ENVIRONMENTAL PROTECTION DEPARTMENT – Air Quality Division
Mailing Address: 115 South Andrews Avenue, Room A-240 · Fort Lauderdale, Florida 33301
954-519-1220 · FAX 954-519-1495

NOTICE OF PERMIT

Mr. Manuel Gonzalez, Manager of Facilities Engineering
Aveva Drug Delivery Systems, Inc.
3250 Commerce Parkway
Miramar, Florida 33025

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dear Mr. Gonzalez:

Enclosed is an operation permit Number 0112384-006-AF to operate an air pollution source issued pursuant to Section 403.087, Florida Statutes, Broward County Standard Operating Agreement and Chapter 27, which adopted Florida Administrative Code (FAC) 62-296 and 62-297. Persons whose substantial interests are affected by this permit have a right, pursuant to Section 120.57, Florida Statutes, to petition for an administrative determination (hearing) on it. The petition must conform to the requirements of Chapters 62-103 and 28-5.201, FAC, and must be filed (received) in the Environmental Protection Department, Air Quality Division, 115 South Andrews Avenue, Room: A-240, Fort Lauderdale, FL 33301, within fourteen (14) days of receipt of this notice. Failure to file a petition within the fourteen (14) days constitutes a waiver of any right such person has to an administrative determination (hearing) pursuant to Section 120.57, Florida Statutes and Chapter 27. This permit is final and effective on the date filed with the Clerk of the Department unless a petition is filed in accordance with this paragraph or unless a request for extension of time in which to file a petition is filed within the time specified for filing a petition and conforms to Rule 62-103.070, FAC. Upon timely filing of a petition or a request for an extension of time, this permit will not be effective until further Order of the Environmental Protection Department. When the Order (Permit) is final, any party to the Order has the right to seek judicial review of the Order pursuant to Section 120.68, Florida Statutes, by the filing of a Notice of Appeal pursuant to Rule 9.110, Florida Rules of Appellate Procedure, with the Clerk of the Environmental Protection Department, Air Quality Division, 115 South Andrews Avenue, Room: A-420, Fort Lauderdale, FL 33301; and by filing a copy of the Notice of Appeal accompanied by the applicable filing fees with the appropriate District Court of Appeal. The Notice of Appeal must be filed within 30 days from the Final Order is filed with the Clerk of the Department.

Executed in Broward County, Florida
BROWARD COUNTY
ENVIRONMENTAL PROTECTION DEPARTMENT

Daniel Brown for
Richard G. Wilkins, Director

cc: FDEP, Southeast District, Air Section

CERTIFICATE OF SERVICE

This is to certify that this NOTICE OF PERMIT and all copies were mailed before the close of business on 3/11/08 to the listed persons.

Kelly Rivera
Clerk

3/11/08
Date

Broward County Board of County Commissioners
Josephus Eggelletion, Jr.• Sue Gunzburger • Kristin D. Jacobs • Ken Keechl • Ilene Lieberman •Stacy Ritter • John E. Rodstrom, Jr •
Diana Wasserman-Rubin • Lois Wexler
www.broward.org

ENVIRONMENTAL PROTECTION DEPARTMENT - Air Quality Division
Mailing Address: 115 South Andrews Avenue, Room A-240 • Fort Lauderdale, Florida 33301
954-519-1220 • FAX 954-519-1495

NOTICE OF AIR POLLUTION PERMIT

CERTIFIED MAIL:
RETURN RECEIPT REQUESTED

ISSUED TO:

PERMITTEE:
Mr. Manuel Gonzalez
Manager of Facilities Engineering
Aveva Drug Delivery Systems, Inc.
3250 Commerce Parkway
Miramar, Florida 33025

AIRS ID NO: 0112384
Permit Number:0112384-006-AF
Issue Date: March 11, 2008
Expiration Date: December 1, 2012

Project: Air operation permit for a facility engaged in the manufacture of transdermal patches.

Lat/Long: 25°58'42"N/ 80° 17'7"W

UTM: Zone 17; 570.83Km. E; 2873.31Km. N

This permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.) Florida Administrative Code (F.A.C.) Rules 62-4 and 62-204 through 62-297 (permitting requirements) and Broward County Code, Chapter 27 (emission limitations) and in conformance with all existing regulations of the Florida Department of Environmental Protection (DEP). The above named Permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Broward County Environmental Protection Department (EPD) and made a part hereof and specifically described as follows:

Operate: An air pollution source consisting of a pharmaceutical manufacturing facility utilizing four coater drying lines (CDL) to manufacture transdermal patches. Two CDLs are used for research, development and production and are heated by 36 kw/hr electric heaters. Emissions vent directly to the atmosphere. Two other CDLs are used for production and air emissions will be treated with a 2.5 mmBTU/hr regenerative thermal oxidation unit with 95 percent VOC destruction efficiency prior to discharge. The thermal oxidation unit is fired by natural gas.

These are the emission units:

EU#001: Coater Drying Line No. 1 for Research, Development and Production
EU #002: Coater Drying Line No. 2 for Research, Development and Production
EU #003: Coater Drying Line No. 3 for Production
EU #004: Coater Drying Line No. 4 for Production

In accordance with: Application to Operate an Air Pollution Source received September 17, 1997 and additional information received October 23, 1997 and Public Notice of Intent issued November 14, 1997,

and published on November 20, 1997 in the Broward Daily Business Review newspaper, application to renew the FESOP received September 20, 2002, additional information received October 24, 2002, renewal application received December 3, 2007 (none are attached).

Location: 3250 Commerce Parkway, Miramar, Broward County, Florida.

To serve: Pharmaceutical Manufacturing Facility (SIC#2384)

Subject to: General Conditions 1-15, facility-Wide Conditions 16- 21 and Specific Conditions 22-45.

Permitting Note: This Federally Enforceable State Operating Permit (FESOP) limits the volatile organic compound and hazardous air pollutant emissions below major source (Title V) thresholds.

This facility becomes subject to 40 CFR 60, Subpart RR and all the cited provisions of this subpart in the specific conditions #25 through 41 if the operation exceeds the requirements of Specific Condition #24.

Attachment 1: Definitions
Attachment 2: Symbols
Attachment 3: 40 CFR 60.7 NSPS Notification and Record keeping Requirements and 40 CFR 60.8, NSPS Performance Test Requirements

General Conditions

1. Terms of Permit. The terms, conditions, requirements, limitations and restrictions set forth in this permit, are "permit conditions" and are binding and enforceable pursuant to Sections 403.141, 403.727, or 403.859 through 403.861, F.S. The Permittee is placed on notice that the EPD will review this permit periodically and may initiate enforcement action for any violation of these conditions.
[Rules 62-4.160 (1), F.A.C.]

2. Permit Validity. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the EPD.
[Rules 62-4.160 (2), F.A.C.]

3. Disclaimer. As provided in subsections 403.087(6) and 403.722(5), F.S., the issuance of this permit does not convey any vested rights or exclusive privileges. Neither does it authorize any injury to public or private property or any invasion of personal rights, or any violations of federal, state or local laws or regulations. This permit is not a waiver of or approval of any other permit that may be required for other aspects of the total project which are not addressed in this permit.
[Rules 62-4.160 (3), F.A.C.]

4. Disclaimer. This permit conveys no title to land or water, does not constitute State recognition or acknowledgment of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interest have been obtained form the State. Only the Trustees of the Internal Improvement Trust Fund may express State opinion as to title.
[Rules 62-4.160 (4), F.A.C.]

5. Liability. This permit does not relieve the Permittee from liability for harm or injury to human health or welfare, animal, or plant life, or property caused by the construction or operation of this permitted source, or from penalties therefore; nor does it allow the Permittee to cause pollution in contravention of Florida Statutes and DEP rule, unless specifically authorized by an order from the EPD.
[Rules 62-4.160 (5), F.A.C.]

6. Operation and Maintenance. The Permittee shall properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed and used by the Permittee to achieve compliance with the conditions of this permit, as required by county and state rules. This provision included the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by EPD and DEP rules.
[Rules 62-4.160 (6), F.A.C.]

7. Onsite Inspection Activities. The Permittee, by accepting this permit, specifically agrees to allow authorized EPD personnel, upon presentation of credentials or other documents as may be required by law and at reasonable times (depending on the nature of the concern being investigated), access to the premises where the permitted activity is located or conducted to:

   (a) Have access to and copy any records that must be kept under conditions of the permit;
   (b) Inspect the facility, equipment, practices, or operations regulated or required under this permit; and
   (c) Sample or monitor any substances or parameters at any location reasonably necessary to assure compliance with this permit or EPD and DEP rules.

   [Rules 62-4.160 (7), F.A.C.]

8. Notice of Noncompliance. If, for any reason, the Permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the Permittee shall immediately provide EPD with the following information:
   (a) A description of and cause of noncompliance; and
   (b) The period of noncompliance, including dates and times, or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to educe, eliminate, and prevent recurrence of the noncompliance. The Permittee shall be responsible for any enforcement action by EPD for penalties or for revocation of this permit.

   [Rules 62-4.160 (8), F.A.C.]

9. Evidence Materials. By accepting this permit, the Permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted facility or activity, that are submitted to the EPD, may be used by the EPD as evidence in any enforcement proceeding arising under the Florida Statues or F.A.C. rules, except where such use is prohibited by Section 403.111 and 403.73, Florida Statutes. Such evidence shall only be used to the extent it is consistent with the Florida Rules of Civil Procedure and appropriate evidentiary rules.
   [Rules 62-4.160 (9), F.A.C.]

10. Rule Changes. The Permittee agrees to comply with changes in DEP rules and Florida Statutes after a reasonable time for compliance; provided, however, the Permittee does not waive any other rights granted by Florida Statutes or DEP rules.
    [Rules 62-4.160 (10), F.A.C.]

11. Permit Transfer. This permit is transferable only upon EPD approval in accordance with Rule 62-4.120 and 62-730.300 F.A.C., as applicable. The Permittee shall be liable for any non-compliance of the permitted activity until the transfer approved by the EPD.
    [Rules 62-4.160 (11), F.A.C.]

12. Work Site Copy. This permit or a copy thereof shall be kept at the work site of the permitted activity.
    [Rules 62-4.160 (12), F.A.C.]

13. Miscellaneous Compliance Requirements. The Permittee shall comply with the following:

    (a) Upon request, the Permittee shall furnish all records and plans required under DEP rules. During enforcement actions, the retention period for all records will be extended automatically unless otherwise stipulated by the EPD.

    (b) The Permittee shall hold at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recording for continuous monitoring instrumentation) required by the permit, copies of all reports required by this permit, and records of all data used to complete the application for this permit. These materials shall be retained at least three years from the date of the sample, measurement, report, or application unless otherwise specified by EPD rule.

    (c) Records of monitoring information shall include:

        1. The date, exact place, and time of sampling or measurements;
        2. The person responsible for performing the sampling or measurements;
        3. The dates analyses were performed.
        4. The person responsible for performing the analyses;

5. The analytical techniques or methods used;
6. The results of such analyses.

[Rules 62-4.160 (14), F.A.C.]

14. Information Submittal. When requested by the EPD, the Permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the Permittee becomes aware the relevant facts were not submitted or were incorrect in the permit application or in any report to the EPD, such facts or information shall be corrected promptly.
[Rules 62-4.160 (15), F.A.C.]

15. Rules Adoption. Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, as amended, are adopted by Broward County Code, Sec. 27-173.
[Broward County Code, Sec. 27-173]

Facility-wide Conditions

16. Objectionable Odor. No person shall cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
[Rule 62-296.320(2), F.A.C.]

17. Volatile Organic Compound Emissions or Organic Solvent Emissions. No person shall store, pump, handle, process, load, unload or use in any process or installation volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the EPD.
[Broward County Board of Ordinances, Sec. 27-175(f)]

18. Concealment. No person shall build, erect, install, or use any article, machine, equipment or other contrivance, the use of which will conceal any emission which would otherwise constitute a violation of any provisions of Broward County Codes.
[Broward County Code, Sec. 27-175(b)]

19. Circumvention. No person shall circumvent any air pollution device, or allow the emission of air pollutants without the applicable air pollution control device operating properly.
[Broward County Code, Sec. 27-175(c)]

20. Maintenance. No person shall operate any air pollution control equipment or systems without proper and sufficient maintenance to assure compliance with Broward County Codes.
[Broward County Code, Sec. 27-175(d)]

21. No person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity, the density of which is equal to or greater than that designated as Number 1 on the Ringelmann Chart (20 percent opacity).
[F.A.C. Rule 62-296.320(4) (b) (1)]

Specific Conditions

Emission Limiting Standards

22. In order to avoid major source (Title V) applicable standards, emissions of any individual HAP and total HAPs from the entire facility shall not exceed 1665 pounds (9.99 tons in any 12 month period) and 4,165 pounds (24.99 tons in any 12 month period) in any calendar month, respectively.
[FESOP application received September 17, 1997 and F.A.C. Rule 62-4.070(3)]

23. In order to avoid major source (Title V) applicable standards, emissions of total VOCs from the entire facility shall not exceed 8.3325 tons in any calendar month (99.9 tons in a 12 month period). Any HAP that is also a VOC must also be included in the total VOC calculations.
[FESOP application received September 17, 1997, F.A.C. Rule 62-4.070(3)]

24. The standards in 40 CFR 60 subpart RR shall apply to CDLs #s 1, 2, 3 and #4. Any facility (emissions unit/source) which inputs to the coating process 45 Mega grams (Mg) (99,119 pounds) of VOC or less per 12 month period is not subject to the emission limits of 40 CFR 60.442(a) [Specific Condition 25], however, the affected facility is subject to the requirements of all other applicable sections of 40 CFR 60 Subpart RR. **If the amount of VOC input exceeds 45 Mg per 12 month period, the coating line will become subject to 40 CFR 60.442(a) and all other sections of 40 CFR 60 Subpart RR, and Specific Conditions 25 through 41 of this permit shall apply.**
[Broward County Code, Sec. 27- 183, which adopts by reference F.A.C. Rule 62-204.800(7) (b) 46, which adopts by reference 40 CFR 60.440]

25. On and after the date on which the performance test required by 40 CFR 60.8 [Attachment 3] has been completed:

    (1) The permittee shall not cause the discharge into the atmosphere from an affected facility not more than 0.20 kg VOC/kg of coating solids applied as calculated on a weighted average basis for one calendar month; or

    (2) The permittee shall demonstrate for each affected facility;

        (i) A 90 percent overall VOC emission reduction as calculated over a calendar month; or

        (ii) The percent overall VOC emission reduction specified in 40 CFR 60.443(b) [Specific Condition 26. (B)] as calculated over a calendar month.

    [Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7) (b) 46, which adopts by reference 40 CFR 60.442(a)]

Compliance Testing Requirements

26. (A) To determine compliance with 40 CFR 60.442 [Specific Condition 25], the owner or operator shall calculate a weighted average of the mass of solvent used per mass of coating solids applied for a one calendar month period according to the following procedures:

    (1) Determine the weight fraction of organics and the weight fraction of solids of each coating applied by using Reference Method 24 or by the coating manufacturer's formulation data.

(2) Compute the weighted average by the following equation:

$$G = \frac{\sum_{i=1}^{n} W_{oi} M_{ci}}{\sum_{i=1}^{n} W_{si} M_{ci}}$$

For each affected facility where the value of G is less than or equal to 0.20 kg VOC per kg of coating solids applied, the affected facility is in compliance with 40 CFR 60.442(a)(1) [Specific Condition 9(1)].

-- or --

(B) To determine compliance with 40 CFR 60.442(a) (2) [Specific Condition 10. (2)], the owner or operator shall calculate the required overall VOC emission reduction according to the following equation:

$$R_q = \frac{G - 0.20}{G} \times 100$$

If R_q less than or equal to 90 percent, then the required overall VOC emission reduction is R_q. If R_q is greater than 90 percent, then the required overall VOC emission reduction is 90 percent.

[Broward County Code, Sec. 27- 173, which adopts by reference F.A.C. Rule 62-204.800(7) (b)46, which adopts by reference 40 CFR 60.443]

27. Where compliance with the emission limit specified in 40 CFR 60.442(a)(2) [Specific Condition 25.(2)] is achieved through the use of a solvent destruction device, the owner or operator shall determine calendar monthly compliance by comparing the monthly required overall VOC emission reduction specified in paragraph 40 CFR 60.443(b) [Specific Condition 26.(B)] of this section to the overall VOC emission reduction demonstrated in the most recent performance test which complied with 40 CFR 60.442(a)(2) [Specific Condition 10]. If the monthly required overall VOC emission reduction is less than or equal to the overall VOC reduction of the most recent performance test, the affected facility is in compliance with 40 CFR 60.442(a)(2).
[Broward County Code, Sec. 27- 173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.443(d)]

28. Where compliance with 40 CFR 60.442(a)(2) [Specific Condition 25.(2)] is achieved through the use of a solvent destruction device, the owner or operator shall continuously record the destruction device combustion temperature during coating operations for thermal incineration destruction devices. For thermal incineration destruction devices the owner or operator shall record all 3-hour periods (during actual coating operations) during which the average temperature of the device is more than 28°C (50°F) below the average temperature of the device during the most recent performance test complying with 40 CFR 60.442(a)(2).
[Broward County Code, Sec. 27- 173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.443(e)]

29. After the initial performance test required for all affected facilities under 40 CFR 60.8 [Attachment 3], compliance with the VOC emission limitation and percentage reduction requirements under 40 CFR 60.442 [see Specific Condition 25] is based on the average emission reduction for one calendar month. A separate compliance test (determination) is completed at the end of each calendar month after the initial performance test, and a new calendar month's average VOC emission reduction is calculated to show compliance with the standard. If a common emission control device is used to recover or destroy solvent from more than one affected facility, the performance of that control device is assumed to be equal for each of the affected facilities. Compliance with 40 CFR 60.442(a)(2) [Specific Condition 25. (2)] is determined by the methods specified in 40 CFR 60.443(d) [Specific Condition 26] and is performed simultaneously on all affected facilities. Startups and shutdowns are normal operation for this source category. Emissions from these operations are to be included when determining if the standard specified at 40 CFR 60.442(a)(2) [Specific Condition 25.(2)]is being attained.
[Broward County Code, Sec. 27- 173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.443]

30. The performance test for affected facilities controlled by a solvent destruction device shall be conducted as follows:

(1) The performance of the solvent destruction device shall be determined by averaging the results of three test runs as specified in 40 CFR 60.8(f) [Attachment 3].

(2) Determine for each affected facility prior to each test run the weighted average mass of VOC per mass of coating solids applied being used at the facility. The weighted average shall be determined as specified in 40 CFR 60.443(a) [Specific Condition 26.(A)]. In this application the quantities of W_{oi}, W_{si}, and M_{ci} shall be determined for the time period of each test run and not a calendar month as specified in 40 CFR 60.441 [Attachment 2: Symbols].

(3) Calculate the resulting percent overall VOC emission reduction as specified in 40 CFR 60.443(b) [Specific Condition 11.(B)].

(4) Determine the percent overall VOC emission reduction of the solvent destruction device by the following equation and procedures:

$$R = \frac{\sum_{i=1}^{n} Q_{bi} C_{bi} - \sum_{i=1}^{m} Q_{aj} C_{ai}}{\sum_{i=1}^{n} Q_{bi} C_{bi} + \sum_{k=1}^{p} Q_{fk} C_{fk}} \times 100$$

(i) The owner or operator of the affected facility shall construct the overall VOC emission reduction system so that all volumetric flow rates and total VOC emissions can be accurately determined by the applicable test methods and procedures specified in 40 CFR 60.446(b) [Specific Condition 32] .

(ii) The owner or operator of an affected facility shall construct a temporary total enclosure around the coating line applicator and flash off area during the performance test for the purpose of capturing fugitive VOC emissions. If a permanent total enclosure exists in the affected facility prior to the

performance test and the EPD, Air Quality Division is satisfied that the enclosure is totally capturing fugitive VOC emissions, then no additional total enclosure will be required for the performance test.

(iii) For each affected facility where the value of R is greater than or equal to the value of R_q calculated in 40 CFR 60.443(b) [Specific Condition 26.(B)], compliance with 40 CFR 60.442(a)(2) [Specific Condition 25.(2)] shall be demonstrated.

[Broward County Code, Sec. 27- 173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.444(c)]

31. The VOC content per unit of coating solids applied and compliance with 40 CFR 60.422(a)(1) [Specific Condition 25.(1)] shall be determined by either Reference Method 24 and the equations specified in 40 CFR 60.443 [Specific Condition 26] or by manufacturers' formulation data. In the event of any inconsistency between a Method 24 test and manufacturers' formulation data, the Method 24 test will govern. The Broward County Environmental Protection Department (BCEPD), Air Quality Division may require an owner or operator to perform EPA Reference Method 24 test during such months as it deems appropriate. For EPA Reference Method 24, the coating sample must be a one liter sample taken into a one liter container at a point where the sample will be representative of the coating applied to the web substrate. [Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.446(a)]

32. The EPA Reference Method 25 shall be used to determine the VOC concentration, in parts per million by volume, of each effluent gas stream entering and exiting the solvent destruction device or its equivalent, and each effluent gas stream emitted directly to the atmosphere. Reference Methods 1, 2, 3, and 4 shall be used to determine the sampling location, volumetric flowrate, molecular weight, and moisture of all sampled gas streams. For EPA Reference Method 25, the sampling time for each of three runs must be at least 1 hour. The minimum sampling volume must be 0.003 dscm except that shorter sampling times or smaller volumes, when necessitated by process variables or other factors, may be approved by the Administrator (EPD). [Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.446(b)]

33. If the owner or operator can demonstrate to the Administrator's (EPD) satisfaction that testing of representative stacks yields results comparable to those that would be obtained by testing all stacks, the Administrator (EPD) will approve testing of representative stacks on a case-by-case basis. [Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.446(c)]. The owner or operator of an emissions unit that is subject to any emissions limiting standard shall conduct a compliance test that demonstrates compliance with the applicable emission limiting standard prior to obtaining a renewed operation permit. In order to avoid major source (Title V) applicable requirements, the standards for which compliance demonstration are required are:

1) Total VOC potential emissions shall not equal or exceed 16,666 pounds/month (8.3325 tons/month, 99.9 tons in a 12 month period).
2) Total HAP potential emissions shall not equal or exceed 4,165 pounds/month (24.99 tons in a 12 month period), and
3) Individual HAP potential emissions shall not equal or exceed 1,665 pounds/month (9.99 tons in a 12 month period).

The owner or operator shall demonstrate compliance with these standards using material balance calculations, the weighted average weight fraction of organics determined by EPA Reference Method

24 and the equation given in 40 CFR 60.433(a)(2) [Specific Condition 26.(A)], and the monthly VOC emission reductions calculated in accordance with the equation given in 40 CFR 60.443(b) [Specific Condition 26.(B)]
[F.A.C. Rule 62-297.310(7)(a)3, F.A.C. Rule 62-4.070(3) and FESOP application received September 17, 1997]

Monitoring of Operations, Recordkeeping and Reporting Requirements

34. The owner or operator shall maintain a calendar month record of all coatings used and the results of the reference test method specified in 40 CFR 60.446(a) [Specific Condition 31] or the manufacturer's formulation data used for determining the VOC content of those coatings.
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.445(a)]

35. The owner or operator of an affected facility operating at the conditions specified in 40 CFR 60.440(b) [inputting less than 45 Mg (99,119 pounds) of VOC or less per 12 month period] shall maintain a 12 month record of the amount of solvent applied in the coating at the facility.
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.445(d)]

36. The owner or operator shall install, calibrate, maintain, and operate a monitoring device which continuously indicates and records the temperature of the solvent destruction device's exhaust gases. The monitoring device shall have an accuracy of the greater of ± 0.75 percent of the temperature being measured expressed in degrees Celsius or ± 2.5° C.
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.445(e)]

37. The owner or operator of an affected facility controlled by a solvent destruction device which uses a hood or enclosure to capture fugitive VOC emissions shall install, calibrate, maintain, and operate a monitoring device which continuously indicates that the hood or enclosure is operating. No continuous monitor shall be required if the owner or operator can demonstrate that the hood or enclosure system is interlocked with the affected facility's oven recirculation air system.
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.445(g)]

38. The records of the measurements required in 40 CFR 60.443 [Specific Conditions 25-29] and 60.445 [Specific Conditions 21-25] must be retained for at least two years following the date of the measurements.
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.445(h)]

39. The performance test data and results from the performance test shall be submitted to the Broward County Environmental Protection Department (EPD), Air Quality Division as specified in 40 CFR 60.8(a) of the General Provisions (40 CFR part 60, subpart A) [Attachment 3].
[Broward County Code, Sec. 27-173, which adopts by reference F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.447(a)]

40. Following the initial performance test, the owner or operator of each affected facility shall submit quarterly reports to the EPD, Air Quality Division of exceedances of the VOC emission limits specified in 40 CFR 60.442 [Specific Condition 23]. If no such exceedances occur during a particular quarter, a report stating

this shall be submitted to the EPD, Air Quality Division semiannually. [Broward County Code, Sec. 27-173, which adopts by reference.
[F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.447(b)]

41. The owner or operator of each affected facility shall also submit reports at the frequency specified in 40 CFR 60.7(c) [Attachment 3] when the incinerator temperature drops as defined under 40 CFR 60.443(e) [Specific Condition 28]. If no such periods occur, the owner or operator shall state this in the report. [Broward County Code, Sec. 27-173, which adopts by reference
[F.A.C. Rule 62-204.800(7)(b)46, which adopts by reference 40 CFR 60.447(c)]

42. The facility will provide reasonable assurances that it is maintaining its synthetic non-Title V status by retaining records of total VOC, total HAPs, and individual HAP usage rates for the entire facility on a daily basis. VOC and HAP content of all coatings and solvents shall be determined by using EPA Reference Method 24 or by the coating manufacturer's formulation records. Calculations of VOC and HAP emissions shall be performed utilizing these daily usage records and mass balance computations. Any HAP that is also a VOC must also be included in the total VOC calculations. These records shall detail VOC/HAP usage for each CDL on a daily, weekly, and monthly basis. Emission calculations shall be performed assuming 100 percent volatilization of VOCs and the most recent VOC emission reduction rate determined. These records and calculations shall be kept on site for the most recent two year period and shall be made available to local, state, and federal air pollution agencies.
[FESOP application received September 17, 1997, and F.A.C. Rule 62-4.070(3)]

43. When the Department, after investigation, has good reason (such as complaints, increased visible emissions or questionable maintenance of control equipment) to believe that any applicable emission standard in F.A.C. Rule 62-204 through 62-297 or in a permit issued pursuant to those rules is violated, it shall require the owner or operator of the emission unit to conduct compliance testing which identifies the nature and quantity of pollutant emissions from the emission unit and to provide a report on the results of said tests to the Department.
[F.A.C. Rule 62-297.310(7)(6)]

44. On or before March 1 of each calendar year, the permittee shall submit either a completed hard copy of Florida Department of Environmental Protection Form 62-210.900(5), Annual Operating Report for Air Pollutant Emitting Facility to EPD, Air Quality Division, or submit an electronic Annual Operating Report to Florida Department of Environmental Protection. This report shall show detailed calculations showing formulae used, process data, and estimates of emissions of VOCs and HAPs.
[F.A.C. Rule 62-210.370(3)]

Operating Permit Renewal Requirements

45. Operating Permit Renewal. Sixty days before the expiration date of this operation permit, the Permittee shall apply for a renewal of permit using the forms incorporated by reference in the specific rule chapter for this type of permit.
[F.A.C. Rule 62-090.(1)]

{Permitting Note: The Permittee may also elect to submit the application electronically using the Electronic Permit Submittal and Processing system (EPSAP) via the http://www.dep.state.fl.us/air/software.htm website, along with the processing fee established in Rule 62-4.050(4), F.A.C. , [62-4.090(1) and 62-4.050(4), F.A.C.]

Executed in Broward County, Florida
Environmental Protection Department

Daniel Burn for
Richard G. Wilkins, Director

ATTACHMENT 1: Definitions

Except as otherwise required by the context, terms used in this subpart are defined in the Act, in subpart A of this part, or in this section as follows:

Coating applicator means an apparatus used to apply a surface coating to a continuous web.

Coating line means any number or combination of adhesive, release, or precoat coating applicators, flashoff areas, and ovens which coat a continuous web, located between a web unwind station and a web rewind station, to produce pressure sensitive tape and label materials.

Coating solids applied means the solids content of the coated adhesive, release, or precoat as measured by Reference Method 24.

Flashoff area means the portion of a coating line after the coating applicator and usually before the oven entrance.

Fugitive volatile organic compounds means any volatile organic compounds which are emitted from the coating applicator and flashoff areas and are not emitted in the oven.

Hood or enclosure means any device used to capture fugitive volatile organic compounds.

Oven means a chamber which uses heat or irradiation to bake, cure, polymerize, or dry a surface coating.

Precoat means a coating operation in which a coating other than an adhesive or release is applied to a surface during the production of a pressure sensitive tape or label product.

Solvent applied in the coating means all organic solvent contained in the adhesive, release, and precoat formulations that is metered into the coating applicator from the formulation area.

Total enclosure means a structure or building around the coating applicator and flashoff area or the entire coating line for the purpose of confining and totally capturing fugitive VOC emissions.

VOC means volatile organic compound.

ATTACHMENT 2: Symbols

All symbols used in this subpart not defined below are given meaning in the Act or in subpart A of 40 CFR 60.

$_a$ = the gas stream vents exiting the emission control device.

$_b$ = the gas stream vents entering the emission control device.

C_{aj} = the concentration of VOC (carbon equivalent) in each gas stream(j) exiting the emission control device, in parts per million by volume.

C_{bi} = the concentration of VOC (carbon equivalent) in each gas stream (i) entering the emission control device, in parts per million by volume.

C_{fk} = the concentration of VOC (carbon equivalent) in each gas stream (k) emitted directly to the atmosphere, in parts per million by volume.

G = the calculated weighted average mass (kg) of VOC per mass (kg) of coating solids applied each calendar month.

M_{ci} = the total mass (kg) of each coating (i) applied during the calendar month as determined from facility records.

M_r = the total mass (kg) of solvent recovered for a calendar month.

Q_{aj} = the volumetric flow rate of each effluent gas stream (j) exiting the emission control device, in dry standard cubic meters per hour.

Q_{bi} = the volumetric flow rate of each effluent gas stream (i) entering the emission control device, in dry standard cubic meters per hour.

Q_{fk} = the volumetric flow rate of each effluent gas stream (k) emitted to the atmosphere, in dry standard cubic meters per hour.

R = the overall VOC emission reduction achieved for a calendar month (in percent).

R_q = the required overall VOC emission reduction (in percent).

W_{oi} = the weight fraction of organics applied of each coating (i) applied during a calendar month as determined from Reference Method 24 or coating manufacturer's formulation data.

W_i = the weight fraction of solids applied of each coating (i) applied during a calendar month as determined from Reference Method 24 or coating manufacturer's formulation data.

Attachment 3: 40 CFR 60.7 NSPS Notification and Record keeping Requirements

(a) Any owner or operator subject to the provisions of this part shall furnish the Administrator written notification as follows:

(a)(1) A notification of the date construction (or reconstruction as defined under 40 CFR 60.15) of an affected facility is commenced postmarked no later than 30 days after such date. This requirement shall not apply in the case of mass-produced facilities which are purchased in completed form.

(a)(2) A notification of the anticipated date of initial startup of an affected facility postmarked not more than 60 days nor less than 30 days prior to such date.

(a)(3) A notification of the actual date of initial startup of an affected facility postmarked within 15 days after such date.

(a)(4) A notification of any physical or operational change to an existing facility which may increase the emission rate of any air pollutant to which a standard applies, unless that change is specifically exempted under an applicable subpart or in 40 CFR 60.14(e). This notice shall be postmarked 60 days or as soon as practicable before the change is commenced and shall include information describing the precise nature of the change, present and proposed emission control systems, productive capacity of the facility before and after the change, and the expected completion date of the change. The Administrator may request additional relevant information subsequent to this notice.

(a)(5) A notification of the date upon which demonstration of the continuous monitoring system performance commences in accordance with 40 CFR 60.13(c). Notification shall be postmarked not less than 30 days prior to such date.

(a)(6) A notification of the anticipated date for conducting the opacity observations required by 40 CFR 60.11(e)(1) of this part. The notification shall also include, if appropriate, a request for the Administrator to provide a visible emissions reader during a performance test. The notification shall be postmarked not less than 30 days prior to such date.

(a)(7) A notification that continuous opacity monitoring system data results will be used to determine compliance with the applicable opacity standard during a performance test required by 40 CFR 60.8 in lieu of Method 9 observation data allowed by 40 CFR 60.11(e)(5) of this part. This notification shall be postmarked not less than 30 days prior to the date of the performance test.

(b) Any owner or operator subject to the provisions of this part shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility; any malfunction of the air pollution control equipment; or any periods during which a continuous monitoring system or monitoring device is inoperative.

(c) Each owner or operator required to install a continuous monitoring system (CMS) or monitoring device shall submit an excess emissions and monitoring systems performance report (excess emissions are defined in applicable subparts) and/or a summary report form (see paragraph (d) of this section) to the Administrator semiannually, except when: more frequent reporting is specifically required by an applicable subpart; or the CMS data are to be used directly for compliance determination, in which case quarterly reports shall be submitted; or the Administrator, on a case-by-case basis, determines that more frequent reporting is necessary to accurately assess the compliance status of the source. All reports shall be postmarked by the 30th day following the end of each calendar half (or quarter, as appropriate). Written reports of excess emissions shall include the following information:

(c)(1) The magnitude of excess emissions computed in accordance with 40 CFR 60.13(h), any conversion factor(s) used, and the date and time of commencement and completion of each time period of excess emissions. The process operating time during the reporting period.

(c)(2) Specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the affected facility. The nature and cause of any malfunction (if known), the corrective action taken or preventative measures adopted. (c)(3) The date and time identifying each period during which the continuous monitoring system was inoperative except for zero and span checks and the nature of the system repairs or adjustments.

(c)(4) When no excess emissions have occurred or the continuous monitoring system(s) have not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(d) The summary report form shall contain the information and be in the format shown in figure 1 unless otherwise specified by the Administrator. One summary report form shall be submitted for each pollutant monitored at each affected facility.

(d)(1) If the total duration of excess emissions for the reporting period is less than 1 percent of the total operating time for the reporting period and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report form shall be submitted and the excess emission report described in 40 CFR 60.7(c) need not be submitted unless requested by the Administrator.

(d)(2) If the total duration of excess emissions for the reporting period is 1 percent or greater of the total operating time for the reporting period or the total CMS downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the summary report form and the excess emission report described in 40 CFR 60.7(c) shall both be submitted.

FIGURE 1--SUMMARY REPORT--GASEOUS AND OPACITY EXCESS EMISSION AND MONITORING SYSTEM PERFORMANCE

Pollutant (Circle One--SO_2/NO_X/TRS/H_2S/CO/Opacity)
Reporting period dates: From _____ to _____
Company:
Emission
Limitation_____
Address:
Monitor Manufacturer and Model No._____
Date of Latest CMS Certification or Audit_____
Process Unit(s) Description:
Total source operating time in reporting period _____

Emission data summary	CMS performance summary
1. Duration of excess emissions in reporting period due to:	1. CMS downtime in reporting period due to:
a. Startup/shutdown.....	a. Monitor equipment malfunctions.....
b. Control equipment problems.....	b. Non-Monitor equipment malfunctions.....
c. Process problems.....	c. Quality assurance calibration.....
d. Other known causes.....	d. Other known causes.....
e. Unknown causes.....	e. Unknown causes.....
2. Total duration of excess emission.....	2. Total CMS Downtime.....
3. Total duration of excess emissions x (100) % 2 source operating time] [Total source operating time].	3. [Total CMS Downtime] x (100) [Total % 2]

1 For opacity, record all times in minutes. For gases, record all times in hours.

2 For the reporting period: If the total duration of excess emissions is 1 percent or greater of the total operating time or the total CMS downtime is 5 percent or greater of the total operating time, both the summary report form and the excess emission report described in 40 CFR 60.7(c) shall be submitted.

Aveva Drug Delivery Systems, Inc.
Permit Number: 0112384-006-AF

On a separate page, describe any changes since last quarter in CMS, process or controls. I certify that the information contained in this report is true, accurate, and complete.

Name

Signature

Title

Date

(e)(1) Notwithstanding the frequency of reporting requirements specified in paragraph (c) of this section, an owner or operator who is required by an applicable subpart to submit excess emissions and monitoring systems performance reports (and summary reports) on a quarterly (or more frequent) basis may reduce the frequency of reporting for that standard to semiannual if the following conditions are met:

(e)(1)(i) For 1 full year (e.g., 4 quarterly or 12 monthly reporting periods) the affected facility's excess emissions and monitoring systems reports submitted to comply with a standard under this part continually demonstrate that the facility is in compliance with the applicable standard;

(e)(1)(ii) The owner or operator continues to comply with all recordkeeping and monitoring requirements specified in this subpart and the applicable standard; and

(e)(1)(iii) The Administrator does not object to a reduced frequency of reporting for the affected facility, as provided in paragraph (e)(2) of this section.

(e)(2) The frequency of reporting of excess emissions and monitoring systems performance (and summary) reports may be reduced only after the owner or operator notifies the Administrator in writing of his or her intention to make such a change and the Administrator does not object to the intended change. In deciding whether to approve a reduced frequency of reporting, the Administrator may review information concerning the source's entire previous performance history during the required recordkeeping period prior to the intended change, including performance test results, monitoring data, and evaluations of an owner or operator's conformance with operation and maintenance requirements. Such information may be used by the Administrator to make a judgment about the source's potential for noncompliance in the future. If the Administrator disapproves the owner or operator's request to reduce the frequency of reporting, the Administrator will notify the owner or operator in writing within 45 days after receiving notice of the owner or operator's intention. The notification from the Administrator to the owner or operator will specify the grounds on which the disapproval is based. In the absence of a notice of disapproval within 45 days, approval is automatically granted.

(e)(3) As soon as monitoring data indicate that the affected facility is not in compliance with any emission limitation or operating parameter specified in the applicable standard, the frequency of reporting shall revert to the frequency specified in the applicable standard, and the owner or operator shall submit an excess emissions and monitoring systems performance report (and summary report, if required) at the next appropriate reporting period following the noncomplying event. After demonstrating compliance with the applicable standard for another full year, the owner or operator may again request approval from the Administrator to reduce the frequency of reporting for that standard as provided for in paragraphs (e)(1) and (e)(2) of this section.

(f) Any owner or operator subject to the provisions of this part shall maintain a file of all measurements, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this part recorded in a permanent form suitable for inspection. The file shall be retained for at least two years following the date of such measurements, maintenance, reports, and records.

(g) If notification substantially similar to that in paragraph (a) of this section is required by any other State or local agency, sending the Administrator a copy of that notification will satisfy the requirements of paragraph (a) of this section. (h) Individual subparts of this part may include specific provisions which clarify or make inapplicable the provisions set forth in this section.

Attachment 3: 40 CFR 60.8, NSPS Performance Test Requirements

(a) Within 60 days after achieving the maximum production rate at which the affected facility will be operated, but not later than 180 days after initial startup of such facility and at such other times as may be required by the Administrator under section 114 of the Act, the owner or operator of such facility shall conduct performance test(s) and furnish the Broward County Environmental Protection Department, Air Quality Division a written report of the results of such performance test(s).

(b) Performance tests shall be conducted and data reduced in accordance with the test methods and procedures contained in each applicable subpart unless the Administrator (1) specifies or approves, in specific cases, the use of a reference method with minor changes in methodology, (2) approves the use of an equivalent method, (3) approves the use of an alternative method the results of which he has determined to be adequate for indicating whether a specific source is in compliance, (4) waives the requirement for performance tests because the owner or operator of a source has demonstrated by other means to the Administrator's (EPD's) satisfaction that the affected facility is in compliance with the standard, or (5) approves shorter sampling times and smaller sample volumes when necessitated by process variables or other factors. Nothing in this paragraph shall be construed to abrogate the Administrator's authority to require testing under section 114 of the Act.

(c) Performance tests shall be conducted under such conditions as the Administrator shall specify to the plant operator based on representative performance of the affected facility. The owner or operator shall make available to the Broward County Environmental Protection Department, Air Quality Division such records as may be necessary to determine the conditions of the performance tests. Operations during periods of startup, shutdown, and malfunction shall not constitute representative conditions for the purpose of a performance test nor shall emissions in excess of the level of the applicable emission limit during periods of startup, shutdown, and malfunction be considered a violation of the applicable emission limit unless otherwise specified in the applicable standard.

(d) The owner or operator of an affected facility shall provide the Broward County Environmental Protection Department, Air Quality Division at least 30 days prior notice of any performance test, except as specified under other subparts, to afford the Broward County Environmental Protection Department, Air Quality Division the opportunity to have an observer present.

(e) The owner or operator of an affected facility shall provide, or cause to be provided, performance testing facilities as follows:

(1) Sampling ports adequate for test methods applicable to such facility. This includes (i) constructing the air pollution control system such that volumetric flow rates and pollutant emission rates can be accurately determined by applicable test methods and procedures and (ii) providing a stack or duct free of cyclonic flow during performance tests, as demonstrated by applicable test methods and procedures.

(2) Safe sampling platform(s).

(3) Safe access to sampling platform(s).

(4) Utilities for sampling and testing equipment.

(f) Unless otherwise specified in the applicable subpart, each performance test shall consist of three separate runs using the applicable test method. Each run shall be conducted for the time and under the conditions specified in the applicable standard. For the purpose of determining compliance with an applicable standard, the arithmetic means of results of the three runs shall apply. In the event that a sample is accidentally lost or conditions occur in which one of the three runs must be discontinued because of forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, or other circumstances, beyond the owner or operator's control, compliance may, upon the Administrator's approval, be determined using the arithmetic mean of the results of the two other runs.