so long as such articles or books are not used as "labeling" to directly promote a branded product. This form of communication to the public is consistent with the type of speech that was specifically exempted from the definition of labeling when used in connection with the sale of dietary supplements to consumers, commonly referred to as the "third party literature exemption," under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). FDCA, the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994). To permit this type of communication to be used as "labeling" to directly promote a branded product could make this speech, as disseminated to consumers only, inherently misleading and under the Central Hudson analysis not entitled to First Amendment protection. Whether speech is "inherently misleading" depends upon a number of factors including; the "possibilities for deception," see Friedman v. Rogers, 440 U.S. 1, 13 (1979), whether "experience has proved that in fact that such advertising is subject to abuse," In re R. M.J., 455 U.S. 191, 203 (1982), and "the ability of the intended audience to evaluate the claims made." Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51, 67.

To ensure that this form of communication directed to the consumer will not mislead the public, Metagenics proposes that all such communications should clearly indicate whether or not the

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publication is peer reviewed and whether or not any commercial relationships or affiliations of the author(s) exist. Speech that is only potentially misleading does not render it able to be proscribed under Central Hudson without further analysis. In its application of Central Hudson, the court in Pearson stated “the States may not place an absolute prohibition on ... potentially misleading information ... if the information also may be presented in a way that is not deceptive. Pearson, 164 F. 3d 650, 655. Adding these disclaimers not only reduces the chance that the consumer will be misled, but it could make “inherently misleading” speech non-misleading or only “potentially misleading” thereby satisfying the first prong of the commercial speech test under Central Hudson.

As a matter of policy, Metagenics believes that the FDA should not be allowed to inhibit the free flow of truthful and not misleading information regarding scientific discovery for any reason because the public has the right to know the latest science in order to make informed choices. History has proven that the public often recognizes beneficial advances in health care, such as folic acid for prevention of neural tube defects and calcium for the prevention of osteoporosis, long before official governmental bodies recognize those advances.<sup>2</sup> The FDA should not impede the public from realizing health benefits available to them as a result of advancing science.

Completing the constitutional analysis of this type of communication to consumers under Central Hudson, Metagenics would agree with the relevant First Amendment case law, that the government may have a substantial interest in protecting the health and safety of consumers and in preventing consumer fraud. Metagenics' proposed conditions regarding this type of communication directly advances the government's substantial interests and they burden no more speech than is necessary.

### C. Communication Directed to Accredited Health Care Providers.

Metagenics also believes that communication to accredited health care professionals, regarding published articles and books documenting research results, scientific evidence and scientific discoveries should not be limited, provided they are used as non-branded, generic “educational materials”. In stark contrast, however, Metagenics believes that it is appropriate for the same “educational materials” to be disseminated along with “labeling” in direct promotion of a branded product so long as such materials are “truthful and non-misleading”. This type of communication is the logical, permissible and likely extension of the existing “third party literature exception” under DSHEA once the regulation is analyzed under, and brought into

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<sup>2</sup> Indeed, FDA's obstinate refusal to recognize these significant public health benefits was specifically recognized by the drafters of DSHEA.

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conformity with, governing First Amendment Law. For the purposes of communications to accredited health care professionals, “truthful and non-misleading” shall mean the following:

- a. The communication shall accurately represent the publication as “peer reviewed” or “non-peer reviewed”;
- b. The communication shall provide a balanced interpretation of the research including research findings that may not be supportive of the labeling (if applicable);
- c. The communication shall accurately represent the commercial relationships or affiliations of the author or the published article or book or the scientists conducting the research;
- d. The communication shall accurately represent the size of any scientific study referenced in the communication;
- e. The communication shall accurately represent the design of any scientific study referenced into the following categories: case study (one subject), non-controlled clinical trial (2 or more subjects), controlled clinical trial and blinded placebo controlled clinical trial; and
- f. The communication shall accurately represent the statistical significance of the results.

Under the first prong of the Central Hudson test, this type of communication made to accredited health care professionals must be truthful and non-misleading to warrant further constitutional analysis. False and inherently misleading speech is not entitled to constitutional protection. The dissemination of truthful and non-misleading published articles and books documenting research results, scientific evidence and scientific discoveries in direct promotion of a branded product to an accredited health care professional is entirely analogous to the litigated speech in Washington Legal Foundation v. Friedman and Washington Legal Foundation v. Henney, which involved a drug manufacturer’s truthful and non-misleading dissemination of research to physicians regarding its drug’s off label uses. In those cases, the court held that the subject speech was not inherently misleading, stating that “conclusions reached by a laboratory scientist or university academic and presented in a peer reviewed journal or text book are not ‘untruthful’ or ‘inherently misleading’ merely because the FDA has not had an opportunity to evaluate the claim” and that speech that is merely “potentially misleading” warrants further analysis under Central Hudson. Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51, 67. The court in Washington Legal Foundation v. Friedman further held that “categorizing the plaintiff’s speech as ‘inherently misleading’ is particularly unsupportable when one considers all of the controls available to the FDA to ensure that the information manufacturers wish to distribute is scientifically reliable.” *Id.* at 68. Some examples of the controls listed in the court’s order include the requirement of conspicuous notification to physicians that the drug’s off-label uses have not been approved by the FDA; that for article reprints, the reprints come from a “bona fide peer review journal” and that textbook reprints be published by a “bona fide independent publisher.” The conditions that Metagenics proposes to regulate speech directed at accredited health care professionals are

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similar to the controls in Washington Legal Foundation v. Friedman some of which are listed above, thereby eliminating any possibility that the type of communication to accredited health care professionals discussed by Metagenics would be misleading in any way.

With regard to the second prong of the Central Hudson analysis, the government would be hard pressed to come up with a single, substantial public health interest in regulating the type of communication to accredited health professionals that Metagenics discusses herein.

Accordingly, any such regulation of this type of communication is unconstitutional. The FDA argued in Washington Legal Foundation v. Friedman, that it had a substantial interest in regulating communications by a drug manufacturer to ensure that physicians receive accurate unbiased information so that they may make informed prescription choices. As the speech in Washington Legal Foundation v. Friedman is analogous to the type of communication to accredited health care professionals discussed by Metagenics herein, the FDA could make a similar argument. However, such argument and any similar argument must fail, as it failed in Washington Legal Foundation v. Friedman, because accredited health care professionals are in the best position to evaluate such speech. If the speech has little or no value, the accredited health care professionals, based on their professional experience, will recognize that fact and weight its value accordingly. The Friedman court supported this rationale, holding in that case, that “a physician’s livelihood depends on the ability to make accurate, life and death decisions based upon the scientific evidence before them. They are certainly capable of critically evaluating journal articles or textbook reprints that are mailed to them.” Washington Legal Foundation v. Friedman, 13 F. Supp 59, 70.

The FDA could also attempt to argue that its substantial interest in regulating this type of communication to accredited health care professionals is more general in scope, in that the FDA is responsible for protecting the health and safety of its citizens. As a general matter, the Supreme Court has held that the government has such a substantial interest. However, under the third prong of the Central Hudson test, any attempted regulation of this type of communication to accredited health care professionals must fail, as a governmental regulation which relates only to accredited health care professionals could not directly advance the government’s more generalized substantial interest of protecting the health and safety of its citizens.

Metagenics asserts that as a matter of policy, any regulation of communication to accredited health care professionals should encourage and permit the open unrestricted flow of information, in order to assist accredited health care professionals in providing health care to consumers and to generally keep accredited health care professionals better informed. Because they are trained to interpret and understand these types of communications there is no need to provide the same level of restriction as suggested by Metagenics for consumers. Since accredited health care professionals are also more informed regarding the individual health needs of their patients than

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a governmental body such as the FDA, accredited health care professionals should not be restricted from accessing information that may assist them in providing improved health care to their patients. In summation, the FDA should not impede the dissemination of truthful and non-misleading generic "educational materials" along with product labeling to accredited health care professionals, as these professionals are trained to understand and interpret this type of information.

#### D. Conclusion

Metagenics is thankful to have been given the opportunity to submit comments and present its views on how the FDA can ensure that its regulations, guidances, policies and practices comply with the First Amendment. It has taken four years, repeated landmark court decisions declaring a number of FDA's regulations, guidances, policies and practices unconstitutional, including Supreme Court's voice on the issue, as well as a tremendous amount of public outcry to finally reach the point whereby the FDA has conceded that it must perform its functions within the confines of the First Amendment. Four years of continued suppression of knowingly permissible speech is long enough, it would be unfair to keep the public in the dark any further.

#### FDA Question No.1 with Responses

As an additional matter, in response to the FDA's requested submission of comments addressing a series of specific questions posed in its notice pertaining to the FDA's regulation of commercial speech, these comments will additionally address question number 1 as follows:

(a) Are there arguments for regulating speech about drugs more comprehensively than, for example, about dietary supplements?

Yes, because the FDA has express statutory authority to comprehensively regulate drugs while lacking the same authority for dietary supplements.

(b) What must the administrative record contain to sustain such a position?

To sustain such a position, it is still necessary for the FDA to comply with the First Amendment and all commercial speech must be analyzed under the Central Hudson test.

(c) In particular, could the FDA sustain a position that certain promotional speech about drugs is inherently misleading, unless it complies with FDA requirements?

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Yes, drugs must be approved. To the extent the FDA is attempting to suggest that these First Amendment decisions endanger the public health by threatening the fundamental structure of the FDCA, it is engaging in sophistry. Nothing in the cases suggests this.

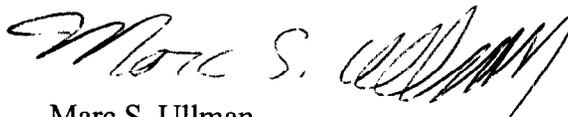
(d) Does anything turn on whether the speech is made to learned intermediaries or to consumers?

Yes, the regulation or suppression of speech made to learned intermediaries is more likely to be declared unconstitutional under the commercial speech analysis as set out in Central Hudson because accredited health care professionals are best trained to interpret and understand the type of speech the FDA is interested in regulating, and, accordingly, no substantial interest exists under Central Hudson, to justify regulating such speech. The regulation or suppression of speech made to consumers is much more likely to be upheld under the commercial speech analysis as set out in Central Hudson because consumers likely lack the same knowledge or sophistication as accredited health care professionals to be able to accurately assess information received if it involves scientific studies or the like.

(e) What is the evidentiary basis for such decision?

The court's decision in Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (1998).

Respectfully submitted,  
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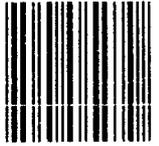
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