

OFFICE OF THE SECRETARY

P.O. Box 942883
Sacramento, CA 94283-0001



December 9, 2010

Ms. Ruth Dixon
Department of Health and Human Services
Food and Drug Administration

Dear Ms. Dixon:

Since 1993, California law has authorized capital punishment by lethal injection pursuant to Penal Code Section 3604. The law states the punishment of death shall be inflicted by the administration of an intravenous injection of substances in a lethal quantity sufficient to cause death. On May 1, 2009, the California Department of Corrections and Rehabilitation (CDCR) promulgated regulations setting forth the requirements for administering capital punishment by lethal injection pursuant to Administrative Procedure Act. Those regulations became effective on August 29, 2010. The regulations provide for the use of three chemicals; sodium thiopental, pancuronium bromide, and potassium chloride.

There is a national shortage of sodium thiopental. California, like many other states, has been actively seeking supplies of the sodium thiopental for future executions. California's supply of sodium thiopental expired on October 1, 2010. On November 22, 2010, CDCR notified the United States District Court for the Northern District of California that it had ordered (b) (5) of sodium thiopental that expires in 2014 from a manufacturer based in England (FDA # 112-99-38358-2). CDCR expected to receive the sodium thiopental during the week of November 29, 2010. Although CDCR followed all proper procedures and the Drug Enforcement Agency and United States Customs has approved the shipment, this shipment is currently be held by your office.

Per your conversation with (b) (7)(C) we are asking for the immediate release and shipment of the (b) (5) of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or (b) (7)(C)

Sincerely,

A handwritten signature in black ink, appearing to read "Ben T. Rice".

BENJAMIN T. RICE
General Counsel

cc: (b) (7)(C)

From: Dixon, Ruth P
Sent: Friday, January 07, 2011 3:43 PM
To: 'Rice, Benjamin@CDCR'
Cc: 'McAuliffe, John@CDCR'; 'Kernan, Scott@CDCR'
Subject: RE: Letter to Ms. Dixon

Attachments: FDA Letter 010711.pdf

Good afternoon,

Enclosed is the FDA letter regarding the FDA Release of entry 112-9938358-2.

Ruth P. Dixon

Supervisory Investigator
New Orleans District
Import Operations

From: Kernan, Scott@CDCR [mailto:Scott.Kernan@cdcr.ca.gov]
Sent: Thursday, December 09, 2010 2:03 PM
To: Dixon, Ruth P
Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR
Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium Thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections

FDA000065

nd Rehabilitation

rom: Gaddi, Kathy@CDCR

ent: Thursday, December 09, 2010 11:58 AM

o: Kernan, Scott@CDCR

bject: Letter to Ms. Dixon

Kathy.Dixon@FDA.HHS.gov

Kathy Gaddi

Executive Assistant to Scott Kernan

Undersecretary, Operations

916) 341-7015

From: Boulmay, Christopher
Sent: Tuesday, November 30, 2010 4:00 PM
To: 'McAuliffe, John@CDCR'
Cc: Kernan, Scott@CDCR; Halpenny, Susan M; Dixon, Ruth P
Subject: RE: FDA entry item # 112-99-38358-2
John,

This entry is currently under review by our DIOP branch. (b) (5)
If you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

Christopher Boulmay

Consumer Safety Officer
US Food & Drug Administration
NOL-DO: Memphis R.P.
Phone: (901) 333-3528
Fax: (901) 333-3577

From: McAuliffe, John@CDCR [mailto:John.McAuliffe@cdc.ca.gov]
Sent: Tuesday, November 30, 2010 3:37 PM
To: Boulmay, Christopher
Cc: Kernan, Scott@CDCR
Subject: FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to (b) (5)
I also called your phone number 901-333-3528 and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

John McAuliffe
California Department of Corrections and Rehabilitation

From: Kernan, Scott@CDCR [Scott.Kernan@cdcr.ca.gov]
Sent: Thursday, December 09, 2010 2:03 PM
To: Dixon, Ruth P
Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR
Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf
Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR
Sent: Thursday, December 09, 2010 11:58 AM
To: Kernan, Scott@CDCR
Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi
Executive Assistant to Scott Kernan
Undersecretary, Operations
(916) 341-7015

From: Dixon, Ruth P
Sent: Thursday, December 09, 2010 2:24 PM
To: Veneziano, Domenic J.
Cc: Halpenny, Susan M
Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf
Good day Domenic,

Before I had the opportunity to return the call to the Undersecretary I received this message with the enclosed letter. Mr. McAuliffe also followed up with a phone call...they will be trying to call the Commissioner's office and you via the general phone numbers [REDACTED] (b) (5) [REDACTED].

Ruth P. Dixon

Supervisory Investigator
New Orleans District
Import Operations

From: Kernan, Scott@CDCR [mailto:Scott.Kernan@cdcr.ca.gov]
Sent: Thursday, December 09, 2010 2:03 PM
To: Dixon, Ruth P
Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR
Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

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Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR
Sent: Thursday, December 09, 2010 11:58 AM
To: Kernan, Scott@CDCR
Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi
Executive Assistant to Scott Kernan
Undersecretary, Operations
(916) 341-7015

From: McAuliffe, John@CDCR [John.McAuliffe@cdcr.ca.gov]
Sent: Monday, December 20, 2010 12:44 PM
To: Dixon, Ruth P
Cc: Kernan, Scott@CDCR
Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf
Ms. Dixon

Could you please update us on the approval of delivery of the Sodium Thiopental to the California Department of Corrections and Rehabilitation. Thank you in advance.

John McAuliffe

From: McAuliffe, John@CDCR
Sent: Thursday, December 09, 2010 12:10 PM
To: McCleave, Kelly@CDCR
Subject: FW: Letter to Ms. Dixon

FYI

From: Kernan, Scott@CDCR
Sent: Thursday, December 09, 2010 12:03 PM
To: Ruth.Dixon@FDA.HHS.gov
Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR
Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR
Sent: Thursday, December 09, 2010 11:58 AM
To: Kernan, Scott@CDCR
Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi
Executive Assistant to Scott Kernan

Undersecretary, Operations
(916) 341-7015