

STATE OF MAINE DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION

BOARD OF PHARMACY

35 STATE HOUSE STATION AUGUSTA, MAINE 04333-0035

Anne L. Head, Esq. Commissioner Geraldine L. Betts

July 27, 2021

To: The Joint Standing Committee on Health and Human Services

Re: Pursuant to L.D. 793, An Act To Improve Accountability of Opioid Manufacturers

Report on Implementation of Public Law 2020 Chapter 536 and Fees Collected From

Opioid Medication and Product Registration

Dear Senator Claxton, Representative Meyer, and Members of the Joint Standing Committee on Health and Human Services:

During the 129th Maine Legislature, President Jackson presented L.D. 793, "An Act To Improve Accountability of Opioid Manufacturers." The bill was enacted as <u>Public Law 2020, Chapter 536</u> on January 12, 2020, effective on June 16, 2020. The bill established an Opioid Use Disorder Prevention and Treatment Fund, to be used for opioid use disorder prevention and treatment services administered by the Department of Health and Human Services. The law provides that the Fund would be financed by fee assessments collected by the Board of Pharmacy from opioid manufacturers. The following is a summary of the Maine Board of Pharmacy's experience with implementation of this law, followed by the Board's report pursuant to Section 4 of L.D. 793¹.

Updates to Agency Licensing Management System

One of the first steps in implementing this new law was to update ALMS² computer configurations to create an intake category for opioid manufacturers and to allow for collection of the fee assessments. The law requires a manufacturer of an opioid medication to pay an annual \$55,000 fee, and any manufacturer that sells, delivers or distributes two million or more units of opioid medication in Maine to pay an annual registration fee of \$250,000. Manufacturers that sell, deliver or distribute two million or less units of an opioid medication in the state in a year are exempt from the \$250,000 fee.

The higher than usual fee assessments presented a situation in which the ALMS software was not capable of collecting and processing the fee payments, if made by credit card, without the Board incurring very high service charges (upwards of \$7,500 for *each* transaction). This presented a transaction cost that the Board of Pharmacy could not absorb.

¹ The Board acknowledges this report to the Joint Standing Committee on Health and Human Services was due March 1, 2021, and we sincerely apologize for the delay. The contents of this memorandum and report more fully explain the factors contributing to the delay.

² "ALMS" stands for Agency Licensing Management System, and is the database used by all of the boards, commissions and regulatory functions of the Office of Professional and Occupational Regulation, to process and track license applications, renewals, and fee payments.

RE: PLC 536 (L.D. 793)

As a result, Board staff worked with individuals in the State Treasury, the Office of Professional and Occupational Regulations accounting division and the ALMS licensing system group to find a resolution to the problem. This process took several months. Thanks to everyone's combined efforts, a separate accounting system, called ACH, now allows our Office to collect large fee amounts without incurring credit card service charges.

All related ALMS reconfigurations were completed in October 2020.

Opioid Medications Excluded from Calculation of Two Million Units Sold, Delivered or Distributed

When calculating the units of an opioid medication to determine whether to assess the product registration fee, the law provides certain opioid medication used for the purpose of medication-assisted treatment (MAT) of substance use disorder be excluded. The law provides that the Board shall periodically provide to DHHS a list of medications exempted. The following is a current list of medication-assisted treatment for substance use disorders that are excluded from the 2 million unit calculation:

Table 1. Medications Exempted from Units of Opioid Medication Calculation

	Bunavail (buprenorphine and naloxone) buccal film					
	Cassipa (buprenorphine and naloxone) sublingual film					
	Probuphine (buprenorphine) implant for subdermal					
	administration					
FDA-approved buprenorphine products approved	Sublocade (buprenorphine extended-release) injection					
for the treatment of opioid dependence	for subcutaneous use					
for the treatment of opioid dependence	Suboxone (buprenorphine and naloxone) sublingual					
	film for sublingual or buccal use, or sublingual tablet					
	Subutex (buprenorphine) sublingual tablet					
	Zubsolv (buprenorphine and naloxone) sublingual					
	tablets					
EDA ammonod mothedone moduets ammonod for	Dolophine (methadone hydrochloride) tablets					
FDA-approved methadone products approved for the treatment of opioid dependence	Methadose (methadone hydrochloride) oral concentrate					
the treatment of opioid dependence	Levo-alpha-acetylmethadol (LAAM or Orlaam)					
FDA-approved naltrexone products approved for	Vivitrol (naltrexone for extended-release injectable					
the treatment of opioid dependence	suspension intramuscular)					

Notice to Maine-Licensed Manufacturers and Evaluation of Exception Requests

On October 6, 2020, notice was sent to all Maine-licensed manufacturers regarding the new opioid fee assessments. The notice provided information regarding the Board of Pharmacy's responsibility to collect the assessment and product registration fee(s) from a manufacturer whose opioid medication product is sold, delivered, or distributed within Maine. See the Notice to Licensed Manufacturers, October 6, 2020. In response, many questions were raised by manufacturers, including questions and requests for additional guidance as to exception requests pursuant to 32 M.R.S. § 13800-C, subsection 2.

The Board responded on May 12, 2021, with a guidance document titled <u>Registration Fee and Report 2020 Opiate Distributions for Exception Requests</u>, which was distributed to all licensed manufacturers. Any manufacturer seeking relief from the \$250,000 product registration fee

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because it purportedly did not sell, deliver, or distribute 2,000,000 or more units of an opioid medication in Maine, was directed to submit to the Board data regarding the manufacturer's distributions of DEA Schedules II-IV (opiates only) by May 26, 2021.

It was discovered during a recent contact with representatives for the Department of Health and Human Services, Prescription Monitoring Program (PMP), that Automation of Reports and Consolidated Orders System (ARCOS) reports³ would greatly assist the Board when considering an exception request from a manufacturer by providing a system of checks and balances. Using these reports will enable verification as to whether the number of opioid drugs sold, delivered, or distributed in Maine by a particular manufacturer met or exceeded 2,000,000 million units.

The representatives from the PMP agreed to share the ARCOS reports received from manufacturers and wholesalers upon receipt. Because the sharing of these reports has just started, it will take some time for the information to be used by the Board when considering a request from a manufacturer for an exception. Over the coming months, the Board will begin its review and consideration of exception requests from the product registration requirement.

Effect of Fees on Prescribing Practices of Opioid Medications

Additional time is needed to evaluate whether the fee assessment and product registration fee have in any way affected or reduced opioid medication prescribing habits. Currently the Board does not have the means to assess or make a determination on the prescribing impact, if any, other than to observe that no complaints have been received claiming that Maine citizens have been unable to obtain opioid medication that was prescribed to them, or that a pharmacist was unable to obtain an opioid prescription medication to dispense upon presentation of a valid prescription drug order.

Conclusion

Attached you will find a summary of the manufacturer fee assessments and product registration fees collected from October 6, 2020, through June 7, 2021, together with a listing of the manufacturers and their contact information.

Implementing this new law has required a significant undertaking by Board staff, in part due to the unexpected difficulty with making adjustments to the ALMS software, combined with the general challenges that have been caused by the pandemic. We appreciate your patience and understanding and will strive for the next reports to be provided in accordance with the law's schedule.

To that end, the next reports to the Joint Standing Committee on Health and Human Services will be due on March 1, 2022, and March 1, 2023. The law is scheduled for repeal on September 1, 2023.

End

³ Public Law Chapter 536 requires manufacturers and wholesalers to provide the PMP with a copy of the report on ARCOS on opioids for Maine filed with the United States Drug Enforcement Administration.

Opioid Use Disorder Prevention and Treatment Fund Public Law 2020 Chapter 536 (LD 793) Effective June 16, 2020

Report on Manufacturer Fee Assessments and Product Registration Fees Collected October 2020 through June 7, 2021

Board of Pharmacy collects a \$55,000 fee assessment from each opioid medication manufacturer, and \$250,000 product registration fee for manufacturers that sell, delivery or distribute 2,000,000 or more units of an opioid medication with Maine. Fees do not apply to a manufacturer of an opioid medication if all of that manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine. Certain opioid medication units are excluded from the calculation of the 2,000,000 units, if prescribed for the purpose of medication-assisted treatment of substance use disorder.

Notices sent to all Maine-licensed Manufacturers, and posted to the Board of Pharmacy webpage

- ➤ Initial notice to Licensed Manufacturers Opening Date for Online Registration: October 6, 2020
- ➤ Registration Fee and Report 2020 Opiate Distributions for Exception Requests and FAQs: May 12, 2021

Number of MFO

- A total of 23 manufacturers reported to the Board that they manufacture opioids.
- A total of 3 manufacturers reported to the Board that they manufacture opioids that are FDA-approved for veterinary use only, and are therefore not subject to the fee assessment.
- ➤ Only 1 manufacturer reported to the Board that it sold, delivered or distributed 2 million or more opioid medication unites in Maine in the preceding year (2020).

Fees collected October 7, 2020 through June 7, 2021

>	\$55,000 Fee assessments	\$1,925,000			
	\$250,000 Product registration fees (collected from one manufacturer)	\$	250,000		
\triangleright	\$325 fee retain by the Board of Pharmacy as provided for under Title 5, § 20010,				
	Section 1(B) for administration and collection and transfer fees to the Fund	(\$	11,375)		
То	\$2	2,163,625			

Licensure Renewal: Manufacturer (MFO) licenses expire December 31, 2021, and are subject to another round of fee assessments. Throughout the year, new manufacturers (initial licensure) will apply for licensure and are subject to the \$55,000 fee assessment upon initial application for licensure. At the time of renewal, an MFO that responds to having manufactured 2 million or more opioids will also be subject to the \$250,000 product registration fee.

Maine Office of Professional and Occupational Regulation

Board of Pharmacy

Report Date: June 7, 2021

End

STATE OF MAINE - DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION - MAINE BOARD OF PHARMACY

Selection File: MFO

MFO30001883 - AMERISOURCE HEALTH SERVICES LLC

Desig. Phys: 2550 JOHN GLENN AVE STE A

Desig. Mail: 2550 JOHN GLENN AVE STE A

COLUMBUS, OH 43217-1188 COLUMBUS, OH 43217-1188

(FRANKLIN) (FRANKLIN)

Desig. Phone: +1 (614) 492-8177 Desig. Fax:

MFO30001884 - AMNEAL PHARMACEUTICALS OF NEW YORK LLC

Desig. Phys: 50 HORSEBLOCK RD Desig. Mail: 400 CROSSING BLVD FL 3

BROOKHAVEN, NY 11719-9509 BRIDGEWATER, NJ 08807-2863

(SUFFOLK) (SOMERSET)

Desig. Phone: +1 (908) 381-2076 Desig. Fax:

MFO30001885 - AMNEAL PHARMACEUTICALS OF NEW YORK, LLC

Desig. Phys: 75 ADAMS AVE Desig. Mail: 400 CROSSING BLVD FL 3

HAUPPAUGE, NY 11788-3605 BRIDGEWATER, NJ 08807-2863

(SUFFOLK) (SOMERSET)

Desig. Phone: +1 (631) 952-0214 Desig. Fax: +1 (631) 656-2505

MFO30001921 - ANESTA LLC

Desig. Phys: 4745 W WILEY POST WAY Desig. Mail: C/O KELLY ODONOGHUE

SALT LAKE CITY, UT 84116-2884 (SALT 1090 HORSHAM RD

LAKE) NORTH WALES, PA 19454-1505

(MONTGOMERY)

Desig. Phone: +1 (801) 525-1405 Desig. Fax: +1 (801) 595-1406

MFO30001867 - ATLAS PHARMACEUTICALS LLC

Desig. Phys: 711 E CAREFREE HWY STE 107 Desig. Mail: 711 E CAREFREE HWY STE 207

PHOENIX, AZ 85085-0103 (MARICOPA) PHOENIX, AZ 85085-0109 (MARICOPA)

Desig. Phone: +1 (844) 661-1829 Desig. Fax: +1 (623) 582-7970

MFO30001887 - ELANCO US INC

Desig. Phys: 12707 SHAWNEE MISSION PKWY Desig. Mail: 12707 SHAWNEE MISSION PKWY

SHAWNEE MISSION, KS 66216-1846 SHAWNEE MISSION, KS 66216-1846

(JOHNSON) (JOHNSON)

Desig. Phone: +1 (317) 220-2913 Desig. Fax:

MFO30001856 - FRESENIUS KABI USA LLC

Desig. Phys: 5200 CORPORATE PKWY Desig. Mail: ATTN QRA - FACILITY LICENSING

WILSON, NC 27893-9412 (WILSON) 7000 CARDINAL PL

DUBLIN, OH 43017-1091 (FRANKLIN)

Desig. Phone: +1 (614) 553-3076 Desig. Fax: +1 (614) 652-0674

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Desig. Phys: 3159 STALEY RD Desig. Mail: ATTN QRA - FACILITY LICENSING

GRAND ISLAND, NY 14072-2028 (ERIE) 7000 CARDINAL PL

DUBLIN, OH 43017-1091 (FRANKLIN)

Desig. Phone: +1 (614) 553-3076 Desig. Fax: +1 (614) 652-0674

MFO30001886 - GOLDEN STATE MEDICAL SUPPLY INC

Desig. Phys: 5187 CAMINO RUIZ Desig. Mail: 5187 CAMINO RUIZ

CAMARILLO, CA 93012-8601 CAMARILLO, CA 93012-8601

(VENTURA) (VENTURA)

Desig. Phone: +1 (805) 477-9866 Desig. Fax: +1 (805) 437-7582

MFO30001860 - HIKMA PHARMACEUTICALS USA INC

Desig. Phys: 1809 WILSON RD Desig. Mail: 1809 WILSON RD

COLUMBUS, OH 43228-9579 COLUMBUS, OH 43228-9579

(FRANKLIN) (FRANKLIN)

Desig. Phone: +1 (614) 276-4000 Desig. Fax: +1 (614) 274-0974

MFO30001865 - HOSPIRA INC

Desig. Phys: HIGHWAY 301 NORTH Desig. Mail: 1855 SHELBY OAKS DR N

ROCKY MOUNT, NC MEMPHIS, TN 38134-7444 (SHELBY)

Desig. Phone: +1 (252) 977-5710 Desig. Fax:

MFO30001866 - HOSPIRA INC

Desig. Phys: 1776 CENTENNIAL DR Desig. Mail: 1855 SHELBY OAKS DR N

MCPHERSON, KS 67460-9301 MEMPHIS, TN 38134-7444 (SHELBY)

(MCPHERSON)

Desig. Phone: +1 (901) 275-0040 Desig. Fax:

MFO30001863 - KINDEVA DRUG DELIVERY LP

Desig. Phys: 19901 NORDHOFF ST Desig. Mail: 19901 NORDHOFF ST

NORTHRIDGE, CA 91324-3213 (LOS NORTHRIDGE, CA 91324-3213 (LOS

ANGELES) ANGELES)

Desig. Phone: +1 (818) 341-1300 Desig. Fax: +1 (818) 709-3055

MFO30001888 - KREMERS URBAN PHARMACEUTICALS INC

Desig. Phys: 1101 C AVE W Desig. Mail: 1101 C AVE W

SEYMOUR, IN 47274-3342 (JACKSON) SEYMOUR, IN 47274-3342 (JACKSON)

Desig. Phone: +1 (812) 523-3457 Desig. Fax: +1 (812) 523-1887

MFO30001895 - MAYNE PHARMA INC

Desig. Phys: 1240 SUGG PKWY Desig. Mail: C/O STATE LICENSE SERVICING

GREENVILLE, NC 27834-9006 (PITT) 1751 STATE ROUTE 17A STE 3 FLORIDA, NY 10921-1061 (ORANGE)

Desig. Phone: +1 (252) 752-3800 Desig. Fax: +1 (252) 758-8522

STATE OF MAINE - DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION - MAINE BOARD OF PHARMACY

MFO30001861 - MYLAN PHARMACEUTICALS INC

Desig. Phys: 781 CHESTNUT RIDGE RD Desig. Mail: PO BOX 4310

> MORGANTOWN, WV 26505-2730 781 CHESTNUT RIDGE RD (MONONGALIA) MORGANTOWN, WV 26505-2730

(MONONGALIA)

Desig. Phone: +1 (304) 599-2595 Desig. Fax:

MFO30001893 - NORWICH PHARMACEUTICALS INC

Desig. Phys: 6826 STATE HIGHWAY 12 Desig. Mail: 6826 STATE HIGHWAY 12

> NORWICH, NY 13815-3335 NORWICH, NY 13815-3335

(CHENANGO) (CHENANGO)

Desig. Phone: +1 (607) 335-3000 Desig. Fax:

MFO30001899 - NOVEL LABORATORIES INC

Desig. Phys: 400 CAMPUS DR Desig. Mail: 400 CAMPUS DR

> SOMERSET, NJ 08873-1145 SOMERSET, NJ 08873-1145

(SOMERSET) (SOMERSET)

Desig. Phone: +1 (908) 603-6000 Desig. Fax:

MFO30001891 - PADDOCK LABORATORIES LLC

Desig. Phys: 3940 QUEBEC AVE N Desig. Mail: 1025 BOULDERS PKWY STE 301

> MINNEAPOLIS, MN 55427-1244 NORTH CHESTERFIELD, VA 23225-5549

(HENNEPIN) (CHESTERFIELD)

Desig. Phone: +1 (763) 546-4676 Desig. Fax:

MFO30001854 - PAR PHARMACEUTICAL INC

Desig. Phys: 1 RAM RIDGE RD Desig. Mail: 1 RAM RIDGE RD

> CHESTNUT RIDGE, NY 10977-6714 CHESTNUT RIDGE, NY 10977-6714

(ROCKLAND) (ROCKLAND)

Desig. Phone: +1 (800) 927-5727 Desig. Fax: +1 (845) 425-8956

MFO30001855 - PURDUE PHARMACEUTICALS L P

Desig. Phys: VP MFG/SUPPLY CHN Desig. Mail: ATTN DONOGH MCGUIRE VP

> 4701 PURDUE DR W **OPERATIONS** WILSON, NC 27893-9680 (WILSON) 4701 PURDUE DR W

WILSON, NC 27893-9680 (WILSON)

Desig. Phone: +1 (252) 265-1900 Desig. Fax:

MFO30001862 - QUVA PHARMA INC

Desig. Phys: 1075 W PARK ONE DR Desig. Mail: 1075 W PARK ONE DR

> SUGAR LAND, TX 77478-2576 (FORT SUGAR LAND, TX 77478-2576 (FORT

BEND) BEND)

Desig. Phone: +1 (888) 339-0874 Desig. Fax:

STATE OF MAINE - DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION - MAINE BOARD OF PHARMACY

MFO30001912 - QUVA PHARMA INC

Desig. Phys: 519 STATE ROUTE 173 Desig. Mail: 519 STATE ROUTE 173

BLOOMSBURY, NJ 08804-4047 BLOOMSBURY, NJ 08804-4047

(WARREN) (WARREN)

Desig. Phone: +1 (888) 339-0874 Desig. Fax:

MFO30001874 - TRIS PHARMA INC

Desig. Phys: 2033 ROUTE 130 Desig. Mail: 2033 ROUTE 130

MONMOUTH JUNCTION, NJ MONMOUTH JUNCTION, NJ

Desig. Phone: +1 (732) 940-2800 Desig. Fax: +1 (732) 940-2855

MFO30001859 - UPSHER-SMITH LABORATORIES LLC

Desig. Phys: 14905 23RD AVE N Desig. Mail: 6701 EVENSTAD DR N

PLYMOUTH, MN 55447-4708 MAPLE GROVE, MN 55369-6026

(HENNEPIN) (HENNEPIN)

Desig. Phone: +1 (763) 315-2000 Desig. Fax: +1 (763) 258-5578

MFO30001919 - WEDGEWOOD CONNECT LLC

Desig. Phys: 17 GREAT OAKS BLVD Desig. Mail: 17 GREAT OAKS BLVD

SAN JOSE, CA 95119-1359 (SANTA SAN JOSE, CA 95119-1359 (SANTA

CLARA) CLARA)

Desig. Phone: +1 (800) 216-5005 Desig. Fax:

LastName	LicensePrefix L	icenseNumber Fee Assesses	IssueDate Expiration Fire	stLicenseDate Mailing Address	Address2	Address4 Address5	City	State	ZipCode County	Country Authority1	Physical Address	Physical Address	Physical Address	Homecity	Home_sta	ate Home_zip Home_county
AMERISOURCE HEALTH SERVICES LLC	MFO	30001883 \$55,000 Original MFO	4-Jan-21 31-Dec-21	4-Jan-21 2550 JOHN GLENN AVE STE A		COLUMBUS, OH 43217-1188	COLUMBUS	ОН	43217-1188 FRANKLIN	Human Opioid Manufacturing	2550 JOHN GLENN AVE STE A		COLUMBUS, OH 43217-1188	COLUMBUS	ОН	43217-1188 FRANKLIN
AMNEAL PHARMACEUTICALS																
NEW YORK LLC AMNEAL PHARMACEUTICALS	MFO OF	30001884 \$55,000 Original MFO	7-Jan-21 31-Dec-21	7-Jan-21 400 CROSSING BLVD FL 3		BRIDGEWATER, NJ 08807-2863	BRIDGEWATER	NJ	08807-2863 SOMERSET	Human Opioid Manufacturing	50 HORSEBLOCK RD		BROOKHAVEN, NY 11719-9509	BROOKHAVEN	NY	11719-9509 SUFFOLK
NEW YORK, LLC	MFO	30001885 \$55,000 Original MFO	7-Jan-21 31-Dec-21	7-Jan-21 400 CROSSING BLVD FL 3		BRIDGEWATER, NJ 08807-2863	BRIDGEWATER	NJ	08807-2863 SOMERSET	Human Opioid Manufacturing	75 ADAMS AVE		HAUPPAUGE, NY 11788-3605	HAUPPAUGE	NY	11788-3605 SUFFOLK
ANESTA LLC	MFO	30001921 \$55,000 Original MFO	24-May-21 31-Dec-21	24-May-21 C/O KELLY ODONOGHUE	1090 HORSHAM RD	NORTH WALES, PA 19454-1505	NORTH WALES	PA	19454-1505 MONTGOMERY	Human Opioid Manufacturing Opioids FDA-approved for	4745 W WILEY POST WAY		SALT LAKE CITY, UT 84116-2884	SALT LAKE CITY	UT	84116-2884 SALT LAKE
ATLAS PHARMACEUTICALS LLC	C MFO	30001867 0 Vet Only	2-Dec-20 31-Dec-21	1-Dec-20 711 E CAREFREE HWY STE 207		PHOENIX, AZ 85085-0109	PHOENIX	AZ	85085-0109 MARICOPA	Veterinary-use ONLY Opioids FDA-approved for	711 E CAREFREE HWY STE 107		PHOENIX, AZ 85085-0103	PHOENIX	AZ	85085-0103 MARICOPA
ELANCO US INC	MFO	30001887 0 Vet Only \$55,000 Original MFO	26-Jan-21 31-Dec-21	26-Jan-21 12707 SHAWNEE MISSION PKWY	(SHAWNEE MISSION, KS 66216-1846	SHAWNEE MISSION	KS	66216-1846 JOHNSON	Veterinary-use ONLY	12707 SHAWNEE MISSION PKWY		SHAWNEE MISSION, KS 66216-1846	SHAWNEE MISSION	KS	66216-1846 JOHNSON
FRESENIUS KABI USA LLC	MFO	30001856 and at Renewal \$55,000	11-Dec-20 31-Dec-21	19-Oct-20 ATTN QRA - FACILITY LICENSING	7000 CARDINAL PL	DUBLIN, OH 43017-1091	DUBLIN	ОН	43017-1091 FRANKLIN	Human Opioid Manufacturing	5200 CORPORATE PKWY		WILSON, NC 27893-9412	WILSON	NC	27893-9412 WILSON
		\$55,000 Original MFO														
FRESENIUS KABI USA LLC GOLDEN STATE MEDICAL	MFO	30001857 and at Renewal \$55,000	11-Dec-20 31-Dec-21	19-Oct-20 ATTN QRA - FACILITY LICENSING	7000 CARDINAL PL	DUBLIN, OH 43017-1091	DUBLIN	ОН	43017-1091 FRANKLIN	Human Opioid Manufacturing	3159 STALEY RD		GRAND ISLAND, NY 14072-2028	GRAND ISLAND	NY	14072-2028 ERIE
SUPPLY INC	MFO	30001886 \$55,000 Original MFO	16-Nov-20 31-Dec-21	16-Nov-20 5187 CAMINO RUIZ		CAMARILLO, CA 93012-8601	CAMARILLO	CA	93012-8601 VENTURA	Human Opioid Manufacturing	5187 CAMINO RUIZ		CAMARILLO, CA 93012-8601	CAMARILLO	CA	93012-8601 VENTURA
HIKMA PHARMACEUTICALS U	IC A	ÉEE 000 Original MEO														
INC	MFO	\$55,000 Original MFO 30001860 and at Renewal \$55,000	15-Dec-20 31-Dec-21	19-Oct-20 1809 WILSON RD		COLUMBUS, OH 43228-9579	COLUMBUS	ОН	43228-9579 FRANKLIN	Human Opioid Manufacturing	1809 WILSON RD		COLUMBUS, OH 43228-9579	COLUMBUS	ОН	43228-9579 FRANKLIN
		\$55,000 Original MFO														
HOSPIRA INC	MFO	30001865 and at Renewal \$55,000 \$55,000 Original MFO	10-Dec-20 31-Dec-21	19-Oct-20 1855 SHELBY OAKS DR N		MEMPHIS, TN 38134-7444	MEMPHIS	TN	38134-7444 SHELBY	Human Opioid Manufacturing	HIGHWAY 301 NORTH		ROCKY MOUNT, NC	ROCKY MOUNT	NC	
HOSPIRA INC	MFO	30001866 and at Renewal \$55,000 \$55,000 Original MFO	10-Dec-20 31-Dec-21	30-Oct-20 1855 SHELBY OAKS DR N		MEMPHIS, TN 38134-7444	MEMPHIS	TN	38134-7444 SHELBY	Human Opioid Manufacturing	1776 CENTENNIAL DR		MCPHERSON, KS 67460-9301	MCPHERSON	KS	67460-9301 MCPHERSON
KINDEVA DRUG DELIVERY LP KREMERS URBAN	MFO	30001863 and at Renewal \$55,000	1-Jan-21 31-Dec-21	30-Oct-20 19901 NORDHOFF ST		NORTHRIDGE, CA 91324-3213	NORTHRIDGE	CA	91324-3213 LOS ANGELES	Human Opioid Manufacturing	19901 NORDHOFF ST		NORTHRIDGE, CA 91324-3213	NORTHRIDGE	CA	91324-3213 LOS ANGELES
PHARMACEUTICALS INC	MFO	30001888 \$55,000 Original MFO	28-Jan-21 31-Dec-21	28-Jan-21 1101 C AVE W		SEYMOUR, IN 47274-3342	SEYMOUR	IN	47274-3342 JACKSON	Human Opioid Manufacturing	1101 C AVE W		SEYMOUR, IN 47274-3342	SEYMOUR	IN	47274-3342 JACKSON
MAYNE PHARMA INC	MFO	30001895 \$55,000 Original MFO	4-Mar-21 31-Dec-21	4-Mar-21 C/O STATE LICENSE SERVICING	1751 STATE ROUTE 17A STE 3	FLORIDA, NY 10921-1061	FLORIDA	NY	10921-1061 ORANGE	Human Opioid Manufacturing	4240 SUCC DIVANV		GREENVILLE, NC 27834-9006	GREENVILLE	NC	27834-9006 PITT
		\$55,000 Original MFO			781 CHESTNUT											
MYLAN PHARMACEUTICALS IN NORWICH PHARMACEUTICALS		30001861 and at Renewal \$55,000	8-Jan-21 31-Dec-21	30-Oct-20 PO BOX 4310	RIDGE RD	MORGANTOWN, WV 26505-2730	MORGANTOWN	WV	26505-2730 MONONGALIA	Human Opioid Manufacturing	781 CHESTNUT RIDGE RD		MORGANTOWN, WV 26505-2730	MORGANTOWN	WV	26505-2730 MONONGALIA
INC	.S MFO	30001893 \$55,000 Original MFO	9-Feb-21 31-Dec-21	9-Feb-21 6826 STATE HIGHWAY 12		NORWICH, NY 13815-3335	NORWICH	NY	13815-3335 CHENANGO	Human Opioid Manufacturing	6926 STATE HIGHWAY 12		NORWICH, NY 13815-3335	NORWICH	NY	13815-3335 CHENANGO
NOVEL LABORATORIES INC	MFO	30001899 \$55,000 Original MFO	11-Mar-21 31-Dec-21	11-Mar-21 400 CAMPUS DR		SOMERSET, NJ 08873-1145	SOMERSET	NI	08873-1145 SOMERSET	Human Opioid Manufacturing			SOMERSET, NJ 08873-1145	SOMERSET	NJ	08873-1145 SOMERSET
PADDOCK LABORATORIES LLC		30001891 \$55,000 Original MFO \$55,000 Original MFO	4-Feb-21 31-Dec-21	4-Feb-21 1025 BOULDERS PKWY STE 301		NORTH CHESTERFIELD, VA 23225-5549		VA	23225-5549 CHESTERFIELD	Human Opioid Manufacturing			MINNEAPOLIS, MN 55427-1244	MINNEAPOLIS	MN	55427-1244 HENNEPIN
PAR PHARMACEUTICAL INC	MFO	30001854 and at Renewal \$55,000 \$55,000 Original MFO	17-Dec-20 31-Dec-21	26-Oct-20 1 RAM RIDGE RD		CHESTNUT RIDGE, NY 10977-6714	CHESTNUT RIDGE	NY	10977-6714 ROCKLAND	Human Opioid Manufacturing	1 RAM RIDGE RD		CHESTNUT RIDGE, NY 10977-6714	CHESTNUT RIDGE	NY	10977-6714 ROCKLAND
		and at Renewal \$250,000	n	ATTN DONOGH MCGUIRE VP												
PURDUE PHARMACEUTICALS	LP MFO	30001855 and \$55,000 \$55,000 Original MFO	30-Dec-20 31-Dec-21	23-Oct-20 OPERATIONS	4701 PURDUE DR W	WILSON, NC 27893-9680	WILSON	NC	27893-9680 WILSON	Human Opioid Manufacturing	VP MFG/SUPPLY CHN	4701 PURDUE DR	W WILSON, NC 27893-9680	WILSON	NC	27893-9680 WILSON
QUVA PHARMA INC	MFO	30001862 and at Renewal \$55,000	1-Jan-21 31-Dec-21	28-Oct-20 1075 W PARK ONE DR		SUGAR LAND, TX 77478-2576	SUGAR LAND	TX	77478-2576 FORT BEND	Human Opioid Manufacturing	1075 W PARK ONE DR		SUGAR LAND, TX 77478-2576	SUGAR LAND	TX	77478-2576 FORT BEND
QUVA PHARMA INC	MFO	30001802 and at keriewai 333,000 30001912 \$55,000 Original MFO	20-Apr-21 31-Dec-21	20-Apr-21 519 STATE ROUTE 173		BLOOMSBURY, NJ 08804-4047	BLOOMSBURY	NJ	08804-4047 WARREN	Human Opioid Manufacturing			BLOOMSBURY, NJ 08804-4047	BLOOMSBURY	NJ	08804-4047 WARREN
2277777777777777	0	\$55,000 Original MFO								Taman opioia mandiacturing	222 27112 1100 12 270					
TRIS PHARMA INC	MFO	30001874 and at Renewal \$55,000	26-Jan-21 31-Dec-21	15-Dec-20 2033 ROUTE 130		MONMOUTH JUNCTION, NJ	MONMOUTH JUNCTION	N NJ		Human Opioid Manufacturing	2033 ROUTE 130		MONMOUTH JUNCTION, NJ	MONMOUTH JUNCTION	N NJ	
UPSHER-SMITH LABORATORIE	ES	\$55,000 Original MFO											·			
LLC	MFO	30001859 and at Renewal \$55,000	21-Dec-20 31-Dec-21	29-Oct-20 6701 EVENSTAD DR N		MAPLE GROVE, MN 55369-6026	MAPLE GROVE	MN	55369-6026 HENNEPIN	Human Opioid Manufacturing Opioids FDA-approved for	14905 23RD AVE N		PLYMOUTH, MN 55447-4708	PLYMOUTH	MN	55447-4708 HENNEPIN
WEDGEWOOD CONNECT LLC	MFO	30001919 0 Vet only	18-May-21 31-Dec-21	18-May-21 17 GREAT OAKS BLVD		SAN JOSE, CA 95119-1359	SAN JOSE	CA	95119-1359 SANTA CLARA	Veterinary-use ONLY	17 GREAT OAKS BLVD		SAN JOSE, CA 95119-1359	SAN JOSE	CA	95119-1359 SANTA CLARA