

FDA-Sole Source- 1227931A
Delfin VapoMeter

Document Type:	Notice of Intent to Sole Source
Solicitation Number:	FDA - Sole Source – 1227931A
Posted Date:	May 2, 2020
Response Date:	May 7, 2020
NAICS Code:	334516, Analytical Laboratory Instrument Manufacturing, Small Size Standard 1,000 Employees.

The Food and Drug Administration intends to make a sole source award for one (1) unit “VapoMeter” by Delfin. The award will be made to:

Delfin USA

11098 Biscayne Blvd, Suite 301
Miami, FL 33161

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 one (1) unit “VapoMeter by Delfin” to support various projects within the Office of Applied Research and Research and Safety Assessment, Division of Toxicology (OARSA/DOT). OARSA/DOT is developing an in vitro buccal membrane absorption model (IVBMAM) to evaluate the buccal absorption of chemicals/constituents of interest to CFSAN (CARTS IF01546). The Delfin VapoMeter is the only fully portable instrument available for the measurement of trans epidermal water loss (TEWL) and evaporation rates. TEWL is a well-known indicator of the skin's barrier function and is a critical element in skin absorption studies conducted by FDA/CFSAN.

Delfin USA. is the sole provider of VapoMeter and the core consumables in USA. The Delfin VapoMeter with the small adapters allows for direct TEWL measurement in the in vitro diffusion cell system, collecting the data on the barrier integrity in rapid, real-time measurement that is most relevant. The skin/buccal tissue membrane integrity in the diffusion cell system is the essential component in determining and evaluating the safety assessment of ingredients and contaminants that pose hazards in skin or buccal exposures. Most importantly, the Delfin VapoMeter will replace the need for barrier integrity assessments using a radiolabeled marker, making the measurement safer.

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 synopsis 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:

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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.