

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION (JOFOC)

In accordance with the authority granted under FAR Part 13, this request for a noncompetitive acquisition is hereby submitted for consideration for acquisition approval.

1. IDENTIFICATION OF THE AGENCY AND THE CONTRACTING ACTIVITY:

Requesting Agency:

USDA, APHIS, Wildlife Services
Pocatello Supply Depot
238 E. Dillon St
Pocatello, ID 83201

Contracting Activity:

USDA, APHIS MRPBS, ASD
Minneapolis Procurement Branch
Butler Square, Fifth Floor
100 North 6th Street
Minneapolis, MN 55403

Proposed Contractor:

Colorado Serum Company

POC: Randell Berrier

SAMS: Colorado Serum Company

DUNS: 007056542

Cage: 63621

2. NATURE AND/OR DESCRIPTION OF THE ACTION BEING APPROVED:

The government is awarding a firm fixed price indefinite delivery indefinite quantity commercial supply contract for the purchase of an estimated 6,000,000 doses of experimental Recombinant Raccoon Pox (RCN virus-vectored vaccine (RCN-F1-V307)). The vaccine will be packaged in 4000 dose aliquots 100ml vials.

3. A DESCRIPTION OF THE SUPPLIES, EQUIPMENT, OR SERVICES REQUIRED TO MEET AGENCY NEEDS (INCLUDING THE ESTIMATED VALUE OF THE ACQUISITION INCLUSIVE OF OPTIONS):

The Contractor will provide 6,000,000 doses of Experimental Recombinant Raccoon Pox (RCN virus-vectored Vaccine RCN-F1-V307) to the USDA Pocatello Supply Depot located at 238 E. Dillon Street in Pocatello ID.

The product is used to manufacture a bait to deliver a plague vaccine to prairie dogs. The estimated dollar value of the contract is \$1,300,000.00.

4. IDENTIFICATION OF THE STATUTORY AUTHORITY PERMITTING NONCOMPETITIVE ACQUISITIONS:

41 U.S.C. 3304 (a) (1)

5. AUTHORITY:

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

6. A DEMONSTRATION THAT THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS OR THE NATURE OF THE ACQUISITION REQUIRES USE OF THE AUTHORITY CITED:

RCN vaccine is the active ingredient in an experimental veterinary biological animal vaccine bait manufactured by the Pocatello Supply Depot. The vaccine used in this bait is an oral sylvatic plague vaccine used to mitigate the occurrence of sylvatic plague outbreaks in prairie dog colonies. This experimental use has been developed through cooperative research conducted by the Colorado Parks and Wildlife, U.S. Department of Agriculture's Animal Plant and Health Inspection Service – Wildlife Services (USDA/APHIS/WS), U.S. Fish and Wildlife Service, and the World Wildlife Fund and is overseen by the USDA/APHIS Center for Veterinary Biologics (CVB). Based on several years of previous research, the RCN vaccine produced by Colorado Serum is the approved and proven vaccine for this vaccine bait. The license to manufacture the vaccine from CVB was only granted to two entities, U.S. Geological Survey and Colorado Serum. The U.S. Geological Survey completed a tech transfer agreement to give Colorado Serum exclusive permission to sell the vaccine. The Pocatello Supply Depot has been asked to manufacture this plague vaccine bait for the first time on a large scale and will need 1,000,000 doses of vaccine to manufacture enough baits to fill all of the orders we have received from Federal, State and Tribal Agencies. Without this vaccine, the PSD will not be able to manufacture the vaccine baits and the chance of outbreaks of sylvatic plague will increase which is a threat to human health and safety as well as a threat to Federal Threatened and Endangered species.

This is an experimental vaccine; Colorado Serum Company is the only vendor authorized by the USDA-APHIS-VS Center for Veterinary Biologics to grow & distribute to government agencies for experimental field use. This specific vaccine is needed to maintain continuity in ongoing research and experimental management projects.

Because no other company is authorized to manufacture and ship this vaccine, award to any other source would result in the need for additional research to determine efficacy of the new vaccine and result in the duplication of costs to find another vaccine. These steps would also create an unacceptable delay to USDA and its partners in this project.

7. A DESCRIPTION OF EFFORTS MADE TO ENSURE THAT OFFERS ARE SOLICITED FROM AS MANY POTENTIAL SOURCES AS IS PRACTICABLE, INCLUDING WHETHER A NOTICE WAS, OR WILL BE, PUBLICIZED AS REQUIRED BY FEDERAL ACQUISITION REGULATION (FAR) SUBPART 5.2, AND IF NOT, WHICH EXCEPTION UNDER FAR 5.202 APPLIES:

Because there is no other manufacturer of RCN vaccine, and because Colorado Serum is the only licensed supplier of RCN vaccine, there was minimal efforts to obtain competition for the product.

Additionally, this justification will be on the Federal Business Opportunities website for a 2-3 week period.

8. A DETERMINATION BY THE CONTRACTING OFFICER THAT THE ANTICIPATED COST TO THE GOVERNMENT WILL BE FAIR AND REASONABLE, AND THE BASIS FOR THAT DETERMINATION:

This vaccine is currently used in research applications, and no comparable material is available for the uses identified. However, the cost per dose for vaccine when produced by the USGS National Wildlife Health Center was \$1/dose and the NWHC was unable to meet anticipated annual needs for the State of Colorado. The cost/dose is comparable to or less than other veterinary vaccines on the commercial market. The Contracting Officer will conduct price analysis to determine that the proposed prices will be fair and reasonable. At this point the government believes the current price quote received is fair and reasonable based on the pricing received from the contractor.

9. A DESCRIPTION OF THE MARKET RESEARCH CONDUCTED (FAR PART 10) AND THE RESULTS, OR AN EXPLANATION OF THE REASON MARKET RESEARCH WAS NOT PERFORMED:

Colorado Serum is the sole manufacturer of RCN vaccine and the USDA/APHIS/WS Pocatello Supply Depot is the main customer for this vaccine for use in a Sylvatic Plague Vaccine Bait.

10. ANY OTHER FACTS SUPPORTING THE USE OF OTHER THAN FULL AND OPEN COMPETITION - FAR 6.303-2(a)(9):

None

11. A LISTING OF SOURCES, IF ANY, THAT EXPRESSED, IN WRITING, AN INTEREST IN THE ACQUISITION:

At this time no other entities have expressed interest.

12. A STATEMENT OF THE ACTIONS, IF ANY. THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS TO COMPETITION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES, EQUIPMENT, OR SERVICES REQUIRED:

In the future competition is not planned because this JOFOC covers all known requirements and there is no indication that this product will be available from any other distributor. However, should additional companies become available the USDA will solicit those entities to determine the best source to purchase RCN Vaccine.

13. I HEREBY CERTIFY THAT THE INFORMATION PROVIDED IN THIS JOFOC IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

(Certification requires the signature of the contracting officer and program manager, and shall include the date.)

Per FAR 13.501 (a) (2) (ii), this justification and approval is being submitted to the competition advocate for approval.

**CORINNE
NYGREN** Digitally signed by
CORINNE NYGREN
Date: 2018.03.06
14:07:04 -06'00'

Corinne Nygren Date
Contracting Officer
USDA APHIS, AAMD, MRP

**PATRICK
DARROW** Digitally signed by PATRICK DARROW
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ou=Department of Agriculture, cn=PATRICK
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Date: 2018.03.06 12:26:21 -07'00'

Patrick Darrow Date
Program Manager
Wildlife Services Pocatello Supply Depot

**LARRY
NELSON** Digitally signed by
LARRY NELSON
Date: 2018.03.06
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Larry Nelson Date
Contracting Competition Advocate
USDA APHIS, AAMD, MRP