FDA-Sole Source- 1244384
Synthetic Dihydrodinophysistoxin-1

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NAICS Code:	325411 -Medicinal and Botanical ManufacturingEnzyme proteins (i.e., basic synthetic chemicals), pharmaceutical use, manufacturing

The Food and Drug Administration intends to make a sole source award for one (10) mg of 14,15-Dihydrodinophysistoxin-1. The award will be made to:

The Ohio State University
Department of Chemistry and Biochemistry
Newman and Wolfrom Laboratory
100 West 18th Avenue
Columbus, OH 43210-1185

In accordance with FAR 6.302-1, **Only one responsible source and no other supplies or services will satisfy agency requirements.**

FDA requires to purchase 10mg of Dihydrodinophysistoxin-1. to synthesize sufficient quantities of the newly described diarrhetic shellfish poisoning (DSP) toxin 14,15 dihydrodinophysistoxin-1 (14,15-dihydro-DTX-1) to establish a toxicity equivalency factor (TEF) to be used by FDA to set the guidance level for this toxin in commercial shellfish under the National Shellfish Sanitation Program, and also for the purposes of method development to extend the recently approved LC-MS/MS method for DSP toxins to include this new compound. The toxicity determination and method extension work will be covered as part of a separate project but are both dependent on the availability of sufficient quantities of analytically pure compound.

The Forsyth Research Group in the Department of Chemistry and Biochemistry at the Ohio State University has uniquely extensive experience and knowledge in the synthetic generation of the marine algal toxin okadaic acid and several naturally occurring congeners, including dinophysistoxins. 14,15-dihydro-DTX-1 differs from okadaic acid by having an extra methyl group (carbon atom) at carbon 35 and two extra hydrogens at carbons 14 and 15. There is no feasible way to convert okadaic acid into DTX1. However, the Forsyth group developed an efficient and convergent total synthetic entry to this class of compounds that is amenable to rapid structural variation. They have published extensively in this area, more so than any other research program, and are regarded as global leaders in this area. A thorough search of the Last Modified: April 5, 2017 Page 5 of 7 scientific literature found that only three other research groups had reported on the total synthesis of okadaic acid (Cambridge University, the University of Tokyo,

and Nagoya University), but none of these groups are still actively publishing in this area. Uniquely, Professor Forsyth's research group is the only one in the Americas to have reported the successful total syntheses of okadaic acid analogs (other naturally occurring derivatives of OA such as DTX2). Building upon their published syntheses of dinophysistoxin 2 (DTX2), they reportedly still have synthetic intermediates (building blocks) in storage from their previous work which could be used to jump start the synthesis of 14,15-dihydro-DTX1. This would lower the cost and time required to complete this time sensitive work.

Furthermore the Forsyth Research Group is the only US entity that is qualified and equipped to fulfill the needs of this requirement for the FDA.

This notice of intent is not a request for competitive quotes. However, all responsible sources may submit a capability statement within five (5) days after the publication of this Sole Source Justification which shall be considered by the agency. Responses received after 5 days or without the required information may not be considered. For information concerning this acquisition contact:

Van A Nixon jr.
Contract Specialist
Email: Van.nixon@fda.hhs.gov
Tel: 301-796-7562

A determination by the Government not to compete because of information received is solely within the discretion of the Government. Information received will normally be considered solely for determining whether to conduct a competitive procurement.