IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FRANCK'S LAB, INC., d/b/a FRANCK'S COMPOUNDING LAB, a corporation, and PAUL W. FRANCK, an individual Defendants.	Civil Action No. 5:10-CV-00147-TJC **DISPOSITIVE MOTION** **DEFENDANTS FRANCK'S LAB, INC. AND PAUL W. FRANCK'S MOTION TO DISMISS**

DEFENDANTS' MOTION TO DISMISS AND
MEMORANDUM OF LAW IN SUPPORT

Defendants Franck's Lab, Inc. and Paul W. Franck ("Franck's") move to dismiss the Complaint in its entirety. For reasons explained below, the Complaint does not plead sufficient facts to support its conclusory allegations, does not adequately state essential elements of a claim for injunctive relief, seeks other relief not permitted under federal law, and improperly seeks to impose non-binding "rules" on an industry regulated under state law.

This case concerns an attempt by the United States Food and Drug Administration ("FDA") to assert regulatory authority over the state-regulated pharmacy practice of compounding veterinary drugs for non-food producing animals using bulk chemical substances. This medically appropriate practice is expressly authorized under state licensing laws and, as FDA has recognized, is relied on by veterinarians to treat individual sick and injured animals when required medications are not commercially available. For more than a century, pharmacists have made substantial business investments, undergone extensive

training, and obtained necessary state certifications to compound animal drugs for licensed veterinarians and the animals under their care.

Congress has never purported to supersede the traditional state regulation of pharmacy compounding practices or to outlaw those practices. Nonetheless, adopting an expansive interpretation of its authority, FDA has concluded that compounding animal drugs — but not human drugs — from bulk substances (*viz.*, commercially available chemical substances) is prohibited. It has taken this extreme position without even attempting to promulgate regulations through notice and comment procedures, which would require it to take into account the perspectives of pharmacists, chemical suppliers, state regulators, veterinarians, and animal owners. Instead, FDA has asserted *in non-binding guidance documents* that compounding animal drugs from bulk substances, unlike human drugs, is strictly prohibited, while asserting unfettered discretion to decide when to enforce the ban. Under FDA's mistaken view, hundreds of state-licensed pharmacists, in collusion with thousands of veterinarians and animal owners, are engaged in continuing violations of federal law and can be forced to close their businesses at anytime at FDA's whim.

For reasons unexplained in the Complaint, FDA seeks a sweeping injunction preventing Franck's from performing the state-approved, medically necessary compounding services it has provided to veterinarians for more than 27 years. FDA has long been aware of Franck's compounding practices, but it offers no allegations explaining why it is seeking to punish Franck's, much less any allegations establishing that Franck's compounding practices are unsafe or medically inappropriate. Nor does the Complaint include allegations justifying FDA's request for drastic and extraordinary injunctive relief. Because the Complaint does

not plead sufficient facts for believing that Franck's has violated federal law, and because it does not state claims upon which relief can be granted, the Complaint should be dismissed.

NATURE OF PROCEEDINGS

The following provides an overview of drug compounding, the relevant statutory and regulatory provisions, and Franck's history as a compounding pharmacy. Because the cited materials are taken from publicly available government documents and materials incorporated into the Complaint, they are properly considered at the motion-to-dismiss stage.

A. Overview of Pharmaceutical Compounding

Compounding "is the professional act by a pharmacist … employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient." Fla. Admin. Code Ann. 64B16-27.700. Examples of compounding include mixing drugs into a single formulation; making suspensions or gels; preparing dosage strengths different from packaged FDA-approved drugs; adding flavorings; and formulating drugs from raw chemicals. Compounding is a "traditional component of the practice of pharmacy," and it is "taught as part of the standard curriculum at most pharmacy schools." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 361 (2002).

For centuries, states have closely regulated compounding practices as "part of their regulation of pharmacies." *Id*. Nearly every state's laws define pharmacy practice to include compounding, and compounding pharmacists are required to be licensed by state Boards of Pharmacy. *See* Fla. Stat. §§ 465.007, 465.009, 460.014. Florida, like many states, imposes detailed requirements and standards of practice on pharmacists involved in compounding. *See* Fla. Admin. Code Ann. 64B16-27.700, 27.797.

Compounding is fundamentally different from drug manufacturing. Unlike "manufactured" drugs, which are mass-produced for a large-scale market in standard formulations and dosages, "compounded" medications are prepared in small quantities at prescribed formulations and dosages to meet the needs of individual patients. Pharmacists may compound medications when they are prescribed for individual patients by a licensed medical practitioner, or in anticipation of prescriptions based on routine, regularly observed prescribing patterns. Fla. Admin. Code Ann. 64B16-27.700(1), (3).

When a drug is not commercially available, or the commercially available drug is unsuitable for a particular patient, compounding is the only way for a patient to obtain necessary medication. At the request of a prescribing physician or veterinarian, a pharmacist may compound a medication by using either (1) a finished drug product, or (2) bulk drug substances. *See* Compl. ¶ 5. The term "bulk," used in this context, does not refer to size, volume, or quantity, but rather the raw chemical materials used in the compounding process. Under Florida law, compounding from bulk substances is an approved part of the practice of pharmacy. *See* Fla. Admin. Code Ann. 64B16-27.700(1)(c). In fact, many experts believe that compounding from bulk substances is more effective, reliable, and safe than compounding from finished drug products. A bulk substance has a certificate of analysis that includes detailed information not available for finished drug products, including the concentration and specification of all ingredients, expiry date, manufacture date, method of analysis, analysis results, and storage conditions.

B. The Veterinary Compounding Industry

Compounded medications have long been used in routine veterinary practice throughout the United States. The pharmaceutical market for equines and small animals is estimated to total approximately $650 to $750 million. Some ten percent of that market involves veterinary compounding, which targets non-food-producing horses and companion animals (dogs and cats). There are hundreds of pharmacies throughout the United States that offer veterinary compounding services.

Veterinarians rely heavily on compounded medications to treat non-food-producing animals. Because obtaining FDA approval to manufacture drugs is costly and time-consuming, and because animal drug sales are often comparatively small, veterinarians could not properly treat animals if they could prescribe only manufactured drugs or medications compounded using manufactured drugs. Veterinarians prescribe medications compounded from bulk when the FDA-approved drug has been discontinued, is not in a form adequate to treat the animal's specific condition, or has an active ingredient in a concentration that is too low to compound an effective medication. *See* Compl. ¶ 11.

C. The Relevant Statutory and Regulatory Provisions

For most of the Nation's history, states have exercised exclusive authority over pharmacy compounding practices. Although Congress has never purported to displace or supersede this traditional area of state authority, in recent years, FDA has interpreted federal law as granting it broad discretion to ban pharmacy compounding.

1. The Federal Food, Drug and Cosmetic Act of 1938

The Federal Food, Drug and Cosmetic Act of 1938 ("FDCA") regulates drug manufacturing, marketing, and distribution. 21 U.S.C. §§ 301–397. The Act's section 505(a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed" with FDA "is effective with respect to such drug." *Id*. § 355(a); *id*. § 360b(a)(1) (requiring FDA approval for new animal drugs). To obtain FDA's approval, a sponsor must file a new animal drug application demonstrating with "substantial evidence" that the drug is safe and effective for its labeled uses. *Id*. § 360b(b).

When Congress enacted the FDCA, it did not purport to displace traditional state authority over pharmacy compounding practices or to sweep compounding practices within the statute's ambit. Nor was the FDCA interpreted in that fashion. *Western*, 535 U.S. at 362. Because obtaining FDA approval for a new drug is a lengthy and costly process, "requiring FDA approval of all drug products compounded by pharmacies for 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." *Id*. at 369. Beginning in the early 1990s, however, FDA became concerned that certain pharmacists were "manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Id*. at 362.

2. Compounding Human Drugs

With respect to human drugs, FDA issued a Compliance Policy Guide in 1992 announcing that "FDA may, in the exercise of its enforcement discretion, initiate federal

enforcement actions … when the scope and nature of a pharmacy's activity raise the kinds of concerns normally associated with a manufacturer and … results in significant violations of the new drug, adulteration, or misbranding provisions of the Act." FDA CPG 7132.16 (Mar. 1992). (This document was reissued in May 2002, *see* FDA CPG § 460.200 (2002).) The Guide recognized that "pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner," and noted that this "traditional activity" was not the subject of the guidance. *Id*. The Guide focused on a specific problem — "an increasing number of establishments … are engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that constitute violations of the Act." *Id*.

Congress "turned portions of this policy into law" when it enacted the Food and Drug Modernization Act of 1997 ("FDAMA"). *Western*, 535 U.S. at 364. Under FDAMA, a pharmacy is permitted to compound human drugs without complying with the FDCA's new drug approval provisions if the pharmacist complies with certain restrictions to ensure that it is not manufacturing drugs. 21 U.S.C. § 353a. *FDAMA explicitly permits the compounding of human drug products using bulk substances. Id*. § 353a(b).

3. Compounding Animal Drugs

With respect to animal drugs, Congress has never enacted a statute regulating compounding practices. Congress amended the FDCA in the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA"), but those amendments addressed only "extra-label" *uses* of animal drugs — the use of an approved animal drug not in accordance with the FDA-

approved use. 21 C.F.R. § 530.3(a). Under AMDUCA, the extra-label use of an animal drug is exempt from the FDCA's approval and labeling requirements if it takes place within the scope of a veterinarian-client-patient relationship, complies with regulations promulgated by FDA, and does not pose a risk to public health. 21 U.S.C. § 360b(a)(4)(A)–(B). AMDUCA does not mention compounding or purport to grant FDA authority to regulate compounding.

FDA's 1996 Regulations. In 1996, pursuant to AMDUCA, FDA promulgated regulations establishing rules for the extra-label use of animal drugs. 21 C.F.R. § 530.1 *et seq.* Although AMDUCA does not grant FDA authority to regulate compounding, FDA's 1996 regulations purport to address compounding of animal drugs through the "use" of FDA-approved animal or human drugs. *See id*. § 530.13. The regulations do not, however, purport to regulate compounding from bulk substances. Instead, the regulations state that "[n]othing in this part shall be construed as permitting compounding from bulk drugs," *id*. § 530.13(a), and refer parties to the agency's non-binding guidance documents. *See id*. § 530.13(c) ("Guidance on the subject of compounding may be found in guidance documents issued by FDA"); 61 Fed. Reg. 57,732, 57,740 (1996) ("limited compounding from bulk substances may be subject to FDA's enforcement discretion").

FDA's 1996 Compliance Policy Guide. FDA's 1996 Compliance Policy Guide sets out the agency's non-binding "policy and regulatory guidelines" with respect to "the compounding of animal drugs by veterinarians and pharmacists." 61 Fed. Reg. 34,849, 34,849 (1996). It recognizes that "[c]ircumstances exist when it may be necessary for a veterinarian to compound, or direct for a pharmacist to compound, an article that will result in an unapproved animal drug." *Id*. at 34,851. The Guide also acknowledges that there "is

occasionally a need to utilize … bulk drug substances." *Id.* The Guide states that the agency "ordinarily would not take regulatory action" if (1) a "legitimate medical need is identified," (2) there is an "appropriate dosage regimen" for the patient's species, age, size, or medical condition, and (3) there is "no marketed approved animal drug" that "may treat the condition diagnosed in the available dosage form." *Id.* The Guide states that "[c]ompounding from bulk drug substances for use in nonfood animals" would not "ordinarily be considered for regulatory action." *Id*. at 34,852.

FDA's 2003 Compliance Policy Guide. In 2003, FDA issued a new guidance document, but failed to publish notice of this document or to invite public comment on the draft, as required by its own regulations. 21 C.F.R. § 10.115. The 2003 Guide asserts that compounding from bulk is prohibited. The Guide nonetheless reaffirms that FDA "will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals." FDA CPG § 608.400. It also states that the agency will consider an enforcement action only "when the scope and nature of activities of veterinarians and pharmacists raise *the kinds of concerns normally associated with a drug manufacturer* and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Act." *Id*. (emphasis added). The Guide includes a non-exclusive list of factors to consider in determining whether a pharmacy is engaged in improper manufacturing, including whether it is compounding drugs from bulk. *Id*.; Compl. ¶ 16.

Consistent with its guidance documents, and in recognition of the fact that compounding is regulated by the states, FDA has permitted, and even encouraged,

pharmacists to compound from bulk. For example, trilostane is used to treat Cushing's disease in dogs. Until 2009, FDA had not approved a commercially available form of the drug, and it did not object to pharmacists compounding the drug from bulk. In 2009, FDA approved VETORYL (trilostane) and announced that because VETORYL was "approved and available for veterinary use in the U.S., trilostane" should no longer be "compounded from bulk." FDA's VETORYL (trilostane) Capsules Ltr. (Sept. 11, 2009), http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm182038.htm. Similarly, in 2007, FDA announced its intent to ensure that "Pergolide remains available to treat Cushing's Syndrome in horses until a new drug application is approved for that use." Emphasizing that all "pharmacy compounding must be done under a valid veterinary prescription," FDA stated that "[b]ulk substances used for pharmacy compounding should be labeled for 'animal use only.'" FDA Public Health Advisory (May 11, 2007), http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm048035.htm.

D. Franck's Lab And Its Alleged "Violative History"

Franck's is a Florida-licensed pharmacy, founded in 1983, that holds licenses to distribute drugs in all but three states. It is one of the nation's premier compounding pharmacies and has been compounding quality drugs for use in both humans and animals for more than 27 years. Compl. ¶ 4. Franck's fills approximately 37,000 veterinarian prescriptions each year and, until it became the target of this action, employed approximately 60 employees. *Id*. (Attempting to address FDA's concerns and negotiate an acceptable resolution, Franck's was forced to close down parts of its business and lay off 20 employees.)

Franck's is inspected each year by the Florida Department of Health and has consistently passed inspections.

Franck's does not compound drugs in formulations and dosages that are commercially available. Moreover, it only compounds drugs that FDA has approved or treats as approved. Franck's animal drug compounding business is limited to providing medications to non-food producing animals. And it only compounds drugs in response to a valid prescription from a licensed veterinarian to treat an individual animal (or in limited quantities in anticipation of future need, as permitted under Florida law). In short, Franck's does not manufacture drugs.

The Complaint alleges that Franck's "Violative History" includes a 2004 and a 2009 FDA inspection. Compl. ¶ 29; *id*. ¶¶ 25–28. In fact, both inspections confirmed that Franck's has complied with FDA's instructions on compounding from bulk substances. (Because FDA's warning letters and Franck's response are central to the Complaint and incorporated by reference, they are appropriately considered at the motion-to-dismiss stage. *Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005).)

FDA's 2004 Inspection. In 2004, FDA inspected Franck's compounding facilities and, in January 2005, issued a warning letter noting that Franck's had compounded veterinary drugs "using bulk active pharmaceutical ingredients." Compl. ¶ 27. FDA's letter stated that it was concerned that Franck's was impermissibly manufacturing drugs. In particular, FDA expressed concern that Franck's was purportedly not compounding for individual patients, was compounding commercially equivalent products, and was compounding drugs for food producing animals.

In response, Franck's stated that it was in full compliance with FDA requirements, *see id.* ¶ 28, and explained its intent to continue compounding using bulk substances. Franck's noted that "[s]tate law and good compounding practices … allow bulk compounding as long as there is a valid patient relationship," and that, because "FDA allows compounding from bulk chemicals for human use, the same rule should apply to veterinary compounding." Franck's nonetheless made clear that it would compound from bulk only those drugs that were commercially unavailable and that FDA had approved for use in animals. Franck's pledged not to compound drugs that are commercially available. Franck's also promised to place warning labels on its products to make clear that the medications it compounds are "not to be used on food producing animals." Franck's closed its letter by inviting FDA to inform Franck's if anything it proposed fell short of expectations:

> Again, it is Franck's intention to comply immediately and completely with any and all FDA and other legal requirements, and welcomes the FDA's involvement in these matters. I have tried to the best of my ability to address each item of concern in your letter. If I have fallen short on anything, if you have additional concerns which were not set forth in your letter, or if you have any other questions or concerns, please contact me immediately and I will see to it that we respond immediately, and to your complete satisfaction.

FDA never responded to Franck's letter or contacted Franck's with concerns.

FDA's 2009 Inspection. In April 2009, a veterinarian asked Franck's to compound an injectable solution of the prescription drug Biodyl for the Venezuelan Lechuza Caracas polo team. Because the veterinarian's written formula for the prescription was described in terms of concentration per 100 milliliters, a concentration value typically articulated in foreign formulas, whereas FDA-approved products are usually described in terms of concentration per milliliter, a Franck's staff member made a mathematical error in converting

one of the ingredients (sodium selenite). Although Franck's *twice* verified the prescription with the veterinarian, neither the veterinarian nor Franck's noticed the mathematical error. The compounded medication was too potent and 21 horses died.

The polo pony incident resulted from a mis-filled prescription and had nothing to do with compounding from bulk. The incident was thoroughly investigated by the Florida Board of Pharmacy, which imposed fines and reprimanded Franck's. Other states have also investigated and concluded that Franck's is in full compliance with state licensing requirements. Out of an abundance of caution, however, Franck's has implemented new standard operating procedures and policies. In June 2009, Franck's also hired an independent third party to audit its facilities, polices, and procedures, and the audit confirmed that Franck's engages in adequate and well-controlled compounding practices.

In May 2009, FDA inspected Franck's facilities. That inspection resulted in FDA issuing an FDA-483 form with five (5) specific observations. None of those observations identify compounding from bulk substances as a matter of concern.

ARGUMENT

I. The Court Should Dismiss Because The Complaint's Allegations Do Not Satisfy The Basic Requirements Of Rule 8.

The Supreme Court has recently reminded federal courts of the importance of ensuring that plaintiffs satisfy the requirements of Rule 8. *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). To survive a motion to dismiss, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S. Ct. at 1949. Mere "labels and conclusions" and "formulaic" recitations are insufficient, as are "naked assertion[s]" devoid of "further factual

enhancement." *Twombly*, 550 U.S. at 555, 557. A complaint must do more than "merely create[] a suspicion" of "a legally cognizable right of action." *Id*. at 555. Instead, a plaintiff must plead "facts" that could allow a court to draw a "reasonable inference" that the defendant is liable. *Iqbal*, 129 S. Ct. at 1949. "Threadbare recitals of the elements of a cause of action, supported by conclusory statements, do not suffice." *Id*.

Iqbal and *Twombly* control this case. Dismissal is required because FDA's inadequate factual allegations do no more than raise a mere possibility of violations.

The Complaint alleges in conclusory fashion that Franck's has engaged in improper "manufacturing." Compl. ¶ 5 ("firm manufactures the vast majority of its animal drugs from active pharmaceutical ingredients"); *id*. ¶ 8 ("Defendants have been, and are now engaged in … manufacturing"). Whether Franck's compounding practices are of a scope and scale that rise to the level of "manufacturing" is critical because, as courts have recognized, there is a fundamental distinction between "compounding" and "manufacturing" in determining whether a pharmacy's activities are legally permissible. As the Supreme Court has emphasized, the "line between small-scale compounding and large-scale drug manufacturing" enables the government to differentiate between "compounded drugs produced on such a small scale that they could not undergo" the FDCA's new drug approval process and those "produced and sold on a large enough scale that they could." *Western*, 535 U.S. at 370. But the Complaint includes no allegations providing any factual basis for characterizing Franck's compounding activities as "manufacturing." The unadorned accusation that Franck's is "manufacturing" drugs is not sufficient to state a claim for relief. *Iqbal*, 129 S. Ct. at 1949.

In other paragraphs, the Complaint suggests that Franck's has violated federal law because it is allegedly "willing to compound commercially available drugs." Compl. ¶ 12. But the only "factual" basis for that assertion is the allegation that Franck's website identifies over 200 products that may be compounded, asserts that Franck's "is the nation's premier veterinary compounder," and states that "Franck's Compounding Lab specializes in compounded medications." *Id*. Those website statements are appropriate and, even if they were not, raise (at best) no more than "a sheer possibility" that Franck's may have acted unlawfully. *Iqbal*, 129 S. Ct. at 1949. That Franck's is willing to compound veterinary drugs does not mean that it is improperly compounding commercially available drugs.

Finally, the Complaint includes thread-bare allegations suggesting that Franck's compounding practices are unlawful because "the firm manufactures the vast majority of its animal drugs from … 'bulk drug substances'" and not "from approved drugs, as required by AMDUCA." Compl. ¶¶ 5, 20. For reasons explained below, Franck's disputes the legal conclusion that animal drugs compounded by pharmacists from bulk qualify as "new animal drugs" within the meaning of the FDCA. *Edwards v. Prime, Inc.*, 602 F.3d 1276, 1291 (11th Cir. 2010) (courts need not accept legal conclusions as true at motion-to-dismiss stage). But even if Congress intended AMDUCA to supplant traditional state regulation of the pharmacy practice of compounding from bulk substances, and to subject that practice to FDA's onerous new drug approval process, the Complaint contains no factual basis for singling out Franck's compounding activities or for distinguishing the nature and scale of Franck's conduct from the legion of other pharmacists that compound animal drugs from bulk. Although the Complaint purports to rely on FDA's 2003 Compliance Policy Guide, *see* Compl. ¶ 16, it

includes no specific factual basis for concluding that Franck's has run afoul of the Guide's instructions or otherwise engaged in activities that raise "the kinds of concerns normally associated with a drug manufacturer." FDA CPG § 608.400. Although the Complaint invokes FDA's 2005 warning letter and selectively quotes from Franck's response, it provides no allegations establishing a plausible basis for concluding that the compounding activities that Franck's announced it would continue were lawful in 2005 but are no longer acceptable in 2010. Likewise, although the Complaint relies on FDA's 2009 inspection, it includes no allegations tying that inspection to the bare conclusion that "Defendants continue to unlawfully compound drugs" from bulk substances "for use in animals." Compl. ¶ 26.

Franck's should not be put in the position of having to guess the factual basis for the government's claims. If FDA has any genuine grounds for maintaining that Franck's is engaged in improper manufacturing, that Franck's is compounding commercially available drugs, or that Franck's compounding practices from bulk are unlawful because they raise concerns normally associated with drug manufacturing, then the government should include those allegations in its Complaint in a manner that establishes a "plausible" — not merely "possible" — basis to believe that wrongdoing has occurred.

II. The Court Should Dismiss Because The Complaint Fails To State Claims On Which Relief Can Be Granted.

The Complaint also should be dismissed under Rule 12(b)(6) because FDA has not pleaded the essential elements of a request for injunctive relief, and because the government is seeking relief that is not permitted under the FDCA.

A. The Complaint Has Not Pleaded The Essential Elements Of A Claim For Injunctive Relief.

The Eleventh Circuit recently noted that it has not resolved what standard applies when the government seeks an injunction under the FDCA. *United States v. Endotec, Inc.*, 563 F.3d 1187, 1194 n.9 (11th Cir. 2009). But other controlling precedents make clear that the government must satisfy the requirements for invoking the court's equitable jurisdiction. Although other circuits have reached a different conclusion, *see id.*, the Eleventh Circuit has held that, when Congress authorizes injunctive relief, it should be presumed to incorporate the traditional equitable requirements. *Klay v. United HealthGroup, Inc.*, 376 F.3d 1092, 1098 (11th Cir. 2004); *United States v. Ernst & Whinney*, 735 F.2d 1296, 1301 (11th Cir. 1984). Unless a statute unequivocally mandates injunctive relief as an automatic remedy for statutory violations, the party requesting an injunction must satisfy the traditional requirements for equitable relief. *Miccosukee Tribe of Indians v. United States*, No. 04-21448, 2008 WL 2967654, at *40 (S.D. Fla. July 29, 2008); *CBS Broad., Inc. v. EchoStar Commc'ns Corp.*, 450 F.3d 505, 526–27 (11th Cir. 2006) (distinguishing between mandatory and discretionary statutory injunctions); *Hecht Co. v. Bowles*, 321 U.S. 321, 329–330 (1944).

These precedents are supported by recent Supreme Court precedent rejecting the notion that a proven statutory violation creates a presumption that injunctive relief is available and should be granted as a matter of course. *Monsanto Co. v. Geerston Seed Farms*, No. 09-475, 2010 WL 2471057, at *15–16 (U.S. June 21, 2010); *see also Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 375 (2008) (a strong likelihood-of-success showing does not mean "a preliminary injunction may be entered based only on a 'possibility' of irreparable harm"); *Nken v. Holder*, 129 S. Ct. 1749, 1763 (2009) (Kennedy,

J., concurring). As the Supreme Court has emphasized, "a major departure from the long tradition of equity practice should not be lightly implied." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). A permanent injunction is a "drastic and extraordinary remedy" that should be granted only if there are no other appropriate, less drastic remedies available. *Monsanto*, 2010 WL 2471057, at *16.

These considerations apply with greater force where, as here, an agency seeks selectively to enforce requirements included in non-binding agency guidelines. In such circumstances, the presumption that an injunction will protect the public and effectuate Congressional policy does not apply. Contrary to FDA's attempt to stamp out all animal drug compounding from bulk, the Supreme Court has recognized that the government "has an important interest" in compounding "so that patients with particular needs may obtain medications suited to those needs." *Western*, 535 U.S. at 369. The grant of jurisdiction to "ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." *Romero-Barcelo*, 456 U.S. at 313; *United States v. Oakland Cannabis Buyer's Coop.*, 532 U.S. 483, 497 (2001). Accordingly, the agency must plead a legitimate basis for asking the Court to exercise its equitable discretion. *Martin v. Franklin Capital Corp.*, 546 U.S. 132, 139 (2005) ("[d]iscretion is not whim" and should be limited "according to legal standards").

The FDCA's injunction provisions are not mandatory. *See* 21 U.S.C. § 332 (district courts "shall have jurisdiction, for cause shown[,] to restrain violations"). In fact, the statute

contemplates that, in many instances, an injunction is unnecessary and that written notice is sufficient to satisfy the statutory requirements and serve the public interest. *See id*. § 336.

The Complaint is therefore deficient because FDA has not included any allegations sufficient to invoke this Court's equitable authority. In particular, although FDA seeks a broad injunction to prevent Franck's from engaging in the traditional pharmacy practice of compounding from bulk, the Complaint includes no allegations that an injunction is needed to prevent irreparable harm (or, indeed, any harm at all), that the unspecified harms the injunction seeks to prevent outweigh the injury to Franck's, or that an injunction is in the public interest. *Klay*, 376 F.3d at 1098. Indeed, if Franck's is compelled to shut down its animal drug business, irreparable harm will be inflicted not only on Franck's and its employees but also on the hundreds of veterinarians, animal owners, and ailing animals that have relied on Franck's high-quality compounding services. Yet the Complaint includes no allegations that even attempt to justify the government's request for the drastic and extraordinary remedy it seeks. Absent such allegations, the government has not properly invoked this Court's equitable authority.

B. The Complaint Seeks Relief That Is Unavailable Under Federal Law.

The Complaint is also deficient because it seeks relief that is unavailable as a matter of law. FDA is seeking authority to "inspect" Franck's, as well as "all records relating to the receipt, compounding, manufacturing, processing, packing, labeling, holding, storing, or distribution of any drug or component." Compl. at 12. In addition, FDA has demanded that Franck's be ordered to pay the costs of the inspections. *Id.* These requests seek to arrogate

— through litigation — inspection authority that FDA does not enjoy under the FDCA and, therefore, to circumvent limits that Congress imposed on FDA's remedial authority.

In the FDCA, Congress provided essentially three judicial remedies for statutory violations: (1) injunctive relief to restrain future violations, *see id*. § 332; (2) civil and criminal penalties, *see id.* § 333; and (3) seizure. *See id.* § 334. In addition, Congress granted FDA *limited* authority to inspect "any factory, warehouse, or establishment in which … drugs … are manufactured, processed, packed, or held, for introduction into interstate commerce." *Id*. § 374(a)(1). Congress carved out an exemption for certain pharmacies from the records inspection provision in the FDCA's 1962 amendments. *See id*. § 374(a)(2)(A). Congress also prohibited FDA from inspecting a company's "financial data, sales data other than shipment data, pricing date, personnel data ... and research data ...." *Id*. § 374(a)(1). The FDCA's "carefully crafted and detailed enforcement scheme provides 'strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly.'" *Mertens v. Hewitt Assocs*., 508 U.S. 248, 254 (1993).

Courts should be especially "'reluctant to tamper with [the] enforcement scheme' embodied in the statute by extending remedies not specifically authorized by its text." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002). Indeed, when Congress has intended to gives courts unrestricted equitable power, it has made its intent clear by broadly wording the grant of authority. *See* 29 U.S.C. § 1132(a)(3) (authorizing "other appropriate equitable relief" under ERISA). Because Congress carefully limited FDA's inspection authority, allowing FDA to expand that authority through litigation would

upend the balance struck by Congress and "work[] an end run around important limitations of the statute's remedial scheme." *Ragsdale v. Wolverine World Wide*, 535 U.S. 81, 91 (2002).

III. The Court Should Dismiss Because The Complaint As Framed Does Not Set Forth A Clear Legal Basis For Recovery.

In addition to lacking adequate factual allegations, and failing to plead the elements of a claim for equitable relief, the Complaint also does not set out the *legal* basis for the government's claims. The Complaint includes no Counts and its bare allegations do not plainly state the legal grounds on which the government is seeking to exercise its purported enforcement authority. In different places, the Complaint suggests in conclusory fashion that Franck's is manufacturing drugs, *see* Compl. ¶¶ 5, 8–9, or compounding commercially available drugs, *see id.* ¶ 27, or compounding drugs outside the context of a valid veterinarian-client relationship. *See id.* But the Complaint does not explain why any of this alleged conduct violates federal law. Accordingly, the Government should be forced to re-plead its Complaint and to state plainly the legal basis on which it seeks to proceed.

In this regard, the Complaint appears to suggest in places that, although Congress has expressly permitted compounding from bulk for human drugs, and although Congress has never purported to regulate (or to grant FDA authority to regulate) animal drug compounding, Franck's is violating federal law merely because it is compounding animal drugs from bulk substances (a practice that is expressly permitted under Florida law). The Complaint's allegations are too vague to decipher, but in guidance documents and in other public statements, FDA has taken the position that it enjoys unfettered authority to impose binding, substantive "rules" that displace traditional state law regulation of pharmacy compounding practices, even though those "rules" have never been promulgated through

proper notice and comment procedures. To the extent that FDA intends to pursue this position here, it should be required to re-plead its Complaint and to state plainly the source of its purported authority. Franck's would then propose that, if FDA is able to file an amended Complaint that satisfies the requirements of Rule 8 and Rule 12, because the dispositive, threshold issue of FDA's authority to regulate compounding practices is critically important and has implications that extend far beyond this case, the issue should be considered by the Court — after full briefing and argument — before any further proceedings occur.

Nothing in the FDCA establishes that compounded drugs fall within the fold of "new animal drugs" subject to its approval, adulteration, and misbranding requirements. To the contrary, legislative history shows that the statute was not intended as a medical practices act and was not supposed to interfere with the "healing arts," including pharmacy practices. S. Rep. No. 361, 74 Cong., 1st Sess. 3 (1935). This legislative intent was borne out by more than a half-century of FDA practice and industry understanding. *See Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 (1995) (statutes should be interpreted consistent with "traditional understandings"). As the Supreme Court has observed, "[f]or approximately the first 50 years after the enactment of the FDCA … [p]harmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs." *Western*, 535 U.S. at 363. To conclude that Congress intended to treat compounded drugs as "new drugs" would "not make sense." *Id*. at 369–70; *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 398 (5th Cir. 2008) ("unlikely that Congress intended to force compounded drugs to undergo the new approval process").

Nor does anything in AMDUCA address compounding. Although Congress knew how to address the issue of compounding in express terms when it wanted to, as it did for human drugs in FDAMA, AMDUCA addresses only the extra-label *uses* of FDA-approved animal drugs. *See Kimbrough v. United States*, 552 U.S. 85, 103 (2007) ("[d]rawing meaning from silence is particularly inappropriate" when "Congress has shown that it knows how to" address an issue "in express terms"). Compounding is not a "use" and AMDUCA never mentions compounding. There is no indication that Congress intended AMDUCA to outlaw widespread pharmacy practices that, both before and after the FDCA's enactment, were closely regulated by the states. *See Reves v. Ernst & Young*, 507 U.S. 170, 183 (1993) (statutes should not be applied "to purposes that Congress never intended"). Nor is there any evidence that Congress intended to take the extraordinary step of wiping out the investment-backed expectations of thousands of pharmacists who provide essential compounding services to veterinarians and depriving the public of those essential services. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) (Congress should not be presumed to address an issue of such "economic and political significance … in so cryptic a fashion"); 139 Cong. Rec. 1447 (1993) (Sen. Heflin) (AMDUCA "not intended to increase or alter overall patterns of drug usage by veterinarians"). Indeed, interpreting AMDUCA to require *all* forms of compounding to comply with the FDCA's new drug approval provisions would lead to absurd results not in the public interest. *See In re Trans Alaska Pipeline Rate Cases*, 436 U.S. 631, 643 (1978) (courts have "some scope for adopting a restricted rather than a literal or usual meaning of [a statute's] words where acceptance of that meaning would lead to absurd results").

FDA has argued elsewhere that its expansive view of the statute is supported by three cases that, noting the breadth of the term "new drugs" in 21 U.S.C. § 321(v)(1), surmised that the FDCA covers veterinary compounding practices. *See, e.g.*, *Medical Ctr.*, 536 F.3d at 403; *United States v. Algon Chem. Inc.*, 879 F.2d 1154 (3d Cir. 1989); *United States v. 9/1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988). But statutory interpretation is not supposed to stretch statutory language to the "outer limits" of its "definitional possibilities." *Dolan v. Postal Service*, 546 U.S. 481, 486 (2006). None of the cases are binding on this Court. And, in any event, none undertook the required analysis. As courts have recognized in other contexts, federal statutes should not be interpreted to push aside regulation in areas of traditional state regulatory concern. *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 546 (1994) (where Congress's intent to override historical state practice "is doubtful, our federal system demands deference to long-established traditions of state regulation"). The relevant question is not whether the FDCA's language is sufficiently capacious when viewed in isolation that compounding from bulk might fall within its scope, but whether the statute includes a "plain statement" showing that the "clear and manifest purpose of Congress" was to supersede traditional state regulation over pharmacy compounding practices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Gregory v. Ashcroft*, 501 U.S. 452, 460–61 (1991) ("plain statement" of intent required when Congress legislates "in areas traditionally regulated by the States"). No such statement is contained in the FDCA.

Essentially recognizing that nothing in the FDCA speaks to the issue of animal drug compounding, FDA has purported to exercise authority to ensure that pharmacies are not engaged in improper drug manufacturing. But if it seeks to exercise that authority FDA must

promulgate a new substantive, legislative rule that draws a reasonable line between compounding and manufacturing. *See United Techs. Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987) (rule is "legislative" if based on agency's power to exercise its judgment as to how best to implement a general statutory mandate). Because the agency is treating the compounding of animal drugs from bulk substances as creating a binding obligation to comply with FDA's new drug approval process, that substantive rule must be promulgated through proper notice and comment rulemaking proceedings. *See* Compl. ¶ 16 (basing Complaint on FDA's policy guidance documents prohibiting bulk compounding); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (rule must be promulgated through notice and comment if agency "bases enforcement actions on the policies or interpretations formulated in the document"). An agency may not, by purporting to "enforce" an illusory statutory prohibition, avoid the rulemaking procedures required to establish a binding, legislative rule. *See Dia Nav. Co., Ltd. v. Pomeroy,* 34 F.3d 1255, 1265 (3d Cir. 1994) (where "INS has stretched the limits of the INA, without the benefit of input from the affected parties ... [t]his plainly amounts to legislative rulemaking"). Regulatory obligations must be set forth with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement. *See Hill v. Colorado*, 530 U.S. 703, 732 (2000).

STATEMENT OF RELIEF REQUESTED

The Court should dismiss the Complaint in its entirety.

Respectfully submitted,

/s/ Mark S. Brown
Mark S. Brown, Esq.
Jeffrey S. Bucholtz, Esq.
(*Pro Hac Vice* Pending)
Alan R. Dial, Esq.
Ashley C. Parrish, Esq.
(*Pro Hac Vice* Pending)
KING & SPALDING LLP
1700 Pennsylvania Ave., N.W., Suite 200
Washington, D.C. 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
Email: mbrown@kslaw.com
Email: jbucholtz@kslaw.com
Email: adial@kslaw.com
Email: aparrish@kslaw.com

/s/ Michael E. Dean
Michael E. Dean, Esq.
Fla. Bar No.: 0115584
DEAN LAW FIRM, LLC
230 NE 25th Avenue, Suite 300
Ocala, Florida 34470
Telephone: (352) 387-8700
Facsimile: (800) 251-9424
Email: mike@deanfirm.com

Counsel for Defendants Franck's Lab, Inc. d/b/a Franck's Compounding Lab and Paul W. Franck

Dated: July 1, 2010

CERTIFICATE OF SERVICE

I hereby certify that on this the 1st day of July, 2010, I electronically filed the foregoing with the Clerk of Court by using CM/ECF system which will send a notice of electronic filing to the following: John W. M. Claud, John.Claud@usdoj.gov; Lacy R. Harwell, Jr., Randy.Harwell@usdoj.gov; and to Jessica L. Zeller, Jessica.Zeller@fda.hhs.gov.

/s/ MARK S. BROWN
Mark S. Brown, Esquire
KING & SPALDING LLP
1700 Pennsylvania Ave., N.W., Suite 200
Washington, D.C. 20006
(202) 737-0500
(202) 626-3737 (fax)
mbrown@kslaw.com

/s/ MICHAEL E. DEAN
Michael E. Dean, Esquire
Fla. Bar No.: 0115584
DEAN LAW FIRM, LLC
230 NE 25th Avenue, Suite 300
Ocala, Florida 34470
(352) 387-8700
(800) 251-9424 (fax)
mike@deanfirm.com