

The Florida Senate Local Funding Initiative Request Fiscal Year 2021-2022

LFIR # 1026

1.	Project Title	Florida Covid Va	accine Phase III -	Oragenics		
2.	Senate Sponsor	Darryl Rouson				
3.	Date of Request	01/14/2021				
	Project/Program De	escription				
	Oragenics is Florida's only company working on a COVID vaccine. By partnering with another Florida manufacturer to conduct research to pre fill syringes (fill finish). This research will be sent to FDA to prepare the tools for clinical trials which will be conducted in Florida in at risk communities and with the veteran population. Clinical trials cost upwards of \$2.5 million and the \$500,000 request enables the research to place the vaccine in the syringe. Unlike current messenger RNA, the vials are no longer available.					
				arned that at least 10 ma	ay be needed to sup	oply the demand.
5.	State Agency to re	ceive requested fu	inds Departr	nent of Health		
,	State Agency conta	acted? Yes				
6. /	Amount of the Non	recurring Request	for Fiscal Year	2021-2022		
	Type of Funding Amount					
Operations 500,000						
	Fixed Capital Outlay	/		0		
- 1	Total State Funds Requested 500,000					
Į					300,000	
		•	1-2022 (includin	g matching funds ava		ect)
7		•	1-2022 (includin	g matching funds ava		ect)
7	Total Project Cost f	for Fiscal Year 202		_	ilable for this proje	ect)
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10. Has the entity requesting this project received any federal assistance related to the COVID-19 pandemic?

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Yes	

If yes, indicate the amount of funds received and what the funds were used for.

Oragenics is working with BARDA, the Department of Defense and other federal agencies on funding.

Oraganics applied for WARP speed funding and will continue to pursue this opportunity once processes are determined.

11. Details on how the requested state funds will be expended

Spending Category	Description	Amount
Administrative Costs:		
Executive Director/Project Head Salary and Benefits		0
Other Salary and Benefits		0
Expense/Equipment/Travel/Supplies/Other		0
Consultants/Contracted Services/Study		0
Operational Costs: Other		
Salary and Benefits		0
Expense/Equipment/Travel/Supplies/ Other	The money will be used to conduct the mouse immunogenicity study demonstrating that the vaccine candidate Terra-CoV 2 generates an appropriate immune response. The study will be included in the FDA Investigational New Drug (IND) application later in 2021. The study will be conducted at a third party vendor, Experimur.	500,000
Consultants/Contracted Services/Study		0
Fixed Capital Construction/Majo	r Renovation:	
Construction/Renovation/Land/ Planning Engineering		0
Total State Funds Requested (m	ust equal total from question #6)	500,000

12. Program Performance

a. What specific purpose or goal will be achieved by the funds requested?

The goal will be for a Florida company to take a COVID vaccine to market.

Oragenics acquisition in March, 2020 of a University of Florida research park company, allowed Oragenics to take the NIH recognized spike protein to the next level of development.

This \$500,000 will provide the next step to begin clinical trials in Black and Brown communities and in the veteran communities.

b. What activities and services will be provided to meet the intended purpose of these funds?

Research and in lab collaboration to ensure the vaccine does not leak from the syringe and that it can be quickly administered.

c. What direct services will be provided to citizens by the appropriation project?



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Florida is in a particularly unique situation as it relates to the supply and demand for a COVID vaccine. The thousands of seniors in and OUT of nursing homes are a primary target. Ease of administration has recently been shown to be difficult.

This funding will allow for those obstacles to be removed and provide a quick delivery of the vaccine. Additionally, Florida's visitors present an opportunity to keep Floridians safe.

d. Who is the target population served by this project? How many individuals are expected to be served?

Citizens of Florida ages 18 and older.

Depending on the production and approval cycles after Phase III clinical trials, Oragencis is poised to produce the needed supply to complement other vaccines.

e. What is the expected benefit or outcome of this project? What is the methodology by which this outcome will be measured?

The benefit is to vaccinate as many Floridians as possible.

The methodology of measurement is scientific and will abide by all CDC and FDA guidance.

f. What are the suggested penalties that the contracting agency may consider in addition to its standard penalties for failing to meet deliverables or performance measures provided for the contract?

Oragenics is willing to have further discussions and establish deliverables based on knowledge from federal agencies that govern vaccine production.

Due to the changing dynamics of the pandemic and disease this question requires additional communication.

13. The owners of the facility to receive, directly or indirectly, any fixed capital outlay funding. Include the relationship between the owners of the facility and the entity.

NA		



The Florida Senate

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14. Requestor Contact Information				
	a. First Name	Amy	Last Name	Maguire
	b. Organization	Oragenics/Shumaker Adv		
	c. E-mail Address	amaguire@shumakeradvisors.com		
	d. Phone Number	(727)656-8413	Ext.	
15.	Recipient Contact	Information		
	a. Organization	Oragenics/Shumaker Adv	isors	
	b. Municipality and County Statewide			
	c. Organization Ty	pe		
	☑For Profit Entity			
	□Non Profit 501(c)(3)			
	□Non Profit 501(c)(4)			
	□Local Entity			
	□University or College			
	□Other (please specify)			
	d. First Name	Alan	Last Name	Joslyn
	e. E-mail Address ajoslyn@oragenics.com f. Phone Number (813)286-7900			
16.	16. Lobbyist Contact Information			
	a. Name	Amy Maguire		
	b. Firm Name	Shumaker Advisors		
	c. E-mail Address	amaguire@shumakeradvisors.com		
	d. Phone Number (727)656-8413			