**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF TEXAS**
**MIDLAND-ODESSA DIVISION**

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|---|---|---|
| MEDICAL CENTER PHARMACY;<br>APPLIED PHARMACY;<br>COLLEGE PHARMACY;<br>MED SHOP TOTAL CARE PHARMACY;<br>PET HEALTH PHARMACY, INC;<br>PLUM CREEK PHARMACEUTICALS, INC.;<br>PREMIER PHARMACY;<br>UNIVERSITY COMPOUNDING PHARMACY;<br>VETERINARY PHARMACIES OF AMERICA;<br>and WOMEN'S INTERNATIONAL PHARMACY, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>JOHN ASHCROFT, in his official capacity as ATTORNEY GENERAL, UNITED STATES DEPARTMENT OF JUSTICE;<br>TOMMY THOMPSON, in his official capacity as SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES; and<br>LESTER CRAWFORD, in his official capacity as the ACTING COMMISSIONER of the UNITED STATES FOOD AND DRUG ADMINISTRATION,<br><br>Defendants. | ) | **Case No.** |

**COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF**

Plaintiffs, Medical Center Pharmacy, Applied Pharmacy, College Pharmacy, Med Shop Total Care Pharmacy, Pet Health Pharmacy Inc., Plum Creek Pharmaceuticals, Inc., Premier Pharmacy, University Compounding Pharmacy, Veterinary Pharmacies Of America, and Women's International Pharmacy, Inc. ("Plaintiffs"), complain against Defendants, John Ashcroft, in his official capacity as Attorney General, United States Department of Justice,

Tommy Thompson, in his official capacity as Secretary of the United States Department of Health and Human Services, and Lester Crawford, in his official capacity as the Acting Commissioner of the United States Food and Drug Administration ("FDA") (collectively, "Defendants" or "Government"), as follows:

## OVERVIEW

Plaintiffs are state licensed pharmacies which, at all times, have been and remain in good standing with the Boards of Pharmacy of their respective states. This is an action to declare as unauthorized and contrary to law and preliminarily and permanently enjoin the FDA's recent unauthorized inspection and enforcement activities against pharmacies and predominantly pharmacies that compound drugs pursuant to a practitioner's prescription, where the physician or veterinarian (collectively, "practitioner(s)") has determined a patient has a medical need not filled by a commercially available manufactured drug. The issues raised herein are:

- the FDA's ongoing, active enforcement of a purely internal Compliance Policy Guideline ("CPG") whereby the FDA is prohibiting pharmacies from compounding drugs for non-food, pet and companion animals from bulk ingredients when the CPG, on its face, specifically states it is not intended to impose duties or obligations on either the FDA or pharmacies and is, at best, per the FDA's own statements, the FDA's current "best thinking" and description of "… what types of [pharmacy] compounding *might* be subject to enforcement action" (emphasis added);

- that even if, *arguendo*, the CPG could be interpreted as a "rule" properly promulgated pursuant to the Administrative Procedures Act ("APA") – it is not – as "current best thinking" and "might" are vague and ambiguous and impose no discernable standards capable of enforcement;

- that the FDA is violating Plaintiffs' First Amendment rights by requiring trade show organizers to require compounding pharmacies to sign a statement that they are in compliance with the CPG. Since trade shows represent an opportunity to advertise, promote and solicit, this FDA edict to trade show producers violates the United States Supreme Court's decision in *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002);

- in an effort to indirectly enforce the unauthorized CPG, the FDA has directed licensed wholesalers and distributors to not sell or distribute bulk ingredients to pharmacies that compound for non-food animal health;

- in an effort to indirectly enforce the unauthorized CPG, the FDA is preventing the purely legal importation of bulk ingredients to veterinary pharmacies;

- that the FDA's position that pharmacy-compounded drugs are "new drugs" is contrary to statute, FDA's own pleadings in other cases, U.S. Supreme Court precedence and the plain language of 21 U.S.C. § 321(p)(1) and (v)(1) (the "New Drug Definitions"); and

- the FDA's actual and attempted inspections of state licensed and state compliant pharmacies which are excluded from inspection in light of the specific exemption contained at 21 U.S.C. §§ 360(g)(1), 374(a)(2)(A), and 802(15). (Sections 360(g)(1) and 374(a)(2)(A) are hereafter referred to as "the Exemption");

## PARTIES AND NON-PARTIES

### Parties

1. Plaintiff, Medical Center Pharmacy ("Medical Center"), is a Texas corporation located at 4410 North Midkiff, Midland, Texas. Medical Center is licensed as a pharmacy by the Texas State Board of Pharmacy. Medical Center is in compliance with Texas pharmacy law and at all relevant times has been in good standing with the Texas State Board of Pharmacy. (Exhibit 1, Affidavit of Steve Rogers). (*See also* Exhibit A to Exhibit 1, Medical Center's Current Texas License).[1]

2. Plaintiff, Applied Pharmacy ("Applied"), is an Alabama corporation located at 3207 International Dr., Suite F, Mobile, Alabama. Applied is licensed as a pharmacy by the Alabama State Board of Pharmacy. Applied is also registered as a pharmacy in Alaska, Arizona, Colorado, Connecticut, Delaware, Florida, Iowa, Indiana, Kentucky, Louisiana, Maine, New Hampshire, Mississippi, North Dakota, Oregon, Oklahoma, South Carolina, Texas, Virginia, Washington and Wyoming. Applied also serves patients in other states where neither a separate

[1] The exhibits to this Complaint, including an index thereto, are simultaneously filed under separate cover.

license nor registration is required. Applied is in good standing with all of the states in which it does business. (Exhibit 2, Affidavit of Sam Kelly). (*See also* Exhibit A to Exhibit 2, Applied's current Alabama license and other state registrations).

3. Plaintiff, College Pharmacy ("College"), is a Colorado corporation located at 3505 Austin Bluffs Parkway, Suite 101, Colorado Springs, Colorado. College is licensed as a pharmacy by the State of Colorado. College is also registered as a pharmacy in Alabama, Arizona, California, Connecticut, Florida, Kentucky, Louisiana, Maine, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, Rhode Island, South Carolina, South Dakota, Tennessee, Washington, West Virginia, and Wyoming. College also serves patients in New Jersey and Wisconsin where no separate license or registration is required. College is in good standing with all of the states in which it does business. (Exhibit 3, Affidavit of Tom Bader). (*See also* Exhibit A to Exhibit 3, College's current Colorado license and other state registrations.)

4. Plaintiff, Med Shop Total Care Pharmacy ("Total Care"), is a Texas corporation located at 470 East Loop 281, Longview, Texas. Total Care is licensed as a pharmacy by the Texas State Board of Pharmacy. Total Care is in good standing with the Texas State Board of Pharmacy. (Exhibit 4, Affidavit of Pat Downing). (*See also* Exhibit A to Exhibit 4, Total Care's current Texas license).

5. Plaintiff, Pet Health Pharmacy Inc. ("Pet Health"), is incorporated in the State of Wisconsin and is located at 12012 North 111$^{th}$ Avenue, Youngtown, Arizona. Pet Health is licensed as a pharmacy by the Arizona State Board of Pharmacy. Pet Health is also registered as a pharmacy in Alabama, Alaska, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio,

Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, and Wyoming. Pet Health also serves patients in the District of Columbia, Georgia, Massachusetts, New Jersey, Pennsylvania, Vermont and Wisconsin where no additional license or registration is required. Pet Health is in good standing with all of the states in which is does business. (Exhibit 5, Affidavit of Wallace Simons). (*See also* Group Exhibit A to Exhibit 5, Pet Health's Current Arizona License and other state registrations).

6. Plaintiff, Plum Creek Pharmaceuticals ("Plum Creek"), is a Texas corporation located at 5211 B W. 9th Avenue, Amarillo, Texas. Plum Creek is licensed as a pharmacy by the Texas State Board of Pharmacy. Plum Creek is also registered as a pharmacy in Alabama, Alaska, Arizona, California, Colorado, Delaware, Idaho, Indiana, Iowa, Kansas, Kentucky, Maryland, Minnesota, Mississippi, Montana, New Hampshire, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Vermont, Virginia, Washington, West Virginia, and Wyoming. Plum Creek also serves patients in Georgia, Massachusetts, New Jersey, Pennsylvania and Wisconsin where no separate license or registration is required. Plum Creek is in good standing with all of the states in which it does business. (Exhibit 6, Affidavit of John Rains) (*See also* Group Exhibit A to Exhibit 6, Plum Creek's current Texas license and other state registrations).

7. Plaintiff, Premier Pharmacy ("Premier"), is a Texas corporation located at 20214 Braidwood, Katy, Texas. Premier is licensed as a pharmacy by the Texas State Board of Pharmacy. Premier is in good standing with the Texas State Board of Pharmacy. (Exhibit 7, Affidavit of Dr. Steven Hotze) (*See also* Exhibit A to Exhibit 7, Premier's current Texas license).

8. Plaintiff, Veterinary Pharmacies of America ("Veterinary"), is a Nevada corporation located at 2854 Antoine, Houston, Texas. Veterinary is licensed as a pharmacy by

the Texas State Board of Pharmacy. Veterinary is also registered as a pharmacy in Alabama, Arizona, California, Colorado, Connecticut, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, and Washington. Veterinary is in good standing with all of the states in which it does business (Exhibit 8, Affidavit of Steve Organ). (*See also* Exhibit A to Exhibit 8, Veterinary's current Texas license and other state registrations).

9. Plaintiff, University Compounding Pharmacy, Inc. ("University"), is a California corporation located at 1875 Third Avenue, San Diego, California. University is licensed as a pharmacy by the California Board of Pharmacy. University is in good standing with the California Board of Pharmacy. (Exhibit 9, Affidavit of John Grasela) (*See also* Exhibit A to Exhibit 9, University's current California license).

10. Plaintiff, Women's International Pharmacy, Inc. (Wisconsin) ("Women's"), is a Wisconsin corporation located at 5708 Monona Drive, Madison, Wisconsin and 13925 West Meeker Boulevard, Suite 13, Sun City West, Arizona. Women's is licensed as a pharmacy by the Arizona State Board of Pharmacy and the Wisconsin Pharmacy Examining Board. Women's is also registered as a pharmacy in Alabama, Alaska, Arkansas, California, Colorado, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, W. Virginia, and Wyoming. Women's also serves patients in the District of Columbia, Georgia, Massachusetts, New Jersey, Pennsylvania, and

Vermont, where no separate license or registration is required. Women's is in good standing with all of the states in which it does business. (Exhibit 5, Affidavit of Wallace Simons) (*See also* Group Exhibit A to Exhibit 5, Women's current Arizona and Wisconsin licenses and other state registrations).

11. John Ashcroft is the Attorney General of the United States and is sued solely in his official capacity.

12. Tommy Thompson is the Secretary of the United States Department of Health and Human Services and is sued solely in his official capacity.

13. Lester Crawford is the Acting Commissioner of the FDA and is sued solely in his official capacity.

**Non-Parties**

14. BET Pharm, LLC ("BET") is a Kentucky limited liability company located at 1222 Richmond Rd., Lexington, Kentucky. BET is licensed in Kentucky and is in good standing with the Kentucky State Board of Pharmacy.

15. Wedgewood Village Pharmacy, Inc. ("Wedgewood"), is a New Jersey corporation located at 405 Heron Drive, Swedesboro, New Jersey. Wedgewood is licensed in New Jersey and is in good standing with the New Jersey Board of Pharmacy.

**JURISDICTION AND VENUE**

16. This Court has subject matter jurisdiction over this matter pursuant to:

- 5 U.S.C. §§ 704 and 706(2)(C) of the Administrative Procedures Act ("APA") because the FDA exceed its statutory authority by routinely conducting inspections of pharmacies exempt under 21 U.S.C. § 374 (a)(2)(A) and by improperly promulgating and enforcing a Compliance Policy Guideline, thereby seeking to regulate pharmacy compounding and declaring pharmacy compounding from bulk ingredients illegal for non-food animals;

- 5 U.S.C. § 553 *et seq*. and § 706(2)(D) because the FDA enacted and is enforcing a rule declaring compounding from bulk ingredients for non-food

animals illegal without following the notice and rule making procedures prescribed by the APA; and

- 28 U.S.C. § 2201 as Plaintiffs seek a declaratory judgment finding that the FDA is not entitled to inspect pharmacies that meet the criteria set forth in 21 U.S.C. § 374(a)(2)(A); that compounded drugs are not "new drugs" and, therefore, not subject to the FDCA requirements; that compounding from bulk ingredients for non-food animals is permitted under Federal law; and that FDA cannot prohibit the Plaintiff from attending trade shows by forcing compliance with the CPG.

17. Venue is proper under 28 U.S.C. § 1391(e) because Plaintiff Medical Center Pharmacy resides in the Western District of Texas.

## FACTS COMMON TO ALL COUNTS

18. "Physician(s)" refers to doctors trained and licensed to treat humans; "veterinarian(s)" refers to doctors trained and licensed to treat animals; and both are from time to time collectively referred to herein as "practitioner(s)."

19. Plaintiffs are ten state licensed pharmacies that specialize in compounding for either human health, non-food, pet and companion animal health, or both.

20. As required by state laws, Plaintiffs' collaborate, consult, and work with practitioners and patients, and prepare and dispense compounded drugs for treatment of humans and non-food pet and companion animals.

### Pharmacy Compounding

21. Compounding has been defined by the United States Supreme Court as:

> Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. **It is a traditional component of the practice of pharmacy, … and is taught as part of the standard curriculum at most pharmacy schools, … Many States specifically regulate compounding practices as**

> **part of their regulation of pharmacies**. (internal citations omitted) (emphasis added)

*Western States*, 535 U.S. at 361.

22. Compounds fill the interstitial spaces where, in the judgment of practitioners, there is no suitable manufactured product available.

23. Pharmacy compounding is a vital, medically necessary, longstanding and integral part of the delivery of health care in the United States for both human and animal health.

24. Compounded drugs are prepared and dispensed by Plaintiffs on the prescription of the practitioner.

25. Pharmacy compounding does not compete with and is not drug manufacturing, and a manufactured drug is *not* the opposite of a compounded drug. The opposite of a compounded drug is the complete unavailability of *any* drug therapy or regimen altogether.

26. Drug manufacturers only make drugs if there is a sufficiently large market to justify the research, development, manufacturing, distribution costs, and a sufficient profit incentive.

27. Commercially manufactured drugs are not available to treat many conditions. Therefore, after practitioners determine that there is no suitable commercially manufactured drug available, they prescribe pharmacy compounds. (Exhibit 10, Affidavit of Professor Judy Thompson, ¶¶ 11,12).

28. This unavailability occurs for many reasons. For example;

- There is no manufactured product to accomplish a desired or preferred medical objective;
- A commercially available product, while available, is nonetheless not suitable because of patient allergies; drug delivery format, *i.e*., tablet, injectible, patch, suppository, *etc*.; flavoring; combination with other drugs, *etc*.;

- A manufactured drug also may not come in the dosage appropriate for a particular patient, *e.g.*, pediatric versus adult dosage (Exhibit 10, Affidavit of Professor Judy Thompson, ¶ 12).

29. Pharmacies compound and dispense drugs pursuant to prescriptions to treat cancer, PMS, menopause, infertility, pain management, and every other conceivable condition or illness. (Exhibit 1, Affidavit of Steve Rogers, ¶ 9 and Exhibit 5, Affidavit of Wallace Simons, ¶ 10).

30. It is the pharmacist's professional responsibility to consult and confer with the practitioner and the patient or pet owner to determine how to best address the patient's medical needs.

31. It is a requirement of all or almost all states that pharmacists have and maintain compounding skills and proficiencies. (Exhibit 10, Affidavit of Professor Judy Thompson, ¶10; Exhibit 3, Affidavit of Tom Bader, ¶ 7.

32. It is a requirement of all or almost all state pharmacy regulations that pharmacies have and maintain compounding equipment. (Exhibit 10, Affidavit of Professor Judy Thompson, ¶10; Exhibit 3, Affidavit of Tom Bader, ¶ 7).

33. Pharmacy compounding is a standard part of all, or almost all, pharmacy school curricula.

**The CPG**

34. On July 8, 2003, the FDA promulgated Compliance Policy Guideline 7125.40 608.400 ("CPG").

35. The CPG claims to prohibit compounding drugs for non-food animals from bulk ingredients.

36. The CPG's preamble declares:

> *This compliance policy guidance is intended to provide guidance and instructions to FDA staff, industry, and the public for obtaining information to help fulfill the Agency's plans regarding the compounding of drugs for use in animals.* ***The compliance policy guidance does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations****. It is intended for FDA personnel, industry, and the public and is available electronically to the public*. (italics in original) (bold is emphasis added).

(Exhibit 12).

37. The CPG's "Introduction" provides:

> This document provides guidance to drug compounders, veterinarians, and the staff of the Food and Drug Administration (FDA) on how the Agency intends to address compounding of drugs intended for use in animals. This guidance describes FDA's **current thinking** on what types of compounding **might be subject** to enforcement action. (emphasis added).

(Exhibit 12).

38. Prior to the CPG, there was no purported prohibition on compounding from bulk ingredients for non-food animals.

39. A CPG is a purely internal FDA guideline which as a matter of law and according to its own preamble establishes that it is not binding on either the FDA or pharmacies.

40. Notwithstanding that the CPG states that it does not confer any rights or bind anyone or any entity, the FDA has commenced enforcing the CPG, through inspections and seizure, as though the CPG were and had the force and effect of law. *See also Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995), 847 F. Supp. 1359 (S.D. Tex. 1994).

41. There is no comparable CPG, statute, or regulation that prohibits or professes to prohibit compounding from bulk ingredients for humans.

42. The bulk compounds that Plaintiffs use in compounding drugs are prepared in FDA registered, inspected, and approved facilities and conform to pharmacy grade standards.

43. The bulk ingredients that Plaintiffs use are obtained from licensed sources.

44. The bulk ingredients that Plaintiffs use are delivered with the normal written assurances and assays of purity and content, examples of which are provided in Group Exhibit 21.

45. Plaintiffs also seek a determination that, consistent with well-established case law, the APA, and the CPG's own preamble and introduction, the CPG, at best, expresses the FDA's "*current*" thinking on what "*might*" be subject to enforcement and cannot have the force and effect of law.

46. Even if, hypothetically, the CPG were enforceable, it is vague, ambiguous, and indefinite, as "current thinking" and what "might" be subject to enforcement provides no or insufficient notice to pharmacies of what is required of them under the CPG.

47. On April 2, 2004, the Director of the Office of Compliance for the FDA Center for Veterinary Medicine ("CVM") sent a notice to all Boards of Pharmacy in the United States ("the Notice"). (Exhibit 13, Notice To Board of Pharmacy).

48. The Notice declares that CVM has issued inspection assignments to FDA field offices to inspect twenty different pharmacies. (Exhibit 13).

49. The Notice states that "compounded drugs for use in animals, except in limited circumstances, is not permitted under Federal law." The Notice misrepresents that Animal Medicinal Drug Use Clarification Act ("AMDUCA") and 21 CFR § 530.13(b) ("AMDUCA Regulation") require that pharmacy compounding can only be done from approved human or

animal drugs, and does not permit pharmacy compounding from bulk ingredients. *See* 21 U.S.C. §360b(4) (5).

50. The Notice misrepresents AMDUCA and the AMDUCA Regulation and is in plain contravention of AMDUCA and the AMDUCA Regulation.

51. The Notice and FDA field activity establish that the FDA intends to continue to enforce its new policy that pharmacy compounding from bulk ingredients is illegal for non-food animals.

52. The Notice asks state boards of pharmacy for their participation and assistance in these purely FDA investigations. (Exhibit 13).

53. The Notice discloses that the FDA will inspect veterinary compounding pharmacies without evaluating the Exemption Criteria and the right of compliant pharmacies to be free from FDA inspection under the Exemption.

54. Recent field events establish that, indeed, before inspecting, FDA has no intention of making any effort to determine whether pharmacies comply with the Exemption Criteria.

55. The Notice is in plain contravention of the statutory mandate of the Exemption.

56. The Notice is in direct contravention of the APA.

57. The Notice reveals an assumption of power and authority not conferred upon the FDA by Congress, that is, to inspect compliant pharmacies.

58. Through the artifice and rubric of the alleged exercise of FDA "discretion," in the absence of any articulated standards, the FDA has unilaterally reserved for itself the right, power, and authority to attempt enforcement and inspections whenever FDA wants to, and all:

- without standards;

- without having gone through proper rule making procedures to unilaterally decide when a compliant pharmacy "might" be compounding from bulk ingredients for non-food animal patients;

- when a compliant pharmacy "might" be compounding a "new drug"; and

- when the FDA simply wants to inspect a compliant pharmacy for an unauthorized purpose or no purpose at all.

**Unauthorized FDA Inspections Of Compliant Pharmacies**

59. FDA is engaging in the unauthorized and attempted unauthorized inspection of pharmacies and primarily, if not exclusively, of compounding pharmacies.

60. During some of these attempted inspections, pharmacies have allowed the inspections. On other occasions, the pharmacy refused FDA inspection access, either because the targeted pharmacy knew its rights under the Exemption or promptly contacted counsel.

61. The FDA recently adopted an unwritten policy to begin *annual* inspections of pharmacies that specialize in compounding. (*See* Exhibit 2, Affidavit of Sam Kelly, ¶ 20).

62. No Federal statute authorizes or permits FDA regulation of pharmacy compounding.

63. In 1989, in *United States v. Baxter Healthcare Corp.*, 712 F. Supp. 1352 (N.D. Ill. 1989), the FDA, in *its* brief, conceded in the district court that the FDA cannot inspect pharmacies compliant with state law under the Exemption. In *Baxter*, the Government informed the Court:

> First, the Act [FDCA] does not authorize the agency to regulate either the practice of pharmacy or the practice of medicine. See, e.g., 21 U.S.C. §360(g)(1) and (2) (exempting licensed pharmacists and practitioners from the drug registration provisions of the Act, provided that they are dispensing or prescribing drugs); §374(a)(2)(A) (exempting pharmacists and licensed practitioners from inspectional provisions provided that they are engaged in their professional practices).

Exhibit 14, Reply Memorandum Of Law In Support Of Plaintiff's Motion For Preliminary Injunction, p.10.

64. During the unauthorized inspections that certain pharmacies permitted, the FDA without limitation, inspected, examined, inventoried, reviewed, sampled, or copied equipment, ingredients, drugs, patient and physician lists, financial records, and other papers, records, and documents.

65. Multiple sections of the Food, Drug and Cosmetic Act ("FDCA") establish that neither pharmacies nor pharmacy compounding are subject to FDA inspection or regulation. 21 U.S.C. § 360(g)(1) (registration and manufacturers) provides:

> The foregoing subsections of this section **shall not apply to**−
>
> (1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (emphasis added)

66. Section 374(a)(2)(A) (inspection) (the Exemption) provides:

> (2) The provisions of the third sentence of paragraph (1) **shall not apply to**−
>
> (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their

> business of dispensing or selling drugs or devices at retail; (emphasis added)

67. Section 802(15) (Controlled Substances Act) provides:

> The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging off such substance or labeling or relabeling of its container; **except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance inconformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice**. The term "manufacturer" means a person who manufactures a drug or other substance. (emphasis added)

68. In Section 21 U.S.C. 802(15), "practitioner" includes pharmacist. *See* 21 U.S.C. §802(21).

69. To be eligible for the Exemption from FDA inspection, the pharmacy must comply with the Exemption criteria set forth in the Exemption. These are:

- compliance with state laws which relate to pharmacy practice;
- dispense and sell pursuant to a practitioner's prescription; and
- dispense or sell, compound or manufacture, in the regular course of business of *their* business at retail (collectively, the "Exemption Criteria").

70. FDA inspection of pharmacies that meet the Exemption Criteria is prohibited.

71. Any FDA inspection of the Plaintiffs' pharmacies violates the Exemption, as each Plaintiff is fully compliant with the Exemption Criteria, and the FDA has never contended otherwise.

72. Plaintiffs seek a declaration that FDA inspections of pharmacies is prohibited under the Exemption and, in the absence of independent pre-inspection evidence based on state

determination that a pharmacy is not in compliance with the Exemption Criteria, to preliminarily and permanently enjoin the FDA from inspecting pharmacies.

**Compounds Are Not "New Drugs"**

73. As a pretext for garnering jurisdiction and authority over pharmacies, predominantly, if not exclusively, pharmacies that compound, the FDA has taken the position that pharmacy compounds are "new drugs" under the FDCA.

74. The New Drug Definitions at 21 U.S.C. §321(p)(1) (for humans) provides:

> The term "new drug" means –
>
> > (1) Any drug (except a new animal drug or an animals feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;…

75. The new animal drug definition in 21 U.S.C. §321(v)(1) is:

> (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; . . . .

76. It is not only uneconomical, but impossible, to evaluate pharmacy compounds under the New Drug Definition.

77. To satisfy the clinical trial component of the FDA's "new drug" pre-market approval process requires:

- a stable, reliable, available, and predictable statistically valid sample;
- adequate and well-controlled investigations, including clinical trials; and
- the application of powerful statistical techniques data from *large* populations of humans and animals.

78. By definition, an adequate data base can never exist for pharmacy compounded drugs as pharmacy compounds are patient specific.

79. The evaluation for "new drugs" is impossible to apply to pharmacy compounds, as they meet *unique* patient medical needs which will never generate a "product" to submit for clinical trials or on which to obtain "general approval."

80. Due to the manner in which pharmacy compounds are prescribed and dispensed (*i.e.*, based on individual patient needs determined by a practitioner), there is no consistent means for determining, on any statistically valid basis, whether they are universally safe and effective "under the conditions prescribed," as these conditions vary from patient to patient and prescribing practitioner to prescribing practitioner.

81. The importance of pharmacy compounds, that is, tailored for individual patients or classes of patients, makes them incapable of going through the "new drug" approval process.

82. In its opening brief to the United States Supreme Court in *Western States* (Exhibit 15), the Government touted the medical necessity of compounded drugs, when it stated:

> Like certain off-label uses, compounding in response to individual medical needs may have important health benefits. It allows physicians and pharmacists to work together to develop customized therapies for patients for whom commercially manufactured drugs are not suitable for various medical reasons. For example, when a patient has an allergy to a component of a commercially available product, or an approved drug does not

> come in a dosage appropriate for an individual or in a delivery system that the patient can tolerate, the physician and pharmacist can work together to create a compounded product that addresses the patient's particularized needs.

Exhibit 15, p. 25-26.

83. In its opening brief in the United States Supreme Court in *Western States*, the Solicitor General of the United States, on behalf of the FDA, openly acknowledged the impossibility of pharmacy compounds being considered or treated as "new drugs." In *Western States*, the Solicitor General informed the United States Supreme Court:

> Of course, it might **theoretically be ideal** if a pharmacy first demonstrated to the FDA that a compounded drug is safe and effective for its intended use before it is sold to an individual patient. **However, because obtaining FDA approval of a new drug is a costly process, requiring FDA approval of all drug products compounded by pharmacies for the particular needs of an individual patient would, as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for those patients who have no alternative treatment**. The cost of developing and obtaining approval of a new drug that is not closely similar to an already approved drug is generally estimated to exceed **$200 million** dollars. (internal citations omitted) (emphasis added).

Exhibit 15, pp. 25-26.

84. In derogation of its own statements in *Western States*, the Government now attempts to convert compounded drugs into "new drugs."

85. In its opening *Western States* brief, the Government further informed the Supreme Court:

> Just as those costs have discouraged manufacturers from developing drugs to treat rare illnesses, the high costs of the approval process would make it uneconomical for a typical pharmacists to obtain approval for a drug that is compounded for a limited number of people−sometimes only a single individual−for whom the product is medically necessary. Requiring approval in those circumstances would not be feasible, and advance approval

> of such individual compounded drugs is less central to protecting the broader public health than is the advance approval of products that are distributed more widely to the public. (internal citation omitted).

Exhibit 15, p. 27.

86. The United States Supreme Court agreed with the FDA and held:

> The Government also has an important interest, however, in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. **And it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process**. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs.

*Western States*, 535 U.S. at 369 (emphasis added).

87. If compounds were "new drugs," then anytime a compounding pharmacy prepared a compound, it would be engaging in illegal activity in violation of 21 U.S.C. § 355, *i.e.*, placing a "new drug" into commerce without going through the new drug approval process.

88. Yet, in *Western States,* the FDA maintained compounding is a legal pharmacy activity.

89. Having made the above statements before the Supreme Court and other courts, and the Supreme Court and other courts having adopted the Government's position, the Government is now prevented, based upon the principles of issue preclusion and collateral and judicial estoppel, from claiming or asserting that compounds are "new drugs" under the New Drug Definitions.

90. Plaintiffs seek a declaration that pharmacy compounds are not and cannot be "new drugs" within the meaning of the New Drug Definitions.

91. Plaintiffs seek a declaration that the Government is estopped by the doctrines of issue preclusion and collateral and judicial estoppel from maintaining that compounds are "new drugs."

92. Plaintiffs seek preliminary and permanent injunction barring the Government from taking action against any pharmacy on the grounds that compounds are "new drugs."

**Unauthorized And Illegal FDA Interference With Plaintiffs' Trade Show Exhibitions And Purchase Of Bulk Ingredients**

93. The veterinary compounding Plaintiffs depend and rely on attending trade shows to promote, advertise and solicit their existence, skills, experiences, services, expertise, and knowledge.

94. Two leading such trade shows are presented by the American Association of Equine Practitioners ("AAEP") and Western Veterinary Conference ("WVC").

95. Upon the directive of the FDA, and as a condition precedent to being allowed to participate in the annual trade shows of AAEP and WVC, AAEP and WVC demanded that pharmacies that compound for non-food animal health sign a certificate that they are compliant with the CPG. (Exhibit 28).

96. It is impossible to "comply" with the CPG, as it imposes no obligations or standards, and is but an FDA muse.

97. In *Western States*, the United States Supreme Court specifically held that compounding pharmacies may advertise, promote, and solicit pharmacy compounding, which is what trade show attendance furthers.

98. The FDA's directive to impose this requirement on veterinary compounding pharmacies is a violation of the First Amendment to the United States Constitution's guarantee of freedom of commercial speech and a direct contempt of the mandate in *Western States*.

99. FDA does not contend that Plaintiffs' attendance and exhibiting is illegal or that Plaintiffs distribute false or misleading information.

100. Plaintiffs do not engage in illegal activity.

101. Plaintiffs do not distribute false or misleading advertising, promotional, or soliciting information.

102. The FDA's directive to trade show producers was issued without regard to or any investigation undertaken whether Plaintiffs might engage in alleged illegal conduct or whether they distribute false or misleading information.

103. In an effort to indirectly enforce the unenforceable CPG, the FDA has directed licensed bulk ingredient wholesalers and distributors to not sell or distribute bulk ingredients to veterinary compounding pharmacies.

104. In an effort to indirectly enforce the unenforceable CPG, the FDA is stopping the importation of bulk chemicals enroute to veterinary pharmacies.

105. The Plaintiff compounding pharmacies seek a declaratory judgment that the FDA's directives to trade show producers and drug wholesalers and distributors are without legal authority.

106. The Plaintiff compounding pharmacies seek preliminary and permanent injunction enjoining the FDA from continuing to issue the aforedescribed directives to *any* trade show sponsor and drug wholesaler and distributor and to withdraw all such directives already issued.

**PLAINTIFFS' INDIVIDUAL COMPOUNDING PHARMACY PRACTICES**

107. Plaintiffs dispense compounds pursuant to the prescription of a physician and only when there is no suitable manufactured commercially available alternative.

108. Plaintiffs compound in the regular course of their businesses of dispensing or selling drugs at retail.

109. Plaintiff, Medical Center, specializes in compounding drugs including, but not limited to, bioidentical hormones, transdermal pain medications for hospice use, sterile hormone injections, sterile opthalmics, and transdermal anti-inflammatory gels. (Exhibit 1, Affidavit. of Steve Rogers, ¶11).

110. Plaintiff, Applied, specializes in compounding custom drugs for various medical disorders including erectile dysfunction, AIDS wasting, and hormonal replacement therapy ("HRT"). (Exhibit 2, Affidavit of Sam Kelly, ¶ 7).

111. Plaintiff, College, specializes in compounding drugs for HRT, pain management, environmental (allergy free) compounds, and for dermatological needs. (Exhibit 3, Affidavit of Tom Bader, ¶ 13).

112. Plaintiff, Total Care, specializes in compounding drugs for chronic pain, hospice patients, pediatrics, geriatrics, HRT for men and women, and the preparation of sterile products. (Exhibit 4, Affidavit of Pat Downing, ¶7).

113. Plaintiff, Plum Creek, specializes in compounding drugs for specific pain management and HRT, as well as compounds for non-food companion and pet animal care. (Exhibit 6, Affidavit of John Rains, ¶¶ 7-9).

114. Plaintiff, Premier, specializes in compounding bio-identical hormones to serve patients who suffer from hormone imbalances and hormone decline. (Exhibit 7, Affidavit of Dr. Steven Hotze, ¶ 6).

115. Plaintiff, University, specializes in compounds for patients who require HRT. (Exhibit 9, Affidavit of John Grasela, ¶ 7).

116. Plaintiff, Women's, specializes in compounded prescriptions containing biologically identical estrogens, progesterone, testosterone, hydrocortisone and pregnenolone. prescribed by physicians for patients with hormone deficiencies. (Exhibit 5, Affidavit of Wallace Simons, ¶ 10).

117. Physicians, in the treatment and cure of terminal patients, require compounded drugs for pain management. For example, terminal cancer patients in hospices require pain killers in doses that are commercially unavailable. Hospice physicians require pharmacists to prepare drugs in the proper dosage forms for terminal patients, to ease suffering in their last days. For example, by using compounded medications, patients can take one pill every four hours instead of forty-five pills every four hours with twenty two pills in between. (Exhibit 16, Affidavit of Dr. Don McLarey, ¶¶ 2, 3).

118. Physicians prescribe compounded drugs to treat conditions such as andropause, adrenal fatigue, osteoporosis and esteropenia. These conditions are treated with commercially unavailable bio-identical hormones. Bio-identical hormones vastly improve the quality of life of patients suffering from these and other conditions. (Exhibit 17, Affidavit of Dr. Kimberley Schroeder, ¶¶ 3 & 4).

119. There is a high suicide rate in patients with untreated chronic pain, so it is an issue of survival as well as compassion. Patients frequently inform physicians they prefer death to continued suffering from pain. Without the availability of compounded pain drugs, physicians, treating chronic pain lose a value therapy or drug regimen. (Exhibit 18, Affidavit. of Dr. Barbara Wilson, ¶¶ 3, 5).

120. Physicians manage pain by prescribing compounded drugs when patients cannot tolerate a commercially manufactured pain medicine because of nausea, vomiting, sedation, or

constipation so severe that hospitalization is required. (Exhibit 18, Affidavit of Dr. Barbara Wilson, ¶ 3).

121. Plaintiffs work closely with thousands of practitioners throughout the United States to determine the appropriate compounded drug dose and delivery format for the patient.

122. Without these compounds and the skill, training and experience of Plaintiffs who specialize in their respective fields, many patients would die or suffer needlessly by going without any treatment whatsoever. (Exhibit 11, Affidavit of Dr. Jeff Jones, ¶ 9; Exhibit 19, Affidavit of Dr. Eric Bergman, ¶ 10; Exhibit 16, Affidavit of Dr. Don McLarey, ¶¶ 4-5; and Exhibit 18, Affidavit of Dr. Barbara Wilson, ¶5).

123. In veterinary medicine, many medications that non-food animals need are commercially unavailable, because the market and profit potential for many veterinary drugs is not great enough to incentivize manufacturers to manufacture a drug. In these instances, veterinarians turn to compounding pharmacies to prepare and dispense pharmacy compounded drugs which are medically necessary to treat animal patients. (Exhibit 20, Affidavit of Professor Donald Mischalski, ¶ 5).

124. Sometimes, the compounded drug is medically needed for an individual patient. On other occasions, there is a class, of human and non-food animal patients with the same or similar condition or illness that needs the same commercially unavailable compounded drug.

125. Veterinary compounding pharmacies have traditionally used bulk ingredients for non-food animal patients to ensure the medically necessary drug is available, effective, and pure.

126. Bulk active ingredients are manufactured in facilities that are registered with and inspected and approved by the FDA.

127. The bulk ingredients are obtained from licensed and regulated sources.

128. The bulk ingredients are received by practitioners with written certifications and analyses and USP standards as to purity, potency, and excipients. Examples of such written assurances are attached as Group Exhibit 21.

129. Compounding drugs from FDA approved drugs, *i.e*., manufactured drugs, whether for human or animal medicine, are frequently inappropriate because of fillers and other inactive ingredients (excipients) that the practitioner has determined will interfere with the drug's effectiveness. (Exhibit 20, Affidavit of Professor Donald Mischalski, ¶ 13). Requiring compounding pharmacies to compound from manufactured drugs would defeat one of the purposes of compounding. Compounding from bulk ingredients for non-food animals is the most efficacious and usually only manner for preparing such commercially unavailable drugs.

130. Plaintiff, Pet Health, specializes in compounding medications for non-food animal patients from bulk ingredients in the dosage and delivery system needed to properly medicate pet and companion non-food animals pursuant to prescription. (Exhibit 5, Affidavit of Wallace Simons, ¶ 15).

131. Plaintiff, Plum Creek, compounds drugs for non-food animals from bulk ingredients in the dosage and delivery form required. (Exhibit 6, Affidavit. of John Rains, ¶ 9).

132. Plaintiff, Veterinary, specializes in compounding medicated pet chews from bulk ingredients in different flavors (beef, tuna, chicken, sea food, liver, *etc*.) to assist owners in making sure that their non-food pet and companion animals take their medication. (Exhibit 8, Affidavit of Steve Organ, ¶ 7).

133. Many drugs for non-food animals that treat life-threatening diseases cannot be compounded other than from bulk ingredients. For example, Plaintiff, Veterinary, would not be

able to compound Cisapride (Propulsid), Metronidazole or Potassium Bromide. (Exhibit 8, Affidavit of Steve Organ, ¶¶ 8-11).

134. If denied access to bulk ingredients, Plaintiff, Applied, would not be able to compound Stanazonol. (Exhibit 2, Affidavit of Sam Kelly, ¶ 11 ).

135. If denied access to bulk ingredients, Plaintiff, Plum Creek, would not be able to compound Yohimbine 10 mg per ml, and Ciprofloxacin. (Exhibit 6, Affidavit of John Rains, ¶ 10).

136. Without pharmacy compounded drugs, pet and companion animals would needlessly suffer and/or die. Cats are difficult to medicate, since they often refuse medication in pill form and have to be medicated by an alternative delivery method not commercially available, *i.e.*, transdermal or liquid form. (Exhibit 19, Affidavit of Dr. Eric Bergman, ¶¶ 5, 6, 10).

137. Without pharmacy compounded drugs feline hyperthyroid would go untreated, leading to the death of pet cats. (Exhibit 22, Affidavit of Dr. Patricia Lane, ¶5; Exhibit 19, Affidavit of Dr. Eric Bergman, ¶ 8; and ).

138. Without pharmacy compounded medications, Feline mega-colon, a fatal feline condition, would go untreated. (Exhibit 8, Affidavit of Steve Organ, ¶ 9).

139. Without pharmacy compounded drugs such as compounded Potassium Bromide, dogs would suffer and die from mal-seizures. (Exhibit 11, Affidavit of Dr. Jeff Jones, ¶¶ 4, 9 and Exhibit 23, Affidavit of Dr. Michael Jones, ¶¶ 7, 9).

140. Police forces depend on dogs whom they have trained and which have developed an expertise. Compounded Potassium Bromide helps these dogs survive mal-seizures, get well and back to work. (Exhibit 11, Affidavit of Dr. Jeff Jones, ¶5).

141. Dogs suffer chronic fungal ear infections, the preferred treatment for which can only be compounded from bulk. Untreated, these ear infections lead to extreme discomfort and eventual hearing loss. (Exhibit 23, Affidavit of Dr. Michael Jones, ¶ 6).

142. Pharmacy compounded drugs are indispensable to treating Addison's disease, which, untreated, leads to cardiac problems, kidney failure, and death. (Exhibit 23, Affidavit of Dr. Michael Jones, ¶ 5).

143. There is no statute or regulation which prohibits pharmacy compounding from bulk for medically necessary drugs for pet and companion, *i.e*., non-food animals.

144. There is no statute which would permit or authorize the promulgation of a regulation which would prohibit pharmacy compounding from bulk medically necessary drugs for pet and companion, *i.e*., non-food, animals.

145. The CPG is the only writing which addresses compounding for non-food animals from bulk ingredients. It:

- is, as a matter of law, not an enforceable rule or regulation, and
- on its face declares that it imposes no obligation on either the regulator, *i.e*., FDA, or regulatees, *i.e*., Plaintiffs, and all similarly situated pharmacies nationwide.

## THE REGULATION OF PHARMACIES

146. There is no federal statute which defines compounding pharmacy and none that regulates it.

147. The FDA is currently enforcing the application of the New Drug Definitions to pharmacy compounded drugs, is enforcing the CPG as though it were enforceable and binding, and is disregarding the Exemption by inspecting compliant pharmacies.

148. State statutes, regulations and state Boards of Pharmacy regulate pharmacies, including compounding pharmacy practice. *See Western States*, 535 U.S. at 361.

149. Congress has never allowed the FDA to regulate pharmacy practice; in fact it expressly carved out exemptions for pharmacies from FDA regulation. The states regulate pharmacy practice. *See Western States*, 535 U.S. at 361-362 and the FDA's own statements in *Baxter*. (Exhibit 14, p. 10).

150. Sections 360(g)(1) and the Exemption permit pharmacies to compound—even manufacture—as long as they do so in accordance with the Exemption Criteria.

151. There is no mechanism or procedure whereby a pharmacy *could* register with the FDA even if it wanted to.

**FDA'S ONGOING UNAUTHORIZED INSPECTION AND ENFORCEMENT**

152. Notwithstanding the clear and unambiguous mandate contained in the Exemption, the FDA is on an aggressive, active, ongoing initiative to regulate state licensed pharmacies that compound. FDA has promulgated an unpublished policy that the FDA will inspect compounding pharmacies annually. (Exhibit 2, Affidavit of Sam Kelly, ¶ 20).

153. There is considerable and constant illegal and unauthorized FDA enforcement activity. The following are recent examples.

**Wedgewood**

154. Wedgewood is not a party.

155. On March 10, 2003, a New Jersey District Office investigator of the FDA applied *ex parte* to the United States District Court of New Jersey for an administrative inspection warrant for Wedgewood's Sewell, New Jersey, facility. (Exhibit 24, Affidavit of George Malmberg ¶ 5).

156. On March 10, 2003 a Warrant for Inspection Under the Federal Food, Drug and Cosmetic Act was obtained *ex parte* from a New Jersey United States Magistrate. (Exhibit 24, Affidavit of George Malmberg ¶ 6).

157. On March 12, 2003, approximately 15 agents from the FDA and Drug Enforcement Administration ("DEA"), and the United States Marshal's Service arrived at Wedgewood to execute the inspection warrant. (Exhibit 24, Affidavit of George Malmberg ¶ 7).

158. Wedgewood initially refused to relinquish any records until an armed United States' Marshall threatened to immediately take the owner, George Malmberg, into custody and seize and remove all the pharmacy's computers, records and more from Wedgewood. Malmberg relented.

159. In the Wedgewood Application as one of the bases for its need to inspect Wedgewood, FDA stated:

> Compounding from bulk drug substances is not permitted. 21 CFR 530.13 (a). Because Wedgewood Pharmacy holds no FDA approval applications, its compounding of drugs for veterinary use from bulk drug substances would violate the Act, 21 U.S.C. 351(a)(5).

(Application for Inspection Warrant, Exhibit 1 to Exhibit 24, George Malmberg's Affidavit).

160. While the agents were at Wedgewood, they inspected every aspect of the pharmacy, including the compounding facilities, compounding components, active ingredients, excipients, documents, and records.

**BET**

161. BET is not a party.

162. BET specializes in compounding reproductive drugs for horses to maintain viable pregnancy in "at risk" mares. (Exhibit 25, Affidavit of Stephen Atwood, ¶¶ 3, 9).

163. On June 30, 2003, two FDA Agents accompanied by a Kentucky Board of Pharmacy ("KBP") representative, inspected BET. According to FDA Agent Culver, the

purpose of the FDA inspection was to determine if BET was a manufacturer because of an alleged undisclosed allegation or complaint. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 5).

164. The FDA inspection lasted from June 30, 2003 through August 6, 2003. One or both FDA Agents were in the pharmacy for a total of 14 days: on June 30, July 1-3, July 7 and 8, July 24, July 28, July 30, and August 1-6. The FDA inspector(s) arrived at 9:45 a.m. and left at approximately 4:00 p.m. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 6).

165. The FDA Agents inspected every aspect of the pharmacy, including the compounding facilities, compounding components, both active ingredients and excipients, and all documents and records. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 7).

166. The Agents demanded and obtained the private and confidential records of BET clients, violating Kentucky Statutes, formulary information, confidential financial records, shipping records, prescription forms containing confidential patient information, again violating Kentucky Statutes and, finally, confidential customer compilations. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 7).

167. The FDA Agents severely disrupted BET's business. The pharmacy was unable to dispense prescriptions in a timely manner because of the continued and onerous demands that the FDA Agents heaped on BET's pharmacists. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 8).

168. The FDA Agents prevented BET pharmacists from compounding medications that veterinarians needed promptly to properly treat their patients. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 8).

169. When BET's drugs are needed, they are needed right away. Without the timely receipt of the drugs, the mares run the risk of death due to miscarriage or the necessity to be euthanized due to pregnancy complications. During the FDA's first inspection, the FDA caused a four to ten day delay in deliveries of drugs to patients. This delay placed pregnant horses' lives and the lives of their foals at risk. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 9).

170. At no time did Agent Culver or the KBP representative indicate that BET was out of compliance with any law or regulation or the Exemption Criteria. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 9A).

171. Agent Culver never alerted BET to the Exemption. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 10).

172. From May 6, 2004 through May 18, 2004, the FDA conducted a second BET inspection. Agent Culver was again accompanied by a KBP representative. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 11).

173. Agent Culver was informed that her prior inspection of BET was unlawful because it had exceeded the statutory grant of authority of the Exemption and was presented with a highlighted copy of the Exemption. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 11).

174. Agent Culver responded that as an FDA agent, she had the authority to inspect anything within the BET premises she saw fit. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 12).

175. During the second inspection, the FDA was so disruptive that it again caused delays in preparing and dispensing BET's compounds, placing pregnant horses and their foals at risk. (Exhibit 25, Affidavit of Stephen Atwood, ¶ 13).

**Veterinary**

176. On January 22, 2004, two FDA agents visited Plaintiff, Veterinary, to perform an inspection.

177. The FDA agents were asked if they had any evidence of any violations of state law or regulation. The FDA agents responded that they did not. The FDA agents were informed that the FDA did not have any authority to inspect Veterinary pursuant to the Exemption and they were requested to leave Veterinary, which they did.

178. The FDA, while at Veterinary, admitted that they did not have any evidence or reason to believe that Veterinary was out of compliance with any Exemption Criteria.

**Applied**

179. On August 25, 2004, the FDA visited Plaintiff, Applied, to inspect. Applied was unaware of the Exemption and, therefore, permitted the inspection. (Exhibit 3, Affidavit of Sam Kelly, ¶ 12). FDA Agent Samuel Collins was accompanied by an Alabama State Board of Pharmacy Inspector, Eddie Bradden. (Exhibit 2, Affidavit of Sam Kelly, ¶ 12).

180. On August 25, 2004, the FDA presented Applied with a Notice of Inspection (the "Notice of Inspection"). (Exhibit 26). The Notice of Inspection recited that FDA's inspectional authority was based on 21 U.S.C. § 374(a)(1). (Exhibit 26). The Notice of Inspection did not reference 21 U.S.C. § 374(a)(2)(A) which would have informed Applied that pharmacies which meet the Exemption criteria are exempt from § 374(a)(1) FDA inspection. *See id.*

181. The FDA acknowledged it had presented no evidence that Applied had violated any of the Exemption Criteria. (Exhibit 2, Affidavit of Sam Kelly, ¶ 21).

182. At all relevant times, Applied has been in compliance with state law. On April 27, 2004, Applied was inspected by the Alabama state inspection at which time the

Alabama Board of Pharmacy found it compliant with Alabama law. (Exhibit 27, Inspection Report Of Applied Pharmacy).

183. On August 25, 2004, the Alabama inspector did not inspect Applied. (Exhibit 2, Affidavit of Sam Kelly, ¶ 15). The Alabama inspector informed he was not present to inspect Applied for any state purpose but was present only "to accompany" the FDA and DEA. (Exhibit 2, Affidavit of Sam Kelly, ¶ 15).

184. Agent Collins informed that he was inspecting Applied to determine if Applied was manufacturing under the guise of compounding. (Exhibit 2, Affidavit of Sam Kelly, ¶ 16). To make this determination, Agent Collins asked to see *all* Applied's records, including its prescriptions and its total sales, to determine its total volume of business. (Exhibit 2, Affidavit of Sam Kelly, ¶ 16).

185. Agent Collins returned to finish his inspection the following day, on August 26, 2004. During this second day of inspection, Agent Collins collected more records, including prescriptions. (Exhibit 2, Affidavit of Sam Kelly, ¶ 17)

186. On August 31, 2004, Agent Collins returned to Applied Pharmacy to report his findings. (Exhibit 2, Affidavit of Sam Kelly, ¶ 18).

187. On August 31, 2004, Agent Collins informed that his FDA supervisor(s) had directed him to conduct an inspection of Applied because it is a compounding pharmacy. (Exhibit 2, Affidavit of Sam Kelly, ¶ 19). Agent Collins further informed that it was now FDA policy that compounding pharmacies were to be inspected by the FDA annually and that Applied should expect yearly inspections. (Exhibit 2, Affidavit of Sam Kelly, ¶ 20).

188. Agent Collins admitted that he was not aware of the existence of the Exemption or any of its Exemption Criteria. (Exhibit 2, Affidavit of Sam Kelly, ¶ 21).

189. Agent Collins informed Applied that compounds prepared pursuant to a prescription in a different dosage than the commercially available product were "new drugs" and, therefore, Applied's compounding pharmacy was subject to FDA jurisdiction. (Exhibit 2, Affidavit of Sam Kelly, ¶ 13).

190. Agent Collins reported that he had no reason to believe that Applied had violated any state law, that he was inspecting Applied solely for violations of Federal law, and had no reason to believe Applied had violated any Alabama pharmacy law or regulation. (Exhibit 2, Affidavit of Sam Kelly, ¶ 21)

**University**

191. On September 7 through 9, 2004, an FDA inspector came to University accompanied by a representative from the California Board of Pharmacy ("CBP"). (Exhibit 9, Affidavit of John Grasela, ¶ 9).

192. The CBP representative did not inspect the pharmacy and was present only to accompany the FDA on only the first day of the FDA's three-day inspection. (Exhibit 9, Affidavit of John Grasela, ¶ 9).

193. In July 2004, the CBP had just found University compliant with state law, since University just passed its annual CBP sterile license inspection. While the CBP inspector was at University during the FDA's inspection, he did not advise that University was now out of compliance with California pharmacy regulations. (Exhibit 9, Affidavit of John Grasela, ¶ 12).

194. Before the inspection, the FDA Agent did not tell University the statutory basis for its authority to inspect or provide any notice of inspection. The FDA did not inform University that pharmacies that meet the Exemption Criteria are exempt from FDA inspection. (Exhibit 9, Affidavit of John Grasela, ¶ 10).

195. The FDA Agent and the CBP representative presented no evidence that University was out of compliance with the Exemption Criteria. (Exhibit 9, Affidavit of John Grasela, ¶ 11).

196. The FDA investigation lasted 2½ business days. The FDA Agent claimed that the investigation was being conducted because of a complaint from a manufacturer that University was compounding a copy of a commercially available medication which physicians require to treat skin cancer. (Exhibit 9, Affidavit of John Grasela, ¶ 13).

197. University only compounds in strengths and delivery forms that are not commercially available. (Exhibit 9, Affidavit of John Grasela, ¶ 14).

198. Prior to the arrival of the FDA, the CBP had already received the same complaint regarding University's alleged duplication of commercially available medication for skin cancer. The CBP performed its investigation and concluded that University only compounds medication which is not commercially available. (Exhibit 9, Affidavit of John Grasela, ¶ 15).

199. The CBP inspector informed the FDA inspector that CBP inquired into this skin cancer medication issue and found nothing. (Exhibit 9, Affidavit of John Grasela, ¶ 16).

200. Pharmacy compounding of alleged copies is not a violation of the FDCA. It is, at worst, a hypothetical or potential patent violation which the FDA does not have standing to enforce.

201. According to the FDA Agent, the FDA was inspecting University for "information gathering." The FDA asked for all of University's records, including prescriptions, invoices of bulk chemicals, *etc*. During this inspection, the FDA also inspected all of University's equipment and facility. (Exhibit 9, Affidavit of John Grasela, ¶ 17).

202. The FDA Agent told University that he had just inspected two pharmacies in Northern California. He explained that he had another pharmacy that he was to inspect at a later date, also in the area. (Exhibit 9, Affidavit of John Grasela, ¶ 19).

**Risk And Irreparable Harm And Injury, Including Criminal Prosecution**

203. Plaintiffs confront a multiplicity of serious threats to their business, personal and business reputations, and personal freedom as the FDA, in violation of federal law, performs inspections and initiates and undertakes enforcement actions, including seizures against Plaintiffs and other pharmacies around the United States, in direct violation of the FDCA, the APA, and its own judicial admissions.

204. Based on the FDA's action, among other immediate threats, Plaintiffs face the threat of criminal prosecutions pursuant to 21 U.S.C. 331 *et seq*.

205. The FDCA provides criminal sanctions for non-compliance. For example, it criminalizes, in part, the following:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> . . . .
>
> (f) The refusal to permit entry or inspection as authorized by section 374 of this title.
>
> (g) the manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> . . . .
>
> (p) The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title.

21 U.S.C. §§ 331(a), (f), (g), and (p).

206. Plaintiffs face disruption, loss and interruption of business, loss of confidence and reputation among patients and practitioners, the inability to grow and expand their businesses since they have no way of predicting or gauging when the FDA will direct enforcement towards them, and more, all because of the FDA's unauthorized and unlawful enforcement conduct.

207. Plaintiffs also risk interference in relationships with practitioners, vendors, and suppliers, and trade organizations, as well as denial of opportunity to advertise, promote, and solicit business.

208. Plaintiffs further suffer irreparable injury by the very violation of the Exemption which was enacted so that they would not be inspected by the FDA, except under extremely narrow circumstances.

209. Plaintiffs suffer irreparable injury, since they are subject to unannounced raids, court proceedings, attendant negative publicity, and legal fees.

210. Plaintiffs further stand to suffer irreparable injury since the FDA's enforcement initiatives unilaterally reverse the state/federal oversight role carefully crafted by Congress and confirmed by the United States Supreme Court in *Western States*.

**Summary**

211. Plaintiffs are exempt from FDA inspection under the Exemption.

212. Plaintiffs engage in state licensed pharmacy compounding, not manufacturing.

213. The FDA's inspections deprive Plaintiffs of their exemption from inspection on the erroneous ground that compounds are "new drugs" under the New Drug Definitions.

214. When a pharmacy has refused FDA inspection, the FDA has acted *ex parte* to obtain an administrative warrant for the inspection. (Warrant for Inspection of Wedgewood, Exhibit 2 to Exhibit 24, Affidavit of George Malmberg).

215. The FDA strategy is to either:

- simply appear and not advise pharmacies of the Exemption and inspect; or

- if the pharmacy is aware of its rights under the Exemption and refuses FDA entry, the FDA obtains *ex parte* warrants, notwithstanding it has no reason to believe the pharmacy will destroy or hide evidence ("spoiliation"), or is in violation of Exemption Criteria.

216. Through either device described in the immediately preceding paragraph, the FDA is able to avoid any meaningful pre-inspection judicial review and interpretation.

**Likelihood Of Success On The Merits,**
**Balancing Of The Harms And The Public Interest**

217. The plain and unambiguous language of the Exemption provision, the plain and unambiguous language of the New Drug Definitions, and the plain and unambiguous language of the CPG's preamble and introduction establish that by the FDA's own words and the statutory language, Plaintiffs have a high likelihood of success on the merits.

218. The FDA's admissions in its briefs in *Western States* and *Baxter* establish Plaintiffs have a high likelihood of success on the merits.

219. Pharmacy compounding from bulk ingredients has been a pharmacy compounding mainstay for over 50 years. There is no new development to justify change.

220. Pharmacy compounds will be unavailable if they are classified as "new drugs" or if compounding from bulk is prohibited. Without pharmacy compounds, human and animal patients will needlessly suffer and die.

## COUNT I

## DECLARATORY JUDGMENT REGARDING THE FDA'S UNAUTHORIZED POLICY THAT COMPOUNDING FROM BULK INGREDIENTS FOR NON-FOOD ANIMALS IS ILLEGAL

221. Plaintiffs who compound veterinary drugs incorporate the allegations contained in paragraphs 1 through 220 of their allegations as paragraph 221 of Count I.

222. The CPG and the Notice declare that compounding from bulk ingredients for non-food animals is illegal.

223. The CPG and the Notice do not have the force and effect of law.

224. The CPG is vague and ambiguous.

225. The FDA has violated 5 U.S.C. § 553 et seq. by promulgating a substantive rule in the CPG and the Notice without providing an opportunity for notice and comment.

226. The FDA does not have authority to promulgate any rule which would embrace the substance of the CPG or the Notice.

WHEREFORE, Plaintiffs request this Court enter an Order:

- Declaring that the CPG and the Notice are unenforceable; and
- Declaring that the FDA does not have the authority to declare compounding from bulk ingredients for non-food animals illegal.

## COUNT II

## INJUNCTIVE RELIEF REGARDING THE CPG

227. Plaintiffs who compound veterinary drugs incorporate the allegations contained in paragraphs 1 through 226 of their allegations as paragraph 227 of Count II.

228. There is a substantial likelihood that Plaintiffs who compound veterinary medication will succeed on the merits.

229. The FDA's policy that compounding from bulk ingredients for non-food animals that it presents in its CPG is contrary to the former FDA position.

230. The FDA has acted in excess of the statutory authority found in the FDCA by declaring compounding from bulk ingredients for non-food animals illegal.

231. The CPG is intended to have the effect and force of law and is, therefore, a substantive rule.

232. The FDA failed to follow the rulemaking procedures required by the APA in promulgating the CPG and thereby violated 5 U.S.C. § 553 *et seq*.

233. The CPG directly contradicts the former FDA position. The FDA has therefore violated APA notice and comment requirements by changing its policy without allowing an opportunity for comment.

234. Without injunctive relief, Plaintiffs who compound veterinary medications and their patients will suffer irreparable harm.

235. Plaintiffs who compound veterinary medications cannot prepare these drugs if they cannot compound from bulk ingredients.

236. The Plaintiffs who compound veterinary medications will therefore be unable to fill their patients' medical needs.

237. In balancing the respective interests and the public interest, because pharmacies have been compounding from bulk ingredients for more than a half century with no known adverse consequences from the use of bulk ingredients and what would be the denial of access to pharmacy compounded drugs by veterinarians and their non-food animal patients; and the threat of criminal prosecution; the balance of interests weighs substantially in favor of granting injunctive relief.

238. Without injunctive relief, diseases such as feline megacolon, hyperthyroid, and chronic urinary tract infections, dog seizures and chronic ear infections will go untreated.

239. Plaintiffs who compound veterinary medications will suffer irreparable damage, as will their patients.

240. The threat that animals will be forced to go without medications and needlessly suffer or die outweighs the FDA's interest in announcing and enforcing a new rule via CPG and the Notice.

241. Enjoining the FDA from prohibiting compounding from bulk for non-food animals serves the public interest. It saves animals' lives and prevents animal suffering.

WHEREFORE, Plaintiffs who compound veterinary drugs request this Court enter an Order to:

- Enjoin the FDA from enforcing its current CPG which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal;
- Rescind its Notice;
- Publish on the FDA website a copy of this Court's order;
- Enjoin the FDA from surreptitiously enforcing the CPG by prohibiting distributors from selling bulk ingredients to Plaintiffs or similarly situated pharmacies and stopping the importation of bulk ingredients destined for veterinary compounding pharmacies; and
- Enjoin the FDA from directing trade show sponsors to coerce Plaintiffs from signing an agreement to refrain from doing something they are permitted to do by law.

## COUNT III

## DECLARATORY JUDGMENT UNDER THE NEW DRUG DEFINITIONS

242. Plaintiffs incorporate the allegations contained in paragraphs 1 through 241 of their allegations as paragraph 242 of Count III.

243. The FDA has taken the position that compounds are "new drugs" under the New Drug Definitions.

244. Under the New Drug Definitions, a "new drug" must be capable of being subjected to the new drug approval process.

245. As recognized by the FDA in its briefs to the United States Supreme Court in *Western States*, if pharmacy compounds were subject to the "new drug" approval process, pharmacy compounds would be eliminated for both humans and animals altogether.

246. The Supreme Court of the United States adopted the FDA's position and held that compounds are not capable of going through the "new drug" approval process.

247. As the United States Supreme Court held in *Western States*, compounds are not capable of being "new drugs" under 21 U.S.C. § 321(p)(1) and by extension 21 U.S.C. § 321(v)(1).

WHEREFORE, Plaintiffs request this Court enter an Order declaring that compounds are not new drugs under 21 U.S.C. § 321(p)(1) and 21 U.S.C. § 321(v)(1).

**COUNT IV**

**INJUNCTIVE RELIEF UNDER THE NEW DRUG DEFINITIONS**

248. Plaintiffs incorporate the allegations in paragraphs 1 through 247 of their allegations as paragraph 248 of Count IV.

249. There is a substantial likelihood that Plaintiffs will prevail on the merits.

250. Practitioners prescribe pharmacy compounds because they are tailor-made and precisely because patients cannot get them otherwise, namely, they are not commercially available.

251. Pharmacy compounded drugs cannot meet FDCA requirements for "new drugs" because they are requested by a practitioner for a special patient or class of patients and therefore cannot be subject to clinical trials.

252. Because obtaining FDA approval for new drugs is a costly process, requiring FDA approval of all pharmacy drugs would eliminate pharmacy compounds and thereby eliminate availability of pharmacy compounded drugs for those patients who have no alternative.

WHEREFORE, Plaintiffs request this Court enter an order to enjoin the FDA:

- from declaring that compounds are "new drugs" under 21 U.S.C. §321(p)(1) or 21 U.S.C. §321(v)(1); and
- from enforcing its position that compounds are "new drugs" under 21 U.S.C. §321(p)(1) or 21 U.S.C. §321(v)(1).

## COUNT V

## DECLARATORY JUDGMENT UNDER THE EXEMPTION

253. Plaintiffs incorporate the allegations contained in paragraphs 1 through 252 of their allegations as paragraph 253 of Count V.

254. The Exemption exempts pharmacies that are compliant with the Exemption Criteria.

WHEREFORE, Plaintiffs request this Court enter an Order to:

- Declare that FDA is prohibited from inspecting pharmacies like Plaintiffs who comply with the requirements of 21 U.S.C. § 374(a)(2)(A); and
- Declare that FDA is prohibited from obtaining an administrative warrant *ex parte* under 21 U.S.C. § 374(a)(2)(A) without evidence of spoliation.

## COUNT VI

## INJUNCTIVE RELIEF UNDER THE EXEMPTION

255. Plaintiffs incorporate the allegations contained in paragraphs 1 through 254 of their allegations as paragraph 255 of Count VI.

256. In light of the FDA submission in *Baxter* and the plain and unambiguous language of the Exemption, Plaintiffs have a high likelihood of success on the merits.

257. By conducting unauthorized inspections, the FDA has deprived the Plaintiffs of their Exemption from FDA inspection.

258. The FDA's unauthorized inspections are outside the statutory authority found in 21 U.S.C. § 374 thereby violating 5 U.S.C. § 706(2)(C).

259. If this Court does not grant this injunction, it is a certainty that the FDA will continue to blatantly ignore the protections afforded the Plaintiffs by the Exemption and force the Plaintiffs to submit to FDA inspection via an administrative warrant and threat of criminal charges.

260. If forced to submit to FDA inspection, the Plaintiffs will suffer irreparable harm with no remedy. Plaintiffs will suffer:

- Severely disrupted business during the FDA investigations, which can last over a period of months, taking days and weeks at a time, putting their patients at risk by not promptly serving their needs and causing them to loose business they cannot recuperate;

- damaged reputations with their clients which discover the inspection when the investigation and any consequences are posted on the FDA website, as has become the FDA's custom; and

- costs associated with defending any action that results from an unauthorized FDA investigation. If Plaintiffs ultimately prevail, they will have no remedy to recuperate any of their litigation costs or any of their lost business, since Plaintiffs cannot sue the FDA for monetary damages, no matter how virtuous the Plaintiff's current position.

261. Plaintiffs suffer the additional irreparable injury of having been denied a right expressly afforded them by Congress.

262. The FDA will suffer no harm by this Court's mandate that the FDA only act within the confines of its authority. The harm the Plaintiffs stand to face by the unauthorized inspections far outweighs any harm that the FDA could suffer.

263. This is all the more true because of the routine inspections, oversight, and regulations imposed on pharmacies by the states.

264. This Court's grant of the preliminary injunction will serve the public interest by forcing the FDA to act within the confines of its statutory mandate. The injunction will also serve the public interest by insuring the continued availability of compounded medications.

WHEREFORE, Plaintiffs request this Court enter an order to:

- Enjoin the FDA from entering or inspecting pharmacies that are in good standing with their respective state boards of pharmacy and have met the Exemption Criteria; and

- Enjoin the FDA from obtaining an administrative warrant *ex parte* for any 21 U.S.C. § 374 inspection absent evidence of the threat of spoliation.

## COUNT VII

## DECLARATORY RELIEF – TRADE SHOW PARTICIPATION AND SUPPLIERS

265. Plaintiffs incorporate the allegations in paragraphs 1 through 264 of their allegations as paragraph 265 of Count VII.

266. The FDA is directing trade show organizations that pharmacies that do veterinary compounding and who seek to exhibit must sign a statement that they comply with the current CPG which bans compounding from bulk for non-food animal before they can exhibit.

267. These trade shows are an important, critical marketing tool for Plaintiffs.

268. The FDA is restricting the Plaintiffs' ability to advertise, promote, and solicit at a trade show by forcing them to comply with a CPG that has no legal effect, and that even informs on its face that it has no legal effect.

269. The FDA's actions violate the First Amendment of the United States and the holding in *Western States* by unlawfully restricting Plaintiffs and other compounding pharmacies' participation in trade shows.

WHEREFORE, Plaintiffs request this Court enter an order declaring that the FDA cannot restrict the Plaintiffs' ability to advertise, solicit, and promote by restricting them from presenting in trade shows or other advertising through the trade organizations.

## COUNT VIII

## INJUNCTIVE RELIEF UNDER *WESTERN STATES*

270. Plaintiffs incorporate the allegations in paragraphs 1 through 269 of their allegations as paragraph 270 of Count VIII.

271. There is a substantial likelihood that Plaintiffs will prevail on the merits.

272. The FDA is directing trade show producers that exhibitors that do veterinary compounding must sign a statement that they comply with the current CPG which bans compounding from bulk for non-food animal before they may exhibit.

273. The FDA is restricting the Plaintiffs' ability to advertise, promote, and solicit at trade shows by forcing them to comply with a policy that has no legal effect.

274. The FDA's actions violate the First Amendment of the United States and the holding in *Western States* by unlawfully restricting veterinary compounding Plaintiffs from participation in trade shows without first surrendering their First Amendment right to commercial free speech.

WHEREFORE, Plaintiffs request this Court enjoin the FDA:

- from requiring that trade show sponsors have their exhibitors sign a statement indicating that they are complaint with the CPG or any FDA CPG; and

- from having FDA agents on the trade show floor to investigate and determine if the Plaintiffs or similarly situated parties are adhering to the CPG or any FDA CPG.

## COUNT IX

## INJUNCTIVE RELIEF UNDER 21 U.S.C. §331(f)

275. Plaintiffs incorporate the allegations in paragraphs 1 through 274 of their allegations as paragraph 275 of Count IX.

276. There is a substantial likelihood that Plaintiffs will prevail on the merits.

277. If Plaintiffs refuse the FDA entry into their pharmacies under 21 U.S.C. §374(a)(2)(A), Plaintiffs run the risk of being criminally sanctioned under 21 U.S.C. §331(f).

278. Plaintiffs meet the Exemption Criteria; they are all in compliance with state law, they dispense pursuant to a prescription, and they dispense or sell at retail, compounding in the ordinary course of their businesses at retail.

279. Plaintiffs are protected from FDA inspection by the Exemption.

WHEREFORE, Plaintiffs request this Court enter as order enjoining the FDA from bringing criminal sanctions against any Plaintiffs for refusing to allow the FDA to inspect their pharmacies pursuant to 21 U.S.C. §374(a)(2)(A).

Respectfully submitted,

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