

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification for Single Source Awards IAW [FAR 13.106-1](#)  
For  
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$150K)**

**Acquisition Plan Action ID: VA770-18-AP-0070**

**1. Contracting Activity:**

Department of Veterans Affairs  
Consolidated Mail Outpatient Pharmacy (CMOP) Acquisitions Division.  
Department of Veterans Affairs  
Network 15 Contracting Office (NCO 15)  
CMOP Division  
3450 S. 4th St Trafficway  
Leavenworth, KS 66048  
**2237# 766-18-1-400-0039**

**2. Brief Description of Supplies/ Services required and the intended use/Estimated Amount:**

The two (2) Pharmaceuticals Line Items 2 and 9 are used as an oral contraceptive.

Line #	VA ID	Description	ACCEPTABLE NDC/PC	Package	Unit	Qty
2	2502	LOW-OGESTREL TAB,28 6/CT, (L0366)	51862-0564-06 BRAND NAME	6 per BX	BX	70
9	3812	AVIANE TAB, PACK OF 28 (A1304)	00555-9045-58 BRAND NAME	BOX OF 6	BX	90

Delivery Date: **11/27/2017**

**3. Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:**

Within the VHA brand name items may be prescribed by physicians when in their clinical judgment, the brand name item will provide a better therapeutic outcome for patients. The brand name of the product is in the CMOP print name. Pharmacists legally must fill the prescription as it was written for Line Items 2 and 9.

**Line Item 2**

LOW-OGESTREL TAB, 28 6/CT, (L0366)

The **Mayne Pharma Inc.**'s Low-Ogestrel® Tablets (norgestrel and ethinyl estradiol tablets USP, 0.3 mg/0.03 mg) provide an oral contraceptive regimen consisting of 21 white tablets followed by 7 peach tablets.

Each white tablet, for oral administration contains 0.3 mg of norgestrel and 0.03 mg ethinyl estradiol and the following inactive ingredients: croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose, and povidone.

**Benefits:**

Low-Ogestrel® (norgestrel and ethinyl estradiol tablets USP, 0.3 mg/0.03 mg) is indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception. Oral contraceptives are highly effective. The efficacy of these contraceptive methods, except sterilization, depends upon the reliability with which they are used. Correct and consistent use of methods can result in lower failure rates.

**Line Item 9**

AVIANE TAB, PACK OF 28 (A1304)

The **Teva Pharmaceuticals USA, Inc.**'s product consists of 21 orange active tablets each containing 0.10 mg of levonorgestrel, USP (-)-13-Ethyl-17-hydroxy-18,19-dinor-17 $\alpha$ -pregn-4-en-20-yn-3-one, a totally synthetic progestogen, and 0.02 mg of ethinyl estradiol, USP, (19-Nor-17 $\alpha$ -pregna-1,3,5(10)-trien-20-yne-3,17-diol). The inactive ingredients present are: FD&C yellow no. 6 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized corn starch, sodium starch glycolate and titanium dioxide.

**Benefits:**

Aviane (levonorgestrel and ethinyl estradiol tablets USP) is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Oral contraceptives are highly effective. The efficacy of these contraceptive methods, except sterilization, the IUD, and Norplant® System, depends upon the reliability with which they are used. Correct and consistent use of methods can result in lower failure rates.

**4. Description of market research conducted and results or statement why it was not conducted:**

This is available through multiple sources on the open market but there is only one manufacturer of this thyroid hormone per physician prescriptions only Brand Name is acceptable.

NAC, FSS, and GSA ADVANTAGE were searched but no contract items were found.

**5. Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

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Nichols Fellows, Lori J.  
Contracting Officer

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Date