Consistent with the terms of the Court's May 22, 2017 scheduling order, the record has been redacted for all information that plaintiff, Texas Department of Criminal Justice (Texas), has identified as confidential. In addition, Defendants have also redacted information that the drug's supplier and broker have separately advised the agency they consider confidential and private, as well as information the agency itself generally treats as confidential. This information has been redacted pending final FDA's review of confidentiality claims, and our filing of the record with these redactions does not necessarily reflect our agreement with all of the claims of confidentiality Defendants have received. Defendants explicitly reserve the right to make an independent determination regarding the proper scope of redactions at a later time. Should we identify any of Texas's redactions that are over-broad or otherwise improper, we will work with Texas's counsel to revise the redactions in the record.

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: [redacted]

Notice Number: 6
April 21, 2017

Filer:
[redacted]

Attention: [redacted]
Broker Box: [redacted]

>

<

Port of Entry: 5309, Houston Intercontinental Airport, Houston, TX
Carrier: [redacted];
Date Received: July 27, 2015
Arrival Date: July 24, 2015

Importer of Record: [redacted]
Consignee: [redacted]

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line	ACS/FDA	Product Description	Quantity	Current Status
*	1	1/1	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	1000 PCS	Refuse 04-21-2017

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a localtion within the metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
1/1	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)

Refused : 1,000 PCS

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article appears to lack adequate directions for use.

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application.

For the District Director of Customs:

Rosa L. Santos, Compliance Officer (Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5269
(214) 253-5316 (FAX)
ROSA.SANTOS@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

Houston CBP Office
2350 North Sam Houston Pkwy East
Suite 1000
Houston/Galveston, TX 77032

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: RLS

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: [redacted]

Notice Number: 6
April 21, 2017

Importer:
[redacted]

>

<

Port of Entry: 5309, Houston Intercontinental Airport, Houston, TX
Carrier: [redacted];
Date Received: July 27, 2015
Arrival Date: July 24, 2015

Filer of Record: [redacted]
Consignee: [redacted]

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line	ACS/FDA	Product Description	Quantity	Current Status
*	1	1/1	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	1000 PCS	Refuse 04-21-2017

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a localtion within the metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
1/1	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)

Refused : 1,000 PCS

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article appears to lack adequate directions for use.

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application.

For the District Director of Customs:

Rosa L. Santos, Compliance Officer (Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5269
(214) 253-5316 (FAX)
ROSA.SANTOS@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

Houston CBP Office
2350 North Sam Houston Pkwy East
Suite 1000
Houston/Galveston, TX 77032

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: RLS

April 20, 2017

VIA ELECTRONIC MAIL

[redacted]

Re: Entry No. [redacted]/Thiopental Sodium[1]
imported by the [redacted]

Dear [redacted]:

I am writing in response to your May 20, 2016, letter on behalf of the [redacted], which responded to the Food and Drug Administration's (FDA) letter of April 15, 2016, setting forth the Agency's tentative decision regarding the admissibility of Entry Number [redacted]. That entry consists of 1,000 one-gram vials of a drug product labeled as [redacted] (Thiopental Sodium USP), which were offered for importation by [redacted] on July 24, 2015. [redacted] has notified FDA that it is importing the detained drugs for use in administering lethal injection.

As we noted in our April 15 letter, for decades, FDA generally exercised enforcement discretion regarding sodium thiopental used for capital punishment purposes. Ref. 7 at 5[2]; *see Heckler v. Chaney*, 470 U.S. 821, 835-36 (1985); *see also* Ref. 1, Ex. 14 at 1-2 (2010 FDA statement explaining that FDA was exercising enforcement discretion). In February 2011, a group of prisoners on death row in Arizona, California, and Tennessee filed suit challenging FDA's release of imported thiopental sodium for use as an anesthetic as part of lethal injection. The plaintiffs argued that FDA acted contrary to law, in an arbitrary and capricious manner, and in abuse of its discretion when the Agency allowed shipments of the misbranded and unapproved new drug thiopental to be imported into the U.S. In March 2012, the United States District Court for the District of Columbia granted the plaintiffs' motion for summary judgment. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd in part, rev'd in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) ("*Beaty/Cook*"). The District Court's March 2012 order, as modified in June 2012, permanently enjoins FDA from "permitting the entry of, or releasing any future

[1] Thiopental sodium is also known as sodium thiopental. In this letter, "thiopental sodium" and "sodium thiopental" are used interchangeably.

[2] To avoid confusion, we have maintained the reference numbers from FDA's tentative decision in this final decision. As a result, FDA's letter dated April 15, 2016 is listed as Reference 7.

shipments of, foreign manufactured thiopental that appears to be misbranded or in violation of 21 U.S.C. [§] 355 [as an unapproved new drug]."

[redacted] contends that *Beaty/Cook* was "wrongly decided," Ref. 8 at 13, but FDA is bound by the terms of the order issued by the District Court in that case. That order requires the Agency to refuse admission to import entries of foreign-manufactured sodium thiopental if the sodium thiopental appears to be an unapproved new drug or a misbranded drug. *See* Refs. 4&5. Therefore, we disagree with [redacted] contention that FDA has room to exercise discretion regarding the foreign-manufactured sodium thiopental [redacted] wishes to import.

We have carefully considered all of the arguments and information in the May 20, 2016, letter, as well as [redacted] previous submissions on behalf of the detained drugs. Based on a review of the entire record in this matter, for the reasons detailed below, we have concluded that the detained drugs in Entry No. [redacted] appear to be unapproved new drugs and misbranded drugs within the meaning of 21 U.S.C. §§ 352(f)(1) & 355(a).

In reaching this conclusion, we reject [redacted] assertion in its May 20 letter that FDA's "interpretations amount to a federal ban on use of thiopental sodium for lethal injection." *See* Ref. 8 at 10-11. Nor is it FDA's purpose or intention to interfere with lawfully conducted capital punishment carried out by lethal injection. As noted below, FDA's determination that the detained drugs cannot be imported under the *Beaty/Cook* order because they appear to be unapproved new drugs and misbranded drugs has no effect on importation of foreign-manufactured sodium thiopental that has an FDA approval and is properly labeled and, thus, is not in violation of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Nor does it require FDA to take action against domestic distribution of sodium thiopental, whether or not it is unapproved or misbranded.

I. Background

A. Statutory Framework

Under the FD&C Act, the Secretary of Health and Human Services may request "samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States . . . ." 21 U.S.C. § 381(a). The FD&C Act further provides that "[i]f it appears from the examination of such samples or otherwise that . . . (3) such article is adulterated, misbranded, or in violation of [21 U.S.C. § 355], . . . then such article shall be refused admission, except as provided in" 21 U.S.C. § 381(b). 21 U.S.C. § 381(a)(3) (emphasis added).

The FD&C Act thus does not require FDA to find that an article that is offered for importation is actually adulterated, misbranded, or in violation of 21 U.S.C. § 355 in order to refuse admission to that article; rather, the Agency has "broad authority to prohibit import" of any article that "appears" to violate the FD&C Act. *Continental Seafoods, Inc. v. Schweiker,* 674 F.2d 38, 43 (D.C. Cir. 1982) (emphasis added); *see Goodwin v. United States,* 371 F. Supp. 433, 436 (S.D. Cal. 1972); *see also United States v. Food, 2998 Cases,* 64 F.3d 984, 992 (5th Cir.

1995) (FDA "can pursue the administrative procedures of § 381 and simply require reexportation of the goods," even where "the government lacks the ability to prove a violation of the [FD&C Act] by a preponderance of the evidence."); *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967), *aff'd*, 405 F.2d 1189 (9th Cir. 1968); *K&K Merch. Group, Inc. v. Shalala*, No. 95Civl0082, 1996 U.S. Dist. LEXIS 4880, *22-23 (S.D.N.Y. 1996) (noting "the wide discretionary power FDA enjoys to determine the factors regarding its decision to grant or refuse admission of imported goods").[3] If an article is refused admission, it must be exported or destroyed within ninety days. 21 U.S.C. § 381(a).

B. The Proceedings

On or about July 24, 2015, [redacted] offered for import 1,000 one-gram vials of a product labeled as [redacted] (Thiopental Sodium USP). On August 5, 2015, U.S. Customs and Border Protection (CBP) detained the shipment. Ref. 1, Ex. 10 at 1. On August 18, 2015, [redacted] through counsel, requested that FDA instruct CBP to lift the detention and let the product proceed to destination. Ref. 1, Ex. 11 at 1-2. By letter dated August 24, 2015, FDA denied that request. Ref. 1, Ex. 12.

On August 24, 2015, FDA issued a "Notice of FDA Action" explaining that Entry [redacted] was detained and subject to refusal of admission based on the following: the product appeared to be misbranded under 21 U.S.C. § 352(f)(1) because its labeling appeared to lack adequate directions for use; the product appeared to be misbranded under 21 U.S.C. § 352(f)(2) because its labeling appeared to lack adequate warning against use in a 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; and the product appeared to be a new drug that lacked an approved new drug application as required by 21 U.S.C. § 355. Ref. 1, Ex. 1 at 1-2. The notice, which was sent to [redacted] as the listed consignee of the entry, specified that testimony regarding the admissibility of the entry must be submitted to FDA by September 14, 2015. *Id.* at 2.

On September 10, 2015, [redacted] through counsel, requested an extension to respond to the Notice of FDA Action. On the same day, FDA granted an extension until October 23, 2015. *See* Ref. 1, Ex. 1 at 3.

[3] As part of its assertion that "no deference is due" to "any of the regulatory or statutory interpretations" in FDA's decision, [redacted] appears to argue that the only questions the Agency is called upon to resolve in this matter are "pure questions of law" to which section 381(a)'s "appearance" standard does not apply. *See* Ref. 8 at 8-9. Although we agree with [redacted] that some of the facts in this matter (e.g., that the detained products are drugs and they lack an approved application) are not in dispute, this matter does not present only undisputed facts and purely legal questions. For example, it involves FDA's determination regarding what conditions are suggested in the detained drugs' labeling.

On October 23, 2015, [redacted] through counsel, submitted written testimony regarding the detained drugs. Ref. 1. The letter explained [redacted] position that the detained drugs should not be refused admission and requested an in-person hearing with appropriate FDA personnel. *Id.* at 1. In submitting the written testimony, [redacted] also requested that FDA transfer the matter to the Director, Office of Enforcement and Import Operations ("OEIO") or his designee, who would serve as the hearing officer for this detention. In a telephone discussion on December 10, 2015, FDA counsel informed you that the Agency did not intend to transfer the matter to OEIO. In a subsequent telephone discussion with FDA counsel on February 2, 2016, FDA asked whether [redacted] still wanted to present information regarding the detained drugs in person. Subsequently, in a series of phone communications on March 11, 2016, you stated that [redacted] concurred with an approach in which FDA would send a written, tentative decision and provide [redacted] with the opportunity to respond before reaching a final decision.

The Agency set forth its tentative conclusions in a letter dated April 15, 2016. In that letter, the Agency provided [redacted] with the opportunity to respond to the tentative conclusions, either in writing or in a meeting, and assured [redacted] that the Agency would take any information provided in response to the April 15 letter into account in reaching a final conclusion regarding the admissibility of the detained drugs. The letter specified that additional testimony regarding the admissibility of the entry must be submitted within 20 calendar days of receipt. Ref. 7 at 15. After receiving the letter, [redacted] through counsel, requested an extension to May 20, which FDA granted. *See* Ref. 9 at 1. [redacted] responded to FDA's tentative conclusions in the May 20 letter, which included five attachments.

C. <u>The Detained Drugs</u>

Entry No. [redacted] consists of 1,000 one-gram vials of [redacted] (Thiopental Sodium USP). Ref. 2 at 2. The labels on the vials of thiopental sodium state:

> 1 gm
> [redacted]
> Thiopental Sodium USP
> Sterile
>
> Rx Only CIII
> [redacted]
> manufacturer and distribution services
> For law enforcement purpose only.
>
> [redacted]
> Code No: [redacted]
> Batch No.: [redacted]
> Mfg. Date: 06/2015
> Exp. Date: 05/2017

Marketed by:
[redacted]

Ref. 3 at 23-24. The label bears no other information. *Id.*; Ref. 1, Ex. 3 at 1. *See also* Ref. 1 at 2 ("Aside from the information printed on the label . . . , there is no additional labeling accompanying the drug specifying information about its properties or uses."). Stickers on the outside of each box of vials repeat the information on the vial label. Ref. 3 at 43. The boxes contain no package inserts, leaflets, or other materials with directions for use or warnings about the use of the thiopental sodium. An outside box label lists the [redacted] as the consignee. *Id.* at 26-27. In addition to the label listing "[redacted]," the certificate of analysis in the entry documentation for the thiopental sodium states that it is "[m]anufactured by" "[redacted]." Ref. 2 at 4.

Thiopental sodium is a barbiturate that depresses nervous system function to render a person unconscious, Ref. 1, Ex. 15 at 3-5 (Goodman and Gilman's, *The Pharmacological Basis of Therapeutics*, 11th ed., at 347-49), which can cause death in a large enough dose. Ref. 1, Ex. 16 at 10 (History of Barbiturates, at 338). As classified among anesthetics, it is an ultrashort-acting agent. *Id.* Like other anesthetics, its effects vary based on patient-specific factors such as weight and age, and its use must be calibrated. Ref. 1, Ex. 15 at 3-5 (Goodman and Gilman's, at 347-349). In addition, thiopental sodium can produce allergic reactions in some individuals. *Id.* at 6 (Goodman and Gilman's, at 350). It is a schedule III controlled substance. Ref. 1 at 2; Ref. 1, Ex. 3.

[redacted] agrees that the detained thiopental sodium is a drug within the meaning of the FD&C Act and does not dispute that the detained drugs are not the subject of an approved new drug application, an approved abbreviated new drug application [redacted] In fact, there are no FDA-approved sodium thiopental products that are currently being marketed for any use.[5]

[4] In its initial submission, [redacted] acknowledged that the thiopental sodium is a drug, because it is intended to affect the structure and function of the body. Ref. 1 at 5 (discussing 21 U.S.C. § 321(g)(1)(C) and stating that "[t]his second definition applies here"). Moreover, in the May 20 letter, [redacted] repeatedly refers to the detained thiopental sodium as "detained drugs." *See* Ref. 8 *passim*.

[5] Previously, for example, Abbott Laboratories held an NDA (NDA 11-679) for Pentothal Sodium (thiopental sodium) Suspension. FDA withdrew that NDA in 2001 at Abbott's request because the drug was no longer marketed. *See* 66 Fed. Reg. 43017 (Aug. 16, 2001). NDA 11-679 remains listed in FDA's Orange Book, meaning that FDA has not determined that Abbott's thiopental sodium drug product was withdrawn for safety or efficacy reasons. Unless FDA makes such a determination, NDA 11-679 can be cited in applications for approval using the abbreviated pathways established in the FD&C Act.

[redacted] is importing the detained drugs for use in administering lethal injection. Ref. 1, Ex. 13 ¶ 5. Specifically, [redacted] states that in the last decade it has "executed 182 offenders by administering lethal injection" and "will continue to execute additional offenders through lethal injection, on a recurring and continuing basis, for the foreseeable future." Ref. 8, Attch. E. [redacted] "has previously purchased and used thiopental sodium in numerous executions," *id.*; *see also* Ref. 1, Ex. 13 ¶ 5. [redacted] "current execution protocol" mandates use of pentobarbital, *see* Ref. 8, Attch. D; however, [redacted] is "preparing for a contingency in which [redacted] may once again utilize thiopental sodium in executions and will do so when necessary if FDA releases its hold on" the detained drugs. Ref. 8, Attch. E; Ref. 1, Ex. 13 ¶ 5.

II. FDA Is Bound by Judicial Order to Refuse Entry to the Detained Sodium Thiopental If It Appears to be an Unapproved New Drug or Misbranded

As noted above, the District Court's March 2012 order, as modified in June 2012, permanently enjoins FDA from "permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental that appears to be misbranded or in violation of 21 U.S.C. [§] 355 [as an unapproved new drug]." Ref. 4 at 1-2; Ref. 5 at 2. We interpret the order to mean what it says: namely, that FDA is required to refuse entry to thiopental produced abroad when it appears that the thiopental is misbranded or an unapproved new drug.

[redacted] argues that, even if FDA concludes that the detained drugs appear to be unapproved new drugs and/or misbranded drugs, the Agency can and should exercise enforcement discretion to admit Entry [redacted]. Ref. 8 at 13. In particular, [redacted] contends that the *Beaty/Cook* decision is distinguishable from the present circumstances because the parties to that case stipulated that the drugs at issue were unapproved new drugs and misbranded. But the question here is not whether this case is similar to *Beaty/Cook* or whether *Beaty/Cook* is persuasive authority that FDA should follow. Rather, the question is whether the terms of the *Beaty/Cook* order cover the circumstances presented in this case. So long as the import entry at issue is "foreign manufactured thiopental that appears to be misbranded or in violation of 21 U.S.C. [§] 355," the District Court's order constrains FDA's enforcement discretion.

Similarly, we reject [redacted] argument that FDA should have discretion to admit the thiopental because *Beaty/Cook* was (in [redacted] view) "wrongly decided." Ref. 8 at 13. [redacted] argument on this ground is effectively a collateral attack on the District Court's order. But the *Beaty/Cook* decision cannot be subjected to collateral attack through this proceeding; the order could only be modified through further judicial action. Until the Court lifts or modifies its injunction order, that order continues to govern FDA's review of thiopental import entries. *See, e.g., GTE Sylvania, Inc. v. Consumers Union of the U.S.*, 445 U.S. 375, 386 (1980) ("persons subject to an injunctive order issued by a court with jurisdiction are expected to obey that decree until it is modified or reversed . . . .").

Because, as discussed below, we conclude that the thiopental at issue here appears to be a misbranded and unapproved new drug, under the injunction order, FDA is without discretion to

permit entry to the foreign-manufactured sodium thiopental [redacted] wishes to import. Consistent with the District Court's order, FDA must refuse entry of this thiopental into the United States.

III. The Detained Thiopental Sodium Appears To Be An Unapproved New Drug

In the April 15 letter, FDA tentatively concluded that the labeling of the detained thiopental sodium suggests the conditions under which it will be used: for lethal injection. [redacted] challenges that tentative conclusion on several grounds. First, [redacted] argues that although FDA may look beyond a product's labeling to determine "whether an article is a 'drug' in the first place . . . based on [its] intended use," the Agency may consider only statements in a drug's labeling to determine whether the drug is a "new drug" under 21 U.S.C. § 321(p). *See* Ref. 8 at 6. Based on this assertion, [redacted] contends that the Agency's tentative conclusion that the detained drugs are new drugs is "erroneous" because the Agency reached its conclusion by relying "primarily on information that is not labeling . . . ." *See id.* (emphasis in original). Second, [redacted] argues that FDA erred in concluding that the labeling of the detained drugs "suggest[s] any condition of use." *Id.* at 7. Third, [redacted] claims that FDA had "no basis for concluding that the detained drugs are not generally accepted [sic] as safe and effective for any use simply because FDA could not find scientific literature documenting studies with this particular distributor's product." *See id.* at 8. We address each of these arguments below.

A. The Meaning of "Conditions . . . Suggested in the Labeling"

In this matter, FDA must determine whether a detained drug that is not approved for any use appears to be a "new drug" as defined in 21 U.S.C. § 321(p). Before turning to [redacted] specific arguments, we begin by addressing the meaning of "suggested" in this inquiry.

As discussed in greater detail below, under the FD&C Act, a "drug" is a "new drug" unless, among other things, it is generally recognized among qualified experts as being "safe and effective for use under the conditions prescribed, recommended, or suggested in [its] labeling." *See* 21 U.S.C. § 321(p)(1) (emphasis added). In this proceeding, [redacted] has equated the phrase "prescribed, recommended, or suggested" with the conditions being "stated" or "specified" in the labeling. For example, in the October 23, 2015, letter, [redacted] argued, "[f]or FDA to establish that a drug is a 'new drug,' the agency must demonstrate that the drug is not generally recognized as safe and effective with respect to specific conditions of use stated in the labeling. When no conditions for use are so specified, it is not possible for FDA to establish that a drug is a 'new drug.'" Ref. 1 at 7 (emphasis added). In its May 20 letter, [redacted] contends that the "plain meaning of the term 'suggested' is 'proposed.'" Ref. 8 at 7 n.10.

The three terms "prescribed," "recommended," and "suggested" each must be given an independent, non-superfluous meaning. According to Webster's New International Dictionary

Second Edition Unabridged (G&C Merriam Co. 1940)[6] (Ref. 10), prescribe means "[t]o lay down authoritatively as a guide, direction, or rule of action" and, as used in medicine, "[t]o direct, designate, or order the use of, as a remedy; as, the doctor *prescribed* medicine." *Id.* at 1 (italics in original). "Recommend" in turn is defined in part as "[t]o commend, or bring forward explicitly, as meriting consideration, acceptance, adoption, election, or the like." *Id.* at 2 (emphasis added).

By comparison, the first definition of "suggest" is "[t]o put (something) into one's mind; to arouse or awaken, often by indirect means, the thought or feeling of, the desire for, the temptation to commit, the will to do, or the like; as, plays that harm by *suggesting* evil; now, often, to propose tentatively; to mention as a hint, a possible explanation or course, etc.; as, to *suggest* a walk in the country, a moratorium; to *suggest* that a change of government is necessary." *See* Ref. 10 at 3 (italics in original, emphasis added). Thus, "suggest" is not limited to things that are explicitly stated, specified, or proposed, as [redacted] contends. "Suggested" has a broader meaning, and something can be "suggested" even if only proposed or hinted at indirectly.

This broader meaning of "suggested" is confirmed by Congress's inclusion of "suggested" following "prescribed" and "recommended." Having already covered conditions of use that are either "prescribed" or "recommended" in the labeling, Congress's inclusion of "suggested" must mean that it applies to situations where the conditions for use are not "la[id] down authoritatively," "direct[ed]," or "commend[ed] . . . explicitly." Thus, because no indications for use are explicitly "prescribed" or "recommended" in the labeling of the detained drugs, it is necessary to consider here what is "suggested" in the drugs' labeling.

B. Statements on the Label of the Detained Sodium Thiopental Suggest Its Use for Lethal Injection

[redacted] contends that FDA may consider only statements in a drug's labeling[7] in determining whether the drug is a "new drug" under 21 U.S.C. § 321(p). *See* Ref. 8 at 6. Based on this assertion, [redacted] argues that the Agency's tentative conclusion that the detained drugs are new drugs is "erroneous" because the Agency based its conclusion "primarily on information that is not labeling . . . ." *See id.* (emphasis in original).[8] We disagree.

---

[6] *See, e.g., Taniguchi v. Kan Pacific Saipan, Ltd.*, 566 U.S. 560, 566-67 (2012) (explaining "When a term goes undefined in a statute, we give the term its ordinary meaning," and considering dictionaries contemporaneous to the regulatory enactment).

[7] As used in the FD&C Act, "label" means "a display of written, printed, or graphic matter upon the immediate container of any article . . . ." 21 U.S.C. § 321(k) (emphasis added). "Labeling" means "all labels and other written, printed, or graphic matter" that is either "upon any article or any of its containers or wrappers" or "accompanying such article." 21 U.S.C. § 321(m).

[8] [redacted] position appears to be that an importer can avoid having a drug that is not approved for any use classified as a "new drug" – and thereby bypass entirely the premarket approval scheme for new drugs mandated by Congress – simply by removing from the drug's labeling any explicit

Four statements appear on the labels of the detained drugs: "Thiopental Sodium USP," "Sterile," "Rx only," and "For law enforcement purpose only." Ref. 3 at 23-24; Ref. 1, Ex. 3 at 1. These statements are indisputably "labeling" because the drugs' labels are part of their "labeling." 21 U.S.C. § 321(m). Taken together, these four statements suggest the conditions under which this unapproved drug will be used: for lethal injection. "Rx only" makes clear that the detained drugs are prescription drugs,[9] meaning that due to their "toxicity or other potentiality for harmful effect, or the method of [their] use, or the collateral measures necessary to [their] use, [they are] not safe for use except under the supervision of a" licensed practitioner. *See, e.g.*, 21 U.S.C. § 353(b)(1)(A). "Sterile" on the label of this single-glass-vial drug suggests that the drugs are likely to be administered by injection, where sterility is critical.

As [redacted] has acknowledged, there are several well-known uses of thiopental sodium. *See* Ref. 8 at 7. Currently, one of the best-known uses of thiopental sodium is for lethal injection, most often for anesthesia in multi-drug protocols, but sometimes as the lethal agent itself. [10] Indeed, sodium thiopental has been described as "the key drug in the three drug protocol used in most executions since lethal injection began in 1982," *see* Owen Dyer, *The Slow*

---

description of the purposes for which it is to be used, while at the same time submitting sworn testimony stating unequivocally the purpose for which that very drug will be used. We do not agree that [redacted] position is correct, but it is not necessary to address it because the labeling of these detained drugs does in fact suggest their conditions of use.

[9] In fact, if the detained drugs are not prescription drugs despite being labeled as such, they are misbranded. *See* 21 U.S.C. § 353(b)(4)(B) (a drug that is not a prescription drug "shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol" Rx only).

[10] *See, e.g.*, *Glossip v. Gross*, 135 S. Ct. 2726, 2732 (2015) ("By 2008, at least 30 of the 36 States that used lethal injection employed" a "three-drug protocol" for lethal injection that included sodium thiopental); *Baze v. Rees*, 553 U.S. 35, 53 (2008) ("Thirty States, as well as the Federal Government, use a series of sodium thiopental, pancuronium bromide, and potassium chloride, in varying amounts."); *Cook*, 733 F.3d at 4 (noting that when the complaint was filed in that case, the states in which the plaintiffs had been sentenced to death "and many others executed prisoners by injecting them with a sequence of three drugs" that included sodium thiopental); Death Penalty Information Center, *State by State Lethal Injection*, http://www.deathpenaltyinfo.org/state-lethal-injection (describing States' use of thiopental sodium in both three-drug and single-drug protocols); Jennifer Horne, *Lethal Injection Drug Shortage*, COUNCIL OF STATE GOVERNMENTS E-NEWSLETTER (Feb. 17, 2011), http://www.csg.org/pubs/capitolideas/enews/issue65_4.aspx; Emma Marris, *Death-row drug dilemma*, NATURE (Jan. 27, 2011) (available at http://www.nature.com/news/2011/110121/full/news.2011.53.html); Jennifer Sullivan, *Killer on Death Row 16 ½ Years is Executed*, Seattle Times (Sept. 10, 2010) (available at http://www.seattletimes.com/ seattle-news/killer-on-death-row-16-years-is-executed).

Death of Lethal Injection, 348 BMJ 2670 (2014), and was used by Texas as part of a three-drug combination for many years.[11]

[redacted] does not dispute that this is a widely-recognized use of the drug, but notes that "thiopental sodium may be used for a variety of different purposes other than lethal injection." Ref. 8 at 7. In particular, [redacted] has asserted that "[t]he standard reference source for pharmacology indicates that sodium thiopental is a barbiturate that produces unconsciousness and anesthesia" and that "[t]his effect is well known; the drug has been used for purposes of anesthesia since before the [FD&C Act] was enacted in 1938." Ref. 1 at 4 n.2.

Because there are possible purposes for sodium thiopental other than use in lethal injection, [redacted] contends "the drug's name does not suggest any particular condition of use." Ref. 8 at 7. But a drug must be GRAS/E for all of the conditions of use suggested in its labeling,[12] and, as discussed below, the detained sodium thiopental is not GRAS/E under *any* conditions of use. In any event, here, the fourth statement on the detained drugs' label—"For law enforcement purpose only," in combination with the name of the drug and other statements, "suggests" that the drug is for use in lethal injection. [redacted] implicitly acknowledges as much when it argues, "The 'law enforcement purpose only' legend . . . provides a warning not to use the product for any medical purpose . . . ." *Id.* (emphasis added). Because, as [redacted] notes, the "law enforcement purpose only" legend conveys that the drugs are not to be used for any "medical purpose" – that is, not for their anesthetic or barbiturate effects apart from lethal injection – we conclude that the statements on the labels of these unapproved drugs collectively suggest (i.e., propose or hint at indirectly) use of the detained drugs in lethal injection.

As noted in the tentative decision, the Agency's interpretation of the detained drug's use is confirmed by [redacted] submissions. *See, e.g.*, Ref. 8, Attch. D at 1 ("[redacted] execution protocol currently requires the use of pentobarbital. However . . . [redacted] considers alternatives to pentobarbital, including thiopental sodium, as a contingency should [redacted] find pentobarbital unavailable."); Ref. 8, Attch. E at 1 ("[redacted] is preparing for a contingency in which [redacted] may

[11] Michael Graczyk, *Execution Drug Cost Quadruples for Texas Prisons*, USA Today (Aug. 15, 2014) (Texas used "three-drug combination of sodium thiopental, pancuronium bromide and potassium chloride" until [redacted]. stopped production of sodium thiopental) (available at https://www.usatoday.com/story/news/local/texas/2014/08/15/texas-execution-drug-costs/14115595/); *Texas May Soon Change the Way it Executes Prisoners,* Dallas Morning News (Feb. 3, 2011) (sodium thiopental was "one of three drugs that Texas uses to administer lethal injections" until it was in shortage) (available at http://www.dallasnews.com/news/texas/2011/02/03/texas-may-soon-change-the-way-it-executes-prisoners); *see also* Ref. 1, Ex. 13 ¶ 5 ([redacted] "has previously purchased and used thiopental sodium in numerous executions").

[12] *United States v. An Article of Drug... Neo-Terramycin Soluble Powder Concentrate*, 540 F. Supp. 363, 379 (N.D. Tex. 1982) ("a finding that a drug is not generally recognized as effective for one or more of the label claims would result in a determination that the product is a new drug, even if it is assumed that it is generally recognized as effective for the remaining label claims."); *see also United States v. An Article of Drug . . . Quinaglute,* 268 F. Supp. 245, 248-49 (E.D. Mo. 1967).

once again utilize thiopental sodium in executions and will do so when necessary if FDA releases its hold on the purchased thiopental sodium that is being detained by FDA."); Ref. 1, Ex. 13 ¶ 5 ("[redacted] has previously purchased and used thiopental sodium in numerous executions before it became commercially unavailable to correctional facilities for such purpose" and "I am attempting to once again utilize thiopental sodium in executions and will do so when necessary if the FDA releases its hold on the purchased thiopental sodium."); Ref. 1 at 4.

We do not agree with [redacted] contention that the Agency is relying "primarily on information that is not labeling to conclude that [the detained drugs] are 'new drugs.'" Ref. 8 at 6 (emphasis in original). In particular, [redacted] points to the tentative conclusion's citation of two court cases and several articles. FDA did not cite those materials as "labeling" for the detained drugs. Rather, the Agency cited the court cases and articles simply to illustrate that sodium thiopental's use in lethal injection is well known. *See* Ref. 7 at 7. Similarly, FDA did not, and does not, rely on [redacted] supporting affidavits as part of the Agency's determination of the "new drug" status of the detained drugs. Instead, we simply note that the interpretation of the labeling of the detained drugs as suggesting use of those drugs in lethal injection is "confirmed by" [redacted] own statements regarding how it plans to use the drugs.

C. The FD&C Act's Definition of "New Drug"

If a product is a drug, then, as a matter of law, it is a "new drug" that must be approved by FDA before it can be lawfully distributed in interstate commerce, unless it satisfies two requirements.[13] First, it must be generally recognized among qualified experts as being safe and effective ("GRAS/E") "for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §§ 321(p)(1), 331(d), 355. Second, even if a drug has become GRAS/E as a "result of investigations to determine its safety and effectiveness for use under such conditions," it remains a new drug unless it has been "used to a material extent or for a material time" other than in those investigations. 21 U.S.C. § 321(p)(2).[14]

---

[13] The definition of "new drug" also contains a limited exception for grandfathered drugs. *See* 21 U.S.C. § 321(p)(1) (a drug that does not meet that section's "generally recognized" standard "shall not be deemed to be a 'new drug' if at any time prior to the enactment of [the FD&C Act] it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use."); *see also* Public Law 87-781, § 107 (reprinted following 21 U.S.C. § 321) (grandfather clause in 1962 Amendments that was not codified). The two grandfather clauses in the FD&C Act have been interpreted very narrowly. *See, e.g.*, *United States v. Allan Drug Corp.*, 357 F.2d 713, 718-19 (10th Cir. 1966) (holding that a drug product "loses the immunity of the Grandfather clause and becomes a new drug" subject to the FDCA's premarket approval requirements even if there is no more than a "mere change in the labeling after the effective date of the Act"); *United States v. Articles of Drug . . . 5,906 Boxes*, 745 F.2d 105, 113 (1st Cir. 1984). [redacted] has not claimed, nor does FDA believe, that these provisions apply to the detained sodium thiopental.

[14] FDA recognizes that health care professionals may choose to use approved drugs for unapproved uses. FDA generally does not regulate the conduct of health care professionals in

1. General Recognition of Safety and Effectiveness

General recognition of effectiveness requires a three-pronged showing. First, there must exist a body of evidence that would at least be sufficient to obtain FDA's approval for the product. *See United States v. 50 Boxes More or Less*, 909 F.2d 24, 26 (1st Cir. 1990); *United States v. 225 Cartons, More or Less, of an Article off Drug … (Fiorinal)*, 871 F.2d 409, 413 (3d Cir. 1989). As the Supreme Court has explained, "'general recognition of effectiveness' requires at least 'substantial evidence' of effectiveness for approval of [a new drug application]." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629 (1973); *see also United States v. Undetermined Quantities of an Article of Drug (Anucort)*, 709 F. Supp. 511, 514 n.2 (D.N.J. 1987), *aff'd*, 857 F.2d 1464 (3d Cir. 1988). The FD&C Act defines "substantial evidence" as evidence consisting of "adequate and well-controlled investigations, including clinical investigations . . . on the basis of which it could fairly and responsibly be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have . . . ." 21 U.S.C. § 355(d); *Warner-Lambert Co. v. Heckler*, 787 F.2d 147, 151 (3d Cir. 1986).

Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and are, thereby, subject to peer evaluation, criticism, and review. *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973); *United States v. Article of Drug . . . 4,680 Pails*, 725 F.2d 976, 987 (5th Cir. 1984); *United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin*, 675 F.2d 994, 1001 (8th Cir. 1982); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803-04 (2d Cir. 1980); *United States v. Sene X Eleemosynary Corp. Inc.*, 479 F. Supp. 970, 977 (S.D. Fla. 1979) (general recognition of safety and effectiveness cannot be established by anecdotal evidence or the fact that a number of physicians throughout the country prescribe the drug); *United States v. Undetermined Quantities of Articles of Drug, Street Drug Alternatives*, 145 F. Supp. 2d 692, 701 (D. Md. 2001) (absence of literature establishing the safety and efficacy of the product is proof that the requisite general recognition does not exist).

Third, there must be a consensus among the qualified experts, based on the adequate and well-controlled published investigations of the product in question, that the product is safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. *See, e.g., Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 141 (3d Cir. 1987) ("[E]ither the unawareness of the drug product by experts generally or a genuine dispute among qualified experts regarding a drug product's safety and effectiveness preclude[s] its qualifying for exclusion as 'generally recognized.'") (internal quotation omitted); *Equidantin*, 675 F.2d at 1000-01 (requiring "general consensus of expert opinion in favor of" the drug); *Premo Pharm.*, 629 F.2d at 803 ("genuine dispute among qualified experts regarding a drug product's safety and effectiveness preclude[s] its qualifying for exclusion as 'generally recognized.'"); *United States v. Article of Drug . . . "Entrol-C Medicated"*, 513 F.2d 1127, 1128 (9th Cir. 1975).

---

prescribing or using a legally marketed drug for an unapproved use within the practice of medicine.

A drug product that fails to meet any one of these three conditions is a new drug as a matter of law. *See 4,680 Pails*, 725 F.2d at 985; *United States v. Seven Cardboard Cases . . . Codeine Capsules*, 716 F. Supp. 1221, 1223-24 (E.D. Mo. 1989); *United States v. 118/100 Tablet Bottles*, 662 F. Supp. 511, 513-14 (W.D. La. 1987); *see also United States v. Articles of Drug . . . Promise Toothpaste*, 826 F.2d 564, 569 (7th Cir. 1987).

2. Material Extent or Material Time

As noted, even if a drug is GRAS/E, it remains a "new drug" if the drug has not been used to a "material extent or for a material time under such conditions." 21 U.S.C. § 321(p)(2). *See Hynson*, 412 U.S. at 631 ("a drug cannot transcend 'new drug' status until it has been used 'to a material extent or for a material time'"); *United States v. Articles of Drug . . . HORMONIN*, 498 F. Supp. 424, 432 (D.N.J.) (stating that a drug is a "new drug" even if recognized as GRAS/E, unless it also has been "'used to a material extent or for a material time' under non-investigative conditions"), *aff'd sub nom. Appeal of Carnrick Labs., Inc.*, 672 F.2d 902 (3d Cir. 1981) and *aff'd sub nom. United States v. Articles of Drug*, 672 F.2d 904 (3d Cir. 1981).

D. The Detained Drugs Appear to Be "New Drugs"

In our April 15 letter, FDA explained that there is no approved new drug application for the detained drugs (*i.e.*, [redacted]). FDA also explained that the detained drugs are not GRAS/E. Specifically, FDA explained that the Agency's searches of the published scientific literature found no adequate and well-controlled trials evaluating [redacted] (or [redacted]) thiopental sodium for use as part of a lethal injection or, for that matter, any other use. FDA therefore tentatively concluded that the detained thiopental sodium is not GRAS/E for use in lethal injection. In its submissions, [redacted] does not claim that any adequate and well-controlled trials evaluating [redacted] (or [redacted]) thiopental sodium have been published in the scientific literature. Nor does [redacted] appear to argue that the detained drugs are actually GRAS/E under any conditions of use. Instead, [redacted] contends that the Agency should not have limited its search of the published scientific literature to studies involving [redacted] (or [redacted]) thiopental product. Ref. 8 at 12. We disagree, but, as discussed below, the point is moot both because there are no published adequate and well-controlled trials evaluating any manufacturer's sodium thiopental for use in lethal injection and because there is no evidence in the record that [redacted] or [redacted] has marketed [redacted] (thiopental sodium USP) to a material extent or for a material time.

1. It Was Proper to Focus the "General Recognition" Analysis on the Detained Drug Product Rather Than Just Its Active Ingredient

As noted, [redacted] contends that "the Tentative Decision has no basis for concluding that the detained drugs are not generally accepted [sic] as safe and effective for any use simply because FDA could not find scientific literature documenting studies with this particular distributor's product." Ref. 8 at 8 (emphasis added). Instead, [redacted] argues, "FDA often establishes general acceptance [sic] of safety and effectiveness with respect to active ingredients (whose finished dosage forms have specific required labeling) – and not with respect to finished

dosage forms manufactured or distributed by a particular company. *See generally* 21 C.F.R. §§ 331-358." *Id.* We disagree.

It is well settled that the FD&C Act's definitions of "drug" and "new drug" apply to the drug product,[15] not just its active ingredient. *United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983). In the *Generix* case, Generix Drug Corporation argued that it was not required to have approved new drug applications to market generic drug products, because those drug products contained the same active ingredients as FDA-approved pioneer drug products. The Supreme Court determined that a generic drug product – that is, one that contains the "same active ingredients as a previously approved pioneer drug" but different inactive ingredients – is a "new drug" subject to the FD&C Act's premarket approval requirement. *Id.* at 455. In reaching that conclusion, the Court held that the "statutory phrase 'any drug'" in the new drug definition ("any drug . . . [which] is not generally recognized as safe and effective . . . or . . . which has not, otherwise than in [safety and effectiveness] investigations, been used to a material extent or for a material time . . . .") applies to the "complete drug product," not just its active ingredient. *Id.* at 457; *see also id.* at 459 ("The term 'drug' is plainly intended throughout the [FD&C] Act to include entire drug products, complete with active and inactive ingredients."). Thus, every drug product remains subject to the premarket approval requirement in section 355(a), "until the product (and not merely its active ingredient) no longer falls within the terms of [section 321(p)]." *Id.* at 461.

Because the *Generix* Court held that the word "drug" in the "new drug" definition refers to an entire finished drug product, including excipients, and not just to the active ingredient, courts generally have held that studies of one drug product are insufficient to support a claim that a similar drug product is GRAS/E. *See Premo Pharm.*, 629 F.2d at 803 (2d Cir. 1980) ("later developed 'me-too' products such as Insulase are required to apply for FDA approval for the undisputed reason that a difference in inactive ingredients, as exists here, when combined with the active ingredient, can affect the safety and effectiveness of the drug product. . . . [T]he purpose of the [FD&C] Act is to subject all such drug products not generally recognized as safe and effective (whether or not labelled 'me-too' products) to the premarket clearance requirements of the Act."); *United States v. Baxter Healthcare Corp.*, 712 F. Supp. 1352, 1356 (N.D. Ill. 1989) ("When examining a product to determine whether it is a drug, new or otherwise, the court must look at the product as a whole, 'complete with active and inactive ingredients.'") (quoting *Generix*, 460 U.S. at 459); *Undetermined Quantities of an Article of Drug (Anucort)*, 709 F. Supp. at 515-16 ("the 'substantial evidence' requirement" can be satisfied "only by (1) adequate and well-controlled studies of the product Anucort itself or by (2)(a) adequate and well-controlled studies of another drug with the same active ingredients as

[15] "Drug product" means "a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3.

Anucort and (b) adequate and well-controlled studies demonstrating that the other drug and Anucort are bioequivalent.").[16]

To determine GRAS/E status for the detained thiopental, the specific drug product (including its active ingredients, excipients, and dosage) would have to be shown to be safe and effective in adequate and well-controlled clinical investigations. Because the relevant question is whether the detained drug products, not just their active ingredients, are GRAS/E for use under the conditions suggested in their labeling, it was appropriate for FDA to search for adequate and well-controlled clinical trials of [redacted] and [redacted] thiopental sodium in the published scientific literature. FDA's searches identified no such studies, nor have any been cited by [redacted] And, as discussed above, in the absence of such studies, it is not possible for the detained drugs to meet the "general recognition" standard.

We do not agree that FDA "often establishes general acceptance [sic] of safety and effectiveness with respect to active ingredients (whose finished dosage forms have specific required labeling) — and not with respect to finished dosage forms manufactured or distributed by a particular company. See generally 21 C.F.R. §§ 331-358." Ref. 8 at 8. [redacted] cites a portion, but not the entirety, of the regulations established as part of the over-the counter (OTC) Drug Review, a regulatory system specific to nonprescription drugs. Thus, [redacted] presents an incomplete picture. In order to be GRAS/E and not misbranded, each individual nonprescription drug product regulated under the OTC Drug Review must comply with the general conditions set forth in 21 C.F.R. Part 330 (and other applicable regulations), as well as with the specific conditions set forth in the applicable OTC drug monograph (the regulations to which [redacted] refers, i.e., 21 C.F.R. §§ 331-358), which include specific OTC uses of active ingredients, along with other parameters, such as dosage forms, dosage strengths, route of administration, and the associated directions and warnings that must be included in labeling. *See generally* 21 C.F.R. § 330.14(a); 21 C.F.R. §§ 331-358. As a result, it is the drug product – not its active ingredient(s) alone – which complies with all of these requirements that is GRAS/E for its intended use.

FDA has not promulgated any drug monographs that apply to prescription drugs, such as sodium thiopental.[17] Moreover, as discussed, FDA has not identified sufficient evidence to show

[16] Likewise, passage of the Hatch-Waxman Amendments to the FD&C Act in 1984, The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. Law 98-417), provides evidence of congressional intent to subject drugs that share very similar characteristics to the application requirement. Under the Hatch-Waxman Amendments, drugs that are bioequivalent to drugs with approved new drug applications still need approved abbreviated new drug applications. This requirement enables FDA to evaluate active ingredients, inactive ingredients, labeling, chemistry, manufacturing, and controls, and other factors, in addition to bioequivalence, that combine to determine the safety and effectiveness of a finished drug product.

that the detained thiopental sodium drug products are, themselves, GRAS/E for use in lethal injection (or under any other conditions of use).

In sum, the GRAS/E status of the detained drugs is not and cannot be established simply by claiming similarity to, or based on data regarding, another drug product, even one with the same active ingredient. It must independently be shown to be safe and effective in adequate and well-controlled clinical investigations, and no such studies have been published regarding the detained sodium thiopental.

In any event, even if [redacted] were correct that the detained sodium thiopental's GRAS/E status can be determined based on published adequate and well-controlled studies of its active ingredient, the result would be the same. We have searched for published adequate and well-controlled studies evaluating the use of the active ingredient sodium thiopental for use in lethal injection, either as a sole agent or in combination with other agents, and no such studies were identified. Thus, it is not possible for sodium thiopental from [redacted], [redacted]., or any other firm to qualify as GRAS/E for use under the conditions suggested by the detained drugs' labeling.

2. [redacted]

Although the detained drugs are not GRAS/E, there are pathways for a manufacturer to distribute a sodium thiopental product by obtaining FDA approval of a new drug application (NDA). For example, a manufacturer could file either a stand-alone NDA under 21 U.S.C. § 355(b)(1), or use the abbreviated pathway in 21 U.S.C. § 355(b)(2) by relying in part on the FDA finding that a previously approved sodium thiopental product it references (e.g., Abbott's Pentothal Sodium (thiopental sodium) Suspension NDA 11-679) is safe and effective as evidence in support of its own safety and effectiveness. Such an application would need to support any differences from the listed drug (such as a new dosage form, indication, or new formulation) with appropriate safety and effectiveness information. Likewise, a section 355(b)(2) applicant could submit published literature to FDA for the Agency's review to help establish safety or efficacy for its requested indication. [redacted] or example, if a manufacturer avails itself of the section 355(b)(2) abbreviated pathway and receives approval for its sodium thiopental product, the drug would not be an unapproved new drug in violation of 21 U.S.C. § 355.

[17] As previously noted, there is no dispute that the detained drugs, which are labeled "Rx only," are prescription drugs. *See* Ref. 1, Ex. 3 (showing "Rx only" on the label); Ref. 1 at 4 n.2 (thiopental sodium "easily satisfies the definition of a prescription drug").

3. The Detained Drugs Have Not Been Used to a Material Extent or for a Material Time

As noted, to bypass the FD&C Act's premarket approval requirement, a drug must also satisfy the "material extent" or "material time" requirement. 21 U.S.C. § 321(p)(2). *See Hynson*, 412 U.S. at 631; *Articles of Drug . . . HORMONIN*, 498 F. Supp. at 432. Like the "general recognition" requirement in subsection 321(p)(1), the material extent/time requirement in subsection 321(p)(2) is specific to the drug product, "not merely its active ingredient." *See Generix*, 460 U.S. at 461.

According to the registration and listing information [redacted] submitted, the "marketing start date" for the detained drugs was June 5, 2015. Ref. 1 Ex. 2. And, we are aware of only one previous shipment of [redacted] thiopental drug product to the United States.[18] The detained drugs have not been used to a material extent or a material time, and thus are new drugs within the meaning of 21 U.S.C. § 321(p)(2). *See Premo*, 629 F.2d at 804 ("although Premo has produced and sold at wholesale some 16,500,000 Insulase tablets (some of which have been seized in Government actions under 21 U.S.C. § 334), there is no evidence that Insulase has been used to a material extent or for any substantial period of time.").

In short, the detained drugs appear to be new drugs for two independent reasons. They are not GRAS/E for use under the conditions suggested in their labeling. And, even if they were GRAS/E under such conditions, they are new drugs because they have not been marketed to a material extent or for a material time.

E. The Detained Drugs Appear to Violate Section 355(a) of the FD&C Act

The FD&C Act mandates that all new drugs distributed in interstate commerce be approved by FDA or be the subject of an investigational new drug application. 21 U.S.C. §§ 331(d), 355(a). As noted, [redacted] does not dispute that the detained drugs are not the subject of an approved new drug application, an approved abbreviated new drug application [redacted] they appear to be unapproved new drugs.

IV. The Detained Drugs Appear to Be Misbranded Under 21 U.S.C. § 352(f)(1)

In addition to appearing to be an unapproved new drug, the detained sodium thiopental appears to be misbranded because its labeling does not bear adequate directions for use, as required by section 21 U.S.C. § 352(f)(1).[19]

---

[18] That shipment was received before the *Beaty/Cook* order was issued.

[19] The Agency tentatively concluded that the detained sodium thiopental also appears to be misbranded because its labeling fails to bear adequate warnings, as required by 21 U.S.C. § 352(f)(2). Because the Agency concludes that the detained drugs appear to be unapproved new drugs and misbranded within the meaning of section 352(f)(1) and because [redacted] indicated a willingness to add warnings to the detained product, it is not necessary to reach a final

In our April 15 letter, the Agency noted that the thiopental sodium that [redacted] is attempting to import includes no directions for those who would administer the drug or receive it. Specifically, it lists no recommended dose and offers no instructions for reconstituting the powder inside the vials. Its labeling includes no precautions, contraindications, or warnings, or other information required in prescribing information for health professionals. Instead, it bears little text beyond "[f]or law enforcement purpose only," "Rx only," "CIII," "1 gm," and manufacturer information. FDA therefore asserted that the labeling provides inadequate directions for a prescription-drug barbiturate that will be administered to humans to produce anesthesia as part of a lethal injection procedure, or, possibly, to be used as the sole drug for lethal injection.

[redacted] contends that the detained thiopental sodium is not misbranded under 21 U.S.C. § 352(f)(1) because it "falls within the exemption established by 21 C.F.R. § 201.125." Ref. 1 at 3.[20] Section 201.125's "law enforcement" exemption, however, occurs in the context where otherwise misbranded drugs are not administered to humans. Thus, applying this exception to excuse the absence of adequate directions for use in the labeling of drugs for lethal injection is not supported by the text and the history of the exemption.

Section 201.125 states:

> A drug subject to § 201.100 or § 201.105, shall be exempt from [21 U.S.C. § 352(f)(1) requiring adequate directions for use] if [1] 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

---

determination regarding whether the detained drugs are misbranded within the meaning of section 352(f)(2). *See* Ref. 1 at 6 n.3 (regarding section 352(f)(2), [redacted] stated "Under FFDCA section 801(b), we further request the opportunity to relabel the detained drug to include the warnings FDA deems adequate.").

[20] [redacted] interpreted our tentative decision as a contention that a drug needs to meet all of the requirements of section 201.100 (which governs prescription drugs for human use) "to fit within section 201.125" (which includes the law enforcement exemption). Ref. 8 at 2 n.4. Instead, our view is that that the detained thiopental sodium fits within neither exemption from the requirement to bear adequate directions for use. [redacted] does not dispute the Agency's tentative conclusion that the detained drugs do not meet the conditions for the exemption from the requirement to bear adequate directions for use in 21 C.F.R. § 201.100. For example, as discussed in FDA's tentative decision, the label of the drug lacks a "recommended or usual dosage," and the labeling on or within the drug's package lacks "adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended . . . ." *See* 21 C.F.R. 201.100(c)(1).

> physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

21 C.F.R. § 201.125 (emphases added). Thus, the law enforcement exemption resides within a regulation with a two-part test for each exemption: the drug must be shipped, sold to, or in the possession of people engaged in particular activities, and it must be to be used only for the specific exempted purpose.

As an initial matter, as noted in our tentative decision, the law enforcement exemption could not have been intended to apply to lethal injection, because FDA issued the regulation adding the exemption to section 201.125 in 1956, well before any State used lethal injection as a method of execution. *See* Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act; Exemption of Certain Drugs and Devices from Labeling Requirements, 21 Fed. Reg. 2309, 2327 (Apr. 11, 1956) (final rule); *Baze*, 553 U.S. at 42 (describing the first State use of lethal injection).

[redacted] argues that the absence of the phrase "not involving clinical use" following "law enforcement" reflects a "conscious decision not to apply the qualifier to the law enforcement exemption." Ref. 8 at 3. Based on this, [redacted] contends that the "law enforcement" exception extends to use of drugs in lethal injection. Nevertheless, in context, FDA inserted the law enforcement exemption into an existing regulation addressing six other possible uses of drugs, not one of which involves administration to humans: instruction in pharmacy, instruction in chemistry, and instruction in medicine not involving clinical use, research not involving clinical use, chemical analysis, and physical testing. In each category that was likely to have implicated administration of the drug to humans – "instruction in medicine" and "research" – FDA explicitly provided that such use is outside the exemption. In the other categories – including law enforcement – no explicit limitation was specified, but it is implied by the context and the time period when FDA issued these regulations. Thus, FDA believes "law enforcement" should be interpreted in the context of "chemical analysis" and "physical testing": the Agency did not attach the "not involving clinical use" modifier because "law enforcement" was understood to refer to activities similar to chemical analysis and physical testing.

[redacted] reading of the regulation is also counterintuitive. As we noted in our tentative decision, if the "not involving clinical use" limitation were to be applied only to categories where it was specifically attached, as [redacted] advocates, the regulation would require "adequate directions" in the labeling for medical school professors administering drugs to humans, but not law enforcement personnel administering drugs to humans. This result cannot be what the Agency intended when adding the "law enforcement" language to section 201.125.

[redacted] also cites to a 2001 dictionary definition to argue that "even if the qualifier ['not involving clinical use'] could be read into the law enforcement exemption," the term "clinical use" should be understood to refer to use involving medical treatment of a patient, and thus the law enforcement exemption could still encompass lethal injection. Ref. 8 at 3. As in other FDA regulations, though, "clinical use" in § 201.125 refers to a use involving administration of drugs to humans. *See, e.g.*, 21 C.F.R. § 312.3 (defining "clinical investigation" to mean "any

experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects").

Interpreting the law enforcement exemption as not extending to administration of drugs to humans is supported by the historical context of the regulation's promulgation. At the time the exemption was added to section 201.125, the Agency was extremely active in investigative law enforcement work related to drug safety. More precisely, FDA promulgated the law enforcement exemption four years after the rest of § 201.125, *see* 21 Fed. Reg. 2327 (Apr. 11, 1956); Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act; Drugs and Devices; Directions For Use; Exemption From Prescription Requirements, 17 Fed. Reg. 6807, 6819-6820 (July 25, 1952) (final rule), and just five months after testifying before Congress about FDA and State efforts on trafficking and misuse of amphetamines and barbiturates, *see* 21 Fed. Reg. 2327; *Traffic In, and Control of, Narcotics, Barbiturates, and Amphetamines, Hearings Before the H. Subcomm. on Ways and Means*, 84th Congress 1119-1120, 1123 (1955) (statement of John L. Harvey, FDA Deputy Commissioner, Nov. 17, 1955). [redacted] dismisses the Agency's discussion of these historical facts as a "post-hoc rationalization." Ref. 8 at 3-4. But these sources indicate that the law enforcement exemption was aimed at facilitating the investigative work that the Agency and Congress were focused on at the time, instead of being specifically intended for facilitating shipment of unlabeled drugs to law enforcement officers to administer to people.

FDA's statements in the preamble to the regulation also support the Agency's interpretation. If FDA had intended the law enforcement exemption as extending to drugs to be administered to humans, it seems implausible that the Agency would have stated that, in the cases where the exemption applied, "the [adequate-directions] labeling requirements are not necessary for the protection of the public health." 21 Fed. Reg. 2309, 2327. By contrast, the Agency's preamble statements are entirely consistent with the exempted uses being investigative activities like officer training and undercover buys. There are uses of drugs that could be characterized as part of law enforcement (e.g., court-mandated antipsychotic medication as a condition of supervised release). Interpreting the law enforcement exemption as broadly as [redacted] advocates would exempt those uses.

Likewise, [redacted] mischaracterizes FDA's past statements. [redacted] alleges that the Agency's 2010 press message document "confirms that the detained drugs fit squarely within the Agency's 1956 statements regarding the exemption." However, when FDA spoke of deferring to law enforcement in its 2010 press message document, the Agency was <u>not</u> interpreting the "law enforcement" provision of section 201.125. Ref. 1, Ex. 14. Instead, the Agency noted that it was "exercising enforcement discretion" in the context of drugs being imported for lethal injection, in light of flexibility under *Heckler v. Chaney* to "prioritiz[e] . . . enforcement resources to most effectively achieve [its] statutory mission." *Id.* The two concepts are distinct.

In short, the 1956 placement of the law enforcement exemption into section 201.125, a regulation with six other categories of uses that do not involve clinical use of drugs, indicates

that when the Agency added the language, it was not intended to extend the exemption to drugs to be administered to humans.[21] Today, FDA continues to believe that the law enforcement exemption was not intended to extend to drugs to be administered to humans.[22] Due to the textual and historical context of this exception, the detained drugs at issue appear to be misbranded.

V. FDA's Conclusions Are Not in Conflict with Congressional Intent and Do Not Lead to Absurd Results

[redacted] offers two additional challenges to FDA's interpretation of the FD&C Act, based on [redacted] interpretation of 18 U.S.C. § 3596 and a 1937 predecessor, and its contention that FDA's decision produces "absurd results." We address these issues in turn.

A. FDA's Interpretations of the New Drug and Misbranding Provisions Are Not in Conflict with Congressional Intent

[redacted] argues that the Agency's interpretations of the new drug and misbranding provisions of the FD&C Act, as applied to the detained drugs, "conflict with congressional intent by restricting State options in implementing capital sentences." Ref. 8 at 10. In particular, citing two statutes that address federal death sentences, [redacted] claims that "Congress has made clear" that States are to be permitted to devise their own procedures for executions "free of any federal interference." *Id.* Because, in [redacted] view, FDA's interpretations of the FD&C Act amount to a "federal ban" on the use of sodium thiopental for lethal injections, they impermissibly restrict State options in implementing capital sentences. *Id.* at 10-11. This argument both misreads the cited statutes and overstates the effect of FDA's determination regarding the detained drugs.

Congress enacted the first statute that [redacted] cites, 18 U.S.C. § 3596,[23] in 1994. Violent Crime Control and Law Enforcement Act, Pub. L. No. 103-322, § 60002, 108 Stat. 1796. This

---

[21] [redacted] notes (Ref. 8 at 3) that FDA could have changed the text of the regulation when separating the drug and device exemptions, but it is not surprising that FDA did not add or subtract modifiers in a revision that was simply a recodification into new sections. Subchapter H—Medical Devices: Reorganization and Republication, 41 Fed. Reg. 6896, 6896 (Feb. 13, 1976).

[22] Thus, we do not dispute the idea that regulations can sometimes accommodate changing technology, *see* Ref. 8 at 3, but disagree on the basic scope of the exemption.

[23] The statute states in relevant part:

> In general. A person who has been sentenced to death pursuant to this chapter [18 U.S.C. §§ 3591 et seq.] shall be committed to the custody of the Attorney General until exhaustion of the procedures for appeal of the judgment of conviction and for review of the sentence. When the sentence is to be implemented, the Attorney General shall release the person sentenced to death to the custody of a United States marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed. If the law of

1994 statute states, among other things, that U.S. Marshals shall supervise a federal death sentence "in the manner prescribed by the law of the State in which the sentence is imposed." *Id.* The law uses language similar to its 1937 predecessor, in which Congress specified that the federal death penalty would be implemented in a manner "prescribed by the laws of the State within which the sentence is imposed." The Capital Punishment Method Act of 1937, Pub. L. No. 156, 50 Stat. 304 (1937) (codified at 18 U.S.C. § 542 (1937) and subsequently repealed). By contrast, previous federal statutes required execution by hanging. *See* Crimes Act of 1790, 1 Stat. 112-119 (1790) ("The manner of inflicting the punishment of death, shall be by hanging the person convicted by the neck until dead."); An Act To Codify, Revise, and Amend the Penal Laws of the United States, Pub. L. No. 350, § 323, 35 Stat. 1151 (1909) ("The manner of inflicting the punishment of death shall be by hanging."). Thus, the statutes discussed by [redacted] address whether the federal government will apply a state-specific method of execution for federal sentences, rather than a uniform federal method. The statutes do not address methods of execution for state-imposed death sentences.

[redacted] has not cited anything in the text or legislative history of either of these statutes to support its contention that Congress aimed to provide unrestricted State options in implementing a death sentence. Likewise, we have not identified any evidence indicating that Congress even considered the 1937 statute when enacting the FD&C Act in 1938. Instead, Congressional statements at the time the Capital Punishment Method Act of 1937 was enacted reflect a desire to move away from hanging to newer methods of execution employed by states.[24] But this does not equate to Congress intending States to develop procedures for implementing capital sentences "free of any federal interference." Ref. 8 at 10.[25]

In any event, there is no conflict because [redacted] overstates the scope and consequence of FDA's decision regarding the detained drugs. [redacted] claims that FDA's "interpretations amount to a federal ban on use of thiopental sodium for lethal injection," Ref. 8 at 10-11, but FDA has not made any determination, one way or the other, about which drugs may be used for lethal

---

> the State does not provide for implementation of a sentence of death, the court shall designate another State, the law of which does provide for the implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such law.

18 U.S.C. § 3596(a).

[24] *See, e.g.,* H. Rep. No. 164, at 1 (1937); S. Rep. No. 690, at 1 (1937).

[25] [redacted] also points to Department of Justice regulations, which were promulgated in an interim period prior to the enactment of 18 U.S.C. § 3596. *See* Ref. 8 at 11 n.15. Those regulations, 28 C.F.R. § 26.2 and § 26.3, require lethal injection in federal death penalty executions. There is no evidence that the Department of Justice intended this regulation to have any effect on the implementation of state executions. Furthermore, many states have altered their procedures to provide for the use of different drugs. *See* Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 Geo. L.J. 1331, 1362-66 (2014).

injection.[26] Instead, FDA has applied the FD&C Act to conclude that the particular drugs [redacted] seeks to import cannot be imported under the *Beaty/Cook* order. Moreover, the supposed result about which [redacted] complains follows directly from the *Beaty/Cook* order. To the extent [redacted] objects to that result, the proper course is to seek approval by FDA, relief from Congress or the court that issued the *Beaty/Cook* order – or use a drug that has been lawfully imported. FDA cannot flout a court order at [redacted] request.

For all of these reasons, we do not agree that FDA's interpretations of the FD&C Act conflict with congressional intent.

B. FDA's Interpretations Do Not Lead to Absurd Results

[redacted] also contends that FDA's interpretations should be rejected because they lead to absurd results. Ref. 8 at 12. In particular, [redacted] points to FDA's tentative conclusions that GRAS/E status, including for use in lethal injection, must be based on adequate and well-controlled clinical trials, and that the detained drugs cannot qualify for the law enforcement exemption. *Id.*

In statutory interpretation, "absurdity is a high bar." *Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 505 (D.C. Cir. 2016). As the Supreme Court has stated, it applies where the plain language of a statute "would produce an absurd and unjust result which Congress could not have intended." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 574 (1982). Thus, an outcome is not absurd merely because it might be unlikely, surprising, or difficult to achieve.

Here, it is not absurd to suggest that the FD&C Act requires a drug to be shown to be safe and effective for use under the conditions suggested in its labeling. There are numerous situations where it is difficult to design appropriate clinical trials, such as testing a treatment for anthrax infection or plague. In such cases, FDA regulations may allow flexibility, or trials may differ from what scientists generally envision, but FDA's statutory mandate remains the same. [redacted] absurdity point also fails to grapple with the total absence of scientific research evaluating the safety or efficacy of the detained drugs for any use. In short, [redacted] has not shown that FDA's position leads to absurd results.

At one time, FDA exercised enforcement discretion with respect to thiopental imports, thus avoiding questions about how to assess the safety and effectiveness of thiopental for lethal injection, or whether the thiopental was or was not approved. FDA is now subject to the Court's order in *Beaty/Cook* with respect to importation of foreign-manufactured sodium thiopental that

[26] We also note that FDA's determination that the detained drugs cannot be imported under the *Beaty/Cook* order because they are unapproved new drugs and misbranded drugs has no effect on importation of foreign-manufactured sodium thiopental that is not in violation of the FD&C Act, for example if a foreign manufacturer obtains FDA approval of a new drug application or abbreviated new drug application. Nor does it require FDA to take action against domestic distribution of sodium thiopental, whether or not it is unapproved or misbranded. *See Heckler*, 470 U.S. at 838.

is unapproved or misbranded. As a result, FDA has conducted its established inquiry to determine whether the detained sodium thiopental is GRAS/E for use under the conditions suggested in its labeling, leading to the conclusion that the drug is not GRAS/E for use in lethal injection – and to determine whether the manufacturer of the detained drugs holds an FDA approval of such drugs, which it does not.

As discussed in greater detail above, we also reject [redacted] contention that requiring a drug to comply with section 352(f)(1) produces absurd results when it is being shipped to law enforcement for use, in lethal injection. We fail to see how requiring a drug to bear labeling explaining, for example, how it should be reconstituted, the appropriate dose, or descriptions of proper methods of administration is inconsistent with the FD&C Act.

VI. Conclusion

For the reasons set forth above, we have determined that the thiopental sodium appears to be an unapproved new drug and misbranded. Based on the order issued in the *Beaty/Cook* case, FDA must refuse admission to the detained drugs. *Beaty*, 853 F. Supp. 2d 30, *aff'd in part, rev'd in part sub nom. Cook*, 733 F.3d 1.

[redacted] has requested that we "retain custody of the detained drugs under conditions that preserve their integrity pending completion of any judicial review," or "confirm that [redacted] will be given 90 days to export the drugs to the original foreign distributor," to hold ready for re-importation if a court rules in [redacted] favor. Ref. 8, Attch. E at 1-2. We confirm that, because we are refusing admission, [redacted] has ninety days from the date of notice of refusal to export or destroy the drugs, consistent with applicable regulations. *See, e.g.*, 21 U.S.C. § 381(a).

Sincerely,

[redacted] Acting Director Southwest Import District

Todd W. Cato
Director, Southwest Import District Office

References:

Reference 1: Release Request for Thiopental Sodium on Behalf of the [redacted], October 23, 2015

Exhibit 1: FDA Notices of Action

. . .

Exhibit 3: Label

. . .

Exhibit 10: CBP Detention Notice

Exhibit 11: Request for Delivery of Imported Sodium Thiopental

Exhibit 12: FDA Response to Request for Delivery

Exhibit 13: Affidavit

Exhibit 14: FDA Statement regarding Sodium Thiopental

Exhibit 15: Excerpt from Goodman & Gilman's The Pharmacological Basis of Therapeutics

Exhibit 16: History of Barbiturates

. . .

Reference 2: Entry Documentation, [redacted]

Reference 3: Photos of Detained Thiopental Sodium

Reference 4: Order issued in *Beaty v. FDA*, March 27, 2012

Reference 5: Order issued in *Beaty v. FDA*, June 22, 2012

Reference 6: Letter from FDA to [redacted], June 23, 2015

Reference 7: Tentative Decision to [redacted], April 15, 2016

Reference 8: Response to April 15, 2016 Tentative Decision on Behalf of the [redacted], May 20, 2016

Attachment A: Documents Pertaining to Federal Execution Protocol

Attachment B: Labeling for *Beaty/Cook* Drugs

Attachment C: Affidavit

Attachment D: Affidavit

Attachment E: Affidavit

Reference 9: Email from FDA to [redacted], April 29, 2016

Reference 10: Webster's New International Dictionary Second Edition Unabridged (G&C Merriam Co. 1940)

REFERENCE 1

From: [redacted]
To: Santos, Rosa L
Cc: [redacted]; Veneziano, Domenic J.; Stearn, Douglas; [redacted].
Subject: [redacted] Request for Release
Date: Friday, October 23, 2015 4:04:13 PM
Attachments: BLEA Texas Submission to FDA FINAL 102315 (with attachments).pdf

---

Hello Ms. Santos. I hope you are having a good Friday.

Please find our request for release of the thiopental sodium detained by FDA and detained by Customs at FDA's request under the above referenced entry number. An authorization letter is included with the attached letter.

We request FDA to release the goods immediately and to instruct CBP to lift that agency's detention to permit immediate delivery to the [redacted]

Alternatively, we request FDA to grant [redacted] an in-person hearing with the appropriate FDA personnel, lift the detention, and release the goods within 30 days from receipt of this submission.

Further, I respectfully request this case be transferred to Douglas Stearn, Director, Office of Enforcement and Imports, or his designee in ORA Headquarters, who will become the Hearing Officer for this detention. Please inform me who the new Hearing Officer will be and the time and place for additional testimony to be given.

Thank you and best regards

[redacted]

[redacted]

* [redacted]

[redacted]

[redacted]

COMMERCIAL CONFIDENTIAL COMMUNICATION

October 23, 2015

Via Electronic Mail: ***rosa.santos@fda.hhs.gov***;

Rosa L. Santos, Compliance Officer
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

Re: Release Request for Thiopental Sodium on Behalf of the [redacted]
(Customs Entry No. [redacted])

Dear Ms. Santos:

We are making this submission, as counsel for the [redacted], in response to the notice of detention issued by FDA on August 24, 2015 and attached as Exhibit 1. As indicated in the notice of detention, and as required by 21 C.F.R. § 1.94, [redacted] has a right to introduce testimony regarding the detained entry as owner and consignee of the imported goods. This submission includes written testimony. We also request the opportunity to have an in-person hearing with appropriate FDA personnel regarding the matters discussed herein.

Background

The detained entry at issue consists of vials of the drug thiopental sodium (also known as sodium thiopental or sodium pentothal). The drug was manufactured and labeled at an FDA-registered facility in [redacted].[1] Ex. 2. The drug is listed with FDA. Ex. 2.

[1] This document contains commercial confidential and proprietary information. Certain words and/or numbers contained in in this document are exempted from disclosure under the Freedom of Information Act ("FOIA") pursuant to Title 19 C.F.R. § 103.12(d), because the information represents "trade secrets and commercial or financial information obtained from any person which is privileged or confidential." Title 19 CFR 103.31a provides further that certain advance electronic information that is required for inbound air, rail, truck, or vessel cargo under various provisions of the Customs Regulations is "per se exempt from disclosure" under 19 CFR 103.12(d). This information includes, for example, the foreign airport of origination, cargo description, quantity, and weight, shippers' name and address, and consignee's name and address for air shipments (and similar information for other shipments). Because the electronic version of this information is exempt from disclosure, the written version of this information provided on the actual entries and entry documents are also "per se exempt" from disclosure. Title 19 CFR 103.31 provides that importers can request that shippers' and consignees' names and addresses on manifests can be protected from disclosure. This demonstrates this same information is confidential if it is found on entries and entry documents. In addition, Customs and Border Protection ("CBP") FOI Office interprets the exemptions so broadly that that Office considers the entire entry to be "business commercial information." *See e.g.,* Memorandum of Understanding ("MOU") Between the U.S. Department of the Treasury U.S. Customs Service and The U.S. Department of Health and Human Services Food and Drug Administration, MOU 225-91-4003, at II.8. (available at

[redacted]

Each vial of the drug bears a label identifying it as Thiopental Sodium and bearing the legend: "For law enforcement purpose only." Ex. 3. There are no statements in the label addressing conditions of use.

Aside from the information printed on the label (discussed herein), there is no additional labeling accompanying the drug specifying information about its properties or uses. The only documentation accompanying the drug includes commercial and customs documentation identifying the name and quantity of the drug. Ex. 4. The customs declaration (Form 3461 line 20) reiterates that the drug is for "law enforcement only." Ex. 5.

The label for each vial of the drug includes a "CIII" legend (indicating that the drug is a schedule III controlled substance). Ex. 3. [redacted] is registered with the Drug Enforcement Administration (DEA) as an importer of this drug. Ex. 6.

Detentions by Customs and FDA

On June 8, 2015, [redacted] filed a Controlled Substance Import Declaration (DEA Form 236), as required by 21 C.F.R. § 1312, with DEA. Ex. 7. This Declaration included a signed statement by [redacted] explaining that [redacted] proposed importation of sodium thiopental was intended for law enforcement purposes.

After a number of communications between DEA and [redacted] DEA issued a written response on July 13, 2015 stating that DEA would notify U.S. Customs and Border Protection (CBP) and FDA of the upcoming importation. According to DEA, FDA had contacted DEA and asserted that (1) the thiopental appeared to be misbranded or in violation of 21 U.S.C. § 355 (New Drug Provision), and (2) it was illegal to import thiopental. Ex. 8. At that time, FDA had not examined the imported thiopental sodium. In fact, the drugs had not yet even been shipped to the United States.

On July 24, 2015, the private label distributor shipped 1000 vials of the drug thiopental sodium, which arrived the same day. Through its Customs Broker [redacted] filed with CBP Entry [redacted] for Immediate Delivery. Ex. 5. FDA reviewed the Entry, examined and

---

http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116790 htm).

Therefore, [redacted] claims on behalf of its supplier, manufacturer, shippers, filers and other parties in its supply chain, all entry information and entry documents, to be "exempt from disclosure" under FOIA. [redacted] express claim of exemption applies similarly to all information in this submission. Prior to FDA or CBP making any response to any request by any person other than [redacted] or its counsel for any information under FOIA or under FDA or CBP regulations governing disclosure, [redacted] expressly asserts these exemptions and requests FDA and/or CBP supply the request(s) and any proposed response for [redacted] to review and redact. *See* 21 C.F.R. § 20.61.

detained the goods by July 29, 2015. Ex. 9. FDA alleged that the goods appeared to be a new drug without an approved new drug application. FDA rescinded the detention the next day without stating any reason. CBP then detained the shipment on August 5, 2015, refusing to allow the goods to travel to destination. The detention notice indicated that the goods were detained at the request of FDA ". . . for FDA [admissibility] and further analysis". Ex. 10. [redacted] did not receive notice of the detention until after August 16, 2015.

On August 18, [redacted] submitted a letter to FDA and CBP requesting that FDA instruct CBP to lift the detention and permit the goods to proceed to destination under [redacted] basic importation bond, as is normally permitted in the course of commercial import transactions. The request included a certification by [redacted] promising that it would not use the thiopental sodium unless and until FDA's pending detention of the goods is resolved. Ex. 11. FDA denied this request on August 24. FDA's letter provided no reasons for its denial. Ex. 12.

On August 24, 2015, FDA issued a new notice of detention. Ex. 1. The FDA notice of detention alleged that the detained shipment of thiopental sodium appears to:

> (1) "lack adequate directions for use" (21 U.S.C. §§ 381(a)(3) and 352(f)(1) (Misbranding));
>
> (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" (21 U.S.C. §§ 381(a)(3) and 352(f)(2) (Misbranding)); and
>
> (3) "be a new drug without an approved new drug application" 21 U.S.C. §§ 381(a)(3) and 355(a) (Unapproved New Drug).

We explain below why the detained shipment does not (and therefore does not appear to) violate the provisions cited in the notice. We therefore respectfully request FDA to lift the detention and release the goods.

I. The Detained Drug Does Not Violate Statutory Requirements Governing Adequate Directions for Use

The detained drug does not violate statutory requirements governing adequate directions for use. FDA has promulgated a number of regulatory exemptions from the statutory requirement, set forth in FFDCA section 502(f)(1), that a drug must bear adequate directions for use. The imported drug falls within the exemption established by 21 C.F.R. § 201.125 (entitled "Drugs for use in teaching, law enforcement, research, and analysis."). The pertinent part of the section 201.125 exemption applies to a drug that is "shipped or sold to, or in the possession of, persons . . . engaged in law enforcement, . . . and is to be used only for . . . law enforcement."

As the attached commercial and customs documentation demonstrates, the detained drug was both shipped and sold to [redacted] Ex. 4. [redacted] also has requested possession of the drug (and would be possessing the drug now if FDA had not denied that request). Ex. 12. When FDA discussed lethal injection in the 2011 policy statement attached in Ex. 14, the agency acknowledged that "state Departments of Correction" are engaged in "law enforcement." The attached affidavit of [redacted] confirms that [redacted] is a law enforcement agency. Ex. 13.

The detained drug also is to be used only for law enforcement. The restrictive legend on the label ("For law enforcement purpose only") makes that clear. In addition, before the detention occurred, [redacted] reaffirmed (in the DEA Form 236) that the drug would only be used for law enforcement purposes. Ex. 7. The attached affidavit of [redacted] elaborates that the specific law enforcement purpose is to effectuate lawfully-imposed capital sentences through lethal injection. Ex 13. Capital punishment is an "aspect of the law enforcement process." *Bell v. Lynaugh*, 858 F.2d 978, 986 (5th Cir. 1988) (Jones, J., concurring). *See also Baze v. Rees*, 533 U.S. 35, 61 (2008) (States may enact laws specifying the "sanction" of capital punishment, which is a means to "'enforce'" a State's laws) (citation omitted) (plurality opinion of Roberts, C.J.).[2]

II. The Detained Drug Does Not Violate Statutory Requirements Governing Adequate Warnings for Users

The detained drug also does not violate statutory requirements governing adequate warnings for users. The pertinent statutory provision is FFDCA section 502(f)(2), which states that a drug is misbranded "[u]nless 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." The "users" to be protected by these "necessary" and "adequate" warnings are patients who take drugs for medicinal purposes. The purpose of section 502(f)(2) is to provide warnings to patients as they take their own drugs. FDA therefore generally has imposed this warning requirement with regard to non-prescription drugs, because

[2] For the section 201.125 exemption to apply, a drug also must fall within the definition of a prescription drug. In pertinent part, FFDCA section 503(b)(1) defines a prescription drug as one "intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). The standard reference source for pharmacology indicates that sodium thiopental is a barbiturate that produces unconsciousness and anesthesia. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, at 347-49 (11th ed. 2006) (attached as Ex. 15). This effect is well known; the drug has been used for purposes of anesthesia since before the FFDCA was enacted in 1938. Ex. 16 at 333. The drug easily satisfies the definition of a prescription drug; it is hard to imagine FDA suggesting that a drug that produces unconsciousness and anesthesia is a non-prescription drug. It therefore is not surprising that the Physicians' Desk Reference has included a listing for a different manufacturer's thiopental sodium as a prescription drug. Ex. 17.

patients may take such drugs without the benefit of any warnings a physician could provide. *See, e.g.*, 47 Fed. Reg. 30012, 30016 (July 9, 1982) ("Section 502(f)(2) . . . states, in part, that any drug marketed OTC must bear in labeling "* * * such adequate warnings * * * as are necessary for the protection of users.").

Section 502(f)(2)'s requirement to warn patient "users" as they self-administer drugs parallels section 502(f)(1)'s "adequate directions for use" requirement. Congress enacted both of these statutory subsections together, in the original 1938 Act, and the language of both has remained unchanged since that time. The two provisions are tied together, with the first addressing (affirmative) directions and the other addressing (prohibitive) warnings. FDA has consistently interpreted the "adequate directions" requirement of section 502(f)(1) as applying only to "use" by lay patients as they take their own drugs. *See* 21 C.F.R. § 201.5 (defining adequate directions for use as "directions under which the layman can use a drug"). The directions for lay patient users required by section 502(f)(1) complement the warnings to lay patient users required by section 502(f)(2).

Here there will be no lay patient "users" taking the detained drugs. This is a circumstance in which the imported substance is a drug that will not be used for medicinal purposes at all. It is well established that "the word 'drug' is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word." *United States v. Bacto-Unidisk*, 394 U.S. 784, 793 (1969). The definitions of the term "drug" set forth in the FFDCA do not require that it must be "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B). To the contrary, a substance may be a drug simply because it is not a food and is "intended to affect the structure or any function of the body of man." *Id*. § 321(g)(1)(C). This second definition applies here.

There are two alternate ways for FDA to conclude that the detained drug does not violate the warning requirement of section 502(f)(2). *First*, FDA can properly conclude that *no* "warnings are necessary for the protection of users" here because there are no patient "users" within the meaning of the statute. There also will be no self-administration of a drug. As explained above, the purpose of section 502(f)(2) is to guide lay patient users as they take their own drugs. Here the drug is being used for a law enforcement purpose (where it will not be self-administered) and not for a medicinal purpose that would require patient warnings. Such warnings are not any more "necessary" for this law enforcement purpose than they would be for the other categories of drugs covered by 21 C.F.R. § 210.125 (which also do not involve patient use) — i.e., drugs used only for "research not involving clinical use, or in chemical analysis, or physical testing."

Sections 502(f)(1) and 502(f)(2) have different mechanisms for addressing situations in which their requirements are not "necessary" to protect patients. Under section 502(f)(1), the default rule is that adequate directions for use must be provided; if such directions are "not necessary for the protection of the public health," FDA must promulgate a regulatory exemption from the default rule. 21 U.S.C. § 352(f). By contrast, there is no default warning requirement (or exemption process) under section 502(f)(2). If section 502(f)(2) warnings are not "necessary

for the protection of users," no warnings are required in the first place. Here the conclusion that section 502(f)(2) warnings are not "necessary" for the detained thiopental sodium draws support from FDA's decision that section 502(f)(1) directions for use are not "necessary." When FDA promulgated the law enforcement exemption (21 C.F.R. § 201.125) in 1956, Commissioner Larrick made a specific finding that the labeling requirements of section 502(f)(1) are "not necessary for the protection of the public health" when a drug is "shipped, sold, or in the possession of persons engaged in law-enforcement." 21 Fed. Reg. 2309, 2327 (Apr. 11, 1956). The same is true for section 502(f)(2) warnings, which are not "necessary" when drugs will only be shipped or sold to, or possessed by, law enforcement personnel and not lay patient "users."

Second, in the alternative, FDA can properly conclude that the label for the detained drug contains a warning that is "adequate" within the meaning of section 502(f)(2). FDA has not promulgated any specific warning requirements for thiopental sodium (although it has done so for other drugs as noted above). Therefore the only potential application of section 502(f)(2) is the general obligation that any warnings that are "necessary" for the protection of "users" must be "adequate." FDA has not established that the detained drug's labeling fails to meet this "adequacy" standard.

It is important to understand that [redacted] has tight controls in place that would prevent diversion of the detained drug from its law enforcement purpose to a situation in which it could reach a lay patient "user." The detained drug is a controlled substance and will be stored under security requirements imposed and monitored by the DEA. *See* Ex. 13. But even in the very unlikely event such a diversion did occur, the "law enforcement purpose only" legend on the label would suffice as a warning that is fully adequate to inform any potential patient "users" (or for that matter any healthcare professionals treating such patients) that the patients should not use the drug for *any* purpose (with *any* dosage or with *any* method or duration of administration or application). FDA has previously recognized that an analogous legend serves as an adequate warning against patient use. *See, e.g.*, Ex. 18 at 8 ("research use only" labeling on in vitro diagnostic products "is meant to serve as a warning, to prevent such products from being used in clinical diagnosis, patient management, or an investigation that is not exempt from 21 CFR part 812"). Here FDA has not demonstrated that the "law enforcement purpose only" legend is not an "adequate" warning under section 502(f)(2).[3]

[3] If FDA were to conclude that warnings under section 502(f)(2) are necessary, and that the "law enforcement use only" legend is an inadequate warning, we request the agency to provide a supporting rationale that includes the warnings FDA deems adequate. Under FFDCA section 801(b), we further request the opportunity to relabel the detained drug to include the warnings FDA deems adequate.

[redacted]

III. The Detained Drug Does Not Violate Statutory Provisions Requiring FDA Approval for New Drugs

The detained drug also does not violate statutory provisions requiring FDA approval for new drugs. FFDCA section 505(a) prohibits introduction of a "new drug" into interstate commerce without an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). This requirement does not apply to the detained drug, because it does not fit within the statutory definition of a "new drug."

In pertinent part, the FFDCA defines a "new drug" as a drug not generally recognized among qualified experts as "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). "Conditions of use" are therapeutic requirements, recommendations, or suggestions. The labeling of the detained drug does not prescribe, recommend, or suggest *any* conditions of use. Ex. 3. For FDA to establish that a drug is a "new drug," the agency must demonstrate that the drug is not generally recognized as safe and effective with respect to specific conditions of use stated in the labeling. When no conditions of use are so specified, it is not possible for FDA to establish that a drug is a "new drug." Because there is no basis for concluding that the detained drug is a "new drug," section 505(a) does not prohibit its distribution without a NDA or ANDA.[4]

When FDA wishes to initiate an enforcement action involving an unapproved drug that does not have conditions of use specified in the labeling, the agency typically claims that the drug lacks "adequate directions for use" (and therefore is misbranded) under FFDCA section 502(f)(1). This enforcement theory has been colloquially known as a "back door" unapproved drug charge, applicable when there is no "new drug" and therefore no violation of section 505(a). Here, however, 21 C.F.R. § 201.125 exempts the detained thiopental sodium from the "adequate directions for use" requirement as explained above.

In essence, the detained drug is in a regulatory posture very similar to that of a prescription chemical, used in pharmacy compounding, that meets the exemption from "adequate directions for use" applicable to "prescription chemicals and other prescription components." *See* 21 C.F.R. § 201.120. As a drug component, the prescription chemical falls within the FFDCA definition of a "drug." *See* 21 U.S.C. § 321(D). But the prescription chemical is not an unapproved *new* drug (prohibited by section 505(a)) even though the chemical lacks an approved NDA or ANDA. The chemical does not meet the statutory definition of "new drug," because its

[4] The FFDCA also defines a "new drug" as a drug that has become generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling (based on investigations under "such conditions") but which has not, otherwise than in "such investigations," been used to a material extent or for a material time under "such conditions." This definition obviously is also tied to conditions of use specified in the labeling. Without any conditions of use specified in the labeling, it is not possible for FDA to establish that a drug fits within this definition of a "new drug."

labeling does not specify any conditions of use. The applicable exemption regulation (21 C.F.R. § 201.120(c)) confirms that the prescription chemical is not itself a "new drug," by referring to the possibility that a "new drug" may be compounded *from* the chemical. 21 C.F.R. § 201.120(c). Instead of specifying conditions of use, the chemical's labeling contains the legend "For prescription compounding." Complying with that requirement and the other provisions of section 201.120 makes it lawful to distribute the unapproved prescription chemical, just as it is lawful to distribute the detained drug under the law enforcement exemption established by 21 C.F.R. § 201.125.

We therefore request FDA to release the goods immediately and to instruct CBP to lift that agency's detention to permit immediate delivery to [redacted] Alternatively, we request FDA to grant [redacted] an in-person hearing with appropriate FDA personnel, lift the detention, and release the goods within 30 days from receipt of this submission.

* * *

If you have any question regarding the above, please do not hesitate to contact me at [redacted].

Sincerely,

[redacted]

[redacted]

cc: Capt. Domenic Veneziano, Director, Division of Import Operations, FDA
Douglas Stearn, Director, Office of Enforcement and Imports, FDA
[redacted], Co-Counsel to [redacted]

Enclosures:

Exhibit 1: FDA Notices of Action

Exhibit 2: Distributor and Manufacturer Registrations & Drug Listings

Exhibit 3: Thiopental Label

Exhibit 4: Airway Bill and Commercial Invoice

Exhibit 5: CBP 3461

Exhibit 6: TDCJ DEA License

Exhibit 7: TDCJ DEA Form 236

Exhibit 8: DEA Letter to [redacted]

[redacted]

Exhibit 9: Withdrawn FDA Detention

Exhibit 10: CBP Detention Notice

Exhibit 11: Request for Delivery of Imported Sodium Thiopental

Exhibit 12: FDA Response to Request for Delivery

Exhibit 13: Affidavit of [redacted]

Exhibit 14: FDA Policy Statement regarding Sodium Thiopental

Exhibit 15: Excerpt from Goodman & Gilman's The Pharmacological Basis of Therapeutics

Exhibit 16: History of Barbiturates

Exhibit 17: Physicians' Desk Reference

Exhibit 18: FDA Guidance Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only

[redacted]

[redacted]

July 27, 2015

To Whom it May Concern:

RE: FDA, DEA and U.S. CBP matters

Please be advised we, the [redacted] have authorized the law firm of [redacted] to engage the U.S. Food and Drug Administration (FDA), the Drug Enforcement Agency, and the Bureau of Customs and Border Protection (CBP) respecting all issues related to the manufacture, distribution, exportation, and importation of FDA-regulated products.

In order to assist us in our matters, we authorize you to discuss our FDA, DEA, and CBP related issues, filings, and records with [redacted] and the other attorneys at the firm, [redacted]; their Regulatory Advisors, [redacted]; their Regulatory Specialist, [redacted] or their paralegals, [redacted]. The firm's telephone number is [redacted]. If you have any questions regarding this authorization, please do not hesitate to contact me at [redacted].

Sincerely,

[redacted]

[redacted]

Exhibit 1

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: [redacted]

Notice Number: 3
August 24, 2015

Importer:
[redacted]

[redacted]

[redacted]

> <

Port of Entry: 5309, Houston Intercontinental Airport, Houston, TX
Carrier: [redacted];
Date Received: July 27, 2015
Arrival Date: July 24, 2015

Filer of Record: [redacted]
Consignee: [redacted]

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line	ACS/FDA	Product Description	Quantity	Current Status
*	001	001	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	1000 PCS	Detained 08-24-2015

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a localtion within the metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	September 14, 2015

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article appears to lack adequate directions for use.

FD&CA Section 502(f)(2), 801(a)(3); MISBRANDING
It appears to lack adequate warning against use in a 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.

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application.

Please direct your response to:

Rosa L. Santos, Compliance Officer (Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5269
(214) 253-5316 (FAX)
ROSA.SANTOS@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: RLS

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number:

Notice Number: 4
September 11, 2015

Filer:

Attention:
Broker Box:

>

<

Port of Entry: 5309, Houston Intercontinental Airport, Houston, TX
Carrier: ;
Date Received: July 27, 2015
Arrival Date: July 24, 2015

Importer of Record: [redacted]
Consignee:

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	1000 PCS	Extension granted 09-10-2015

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a localtion within the metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

EXTENSION REQUEST GRANTED

Line ACS/FDA	Product Description	Respond By
001/001	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	October 23, 2015

Rosa L. Santos, Compliance Officer (Region/District) (214) 253-5269
(214) 253-5316 (FAX)

U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

ROSA.SANTOS@FDA.HHS.GOV

This extension is granted until the dates shown above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: ARM

Exhibit 2

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Drug Establishments Current Registration Site

Search Results for [redacted]

Download data (downloadExcel.cfm)

Firm Name	Facility Establishment Identifier	Data Universal Numbering System Number	Address	Expiration Date
[redacted]		[redacted]	[redacted]	12/31/2015

« ‹ 1 › »

Data Current through: October 09, 2015

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Pragmatic Structured Product Labeling Editor ("SPL XForms")

Template ▾ Load Template | Load File | Save | Save In | Reset | Validate

Submit to FDA

Header | Data Elements | Content Of Labeling | **SPL View** | XML View | Help

[redacted]

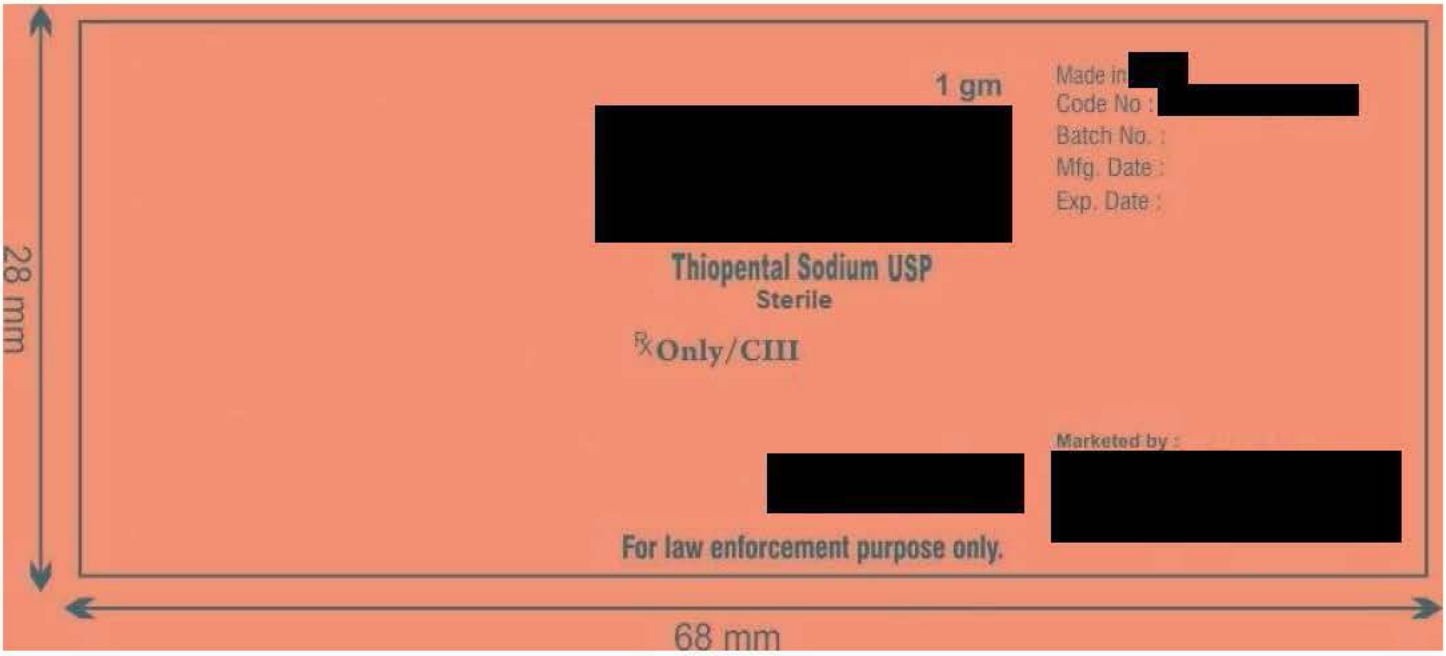
Thiopental Sodium USP

Sterile

Rx Only/CIII

[redacted]

For law enforcement purpose only.



[redacted]

thiopental sodium powder

Product Information

Product Type	BULK INGREDIENT	**Item Code (Source)**	[redacted]
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THIOPENTAL SODIUM (UNII: 49Y44QZL70) (THIOPENTAL - UNII:JI8Z5M7NA3)	THIOPENTAL	100 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	[redacted]	1 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
bulk ingredient		06/05/2015	

Labeler [redacted]

Establishment

Name	Address	ID/FEI	Business Operations
[redacted]		[redacted]	[redacted]

Revised: 6/2015 [redacted]

For help, click the "Help" tab. Refer to the FDA SPL XForms web page for troubleshooting help and other advisories. For any remaining unanswered questions email may be sent to spl@fda.hhs.gov and spl@pragmaticdata.com.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Establishments Current Registration Site

Search Results for [redacted]

Download data (downloadExcel.cfm)

Firm Name	Facility Establishment Identifier	Data Universal Numbering System Number	Address	Expiration Date
[redacted]		[redacted]	[redacted]	12/31/2015

« ‹ 1 › »

Data Current through: October 09, 2015

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Pragmatic Structured Product Labeling Editor ("SPL XForms")

Template ▾ Load Template | Load File | Save | Save In | Reset | Validate

Submit to FDA

Header | Data Elements | Content Of Labeling | **SPL View** | XML View | Help

[redacted]

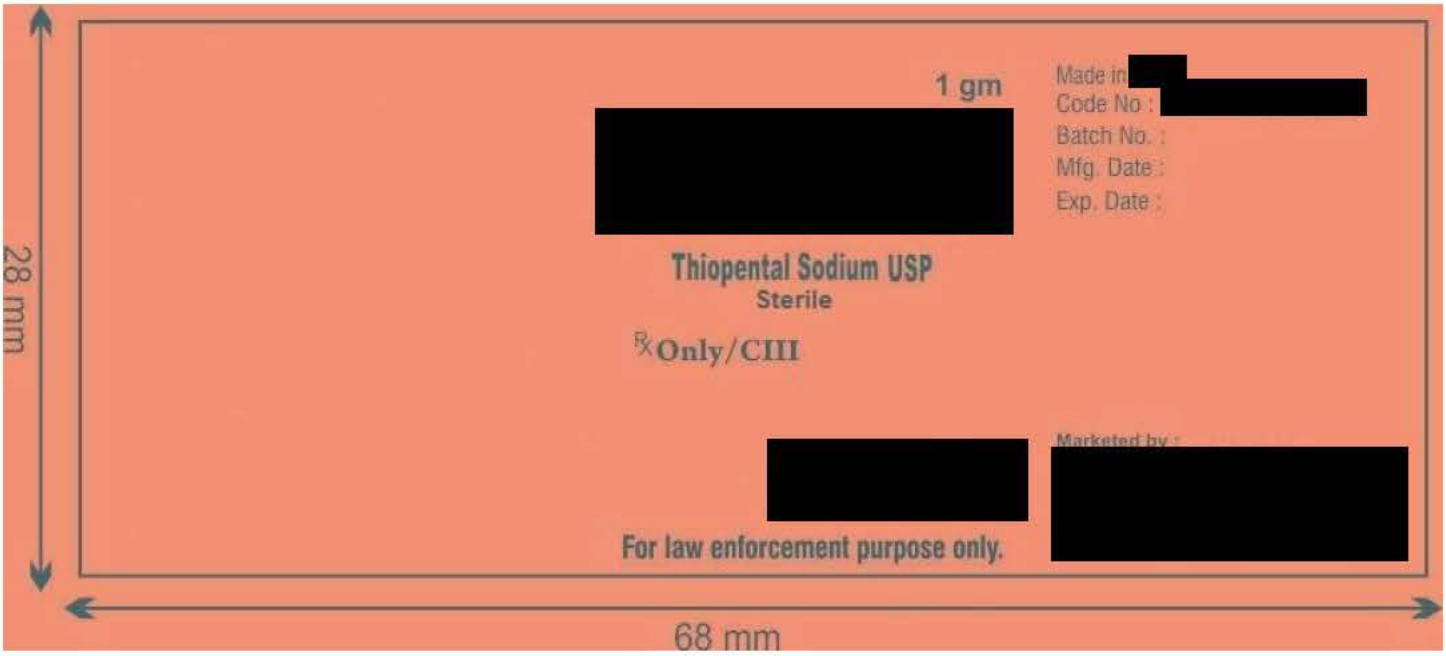
Thiopental Sodium USP

Sterile

Rx Only/CIII

[redacted]

For law enforcement purpose only.



[redacted]

thiopental sodium powder

Product Information

Product Type	BULK INGREDIENT	**Item Code (Source)**	[redacted]
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THIOPENTAL SODIUM (UNII: 49Y44QZL70) (THIOPENTAL - UNII:JI8Z5M7NA3)	THIOPENTAL	100 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	[redacted]	1 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
bulk ingredient		06/05/2015	

Labeler [redacted]

Establishment

Name	Address	ID/FEI	Business Operations
[redacted]		[redacted]	[redacted]

Revised: 6/2015 [redacted]

For help, click the "Help" tab. Refer to the FDA SPL XForms web page for troubleshooting help and other advisories. For any remaining unanswered questions email may be sent to spl@fda.hhs.gov and spl@pragmaticdata.com.

Exhibit 3

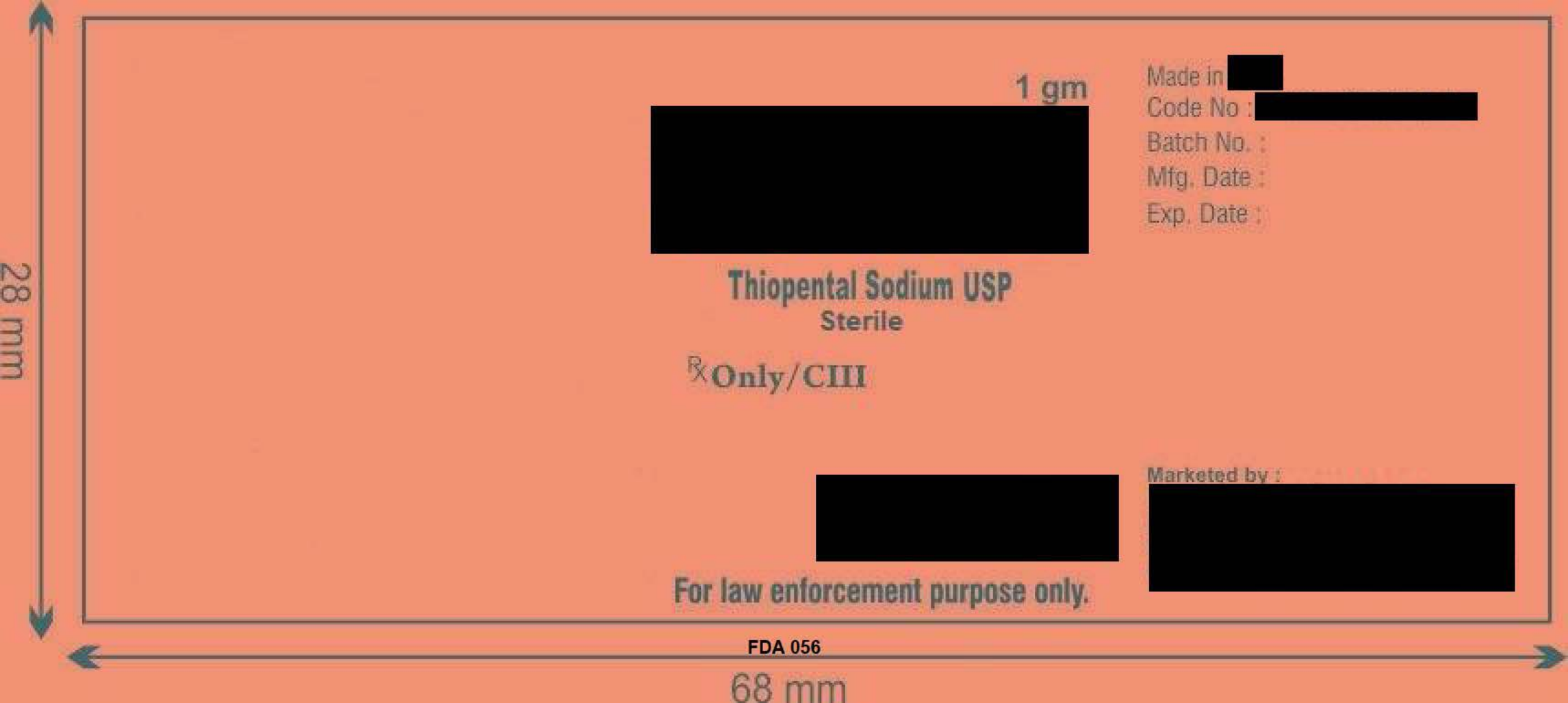

1 gm
[redacted]
Made in [redacted]
Code No : [redacted]
Batch No. :
Mfg. Date :
Exp. Date :
Thiopental Sodium USP
Sterile
℞ Only/CIII
[redacted]
Marketed by :
[redacted]
For law enforcement purpose only.
28 mm
FDA 056
68 mm

Exhibit 4

[redacted]

CUSTOM INVOICE

SHIPPER [redacted]		INVOICE NO & DATE [redacted] 04/07/2015	EXPORTERS REF [redacted]
CONSIGNEE ATTN: [redacted] **DEA Number:** [redacted] **Phone Number:** [redacted]		**Buyers Order No:** [redacted]	
PRE CARRIAGE BY [redacted]	PLACE OF RECEIPT OF PRE CARRIER	COUNTRY OF ORIGIN [redacted]	COUNTRY OF FINAL DESTINATION **USA**
VESSEL / FLIGHT NO	PORT OF LOADING [redacted]		
PORT OF DISCHARGE	FINAL DESTINATION **Huntsville, Texas**		

DESCRIPTION OF GOODS MARKS & NO/ NO & KIND OF PACKAGE CONTAINER NO:	QUANTITY	AMOUT per unit (USD)	AMOUNT (USD)
Thiopenta Sodium USP 1gm Vial	1000 Vials	[redacted]	[redacted]
Value Given For Custom Purpose: [redacted]			[redacted]
Declaration: We declare that this invoice shows the actual price of the goods Described and that all the particulars are true and correct	SIGNATURE / DATE		

[redacted]

[redacted]

Air Waybill

Issued by

[redacted]

[redacted]

[redacted]

[redacted]

FREIGHT PREPAID

PRIORITY

[redacted]

DFW [redacted] PPPP PP NVD

DALLAS

NOTIFY TO: [redacted]

CONTENTS: CHEMICALS
NON HAZARDOUS

[redacted] [redacted] [redacted] 426/- [redacted]/-

DIMS [redacted]

12k vol.wt

11502/-

AWB 150/-PCA 250/-OSC 100/-STAX 70/-

AWC 150/-SCC 100/-EU 455/-

570/-

705/-

OC

12777/-

9/7/15

[redacted]

[redacted]

FDA 059

Exhibit 5

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection
ENTRY/IMMEDIATE DELIVERY

Form Approved
OMB No. 1651-0024

BOX: [redacted] [redacted] AMS CARRIER [redacted]

19 CFR 142.3, 142.16, 142.22, 142.24 ABI CERTIFIED

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
072415		01 CONSMPTION	[redacted]
5. PORT	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER	
5309		[redacted]	
	8. CONSIGNEE NUMBER		9. IMPORTER NUMBER
	[redacted]		[redacted]
10. ULTIMATE CONSIGNEE NAME		11. IMPORTER OF RECORD NAME	
[redacted]		[redacted]	
12. CARRIER CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(S)/NAME(S)	
[redacted]	[redacted]	[redacted]	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE
5501			[redacted]

20. DESCRIPTION OF MERCHANDISE
THIOPENTIAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY

21. IT/BL/ AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.
I	[redacted]		[redacted]		[redacted]
M	[redacted]	[redacted]			

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT

FI

PHONE NO. [redacted]

DATE 07/29/15

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CBP EXAMINATION REQUIRED

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:	SIGNATURE	DATE

29. BROKER OR OTHER GOVT. AGENCY USE

02 FDA HOLD	07/27/15
14 FDA DOCUMENTS REQUIRED	07/27/15
02 FDA HOLD	07/28/15
14 FDA DOCUMENTS REQUIRED	07/28/15
04 FDA EXAM/SAMPLE	07/29/15
01 FDA EXAM	07/29/15

PAPERWORK REDUCTION ACT STATEMENT: An agency may not conduct or sponsor an information collection and a person is not required to respond to this information unless it displays a current valid OMB control number and an expiration date. The control number for this collection is 1651-0024. The estimated average time to complete this application is 15 minutes. If you have any comments regarding the burden estimate you can write to U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., Washington DC 20229.

Exhibit 6

[redacted]

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2015	FEE EXEMPT

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,	IMPORTER	01-21-2015

[redacted]

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2015	FEE EXEMPT

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,	IMPORTER	01-21-2015

[redacted]

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

Form DEA-223 (4/07)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

FDA063

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2015	FEE EXEMPT
SCHEDULES	**BUSINESS ACTIVITY**	**ISSUE DATE**
3N.	IMPORTER	01-21-2015

[redacted]

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (4/07)

REPORT CHANGES PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at 1-(800) 882-9539 - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 28083
Washington, DC 20083

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

2330

Exhibit 7

TX002

U.S. Department of Justice / Drug Enforcement Administration

CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION

(Read Instructions on reverse before completing)

OMB APPROVAL
No. 1117-0009
EXPIRATION DATE: 9/30/2016
See reverse for Privacy Act

1. CHECK ONE

☑ IMPORT DECLARATION — Nonnarcotic Substances in Schedules III, IV, V

☐ EXPORT DECLARATION — Nonnarcotic Substances in Schedules III, and IV and all substances in Schedule V

U.S. CUSTOMS CERTIFICATION

Date of Departure/Arrival

Date of Certification

Signature of Customs Official

DEA Transaction ID

IMPORTER/EXPORTER (Name and Address)

[redacted]

DEA REGISTRATION NO. [redacted]

BROKER OR FORWARDING AGENT, IF USED (Name and Address)

[redacted]

2. CONTROLLED SUBSTANCES TO BE IMPORTED OR EXPORTED

2a. NAME AND QUANTITY OF DRUG OR PREPARATION *(Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC Number)*	2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION expressed as acid, base or alkaloid. *(Enter names of controlled substances contained in the drug, compound, or preparation)*	2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY *(Completed by registrant at time of transaction)*
Thiopental 1,000 vials 993.6 mg powder / vial (Thiopental Sodium) 914.1 mg powder / vial (Thiopental) DEA Number: [redacted] NDC Number:	Thiopental 1,000 vials / shipment x 914.1 mg / vial = 914100 mg / shipment = 914.1 g / shipment of Thiopental	

3a. ☑ FOREIGN (for U.S. import) ☐ DOMESTIC (for U.S. export) PORT OF **EXPORTATION** AND APPROX. DEPARTURE DATE

[redacted]

3b. ☐ FOREIGN (for U.S. export) ☑ DOMESTIC (for U.S. import) PORT OF **IMPORTATION** AND APPROX. ARRIVAL DATE

George Bush Intercontinental / Houston Airport (IAH) - June 23, 2015

4a. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known)

Air Freight

4b. NAME OF ALL INTERMEDIATE CARRIERS

[redacted]

5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR

[redacted]

I hereby certify that the substance(s) listed in Section 2 are to be ☑ Imported (conform to 21 U.S.C. § 952(b)) ☐ Exported (conform to 21 U.S.C. § 953(e)) and are intended for ☐ Medical, ☐ Scientific, or ☑ Other legitimate uses (attach explanation for other legitimate use).

☐ The above named substances are to be Re-Exported (Attach documentation per Title 21, CFR 1312.27) to (list countries):

If the form is being used as an "Export Declaration", attach documentation that the consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances. If the controlled substances are being re-exported from the first country to second countries, attach documentation that the consignee in the country of ultimate destination is authorized under the laws and regulations of that country to receive the controlled substances.

SIGNATURE OF AUTHORIZED INDIVIDUAL OF IMPORTER /	DATE	NAME OF FIRM AND TELEPHONE NUMBER
[redacted]	June 8, 2015	[redacted]

DEA FORM–236 COPY 3

FDA 066

[redacted]

TX002

Explanation for the Legitimate Use of Thiopental Being Imported Under 21 U.S.C. § 952

This product is being imported for use by the [redacted] law enforcement activities. The product complies with federal statutory and regulatory requirements. The [redacted] will not use this product for activities other than law enforcement activities.

[redacted]

June 8, 2015
Date

[redacted]

Exhibit 8

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JUL 13 2015

[redacted]

Dear [redacted]

This letter is confirmation of previous communications with Associate Attorney [redacted] on June 18, 2015 and June 24, 2015 regarding the proposed importation of sodium thiopental. As you know, the Drug Enforcement Administration (DEA) was notified by the Food and Drug Administration (FDA) that the sodium thiopental the [redacted] seeks to import is an unapproved drug product in the United States and it appears to be misbranded or in violation of 21 U.S.C. § 355. According to the FDA, there is no approved application for sodium thiopental, and it is illegal to import an unapproved new drug into the United States.

In light of the information provided by the FDA and the [redacted] recently submitted DEA Controlled Substances Import/Export Declaration, DEA Form 236, the DEA notified the Customs Border and Protection and the FDA of the potential illegal importation of sodium thiopental.

If you have any questions regarding this matter, please contact [redacted] Chief, Regulatory Section at [redacted]

Sincerely,

[redacted]
Assistant Administrator
Office of Diversion Control

Exhibit 9

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: [redacted]

Notice Number: 2
July 29, 2015

Filer:
[redacted]

Attention:
Broker Box: [redacted]

>

<

Port of Entry: 5309, Houston Intercontinental Airport, Houston, TX
Carrier: [redacted]
Date Received: July 27, 2015
Arrival Date: July 24, 2015
Importer of Record: [redacted]
Consignee:

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	THIOPENTAL-NA STERILE PWDR (LAW ENFORCEMENT ONLY)	1000 PCS	Detained 07-29-2015

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a localtion within the metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By

001/001 THIOPENTAL-NA STERILE PWDR August 18, 2015
(LAW ENFORCEMENT ONLY)

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application.

Please direct your response to:

Rosa L. Santos, Compliance Officer (Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5269
(214) 253-5316 (FAX)
ROSA.SANTOS@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: AO

Exhibit 10

2350 N Sam Houston Pkwy E, Ste 1000
Houston, TX 77032

Detention Number: 15- 016

NOTICE OF DETENTION

U.S. Customs and Border Protection

Port Code: 5309 Port Name: Houston Location of Merchandise:

Date of Detention: 8/5/2015 Entry number: [redacted]

Broker: [redacted]

Importer: [redacted] Importer Number: [redacted]

Reason for Detention: Detain for FDA admissibility and further analysis

Estimated length of Detention: 30 Days

Tests or Inquiries to be Conducted:

Additional Information/Action Requested of Importer:

Requested By: SCBPO [redacted] Date of Request: 8/4/2015

Detaining Officer: SCBPO [redacted] Supervisory Approval By: SCBPO [redacted]

Customs Point of Contact: SCBPO [redacted] Phone Number: [redacted]

(This detention may be released only by the Team or by the Inspector who initiated it. Before releasing this merchandise, contact the detaining officer).

Additional Remarks:

Extension of Detention Period Until: Extension Authorized by:

Dispositon: Disposition Date:

Shipments may be detained for up to 30 days, unless statutory or interagency agreements mandates that a longer period of time is required, or the importer/broker requests a longer detention period through the Port Director.

U.S. Customs and Border Protection is providing information appearing on, and, subject to bonding requirements, unredacted samples of, products and their packaging and labels, or photographs of such products, packaging, and labels that bear or consist of a mark suspected of being counterfeit of a mark you have recorded with CBP. The information that you are receiving may be protected by the Trade Secrets Act and may only be used to assist CBP with its infringment determination.

AGREEMENT TO REDELIVER MERCHANDISE: If merchandise is release conditionally from Customs custody to the principle before all required evidence is produced, before its quantity and value are determined, the principle agrees to redeliver timely, on demand by Customs, the merchandise released if it fails to comply with the laws or regulations governing admission into the United States.

(Section 113.62(d)(1) Customs Regulations

Exhibit 11

[redacted]

[redacted]

CONFIDENTIAL COMMERCIAL COMMUNICATION

August 18, 2015

Via Email: ***douglas.stearn@fda.hhs.gov; domenic.veneziano@fda.hhs.gov; steven.scofield@cbp.dhs.gov***

Douglas Stearn
Director
Office of Enforcement and Import Operations
U.S. Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857

Re: Request for Delivery of Imported Sodium Thiopental to Destination

Dear Mr. Stearn,

We represent [redacted]. Please see attached authorization letter. Presently the Customs Service Port at the Bush International Airport in Houston has detained our client's shipment of thiopental sodium – entry number [redacted] (entered July 27, 2015). Neither we nor our client's broker has received the CBP Detention Notice explaining the reason for the detention now over 15 days since arrival.

According to the Detention Notice, CBP is detaining the goods at the request of FDA. Therefore, we request that FDA instruct CBP to lift the detention and permit the goods to proceed to destination under the importer's basic importation bond as is ordinary in the course of commercial import transactions.

[redacted] needs to receive the goods at destination to complete the transaction for the goods. To that end, [redacted] has declared in writing that upon receipt of the goods at destination it will not use the product unless and until FDA's pending detention of the good is resolved. See attached.

* * *

If you have any questions regarding the foregoing, please feel free to contact me or my Senior Associate, [redacted] by phone [redacted] or email at [redacted].

Sincerely,

[redacted]

[redacted]

Cc: [redacted] (co-counsel)

[redacted]

July 27, 2015

To Whom it May Concern:

RE: FDA, DEA and U.S. CBP matters

Please be advised we, the [redacted], have authorized the law firm of [redacted] to engage the U.S. Food and Drug Administration (FDA), the Drug Enforcement Agency, and the Bureau of Customs and Border Protection (CBP) respecting all issues related to the manufacture, distribution, exportation, and importation of FDA-regulated products.

In order to assist us in our matters, we authorize you to discuss our FDA, DEA, and CBP related issues, filings, and records with [redacted] and the other attorneys at the firm. [redacted] their Regulatory Advisors, [redacted] their Regulatory Specialist, [redacted] or their paralegals. [redacted]. The firm's telephone number is [redacted]. If you have any questions regarding this authorization, please do not hesitate to contact me at [redacted].

Sincerely,

[redacted]

[redacted]

[redacted]

August 4, 2015

Captain Domenic Veneziano, Director
Division of Import Operations
Food and Drug Administration

Re: Entry #[redacted]

Dear Captain Veneziano:

I understand that the FDA is seeking to detain the shipment covered by the above-referenced entry. I am writing to let you know that we need to take possession of the shipment in order to complete the transaction. If the [redacted] were to take possession, it would be subject to a customs bond that requires [redacted] to relinquish possession if the detention issue is finally resolved against it. [redacted] promises that if it takes possession of the shipment before resolution of the detention issue, it will not use the product unless and until the FDA's detention issue is finally resolved in [redacted] favor.

Thank you for your consideration.

Sincerely,

[redacted]

[redacted]

Exhibit 12

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 24, 2015

[redacted]

Dear [redacted]:

This letter is in response to your August 18, 2015 letter regarding import entry [redacted] a shipment of sodium thiopental imported by the [redacted].

In your letter, you request that FDA instruct CBP to lift the detention and permit the goods to proceed to destination. FDA has determined that this shipment should not be allowed to move to destination at this time and thus will not be requesting that CBP lift its detention.

If you should have any further questions related to this matter, please feel free to contact me at 301-796-6673 or at Domenic.Veneziano@fda.hhs.gov

Sincerely,

CAPT Domenic J. Veneziano,
Director, Division of Import Operation
United States Public Health Service

Exhibit 13

AFFIDAVIT OF [redacted]

State of Texas §
§
County of Walker §

Before me, the undersigned authority, on this day personally appeared [redacted], who after being duly sworn according to law, upon his oath, deposed and said:

My name is [redacted] I am over 18 years of age, fully competent to make this affidavit, and personally acquainted with the facts herein. I have been employed by the [redacted] since June of 1981. I have held the positions of [redacted]. I am currently the [redacted] and have held that position since [redacted]. I am responsible for the [redacted] spread throughout the state of Texas. One of those facilities is the [redacted], located in [redacted].

The primary mission of the [redacted], as with any law enforcement agency in Texas, "is to provide public safety." Tex. Gov't Code § 493.001. Part of that mission includes, as mentioned above, the incarceration of adult felony offenders. Tex. Gov't Code § 494.001. Another part is carrying out a sentence of death. Tex. Code Crim. Proc. art. 43.14(a). As to the latter, Texas law requires an offender to be executed "by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death." *Id.* And under that law, I am responsible for determining the lethal-injection procedure for the execution of an offender. *Id.*

[redacted]

[redacted] stores its lethal-injection chemicals at the [redacted] in a locked, secure room. This area has been licensed and inspected by the Texas Department of Public Safety and the Drug Enforcement Administration. Each aforementioned entity is responsible for the registration and licensing of controlled substances in the state of Texas. The lethal-injection chemicals are stored in a physical location that is separate from the pharmacy that is also at the [redacted]. The attached Exhibit A is a true and correct copy of the [redacted] Execution Procedure, July 2012, which describes the process of handling the chemicals on the day of execution.

[redacted] has purchased the thiopental sodium currently being detained by the FDA. [redacted] has previously purchased and used thiopental sodium in numerous executions before it became commercially unavailable to correctional facilities for such purpose. In order to resume use of thiopental sodium for executions, no legislative or regulatory action is necessary. My responsibilities to determine the lethal injection procedure include the discretionary decision to determine which substance or substances to use. As part of my statutory duty to ensure that lawful capital sentences are carried out via lethal injection, I am attempting to once again utilize thiopental sodium in executions and will do so when necessary if the FDA releases its hold on the purchased thiopental sodium.

Further Affiant sayeth not.

[redacted]

NOTARY PUBLIC STATE OF TEXAS

[redacted]

Notary Public, State of Texas
My Commission Expires
10 12 2016

Notary Without Bond

[redacted]

SWORN TO AND SUBSCRIBED BEFORE ME on this the 21st day of October, 2015.

[redacted]

Notary Public in and for the State of Texas

[redacted]

Exhibit A

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CORRECTIONAL INSTITUTIONS DIVISION

EXECUTION PROCEDURE

July 2012

FDA 085

ADOPTION OF EXECUTION PROCEDURE

In my duties as Division Director of the Correctional Institutions Division, I hereby adopt the attached *Execution Procedure* for use in the operation of the Texas Department of Criminal Justice Death Row housing units and perimeter functions. This *Procedure* is in compliance with Texas Board of Criminal Justice Rule §152.51; §§492.013(a), 493.004, Texas Government Code, and Article 43.14 – 43.20, Code of Criminal Procedure.

R C Thaler

Rick Thaler
Director, Correctional Institutions Division

7-09-2012

Date

EXECUTION PROCEDURES

PROCEDURES

I. Procedures Upon Notification of Execution Date

A. The clerk of the trial court pursuant to Tex Code of Criminal Procedure art. 43.15 shall officially notify the Correctional Institutions Division (CID) Director, who shall then notify the Death Row Unit Warden, and the Huntsville Unit Warden of an offender's execution date. Once an execution date is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief, and the Death Row Supervisor.

B. The Death Row Supervisor shall schedule an interview with the condemned offender and provide him with the Notification of Execution Date (Form 1). This form provides the offender with a list of the information that shall be requested from him (2) two weeks prior to the scheduled execution.

C. The condemned offender may be moved to a designated cell. Any keep-on-person (KOP) medication shall be confiscated and administered to the offender as needed by Unit Health Services staff.

II. Stays of Execution

A. Official notification of a stay of execution shall be delivered to the CID Director, the Death Row Unit Warden, and the Huntsville Unit Warden through the Huntsville Unit Warden's Office. **Staff must not accept a stay of execution from the offender's attorney.** After the official stay is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief and Death Row Supervisor.

B. Designated staff on the Death Row Unit shall notify the offender that a stay of execution has been received.

III. Preparation of the Execution Summary and Packet

A. Two Weeks (14 days) Prior to the Execution

1. The Death Row Unit shall begin preparation of the Execution Summary. The Execution Summary (Form 2) and the Religious Orientation Statement (Form 3) shall be forwarded to the Death Row Supervisor or Warden's designee for completion. A copy of the offender's current visitation list and recent commissary activity shall also be provided.

2. The Death Row Supervisor shall arrange an interview with the condemned offender to gather the information necessary to complete the Execution Summary and Religious Orientation Statement.

3. An offender may request to have his body donated to the Texas State Anatomical Board for medical education and research. The appropriate paperwork shall be supplied to the offender upon request.

4. The Execution Summary must be completed and returned by the Death Row Supervisor or Warden's designee in sufficient time to be forwarded to the CID Director's Office by noon of the 14th day. After approval by the CID Director, the summary shall be forwarded to the Death Row Unit Chaplain, the Huntsville Unit Warden's Office, and Public Information.

5. If the offender wishes to change the names of his witnesses, and it is less than fourteen (14) days prior to the scheduled execution, the offender shall submit a request in writing to the CID Director through the Death Row Unit Warden, who shall approve or disapprove the changes.

6. The Death Row Unit is responsible for completion of the Execution Packet, which shall include:

   a. Execution Summary;

   b. Religious Orientation Statement;

   c. Copy of the Offender Travel Card;

   d. Current Visitation List;

   e. Execution Watch Notification;

   f. Execution Watch Logs;

   g. I-25 Offender's Request for Trust Fund Withdrawal;

   h. Offender Property Documentation (PROP-05 and PROP-08); and

   i. Other documents as necessary.

7. The Death Row Supervisor or the Warden's designee shall notify staff (Form 4) to begin the Execution Watch Log (Form 5).

8. The Execution Watch Log shall begin at 6:00 a.m. seven (7) days prior to the scheduled execution. The seven (7) day timeframe shall not include the day of the execution. The offender shall be observed, logging his activities every 30 minutes for the first six (6) days and every 15 minutes for the remaining 36 hours. The Public Information Office may request information from the Execution Watch Log on the day of execution.

9. The original Execution Packet and the offender's medical file shall be sent with the condemned offender in the transport vehicle to the Huntsville Unit or the Goree Unit for a female offender. The Death Row Unit Warden shall maintain a copy of the Execution Packet on the Death Row Unit.

10. If there are any changes necessary to the Execution Packet, staff shall notify the CID Director's Office and the Huntsville Unit Warden's Office.

B. The Day of Execution

1. On the morning of the day of the execution prior to final visitation, all of the offender's personal property shall be packed and inventoried. The property officer shall complete an "Offender Property Inventory" (PROP-05) detailing each item of the offender's property. The property officer shall also complete a "Disposition of Confiscated Offender Property" (PROP-08) indicating the offender's choice of disposition of personal property.

   a. If disposition is to be made from the Huntsville Unit a copy of the property forms should be maintained by the Death Row Unit Property Officer and the originals forwarded to the Huntsville Unit with the property.

   b. If disposition is to be made from the Death Row Unit a copy of the property forms will be placed in the Execution Packet and the original forms maintained on the Death Row Unit through the completion of the disposition process.

   c. The Mountain View Unit Warden shall ensure that a female offender brings personal hygiene and gender-specific items to the Huntsville Unit as appropriate.

2. Designated staff shall obtain the offender's current Trust Fund balance and prepare the Offender's Request for Trust Fund Withdrawal (I-25) for completion by the offender.

   a. The following statement should be written or typed on the reverse side of the I-25, "In the event of my execution, please distribute the balance of my Inmate Trust Fund account as directed by this Request for Withdrawal." The offender's name, number, signature, thumbprint, date, and time should be below this statement. Two (2) employees' names and signatures should be below the offender's signature as witnesses that the offender authorized the form.

b. This Request for Withdrawal form shall be delivered to the Inmate Trust Fund for processing by 10:00 a.m. CST the next business day following the execution.

3. A female offender may be transported to the Goree unit prior to the day of the execution. The Execution Transport Log for Female Offenders (Form 7) shall be initiated at the Mountain View Unit. The Goree Unit staff will initiate the Execution Watch Log upon arrival on the Goree Unit, permit visitation as appropriate and transport the offender to the Huntsville Unit. The Transport Log shall resume when the offender departs the Goree Unit.

4. The condemned offender shall be permitted visits with family and friends on the morning of the day of the scheduled execution. No media visits shall be allowed at the Goree Unit.

   NOTE: Special visits (minister, relatives not on the visitation list, attorney, and other similar circumstances) shall be approved by the Death Row or Goree Unit Warden or designee. Exceptions may be made to schedule as many family members to visit prior to the offender's scheduled day of execution. These are considered to be special visits. No changes shall be made to the offender's visitation list.

5. The Execution Watch Log shall be discontinued when the Execution Transport Log for Male Offenders (Form 6) is initiated.

6. When appropriate the offender shall be escorted to 12 building at the Polunsky or the designated area at the Mountain View or Goree Unit and placed in a holding cell. The appropriate Execution Transport Log shall be initiated and the offender shall be prepared for transport to the Huntsville Unit. The offender shall be removed from the transport vehicle at the Huntsville Unit and escorted by Huntsville Unit security staff into the execution holding area.

7. Any transportation arrangements for the condemned offender between units shall be known only to the Wardens involved, the CID Director, as well as those persons they designate as having a need to know. No public announcement shall be made concerning the exact time, method, or route of transfer. The CID Director's Office and the Public Information Office shall be notified immediately after the offender arrives at the Huntsville Unit

8. When the offender enters the execution holding area the Execution Watch Log shall immediately resume. The restraints shall be removed and the offender strip-searched.

9. The offender shall be fingerprinted, placed in a holding cell, and issued a clean set of TDCJ clothing.

10. The Warden shall be notified after the offender has been secured in the holding cell. The Warden or designee shall interview the offender and review the information in the Execution Packet.

11. Staff from the Public Information Office shall also visit with the offender to determine if he wishes to make a media statement and to obtain authorization, if necessary, to release the statement.

12. The offender may have visits with a TDCJ Chaplain(s), a Minister/Spiritual advisor who has the appropriate credentials and his attorney(s) on the day of execution at the Huntsville Unit; however, the Huntsville Unit Warden must approve all visits.

13. There shall be no family or media visits allowed at the Huntsville Unit.

IV. Drug Team Qualifications and Training

A. The drug team shall have at least one medically trained individual. Each medically trained individual shall at least be certified or licensed as a certified medical assistant, phlebotomist, emergency medical technician, paramedic, or military corpsman. Each medically trained individual shall have one year of professional experience before participating as part of a drug team, shall retain current licensure, and shall fulfill continuing education requirements commensurate with licensure. Neither medically trained individuals nor any other members of the drug team shall be identified.

B. Each new member of the drug team shall receive training before participating in an execution without direct supervision. The training shall consist of following the drug team through at least two executions, receiving step-by-step instruction from existing team members. The new team member will then participate in at least two executions under the direct supervision of existing team members. Thereafter, the new team member may participate in executions without the direct supervision of existing team members.

C. The Huntsville Unit Warden shall review annually the training and current licensure, as appropriate, of each team member to ensure compliance with the required qualifications and training.

V. Pre-execution Procedures

A. The Huntsville Unit Warden's Office shall serve as the communication command post and entry to this area shall be restricted.

B. Inventory and Equipment Check

1. Designated staff on the Huntsville Unit are responsible for ensuring the purchase, storage, and control of all chemicals used in lethal injection executions for the State of Texas.

2. The drug team shall obtain all of the equipment and supplies necessary to perform the lethal injection from the designated storage area.

3. An inventory and equipment check shall be conducted.

4. Expiration dates of all applicable items are to be checked on each individual item. Outdated items shall be replaced immediately.

C. Minister/Spiritual and attorney visits shall occur between 3:00 and 4:00 p.m. CST unless exceptional circumstances exist. Exceptions may be granted under unusual circumstances as approved by the Huntsville Unit Warden.

D. The offender shall be served his last meal at approximately 4:00 p.m. CST.

E. The offender shall be afforded an opportunity to shower and shall be provided with clean clothes at some time prior to 6:00 p.m. CST.

F. The CID Director or designee, the Huntsville Unit Warden or designee and the Huntsville Unit Chaplain or a designated approved TDCJ Chaplain shall accompany the offender while in the Execution Chamber.

VI. Set up Preparations for the Lethal Injection

A. One (1) syringe of normal saline shall be prepared by members of the drug team.

B. The lethal injection drug shall be mixed and syringes shall be prepared by members of the drug team as follows:

Pentobarbital – 100 milliliters of solution containing 5 grams of Pentobarbital.

C. The drug team shall have available a back-up set of the normal saline syringe and the lethal injection drug in case unforeseen events make their use necessary.

VII. Execution Procedures

A. After 6:00 p.m. CST and after confirming with the Office of the Attorney General and the Governor's Office that no further stays, if any, will be imposed and that imposition of the court's order should proceed, the CID Director or designee shall give the order to escort the offender into the execution chamber.

B. The offender shall be escorted from the holding cell into the Execution Chamber and secured to the gurney.

C. A medically trained individual shall insert intravenous (IV) catheters into a suitable vein of the condemned person. If a suitable vein cannot be discovered in an arm, the medically trained individual shall substitute a suitable vein in another part of the body, but shall not use a "cut-down" procedure to access a suitable vein. The medically trained individual shall take as much time as is needed to properly insert the IV lines. The medically trained individual shall connect an IV administration set, and start a normal saline solution to flow at a slow rate through one of the lines. The second line is started as a precaution and is used only if a potential problem is identified with the primary line. The CID Director or designee, the Huntsville Unit Warden or designee, and the medically trained individual shall observe the IV to ensure that the rate of flow is uninterrupted.

D. Witnesses to the execution shall be brought into the appropriate viewing area ONLY AFTER the Saline IV has been started and is running properly, as instructed by the Huntsville Unit Warden or designee.

E. The CID Director or designee shall give the order to commence with the execution.

F. The Huntsville Unit Warden or designee shall allow the condemned person to make a brief, last statement.

G. The Huntsville Unit Warden or designee shall instruct the drug team to induce, by syringe, substances necessary to cause death.

H. The flow of normal saline through the IV shall be discontinued.

I. The lethal dose of Pentobarbital shall be commenced. When the entire contents of the syringe have been injected, the line shall be flushed with an injection of normal saline.

J. The CID Director or designee and the Huntsville Unit Warden or designee shall observe the appearance of the condemned individual during application of the Pentobarbital. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the CID Director or designee

shall instruct the drug team to administer an additional 5 grams of Pentobarbital followed with a saline flush.

K. At the completion of the process and after a sufficient time for death to have occurred, the Warden shall direct the physician to enter the Execution Chamber to examine the offender, pronounce the offender's death, and designate the official time of death.

L. The body shall be immediately removed from the Execution Chamber and transported by a coordinating funeral home. Arrangements for the body should be concluded prior to execution.

VIII. Employee participants in the Execution Process shall not be identified or their names released to the public. They shall receive an orientation with the Huntsville, Goree, Polunsky, or Mountain View Unit Wardens, who shall inform the employees of the TDCJ ED-06.63, "Crisis Response Intervention Support Program" (CRISP). The employees shall be encouraged to contact the Regional CRISP Team Leader following the initial participation in the execution process.