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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2015-N-1196-0003

RE: Comments to the Draft Guidance for Compounding Animal Drugs From Bulk Drug Substances

Dear Sir or Madam,

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) *Draft Guidance for Industry #230: Compounding Animal Drugs From Bulk Drug Substances (GFI)* published on 19 May 2015.

The International Academy of Compounding Pharmacists (IACP) is a professional association representing more than 4,000 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications.

IACP has strong concerns with the proposed GFI. As proposed, the published GFI represents a significant departure from the *Compliance Policy Guidance: Compounding of Drugs for Use in Animals* issued by the agency on July 14, 2003. That CPG was issued on an emergency basis without a public comment period which our Academy raised concerns about directly to the agency and to Congress itself. Despite a publicly announced intent to withdraw the CPG and obtain stakeholder feedback in 2004, the CPG remained in place until the announcement of its withdrawal published concurrently with the release of this draft GFI in the *Federal Register*.

In addition, FDA lacks the authority to regulate animal compounding as is asserted within the GFI. FDA assumes under the GFI that all compounding is manufacturing and thus concludes that the FDCA grants FDA the authority needed to regulate animal compounding.

INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

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To the contrary, the *Food Drug and Cosmetic Act* (FDCA) does not address compounding drugs for use in animals and a magnitude of case law has made clear that FDA lacks the authority under the FDCA to regulate animal compounding in the manner asserted within the GFI. This matter has been decided time and time again, and IACP is very concerned with FDA's continued action in ignoring these holdings. Congress has also been clear that the intent was never to grant FDA the broad authority that FDA has asserted within the GFI. Most recently, Congress had the opportunity to address animal compounding within the *Drug Quality and Security Act (DQSA)*. Congress, once again, chose not to grant FDA authority under the DQSA to regulate animal compounding.

In addition, FDA continues to ignore that animal compounding is a State regulated industry. As such, IACP is gravely concerned with many issues within this GFI that create distinct conflicts with existing State regulated pharmacy practice laws and regulations, that authorizes the preparation and distribution of veterinary medications by 503B outsourcing facilities without the necessary enabling statutory authority from Congress, and will have a detrimental impact on the availability of medications for use by veterinarians in the care and treatment of animals within their practices.

FDA also fails to acknowledge the true impact of the GFI refusing to recognize that the draft GFI would drastically reduce access to animal medications. While IACP fully supports protecting animal healthy, FDA must balance this objective with preserving access to vital medications. The scheme proposed by FDA within the GFI would drastically reduce access to animal medications while also interfering with the patient, practitioner, and pharmacist triad.

I. Congress and the Courts have been Clear that FDA Lacks the Authority under the FDCA to Regulate Animal Compounding as is Asserted within the GFI.

In the draft notice as well as the GFI, FDA cites the FDCA as the source of FDA's authority to regulate animal compounding. Specifically, FDA states that comments can be submitted "on FDA's application of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to the compounding of animal drugs from bulk drug substances."¹ FDA goes on to detail its source of authority stating that

Sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the FD&C Act do not apply to the compounding of animal drugs. The FD&C Act does not distinguish between compounding animal drugs from bulk drug substances and any other manufacturing or processing of animal drugs. Except with respect to the limited exemption provided by the FD&C Act described in this document, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to compounded animal drugs.²

¹ See FDA Draft Guidance #230, Guidance for Industry, Compounding Animal Drugs from Bulk Drug Substances at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM446862.pdf>.

² *Id.* at 2.

Therefore, FDA has made clear that the authority the Agency is purporting within the GFI stems from sections 503A and 503B within the DQSA. Specifically, FDA outlined that because the DQSA sections 503A and 503B grant FDA authority to regulate manufacturing, that animal compounding itself is in fact manufacturing. As such, FDA then goes forth in the GFI and details when animal compounding will not be considered manufacturing by stating:

FDA does not generally intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), and 502(f)(1) of the FD&C Act if a State licensed pharmacy or a licensed veterinarian compounds drugs intended for use in animals from bulk drug substances in accordance with all of the applicable conditions set out in the guidance. In addition, the draft guidance provides that FDA does not generally intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if the drug product is compounded from a bulk drug substance by an outsourcing facility and that meets all of the applicable conditions set out in the guidance, and the drug product is compounded from a bulk drug substance that appears on Appendix A of the draft guidance.³

Thus, FDA is relying upon the FDCA and the authority Congress gave FDA under Sections 503A and 503B of the DQSA to regulate drug manufacturing to actually regulate the act of compounding for animals. To do so, FDA had to conclude that the act of compounding for animals is in fact manufacturing. Specifically, the Agency is claiming that all compounding, human and animal is in fact manufacturing and that the Agency has the authority to carve out exemptions where the new drug process is not applicable under the FDCA.

FDA's assertions that the Agency was granted authority by Congress to regulate animal compounding by the FDCA due to the FDCA's directive to FDA to regulate manufacturing coupled with a silence on animal compounding, does not hold up not only within the actual text of the FDCA but also within legislative intent as well as countless Judicial holdings.

Therefore, FDA is badly mistaken that the FDCA grants the Agency the authority it asserts within the GFI. FDA was never given authority, legislatively or otherwise, to regulate animal compounding in the manner that the Agency purports within the GFI.

³ See FDA Draft Guidance #230, Guidance for Industry, Compounding Animal Drugs from Bulk Drug Substances at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM446862.pdf>.

A. The Food Drug and Cosmetic Act (FDCA) Does Not Grant FDA the Authority to Regulate Animal Compounding as Asserted within the GFI.

- i. Plain text of FDCA targets drug manufacturing and thus does not give FDA authority to regulate drug compounding for animals.

The FDCA targets drug manufacturing. Congress was clear by the plain language found within the legislation as well as through Congressional intent that the FDCA was never intended to grant FDA broad sweeping authority over animal compounding. As such, animal compounding is not governed by the FDCA. In fact, Congress had the opportunity to depart from the prior language found within the FDCA and prior intent and grant FDA the long sought after authority over animal compounding by including language within the most recently passed DQSA. Congress, once again, chose not to grant FDA this authority over animal compounding. As such, FDA does not have the authority to extend §§503A and 503B to animal compounding.

Since FDA asserts the FDCA as the source of the Agency's authority to regulate animal compounding, one does not have to look much further than the legislative text of the FDCA to see that Congress never intended to grant FDA with this broad authority. However, FDA has historically held that despite the clear legislative language that Congress in fact intended to grant FDA this broad sweeping authority to regulate animal compounding. Specifically, FDA asserts that animal compounding falls within the definition of "new drug" as found within the FDCA. FDA has asserted this argument in many court cases and has provided a long line of judicial precedent on this issue that also state that Congress never intended to grant FDA this broad sweeping authority.

As such, one can look to an array of court cases including *United States of America vs. Franck's Lab*, United States District Court for the Middle District of Florida, (*Francks*).⁴

In the *Francks* case, FDA also asserted that all animal compounding was in fact manufacturing and as such fell under the purview of the FDA. Once again, FDA asserts in the GFI that:

The FD&C Act does not generally distinguish between compounding and other methods of animal drug manufacturing. Animal drugs that are not approved or indexed are considered "unsafe" under section 512(a)(1) of the FD&C and Although sections 503A (21 U.S.C. 353a) and 503B of the FD&C Act provide certain statutory exemptions for compounded human drugs, these sections do not provide exemptions for drugs compounded for animal use. The compounding of an animal drug from bulk drug substances results in a new animal drug that must comply with the FD&C Act's approval/indexing requirements.⁵ Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements (section 501(a)(2)(B)) of the FD&C Act and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act). adulterated under section 501(a)(5) of the FD&C Act.⁵

⁴ *United States of America vs. Franck's Lab*, United States District Court for the Middle District of Florida.

⁵ See FDA Draft Guidance #230, Guidance for Industry, Compounding Animal Drugs from Bulk Drug Substances at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM446862.pdf>.

As discussed above, animal drugs are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act.⁶

However, these statements are incorrect and fail to acknowledge that the FDCA was intended to target manufacturers which is not compounding pharmacists. In *Francks*, FDA urged the Court to “follow the holdings of the Third, Fifth, and Seventh Circuits [in *Algon*, *Medical Center*, and *9/1 Kg. Containers*] that compounded animal drugs are ‘new animal drugs’ within the meaning of the FDCA and decline [Franck’s] invitation to re-litigate the issue.”⁷

In this case, FDA asserted that the plain language of the FDCA, which was enacted in 1938, granted FDA “the enforcement authority to prevent pharmacists from bulk compounding medications for non food-producing animals.” Specifically, FDA asserted “that it needs no more than the plain language of the 1938 FDCA to enjoin Franck’s bulk compounding, a position it asserts has been confirmed by three courts of appeal.” As the court noted, FDA took the position that “the bright-line position that *any* compounding of animal medications from bulk substances violates its enabling statute, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. (“FDCA”), even when conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription. Franck’s admits that it routinely engages in this practice, but contends that it does not violate the FDCA.”⁸

In holding that FDA did not have the broad sweeping authority to regulate bulk ingredient animal compounding, the Court undertook an analysis on whether the act of drug compounding is in fact manufacturing and thus regulated under the FDCA. The Court held that Congress never intended for animal compounding to be deemed manufacturing and thus targeted by the FDCA. Specifically, the Court held that

This Court cannot find that Congress has “directly and plainly” said that traditional pharmacy compounding of animal drugs must meet the requirements of the FDCA’s new drug approval provisions. See ABA I, 430 F.3d at 467; *American Bar Ass’n v. F.T.C.*, 671 F.Supp.2d 64, 73 (D.D.C. 2009)(“ABA II”), *vacated on mootness grounds*, *American Bar Ass’n v. F.T.C.*, 636 F.3d 641, 644 (D.C. Cir. 2011).⁹

⁶ See FDA Draft Guidance #230, Guidance for Industry, Compounding Animal Drugs from Bulk Drug Substances at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM446862.pdf>.

⁷ *United States of America vs. Franck’s Lab*, United States District Court for the Middle District of Florida, pg. 45.

⁸ *Id.* at 38.

⁹ *Id.* at 39.

The Court went on to explain that, “the elephant-in-mouseholes doctrine is equally applicable here: it is not at all clear that Congress meant to hide the elephant of the FDA’s regulation of traditional pharmacy compounding in the mousehole of the FDCA’s new drug approval process.”¹⁰

The Court asserted that

Every court that has addressed the issue—no matter the context—has recognized that the FDA new drug approval process is an “especially poor fit” for regulating traditional pharmacy compounding, one that would potentially eradicate traditional compounding despite the recognized importance, historical acceptance, and decades-long state regulation of the practice. See, e.g., *W. States*, 535 U.S. at 369-70.¹¹

Furthermore, the Court went on to explain that

“[I]t 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”); *Med. Ctr.*, 536 F.3d at 398 (“[I]t seems unlikely that Congress intended to force compounded drugs to undergo the new drug approval process, a requirement that would have made compounding nearly impossible and thus nonexistent”); see also *Algon*, 879 F.2d at 1161 (noting the argument that “limiting drugs that veterinarians can compound to those lawfully obtainable [at the time, approved animal drugs] means for all practical purposes that veterinarians will be unable to compound”); *9/1 Kg. Containers*, 854 F.2d at 177 (“The testing required to obtain a new animal drug approval is costly and extended. . . . Testing must isolate the effects of the drug in question from all other environmental influences, then follow the animals for years (even generations of animals) to identify the consequences. This requires data from large populations of animals and the application of powerful statistical techniques. No solitary medical professional can carry out this program of knowledge acquisition for even one drug, let alone for the bevy of drugs a veterinarian may choose to compound.”)¹²

ii. *Silence within the FDCA also does not grant FDA the authority to regulate animal compounding.*

Thus, it’s clear that the Courts have long agreed that the new drug process is not a good fit for compounded medications. As such Courts have held that animal compounding is not manufacturing. To the contrary, FDA in the past as well as in the current GFI asserted that the direct authorization within the FDCA to the Agency to regulate manufacturing coupled with the

¹⁰*Id.* At 48.

¹¹*Id.* at 56-57.

¹²*Id.* at 57.

silence on animal compounding, grants FDA authority to regulate animal compounding. In essence, FDA relies on the argument that silence by Congress on an issue actually provides FDA with authority to regulate that issue.

However, the Courts have long decided this issue and have held that FDA is mistaken in this assertion. In fact, the Court in *Francks* refused to recognize FDA's argument and stated that "if we were 'to *presume* a delegation of power' from the absence of 'an express *withholding* of such power, agencies would enjoy virtually limitless hegemony."¹³

As such, the Court held that absence of direct grant of authority is not a grant of authority. Furthermore, the Court in *Francks* went on to state

Though nothing in the FDCA or its amendments actually *prohibits* compounding by a state-licensed pharmacist, the FDA posits that an explicit prohibition is not required for the agency to enforce against the practice. Rather, the FDA argues that because the statute includes no *exemption* for state-licensed pharmacists or for compounded medications, traditional pharmacy compounding practices are subject to the same regulatory requirements as new drugs that are manufactured, marketed, and distributed in interstate commerce. The lack of a blanket exemption for pharmacy compounded drugs is at least somewhat instructive because the FDCA does exclude certain "grandfathered" old drugs and investigational drugs from the scope of its "new animal drug" provisions.¹⁴

The Court in *Francks* went on to conclude that animal compounding in fact not manufacturing under the FD&C Act and thus does not have to go through the new drug approval process. In doing so, the Court acknowledged that pharmacists do not enjoy a uniform exemption from the new drug scheme, but that 1962 amendments to the FDC Act do "exempt from certain "FDA registration and inspection requirements 'pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy' and dispense drugs "upon prescriptions of practitioners' for their patients, 'and which do not manufacture . . . [or] compound . . . drugs . . . for sale *other than in the regular course of their business of dispensing or selling drugs.*' See 21 U.S.C. § 360(g)(1) (requiring drug manufacturers to register annually with the FDA)(emphasis added); *id.* § 374(a)(2)(A) (granting FDA agents right to inspect manufacturing facilities "[f]or purposes of enforcement of this chapter").¹⁵

The Court in *Francks* also noted that these provisions contain the only mention of compounding within the FD&C Act and "expressly distinguishes drug manufacturers from pharmacists engaged in the practice of traditional compounding." As such, the Court in *Francks* concluded that "[t]he presence of these exemptions could be interpreted as a congressional policy decision to distinguish compounding from manufacturing."¹⁶

¹³ ABA I, 430 F.3d at 468 (emphases in original) (quoting *Ry. Labor*, 29 F.3d at 671).

¹⁴ See 21 U.S.C. § 321(v)(1), § 360b(j) as cited in *United States of America vs. Franck's Lab*, United States District Court for the Middle District of Florida, pg. 59.

¹⁵ *United States of America vs. Franck's Lab*, United States District Court for the Middle District of Florida, pg. 59.

¹⁶ *Id.* at 60.

iii. Legislative history of the FDCA also does not grant FDA authority over animal compounding.

In addition to the plain language of the FDCA the legislative history of the FDCA also supports the view that manufacturers, not compounding pharmacists, were the intended target of the FDCA and the definition of “new drug” found within the FDCA.

As *Francks* notes, when Congress was drafting the FDCA, “Congress appeared to be focused on the fact that manufacturing—unlike the practice of pharmacy—was conducted by unlicensed, unregulated nonprofessionals, it seems unlikely that it would have intended to subject professionally dispensed drugs to the same regulatory scheme.”¹⁷

The Court went on to note that

“[t]his distinction is even more compelling when one considers the FDCA scheme’s poor fit with a traditionally compounded animal medication. The FDCA provides that the introduction or delivery for introduction into interstate commerce of any “new animal drug” without FDA approval is unlawful unless an application is filed that includes, among other things, “a full list of the articles used as components of such drug.” 21 U.S.C. §§ 360b(a)(1), (b)(1)(B). And it requires “full reports of investigations” as part of the application, *id.* § 360b(b)(1)(A), which the FDA has long interpreted to require that new drugs be subject to extensive testing and well-controlled studies to determine their safety and effectiveness. Given that traditionally compounded medications are prepared for individual animal patients in response to a valid veterinary prescription, meaning each compounded medication has unique components and is ill-suited for “adequate and well-controlled studies,” it just does not seem plausible that Congress would have intended to subject pharmacy compounded drugs to the lengthy and expensive new animal drug approval process. See *Med. Ctr.*, 536 F.3d at 398; *W. States*, 535 U.S. at 369-70. The statutory “fit” is especially poor when compounded medications are the best—and sometimes only—way to treat an animal.”¹⁸

The Court in *Francks* went on to state that “[f]urther, “deference to the agency’s interpretation under *Chevron* is warranted only where ‘Congress has left a gap for the agency to fill pursuant to an express or implied delegation of authority to the agency.’” *Am. Bar Ass’n v. F.T.C.*, 430 F.3d 457, 468 (D.C. Cir. 2005) (“ABA I”) (quoting *Ry. Labor Exec. Ass’n v. Nat’l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*)). Put differently, “the existence of [statutory] ambiguity is not enough per se to warrant deference to the agency’s interpretation. The ambiguity must be such as to make it appear that Congress either explicitly or implicitly delegated authority to cure that ambiguity.”¹⁹

¹⁷ *Id.* at 61.

¹⁸ *Id.* At 62.

¹⁹ *Id.* at 42.

It is clear under the FDCA and now under the DQSA that no gap by Congress has been left to warrant FDA the ability to assert the silence within the FDCA as the basis for the Agency's authority over animal compounding.

In conclusion, FDA was not granted authority by Congress by the plain language or legislative intent of the FDCA or by Court decisions pertaining to the FDCA to regulate animal compounding. As such, FDA lacks the authority to regulate animal compounding as asserted within the GFI.

II. FDA lacks authority to extend sections 503A and 503B within the DQSA to animal compounding.

In addition to asserting authority to regulate animal compounding pursuant to the FDCA, FDA also references §503A specifically within the FDCA as well as the newly created §503B as passed within the DQSA.

Specifically, FDA goes so far in the GFI to detail ten new requirements that §503B outsourcing facilities must meet in order to not be held out as manufacturers.

As outlined above, the FDCA does not authorize FDA to regulate animal compounding. Congress had the opportunity to grant FDA such authority in the most recently enacted DQSA, which opened up the FDCA and added §503B. To the contrary, Congress choice to reinstate §503A and create §503B for human compounding. As such, in the plain language of the DQSA, Congress took pains to state that the DQSA only applies to human compounding. Thus, Congress certainly never intended FDA to utilize the DQSA and §503A and 503B found within to regulate animal compounding.

FDA has recognized this distinction between human drug compounding and animal compounding itself many times. In guidance the Agency has put out regarding the implementation of the DQSA §§503A and 503B, FDA itself has stated that the DQSA guidance does not apply to animal compounders as DQSA only applies to human drug compounding. FDA also directed in the §503B outsourcing facility guidance that animal compounders not register as §503B outsourcing facilitates stating that DQSA §503B only applies to human compounding.

How FDA has previously stated multiple times the Agency's understanding that DQSA only applies to human compounding but now asserts the very authority of the DQSA in order to regulate animal compounding is egregious. As a Federal Agency, FDA cannot take legislation passed by Congress and change the plain language and legislative intent in order to implement the legislation in a manner that fits the Agency's agenda. As *Francks* pointed out, to allow an Agency to take such action, would render an Agency's power limitless and certainly able to circumvent the legislative process. That is not the role of FDA. FDA is bound by the plain language of DQSA and was given no authority by Congress to regulate animal compounding.

As such, FDA lacks the authority to create a bulk ingredient list for 503B outsourcing facilities for animal compounding under §503B. As detailed above, §503B, by the plain language of the statute, only applies to human drug compounding. As such, FDA cannot enforce registration by animal compounders as §503B outsourcing facilities and lacks authority to create API lists that animal compounders must adhere to.

In conclusion, the attempt by FDA to take legislation that clearly states is solely applicable to human compounding and cite the legislation as the source of authority for broad sweeping power within the animal compounding industry is egregious and is in direct conflict with the plain language of the FDCA, the clear legislative intent of the FDCA, many court holdings upholding the clear intent of the FDCA, and the plain language of the DQSA. Congress has never granted FDA the authority that it has sought and now purports within the GFI over animal compounding.

III. Animal compounding is a State regulated industry.

The Agency acknowledges within the first few paragraphs of the GFI that the GFI is in fact federal guidance and not regulation and represents the Agency's current thinking on the subject. Since animal compounding has always been regulated by States, FDA fails to even acknowledge that the GFI ventures into a fully State regulated industry and fails to offer any guidance as to how the Agency envisions State role following the GFI. Currently, States implement a wide range of compounding rules. Pharmacists as well as veterinarians are licensed by State government authorities and currently operate under their State laws.

In addition, in enacting Food and Drug Modernization and Accountability Act of 1997 (FDAMA), Congress also recognized that regulation of compounding was historically the province of the States, "States currently have the authority to license pharmacists and regulate pharmacies, including the scope of pharmacy practice. All states include compounding as a core component of the profession of pharmacy."²⁰

The history of the FDA's regulation of pharmacy compounding has been reviewed several times, most notably by the Supreme Court in *Western States*, 535 U.S. at 360-66. *Western States* also explained that "[c]ompounding is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools."²¹ "Because the practice of pharmacy is state-governed, the States, including Florida, regulate compounding as part of their regulation of pharmacists."²² "The pharmacist-prescriber-patient relationship forms the basis of what is commonly known as "traditional pharmacy compounding."²³

²⁰ Food and Drug Modernization and Accountability Act of 1997, S. Rep. No. 105-43 at 67 (1997).

²¹ *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) as cited in *United States of America vs. Franck's Lab Inc.*, No. 5:10-cv_00147 (M.D. Fla. September 12, 2011) at 10.

²² *United States of America vs. Franck's Lab Inc.*, No. 5:10-cv_00147 (M.D. Fla. September 12, 2011) at 11.

²³ *Id.* at 20.

Francks also distinguished the federally regulated practice of manufacturing and the State regulated practice of animal compounding by stating, “[m]oreover, unlike manufacturers, compounding pharmacists are licensed professionals who must operate in conformance with applicable state laws that regulate the practice of pharmacy.”²⁴

As proposed, this GFI would override the authority of states to govern veterinary medical practice by eliminating the ability of veterinarians and compounding pharmacists to prepare medications for administration to or treatment of animals within their practice setting. Commonly referred to as “office-use”, states have by statute and regulation authorized pharmacists to prepare and deliver to a veterinarian quantities of compounded medications for the treatment of animals under their care. The GFI, if adopted, would override this state authority as the current language requires that any prescription for a compounded medicine must be for an individually identified animal – language that, as mentioned above, seems to be copied from the DQSA §503A and applied to veterinary practice without any Congressional authorization or intent.

Within the past six months, two states – Florida and Louisiana – have taken action to formally permit the preparation and dispensing of compounded medications for veterinary office-use. The Florida legislature enacted HB 1049 with an effective date of July 1, 2015, to authorize office-use compounding for veterinarians. In July 2015, the Louisiana Board of Pharmacy amended §2535 of state Chapter 25, Prescriptions, Drugs, and Devices to allow pharmacies to compound medications for office-use by veterinarians.

The regulation of veterinary medical practice, indeed, that of pharmacy practice is reserved to the states. This proposed GFI violates that core principal of jurisdictional authority.

IV. The Draft GFI Would Drastically Reduce Access to Animal Compounding Medications

Compounding medications for animals is widely accepted and heavily State regulated practice. Compounding from bulk ingredients is a necessary practice for animal compounding in order to treat the many different species and conditions. The ever increasing drug shortages and unavailability of FDA approved drugs also increases the need for compounded animal medications.

Despite the fact, as analyzed above, that FDA lacks the authority to regulate animal compounding under the FDCA, in the GFI, FDA prohibits all traditional 503A pharmacies and veterinarians from compounding drugs for office-use. While the GFI fails to define “office-use”, this terminology is often associated with the ability of a practitioner to administer to a patient in an office setting by placing an order with a pharmacist. As such, practitioners as well as pharmacists may hold prescription in their facilities on hand as “anticipatory” compounding.

²⁴ *United States of America vs. Franck’s Lab, Inc.*, No. 5:10-cv-00147 (M.D. Fla. September 12, 2011) at 11.

However, under the GFI, a pharmacist would not be able to dispense this medication to a veterinarian in order for the veterinarian to have on hand for emergency situations. Veterinarians would also not be allowed to take compounded medications made by themselves or a pharmacist outside of their offices for treatment of animals. To the contrary, the pharmacist as well as the veterinarian would only be allowed to dispense/administer a compounded medication pursuant to prescription for a specific animal.

Specifically, FDA within the GFI states that in order to qualify for the exemption found within the FDCA, a traditional 503A pharmacy and a veterinarians must abide by the following:

The drug is dispensed after the receipt of a valid prescription from a veterinarian for an individually identified animal patient that comes directly from the prescribing veterinarian or from the patient's owner or caretaker to the compounding pharmacy. A drug may be compounded in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months.

This prohibition of office-use would drastically alter the veterinarian practice of treating animals in barns, fields, zoos, and shelters. In rural America, upwards of half a veterinarian's day can be spent out in the field and barns treating animals. When the veterinarian leaves their office that morning, it is customary to take medications with them that might be needed during the treatment of animals. When the medication leaves the facility it is not prescribed for a specific patient and thus would classify as "office-use." FDA is prohibiting all office-use compounding of bulk ingredients by veterinarians and pharmacists within the GFI. In doing so, FDA is drastically impacting a fundamental and well-accepted practice in animal medicine. The prohibition would eliminate the ability for veterinarians to obtain a prescription for a collection of animals, such as in a zoo, a barn, laboratory, or for Game and Fish purposes.

In the past, FDA has claimed many times that compounding should not occur from bulk ingredients, and by prohibiting all office-use compounding from bulk ingredients, it appears FDA is continuing to hold that compounding from bulk is somehow less appropriate. This is the same argument that FDA asserted during the *Francks* case. In responding to that claim, the Court in *Francks* stated,

Between the two, compounding from bulk substances has become the "widely preferred" method among veterinarians due to "concerns about the quality, safety, and efficacy of animal medications compounded from finished products." (Allen Dec. ¶¶ 17, 24.) Pharmacists also favor compounding from bulk because use of bulk ingredients ensures that the compounded medicine is of the expected purity,²² potency,²³ and quality; further, it is often not practical²⁴ or possible²⁵ to compound a medically necessary animal drug from an FDA-approved finished drug product. (Id. ¶¶ 17, 23-25.) In addition, the standards for potency and purity of compounded medications required by the United States Pharmacopeia ("USP"), which the original FDCA recognized as its "official

compendium,” Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (“1938 FDCA”) § 201(j), are more readily obtained using bulk ingredients.²⁵ (Allen Dec. ¶¶ 27-32.)²⁵

The Court went on to state, “[a]s a result, compounding from a finished drug product “is more likely to result in a compounded preparation outside of the [USP’s] required potency and purity specifications than compounding from a bulk ingredient.” (Id. ¶ 29.)²⁶

FDA’s sole solution to the drastic impact on animal access to compounded medications from bulk ingredients is for veterinarians to partner with §503B outsourcing facilities in order to obtain office-use compounded medications. However, FDA also states that §503B outsourcing facilities will only be able to compound from the bulk ingredients listed on the API bulk list which FDA is currently taking nominations. As analyzed above, §503B within the DQSA only pertains to human compounding. Specifically, outsourcing facilities in compliance with §503B are only exempt from the *human drug approval requirements* in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1).

As such, FDA cannot create an API list for outsourcing facilities no more than it can require animal compounders to register as §503B outsourcing facilities. Even if this scheme were permitted, FDA has done away with office-use compounding by veterinarians and traditional 503A pharmacies and stands to restrict what bulk ingredients §503B outsourcing facilities can use in compounding medications for animals. To think that this scheme would not drastically decrease access to animal medications is badly misinformed.

In conclusion, pharmacists as well as veterinarians often prefer compounding from bulk ingredients. By completely doing away with all compounding from bulk ingredients for office-use would drastically decrease access to animal medications while also drastically altering the current practice of animal medicine. In passing the FDCA, Congress expressed intent to preserve patient access to compounded medications. Not only did Congress never authorize FDA to utilize the FDCA and subsequently the DQSA in a manner to regulate animal compounding, Congress also never intended for either legislation to be utilized in a manner to drastically decrease patient access to the very drugs they choose and depend on.

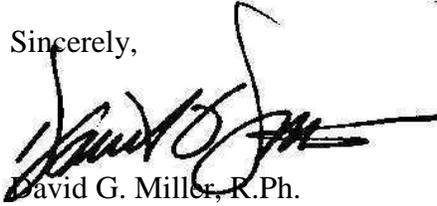
²⁵ *United States of America vs. Franck’s Lab*, United States District Court for the Middle District of Florida,

²⁶ *Id.* at 13-14.

IACP requests that this *Guidance for Compounding Animal Drugs From Bulk Drug Substances (GFI #230)* be withdrawn in its entirety.

Thank you for the opportunity to submit our comments and IACP looks forward to working with FDA in the future on this very important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'David G. Miller', with a stylized flourish extending to the right.

David G. Miller, R.Ph.
Executive Vice President & CEO