

Exhibit D

Control # 2022-4910	DFOI Request Status Acknowledgement Letter	Status Date 07/07/2022	.	ON-LINE
Request Information				
Recd date	Due Date	Agency Track		
07/07/2022	08/04/2022	Simple		
Requester		Requester Reference		
Florida Agency for Health Care Administration				
Requester Address		Bill To		
2727 MAHAN DRIVE MS#6, TALLAHASSEE, FL 32308, US		Florida Agency for Health Care Administration 2727 MAHAN DRIVE MS#6, TALLAHASSEE, FL 32308, US, Attn: Simone Marstiller, 850-412-4118, Jason.Weida@ahca.myflorida.com		
Primary Phone	Requester Email	Signature		
850-412-4118	Jason.Weida@ahca.myflorida.com	Simone Marstiller		
Requester Type		Date Range		
Other		01/05/2019 - 07/06/2022		
Subject				
1. Records relating to Florida's SIP proposal. 2. Records relating to Canadian drug importation programs, including SIP proposals, for the following states: Colorado, New Mexico, New Hampshire, Vermont, and Maine ETC				
Orig. Subject				
1. Records relating to Florida's SIP proposal. 2. Records relating to Canadian drug importation programs, including SIP proposals, for the following states: Colorado, New Mexico, New Hampshire, Vermont, and Maine. 3. Records relating to the Canadian drug importation program and private pharmaceutical stakeholders, including pharmaceutical companies, lobbying groups, and advocacy groups, including the Pharmaceutical Research and Manufacturers of America (PhRMA). 4. Records relating to the development of the SIP review and approval process, including the development of the standards for ascertaining "cost savings to the American consumer." 5. Records relating to the "risk" to the American public's health and safety. 6. Records relating to standards for laboratory testing. 7. Records related to Tab A hereto, which is an FDA presentation titled "Section 804 Importation Program: Overview of Final Rule and Implementation," dated March 31, 2022. 8. Records relating to a completeness review. 9. Records relating to a substantive review and the timeline for such a review. 10. Records related to Tab B hereto, which is an FDA presentation titled "Projecting Cost Savings for the American Consumer," dated March 31, 2022. 11. Records relating to the Canadian drug importation program and HHS guidelines for Regulatory Impact Analysis. 12. Records relating to "analytic approaches." 13. Records relating to "measuring prices." 14. Records relating to the basis or bases for denial of a SIP proposal.				
Max Amount	Action Office(s):			
\$0.00	FDA/OC/OES/DFOI/			
Actual Fees (All Offices)				
\$0.00				
Action Office Information				

FDA/OC/OES/DFOI/

Status	AO Track	Accepted	Subject
Pending Action	Simple	07/11/2022	
Products	Remarks	Actual Fees	
		\$ 0.00	

Status History

Status	Remarks	Date	Changed By
Pending Action		07/11/	Kotler, Sarah B
Pending Acceptanc		07/07/	Kotler, Sarah B

WAIVER REQUEST

Status	Request Date	Follow-up Date	Status Date	Remarks
Pending Approval	07/07/	07/21/	07/07/	The Requester requests a waiver of search, review, and duplication fees because disclosure of the requested records (1) "is likely to contribute significantly to public understanding of the operations or activities of the Government," and (2) "is not primarily in the commercial interest of the requester." Regarding the public understanding prong, first, the request concerns "identifiable operations or activities of the federal government." As described above, the requested records will shed light on the operations or activities of the FDA in implementing the Canadian drug importation program. Second, the request seeks "meaningful information about Government operations or activities that is not already public knowledge." Here, the information is meaningful because the availability of quality, low-cost drugs is a matter of great public interest and concern in Florida, as elsewhere, and this information will

Status	Request Date	Followup Date	Status Date	Remarks
				<p>bring greater public understanding to the Canadian drug importation program and the FDA's efforts to implement that program. In addition, this information is not already public knowledge. To date, neither the FDA nor any other government agency has released the information sought in this FOIA request. Third, the requested information "will advance the understanding of the general public as distinguished from a narrow segment of interested persons," the Requester has the "knowledge or expertise as may be necessary to understand the information," and the Requestor's "intended use of the information would be likely to disseminate the information to the public." As described above, AHCA is a state agency "responsible for the administration of the Florida Medicaid program, licensure and regulation of Florida's health facilities, and for providing information to Floridians about the quality of care they receive." By definition, AHCA has the knowledge and expertise to understand the information sought and to facilitate its public dissemination quickly and effectively. And, as described, AHCA will disseminate this information to the public. Lastly, "the public's understanding of the Government's operations [would] be substantially greater as a result of the disclosure." As stated, the Requester intends to disseminate any information obtained through this request to the public, contributing to the public's enhanced understanding of the Canadian drug importation program</p>

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				<p>and the FDA’s role in implementing the program. To date, the FDA has not released any of the information sought in this FOIA request. Because the disclosure will be the first such disclosure to the public about an important government program, the public’s understanding of the FDA’s operations will be substantially greater than it is currently. Regarding the commercial interest prong, the Requester does not have any commercial interest in the disclosure of the requested records. AHCA does not seek to commercially benefit from this information. Nor could it possibly do so. Rather, the dissemination of information to the public will be at no cost and for the purpose of educating the public and promoting AHCA’s mission.</p>

EXPEDITE REQUEST

Reason	Status	Request Date	FollowUp Date	Status Date	Remarks
Need to Inform Public	Pending Approval	07/07/2022		07/07/2022	<p>The Requester requests that the FDA provide expedited processing of this FOIA request because “there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.” First, the Requestor is “primarily engaged in disseminating</p>

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					<p>information to the general public and not merely to a narrow interest group." AHCA is a state agency with a mission of facilitating "Better Health Care for All Floridians." As part of that mission, AHCA is "responsible for the administration of the Florida Medicaid program, licensure and regulation of Florida's health facilities, and for providing information to Floridians about the quality of care they receive." Dissemination of information about government activities, particularly with respect to healthcare, is a critical and substantial component of AHCA's mission. Because doing so is vital to its work, AHCA will disseminate any information obtained through this request to the public, contributing</p>

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					<p>to the public's enhanced understanding of the Canadian drug importation program and the FDA's role in implementing the program. Second, there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly." Here, the requested records will shed light on the role of the FDA in implementing a program of great interest and importance to the people of Florida. The availability of essential, low-cost drugs is a matter of great public interest and concern in Florida and across America, especially because many vulnerable citizens need these drugs but cannot afford to pay for them. Moreover, the need for this information is urgent. Outpatient</p>

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					<p>prescription drug prices have increased exponentially and continue to rise. At the same time, many Americans cannot afford essential drugs, "forcing them to choose whether to maintain their health, pay the rent or mortgage, or put food on the table." As the U.S. Department of Health and Human Services recently recognized, being forced to make that choice sometimes has dire health consequences: "High drug prices result in access and affordability challenges for many Americans. Twenty-four percent of adults taking prescription drugs say they are hard to afford, and nearly 10 percent of adults report not taking medication as prescribed in order to save money. Some have died as a result." Given this tragic choice</p>

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					<p>many American face, information about what the FDA is doing to implement a government program designed to address skyrocketing drug prices should be disseminated quickly. Third, this FOIA request "specifically concerns identifiable operations or activities of the Federal Government." Here, the requested records will shed light on the operations or activities of the FDA, an agency of the federal government, in implementing the Canadian drug importation program. As required by federal regulation, I hereby certify that the above information is true and correct to the best of my knowledge and belief.</p>

OTHER IDENTIFIERS

Source	Identifier	Remarks
Confirmatio #	FDA22084737	
Max Amount	0.0	

ASSIGNMENT/ASSIGNMENT NOTES

Total # of Assignments : 1

Assigned To	Action/S Matter	Assigned Date/Due Date	Assigned By/Assigned Office	Status/Date	Search/Rev
Kotler, Sarah B	Process,	07/11/2022 08/03/2022	Kotler, Sarah B/ FDA/OC/OES/DFOI/	Accepted/ 07/11/2022	00: 00/ 00: 00

Documents

File Name	Doc Category	Doc Date	Create Date	Remarks
FDA Receipt of FOI Request Control # 2022-4910.PDF	Response	07/0	07/07/	
Acknowledgement Letter.PDF	Response	07/0	07/07/	
2022.07.06 Florida FOIA Requert to FDA (Expedited Processing Requested).pdf	Request		07/07/	