

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Officer 15, Consolidated Mail Outpatient Pharmacy Acquisition Team. Justification for other than full and open competition for Balziva, Diltiazem and Estradiol in reference to 760-14-3-050-0656 for CMOP Leavenworth.
2. **Nature and/or Description of the Action Being Processed:** Department of Veterans Affairs, NCO 15, CMOP Division plans to solicit via open market on the Government-wide point of entry at www.FBO.gov for National Drug Code (NDC) Specific pharmaceuticals (Balziva, Diltiazem and Estradiol) that are not found on contract.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** CMOP Leavenworth has a requirement for Balziva Tab (NDC #0055-9034-58), an oral contraceptive used to prevent pregnancy. Diltiazem (Mylan-SR NDC# 00378-6090-01 & Dilacor-XR NDC# 52544-0484-01) is used to treat blood pressure/angina at different releases. Estradiol Gel (NDC# 17139-0617-40) is used to treat symptoms of menopause. The products are NDC specific due to particular brand(s) being prescribed by VA Physicians. If the CMOP National File entry has a specific brand or item number in the prescription description, the CMOP is only allowed to dispense that exact item match. VA doctors writing a prescription do so based on clinical need and write the prescription accordingly to provide critical patient care.

Balziva Tab, 28; NDC# 00555-9034-58

Diltiazem (Mylan – SR) 90 MG CA CAP (100); NDC# 00378-6090-01

Diltiazem (Dilacor – XR) 240MG SA CAP; NDC# 52544-0484-01

Estradiol 0.06% Transdermal Gel; NDC# 17139-0617-40

The estimated annual dollar value for the above pharmaceuticals is [REDACTED]

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (XX) (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;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** These are brand name only requirements based on clinical need in accordance with written prescriptions in order to provide critical patient care. Balziva (NDC# 00555-9034-58), Diltiazem (Mylan SR NDC# 00378-6090-01 & Dilacor XR NDC# 52544-0484-01) and Estradiol (NDC#17139-0617-40) are essential to the well-being of the veteran and are required per Medical Officers' direction. No other product will meet the Government's needs.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A pre-solicitation notice will be publicized on the Federal Business Opportunities website at www.fbo.gov . The request for quote will follow the pre-solicitation notice and will also be posted on the FBO website. Typically we will award to a small business concern and not the manufacturer.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** CMOP Leavenworth submitted a funded purchase request (2237) 760-14-3-050-0656 in which pricing was estimated based on previous use and purchase history.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** There are no newly developed, clinically acceptable substitutions for Balziva (NDC# 00555-9034-58), Diltiazem (NDC# 00378-6090-01 & 52544-0484-01) and Estradiol (NDC#17139-0617-40). The VA pharmaceutical catalog search tool was utilized to see if these items are on contract. The NAC Contract Management tool was searched to see if any of the items were available on any other existing contract. All queries returned negative responses; the responses have been compiled into a PDF file and uploaded to the eCMS action Briefcase under P02.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Not Applicable.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Not applicable, as this will be procured by way of an open market solicitation and every effort will be made to award all line items to small business concerns.
11. **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:** The products being procured are National Drug Code specific, but competition will be achieved through full and open solicitation. There is no opportunity to overcome the barrier that the brand specificity represents because the products are prescribed by VA doctors and are critical to patient care.