IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Galveston Division

TEXAS DEPARTMENT OF CRIMINAL JUSTICE, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as the Commissioner of Food and Drugs, and UNITED STATES OF AMERICA, Defendants.	Civil Action No. _____

PLAINTIFF TEXAS DEPARTMENT OF CRIMINAL JUSTICE'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. In this case, Plaintiff Texas Department of Criminal Justice ("TDCJ") challenges unreasonable delay in an action by the U.S. Food and Drug Administration ("FDA") determining the admissibility, into domestic commerce, of an import shipment of the drug thiopental sodium. TDCJ is responsible for administering criminal sentences in Texas and has attempted to import the drug to carry out capital sentences through lethal injection. More than seventeen months ago, in July 2015, FDA detained the imported drugs at the border. More than sixteen months ago, in August 2015, FDA claimed three specific legal grounds for potentially refusing the drugs' entry into domestic commerce. None of these grounds is valid. An FDA "law enforcement" exemption precludes application of one of the legal requirements at issue. And the other two legal requirements also do not apply, among other things because the drugs will not be used for patient treatment and have labeling that prohibits any patient treatment use.

2. TDCJ has submitted detailed legal arguments to FDA explaining why this import is lawful. Yet FDA has refused to make a final decision as to the drugs' admissibility, effectively preventing their importation without any definitive legal justification. To make a final decision, FDA only needs to address pure questions of law that the agency itself has raised. Nonetheless, the time that FDA has taken to determine whether its own legal theories are valid exceeds the time that the Supreme Court of the United States typically takes to resolve the most complex legal issues facing the Nation. Because FDA's delay is unreasonable, TDCJ requests the Court to declare that the delay is unlawful and compel FDA to render a final admissibility decision.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action under 28 U.S.C. § 1331, to provide remedies set forth in 5 U.S.C. § 706 and 28 U.S.C. § 2201.

4. Venue is proper in this District under 28 U.S.C. § 1391(e)(1)(B), because a substantial part of the events or omissions giving rise to Plaintiff's claim occurred, and the property that is the subject of this action is situated, in this District. Venue is proper in this District under 28 U.S.C. § 1391(e)(1)(C), because Plaintiff resides in this District.

PARTIES

5. Plaintiff TDCJ is a law enforcement agency of the State of Texas with headquarters in this District, at 861-B IH 45 North, Huntsville, Texas. TDCJ administers correctional facilities within this District and throughout the State of Texas. TDCJ is the sole agency in the State of Texas with the authority and responsibility to administer lawfully-imposed capital sentences through lethal injection. For purposes of this suit, TDCJ represents the interests of the State of Texas.

6. Defendant FDA has federal regulatory authority over the thiopental sodium drugs at issue in this case. Defendant Robert M. Califf is the Commissioner of Food and Drugs and the top official of Defendant FDA. Defendant Califf is named as a defendant in his official capacity as the Commissioner of Food and Drugs. Defendant United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of failure to act, by an agency of the United States, that has affected Plaintiff adversely and will continue to do so unless remedied by this Court.

STATUTORY AND REGULATORY BACKGROUND

FDA's Approval Process for "New Drugs"

7. The Federal Food, Drug, and Cosmetic Act ("FFDCA") establishes a premarket approval process that requires FDA approval before pharmaceuticals known as "new drugs" may be distributed in interstate commerce. 21 U.S.C. § 355(a). In order to obtain FDA approval to market and sell a brand-name "new drug," the sponsoring company must submit a New Drug Application ("NDA"). An NDA must outline and explain the drug's ingredients, the results of clinical tests, the results of animal studies, how the drug behaves in the body, and how the drug is manufactured, processed, and packaged. Before approving an NDA, FDA must evaluate numerous statutorily-defined criteria, including whether the drug is safe and effective for its intended use. *See* 21 U.S.C. §§ 355(b), (d).

8. In order to obtain FDA approval to market and sell a generic "new drug," the sponsoring company typically must submit an Abbreviated New Drug Application ("ANDA"). An ANDA applicant may obtain FDA approval without conducting the full battery of clinical and non-clinical studies required for an NDA. *See generally* 21 U.S.C. § 355(j). An ANDA applicant may rely upon a prior FDA finding of safety and efficacy for the approved brand-name drug that is referred to in the ANDA, provided that the proposed generic drug is the "same" with regard to active ingredients, dosage form, route of administration, strength, and labeling. *Id*. § 355(j)(2)(A)(i), (ii), (iii), and (v).

9. FDA premarket approval requirements apply only to "new drugs" as that term is defined in 21 U.S.C. § 321(p). For FDA to demonstrate that a drug is a "new

drug," the agency must establish that it is (1) not generally recognized by pertinent experts as "safe and effective for use under the conditions prescribed, recommended, or suggested in" the drug's labeling; or (2) a drug that has become so recognized as a result of certain investigations, but which has not, other than in those investigations, been used to a material extent or for a material time under such conditions. 21 U.S.C. § 321(p). The FFDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

10. Determining a drug's "new drug" status based on statements in its labeling is a fundamental foundation of FDA's drug approval regime. A drug may be "generally recognized as safe and effective" for some uses but not for others. *See, e.g.*, 21 C.F.R. § 330.1(c)(2). Labeling statements identify the uses for which approval is required (absent general recognition of safety and effectiveness for that use). The approval standard accordingly parallels the "new drug" standard. FDA bases approval of a brand-name new drug (through an NDA) on adequate and well-controlled investigations of the drug's effectiveness "under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). When it approves an NDA, FDA determines that the brand-name new drug is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *See* 21 U.S.C. §§ 355(d)(1), (d)(5).

11. The approval of a generic version of a brand-name "new drug" is similarly tied fundamentally to conditions of use prescribed, recommended, or suggested in the

labeling. An ANDA must contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved" for the corresponding brand-name drug. 21 U.S.C. § 355(j)(2)(A)(i); *see also* 21 C.F.R. § 314.94(a)(4)(i). For FDA to approve the ANDA, the agency must determine that (absent certain exceptions) "the labeling proposed for the drug is the same as the labeling approved for" the corresponding brand-name drug. 21 U.S.C. § 355(j)(4)(G).

Drugs That May be Lawfully Marketed Without FDA Premarket Approval

12. If a drug is generally recognized by pertinent experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling (and has been used under such conditions to a material extent or for a material time), the drug is not a "new drug" within the meaning of 21 U.S.C. § 321(p). Accordingly, such a drug may be lawfully marketed without prior FDA approval. FDA promulgates monograph regulations defining the conditions under which many such drugs are generally recognized as safe and effective. Numerous drugs are currently marketed lawfully without prior FDA approval, because the drugs comply with these monograph requirements. *See generally* 21 C.F.R. pt. 330.

13. The FFDCA also does not require premarket approval of a drug if it has *no* conditions of use prescribed, recommended, or suggested in a drug's labeling. It is not possible for FDA to establish that such a drug is a "new drug," because there are no conditions of use prescribed, recommended, or suggested in the labeling for the agency to evaluate for general recognition of safety and effectiveness. Because such a drug is not a

"new drug," premarket approval requirements do not apply. If FDA wishes to restrict distribution of an unapproved drug with no conditions of use prescribed, recommended, or suggested in its labeling, the agency does so through other regulatory requirements.

The "Adequate Directions for Use"
Requirement and the Law Enforcement Exemption

14. 21 U.S.C. § 352(f)(1) is one of the provisions that FDA typically relies upon if it wishes to restrict distribution of an unapproved drug with no conditions of use prescribed, recommended, or suggested in its labeling. Section 352(f)(1) states that a drug "shall be deemed to be misbranded . . . unless its labeling bears adequate directions for use." FDA's regulations provide that "[a]dequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. A drug that has no conditions of use prescribed, recommended, or suggested in its labeling generally lacks adequate directions for use, because its labeling omits "[s]tatements of all conditions, purposes, or uses for which such drug is intended." *Id*. § 201.5(a).

15. A drug that is misbranded under section 352(f)(1) because it lacks adequate directions for use in its labeling is subject to a range of enforcement remedies under the FFDCA, including import refusal, seizure, and injunction. 21 U.S.C. §§ 331(a), 332(a), 334(a), 381(a).

16. Section 352(f)(1) authorizes FDA to promulgate regulations exempting drugs from the "adequate directions for use" labeling requirement if that requirement "is not necessary for the protection of the public health." Under this authority FDA has

exempted numerous categories of drugs from the "adequate directions for use" requirement.

17. This case involves one such drug labeling exemption: 21 C.F.R. § 201.125, which governs "[d]rugs for use in teaching, law enforcement, research, and analysis." Section 201.125 applies to prescription drugs as defined in 21 U.S.C. § 353(b)(1)(A). Under section 201.125, a prescription drug is "exempt from [21 U.S.C. § 352(f)(1)] if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing." 21 C.F.R. § 201.125.

18. In this case, the drugs at issue fall within the exemption that applies to drugs "shipped or sold to . . . persons . . . engaged in law enforcement, . . . and [are] to be used only for such . . . law enforcement." 21 C.F.R. § 201.125.

Requirements for Warnings to Protect Patients

19. The FFDCA also requires that patients who use drugs are protected by necessary and adequate labeling warnings. 21 U.S.C. § 352(f)(2) states that a drug "shall be deemed to be misbranded . . . unless its labeling bears . . . such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users."

20. In this case, no labeling warnings are necessary to protect patients, because the drugs at issue will not be used for patient treatment.

FDA's Process for Refusing Admission of Imports Into Domestic Commerce

21. The FFDCA establishes a regime in which FDA and the U.S. Bureau of Customs and Border Protection ("Customs") work together to admit into domestic commerce (or refuse admission of) drugs that are offered for import. In general, Customs has the formal responsibility to police the border (just as it does for all other products offered for import), and FDA provides the substantive expertise necessary to evaluate whether drugs should be admitted into domestic commerce.

22. The FFDCA gives Customs authority to collect samples of drugs offered for import and deliver them to FDA, at FDA's request. 21 U.S.C. § 381(a). In practice, Customs has delegated this authority to FDA, so that FDA is the agency that collects the samples. When FDA decides to collect a sample, FDA detains the drugs by issuing a "hold" order that prevents introduction of the drugs into domestic commerce. The drugs are detained for purposes of the examination described below. 21 C.F.R. § 1.90.

23. The FFDCA gives FDA authority to conduct an "examination" of a sample of imported drugs. 21 U.S.C. § 381(a). The purpose of the examination is for FDA to determine whether it "appears from the examination of such samples" that the agency should refuse the drugs' admission into domestic commerce. *Id*. Section 381(a) allows FDA to refuse admission of a drug into domestic commerce, among other things, if the drug violates the premarket approval requirements of 21 U.S.C. § 355 or the misbranding requirements of 21 U.S.C. § 352.

24. If it "appears from the examination of such samples" of imported drugs that any of the enumerated statutory criteria for refusal of admission have been met (21 U.S.C. § 381(a)), FDA issues a "Notice of Action" order that detains the drugs and prevents their admission into domestic commerce. At the same time, FDA gives the owner or consignee notice and an opportunity for an informal hearing. 21 U.S.C. § 381(a); 21 C.F.R. § 1.94(a). If the owner or consignee persuades the agency that the drugs should not be refused, FDA issues a "Notice of Release" admitting the drugs into domestic commerce. If FDA decides to refuse admission of the drugs, the agency issues a "Notice of Refusal of Admission." "Notices of Release" and "Notices of Refusal of Admission" are "orders" within the meaning of 5 U.S.C. § 551(6) because they are the agency's final disposition in a matter other than rulemaking.

25. Customs enforces FDA's final agency action refusing admission of an import. For most imported drugs, Customs conditionally releases the drugs to the custody of their owner or consignee at the time of importation, provided that the importer posts a bond that would be forfeited if the drugs are not returned to Customs custody when requested. 19 C.F.R. § 113.62. If FDA issues a Notice of Refusal of Admission for such drugs, Customs (under the basic importation bond) enforces FDA's final agency acting by demanding redelivery of the drugs from the owner or consignee, so that Customs can require their export or destruction (with the owner or consignee choosing whether the drugs will be exported or destroyed). 19 C.F.R. § 141.113(c)(3); 21 U.S.C. § 381(a).

26. Under very unusual circumstances, even where the owner or consignee has otherwise complied with the basic importation bond requirements, Customs does not release the drugs to the custody of their owner or consignee at the time of importation and instead transfers the drugs to the custody of FDA pending consideration of their admissibility into domestic commerce. If FDA later issues a Notice of Refusal of Admission for such drugs, Customs enforces FDA's final agency action by requiring their export or destruction (with the owner or consignee choosing whether the drugs will be exported or destroyed). 21 U.S.C. § 381(a).

THE PARTIES' DISPUTE

27. This case arises out of a dispute concerning the importation of a drug (thiopental sodium) by TDCJ solely for a law enforcement use: effectuating lawfully-imposed capital sentences through lethal injection. FDA has delayed more than seventeen months making a final determination on admissibility of that importation.

28. Thiopental sodium is a barbiturate that produces unconsciousness and anesthesia. This effect is well known; the drug has been used for purposes of anesthesia since before the FFDCA was enacted in 1938. Thiopental sodium has been used in hospitals for many decades as a prescription anesthetic. In addition, for many years and in numerous different jurisdictions, thiopental sodium has been used (alone or in combination with other drugs) to impose capital sentences through lethal injection.

29. TDCJ has previously purchased and used thiopental sodium in numerous executions, before it became commercially unavailable to Texas correctional facilities for

that purpose. Through the import at issue in this case, TDCJ is attempting once again to utilize thiopental sodium for purposes of imposing lawful capital sentences.

The Drugs Offered for Import

30. Each vial of drug offered for import by TDCJ and at issue in in this case bears a label identifying the drug as thiopental sodium and containing the legend: "For law enforcement purpose only." There are no statements in the drug's label or labeling prescribing, recommending, suggesting, or otherwise addressing the drug's conditions of use.

The Notification Procedures Followed by TDCJ Prior to Importation

31. On June 8, 2015, TDCJ filed a Controlled Substance Import Declaration with DEA explaining that TDCJ proposed to import thiopental sodium intended for law enforcement purposes. Consistent with applicable regulations, TDCJ is registered with the Drug Enforcement Administration as an importer of this drug. *See* 21 U.S.C. § 957(a)(1).

32. After a number of communications between DEA and TDCJ, DEA issued a written response on July 13, 2015, stating that DEA had notified Customs and FDA of the upcoming importation. According to DEA, FDA had contacted DEA and asserted that it was illegal to import the drug, because it appeared to be misbranded or in violation of the new drug approval requirements of 21 U.S.C. § 355.

33. On July 24, 2015, the foreign distributor shipped 1000 vials of thiopental sodium via air freight to TDCJ. The shipment arrived at the Houston, Texas international airport the same day.

FDA's Detention of the Thiopental Sodium

34. FDA examined the goods by July 29, 2015. Following an initial detention of the goods by FDA that was rescinded without explanation, Customs detained the goods on August 5, 2015. The Customs Detention Notice indicated that the goods were detained at the request of FDA " . . . for FDA [admissibility] and further analysis."

35. On August 24, 2015, FDA issued a new notice of detention. The notice of detention alleged that the detained shipment of thiopental sodium appears to: "(1) lack adequate directions for use" in violation of 21 U.S.C. § 352(f)(1); "(2) lack adequate warning against use in pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to protect users" in violation of 21 U.S.C. § 352(f)(2); and "(3) be a new drug without an approved new drug application" in violation of 21 U.S.C. § 355(a).

The Informal Hearing on Admissibility

36. On October 23, 2015, TDCJ filed a written submission with FDA presenting written testimony, argument, and exhibits in connection with the informal hearing on refusal of admission required by 21 C.F.R. § 1.94.

37. TDCJ's October 23 submission explained that the drugs do not violate the "adequate directions for use" requirement of 21 U.S.C. § 352(f)(1), because the drugs fall within the "law enforcement" exemption to that requirement established by FDA regulation (21 C.F.R. § 201.125).

38. TDCJ's October 23 submission also explained that the drugs do not violate the warning requirement of 21 U.S.C. § 352(f)(2), because that requirement does not

apply under circumstances where there are no patients using the drugs. In the alternative, TDCJ argued that even if the requirement did apply, the "law enforcement purpose only" legend on the drugs' label satisfied the requirement.

39. Finally, TDCJ's October 23 submission explained that the drugs at issue do not violate the drug approval requirements of 21 U.S.C. § 355(a), because those requirements only apply to "new drugs," and the thiopental sodium at issue is not a "new drug," because there are no conditions of use prescribed, recommended, or suggested in its labeling.

40. On April 15, 2016, FDA issued a Tentative Decision on admissibility of the drugs. The Tentative Decision stated that the agency had tentatively determined that the thiopental sodium appeared to be an unapproved new drug that violated 21 U.S.C. § 355(a) and appeared to be a misbranded drug that violated 21 U.S.C. §§ 352(f)(1) and 352(f)(2).

41. TDCJ responded to FDA's Tentative Decision on May 20, 2016, explaining again that the thiopental sodium does not violate any of the three statutory provisions at issue.

FDA's Failure to Issue a Final Decision
on the Admission of the Thiopental Sodium into Domestic Commerce

42. As of the date of this Complaint, FDA has failed to issue a Final Decision regarding admissibility of the thiopental sodium that TDCJ has offered for import into domestic commerce.

43. The thiopental sodium at issue currently remains detained in the custody of FDA within this District.

44. The issues presented for resolution by FDA, concerning admissibility of the drugs at issue, are pure questions of law (involving a small administrative record) that can be resolved without a substantial investment of agency resources. On information and belief, FDA's failure to issue a Final Decision regarding the admissibility of the drugs is not legitimately attributable to limitations in agency resources.

45. FDA's failure to issue a Final Decision regarding admissibility of the drugs directly harms, and unfairly prejudices, TDCJ by preventing TDCJ from utilizing the drugs (which TDCJ has purchased and owns) for lethal injection.

COUNT I
Agency Action Unlawfully Withheld
or Unreasonably Delayed in Violation of 5 U.S.C. § 706(1)

46. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 45 above.

47. FDA's process for determining admissibility of the drugs at issue is an "adjudication" within the meaning of 5 U.S.C. § 551(7), because it is an agency process for formulation of an "order" within the meaning of 5 U.S.C. § 551(6). FDA's Final Decision on the admissibility of the drugs at issue would be an "order" within the meaning of 5 U.S.C. § 551(6) because it would be the final disposition of FDA in a matter other than rulemaking. FDA's Final Decision on the admissibility of the drugs at issue also would be an "agency action" within the meaning of 5 U.S.C. § 551(13) and a "final agency action" within the meaning of 5 U.S.C. § 704.

48. 21 U.S.C. § 381(a) imposes a mandatory duty on FDA to issue a Final Decision on the admissibility of the drugs at issue.

49. 5 U.S.C. § 555(b) imposes a mandatory duty on FDA to issue a Final Decision on admissibility of the drugs at issue within a reasonable time.

50. By failing to issue a Final Decision on admissibility of the drugs more than seventeen months after FDA ordered the drugs' detention for potential refusal of their admission into domestic commerce, and more than sixteen months after FDA identified the three specific legal grounds for the detention and potential refusal of admission, FDA has failed to issue the Final Decision within a reasonable time as required by 5 U.S.C. § 555(b). For the same reason, FDA's failure to issue the Final Decision is an agency action unlawfully withheld or unreasonably delayed within the meaning of 5 U.S.C. § 706(1).

51. Under 5 U.S.C. § 706(1), the Court should issue an injunction compelling FDA to issue the Final Decision on admissibility of the drugs.

52. Under 28 U.S.C. § 2201, this Court should declare that FDA's failure to render a Final Decision on admissibility of the drugs is an agency action unlawfully withheld or unreasonably delayed within the meaning of 5 U.S.C. § 706(1).

53. TDCJ has no other adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

PRAYER FOR RELIEF

Plaintiff respectfully requests the Court to grant the following relief:

I. Issue a mandatory injunction compelling FDA to issue the Final Decision on admissibility of the thiopental sodium offered for import;

II. Issue a declaratory judgment declaring that FDA has unlawfully withheld or unreasonably delayed issuing the Final Decision on admissibility of the imported thiopental sodium offered for import; and

III. Award such other relief as this Court deems just and proper.

Respectfully submitted,

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