

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: _____ VA770-18AP-0136 _____

1. Contracting Activity:

Department of Veterans Affairs
Network 15 Contracting Office
3450 South 13th Street
Leavenworth, KS 66048

The purchase request number is 761-18-1-015-0067
Items are to be delivered to the Chelmsford CMOP.

2. Nature and/or Description of the Action Being Processed:

The Chelmsford-CMOP, 10 Industrial Ave, Chelmsford, MA 01824-3610, Consolidated Mail Outpatient Pharmacy is requesting approval to purchase BRAND NAME specific NDC drug items. This is a new procurement and will be a firm fixed price contract.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Line 1 - (T0606) - TRIVORA TAB,28

- NDC 51862-0510-06
- Quantity of request: 48
- Supplier: MAYNE PHARM
- Trivora (ethinyl estradiol and levonorgestrel) prevents pregnancy in three ways, utilizing a combination of the female hormones estrogen and progestin. Trivora hormones prevent the release of an egg from one of the ovaries (ovulation). The hormones also thicken the cervical mucus, inhibiting sperm from reaching and fertilizing the egg. Lastly, Trivora prevents the uterine lining from thickening, making it less hospitable to implantation.
- All brands, including Trivora, that contain the progestin levonorgestrel have been FDA approved for use as an Emergency Contraceptive.
- Trivora has been shown to prevent pregnancy in over 99% of situations when it is the only birth control method utilized and when Trivora is used exactly as directed.
- Trivora is an effective method of birth control when used correctly. All birth control pills, Trivora included, have also been shown to have the following possible benefits:
 - Menstrual cycle may become more regular
 - Menstrual blood flow may become lighter (reducing the chances of anemia)
 - Cramps or other pain during menstruation may become less frequent and less intense
 - Noncancerous cysts or lumps in the breast may be less common
 - Ectopic pregnancies may occur with less frequency

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

- The chance of acute pelvic inflammatory disease may be lower

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

- (X) (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)

Within the VHA brand name drugs may be prescribed by physicians when in their clinical judgment the brand name drug will provide a better therapeutic outcome for patients. Brand name drugs are requested when there is a clinical requirement for the drug. In this case, the brand specific drug name is requested on the list above.

Products have been prescribed for patients by VA Physicians. Pharmacy employees do not have the training and/or authority to countermand physician orders. "Brand Specific" products are the same thing as "dispense as written" on a physician prescription. No NDC substitutions are permitted. In the VA, Pharmacy Benefits Management (PBM) has determined that CMOP IDs in the National Drug File (NDF) will most always identify "brand specific" products in the VA PRINT NAME. This is not always inclusive where a particular NDC has been determined to be "formulation specific" by clinical evaluation performed by the PBM or in the case where only one product in the marketplace has been identified to contain the specific ingredients to match the product code.

6. 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: At this time, the physician has stated the above mentioned name brand drugs are the only brands that will meet the specific needs of the patients.