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February 25, 2005

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Subject: Docket No. 2004P-0074 - Letter in Support of the Citizen Petition filed on behalf of Savient Pharmaceuticals

Dear Sir or Madam:

This letter is submitted on behalf of Savient Pharmaceuticals Inc., ("Savient") in support of its February 2004 Citizen Petition, and requests that the Food and Drug Administration ("FDA") apply all appropriate impurity standards to the drug substances used in oxandrolone drug products. We believe that such an action is essential in light of the use of the drug, and its interactions, as set forth in the Citizen Petition.

As discussed below, FDA's standards for impurities in generic pharmaceutical drug substances have increased in stringency in recent years. Higher standards for impurities in these drug substances represent a prudent step in patient protection, and are reflected both by international consensus, FDA regulatory requirements, and in more

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recently published monographs in the United States Pharmacopeia ("USP"). For drugs like oxandrolone, which present significant drug interaction issues, the higher standards are even more critical. The original Citizen Petition provided a detailed description of the potential for drug-drug interactions between oxandrolone and warfarin. Of particular concern is the potential for significant variation in the degree of the interaction between the two drugs, should a generic oxandrolone drug product differ in bioequivalence from Oxandrin®, the reference listed drug ("RLD") product. Differences in impurity profiles in the drug substances used to manufacture oxandrolone-containing drug products potentially also represent a safety issue.

Generic Drug Requirements

Generic pharmaceuticals sold under FDA-approved Abbreviated New Drug Applications ("ANDAs") represent a significant percentage - almost 50% - of the approved dosage units sold in the United States pharmaceutical market, and public confidence in the safety of these drugs is essential to the healthcare system. These products must be held to the same safety standards and policies, including chemistry and purity, as the branded pharmaceuticals on which they are based. To do otherwise risks not only patient safety, but is also contrary to the Federal Food Drug and Cosmetic Act ("FFDCA"), which requires that generic drug applicants provide "information to show that the active ingredient of the [generic drug] is the same as that of the listed [pioneer] drug."¹ The scientific premise of this legal requirement is that if the two drug substances are the same in all relevant characteristics, the safety and efficacy of that generic drug

¹ FFDCA § 505(j)(2)(A)(ii). As discussed *infra*, other provisions of the FFDCA are also implicated.

substance can be presumed, based upon the demonstrated safety and efficacy of the drug substance in the pioneer drug.

One key component of drug safety is the method used and specifications set forth for assessing impurities in the drug substance used in these pharmaceutical products. FDA's views on impurities are reflected in the Agency's January 2005 draft Guidance for Industry - ANDAs: Impurities in Drug Substances. These views are supported by the scientific, medical, and regulatory communities and emphasize that improving and/or ensuring the adequacy of methodology used to determine the purity of drug substances is necessary to maintain the assurance of their safety. FDA regulations and policy provide that the chemistry, manufacturing and controls ("CMC") requirements for an ANDA drug must be as rigorous as the CMC requirements for the pioneer product. One component of this requirement is that the impurities in the ANDA drug substance must meet the same objective standards as impurities in the drug substance for the RLD and as the purity of the drug substance for the RLD, evolves, the purity of the drug for the generic must also evolve. This requirement is based not only on the legal standard for ANDAs found in the FDCA, but is also required by FDA's mission of protecting the public health. In this era of multiple drug use by individuals and drug interactions, the need for drug substances with more thoroughly characterized impurities and therefore, methodologies to provide this information, is becoming ever more important. It is simply not possible to know whether impurities are compromising safety or effectiveness unless they are properly analyzed - individually and collectively.

Impurities in Generic Drug Substances

The current standard for impurities in drug substances is provided by FDA guidance on and by a consensus document created by the International Committee on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"). This document, ICH Q3A, accurately reflects the international industry and regulatory consensus on the identity and quantity of impurities for drug substances. The ICH Q3A was adopted by FDA as guidance in January 1996, and a revised version was adopted in February 2003.

By its express language, "ICH Q3A is intended to provide guidance for registration applications on the content and qualifications of impurities in new drug substances produced by chemical synthesis, and not previously registered in a region or member state." Therefore, this guidance does not, on its own, apply to drug substances in generic drugs, since that same drug substance would have been approved in a previous application. However, FDA created guidance specifically for the impurities found in ANDA drug substances, and in that guidance, the agency applied the ICH Q3A impurity standards to generic drugs. That guidance, "Guidance for Industry - ANDAs: Impurities in Drug Substances," finalized in November 1999, provides that "generic drugs are not covered by ICH Q3A; however, many of the recommendations in ICH Q3A are applicable to drug substances used in generic drug products. To provide, to the extent possible, comparable processes for new and generic drug review, this guidance was developed using the ICH Q3A framework."

The ICH Q3A 2003 revision provided details on the requirements for drug substance impurities, and in some cases, lowered the threshold limits beyond those in the 1996 version (and adopted in FDA's 1999 guidance). As a result of this revision, FDA began the process of revising its 1999 guidance. The outcome of this process is the current February 2005 draft ANDAs: Impurities in Drug Substances guidance. Although this guidance does not differ dramatically from the earlier 1999 guidance, it does incorporate many elements of the ICH Q3A, including the general impurity limits. Further, the 2005 guidance also expressly incorporates USP impurity limits, where such limits are provided in a particular drug substance monograph. The guidance states: "In establishing impurity acceptance criteria, the first critical consideration is whether an impurity is specified in the United States Pharmacopeia (USP). If there is a monograph in the USP that includes a limit for an identified specified impurity, we recommend that the acceptance criterion be set no higher than the official compendial limit." This recommendation is in general accord with FDA's treatment of compendial standards in other situations.

A More Stringent and Better Method for Assessment of the Purity of Oxandrolone Drug Substance

USP has published, in its Pharmacopeial Forum, Volume 31, #1, (January-February 2005), In-Process Revision section, pages 64-67, an HPLC method of detection and quantification of impurities that represents the most stringent method available for

analysis of this drug substance. The HPLC method recommended for inclusion in the monograph for oxandrolone drug substance identifies and provides limits for seven impurities that may be found in oxandrolone, as opposed to the current method that is capable of identifying and quantifying only two impurities. This new impurities method is the result of considerable research and methods development, and is very much in keeping with the spirit of FDA's increased emphasis on drug substance impurities, their identification and accurate quantification whenever possible. This method is scheduled to become official in USP as of January 2006. We request that FDA consider compliance with this more stringent impurities methodology in view of its ability to more thoroughly identify and quantify known impurities in the drug substance as an important factor in any pending ANDA applications for oxandrolone-containing products. This methodology represents the best available scientifically based standard for the drug, and Savient is prepared to fully embrace and utilize the more stringent oxandrolone drug substance methodology we describe.

For decades, FDA's policy for analytical methodology and CMC standards in drug substance development, has encouraged the use of the most up-to-date technology. Evolving standards are an important element in the refinement of current Good Manufacturing Practices (21 USC § 351), and new standards and methods must be applied to all new drug applications, both NDAs and ANDAs. Finally, it is important to note that under FFDCA § 501(b), a drug defined in an official compendium whose strength, quality, or purity differs from standards set forth in that compendium shall be deemed adulterated unless the difference is "plainly stated on its label." Thus, it is

incumbent upon FDA to assess impurities in new drug applications, review relevant compendial standards, and either ensure compliance with those standards or carefully consider how any differences should be labeled. Of course, labeling differences could undermine the status of ANDAs.

Impurities in Generic Oxandrolone Drug Products

The impurities standard provided by the ICH 3QA, and FDA's 2005 draft guidance require that there be an appropriate and reasonable assessment of the process used to manufacture drug substance in terms of the identities, relative quantities and qualities of impurities present. Such requirements take on increased importance in situations where the differences between the generic and the listed pioneer drug are more critical. Oxandrolone is an example of a drug where minor variations between the pioneer and generic drugs may have serious health consequences. Stringent bioequivalence requirements are one mechanism to reduce such differences, and were the subject of the original petition. Impurity profiles represent another area where differences between Oxandrin® and generic oxandrolone drug products must be carefully scrutinized.

In summary:

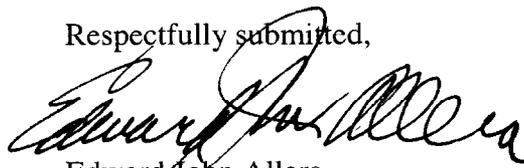
1. A more stringent method for identification and quantification of impurities in oxandrolone drug substance has been published in the current USP Pharmacopeial Forum, Volume 31, #1, (January-February 2005), In-Process Revision section, pages 64-67 attached).

2. This method is consistent with the Agency's 2005 Draft Guidance for Impurities in ANDA drugs.
3. Savient, as the NDA holder, embraces this new method, and plans to implement its more stringent standards as soon as it becomes official in USP, and will provide appropriate notification to the Agency.
4. Savient is concerned that any new ANDAs for oxandrolone be reviewed in the context of the upcoming, more stringent method for analysis of impurities in drug substance as proposed in USP PF.

* * *

For the foregoing reasons, we request that the Agency consider the issues discussed herein, and the significance of impurities and policies regarding same, in the review of any ANDAs for oxandrolone drug products. Specifically, we request that FDA apply the standards for impurities as provided in the ICH 3QA, the 2005 guidance, and in the soon to be published USP monograph for oxandrolone drug substance.

Respectfully submitted,



Edward John Allera
Donald E. Segal
Theodore M. Sullivan

Compound	Approximate		Limit (w/w, %)
	Relative Retention Time	Relative Response Factor	
Nabumetone	1.0	—	—
6-Methoxy-2-naphthaldehyde	0.73	0.12	0.1
4-(6'-Methoxy-2'-naphthyl)-butan-2-ol	0.85	0.94	0.1
1-(6'-Methoxy-2'-naphthyl)-but-1-en-3-one (nabumetone related compound A)	0.93	0.25	0.1
5-(6'-Methoxy-2'-naphthyl)-3-methylcyclohex-2-en-1-one	1.2	0.42	0.1
5-(6'-Methoxy-2'-naphthyl)-3-methylcyclohexan-1-one	1.9	1.02	0.1
1,5-Di-(6'-methoxy-2'-naphthyl)-pentan-3-one	2.6	0.91	0.1
6,6-Dimethoxy-2,2'-binaphthyl	2.7	0.10	0.3
Individual unknown impurity	—	—	0.1
Total impurity	—	—	0.8

▲(USP29)

BRIEFING

Oxandrolone, USP 28 page 1426 and page 148 of PF 30(1) [Jan.–Feb. 2004]. It is proposed to replace the liquid chromatographic procedure in the test for *Related compounds* with a linear gradient elution method that provides greater sensitivity to the impurities and makes the method stability indicating. The previously proposed revision to the test for *Related compounds*, which appeared in PF 30(1), is being canceled. It is also proposed to further revise the *Assay* to make additional modifications to the *Mobile phase*, *Standard preparation*, *Chromatographic system*, and *Procedure*.

(PA1: C. Anthony) RTS—41280-1

Change to read:

» Oxandrolone contains not less than 97.0

■98.0_{■15} (USP28)
percent and not more than 100.5■102.0_{■15} (USP28)
percent of C₁₉H₃₀O₃, calculated on the dried basis.**Change to read:**

USP Reference standards (11)—USP Oxandrolone RS

▲USP Oxandrolone Related Compound A RS. USP Oxandrolone Related Compound B RS. USP Oxandrolone Related Compound C RS. ▲(USP29)

Change to read:

Identification—

A: *Infrared Absorption* (197K).

B: Prepare a solution in chloroform containing 5 mg per mL. Apply 10 µL each of this solution and a solution of USP Oxandrolone RS in chloroform, containing 5 mg per mL, to a suitable thin-layer chromatographic plate (see *Chromatography* (621)) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform and methanol (19:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by lightly spraying with dilute sulfuric acid (1 in 2) and heating on a hot plate or under a lamp until spots appear; the R_f value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

■ The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*. ■ 15 (USP28)

Delete the following:

■ ~~Ordinary Impurities (466)—
Test solution—methanol;
Standard solution—methanol;
Application volume—10 µL;
Eluent—a mixture of toluene and isopropyl alcohol (90:10), in a nonequilibrated chamber;
Visualization—5. ■ 15 (USP28)~~

Add the following:

▲ Related compounds—

Solution A: acetonitrile.

Solution B: water.

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

Standard solution 1—Weigh accurately 5 mg of USP Oxandrolone Related Compound A RS and 5 mg of USP Oxandrolone Related Compound C RS into a 50-mL volumetric flask, dissolve in 25 mL of acetonitrile using an ultrasonic bath, dilute with acetonitrile to volume, and mix.

Standard solution 2—Weigh accurately 5 mg of USP Oxandrolone RS and 3 mg of USP Oxandrolone Related Compound B RS into a 25-mL volumetric flask, dissolve in 1 mL of acetonitrile, add 1.00 mL of *Standard solution 1*, dilute with acetonitrile to volume, and mix.

Standard solution 3—Dilute 1.0 mL of *Standard solution 2* with 4.0 mL of acetonitrile and 5.0 mL of water and mix.

Test solution—Weigh accurately 40 mg of Oxandrolone into a 10-mL volumetric flask, dissolve in 5.0 mL of acetonitrile using an ultrasonic bath, dilute with water to volume, and mix. [NOTE—*Test* and blank solutions are made up fresh and injected immediately.]

Chromatographic system—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The column temperature is maintained at 40°. The flow rate is about 0.7 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	<i>Solution A</i> (%)	<i>Solution B</i> (%)	Elution
0	50	50	equilibration
0–30	50→100	50→0	linear gradient
30–32	100→50	0→50	linear gradient
32–40	50	50	re-equilibration

Chromatograph *Standard solution 3*, and record the peak responses as directed for *Procedure*. The resolution, *R*, between oxandrolone related compound A and oxandrolone related compound B is not less than 1.5, and the resolution, *R*, between oxandrolone related compound B and oxandrolone is not less than 2.0; the tailing factor is not more than 1.1; and the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 50 µL) of *Standard solution 3* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of oxandrolone

In-Process Revision

related compound A and oxandrolone related compound C in the portion of Oxandrolone taken by the formula:

$$1000(C/W)(r_v/r_s),$$

in which *C* is the concentration, in mg per mL, of oxandrolone related compound A or oxandrolone related compound C in *Standard solution 3*; *W* is the weight of Oxandrolone taken to prepare the *Test solution*; *r_v* is the peak area of oxandrolone related compound A or oxandrolone related compound C in the chromatogram of the *Test solution*; and *r_s* is the peak area obtained for oxandrolone related compound A or oxandrolone related compound C in the chromatogram of *Standard solution 3*.

Calculate the percentage of each impurity, other than oxandrolone related compound A and oxandrolone related compound C, by the formula:

$$100F(C/W)(r_i/r_s),$$

in which *F* is the relative response factor for each impurity; *C* is the concentration, in mg per mL, of USP Oxandrolone RS in *Standard solution 3*; *W* is the weight of Oxandrolone taken to prepare the *Test solution*, *r_i* is the peak area of each impurity in the chromatogram of the *Test solution*, and *r_s* is the peak area obtained for oxandrolone in *Standard solution 3*. The impurities meet the requirements specified in the table below.

Compound	Relative Retention Time	Relative Response Factor	Limit (%)
4-Oxa-isomer (17β-hydroxy-17α-methyl-4-oxa-5α-androstan-3-one) Oxandrolone related compound B	0.94	0.73	0.3
Anhydro-oxandrolone (17β,17-dimethyl-2-oxa-18-nor-5α-androstan-3-one) Oxandrolone related compound C	3.29	—	0.5
Secodicarboxylic acid (17β-hydroxy-17α-methyl-2-nor-5α-androstan-1,3-dioic acid)	0.46	0.25	0.1
7,8-Didehydro-oxandrolone (17β-hydroxy-17α-methyl-2-oxa-5α-andrist-7-en-3-one) Oxandrolone related compound A	0.90	—	0.1
Oxandrolone open lactone methylester (methyl-(1,17β-dihydroxy-17α-methyl-1,3-seco-2-nor-5α-androstane-3-oate)	1.09	0.66	0.1
Secoacid anhydride (17β-hydroxy-17α-oxa-5α-androstan-1,3-dione)	1.12	0.40	0.1
Oxandrolone-17-acetate (17β-hydroxy-17α-methyl-2-oxa-5α-androstan-3-one 17-acetate)	2.14	0.54	0.1
Unknown impurities	—	1.00	0.1
Total impurities	—	—	1.0

▲USP29

Change to read:

Assay—Transfer about 500 mg of Oxandrolone, accurately weighed, to a 250-mL conical flask, and add 25.0 mL of 0.1 N alcoholic potassium hydroxide VS. Insert into the neck of the flask, by means of a perforated stopper, an air condenser consisting of a glass tube 70 to 80 cm in length and 5 to 8 mm in diameter, and heat the flask on a steam bath for 30 minutes, frequently rotating the contents. Cool, add 1 mL of phenolphthalein TS, and titrate the excess alkali with 0.1 N hydrochloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N alcoholic potassium hydroxide is equivalent to 30.64 mg of $C_{19}H_{26}O_2$.

Mobile phase—Prepare a filtered and degassed mixture of 0.01% (v/v) glacial acetic acid in water and acetonitrile (64:36) (50:50). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

System suitability solution—Weigh accurately 30 mg of USP Oxandrolone RS into a 10-mL volumetric flask, dissolve in and dilute with acetonitrile to volume, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Oxandrolone RS in acetonitrile, and dilute quantitatively, and stepwise if necessary, with acetonitrile to obtain a solution having a known concentration of about 5 3 mg per mL. [NOTE—Sonicate if necessary to dissolve.]

Assay preparation—Transfer to a suitable volumetric flask an accurately weighed quantity of Oxandrolone, and dissolve in and dilute with acetonitrile to volume to obtain a solution having a concentration of about 5 3 mg per mL.

Chromatographic system (see *Chromatography* (621))—The liquid chromatograph is equipped with a 498-nm 210-nm detector and a 4.6-mm × 25-cm column that contains

The flow rate is about 1.0 0.8 mL per minute. Chromatograph the *Standard preparation* and the *System suitability solution*, and record the peak responses as directed for *Procedure*. The column efficiency is not less than 2000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 μ L 20 μ L) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{19}H_{26}O_2$ taken by the formula:

$$VC(r_U/r_S)$$

in which *V* is the final volume, in mg per mL, of the *Assay preparation*; *C* is the concentration, in mg per mL, of USP Oxandrolone RS in the *Standard preparation*; and *r_U* and *r_S* are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively. Δ USP 28

BRIEFING

Oxandrolone Tablets, USP 28 page 1427. It is proposed to replace the *Disintegration* test with a *Dissolution* test. The chromatographic procedure in the *Dissolution* test was validated using the RTX-5 brand of column containing packing G27. In the absence of any adverse comment, it is proposed to implement this revision via the *Second Interim Revision Announcement* pertaining to *USP 28-NF 23*, with an official date of April 1, 2005.

(BPC: M. Marques) RTS—41372-1

Delete the following:

Disintegration (704)—15 minutes_{0.2}

Add the following:

Dissolution (711)—

Medium: a solution of water and isopropanol (7:3); 500 mL.

Apparatus 2: 100 rpm.

Time: 60 minutes.

Directions



105 North Union Street
Alexandria, Virginia 22314
Tel: (703) 838-4565
Fax: (703) 549-6877

Open daily 10 am - 5 pm (except Christmas, New Year's Day, Easter, 4th of July, Thanksgiving)
[click for Parking Information](#)

MAP your personal course to the Torpedo Factory

Click the map link above for an interactive map that you can zoom in and out of and create a list of directions from your current location automatically. OR, follow the prepared directions from your general vicinity below.



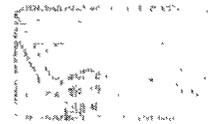
Directions:

From Maryland (Baltimore) or other points north (New York):

Take I-95 South which becomes part of the I-495 Capital Beltway towards Richmond. Take Exit 1-B (Route 1 North) off the Beltway and follow the signs to Old Town Alexandria. Go 6 blocks, turn right on King Street to the river and turn left on Union Street (last street before the river); 1/2 block to the Torpedo Factory Art Center on the right. Find out where to park below.

From Virginia (Richmond) or other points south:

Take I-95 North which becomes part of the I-495 Capital Beltway towards Baltimore. Take Exit 1-B (Route 1 North) off the Beltway and follow the signs to Old Town Alexandria. Go 6 blocks, turn right on King Street to the river and turn left on Union Street (last street before the river); 1/2 block to the Torpedo Factory Art Center on the right. Find out where to park below.



From D.C. or Arlington, Virginia area:

Cross the river to G.W. Parkway, go south past Reagan National Airport to Alexandria. Turn left on Queen Street to the river (end of street); Turn right. 1.5 blocks to the Torpedo Factory Art Center on the left. Find out where to park below.

From West Virginia or other points west:

Take I-66 East to the I-495 Capital Beltway heading south towards Richmond. Remain on Beltway (I-95) towards Baltimore and take Exit 1-B (Route 1 North) off the Beltway and follow the signs to Old Town Alexandria. Go 6 blocks, turn right on King Street to the river and turn left on Union Street (last street before the river); 1/2 block to the Torpedo Factory Art Center on the right. Find out where to park below.

From Maryland (Annapolis) or other points east (Chesapeake Bay and surrounding beaches):

Take I-50 West to the I-495 Capital Beltway (I-95) towards Richmond. Take Exit 1-B (Route 1 North) off the Beltway and follow the signs to Old Town Alexandria. Go 6 blocks, turn right on King Street to the river and turn left on Union Street (last street before the river); 1/2 block to the Torpedo Factory Art Center on the right. Find out where to park below.

Metro/Bus Directions:

The closest Metro station to the Torpedo Factory is King Street on the Blue or Yellow line. It's a 15-minute walk down to the end of King Street heading east to the waterfront. Turn left on Union Street (last street before the river); 1/2 block to the Torpedo Factory Art Center on the right. Taxi service from King Street Metro costs approximately \$5.00 per person one way. DASH Bus service is also available at the King Street Metro station. Take the #2 or #5 DASH to the corner of King & Fairfax Streets, walk 2 blocks east on King Street to Union Street.



Parking:

[click for Parking Location Map](#)

Street parking is available in most areas of Alexandria. Visitor parking in residential areas of Old Town is restricted to two or three hours. Metered parking is limited to two hours. Parking regulations are strictly enforced. A free 24-hour parking pass is available at the Ramsay House Visitors Center (open daily from 9-5) at 221 King Street. The passes are valid at two-hour meters only. There are also many convenient parking garages in the historic Old Town area, several offering reduced rates weekday evenings and all day Saturday and Sunday

PARKING GARAGES LOCATED WITHIN WALKING DISTANCE OF THE TFAC:**• CENTRAL PARKING**

115 South Union Street
Alexandria, VA 22314

\$4 per hr/\$ 8 Maximum. After 3 pm/Flat Rate:\$8

Hours of Operation:
Monday - Thursday 7 am - midnight
Friday 7 am - 3 am
Saturday 10 am - 3 am
Sunday Noon - 8 pm

• CENTRAL PARKING

110 South Union Street
300 North Lee Street

\$4 per hr/\$ 8 Maximum.
Special rate for Torpedo Factory Art Center: Mon - Fri \$5.00 max.Saturday \$7.00

Hours of Operation:
Monday - Wednesday Closed
Thursday 5:30 pm - midnight
Friday 5:30 pm - 3 am
Saturday 10 am - 3 am
Sunday Noon - 8 pm

• COLONIAL PARKING

101 North Union Street
Alexandria, VA 22314

\$4.50 per hr/\$9 Maximum

Hours of Operation:
Monday - Thursday 7 am - 1am
Friday 7 am - 3 am
Saturday 8 am - 3 am
Sunday 8 am - Midnight

• APCOA PARKING

220 North Union Street
Alexandria, VA 22314

\$3 per hr/\$7 Maximum - Mon - Fri 7am - 5pm.
\$2 per hr/\$4 Maximum Weekday evenings after 5pm (Saturday, Sundays and Holidays)

Hours of Operation:
Monday - Thursday 7 am - 1 am
Friday & Saturday 7 am - 2:30 am
Sunday 10 am - 1 am

• THOMPSON ALLEY GARAGE

10 Thompson's Alley
Alexandria, VA 22314

\$1.50 per hr/\$6 Maximum - Mon - Fri 8am - 5pm
\$1.50 per hr/\$3 Maximum - Mon - Thurs after 5pm. Sat 9 - 5pm, and all day Sunday.
\$2.25 per hr/\$4.50 Maximum Fri and Sat after 5pm

Hours of Operation:
Monday - Friday 8 am - 11 pm
Saturday 9 am - 11 pm
Sunday 10 am - 10 pm

For more parking information in the City of Alexandria. Go here.

Additional Directions may be obtained by calling 703.838.4565.

[HOME]

