

STATEMENT OF WORK

REQUIREMENT TITLE

One (1) Free-standing Polypropylene Ductless Fume Hood Enclosure

BACKGROUND

The Forensic Chemistry Center (FCC) in The Office of Regulatory Affairs/Office of Regulatory Science/Medical Products, and Specialty Labs (ORA/ORS/OMPSLO) requires the purchase of one (1) free-standing polypropylene ductless fume hood enclosure. FCC provides forensic sample analyses in support of criminal, regulatory, consumer complaint and import investigations of FDA-regulated products. A free-standing polypropylene ductless fume hood enclosure is required for the safe storage and handling of bulk/oversized opioid submissions.

PURPOSE

FCC has provided field support to Import Mail Facilities (IMFs), Express Courier Hubs (ECHs) and FDA/Office of Criminal Investigations (OCI) in the analysis of bulk APIs and solid dosage forms. FCC is developing methods capable of rapidly screening both bulk active pharmaceutical ingredients (APIs) and solid dosage forms for authenticity and active ingredients including opioids. As such, a free-standing polypropylene ductless fume hood enclosure is required for storage of bulk /oversized opioid submissions allowing for proper containment and safety applications for the laboratory.

SCOPE

The FCC requires one (1) free-standing polypropylene ductless fume hood enclosure. The system must meet or exceed the following requirements:

I. Minimum Performance Requirements/Salient Characteristics

All the following system requirements are minimum requirements. Equivalent requirements that differ from these minimum requirements shall be justified by the proposing vendor and evaluated by the FCC prior to purchase.

- The system shall include a free-standing polypropylene ductless fume hood enclosure for storage of non-flammable laboratory materials.
- The system shall filter gases and particulates through activated carbon and HEPA filters and recirculate clean air into the room.
- The system shall be shipped fully assembled
- The system shall include sufficient pre-filters, HEPA filters and multipurpose bonded carbon filters to cover the first year of operation.

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- The system shall be designed so that filters and electronics are located above the workspace. This minimizes exposure to the filters and electronics in the case of a chemical spill.
- The system shall be constructed using structural polypropylene with polycarbonate viewing panels for chemical resistance.
- The system shall plug directly into a standard 110V electrical outlet
- The system shall have fluorescent lighting with protection from vapors
- The system shall have a post-filter brushless, sparkless blower for safety to prevent contamination
- The system shall have activated carbon and HEPA filters.
- The system shall allow monitoring of fume hood face velocity with variable airflow control to user preset value
- The system shall have a low airflow alarm to warn the user both visually and audibly
- The system shall have an exterior footprint of no larger than approximately external dimensions (WxDxH): 48 in x 30.25 in x 32.25 in x 44 in
- The system shall have an interior workspace of no smaller than (WxDxH): 47 in x 22 in x 25 in x 44.25 in

II. Trade and Service Specifications

- The system must be a newly manufactured unit, not used and refurbished or previously used for demonstration. The Government must be able to expect routine customer service and technical support to be available from the vendor during its lifecycle.
- A minimum of a one-year Original Equipment Manufacturer (OEM) warranty is required with the purchase and shall include at a minimum: coverage on all non-consumable items and parts supplied including the base instrument and any accessories.
- The system shall be delivered with all necessary supplies and accessories required for installation and start-up.
- FOB Point destination.

Deliverables

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Table 1. Deliverables / Schedule

Deliverable	Quantity	Delivery Date
Free-Standing Ductless Hood	1	NLT 35 days after award.
Filters Supply	Sufficient to last one year under regular normal operating conditions	No later than 35 days after BPA Call award

Shipping Destination

One (1) polypropylene free-standing ductless fume hood enclosure to be shipped to the following laboratory:

US FOOD & DRUG ADMINISTRATION
11698 NW 25TH ST SUITE 106
MIAMI FL 33122
POC: Will be identified at time of award

Period of Performance

The equipment will be purchased so the Period of Performance runs from the date of contract award through the end of the Original Equipment Manufacturers (OEM) warranty period (minimum one year).

Equipment shall be delivered no later than 35 days after contract award.

Quotation Instructions

All quotes are due by e-mail to Nina Montgomery, Nina.Montgomery@fda.hhs.gov on or before February 23, 2023 at 10:00 am (Eastern Standard Time).