

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

ALL ONE GOD FAITH, INC.,)
d/b/a Dr. Bronner's Magic Soaps)
d/b/a Dr. Bronner's & Sun Dog's Magic)
751 N. Citracado Pkwy.)
Escondido, California 92029)

and)

ORGANIC CONSUMERS ASSOCIATION)
6101 Cliff Estate Road)
Little Marais, Minnesota 55614,)

Plaintiffs)

Civil Action No. _____

v.)

UNITED STATES DEPARTMENT)
OF AGRICULTURE)
1400 Independence Ave., S.W.)
Washington, D.C. 20250,)

and)

THE HONORABLE MIKE JOHANNIS,)
in his capacity as SECRETARY OF)
AGRICULTURE)
1400 Independence Ave., S.W.)
Washington, D.C. 20520)

Defendants)
_____)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs bring this action for declaratory and injunctive relief and allege as follows:

INTRODUCTION

1. This action is brought under the Administrative Procedure Act, 5 U.S.C. §704, for a declaratory judgment that two policy statements issued by defendant United States Department of Agriculture (“USDA”) under USDA’s National Organic Program (“NOP”), which statements USDA has indicated its intention to enforce, are legally invalid and unenforceable, and for a permanent injunction enjoining their enforcement. The challenged policy statements reverse an earlier USDA “Policy Statement” interpreting USDA’s regulations to permit certification as “Organic” or “Made with Organic” under the NOP, of non-food finished products containing agricultural ingredients.

2. Plaintiff All One God Faith, Inc. d/b/a Dr. Bronner’s Magic Soaps and d/b/a Dr. Bronner’s & Sun Dog’s Magic (“Dr. Bronner’s”) manufactures and distributes a well-known line of bar and liquid soaps, and lotions and balms, under the “Dr. Bronner’s Magic Soaps” and “Dr. Bronner’s & Sun Dog’s Magic” brands. These products are all labeled, sold, promoted and advertised as “Soaps Made with Organic Oils” or “Organic Lotions/Balms”, “Certified to USDA NOP Standards,” in accordance with the NOP regulations. In the case of “Organic” products, they display the “Certified Organic” USDA seal on the label.

3. USDA’s “Policy Statement”, issued in May 2002, made clear that producers of non-food finished products made from agricultural ingredients could seek certification, under the NOP, of their production operations and qualified products, entitling them to label their products as “Made with Organic” ingredients or “Organic,”

and to represent and market their certified compliance with NOP standards including, in the case of “Organic,” products, to display the “Certified Organic” USDA seal.

4. In reliance on that “Policy Statement,” plaintiff Dr. Bronner’s invested substantial amounts in procuring expensive special ingredients and in upgrading its operations in order to obtain certification under NOP. Based on such certification, Dr. Bronner’s has labeled its liquid and bar soap, lotion and balm products as “Made with Organic Oils” or “Organic,” and communicated through labeling and marketing that these products have been certified as meeting NOP standards. In the case of “Organic” products, those labels display the USDA “Certified Organic” seal. Other companies have similarly relied on the May 2002 “Policy Statement” in making investments in ingredients and equipment, in order to obtain certification, and in labeling and marketing their products based on such certification. Each of the three leading USDA-accredited certifying agencies in the nation certified such products based on this “Policy Statement”.

5. Plaintiff Organic Consumers Association (“OCA”) represents over 30,000 companies and individuals, including many consumers who desire to purchase, among other things, personal and body care products that can reliably be called “Organic” or “Made with Organic” in that they are certified to NOP standards. These consumers desire reliable information indicating that such products have been ecologically produced and do not contain any of a number of specified chemicals and substances that consumers fear could trigger allergic reactions or cause health problems for such consumers. These consumers include individuals who have relied on the “Made with Organic” and “Organic” labeling and certification of personal care products under the NOP, and on the display of the USDA seal, in purchasing personal and body care products to ensure that

the products they purchase and consume are ecologically produced and/or cannot contain certain ingredients they fear can cause allergic reactions or health problems.

5. As set forth in detail below, in a new “Guidance Statement” issued in April 2004 and in a “Response” Statement issued in April 2005, USDA reversed its previous interpretation set forth in the May 2002 Policy Statement. In April 2004, USDA asserted the position that producers of non-food products such as pet foods and body and personal care products, containing agricultural ingredients, *cannot* seek certification under NOP. In the April 2004 statement, USDA set a deadline of October 21, 2005 for producers of pet foods, personal and body care products to discontinue use of labeling indicating that their products are certified “Made with Organic” or “Organic” in accordance with NOP standards, including discontinuing use of the USDA seal.

6. As a result of these latter pronouncements, Dr. Bronner’s will be required to discontinue the labeling and marketing it has been entitled to use under NOP by virtue of the certification of its products to NOP standards as permitted by the May 2002 “Policy Statement.” Under the April 2004 “Guidance Statement,” Dr. Bronner’s must discontinue use of such labeling and marketing on or before October 21, 2005. Continued use of such labeling and marketing after that time could result in a USDA enforcement action including imposition of civil penalties.

7. Further, distributors and retailers of Dr. Bronner’s products already in the distribution chain and on retailers' shelves may refuse to sell those products because they fear potential enforcement actions by USDA that may result in civil penalties.

8. Under the Administrative Procedure Act, the May 2002 “Policy Statement” was a valid interpretation by USDA of its own regulations. The April 2004

“Guidance Statement” and the April 2005 “Response” reversed those interpretations, without any notice or opportunity for comment as required by the APA.

9. The April 2004 and April 2005 statements are therefore invalid; and a declaratory judgment should be issued to that effect. USDA should be enjoined from enforcing the April 2004 “Guidance Statement” or April 2005 “Response” statement and from enforcing the NOP regulations based on either the April 2004 “Guidance Statement” or the April 2005 “Response” statement.

JURISDICTION AND VENUE

10. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1331 and 28 U.S.C. §1346(a)(2); and pursuant to the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202 and the APA, 5 U.S.C. §704. Venue is proper in this Court pursuant to 28 U.S.C. §1391(e).

PARTIES

11. Plaintiff All One God Faith, Inc. (“Dr. Bronner’s”) is, and at all times herein mentioned was, a California corporation. Its principal place of business is located at 751 N. Citracado Pkwy., Escondido, California 92029. Plaintiff’s registered “doing business as” names are “Dr. Bronner’s Magic Soaps” and “Dr. Bronner & Sun Dog’s Magic.” Plaintiff Dr. Bronner’s engages in the business, among other things, of manufacturing and selling, throughout the United States, personal care and cosmetic products including the nation’s top-selling natural liquid and bar soap in a number of varieties under the “Dr. Bronner’s Magic Soaps” brand, and lotions and balms under the “Dr. Bronner’s & Sun Dog’s Magic” brand.

12. Plaintiff Organic Consumers Association (“OCA”) is a Minnesota non-profit corporation. OCA's principal place of business is located at 6101 Cliff Estate Road, Little Marais, Minnesota 55614. OCA is a grassroots organization dedicated to educating and advocating the interests of consumers in achieving a healthy, safe and sustainable system of production and consumption of food, personal care and other consumables. OCA has a membership of 30,000 consumers and producers of organic products. Its network of volunteers, activists and subscribers to its information service numbers over 500,000 individuals and businesses located across the United States.

13. Among the consumers who belong to and whose interests are advocated and represented by OCA are consumers who desire to purchase personal and body care products that are certified “Organic” or “Made with Organic” under the NOP. These consumers include individuals who have relied on the “Made with Organic” and “Organic” labeling and certification of personal care products to the NOP standards, and the display of the USDA seal, in purchasing personal and body care products and, specifically, have relied on such labeling and certification to ensure that the products they purchase and consume are ecological and do not contain many of the substance or chemicals they fear can cause allergic reactions or health problems.

14. Because of the recent wide incidence of unregulated branding and labeling of personal care products as “organic” in both the mainstream and specialty retail marketplace, the OCA has launched a “Coming Clean” campaign to advocate that labeling and branding of personal and body care products as “Organic” be restricted to products whose main as well as secondary ingredients are made from NOP-certified organic materials, and which do not contain conventional synthetic ingredients and

preservatives. It is essential that qualified producers have the ability to represent that their specified products have been certified as being in compliance with NOP standards, in order to enable those consumers, whose interests are represented and advocated by OCA, to distinguish truly organic personal care products from those which are misleadingly branded or labeled as organic (the main ingredients of which are not made from organic materials and contain conventional synthetic ingredients that are disallowed by NOP regulations that such consumers seek to avoid).

15. Defendant United States Department of Agriculture (“USDA”) is an agency of the United States within the meaning of the APA. USDA is the agency charged with implementing the National Organic Program under the federal Organic Food Products Act of 1990, 7 U.S.C. §§6501 *et seq.*

16. Defendant Mike Johanns is the Secretary of the Department of Agriculture and has the statutory responsibility and authority for enforcing and implementing the regulations of USDA including the National Organic Program.

FACTUAL ALLEGATIONS

A. Legal Framework

17. The federal Organic Food Products Act of 1990, 7 U.S.C. §§6501 *et seq.* (“OFPA”), requires USDA to implement a National Organic Program (NOP), providing for establishment and enforcement of standards for labeling of agricultural and food products as “organic.” Pursuant to this authority, USDA has issued regulations establishing standards for growing and raising organic agricultural products, 7 C.F.R.

Part 205, Subpart C, and governing use of the term “organic” with regard to agricultural and food products. 7 C.F.R. Part 205, Subpart D.

18. OFPA requires that agricultural and food products labeled “Organic” or “Made with Organic” be certified by a certifying agent accredited by USDA, as meeting the requirements of the regulations, and forbids the labeling as “Organic” of food and agricultural products that have not been so certified. 7 U.S.C. §§6514(a), 6515, 6519.

19. In December 2000, USDA issued regulations implementing the OFPA. National Organic Program. 7 C.F.R. Part 205, adopted at USDA, Agricultural Marketing Service, National Organic Program, Final Rule, 65 *Fed. Reg.* 80548 (Dec. 21, 2000).

20. Under OFPA and the NOP regulations, products labeled as “Organic,” “100% Organic” and “Made with Organic” ingredients must contain certain portions of organically produced ingredients, and not include non-allowed ingredients.

21. To be considered “organically” produced, ingredients must be produced by farms or processing operations certified by a state government or private certifying entity that is accredited by USDA. 7 C.F.R. §§205.100, 205.300. Each production, handling or manufacturing operation that produces any agricultural product intended to be labeled or sold as “Organic” or “Made with Organic” must be certified, by a USDA-accredited certifying agent as meeting all the requirements of the NOP in its production facilities and processes. 7 C.F.R. §205.100. Certification indicates that the farm or processing operation meets the standards for farming, production and handling set forth in the NOP regulations. *Id.* §205.2 (definition of “Certified operation”).

22. A processed product sold or labeled as “100 percent Organic” must contain only organically produced ingredients. 7 C.F.R. §205.301(a).

23. A processed product labeled “Organic” must “contain (by weight or fluid volume, excluding water and salt), not less than 95% organically produced raw or processed agricultural products.” 7 C.F.R. §205.301(b). Any “remaining product ingredients must be organically produced,” in accordance with standards set forth in the regulations, “unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced” products produced consistent with the regulatory standards. *Id.*

24. To be labeled “Made with Organic”, a multi-ingredient product must contain, by weight or fluid volume, excluding water and salt, at least 70 percent organically produced ingredients, produced and handled in accordance with the NOP regulations, and must not contain non-allowed synthetic ingredients in the non-organic portion. 7 C.F.R. §205.301(c).

25. Products eligible to be labeled “100% Organic” and “Organic” can lawfully be so labeled and marketed as certified to NOP standards and can display the “USDA Certified Organic” seal. *Id.* § 205.303(a).

26. If NOP’s Program Manager has reason to believe that a certified production operation has violated or is not in compliance with the NOP regulations, in the labeling and marketing of its products or otherwise, the Program Manager may conduct proceedings, in accordance with procedures set forth in the regulations, to suspend or revoke the certification of the production operation. 7 C.F.R. §205.660. Such proceedings may also be conducted by a State organic program’s governing state official or by the private certifying agent. *Id.* §205.662, 205.668.

27. In addition to suspension or revocation, any certified operation that knowingly sells, markets or labels a product as “Organic” or “Made with Organic” to NOP standards, in violation of the OFPA or the NOP regulations, is subject to a civil penalty of not more than \$10,000 per violation. 7 U.S.C. §6519; 7 C.F.R. §205.662(g)(1).

B. Application to Non-Food Processed Products

28. During the rulemaking for the NOP Regulations, some commenters requested that the final regulations include certification standards for cosmetics, body care products and dietary supplements made with organically-produced agricultural products.

29. The final regulations did not include such standards; the preamble explained that, “The ultimate labeling of cosmetics, body care products and dietary supplements...is outside the scope of these regulations.” 65 *Fed. Reg.* at 80557.

30. On May 2, 2002, however, USDA issued what it called a “Policy Statement on National Organic Program Scope.” This document stated that:

Producers and handlers of any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption may seek certification under the National Organic Program (NOP) as an organic producer or handler. Please note, the term consumption is not limited to products that are used for food....

Specifically, we have been asked if the regulations under the NOP apply to the following products, classes of products and production systems: mushrooms; pet foods; aquatic animals; fabrics; cosmetics; **body care products**; over-the-counter medications; dietary supplements; fertilizers; soil amendments; and products from greenhouse, apiculture and

hydroponic systems. ***Because these and other products, classes of products and production systems contain agricultural products the producers and handlers of such products, classes of products, and production systems are eligible to seek certification under the NOP.***

(emphasis added).

31. The May 2002 “Policy Statement” noted that these classes of non-food products “must also be produced, handled and labeled in compliance with any other applicable Federal statutes and their implementing regulations,” presumably referring to rules issued by the Food and Drug Administration and other agencies.

32. The May 2002 “Policy Statement” concluded by stating that “After October 21, 2002, as needed, the NOP may engage in additional rulemaking to clarify the application of the existing regulations to specific products, classes of products or production systems.”

33. While the May 2002 “Policy Statement” did obligate the NOP’s certifiers to certify qualified non-food products, it remained the case that USDA was not legally obligated to regulate, control or prohibit “organic” labeling of non-food products for which no certification is sought or obtained under the NOP regulations. Any company that does obtain certification of its non-food products under the NOP, however, makes itself subject to NOP regulation and enforcement as to the organic manufacture, labeling and marketing of those products. Accordingly, those producers who voluntarily subject themselves and their operations to the NOP regime, and successfully obtain certification, are able accurately to communicate to consumers their compliance with the NOP standards through marketing and labeling as “Organic” and “Made with Organic” to NOP standards and display of the USDA seal.

34. Producers of personal care products who do not obtain certification under NOP are able to, and often do, use the terms “Organic” or “Made with Organic” in labeling and marketing products that do not comply with NOP standards, but those producers *cannot* represent on their labels or in their marketing that their products have been certified as being in compliance with the NOP standards and regulations.

C. Producers’ Reliance on May 2002 Policy Statement

35. As a result of the May 2002 “Policy Statement,” producers of pet foods, body care, cosmetic and other classes of non-food agricultural finished products containing agricultural ingredients including Dr. Bronner’s and other companies (including but not limited to the two largest private-label bar soap companies in the country, Bradford and Twincraft), were able to invest in and obtain certification under NOP, thereby allowing them not only to label their products as “Organic” or “Made with Organic” but also to communicate via labels and marketing to consumers that a USDA-accredited certifying agent had officially recognized their compliance with NOP standards in manufacturing, labeling and marketing of such products.

36. In manufacturing, labeling and marketing its line of liquid and bar soaps as certified “Made with Organic” and lotions and balms as certified “Organic” to the NOP standards, Dr. Bronner’s uses certified organic oils and organic essential oils, and does not use any synthetic surfactants, petrochemicals, chelating agents, preservatives, dyes, whiteners or fragrances. For example, Dr. Bronner’s liquid “Peppermint Pure Castile Soap Made with Organic Oils” contains: Water, Saponified Organic Coconut and Olive Oils, Organic Jojoba Oil, Organic Hemp Oil, Organic Peppermint Oil, Organic Mentha Arvensis, Citric Acid and Natural Tocopherols (Vitamin E).

37. As a result of and in reliance on the May 2002 “Policy Statement,” Dr. Bronner’s made considerable investments in ingredients and production systems, to date totaling more than \$5 million, to enable Dr. Bronner’s to obtain, label and market its certification, under NOP, of its bar and liquid soap, lotion and balm products. These investments included procuring and paying for certified organic oils such as coconut and peppermint, that cost over twice as much as the conventional versions of such oils; designing and producing new packaging and labeling; advertising and marketing; implementing required production systems, equipment and control; paying for expert consulting services; and paying fees required for certification.

38. In late spring and summer of 2003, Dr. Bronner’s initially invested in organic materials and processes needed for NOP certification as to sixty percent (60%) of its product line by dollar revenue (at the time, approximately \$6 million of \$10 million). The NOP certification and labeling has proven so successful commercially, that as of the spring of 2005, Dr. Bronner’s has invested in converting its remaining soap products to NOP “Made with Organic” standards.

39. Far and away the largest portion of Dr. Bronner’s investment is the higher price of the certified organic materials, which Dr. Bronner’s must inventory up to a year’s worth at a time to ensure adequate supply. Dr. Bronner’s organic material costs since summer 2003 have amounted to about \$5 million. Dr. Bronner’s has also spent considerable sums in marketing, promotional discounting and advertising the soaps certified to NOP standards, amounting to well over \$500,000. Estimated direct packaging redesign, production process, equipment and certification costs to enable certification to NOP standards is in excess of \$100,000. The research and development,

design work and ingredients' sourcing of Dr. Bronner's organic lotions and balms introduced to the market in the winter of 2005 has amounted to over \$100,000, and the marketing, advertising and promotional budget for the spring and summer 2005 roll-out is budgeted at \$300,000.

40. On July 30, 2003, after analyzing Dr. Bronner's products and the proposed labels therefor, a USDA-accredited certifying agent in the US, Oregon Tilth Certified Organic of Salem Oregon ("Oregon Tilth") certified Dr. Bronner's as a "certified operation" that "has complied with the Organic Foods Production Act of 1990 and the applicable organic production and handling standards established by the USDA National Organic Program" with respect to nine specific bar soap products and six specific liquid soap products. In reliance and based on this certification, Dr. Bronner's, beginning in the summer of 2003 and continuing through to the present time, has labeled and marketed these products as "Made with Organic Oils" certified to NOP standards.

41. On February 27, 2005, Oregon Tilth, after analyzing a number of Dr. Bronner's products and the proposed labels for those products, certified Dr. Bronner's as "Organic", in accordance with the certifying agent's own standards identical to those of NOP, with respect to body balm, lip balm and lotion products; and with respect to a number of bar and liquid soap products that were certified as products "Made with Organic Ingredients." In reliance and based on this certification, Dr. Bronner's has at all relevant times since February 27, 2005 and continuing to the present time, labeled and marketed its "Organic" products, as listed on the February 27 certification, as "Certified Organic", *i.e.*, certified to NOP standards, and has displayed the USDA seal on such labels.

42. On information and belief, based and in reliance on the May 2002 “Policy Statements,” a number of producers of body or personal care products, other than Dr. Bronner’s, sought and received certification from leading USDA-accredited certifying agents as certified producers of “Organic” and/or “Made with Organic Ingredients” products; and have labeled and marketed their products based on such certification(s), under and in accordance with the NOP regulations, as “Organic” or “Made with Organic” certified to NOP standards, and, in the case of “Organic” products, have displayed the USDA seal.

43. On information and belief, such other producers include (a) Aubrey’s Organics, which has been certified by USDA-accredited certifying agent Quality Assurance International (“QAI”) the largest such certifying agency in the nation, with respect to Aubrey products including its “Natural Spa Sea Wonders” body polish, bath salts, massage oil and other products, enabling Aubrey’s to label and market those products as certified “Organic” to NOP standards and to display the USDA seal; (b) Bradford Soap Works which has been similarly certified by QAI in spring/summer of 2002 with respect to production of bar soaps “Made with Organic” ingredients; (c) Twincraft, which has been certified by QAI in spring/summer of 2002 with respect to production of a soap base “Made with Organic” ingredients; (d) Sensibility Soaps, which has been certified by USDA-accredited certifying agent Pennsylvania Certified Organics, with respect to soaps, lotions, balms and other products in fall of 2004 qualifying as “Organic” and the labels for which accordingly bear the USDA seal; and (e) Applied Organics which has been certified by USDA-accredited certifying agent California Certified Organic Farmers in the summer of 2004 with respect to production of a “Nude

Certified Organic Lubricant” that displays the USDA organic seal. QAI, Oregon Tilth, and CCOF are the three largest, most reputable and well-known certifiers in the US, and between them certify the majority of organic products and operations in the US.

Bradford and Twincraft, which obtained their certification before Dr. Bronner’s, are the largest private label bar soap manufacturers in the U.S. and make bar soaps for many of Dr. Bronner’s competitors, a significant factor in the decision by Dr. Bronner’s to make a major investment in and obtain NOP certified standing for its products.

44. On information and belief, since issuance of the May 2002 “Policy Statement” enabled producers of body and personal care products to seek certification under NOP and label their products accordingly, a number of consumers, including but not limited to members of OCA, have sought out and relied upon the labeling and marketing of personal and body care products certified to NOP standards as “Organic” or “Made with Organic” and, in the case of certified “Organic” products, have sought out and relied upon the display of the USDA seal, in their purchase of body care products. Specifically, on information and belief, such consumers have relied upon such labeling and marketing as an indication that such products do meet the standards of NOP and, accordingly, are ecologically produced and do not contain certain ingredients which may cause allergic reactions or other health problems for such consumers.

D. The April 2004 Guidance Statement

45. Almost two years after issuance of the May 2002 “Policy Statement, without any advance notice or opportunity for comment, on April 13, 2004, USDA issued a “Guidance Statement” that completely reversed the May 2002 “Policy Statement.” The new “Guidance Statement” stated, in pertinent part, that:

Because OFPA does not extend to cover nonagricultural products, and because USDA has no regulatory authority over such products, producers of the following products are not eligible to seek certification under the National Organic Program:

Personal care products, body care products, cosmetics, and other related products.....

The products listed above may not display the USDA organic seal and may not imply that they are produced or handled to the USDA NOP standards. Consumers should be aware that the use of labeling terms such as “100% organic,” “organic,” or “made with organic ingredients” on these products may be truthful statements. But these statements do not imply that the product was produced in accordance with the USDA NOP standards nor that the producer is certified under the NOP standards.

Operations producing the products listed above that use labeling or other market information that implies or states that the products are in compliance with the USDA NOP standards, or products that carry the USDA seal, have until October 21, 2005, to use existing supplies of labels and packaging. Failure to comply with the requirement may result in an enforcement action.

46. The NOP’s assertion, in the April 2004 “Guidance Statement,” that personal care products cannot be certified under NOP because they are “non-agricultural” is factually incorrect. For example, certified organic olive oil does not magically become “non-agricultural” when used as an ingredient in a massage oil rather than as an ingredient in a salad dressing. The NOP’s definition of “agricultural” is:

Any agricultural commodity or product, whether raw or processed... that is marketed in the United States for human or livestock consumption.

The 2002 “Policy Statement” made explicitly clear that the term “consumption” in the NOP is not limited to foods: “Please note, the term consumption is not limited to products that are used for food...”.

47. Personal care products applied topically on the skin are “consumed” by people not only in the general intended sense used above, but also in that their ingredients

can be absorbed into the bloodstream through the skin to some degree. The OCA represents consumers who are particularly concerned about the absorption of conventional synthetic ingredients they suspect may have adverse health consequences. The Environmental Working Group completed last year a comprehensive analysis entitled: “Skin Deep, A Safety Assessment of Ingredients in Personal Care Products” (http://www.ewg.org/reports/skindeep/report/executive_summary.php) and in the executive summary stated that:

The absence of government oversight for this \$35 billion industry leads to companies routinely marketing products with ingredients that are poorly studied, not studied at all, or worse, known to pose potentially serious health risks....

Individual ingredients vary tremendously in their ability to soak through the skin. Some absorb in only miniscule amounts, while others can quite easily penetrate the skin to the blood vessels below. Few individual ingredients pose excessive risks, but most people use many products in the course of a day, so it well may be that these risks are adding up....

The more we study low dose exposures, the more we understand that they can cause adverse effects ranging from the subtle and reversible, to effects that are more serious and permanent.

Overall, our investigation of product safety shows cause for concern, not alarm. Much more study is needed to understand the contribution of exposures from personal care products to current human health trends.

Products such as lip balms and personal lubricants are consumed even more directly into the body. OCA represents consumers who use NOP standards as a reliable indicator that many synthetic ingredients and compounds of concern are not included in personal care products certified to NOP standards.

48. Based on widespread outcry from organic consumers as well as the industry, at a press conference on May 26, 2004, then-Secretary of Agriculture Ann Veneman

announced that she was directing the USDA Agricultural Marketing Service, of which NOP is a unit, formally to rescind the April 2004 Guidance Statement.

49. Thereafter, Senator Patrick Leahy (D-Vt), an original author of the OFPA, posted on his website the following under “Reaction Of Senator Patrick Leahy To Secretary Veneman’s Withdrawal Of Changes To The Organic Program Wednesday, May 26, 2004”:

“Secretary Veneman has listened to the concerns the organic community has raised, and I commend her for retracting these far-reaching changes. The secretary has decided to follow the law and to consult with the National Organic Standards Board, and that is welcome news.

“Organic producers and consumers are united in wanting the new organic program to work. For it to work, the standards have to mean something. The organic standards and labeling program is still in its infancy, and this is a critical time for its credibility. This program’s credibility has been built with full public and stakeholder participation, and we need to keep it that way.”....

Specifically, Leahy was asking USDA to rescind:

The “National Organic Program Scope” Guidance statement (issued April 14, 2004), which suggested that producers of pet foods, personal care products, fertilizers and aquatic animals can make “organic” claims on their labels but will not be regulated by the National Organic Program. Leahy noted that OFPA’s purpose is to regulate the use of organic labels on organic products and that opening this loophole conflicts with the law’s intent. Leahy asked, at the very least, for a formal rulemaking process for any such proposals....

50. Secretary Veneman’s announcement made clear that, pending any further rulemaking by the agency, the status quo prior to the pre-April 2004 Guidance Statement would prevail, that is, the 2002 “Policy Statement” would remain in effect. To the best of plaintiffs’ information and belief, however, no action was ever taken and no document was ever issued to formally rescind the April 2004 Guidance Statement, although the 2004 Guidance Statement was removed from the NOP’s website.

E. The 2005 “Response” Statement

51. OFPA authorized USDA to appoint a 15-member “National Organic Standards Board” (“NOSB”) to assist USDA in developing standards for substances to be used in organic production and to advise USDA on implementation of the NOP. 7 U.S.C. §6518.

52. In or about the fall or winter of 2004, NOSB issued “feedback” statements on several issues related to implementation of NOP, including the scope of the NOP regulations. Dr. Bronner’s was unaware of these “feedback” statements until USDA issued and made public its response.

53. On April 22, 2005, USDA posted a “response” to these “feedback” statements on USDA’s website. In introducing these “responses,” USDA stated that, “All USDA certifying agents and certified operations should consider the USDA response as the most current guidance on each of these matters.”

54. USDA’s “Response,” to be considered its current “guidance statement” with respect to the scope of the NOP regulations, states that if OFPA were amended to specifically cover personal care products, NOP would undertake rulemaking to propose standards for the production, handling and labeling of such products; but that, “Until such time, *these finished products may not display the USDA seal or be represented as NOP-certified*. Only the organic agricultural ingredients contained in these products may be represented as certified to NOP standards” (emphasis added).

F. Impact of “Guidance” Statement and “Response”

56. Based on the April 2004 “Guidance” Statement and April 2005 “Response,” Dr. Bronner’s will be forced to stop labeling and marketing its products as certified to

NOP standards for “Made with Organic” and “Organic” products, and to stop displaying the USDA seal on its “Organic” products, or else face the threat of USDA enforcement action.

57. Based on the April 2004 “Guidance Statement” and April 2005 “Response,” distributors and retailers of Dr. Bronner’s products labeled and marketed as being in compliance with the NOP “Made with Organic” and “Organic” standards may be forced to stop selling even existing inventories of Dr. Bronner’s products.

58. If Dr. Bronner’s is forced to discontinue the labeling and marketing of its products’ compliance with NOP standards, as permitted by the May 2002 “Policy Statement,” Dr. Bronner’s will suffer severe economic harm.

59. As a result of its substantial investment enabling it to obtain certification to NOP standards of its personal care products, Dr. Bronner’s currently enjoys a competitive advantage. Many of Dr. Bronner’s competitors characterize their soap, lotions, balms and other personal care products as “Organic” or “Made with Organic” but are not able to represent that these products meet the NOP standards because the competitor does not manufacture its product using a sufficient proportion of certified organic ingredients and/or uses conventional synthetic ingredients including petrochemical substances not allowed under the NOP. Accordingly, these competitors are not able to label or market their products as complying with NOP standards.

60. Many consumers who want to purchase “organic” products prefer to purchase those products that have been certified by a government-approved certifying agent as meeting the US. Government’s, *i.e.*, USDA’s NOP standards, for products that are “Organic” or “Made with Organic”. Many of these consumers purchase Dr.

Bronner's products rather than competitors' products because Dr. Bronner's products have been so certified.

61. If Dr. Bronner's is forced to discontinue labeling and marketing its products as "Organic" or "Made with Organic" certified to NOP standards, and in the case of "Organic" products, to discontinue displaying the USDA seal, Dr. Bronner's competitive advantage—which it has invested over \$5 million to achieve—will be destroyed. As a result, Dr. Bronner's will lose a significant amount of sales and suffer substantial economic harm; and its investment will have been wasted.

62. Further, among consumers who prefer certified organic products, accounting for a substantial portion of the market for Dr. Bronner's products, Dr. Bronner's loss of its ability to represent, label and market that it has been officially certified as meeting the NOP standards for "Made with Organic" and "Organic" products will be perceived negatively.

63. If distributors and retailers are forced to, or decide that they must, discontinue sales even of existing inventories of Dr. Bronner's products, based on the NOP's 2004 "Guidance Statement" and NOP's 2005 "Response", Dr. Bronner's will suffer immediate, substantial economic harm.

64. If Dr. Bronner's and other producers of body and personal care products whose operations have been certified organic and whose products are currently labeled and marketed as "Organic" and display the USDA seal, and/or are currently labeled and marketed as "Made with Organic" ingredients certified to NOP standards, are forced by USDA's April 2004 Guidance Statement and 2005 Response statement to discontinue such labeling and marketing, consumers who are members of, and whose interests are

represented by OCA, will suffer substantial harm in that they will be deprived of access to truthful labeling and marketing information on which they can rely, in purchasing body and personal care products that are ecologically produced and do not contain many of the synthetic ingredients such consumers wish to avoid putting on their skin

65. On May 6, 2005, Dr. Bronner's, through counsel, sent a letter to the NOP Program manager, asking if NOP intended to enforce either or both the April 2004 "Guidance Statement" or the April 2005 "Response," requesting a reply by May 31. No reply has been received. As a result of the April 2004 "Guidance Statement" (that apparently was never formally rescinded) and April 2005 "Response," Dr. Bronner's faces the threat of a USDA enforcement action unless it discontinues labeling and marketing its products as meeting NOP's "Organic" and "Made with Organic" standards, and, in the case of "Organic" products, discontinues use of the "USDA Certified Organic" seal.

COUNT I

66. Plaintiff re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs.

67. The May 2002 "Policy Statement" was a valid interpretation by USDA of its own regulations under NOP.

68. At all times since issuance of the May 2002 "Policy Statement," USDA has consistently permitted accredited certifying entities to consider and grant applications for certification from producers of qualified non-food products containing agricultural ingredients. That certification enabled those producers, including Dr. Bronner's, to label and market their products as meeting NOP's "Organic" or "Made with Organic"

standards, and, in the case of “Organic” products, to display the USDA “Certified Organic” seal.

69. The April 2004 “Guidance Statement” and the April 2005 “Response” statement reversed the valid and binding interpretation of its regulations that USDA had adopted in the May 2002 “Policy Statement,” and that USDA had applied continuously since that time, on which Dr. Bronner’s justifiably and reasonably relied in making a substantial investment in organic ingredients to make products that could be certified to the NOP standards. Dr. Bronner’s was hardly alone in its understanding of and reliance on the May 2002 “Policy Statement,” in that the nation’s three largest USDA NOP accredited certifying agencies also interpreted the May 2002 “Policy Statement” as a directive to certify qualified personal care products, and numerous other companies’ qualified products were so certified.

70. The April 2004 “Guidance” document clearly forbids certifying entities from issuing any further certifications for personal care products certified to NOP standards, and effectively bound USDA itself not to recognize any such certifications in the future. Producers of these products already granted certification will be deprived of their right to label and market their products as meeting NOP’s standards for “Organic” and “Made with Organic”, and in the case of “Organic” products to display the USDA seal—rights which they clearly enjoyed until the April 2004 “Guidance” was issued. Thus the April 2004 “Guidance” purports to bind USDA and private parties (certifying entities and companies) with the force of law.

71. That USDA intended the April 2004 “Guidance Statement” to have binding effect is made clear by that document’s inclusion of a “transition provision” requiring

producers, by October 21, 2005, to stop using any labeling or marketing with the previously-permissible representation of compliance with NOP standards.

72. The April 2004 “Guidance Statement” was issued without any notice or opportunity for comment as required by the APA, 5 U.S.C. §553.

73. The April 2005 “Response” commands producers in binding terms that “finished products may not display the USDA seal or be represented as NOP-certified.” This statement represents a clear reversal of the interpretation adopted by USDA in its May 2002 “Policy Statement” and is clearly intended to bind private parties with the force of law

74. The April 2005 “Response” statement was issued without any notice or opportunity for comment as required by the APA, 5 U.S.C. §553.

75. The April 2004 “Guidance” and the April 2005 “Response” are substantive, legislative rules that were issued without notice or opportunity to comment as required by the APA, 5 U.S.C. §553.

76. Because they were issued without notice or opportunity for comment as required by the APA, 5 U.S.C. §553, the April 2004 “Guidance Statement” and the April 2005 “Response” statement are invalid and unenforceable.

IRREPARABLE INJURY AND INADEQUATE REMEDY AT LAW

77. Based on the allegations in the preceding paragraphs, and because no damages can be recovered from the U.S. Government for economic loss sustained as a result of regulatory action, the April 2004 “Guidance” and April 2005 “Response”, to the

extent they are enforced by USDA, are causing and will continue to cause immediate and irreparable injury to Dr. Bronner's

78. To the extent the April 2004 "Guidance Statement" and the April 2005 "Response" statement are enforced by the USDA, thereby requiring producers of body care and personal care products to discontinue labeling and marketing their products as meeting the NOP standards for "Made with Organic" or "Organic," consumers whose interests are represented and advocated by OCA will be irreparably injured because they will lack accurate and valuable information about personal and body care products they wish to purchase and will be forced to guess about the extent to which those products are truly "Organic" or "Made with Organic" products, thereby depriving them of their desire to support ecologically produced products, and depriving them of their ability to use truthful labeling and marketing information to avoid ingredients to which they may be allergic or perceive will otherwise cause negative health consequences to them.

79. Dr. Bronner's and OCA have no adequate remedy at law for the redress of this injury, and therefore seek to have USDA's enforcement of the NOP regulations based on the April 2004 "Guidance" and April 2005 "Response" permanently enjoined.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for the following relief:

- (1) An order and judgment, pursuant to the Declaratory Judgment Act, 28 U.S.C. §2201, declaring the April 2004 "Guidance" and April 2005 "Response" invalid and unenforceable;

- (2) An order and judgment enjoining defendants USDA and Secretary Johanns, from enforcing the April 2004 “Guidance” or April 2005 “Response” or from using either in any way as a basis for enforcement of the USDA’s regulations;
- (3) Costs and attorneys fees as authorized by law; and
- (4) Such other and further relief as the Court may deem just and appropriate.

Respectfully submitted,

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