IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH US,
1350 Connecticut Avenue, N.W.,
5th Floor,
Washington, D.C. 20036;

DURK PEARSON and SANDY SHAW,
P.O. Box 552,
Tonopah, NV 89049;

and

COALITION TO END FDA AND FTC CENSORSHIP,
1050 17th St., N.W.,
Suite 600,
Washington, D.C. 20036,

Plaintiffs,

v.

KATHLEEN SEBELIUS,
in her official capacity as Secretary,
United States Department of Health and Human Services,
200 Independence Avenue, S.W.,
Sixth Floor,
Washington, D.C. 20201;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201;

MARGARET A. HAMBURG, M.D.,
in her official capacity as Commissioner,
United States Food and Drug Administration,
5600 Fishers Lane,
Room 1471,
Rockville, MD 20857;

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

FOOD AND DRUG ADMINISTRATION,)
5600 Fishers Lane,)
Rockville, MD 20857;)
)
and the UNITED STATES OF AMERICA,)
)
***Defendants*.**)
_____)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiffs file this complaint to challenge certain regulations adopted as part of Defendants' Dietary Supplement Current Good Manufacturing Practices ("GMP") final rule promulgated pursuant to the Administrative Procedure Act and codified in Title 21, Part 111 of the United States Code of Federal Regulations.

2. The following regulations violate the Food, Drug, and Cosmetic Act ("FDCA") provisions governing when a dietary supplement may be deemed adulterated, 21 U.S.C. § 342(f), (g): 21 CFR 111.8; 21 CFR 111.14; 21 CFR 111.16; 21 CFR 111.23; 21 CFR 111.25; 21 CFR 111.35; 21 CFR 111.8; 21 CFR 111.95; 21 CFR 111.103; 21 CFR 111.140; 21 CFR 111.153; 21 CFR 111.180; 21 CFR 111.210; 21 CFR 111.260; 21 CFR 111.303; 21 CFR 111.325; 21 CFR 111.353; 21 CFR 111.375; 21 CFR 111.403; 21 CFR 111.430; 21 CFR 111.453; 21 CFR 111.475; 21 CFR 111.503; 21 CFR 111.535; 21 CFR 111.553; 21 CFR 111.570; and 21 CFR 111.605-111.610. Those regulations declare the failure to keep adequate records per se adulteration without requiring FDA to prove as a condition precedent that a dietary supplement presents a significant or unreasonable risk of illness or injury or that a dietary supplement has been prepared, packed, or held under conditions that violate the GMPs, 21 U.S.C. § 342(f), (g). Similarly, certain regulations pertaining to Quality Control oversight violate the FDCA

because those so-called "in-process" quality control procedures actually have no bearing on whether the finished supplement is adulterated within the meaning of 21 USC 342(f),(g): 21 CFR 111.12(a); 21 CFR 111.30(c), (d), (e); 211CFR 111.60(b); 21 CFR 111.65; 21 CFR 111.70(c)(3); 21 CFR 111.75(a), (c)(4), (d)(2); 21 CFR 111.103-111.140; 21 CFR 111.115(c); 21 CFR 111.160(c)(2)-(3); 21 CFR 111.165(c)(2)-(3); 21 CFR 111.260(l); 21 CFR 111.315.

3. The following regulations violate the Administrative Procedure Act prohibition on arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A), and on abuse of agency discretion, 5 U.S.C. § 706(2)(A), as well as the Fifth Amendment Due Process Clause prohibition on vague criminal laws (the violations being prosecutable under the criminal adulteration provisions of the FDCA, 21 U.S.C. § 333): 21 CFR 111.3; 21 CFR 111.10(b)(2), (9); 21 CFR 111.12(a), (c); 21 CFR 111.13; 21 CFR 111.15(a)(3), (a)(4), (e)(1), (f); 21 CFR 111.20(a), (b), (c), (d)(1)(i), (d)(iii), (d)(iii), (d)(v), (d)(2), (e), (h); 21 CFR 111.27(a); 21 CFR 111.70(a), (b)(3), (c), (d), (e); 21 CFR 111.90(b)(1); 21 CFR 111.410(a); 21 CFR 111.455; and 21 CFR 111.470. Those regulations fail to provide the regulated class adequate direction to know what steps must be taken to comply with the law.

4. Following notice and comment rulemaking, the United States Food and Drug Administration ("FDA") issued the dietary supplement GMP Final Rule on June 22, 2007. *See Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Final Rule,* 72 Fed. Reg. 34752 (June 25, 2007) (hereinafter "Final Rule"). The regulations are presently

applicable to companies with greater than 20 employees and will be applicable to all companies regardless of size beginning June 2010.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

6. The Plaintiffs' requested relief is authorized under 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief), and the Plaintiffs' cause of action proceeds as a matter of right under the Administrative Procedure Act. *See* 5 U.S.C. 702.

7. Plaintiffs' complaint is timely filed within six years of the Final Agency action. *See* 28 U.S.C. § 2401(a); *see also* Final Rule, 72 Fed. Reg. 34752 (2007).

8. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) because the Defendants reside in this district and a substantial part of the events giving rise to this action occurred in this district.

PARTIES

9. The Alliance for Natural Health is an international, not-for-profit, non-governmental organization with headquarters in Washington, D.C. and with a United States division that is one of the plaintiffs in this action: Alliance for Natural Health US ("ANH US"). ANH US is the successor to the American Association for Health Freedom which, in turn, is the successor to the American Preventive Medical Association. Founded in 2002, ANH US represents practitioners, medical doctors, scientists,

consumers, and patients who variously manufacture, sell, distribute, and recommend and use dietary supplements. ANH US's mission objectives include the promotion of natural health and access to dietary supplements. As an alliance, the ANH US represents individuals and entities within the dietary supplement industry that are adversely affected by the FDA's GMP Final Rule. ANH US members suffer injury resulting from the significant financial burdens imposed by the FDA's GMP Final Rule. By FDA's own admission, implementation of the GMPs is expected to eliminate as much as 12% of the dietary supplement industry, decrease the variety of dietary supplements available on the market, reduce entry into the dietary supplement industry, and increase the cost of dietary supplements. *See* Final Rule, 72 Fed. Reg. at 34921, 34938 (adverse economic effects on small entities).

10. Durk Pearson and Sandy Shaw are scientists residing in Nevada. They design dietary supplement formulations and license them to manufacturing and retailing companies for sale to consumers. They are authors of four books on aging and age-related diseases, including the number one, million-plus copy New York Times best seller *Life Extension: A Practical Scientific Approach* (1982). They have also published three other health books, two of which were best sellers: *The Life Extension Companion* (1984); *The Life Extension Weight Loss Program* (1986); and *Freedom of Informed Choice—FDA Versus Nutrient Supplements* (1993). The companies licensed to manufacture and sell Pearson and Shaw's formulations have experienced increased costs of compliance associated with those rule sections challenged here, which has compelled them to reduce the number and kind of Pearson and Shaw formulations they carry, thereby causing Pearson and Shaw to suffer from a lessening in their royalty income and

a loss of the economic value of the formulations no longer sold to the public. Durk Pearson and Sandy Shaw submitted citizen comments in August 2003 challenging the FDA's GMP Proposed Rule and, in particular, took issue with the actions taken that resulted in the rule sections here challenged. Pearson and Shaw joined as commenters in docket number FDA-1996-0028-0353. Pearson and Shaw filed two additional comments individually.[1]

11. The Coalition to End FDA and FTC Censorship (CEC) is an association of 100 persons, including companies, that sell dietary supplements and have united for the purpose of advocating that federal government agencies not block consumer access to accurate representations concerning the existing science on the role of nutrients in treating and preventing disease. The Coalition joined Durk Pearson and Sandy Shaw in filing comments in opposition to the GMP Proposed Rule and, in particular, to the actions taken that resulted in the rule sections here challenged. The Coalition believes FDA's use of the GMPs anticompetitive, designed to eliminate companies without regard to whether they in fact present a risk to the public from adulterated products.

STATEMENT OF FACTS

12. By FDA's own estimate, enforcement of the GMPs will eliminate 12% of companies that sell dietary supplements, *See* Final Rule, 72 Fed. Reg. at 34920, 34938, will reduce the variety of dietary supplements on the market, will increase the cost of

[1] *See* Comments of Durk Pearson & Sandy Shaw, Docket No. 96N-0417 (submitted Aug. 11, 2003); Additional Comments of Durk Pearson & Sandy Shaw, Docket No. 96N-0417 (submitted Sep. 4, 2003). While the FDA docket does not assign a number for each of the above comments, a post office certified return receipt confirms that the dockets management branch did receive them in a timely manner.

dietary supplements, and will reduce the number of new market entrants. *Id.* at 34938 ("[s]ome [small companies] may decide it is too costly and either change product lines or go out of business"). FDA estimates that the Final Rule will produce anti-competitive effects not only by diminishing new market entry but also by imposing what may be unaffordable costs on dietary supplement companies whose revenue is less than $5 million per year. *See* Final Rule, 72 Fed. Reg. at 34938 ("[e]stablishments with above average costs, and even establishments with average costs, could be hard pressed to continue to operate"). Expert analysis projected that the GMPs will reduce demand and sales of supplements greatly. *See* Paul H. Rubin, GMP Economic Impact Assessment, FDA-1996-N-0028-0355, at 18. The great impact on small business renders the "costs of the [Final Rule] vastly greater than benefits." *Id.* at 16. Moreover, "[m]ost of the effect of reduced sales will fall on small firms … because costs of small firms will increase more than costs of larger firms." *Id.*

13. In the 1970s, the FDA sought to make vitamin and mineral supplements over-the-counter ("OTC") drugs. *See* Statement of Senator Hatch, 139 Cong. Rec. S4561-02, at S4577 (Apr. 7, 1993), *available at*, 1993 WL 102951. In 1976, Congress passed the Proxmire Amendments, stopping FDA from establishing standards that limited the potency of vitamins and minerals in foods and supplements or regulating them as drugs based solely on potency. *See, e.g.*, FDA Release; "Milestones of Drug Regulation in the United States," *at*, http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/CDER/CenterforDrugEvaluationandResearchBrochureandChronology/ucm114463.htm; FDA Release, "This Week In FDA History – April 22, 1976," *at*,

http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117726.htm. FDA regulated dietary supplements as food additives. *See* Statement of Dan Burton, H.R. Rep. 106-1053, 106th Cong. 2nd Sess. 2001, at 71 ("[i]n their zealous regulatory efforts against dietary supplements, the FDA claimed that dietary supplements were 'food additives' like chemicals added to foods for processing"), *available at*, 2001 WL 32054. Accordingly to FDA, dietary supplements could be marketed only with pre-market approval under the food additive provisions of the Food, Drug, and Cosmetic Act ("FDCA"). *Id.* The additive approval process posed significant hurdles for dietary supplement manufacturers. Manufacturers seeking approval for food additives faced a regulatory process lasting an average of several years at a cost of several million dollars. *See, e.g.*, Institute of Medicine, Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies, Summary at 2 (1999), *available at*, http://books.nap.edu/openbook.php?record_id=9453&page=1. In 1994, Senator Hatch explained that under FDA's restrictive interpretation of dietary supplements, "FDA could not lose, as it needed only to furnish an affidavit from one of its scientists stating that experts generally did not regard the product as safe. The actual safety of the product was never at issue." *See* Proceedings and Debates of the 103rd Congress, Second Session, 140 Cong. Rec. S11708-01, at S11711 (Aug. 13, 1994), *available at*, 1994 WL 424972; *see also U.S. v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part: Viponte Ltd. Black Currant Oil Batch No. BOOSF 039, etc., and Traco Labs*, 984 F.2d 814, 819 (7th Cir. 1993) (observing FDA bias and holding that "FDA's food additive definition is so broad … that it would … classify every component of food—even single active ingredients—as food additives. Thus, it would seem, even the addition of water to

food would make the food a food additive. The only justification for this Alice-in-Wonderland approach is to allow FDA to make an end-run around the statutory scheme and shift the burden of proving safety of a substance in all circumstances").

14. In 1994, Congress enacted and the President signed into law the Dietary Supplement Health and Safety Act ("DSHEA"). DSHEA was designed to protect public access to dietary supplements. *See* Statement of Senator Hatch, 140 Cong. Rec. S11705-06, at S11706 (Aug. 13, 1994), *available at*, 1994 WL 424971. Speaking on behalf of several cosponsors, Senator Hatch stated that "[f]or more than three decades, FDA has tried to restrict severely the ability of the dietary supplement industry to sell and market its products and, consequently, the ability of consumers to buy them. The agency has repeatedly attempted to impose unnecessarily stringent standards that would leave many if not most supplement companies with no practical choice but to close their doors." *See* Statements on Introduced Bills and Joint Resolutions, 139 Cong. Rec. S4561-02, at S4577 (Apr. 7, 1993), *available at*, 1993 WL 102951.

15. The express purpose of DSHEA was to ensure that "the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of dietary supplements." *See* 140 Cong. Rec. S11705-06, at S11706 (Aug. 13, 1994), *available at*, 1994 WL 424971. Concerning dietary supplement adulteration, Congress placed "the burden of proof . . . on the Food and Drug Administration to prove that a product is unsafe before it can be removed from the marketplace." *Id.*

16. Under the DSHEA adulteration provision, 21 U.S.C. § 342(f)(1), Congress placed the burden of proof on FDA to establish that a dietary supplement was unsafe:

"[i]n any proceeding under the subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated."

17. Under the DSHEA adulteration provision, in 21 U.S.C. § 342(g), Congress delegated authority to the Secretary of Health and Human Services to prescribe good manufacturing practices for dietary supplements. The FDA's dietary supplement GMPs were to "be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology." 21 U.S.C. § 342(g). *See, e.g.*, Senate Report No. 103-410, 103rd Cong., 2nd Sess. (Labor and Human Resources Committee) (Oct. 8, 1994), *available at*, 1994 WL 562259 ("[g]iven the FDA's historical bias against dietary supplements, the Committee believes it is necessary place the above limitations on FDA's authority to promulgate regulations").

18. On February 6, 1997, the FDA published an Advance Notice of Proposed Rulemaking ("ANPR") for GMPs. *See Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements*, 62 Fed. Reg. 5700 (Feb. 6, 1997).

19. Nine years after passage of the DSHEA, in 2003, the FDA published its Proposed Rule for dietary supplement GMPs. *See Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rule*, 68 Fed. Reg. 12158 (Mar. 13, 2003). The FDA received over 400 comments in response to its proposed regulation. Durk Pearson and Sandy Shaw filed comments in opposition to the GMP Final Rule. *See* FDA-1996-N-0028-0353 (Aug. 11, 2003).

20. In their submissions to FDA, the commenters opposed the proposed GMP Final Rule because they contained unduly vague language that afforded FDA enforcement officers virtually unbridled discretion to require changes to any business practice without first establishing satisfaction of the statutory requirement that FDA prove a dietary supplement to present a significant or unreasonable risk or illness or injury or establishing that a dietary supplement had been prepared, packed, or held under conditions that violate the GMPs. *See id.* at 7. The commenters complained that the GMPS did not provide the regulated class adequate direction to achieve compliance with the law. *Id.* at 22-30. The commenters further stated that the Proposed Rule exceeded FDA's statutory authority because the agency's proposed regulatory regime permitted FDA to bar products from the market without having met its burden in 21 U.S.C. § 342(f), (g). *Id.* at 15-16. Moreover, the commenters stated that FDA failed to propose or consider less burdensome alternatives commensurate with the risks to public health imposed by dietary supplements, a violation of Executive Order No. 12866 and the Administrative Procedure Act prohibition on arbitrary and capricious agency action and abuse of agency discretion. *Id.* at 41-42; *see also* Final Rule, 72 Fed. Reg. at 34788 (discussing argument under 21 U.S.C. § 342(f) and (g)); Final Rule, 72 Fed. Reg. at 34787-88 (discussing challenges to GMP regulations under Fifth Amendment Due Process Clause); 72 Fed. Reg. at 34775 (discussing challenges under Executive Order No. 12866).

21. FDA published the Final Rule on June 22, 2007. *See* Final Rule, 72 Fed. Reg. 34752 (June 25, 2007). FDA based the Final Rule on 21 U.S.C. § 342(g) which reads, in pertinent part:

> A food shall be deemed adulterated—
>
> If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

21 U.S.C. § 342(g)(1).

22. FDA has interpreted 21 U.S.C. § 342(g) as a grant of discretion to declare a dietary supplement adulterated for *any* violation of the Final Rule, without proof that a dietary supplement was prepared, packed, or held under conditions that violate the GMPs, 21 U.S.C. § 342(g). *See* Final Rule, 72 Fed. Reg. at 34764.

23. Under the GMPs, FDA reserves to itself unbridled discretion to declare inadequate any record required to be kept and to deem on that basis alone a dietary supplement adulterated without meeting the statutory requirements in 21 USC 342(f), (g). *See* Final Rule, 72 Fed. Reg. at 34764 ("[a] failure to follow the requirements in this final rule … could result in an enforcement action by the agency under section 402(g) of the Act because the dietary supplement is adulterated in that it was prepared, packed, labeled, or held under conditions that do not meet GMPs for dietary supplements"); *see, e.g.*, 21 CFR 111.205; 21 CFR 111.375, 21 CFR 111.430, 111.475; 21 CFR 111.255; 21 CFR 111.260(a); 21 CFR 111.570; 21 CFR 111.140; 21 CFR 111.14.

24. The FDA's interpretation of the DSHEA adulteration amendment causes Section 342(g) to conflict with the purpose of Section 342(f), making the law internally inconsistent and the interpretation arbitrary and capricious. Under Section 342(f), the FDA bears the burden to show that a dietary supplement presents a risk of illness or injury before it may lawfully remove the product from the market. FDA renders Section 342(f) a dead letter by interpreting Section 342(g) to require no proof of risk of harm to

the public but to permit a finding of adulteration even when finished products pose no risk of injury.

25. Violation of any GMP regulation is considered by FDA to be *per se* adulteration without establishing satisfaction of the statutory requirement that FDA prove the supplement to present a significant or unreasonable risk of illness or injury or prove the supplement to have been prepared, packed, or held under conditions that violate the GMPs. Without proof of risk of illness or injury or of conditions under which a dietary supplement has been prepared, packed, or held, under the Final Rule the FDA may declare a dietary supplement adulterated if any record is deemed incomplete or inadequate.

26. The regulations requiring quality control oversight, for example, are redundant and have no bearing on whether a supplement has been packed, held, or prepared in a manner that presents a risk of illness or injury. Under the dietary supplement GMPs, however, a manufacturer can produce a dietary supplement meeting the specifications for quality, and have records demonstrating that quality, but FDA can deem the product adulterated if a single record or record entry is deemed incomplete or missing. *See, e.g,* 21 CFR 111.105(d) (stating that manufacturer violates GMPs if it lacks written procedures for how quality control personnel should "review and approve … documentation"); *see also* Quality Control regulations: 21 CFR 111.12(a); 21 CFR 111.30(c), (d), (e); 211CFR 111.60(b); 21 CFR 111.65; 21 CFR 111.70(c)(3); 21 CFR 111.75(a), (c)(4), (d)(2); 21 CFR 111.103-111.140; 21 CFR 111.115(c); 21 CFR 111.160(c)(2)-(3); 21 CFR 111.165(c)(2)-(3); 21 CFR 111.260(l); 21 CFR 111.315.

27. 21 C.F.R. 111.70(a) requires that manufacturers establish "a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement …" FDA provides no further meaning to guide the regulated class, reserving to itself unbridled discretion to determine whether a specification for some undefined "point, step, or stage" is missing.

28. 21 C.F.R. 111.12(a)(1) requires "*qualified* employees" without defining what level of qualification is sufficient. 21 C.F.R. 111.13(a) requires "*qualified* personnel to supervise" and states that each supervisor must be "qualified by education, training, or experience." But Section 111.13(a)-(b) does not state what degree of education, training or experience is sufficient to satisfy the rule.

29. 21 C.F.R. 111.15(f) requires that plumbing in a facility to be "of an adequate size and design and be adequately installed and maintained," but the definition of "adequate" is left undefined.

30. Section 111.15(h) requires "adequate, readily accessible bathrooms" but again the nature of "adequate" and "readily accessible" is left undefined.

31. Section 111.15(i) requires hand-washing facilities that are "adequate, convenient, and furnish running water at a suitable temperature," but the definitions of "suitable" temperature and "adequate" or "convenient" are left undefined.

32. 21 C.F.R. 111.20 requires that physical plants used in manufacturing "[b]e *suitable* in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations," and plants must have "*adequate* space for the orderly placement of equipment and holding of materials …" Similarly, Section 111.20(e) requires "*adequate* light" in areas of the manufacturing plant. Section 111.25(a)(1) requires the use of

"equipment and utensils that are of *appropriate* design, construction, and workmanship to enable them to be *suitable* for their intended use and to be *adequately* cleaned and properly maintained." The terms suitable, adequate, and appropriate are left undefined.

33. FDA's failure to identify in the rules challenged here what the regulated class must do to achieve compliance unfavorably contrasts with the technical regulations of other federal agencies. The Occupational Safety and Health Administration routinely promulgates technical rules with specificity and such rules do apply to the variety of conditions existing at different work environments. *See, e.g.*, 29 C.F.R. 1926.56(a) (providing "minimum illumination intensities" in units of measure (foot-candles) for a variety of areas ranging from "general construction area lighting" to "first aid stations, infirmities, and offices"); 29 C.F.R. § 1926.51(c)(1) (providing specific number of toilets required based on number of employees); 29 C.F.R. § 1926.51(f)(4)(i) (providing specific number of showers required for every 10 employees of each sex, "or numerical fraction thereof"); 29 C.F.R. § 1926.32(m) (defining the word "qualified" as the term is used throughout the subsequent regulations).

34. The use of ambiguous language throughout the Final Rule denies the regulated class any basis, let alone a reasonable one, upon which to discern what actions will comply with the law and provides FDA unbridled discretion to declare members of the regulated class not in compliance and, thus, violators of the law of adulteration, carrying with it criminal penalties. *See* 21 U.S.C. § 333.

COUNT I

BY DEEMING ANY VIOLATION OF THE FINAL RULE *PER SE* ADULTERATION, FDA HAS VIOLATED 21 USC 342(f), (g); HAS EXCEEDED THE AGENCY'S STATUTORY AUTHORITY; HAS ACTED ARBITRARILY AND CAPRICIOUSLY; AND HAS ABUSED ITS DISCRETION IN VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

35. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 34, *supra*.

36. It was unlawful in the Final Rule for the FDA to deem non-adherence to the GMPs *per se* adulteration without requiring as a condition precedent that FDA meet its statutory burden of proof under 21 U.S.C. § 342(f) and (g). Yet under the following rules violations are deemed adulteration without requiring FDA to satisfy the statutory burdens: 21 CFR 111.8; 21 CFR 111.14; 21 CFR 111.16; 21 CFR 111.23; 21 CFR 111.25; 21 CFR 111.35; 21 CFR 111.8; 21 CFR 111.95; 21 CFR 111.103; 21 CFR 111.140; 21 CFR 111.153; 21 CFR 111.180; 21 CFR 111.210; 21 CFR 111.260; 21 CFR 111.303; 21 CFR 111.325; 21 CFR 111.353; 21 CFR 111.375; 21 CFR 111.403; 21 CFR 111.430; 21 CFR 111.453; 21 CFR 111.475; 21 CFR 111.503; 21 CFR 111.535; 21 CFR 111.553; 21 CFR 111.570; and 21 CFR 111.605-111.610. Moreover, the following regulations concerning quality control oversight impose redundant requirements that have no bearing on whether the product was packed, held, or prepared in a manner likely to cause adulteration, thus failing to satisfy the statutory requirement in 21 U.S.C. § 342(g): 21 CFR 111.12(a); 21 CFR 111.30(c), (d), (e); 211CFR 111.60(b); 21 CFR 111.65; 21 CFR 111.70(c)(3); 21 CFR 111.75(a), (c)(4), (d)(2); 21 CFR 111.103-111.140; 21 CFR 111.115(c); 21 CFR 111.160(c)(2)-(3); 21 CFR 111.165(c)(2)-(3); 21 CFR 111.260(l); 21 CFR 111.315.

37. Under 21 U.S.C. § 342 (f) and (g), the FDA must prove either (1) that a dietary supplement presents a significant or unreasonable risk of illness or injury under the conditions of use recommended, suggested in labeling, or (2) that the conditions under which a dietary supplement "has been prepared, packed, or held" fails to satisfy the GMPs (21 U.S.C. § 342(g)). Under Section 342(f), unless a dietary supplement is proven to present a significant or unreasonable risk of illness or injury it is not adulterated. Under Section 342(g), unless a GMP violation affects the "conditions" under which dietary supplements have been "prepared, packed, or held" then the violation is not adulteration. Because FDA's Final Rule does not require, as a condition precedent to a finding of "adulteration," satisfaction of FDA's burden of proof under 21 U.S.C. § 342(f) or 21 U.S.C. § 342(g), the Final Rule violates those statutory sections and exceeds FDA's statutory authority.

38. FDA's construction of 21 U.S.C. § 342(g) conflicts with and eviscerates the plain meaning of 21 U.S.C. § 342(f). Congress rested with FDA the burden of proving that a dietary supplement presents a risk of illness or injury before FDA can remove the product from the market. *See* 21 U.S.C. § 342(f). In its Final Rule, FDA concludes that it has no duty to prove a finished product to present a risk of illness or injury before deeming it adulterated in violation of the plain and intended meaning of 21 U.S.C. § 342(f), (g).

39. In addition, the Final Rule is arbitrary and capricious agency action within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), because there is no requirement that the facts found support the legal conclusion of adulteration; rather, the rule permits FDA to deem facts to constitute adulteration (such as the inadequacy of

kept records) without proof of risk of illness or injury or of conditions of preparing, packing, or holding dietary supplements in violation of the GMPs.

40. Moreover, the action is an abuse of agency discretion within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), because the FDA has granted itself unlimited discretion to declare dietary supplements adulterated without satisfying the statutory conditions precedent for such a determination in 21 U.S.C. § 342(f), (g).

41. To comply with the statutory requirements, FDA had to limit adulteration to those instances in which it satisfied its burden of proof under 21 U.S.C. § 342(f), (g) or create an express exemption from adulteration for acts or omissions in violation of the Final Rule that did not satisfy its burden of proof under 21 U.S.C. § 342(f), (g). FDA did neither and, so, violated 21 U.S.C. § 342(f), (g).

COUNT II

FDA'S GMPs VIOLATE EXECUTIVE ORDER NO. 12866 AND, THEREFORE, ARE INCONSISENT WITH LAW IN VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

42. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 41, *supra*.

43. Executive Order No. 12866 commands that, in promulgating new regulations, "[e]ach agency shall tailor its regulations and guidance documents to impose the least burden on society, including individuals, businesses of differing sizes, and other entities, consistent with obtaining the regulatory objectives …" *See* Executive Order 12866, § 1(11) (Sep. 30, 1993); *see also* Executive Order 12291, 46 Fed. Reg. 13193

(requiring that agencies consider alternative approaches and choose "the least burdensome of the acceptable alternatives").

44. Executive Orders have the force and effect of a statute when they have a distinct statutory foundation. *Ass'n for Women in Science v. Califano*, 566 F.2d 339, 344 (D.C. Cir. 1977). The President's proclamations and orders have the force and effect of law when issued pursuant to a statutory mandate or delegation of authority from Congress. *See Independent Meat Packers Ass'n v. Butz*, 526 F.2d 228, 234 (8th Cir. 1975). Agency action controlled by executive order is subject to the APA. *See National Wildlife Federation v. Babbit*, D.D.C. No. 88-0301 (July 30, 1993), *available at*, 1993 WL 304008. Because Executive Orders have the force of law, agency action that conflicts with such orders violates the APA's prohibition against agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

45. The FDA's Final Rule violates Executive Order 12866 because the burden on industry seeking to comply with the regulations outweighs the benefit society will receive from the Final Rule. The degree of harm caused by dietary supplements does not justify the heavy burden industry suffers from the Final Rule. Dietary supplements present a negligible health risk when compared with foods and drugs. Yet FDA has imposed a strict regulatory regime reminiscent of the drug GMPs and are not modeled on food GMPs as is required by statute. FDA did not choose the least burdensome means to achieve its objectives.

46. Accordingly, the Final Rule violates Executive Order No. 12866 and, therefore, the Administrative Procedure Act's prohibition against agency action that is "not in accordance with law." 5 U.S.C. 706(2)(A).

COUNT III

FDA'S DIETARY SUPPLEMENT GMPs VIOLATE THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT AND THE ADMINISTRATIVE PROCEDURE ACT PROHIBITION ON ARBITRARY AND CAPRICIOUS AGENCY ACTION AND ABUSE OF AGENCY DISCRETION BECAUSE THEY ARE UNCONSTITUTIONALLY VAGUE

47. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 46, *supra*.

48. The following specific regulations fail to provide the regulated class with sufficient information to discern how to comply with the Final Rule and avoid criminal prosecution for adulteration: 21 CFR 111.3 (definition of "product complaint"); 21 CFR 111.10(b)(1), (3), (4), (9); 21 CFR 111.12(a); 21 CFR 111.13; 21 CFR 111.14; 21 CFR 111.15(a)(3), (a)(4), (c)(1), (e)(1), (f), (h), (i), (j), (k); 21 CFR 111.20(a), (b), (d)(i), (d)(iii), (d)(v), (e), (h); 21 CFR 111.27; 21 CFR 111.87(b)(1); 21 CFR 111.103-111.140; 21 CFR 111.155(c)(2), (c)(3); 21 CFR 111.160(c)(2)(3); 21 CFR 111.165(c)(2), (c)(3); 21 CFR 111.410(a); 21 CFR 111.455(b); 21 CFR 111.470. As such, they are unconstitutionally vague in violation of the Fifth Amendment to the United States Constitution.

49. Companies that market adulterated dietary supplements can be subject to criminal penalties. *See* 21 U.S.C. § 333(a). Violation of the Final Rule renders a product adulterated as a matter of law. *See* 21 U.S.C. § 342(g). FDA was constitutionally obliged in the Final Rule to define all prohibited acts with sufficient specificity to enable the regulated class to discern what steps it must take to comply with the law. FDA was required to give "fair notice that contemplated conduct is forbidden," *Grayned v. City of*

Rockford, 408 U.S. 104, 108 (1972); *Papachristou et al. v. City of Jacksonville*, 405 U.S. 156, 162 (1972), and provide "explicit standards" so that it avoids "arbitrary and discriminatory enforcement." *Grayned*, 408 U.S. at 108. Members of the regulated class were supposed to be provided information sufficient to tell them when they are "in danger of triggering an adverse reaction" but were not and, so, the Final Rule is unconstitutionally vague. *Timpinaro v. SEC*, 2 F.3d 453, 460 (D.C. Cr. 1993. The Final Rule fails to pass muster because the regulatory language did not satisfy the minimum requirement of giving the regulated class "reasonable certainty" of what acts are prohibited. *See Boyce Motor Lines v. United States*, 342 U.S. 337, 340 (1952). The Final Rule is thus unconstitutionally vague under the Due Process Clause of the United States Constitution.

50. In addition, because there is no clear description in these sections of which facts found will be deemed adulteration, there is no reasonable relation between the facts found and the legal conclusion of adulteration to permit the Final Rule to pass muster under the Administrative Procedure Act's provisions requiring that agency action not be arbitrary and capricious. *See Motor Vehicle Equipment Mfrs. Ass'n, Inc. v. EPA*, 627 F.2d 1095, 1105-06 (D.C. Cir. 1979) (agency must reach result which rationally flows from facts and present a rational basis for its decision).

51. Moreover, the declaration that any act of non-compliance with the Final Rule will be deemed adulteration is an abuse of discretion because it grants the FDA unbridled discretion to declare virtually any act or omission adulteration without providing clear guidelines to enable the regulated class to conform its conduct to the law. *See Armstrong v. District of Columbia Pub. Library*, 154 F.Supp. 2d 67, 82 (D.D.C.

2001) (regulations cannot be so imprecise and amorphous as to leave unbridled subjective discretion to whomever enforces the law at the time); *Environmental Defense Fund v. EPA*, 852 F.2d 1316, 1326 (D.C. Cir. 1988) (a reviewing court shall set aside agency actions found to arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law).

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court,

(1) **Declare** that 21 CFR Part 111, in which FDA grants itself authority to declare dietary supplements adulterated without satisfying the statutory conditions precedent in 21 U.S.C. § 342(f) (i.e., that the dietary supplement presents a significant or unreasonable risk of illness or injury) and in 21 U.S.C. § 342(g) (i.e., that the conditions under which the dietary supplement has been prepared, packed, and held violate the GMPs) a violation of 21 U.S.C. § 342(f); (g) and the Administrative Procedure Act prohibitions on arbitrary and capricious agency action and abuse of agency discretion, 5 U.S.C. § 706(2)(A). In particular, Plaintiffs ask this Court to declare the following provisions of the Final Rule invalid because they violate 21 U.S.C. § 342(f), (g) and the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), arbitrary and capricious and abuse of discretion subpart: 21 CFR 111.8; 21 CFR 111.14; 21 CFR 111.16; 21 CFR 111.23; 21 CFR 111.25; 21 CFR 111.35; 21 CFR 111.8; 21 CFR 111.95; 21 CFR 111.103; 21 CFR 111.140; 21 CFR 111.153; 21 CFR 111.180; 21 CFR 111.210; 21 CFR 111.260; 21 CFR 111.303; 21 CFR 111.325; 21 CFR 111.353; 21 CFR 111.375; 21 CFR 111.403; 21 CFR 111.430; 21 CFR 111.453; 21 CFR 111.475; 21 CFR 111.503; 21 CFR 111.535; 21

CFR 111.553; 21 CFR 111.570; and 21 CFR 111.605-111.610.. Moreover, Plaintiffs ask this Court to declare the following provisions of the Final Rule concerning quality control oversight invalid because they violate 21 U.S.C. § 342(f), (g), and the APA, 5 U.S.C. § 706(2)(A): 21 CFR 111.12(a); 21 CFR 111.30(c), (d), (e); 211CFR 111.60(b); 21 CFR 111.65; 21 CFR 111.70(c)(3); 21 CFR 111.75(a), (c)(4), (d)(2); 21 CFR 111.103-111.140; 21 CFR 111.115(c); 21 CFR 111.160(c)(2)-(3); 21 CFR 111.165(c)(2)-(3); 21 CFR 111.260(l); 21 CFR 111.315;

(2) **Declare** the following provisions of the Final Rule unconstitutionally vague in violation of the Due Process Clause of the Fifth Amendment to the United States Constitution and arbitrary and capricious and an abuse of agency discretion under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law), 5 U.S.C. § 706(2)(C) (in excess of statutory jurisdiction, authority, or limitations, or short of statutory right): 21 CFR 111.3 (definition of "product complaint," 21 CFR 111.10(b)(2), (9); 21 CFR 111.12(a), (c); 21 CFR 111.13; 21 CFR 111.15(a)(3), (a)(4), (e)(1), (f); 21 CFR 111.20(a), (b), (c), (d)(1)(i), (d)(iii), (d)(iii), (d)(v), (d)(2), (e), (h); 21 CFR 111.27(a); 21 CFR 111.70(a), (b)(3), (c), (d), (e); 21 CFR 111.90(b)(1); 21 CFR 111.410(a); 21 CFR 111.455; and 21 CFR 111.470);

(3) **Declare** that the Defendants violated Executive Order No. 12866 and, therefore, violated the Administrative Procedure Act (5 U.S.C. § 706(2)(A)) by acting contrary to law;

(4) **Enjoin** FDA from taking enforcement action against manufacturers, packagers, labelers, and holders of dietary supplements under the Final Rule provisions

challenged here without first proving that a dietary supplement presents a significant or unreasonable risk of illness or injury pursuant to 21 U.S.C. § 342(f) or without first proving that the dietary supplement has been prepared, packed, or held under conditions that violate the GMPs pursuant to 21 U.S.C. § 342(g);

(5) **Order** that FDA revise its Final Rule to specify the steps regulatees must at a minimum take to comply with each of the following regulations: 21 CFR 111.10(b)(2), (9); 21 CFR 111.12(a), (c); 21 CFR 111.13; 21 CFR 111.15(a)(3), (a)(4), (e)(1), (f); 21 CFR 111.20(a), (b), (c), (d)(1)(i), (d)(iii), (d)(iii), (d)(v), (d)(2), (e), (h); 21 CFR 111.27(a); 21 CFR 111.70(a), (b)(3), (c), (d), (e); 21 CFR 111.90(b)(1); 21 CFR 111.410(a); 21 CFR 111.455; and 21 CFR 111.470;

(6) **Order** under Executive Order No. 12866 that FDA implement the least restrictive regulatory model that satisfies FDA's objectives in light of the far lower degree of risk of illness or injury associated with ingestion of products lawfully sold as dietary supplements as compared to those lawfully sold as foods and drugs;

(7) Retain jurisdiction of this action to ensure compliance with this Court's decree; and

(8) Grant such other and further relief as the Court deems just and proper.

TRIAL BY THE COURT WITHOUT A JURY

Pursuant to 28 U.S.C. § 2402, this action shall be tried by the court without a jury.

Respectfully submitted,

ALLIANCE FOR NATURAL HEALTH US;
DURK PEARSON and SANDY SHAW;
COALITION TO END FDA AND FTC CENSORSHIP,

By _____/s/_____

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