
From: (b) (6)
Sent: Wednesday, June 28, 2017 9:52 AM
To: 'pvlarton@abr-inc.com'
Subject: FDA RFQ
Importance: High

Good morning Ms. Larton,

My name is (b) (6) and I am a Contract Specialist with the FDA. I am tasked with the purchase of tissues suitable for HM research. I would like to request a quote. Please review the Statement of Work and quote your pricing as outlined.

Pricing Table

CLIN	Service and Supply Description	Quantity	Unit Price	Firm-Fixed Price
10001	Human Fetal Tissue – Liver	16		
10002	Human Fetal Tissue – Thymus	16		
10003	HIV HepB HepC Testing	16		
10002	Shipping and Delivery	16		
	Total			

The total price for the requirement is \$_____.

Company Name: _____ DUNS Number: _____

Statement of Work:

Statement of Needs: The Division of Applied Regulatory Science (DARS) OCP/OTS/CDER is conducting a research program to evaluate the usefulness of humanized mice (HM) for regulatory purposes. The HM are created by surgical implantation of human tissue into mice that have multiple genetic mutations that block the development of the mouse immune system at a very early stage. The absence of the mouse immune system allows the human tissues to grow and develop into functional human tissues. As part of this process DARS needs to repeatedly acquire the proper type of tissues. In order for the humanization to proceed correctly we need to obtain fetal tissue with a specific set of specialized characteristics.

Statement of Work: The supplier will provide human fetal tissue with the following characteristics:

- Age range 16-24 weeks
- Liver and thymus tissue from the same donor unless liver only is requested.
- Tissue must be fresh and never frozen.
- No tissues where the mother is known to be positive for HIV or for Hepatitis A, B, or C viruses.
- No known chromosomal abnormalities.
- Testing for HIV, Hepatitis B & C will be completed on maternal blood for all tissues procured and results provided when available.

Timing of need for tissues affected by a variety of factors that cannot be specified in advance therefore; the supplier will be notified of the need for tissue by email or phone and will notify the investigator by email as to the availability of tissues. Tissue will be requested approximately two to three times per month.

Period of Performance:

Twelve months from the date of award of the contract; on or around 7/7/2017 – 7/6/2018

In order to expedite the services required please return your quote to me by 3:00 pm Eastern Time on 30 June 2017. If you do not wish to submit a quote on this requirement, I would appreciate it if you would let me know.

Please let me know if you have any questions. Thank you.

Best regards,

(b) (6)

Contract Specialist

OAGS, FDA

Phone: (b) (6)