Department of Veterans Affairs
Office of Acquisition and Logistics
National Acquisition Center, National Contract Service
Hines, Illinois 60141

Justification for Other than Full and Open Competition
Tracleer Tablets

This document sets forth the justification and approval for other than full and open competition for the acquisition described herein, under the authority of FAR 6.302-1 "Only one responsible source and no other supplies or services will satisfy agency requirements".

1. Nature and/or description of the action being provided.

The National Contract Service, National Acquisition Center of VA's Office of Acquisition and Logistics plans to enter into a sole-source contract with for the procurement of Tracleer®, a branded medication with no generic alternative. Tracleer® patent expired on November 15, 2015. However, FDA requires a Risk Evaluation and Mitigation Strategy (REMS) program because of the potentially dangerous side effects of the drug. Due to the complexity of a required REMS program, generics are not expected to be approved and on the market for at least 6 months to a year. Tracleer® will be available only from Actelion. Tracleer® will be removed from the Actelion Federal Supply Schedule Contract (V797P-5160B) because the manufacturing of the product has been moved to India, a non- Trade Agreements Act (TAA) country.

2. Description of the supplies/services required to meet the Agency's needs.

Tracleer® is a prescription medicine indicated for patients with certain types of pulmonary arterial hypertension (PAH). Pulmonary arterial hypertension is a chronic and currently incurable disease that causes the walls of the arteries of the lungs to tighten and stiffen. In someone with PAH, the right side of the heart has to work harder to push blood through narrowed arteries in the lungs. Eventually, the extra stress causes the heart to enlarge and become less flexible, compromising the heart's ability to push blood out of the heart, through the lungs, and into the rest of the body. Delay in therapy can eventually lead to heart failure and death.

Tracleer® tablets are available in the following strengths and package sizes: 62.5MG in bottles of 30s and 60s and 125MG in bottles of 30s and 60s. As a result of these two strengths of this patented drug being sourced by Actelion from a TAA non-designated country, they are end products that are not available to the Federal Government from a U.S. or TAA designated country source. A separate Non Availability Determination pursuant to Federal Acquisition Regulation Part 25 has been made for the acquisition of this drug from a non-TAA country.

The estimated annual dollar value is $3,750,003, and the total contract value is $7,500,000, if the option year is exercised. The procurement will include the following line items:

ITEM	NDC	DESCRIPTION	PACKAGE SIZE (BT)
1	66215-0101-03	TRACLEER 62.5MG TAB	30
2	66215-0101-06	TRACLEER 62.5MG TAB	60
3	66215-0102-03	TRACLEER 125MG TAB	30
4	66215-0102-06	TRACLEER 125MG TAB	60

3. Identification of the statutory authority permitting other than full and open competition.

The statutory authority permitting other than full and open competition is 41 U.S.C. 253 (c)(1) and FAR 6.302-1, which authorizes under certain conditions, contracting without providing for full and open competition when the supplies or services required by the agency are available from only one responsible source, and no other type of supplies or services will satisfy agency requirements, full and open competition need not be provided. Tracleer® is available only from one source, Actelion.

4. Demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the authority cited.

Tracleer® is a drug available only from one source, Actelion. Although Actelion's patent expired on November 15, 2015, for the reasons stated in paragraph 2, above, the two strengths are not available through Actelion's Federal Supply Schedule Contract necessitating the acquisition of non-TAA Tracleer® strengths through a separate contract for continued contract coverage to VA and other Government agencies participating in this contract.

5. Description of the 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 Subpart 5.2 and, if not, which exception under 5.202 applies.

A pre-solicitation notice will be publicized on the Federal Business Opportunities website at www.fbo.gov with the Government's intent to sole source Tracleer® . The Justification for Other than Full and Open Competition also will be made available at www.fbo.gov.

6. A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable.

Tracleer® is a covered drug. Pursuant to Public Law 102-585, Veterans Health Care Act of 1992, Section 603, pricing for covered drugs is capped at no greater than 76% of the non-Federal Average Manufacturer Price (non-FAMP) for VA, DOD, HHS (which includes IHS) and the U.S. Coast Guard. These four government agencies are known as the Big4. Therefore, under this contract, VA and IHS (participants under this contract) will receive at least a 24% discount from the net prices wholesalers pay to manufacturers for covered drugs. This is commonly known as the Federal Ceiling Price (FCP). The FCP is calculated and established annually by the VA. VA, FHCC, and IHS will pay no more than the calculated FCP for Tracleer®. DOD

elected not to participate under this procurement; therefore DOD will not be an eligible participant under the subsequent contract. BOP is not part of the Big4. If different prices are proposed for BOP, the determination that the prices are fair and reasonable will be made on a comparison of previous FSS prices awarded for BOP and a comparison of prices offered to the Big4.

7. A description of the market research conducted, the results or a statement of the reason market research was not conducted.

Market research was not conducted as the product being procured is under patent. Although the patent expired on November 15, 2015, there is no alternative source.

8. List of sources, if any that expressed interest in the acquisition.

Not applicable for the reasons already stated in this document.

9. Statement of actions the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the supplies or services required.

The procurement of this drug will be made under competitive, negotiated procedures once alternative generics are made available.

TECHNICAL AND REQUIREMENTS CERTIFICATION

I certify that the facts and representations under my cognizance which are included in this justification and which form a basis for this justification are complete and accurate.

Suzanne Lenz, R.Ph
Pharmacy Benefits Management

12/24/2015
Date

CONTRACTING OFFICER CERTIFICATION

I certify that this justification is accurate and complete to the best of my knowledge and belief.

Erika Moreno

Erika Moreno
Contracting Officer
VA National Acquisition Center, Hines, Illinois

12/24/2015
Date

LEGAL REVIEW

Office of General Counsel
VA National Acquisition Center

Date

HEAD OF CONTRACTING ACTIVITY REVIEW AND APPROVAL

Approval of this action is granted based on the above Justification and Certifications from Pharmacy Benefits Management and the Contracting Officer.

Craig Robinson
Head of Contracting Activity
VA National Acquisition Center, Hines, Illinois

Date