

STATE OF NEBRASKA

DEPARTMENT OF CORRECTIONAL SERVICES

Scott R. Frakes

Director



Pete Ricketts
Governor

6 July 2015

Ms. Amy A. Miller
Attorney at Law
ACLU
amiller@aclunebraska.org

Re: Public Records Request June 2015

Dear Ms. Miller,

In response to your request for documents relating to the recent announcement that Nebraska has attempted to obtain and/or has obtained pharmaceuticals for the purposes of carrying out a lethal injection execution, limited to the time period of June 5, 2015 through June 30, 2015, attached please find copies of the following:

1. E-mail from Matt Miltenberger to Scott Frakes dated 26 June 2015, including attachment, 2 pages.
2. E-mails between Cathy Gallagher and Scott Frakes dated June 18 and June 19, 2015, 2 pages.
3. E-mail from Kathy Blum to Cathy Gallagher dated June 24, 2015, including attachment, 2 pages.
4. Letter from Scott Frakes to the Drug Enforcement Agency dated 29 May 2015, 1 page.

Sincerely,

Julie D. Smith,
General Counsel

Frakes, Scott

From: Miltenberger, Matt
Sent: Friday, June 26, 2015 11:22 AM
To: Frakes, Scott
Subject: FW: harris fda establishment registration is CURRENT fwiw

From: Lopez, Dave
Sent: Friday, June 26, 2015 10:13 AM
To: Miltenberger, Matt
Cc: Smith, James; Bydalek, Dave; Post, Ryan
Subject: FW: harris fda establishment registration is CURRENT fwiw

Matt-

Per your request, below is the screenshot from the FDA's website indicating Harris Pharma's FDA establishment registration. I'll add the caveat that this was the result of some cursory searching on their website and we haven't done any full-scale research (yet) as to its legal significance. We have not yet reached a final determination as to its impact on our current import issue.

Dave.

21 U.S. Code Chapter 1 X			
W: Federal Food, Drug, and Cosmetic Act X			
FDA Law Blog: FDA Regulations X			
Cook v. Food & Drug Admin. X			
FDA Drug Establishments C X			
www.accessdata.fda.gov/scripts/cder/drfs/getdrfs.cfm			
SGstyle NEJud NEApp NEDisc NEPIdg NEProc SSCALES JUSTICE EFILE 8th 8thR DNeB ECF			
Home > Drug Databases > Drug Establishments Current Registration Site			
Drug Establishments Current Registration Site			
Search Results for harris			
Firm Name	Facility Establishment Identifier	Data Universal Numbering System Number	Address
George's Harrisonburg Feedmill	1126242	961948325	61 Kratzer Road, Harrison Virginia (VA) 22802, Unit (USA)
Harris Pharma LLP		859036525	RDB Boulevard, Level 8, Sector V, Block EP & GP, City, Kolkata, West Beng India (IND)
Harrison Poultry Inc. DBA Harrison Milling Co.	3004257159	010109858	243 E Midland Ave., Win (GA) 30680, United State
Harrison Specialty Co., Inc.		001000355	15 University Road, Cant Massachusetts (MA) 020 States (USA)
1			

David A. Lopez
Assistant Attorney General
Nebraska Department of Justice
2115 State Capitol
Lincoln, Nebraska 68509-8920

402.471.3882 phone
402.471.3297 fax
Dave.Lopez@nebraska.gov

Frakes, Scott

From: Gallagher, Cathy A. <Cathy.A.Gallagher@usdoj.gov>
Sent: Friday, June 19, 2015 8:54 AM
To: Frakes, Scott
Cc: Gallagher, Cathy A.
Subject: RE: DEA - Import Declaration - Denied

Good Morning Scott,

In talking with another state on the same issue, I have been informed that correct NDC # is 69860-001-01. You are using the same manufacturer in India. I am in discussion with my upper management. Until totally resolved, if product is shipped CBP has been alerted to detain and not seize the product. I am hopeful to resolve this issue today. I am not in the office and do not have your counsels' names with me. Please forward my e-mail.

Thanks,
Cathy

Cathy Gallagher, Chief
Regulatory Section

From: Gallagher, Cathy A.
Sent: Thursday, June 18, 2015 10:42 AM
To: 'scott.frakes@nebraska.gov'
Cc: Gallagher, Cathy A.
Subject: RE: DEA - Import Declaration - Denied

Scott,

I have to deny the declaration since the product is not FDA approved. I will be notifying CBP to not allow the shipment into the U.S. The NDC # G2100-0300-** is not valid and cannot be used. This number should not have been provided by DEA. I just spoke to your counsel, Mark Boyer and Kathy Blum and explained the issue.

Thanks,
Cathy

Cathy Gallagher, Chief
Regulatory Section

From: Gallagher, Cathy A.
Sent: Thursday, June 18, 2015 9:01 AM
To: 'scott.frakes@nebraska.gov'

Cc: Gallagher, Cathy A.
Subject: RE: DEA - Import Declaration

Clarification: Is the product manufactured in an FDA-Approved facility?

From: Gallagher, Cathy A.
Sent: Thursday, June 18, 2015 8:58 AM
To: 'scott.frakes@nebraska.gov'
Cc: Gallagher, Cathy A.
Subject: DEA - Import Declaration

Good Morning Scott,

In regard to state of Nebraska's Dept. of Correction's Import Declaration 5159973, can you please verify that the Thiopental being imported is approved in the finished form by the FDA? The product should have an FDA approved NDC #. The one on the application G2100-3000-** is not a correct #. Has the substance be imported yet?

Please call me at 202-307-7194 or on my BB at 202-373-8643.

Thanks,
Cathy Gallagher

Cathy Gallagher, Chief
Regulatory Section
Office of Diversion Control

From: Blum, Kathy
Sent: Wednesday, June 24, 2015 2:30 PM
To: 'Cathy.A.Gallagher@usdoj.gov'
Subject: Form 236
Attachments: 20150624142229354.pdf

Ms. Gallagher,

Attached is the Nebraska Department of Correctional Services revised Form 236. The form has been revised to reflect the corrected NDC Number you provided us.

Kathleen A. Blum
Associate Legal Counsel
Nebraska Department of Correctional Services
Phone: 402-479-5901
Fax: 402-479-5623
E-mail: kathy.blum@nebraska.gov

U.S. Department of Justice / Drug Enforcement Administration CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION <i>(Read Instructions on reverse before completing)</i>		OMB APPROVAL No. 1117-0009 EXPIRATION DATE: 9/30/2016 See reverse for Privacy Act	
1. CHECK ONE <input checked="" type="checkbox"/> IMPORT DECLARATION Nonnarcotic Substances in Schedules III, IV, V <input type="checkbox"/> 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	
IMPORTER/EXPORTER (Name and Address) Nebraska State Penitentiary 4201 14th South Street Lincoln, NE 68502		BROKER OR FORWARDING AGENT, IF USED (Name and Address) Not Applicable	
DEA REGISTRATION NO. 0414104 RN0414184		DEA Transaction ID 5159973	
2. CONTROLLED SUBSTANCES TO BE IMPORTED OR EXPORTED			
2a. NAME AND QUANTITY OF DRUG OR PREPARATION <i>(Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC Number)</i> Sodium Thiopental 1gm Vial Quantity: 1,000 vials CSA Drug Code: 2100 NDC Number: 02100-0000 69860-001-01		2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION expressed as acid, base or alkaloid. <i>(Enter names of controlled substances contained in the drug, compound, or preparation)</i> Sodium Thiopental 1,000 Vials multiplied by 1 gram Sodium Thiopental = 1,000 grams Sodium Thiopental No Conversion Factor Applies to Sodium Thiopental per DEA instruction.	
		2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY <i>(Completed by registrant at time of transaction)</i>	
3a. <input checked="" type="checkbox"/> FOREIGN (for U.S. Import) <input type="checkbox"/> DOMESTIC (for U.S. export) PORT OF EXPORTATION AND APPROX. DEPARTURE DATE Kolkata, India June 18, 2015 (Approximate)		3b. <input type="checkbox"/> FOREIGN (for U.S. export) <input checked="" type="checkbox"/> DOMESTIC (for U.S. Import) PORT OF IMPORTATION AND APPROX. ARRIVAL DATE Omaha, NE June 21, 2015 (Approximate)	
4a. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known) Fedex		4b. NAME OF ALL INTERMEDIATE CARRIERS N/A	
5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR Harris Pharma LLP Level 8, RDB Boulevard, Plot K1, Sector V, Salt Lake City Kolkata 700091, West Bengal, India			
I hereby certify that the substance(s) listed in Section 2 are to be <input checked="" type="checkbox"/> Imported (conform to 21 U.S.C. § 952(b)) <input type="checkbox"/> Exported (conform to 21 U.S.C. § 953(e)) and are intended for <input type="checkbox"/> Medical, <input type="checkbox"/> Scientific, or <input checked="" type="checkbox"/> Other legitimate uses (attach explanation for other legitimate use). <input type="checkbox"/> 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 / EXPORTER, BROKER OR FORWARDING AGENT  Print Name: Scott Frakes		DATE 5/29/2015 NAME OF FIRM AND TELEPHONE NUMBER State of Nebraska Department of Corrections (402) 479-5630 E-mail: scott.frakes@nebraska.gov	

STATE OF NEBRASKA

DEPARTMENT OF CORRECTIONAL SERVICES

Scott R. Frakes

Director



Pete Ricketts
Governor

May 29, 2015

Drug Enforcement Agency
Attention: ODGI Import/Export Unit (Ms. Kara Sweeney)
8701 Morrisette Drive
Springfield, Virginia 22152

RE: Form 236 Legitimate Use Declaration

To Whom It May Concern,

I, Scott R. Frakes, as Director of the Nebraska Department of Correctional Services do hereby notify the United States Drug Enforcement Agency that I have sought the importation of Sodium Thiopental pursuant to DEA Form 236. The shipment of 1,000 vials containing 1 gram each of Sodium Thiopental will solely be used for the legitimate purpose of the Nebraska Department of Correctional Services carrying out lethal injections for those persons sentenced to death in the State of Nebraska.

Sincerely,

Scott R. Frakes, Director

Nebraska Department of Correctional Services