

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (<SAT)**

**Acquisition Plan Action ID:** VA-18-00085505\_VA770-18-AP-0590

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 15, National CMOP 770 NCO15 Contracting, 770-18-3-801-0189
- 2. Nature and/or Description of the Action Being Processed:** This sole source justification for a generic prescription drug Zonisamide (Zonegran). CMOP has to restrict this award to the following NDC's ONLY for each Zonisamide strength:

Zonisamide 25mg Cap	NDC 00378-6725-01
Zonisamide 50mg Cap	NDC 00378-6726-01
Zonisamide 100mg Cap	NDC 00378-6727-01

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is for Zonisamide in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** This award will be for a three month supply of Zonisamide 25mg, Zonisamide 50mg, and Zonisamide 100mg totaling \$000000.
- 4. Statutory Authority Permitting Other than Full and Open Competition:**
  - (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
  - (2) Unusual and Compelling Urgency per FAR 6.302-2;
  - (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
  - (4) International Agreement per FAR 6.302-4
  - (5) Authorized or Required by Statute FAR 6.302-5;
  - (6) National Security per FAR 6.302-6;
  - (7) Public Interest per FAR 6.302-7;

**FAR13.5 Simplified Procedures for Certain Commercial Items:**

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This sole source justification is for a generic prescription drug Zonisamide (Zonegran). Zonisamide is a medication used to treat the symptoms of epilepsy and Parkinson's disease. **This drug is currently on the PBM Drug Standardization List and the NDC and/or manufacture cannot be substituted.** It is imperative for patient safety that CMOPs continue to dispense the same manufactured medication to prevent a potential patient safety issue with a substitution of another manufactured product. Switching manufacturers could potentially cause patients to experience partial or full seizures, focal impaired awareness, and refractory seizures. These seizure events are unpredictable when not controlled properly with steady and consistent medication. Changing the chemical compounding and the manufacture makeup risks patient safety, family safety, and the surrounding public as it increases a higher probability of a patient having a seizure event. Therefore, CMOP must restrict this solicitation to the following NDC's:
- |                      |                   |
|----------------------|-------------------|
| Zonisamide 25mg Cap  | NDC 00378-6725-01 |
| Zonisamide 50mg Cap  | NDC 00378-6726-01 |
| Zonisamide 100mg Cap | NDC 00378-6727-01 |
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** All Open Market Offers will have to provide the NDC's above or the offer will be deemed unacceptable.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** For a three month supply of product, \$000000 was calculated using market prices on 5/2/18. These prices are considered fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was not conducted as the announced shortage of this item was just published on 5/2/18. In response to the announced shortage, National CMOP moved to submit a 2237 for a three month supply in an attempt to acquire this NDC as soon as possible. Next, CMOP moved forward with this Sole Source Justification to procure the item to maintain excellent patient care and to provide PBM the needed time to evaluate if a replacement product needs to be considered moving forward.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition: Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** This is a National Contract item that is no longer in a steady supply chain and could even be discontinued by the manufacture. This item needs to be acquired quickly as not to present a potential patient care issue.
10. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** National CMOP Logistics has placed an Open Market Request and this Sole Source Justification.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format <SAT

**11. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

X

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Supply System Analyst

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Name \_\_\_\_\_ Date \_\_\_\_\_  
Title \_\_\_\_\_  
Facility \_\_\_\_\_

**12. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#): *This part if filled out by Contracting Staff as part of the Justification***

a. **Contracting Officer or Designee's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

\_\_\_\_\_  
Name \_\_\_\_\_ Date \_\_\_\_\_  
Title \_\_\_\_\_  
Facility \_\_\_\_\_

b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Name \_\_\_\_\_ Date \_\_\_\_\_  
**NCO/PCO XX Duty Title**  
Facility \_\_\_\_\_

c. **VHA SAO HCA Review and Approval**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$) or approve ) for other than full and open competition.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
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\_\_\_\_\_  
Name  
VHA Head of Contracting Activity (HCA)

\_\_\_\_\_  
Date

- d. **VHA Senior Procurement Executive Approval (over \$68 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

\_\_\_\_\_  
Deputy Assistant Secretary for Acquisition and Logistics  
Senior Procurement Executive (SPE)  
Department of Veterans Affairs

\_\_\_\_\_  
Date