

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

Case No. 03-5020

**Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw;
and the American Association for Health Freedom,**

Appellants,

v.

**Tommy G. Thompson, Secretary, United States Department of Health and Human
Services; United States Department of Health and Human Services;
Mark B. McClellan, M.D., Commissioner of Food and Drugs, Food and Drug
Administration; and the United States of America,**

Appellees.

***AMICUS CURIAE* BRIEF OF
THE AMERICAN HERBAL PRODUCTS ASSOCIATION**

***Filed in support of Appellants seeking Reversal
of the decision of the United States District Court
for the District of Columbia***

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May 28, 2003

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the American Herbal Products Association states as follows:

Parties and Amici

Except for the American Herbal Products Association itself, all parties, intervenors, and amici appearing before the district court and in this court are listed in the Brief for Appellants.

Rulings under Review

References to the rulings at issue appear in the Brief for Appellants.

Related Cases

There are no related cases within the meaning of Circuit Rule 28(c)(1)(C).

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Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY OF ABBREVIATIONS

Act	Federal Food, Drug and Cosmetic Act
Agency	Food and Drug Administration
APA	Administrative Procedure Act
AHPA	American Herbal Products Association
BPH	Benign Prostatic Hyperplasia
DSHEA	Dietary Supplement Health and Education Act
FDA	Food and Drug Administration
FDCA	Federal Food, Drug and Cosmetic Act
NLEA	Nutrition Labeling and Education Act

STATUTES AND REGULATIONS

In accordance with Federal Rule of Appellant Procedure 28(f) and Circuit Rule 28(a)(5), pertinent statutes and regulations not contained in the Brief for Appellants are included in an Addendum to this Brief.

CONCISE STATEMENT

The American Herbal Products Association (“AHPA”), based in Silver Spring, Maryland, is the national trade association and voice of the herbal products industry. It is comprised of growers, processors, manufacturers, and marketers of herbs and herbal products, including Saw Palmetto and products containing Saw Palmetto. AHPA serves its members by promoting the responsible commerce of dietary supplements and other products that contain herbs.

AHPA and its members have a substantial interest in assuring that the provisions of the Federal Food, Drug and Cosmetic Act that pertain to dietary supplements, including the Dietary Supplement and Education Act of 1994 and the Nutrition Labeling and Education Act of 1990, are properly interpreted by the Food and Drug Administration so that the dissemination of information regarding the health supporting properties of dietary supplements is not stifled by improper government regulation and enforcement. AHPA and its members therefore have a particular interest in this Court’s ruling on the Saw Palmetto health claim as well as in the Court’s interpretation of the health claim provisions of the Federal Food, Drug and Cosmetic Act, both of which are at issue in this appeal. Accordingly, on March 5, 2003, AHPA’S Board of Trustees authorized its counsel to file an *amicus curiae* brief on behalf of AHPA in support of the position taken by the plaintiffs below in this action.

ARGUMENT

I. Brief Statement of the Case and Summary of Argument

Appellants (hereinafter “Whitaker, et al.”) filed a health claim petition with the Food and Drug Administration (“FDA” or “Agency”) seeking permission to include the following truthful statement on the labels and in the labeling of their Saw Palmetto dietary supplements:

“Consumption of 320 mg of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH).” Included in the petition was the extensive scientific data supporting the proposed health claim. The FDA declined to evaluate the merits of Whitaker, et al.’s petition. Instead FDA rejected the petition on the basis that claims about a nutrient’s ability to treat disease or mitigate the symptoms of disease (“treatment claims”), such as the claim proposed by Whitaker, et al., are outside the scope of the health claims authorizing provision of the Federal Food, Drug and Cosmetic Act (“FDCA” or “Act”). Despite the broad language of the relevant statutory provision defining the scope of permissible health claims, the FDA asserted that health claims may only address a nutrient’s ability to prevent disease or reduce the risk of developing a disease (“prevention claims”).

Whitaker, et al. challenged the FDA’s summary rejection of their health claim petition. The district court deferred to the FDA’s narrow interpretation of the health claim authorizing provision of the FDCA and concluded that the FDA’s rejection of the petition did not violate the FDCA, the Administrative Procedure Act (“APA”), or the First Amendment. It is AHPA’s position that the district court’s interpretation of the FDCA is fundamentally flawed. As explained in section II below, the FDCA’s health claims authorizing provision states without qualification that a health claim may refer to any relationship between a nutrient and a disease,

and so-called treatment claims, such as that proposed by Whitaker, et al., fall squarely within its ambit. Because the district court’s APA and First Amendment analyses were predicated upon its erroneous statutory interpretation, those analyses are flawed as well. Moreover, AHPA contends that the alleged negative public health consequences that FDA predicts will flow from allowing treatment claims to be made as health claims are illusory. In section III below, AHPA explains why FDA’s concerns are unwarranted and cannot justify disregarding the clear direction of Congress.

For these reasons, as well as the reasons set forth in Appellant’s brief, this Court should reverse the decision of the district court, and order that court to order the FDA to evaluate Whitaker, et al.’s Saw Palmetto health claim as required by the health claims authorizing provision of the FDCA.

II. The Unambiguous Language of the FDCA Permits Health Claims Regarding a Nutrient’s Ability to Treat Disease or to Mitigate the Symptoms of Disease

The district court committed reversible error when it deferred to the FDA’s conclusion that claims to treat a disease or to mitigate the symptoms of disease cannot qualify as health claims under the provisions added to the FDCA as part of the Nutrition Labeling and Education Act of 1990 (“NLEA”). As defined by Congress, a permissible health claim is one that “characterizes the relationship of any nutrient . . . to a disease or health-related condition.” 21 U.S.C. § 343(r)(1)(B).

With respect to conventional foods, the Congress directed the FDA to promulgate regulations authorizing such health claims when the available scientific evidence satisfies a particular evidentiary standard – known as the significant scientific agreement standard. 21

U.S.C. § 343(r)(3)(B)(i). Those regulations are to describe both “the relationship between a nutrient . . . and a disease or health-related condition” and “the significance of each such nutrient in affecting such disease or health-related condition.” 21 U.S.C. § 343(r)(3)(B)(ii).

In contrast, with respect to dietary supplements, Congress authorized the FDA to establish a procedure and standard for approval of health claims:

A [health claim under Section 343(r)(1)(B)] made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

21 U.S.C. § 343(r)(5)(D).

Prior to passage of the NLEA in 1990, the FDCA did not specifically refer to dietary supplements and they were regulated as simple foods unless they were intended for drug use. The FDCA defines “drugs” as, among other things, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” 21 U.S.C. § 321(g)(1)(B). Recognizing that foods and dietary supplements bearing authorized health claims could therefore be considered drugs under this definition, Congress specified that use of an authorized health claim does not cause a food or dietary supplement to become a drug: “A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim.” 21 U.S.C. § 321(g)(D).

There can be no serious dispute – and the lower court did not disagree – that the relevant statutory language “characterizes the *relationship* of any nutrient . . . to a disease or health-related condition” is clearly broad enough to encompass claims that a nutrient treats a disease or

mitigates the symptoms of a disease. “Relationship” refers broadly to any connection or association between two things. *See, e.g., Babbitt v. Sweet Home Chapt. of Communities for a Great Oregon*, 515 U.S. 687, 697-98 (1995) (interpreting term in statute in accordance with its ordinary, dictionary definition). The broad, unqualified term “relationship” cannot reasonably be read to refer to only certain connections or associations (prevention) and not others (treatment). *See United States v. James*, 478 U.S. 597, 605 (1986) (breadth of term “damage” does not render it ambiguous; term interpreted in accordance with its broad, inclusive meaning). Through its use of broad, unqualified language – “characterizes the *relationship* of any nutrient . . . to a disease or health-related condition” – Congress has directly spoken to the question at issue in this case. Because the intent of Congress is clear, the FDA and this Court must give effect to that unambiguously expressed intent. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984) (“*Chevron*”).

Despite the expansive language used by Congress, the lower court concluded that Congress’ intent regarding the scope of health claims is not clear from the FDCA or relevant legislative history, thus necessitating a *Chevron* step two analysis. *Whitaker v. Thompson*, 239 F.Supp.2d 43, 51 (D.D.C. 2003). Though the district court devoted several paragraphs of its opinion to its *Chevron* step one analysis, it is difficult to discern the source of the ambiguity perceived by the court. While the court did focus on two FDCA provisions, neither of these provisions create any ambiguity. Similarly, the court’s reliance on legislative history is misplaced.

A. The Grant of Authority Allowing the FDA to Adopt “a Procedure and Standard” Regarding Health Claims for Dietary Supplements does not Introduce Any Ambiguity into the Health Claim Definition

The lower court suggested that the provision allowing the FDA to adopt, by regulation, “a procedure and standard” regarding health claims for dietary supplements granted the FDA wide discretion in approving health claims, thus creating ambiguity about the appropriate scope of health claims. *Whitaker*, 239 F.Supp.2d at 49-50. The most natural reading of this provision, however, is that it simply authorized the FDA to promulgate regulations outlining a procedure and an evidentiary/scientific standard for approval of dietary supplement health claims. Indeed, this is precisely how the FDA has previously interpreted this provision. In 1993, the FDA adopted regulations concerning health claims for conventional foods. *Food Labeling; General Requirements for Health Claims for Foods*, 58 Fed. Reg. 2478 (Jan. 6, 1993). These regulations described the applicable substantive/evidentiary standard set forth in the Act for health claims for conventional foods – significant scientific agreement – (21 C.F.R. § 101.14(c)) and procedures for submission of a health claim petition (21 C.F.R. § 101.70). *Id.* at 2533-36. Later that year, in response to the Congressional mandate that the FDA adopt “a procedure and standard” for dietary supplement health claims, the FDA proposed to apply the same substantive standard and procedures to dietary supplements. *Food Labeling; General Requirements for Health Claims for Dietary Supplements; Proposed Rule*, 58 Fed. Reg. 33700 (June 18, 1993). The next year, the FDA made this proposal final and made dietary supplements subject to the same substantive evidentiary standard as foods (significant scientific agreement, 21 C.F.R. § 101.14(c)) and adopting the same health claim petition procedures (21 C.F.R. § 101.70). *Food Labeling;*

General Requirements for Health Claims for Dietary Supplements; Final Rule, 59 Fed. Reg. 395 (Jan. 4, 1994).

Consistently throughout this rulemaking, the FDA interpreted Congress' grant of authority to adopt a "standard" to refer only to a substantive scientific/evidentiary standard. Indeed, the bulk of the preamble to the FDA's proposed rule was devoted to considering whether the Agency should adopt the same scientific standard Congress specified for conventional foods (*i.e.*, significant scientific agreement), a more lenient scientific standard, or a more strict scientific standard. 58 Fed. Reg. 33700, 33702-706. Nowhere in the proposed or final rules does the FDA suggest that its authority to adopt a "standard" enabled the Agency to redefine the scope of permissible health claims, or even injected ambiguity into that definition. Indeed, this Court has acknowledged that in response to the statutory grant of authority to promulgate "a procedure and standard" the FDA adopted a standard in 21 C.F.R. § 101.14(c) (significant scientific agreement) and a procedure in 21 C.F.R. § 101.70 (petition process). *Pearson v. Shalala*, 164 F.3d 650, 653 (D.C. Cir. 1999); *see also National Council for Improved Health v. Shalala*, 122 F.3d 878, 880-81 (10th Cir. 1997) (explaining that 21 C.F.R. § 101.14, setting forth a substantive standard for health claim approval, and 21 C.F.R. § 101.70, setting forth procedural guidelines, were adopted in response to 21 U.S.C. § 343(r)(5)(D)).

Nothing in the text of the provision granting authority to adopt "a procedure and standard," the associated legislative history, or the FDA's subsequent interpretation of this provision suggests in any way that Congress intended to authorize the FDA to narrow the scope of the health claims definition. It is simply unreasonable to read this limited grant of authority to

allow the FDA, on an *ad hoc* basis, to narrowly interpret the phrase “characterizes the *relationship* of any nutrient . . . to a disease or health-related condition.”

Moreover, interpreting this provision to authorize the FDA to redefine the permissible scope of health claims creates an inexplicable anomaly in the statute. The grant of authority to promulgate “a procedure and standard” applies *only* to dietary supplement health claims. 21 U.S.C. § 343(r)(5)(D). Accordingly, were this provision interpreted to authorize the FDA to adopt a more narrow definition of health claim to exclude treatment claims, that narrow definition would only apply to health claims for dietary supplements, and treatment claims would be permissible for conventional foods. Because Congress used the same broad statutory language to define health claims for both conventional foods and dietary supplements – “characterizes the *relationship* of any nutrient . . . to a disease or health-related condition” – there is no basis to conclude that Congress use of the “procedure and standard” provision empowers FDA to severely limit the types of health claims available for dietary supplements. Surely if Congress intended the scope of health claims for conventional foods to differ from that of dietary supplements, it could and would have communicated its intent in a more straightforward manner (*e.g.*, by adopting two different definitions). In sum, the lower court’s strained reading of the “procedure and standard” provision to create ambiguity in the health claim definition must be rejected in favor of the straight forward interpretation previously adopted by the FDA.

B. The Drug Definition does not Introduce Any Ambiguity into the Health Claim Definition

The lower court’s *Chevron* step one analysis and conclusion that Congress did not express clear intent regarding the proper scope of health claims was also premised on the FDCA

drug definition. The court emphasized that the definitions of drug and dietary supplement are not mutually exclusive. In this regard the court focused on Congress' use of the term "solely" in the exclusion from the drug definition for supplements bearing health claims: "a . . . dietary supplement for which a [health claim is made] is not a drug solely because the label or the labeling contains such a claim." 21 U.S.C. § 321(g)(1)(D). According to the district court, "solely" indicates that Congress intended the FDA to retain discretion to classify a health claim as a drug claim. *Whitaker*, 239 F.Supp.2d at 49-50.

This provision, enacted as part of NLEA, does not bear upon the scope of NLEA's health claims definition. It does not suggest that Congress authorized or expected the FDA to narrow the health claims definition, nor does it create ambiguity in that definition. On the contrary, this provision states that use of an authorized health claim does not preclude the FDA from finding that *other* claims made for the same dietary supplement product are drug claims. In other words, use of an authorized health claim on the label of a dietary supplement (*e.g.*, folate reduces the risk of neural tube defects) does not give a manufacturer blanket immunity to include other claims for the product that would otherwise be classified as drug claims (*e.g.*, folate cures cancer). Rather than impliedly authorizing the FDA to refuse to evaluate a certain subset of claims that fall within the broad health claim definition, this provision simply preserves the FDA's authority, when applicable, to otherwise proceed against a dietary supplement making drug claims, including those dietary supplements that bear authorized health claims.

C. Legislative History Does Not Create Ambiguity in the Health Claim Definition or Contradict the Act's Plain Language

The lower court concluded that the legislative histories of the FDCA, NLEA and the Dietary Supplement Health and Education Act of 1994 (“DSHEA”) do not demonstrate a clear congressional intent regarding the appropriate scope of health claims. As an initial matter, there was no need for the lower court to examine legislative history, given the unambiguously broad language Congress used to define the permissible scope of health claims. *See Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992).

In any event, the legislative histories are fully consistent with the plain language of the Act. Neither the lower court nor the FDA in its filings below cited any legislative history in which Congress suggested that health claims should be limited to some narrow subset of claims that “characterize[] the *relationship* of any nutrient . . . to a disease or health-related condition.” The absence of any express Congressional statement that health claims could include claims about a nutrient’s ability to treat disease or mitigate the symptoms of disease is wholly irrelevant; of course there was no reason for Congress to include in legislative history that which was already plain from the language of the Act.¹ Equally irrelevant is the fact that examples of health claims mentioned in the legislative histories are what the FDA considers prevention claims. None of these examples were offered by Congress to redefine or narrow the phrase “characterizes the relationship of any nutrient . . . to a disease or health-related condition.” Rather, they are examples of health claims that were, at the time, proposed, being made, or under consideration. In sum, nothing in the legislative history suggests that Congress intended a more narrow health claim definition than that stated in the FDCA, and certainly no excerpt can be said to clearly

¹ In fact, as noted by Appellants in their brief, a post-enactment committee report indicates that members of Congress understood nutrient-disease relationships to include treatment claims. *See Appellant’s Brief*, page 25, n.11.

express Congressional intent that FDA put limits on the broad language of the statute. *See Davis County Solid Waste Management v. EPA*, 101 F.3d. 1395, 1405-06 (D.C. Cir. 1996) (plain meaning controls unless it is demonstrably at odds with Congressional intent) (citations omitted); *Ethyl Corp. v. EPA*, 51 F.3d. 1053, 1062-63 (D.C. Cir. 1995) (cryptic legislative history insufficient to overcome the plain language).

III. The FDA's Policy Concerns are Unwarranted, and in any Event Cannot Justify Ignoring the FDCA's Plain Language

In the proceedings below, the FDA attempted to justify its interpretation of the Act by pointing to negative public health consequences that will purportedly flow from allowing treatment claims to be made as health claims. These concerns appear to have affected the district court's analysis. As demonstrated below, FDA's concerns are unwarranted, but even if they were well-founded, policy concerns never authorize an agency to disregard the clear direction of Congress.

A. There is No Basis to Conclude that Consumers Will Improperly Use Dietary Supplements Containing Saw Palmetto if They are Marketed with the Proposed Health Claim

The FDA expressed concern that men experiencing lower urinary tract symptoms may self-medicate with Saw Palmetto and delay timely and accurate diagnosis of other conditions, such as cancer. As an initial matter, the Agency offered nothing more than supposition that this would occur.² Even if the concern were valid, however, it could be fully addressed through a

² The FDA cited to its 1990 final rule on BPH drug products for over-the-counter use, suggesting that this document somehow proves the validity of the FDA's concerns. In fact, while the Agency expressed this same concern in the 1990 final rule, it cited to no data or other evidence in that document supporting its theory that men will delay consultation with a physician if products for relief of the symptoms of BPH are available over-the-counter. *See Benign Prostatic Hypertrophy Drug Products for Over-the-Counter Human Use; Final Rule*, 55 Fed.

requirement that the Saw Palmetto health claim be accompanied by information about the need for regular prostate exams. For example, AHPA recommends that the following or similar language appear on the label of any products containing Saw Palmetto: “Notice: The National Institute on Aging recommends that men get regular medical checkups with a thorough prostate exam. You should inform your health care practitioner that you are using this product.” Whitaker, et al. have repeatedly stressed their willingness to include any such language the FDA deems appropriate.

While FDA declared thirteen years ago that cautionary language about the need for routine prostate exams was inadequate to address its concern regarding self-medication, 55 Fed. Reg. 6926, 6929, this Court has since rejected the FDA’s paternalistic view of consumers, and held that the FDA cannot constitutionally suppress a health claim when it can be rendered nonmisleading through the addition of a disclaimer. *Pearson v. Shalala*, 164 F.3d 650, 655, 657 (D.C. Cir. 1999). Significantly, the *Pearson* court indicated that FDA should not reject disclaimers as inadequate unless the Agency has “empirical evidence” that disclaimers would “bewilder consumers and fail to correct for deceptiveness.” *Id.* at 659-60. The FDA has offered no such empirical evidence in these proceedings or in the course of its 1990 rulemaking.

In the final analysis, there is no reason to believe that men will improperly use dietary supplements containing Saw Palmetto if they are marketed with the proposed health claim. Indeed, approving the Saw Palmetto health claim with accompanying language concerning the need for routine prostate exams would benefit, not harm, the public health. If approved, the labels of most Saw Palmetto products will likely bear the health claim along with any additional

Reg. 6926, 6928-29 (Feb. 17, 1990).

language regarding the need for regular prostate exams required by FDA. Thus, approval of the proposed health claim would likely result in a wider dissemination of the National Institute on Aging's important recommendation for regular prostate exams.

B. Interpreting the Health Claims Provision in Accordance with its Plain Meaning will not Eviscerate the Drug Approval Requirements

FDA also complained that interpreting the health claim definition in accordance with its plain meaning would allow a host of drugs that are derived from plant compounds to be sold as dietary supplements bearing health claims, thus avoiding the preapproval and labeling requirements applicable to drugs. This is simply untrue.

Congress specifically considered and addressed situations in which an ingredient in a dietary supplement is also approved by the FDA for use as a drug, antibiotic, or biologic. A substance first marketed as a dietary supplement or as a food *prior* to FDA approval as a drug, antibiotic, or biologic may remain on the market as a dietary supplement. 21 U.S.C. § 321(ff)(3)(A). However, these type of products may be removed from the dietary supplement market if, after informal rulemaking, the FDA finds that when used according to the dietary supplement labeling, the product is unsafe. 21 U.S.C. § 321(ff)(3)(A). In contrast, dietary supplement manufacturers may not sell a substance not previously marketed as a dietary supplement or food if it has first been approved as a drug, antibiotic, or biologic. 21 U.S.C. § 321(ff)(3)(B)(i). Relatedly, if a substance has first been authorized by the FDA for investigation as a new drug, antibiotic, or biologic, substantial clinical investigations have begun, and the existence of those investigations is public, the substance may not be marketed as a dietary supplement unless the FDA first issues a regulation authorizing the marketing as a dietary

supplement. 21 U.S.C. § 321(ff)(3)(B)(ii). The FDA has successfully enforced these provisions to ensure that products containing drug ingredients are not marketed as dietary supplements. *See Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000).

With respect to botanicals currently marketed as drugs, but not approved under the FDCA, the safety standard applicable to dietary supplements would preclude their marketing as dietary supplements. A dietary supplement is adulterated if it presents a serious or unreasonable risk of illness or injury under the conditions of use recommended in the labeling, or under ordinary conditions of use, if no conditions are recommended in the labeling. 21 U.S.C. § 342(f)(1)(A). Moreover, no provision of the FDCA provides for the prescription marketing of dietary supplements. Accordingly, any product that either requires the supervision of a licensed practitioner to ensure safe use (due to side effects, for instance) or that treats or mitigates a disease that requires a professional diagnosis, could not satisfy the relevant dietary supplement safety standard. Thus, the botanical digitalis, long used in the treatment of heart conditions, could not be marketed as a dietary supplement because it is not safe for use without professional supervision.

Finally, the FDA seems to have overlooked its own role as gatekeeper with respect to the FDCA's health claims provision. Manufacturers cannot simply go to market with such claims, they must present the proposed claim to FDA for evaluation. If FDA determines that a claim, if granted, would render a food or dietary supplement adulterated and subject to regulatory action, it could certainly articulate the factual basis for its position and respond. There is nothing in the health claims provision that requires FDA to ignore the other food and dietary supplement regulatory and enforcement provisions of the FDCA.

In sum, there is no basis for the FDA's speculation that a large number of drugs will be marketed as dietary supplements if the FDCA health claims provision is interpreted in accordance with its plain meaning.

C. Policy Concerns Do Not Authorize the FDA to Disregard Clear Congressional Direction

As explained above, the policy concerns the FDA offered in support of its interpretation of the FDCA are illusory. However, even if the FDA's concerns were demonstrably well-founded, the Agency's only recourse is to request that Congress amend the FDCA, for policy concerns, no matter how compelling, cannot trump clear Congressional direction reflected in the plain language of a statute. *See, e.g., Backcounty Against Dumps v. EPA*, 100 F.3d 147, 151-52 (D.C. Cir. 1996) (rejecting EPA's statutory interpretation and, with respect to EPA policy argument, noting, "[a]lthough treating tribes differently from states may be unfair as a policy matter, and may be the result of Congressional inadvertence, the remedy lies with Congress, not with the EPA or the courts").

CONCLUSION

For the foregoing reasons, as well as those set forth in Appellant's brief, AHPA respectfully requests that this Honorable Court reverse the decision of the district court.

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May 28, 2003

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 4365 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Rule 32(a)(2) of the Circuit Rules of the United States Court of Appeals for the District of Columbia Circuit.

This brief complies with the type face and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and 32(a)(6) and Circuit Rule 32(a)(1) because this brief has been prepared in a proportionally spaced typeface using WordPerfect Version 9 in Times New Roman 12 point type for footnotes and the body of the brief.

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PROOF OF SERVICE

I, Anthony L. Young, hereby certify that on the 28th day of May, 2003, I served, via hand delivery, a copy of the “*Amicus Curiae* Brief of the American Herbal Products Association” on the following persons:

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Anthony L. Young (No. 24565)

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

Case No. 03-5020

ADDENDUM

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