FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC
17 - 25 HUGHES AVE
IRVINE, CA 92618

NOTICE

IN ACCORDANCE WITH RULE 206, THIS PERMIT TO OPERATE OR A COPY THEREOF MUST BE KEPT AT THE LOCATION FOR WHICH IT IS ISSUED.

THIS PERMIT DOES NOT AUTHORIZE THE EMISSION OF AIR CONTAMINANTS IN EXCESS OF THOSE ALLOWED BY DIVISION 26 OF THE HEALTH AND SAFETY CODE OF THE STATE OF CALIFORNIA OR THE RULES OF THE SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT. THIS PERMIT SHALL NOT BE CONSTRUED AS PERMISSION TO VIOLATE EXISTING LAWS, ORDINANCES, REGULATIONS OR STATUTES OF ANY OTHER FEDERAL, STATE OR LOCAL GOVERNMENTAL AGENCIES.

Barry R. Wallerstein, D. Env.
EXECUTIVE OFFICER

By _____
Mohsen Nazemi, P.E.
Deputy Executive Officer
Engineering & Compliance

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TEVA PARENTERAL MEDICINES, INC

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SECTION A: FACILITY INFORMATION

LEGAL OWNER &/OR OPERATOR:	TEVA PARENTERAL MEDICINES, INC
LEGAL OPERATOR (if different than owner):	
EQUIPMENT LOCATION:	17 - 25 HUGHES AVE IRVINE, CA 92618-1902
MAILING ADDRESS:	19 HUGHES AVE IRVINE, CA 92618-1902
RESPONSIBLE OFFICIAL:	JIM D SMITH
TITLE:	ASSOCIATE DIRECTOR, ENV. HEALTH & SAFETY
TELEPHONE NUMBER:	(714) 455-4712
CONTACT PERSON:	JIM D SMITH
TITLE:	ASSOCIATE DIRECTOR, ENV. HEALTH & SAFETY
TELEPHONE NUMBER:	(714) 455-4712
TITLE V PERMIT ISSUED:	July 11, 2002
TITLE V PERMIT EXPIRATION DATE:	July 10, 2007

TITLE V	RECLAIM	
YES	NOx:	NO
	SOx:	NO
	CYCLE:	0
	ZONE:	COASTAL

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SECTION B: RECLAIM Annual Emission Allocation

NOT APPLICABLE

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SECTION C: FACILITY PLOT PLAN

(TO BE DEVELOPED)

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SECTION E: ADMINISTRATIVE CONDITIONS

The operating conditions in this section shall apply to all permitted equipment at this facility unless superseded by condition(s) listed elsewhere in this permit.

1. The permit shall remain effective unless this permit is suspended, revoked, modified, reissued, denied, or it is expired for nonpayment of permit processing or annual operating fees. [201, 203, 209, 301]

    a. The permit must be renewed annually by paying annual operating fees, and the permit shall expire if annual operating fees are not paid pursuant to requirements of Rule 301(d). [301(d)]
    b. The Permit to Construct listed in Section H shall expire one year from the Permit to Construct issuance date, unless a Permit to Construct extension has been granted by the Executive Officer or unless the equipment has been constructed and the operator has notified the Executive Officer prior to the operation of the equipment, in which case the Permit to Construct serves as a temporary Permit to Operate. [202, 205]
    c. The Title V permit shall expire as specified under Section K of the Title V permit. The permit expiration date of the Title V facility permit does not supercede the requirements of Rule 205. [205, 3004]

2. The operator shall maintain all equipment in such a manner that ensures proper operation of the equipment. [204]

3. This permit does not authorize the emissions of air contaminants in excess of those allowed by Division 26 of the Health and Safety Code of the State of California or the Rules and Regulations of the AQMD. This permit cannot be considered as permission to violate existing laws, ordinances, regulations, or statues of other governmental agencies. [204]

4. The operator shall not use equipment identified in this facility permit as being connected to air pollution control equipment unless they are so vented to the identified air pollution control equipment which is in full use and which has been included in this permit. [204]

5. The operator shall not use any equipment having air pollution control device(s) incorporated within the equipment unless the air pollution control device is in full operation. [204]

6. The operator shall maintain records to demonstrate compliance with rules or permit conditions that limit equipment operating parameters, or the type or quantity of material processed. These records shall be made available to AQMD personnel upon request and be maintained for at least five years. [204]

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SECTION E: ADMINISTRATIVE CONDITIONS

7. The operator shall maintain and operate all equipment to ensure compliance with all emission limits as specified in this facility permit. Compliance with emission limits shall be determined according to the following specifications, unless otherwise specified by AQMD rules or permit conditions: [204]

   a. For internal combustion engines and gas turbines, measured concentrations shall be corrected to 15 percent stack-gas oxygen content on a dry basis and be averaged over a period of 15 consecutive minutes; [1110.2, 1134]
   b. For other combustion devices, measured concentrations shall be corrected to 3 percent stack-gas oxygen content on a dry basis and be averaged over a period of 15 consecutive minutes; [1146, 1146.1, 204]
   c. For non-combustion sources, compliance with emission limits shall be determined and averaged over a period of 60 minutes; [204]
   d. For the purpose of determining compliance with Rule 407, carbon monoxide (CO) shall be measured on a dry basis and be averaged over 15 consecutive minutes, and sulfur compounds which would exist as liquid or gas at standard conditions shall be calculated as sulfur dioxide (SO2) and be averaged over 15 consecutive minutes; [407]
   e. For the purpose of determining compliance with Rule 409, combustion contaminant emission measurements shall be corrected to 12 percent of carbon dioxide (CO2) at standard conditions and averaged over a minimum of 15 consecutive minutes. [409]
   f. For the purpose of determining compliance with Rule 475, combustion contaminant emission measurements shall be corrected to 3 percent of oxygen (O2) at standard conditions and averaged over 15 consecutive minutes or any other averaging time specified by the Executive Officer. [475]

8. The operator shall, when a source test is required by AQMD, provide a source test protocol to AQMD no later than 60 days before the proposed test date. The test shall not commence until the protocol is approved by AQMD. The test protocol shall contain the following information: [204, 304]

   a. Brief description of the equipment tested.
   b. Brief process description, including maximum and normal operating temperatures, pressures, throughput, etc.
   c. Operating conditions under which the test will be performed.
   d. Method of measuring operating parameters, such as fuel rate and process weight. Process schematic diagram showing the ports and sampling locations, including the dimensions of the ducts and stacks at the sampling locations, and distances of flow disturbances, (e.g. elbows, tees, fans, dampers) from the sampling locations (upstream and downstream)
      .

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SECTION E: ADMINISTRATIVE CONDITIONS

e. Brief description of sampling and analytical methods used to measure each pollutant, temperature, flow rates, and moisture.
f. Description of calibration and quality assurance procedures.
g. Determination that the testing laboratory qualifies as an "independent testing laboratory" under Rule 304 (conflict of interest).

9. The operator shall submit a report no later than 60 days after conducting a source test, unless otherwise required by AQMD rules or equipment-specific conditions. The report shall contain the following information: [204]

a. The results of the source test.
b. Brief description of the equipment tested.
c. Operating conditions under which the test was performed.
d. Method of measuring operating parameters, such as fuel rate and process weight. Process schematic diagram showing the ports and sampling locations, including the dimensions of the ducts and stacks at the sampling locations, and distances of flow disturbances, (e.g. elbows, tees, fans, dampers) from the sampling locations (upstream and downstream) .
e. Field and laboratory data forms, strip charts and analyses.
f. Calculations for volumetric flow rates, emission rates, control efficiency, and overall control efficiency.

10. The operator shall, when a source test is required, provide and maintain facilities for sampling and testing. These facilities shall comply with the requirements of AQMD Source Test Method 1.1 and 1.2. [217]

11. Whenever required to submit a written report, notification or other submittal to the Executive Officer, AQMD, or the District, the operator shall mail or deliver the material to: Deputy Executive Officer, Engineering and Compliance, AQMD, 21865 E. Copley Drive, Diamond Bar, CA 91765-4182. [204]

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SECTION F: RECLAIM Monitoring and Source Testing Requirements

NOT APPLICABLE

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SECTION G: Recordkeeping and Reporting Requirements for RECLAIM Sources

NOT APPLICABLE

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SECTION I: PLANS AND SCHEDULES

This section lists all plans approved by AQMD for the purposes of meeting the requirements of applicable AQMD rules.

NONE

NOTE: This section does not list compliance schedules pursuant to the requirements of Regulation XXX - Title V Permits; Rule 3004(a)(10)(C). For equipment subject to a variance, order for abatement, or alternative operating condition granted pursuant to Rule 518.2, equipment specific conditions are added to the equipment in Section D or H of the permit.

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SECTION J: AIR TOXICS

NOT APPLICABLE

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SECTION K: TITLE V Administration

GENERAL PROVISIONS

1. This permit may be revised, revoked, reopened and reissued, or terminated for cause, or for failure to comply with regulatory requirements, permit terms, or conditions. [3004(a)(7)(C)]

2. This permit does not convey any property rights of any sort or any exclusive privilege. [3004(a)(7)(E)]

Permit Renewal and Expiration

3. (A) Except for solid waste incineration facilities subject to standards under Section 129(e) of the Clean Air Act, this permit shall expire five years from the date that this Title V permit is issued. The operator's right to operate under this permit terminates at midnight on this date, unless the facility is protected by an application shield in accordance with Rule 3002(b), due to the filing of a timely and complete application for a Title V permit renewal, consistent with Rule 3003. [3004(a)(2), 3004(f)]

   (B) A Title V permit for a solid waste incineration facility combusting municipal waste subject to standards under Section 129(e) of the Clean Air Act shall expire 12 years from the date of issuance unless such permit has been renewed pursuant to this regulation. These permits shall be reviewed by the Executive Officer at least every five years from the date of issuance. [3004(f)(2)]

4. To renew this permit, the operator shall submit to the Executive Officer an application for renewal at least 180 days, but not more than 545 days, prior to the expiration date of this permit. [3003(a)(6)]

Duty to Provide Information

5. The applicant for, or holder of, a Title V permit shall furnish, pursuant to Rule 3002(d) and (e), timely information and records to the Executive Officer or designee within a reasonable time as specified in writing by the Executive Officer or designee. [3004(a)(7)(F)]

Payment of Fees

6. The operator shall pay all required fees specified in Regulation III - Fees. [3004(a)(7)(G)]

Reopening for Cause

7. The Executive Officer will reopen and revise this permit if any of the following circumstances occur:

   (A) Additional regulatory requirements become applicable with a remaining permit term of three or more years. Reopening is not required if the effective date of the requirement is later than the expiration date of this permit, unless the permit or any of its terms and conditions has been extended pursuant to paragraph (f)(4) of Rule 3004.

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(B) The Executive Officer or EPA Administrator determines that this permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of this permit.

(C) The Executive Officer or EPA Administrator determines that the permit must be revised or revoked to assure compliance with the applicable requirements. [3005(g)(1)]

COMPLIANCE PROVISIONS

8. The operator shall comply with all regulatory requirements, and all permit terms and conditions, except:

(A) As provided for by the emergency provisions of condition no. 17 or condition no. 18, or

(B) As provided by an alternative operating condition granted pursuant to a federally approved (SIP-approved) Rule 518.2.

Any non-compliance with any federally enforceable permit condition constitutes a violation of the Federal Clean Air Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or revision; or denial of a permit renewal application. Non-compliance may also be grounds for civil or criminal penalties under the California State Health and Safety Code. [3004(a)(7)(A)]

9. The operator shall allow the Executive Officer or authorized representative, upon presentation of appropriate credentials to:

(A) Enter the operator's premises where emission-related activities are conducted, or records are kept under the conditions of this permit;

(B) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(C) Inspect at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit; and

(D) Sample or monitor at reasonable times, substances or parameters for the purpose of assuring compliance with the facility permit or regulatory requirements. [3004(a)(10)(B)]

10. All terms and conditions in this permit, including any provisions designed to limit a facility's potential to emit, are enforceable by the EPA Administrator and citizens under the federal Clean Air Act, unless the term or condition is designated as not federally enforceable. Each day during any portion of which a violation occurs is a separate offense. [3004(g)]

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11. A challenge to any permit condition or requirement raised by EPA, the operator, or any other person, shall not invalidate or otherwise affect the remaining portions of this permit. [3007(b)]

12. The filing of any application for a permit revision, revocation, or termination, or a notification of planned changes or anticipated non-compliance does not stay any permit condition. [3004(a)(7)(D)]

13. It shall not be a defense for a person in an enforcement action, including those listed in Rule 3002(c)(2), that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit, except as provided for in "Emergency Provisions" of this section. [3004(a)(7)(H)]

14. The operator shall not build, erect, install, or use any equipment, the use of which, without resulting in a reduction in the total release of air contaminants to atmosphere, reduces or conceals an emission which would otherwise constitute a violation of Chapter 3 (commencing with Section 41700) of Part 4, of Division 26 of the California Health and Safety Code or of AQMD rules. This rule shall not apply to cases in which the only violation involved is of Section 41700 of the California Health and Safety Code, or Rule 402 of AQMD Rules. [408]

15. Nothing in this permit or in any permit shield can alter or affect:

    (A) Under Section 303 of the federal Clean Air Act, the provisions for emergency orders;

    (B) The liability of the operator for any violation of applicable requirements prior to or at the time of permit issuance;

    (C) The applicable requirements of the Acid Rain Program, Regulation XXXI;

    (D) The ability of EPA to obtain information from the operator pursuant to Section 114 of the federal Clean Air Act;

    (E) The applicability of state or local requirements that are not "applicable requirements", as defined in Rule 3000, at the time of permit issuance but which do apply to the facility, such as toxics requirements unique to the State; and

    (F) The applicability of regulatory requirements with compliance dates after the permit issuance date. [3004(c)(3)]

16. For any portable equipment that requires an AQMD or state permit or registration, excluding a) portable engines, b) military tactical support equipment and c) AQMD-permitted portable equipment that are not a major source, are not located at the facility for more than 12 consecutive months after

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commencing operation, and whose operation does not conflict with the terms or conditions of this Title V permit: 1) the facility operator shall keep a copy of the AQMD or state permit or registration; 2) the equipment operator shall comply with the conditions on the permit or registration and all other regulatory requirements; and 3) the facility operator shall treat the permit or registration as a part of its Title V permit, subject to recordkeeping, reporting and certification requirements. [3004(a)(1)]

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EMERGENCY PROVISIONS

17. An emergency[1] constitutes an affirmative defense to an action brought for non-compliance with a technology-based emission limit only if:

    (A) Properly signed, contemporaneous operating records or other credible evidence demonstrate that:

        (1) An emergency occurred and the operator can identify the cause(s) of the emergency;

        (2) The facility was operated properly (i.e. operated and maintained in accordance with the manufacturer's specifications, and in compliance with all regulatory requirements or a compliance plan), before the emergency occurred;

        (3) The operator took all reasonable steps to minimize levels of emissions that exceeded emissions standard, or other requirements in the permit; and,

        (4) The operator submitted a written notice of the emergency to the AQMD within two working days of the time when the emissions limitations were exceeded due to the emergency. The notice shall contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken; and

    (B) The operator complies with the breakdown provisions of Rule 430 - Breakdown Provisions, or subdivision (i) of Rule 2004 - Requirements, whichever is applicable. [3002(g), 430, 2004(i)]

18. The operator is excused from complying with any regulatory requirement that is suspended by the Executive Officer during a state of emergency or state of war emergency, in accordance with Rule 118 - Emergencies. [118]

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1 "Emergency" means any situation arising from sudden and reasonably unforeseeable events beyond the control of the operator, including acts of God, which: (A) requires immediate corrective action to restore normal operation; and (B) causes the facility to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency; and (C) is not caused by improperly designed equipment, lack of preventative maintenance, careless or imporper operation, or operator error.

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RECORDKEEPING PROVISIONS

19. In addition to any other recordkeeping requirements specified elsewhere in this permit, the operator shall keep records of required monitoring information, where applicable, that include:

    (A) The date, place as defined in the Title V permit, and time of sampling or measurements;

    (B) The date(s) analyses were performed;

    (C) The company or entity that performed the analyses;

    (D) The analytical techniques or methods used;

    (E) The results of such analyses; and

    (F) The operating conditions as existing at the time of sampling or measurement. [3004(a)(4)(B)]

20. The operator shall maintain records pursuant to Rule 109 and any applicable material safety data sheet (MSDS) for any equipment claimed to be exempt from a written permit by Rule 219 based on the information in those records. [219(t)]

21. The operator shall keep all records of monitoring data required by this permit or by regulatory requirements for a period of at least five years from the date of the monitoring sample, measurement, report, or application. [3004(a)(4)(E)]

REPORTING PROVISIONS

22. The operator shall comply with the following requirements for prompt reporting of deviations:

    (A) Breakdowns shall be reported as required by Rule 430 - Breakdown Provisions or subdivision (i) of Rule 2004 - Requirements, whichever is applicable.

    (B) Other deviations from permit or applicable rule emission limitations, equipment operating conditions, or work practice standards, determined by observation or by any monitoring or testing required by the permit or applicable rules that result in emissions greater than those allowed by the permit or applicable rules shall be reported within 72 hours (unless a shorter reporting period is specified in an applicable State or Federal Regulation) of discovery of the deviation by contacting AQMD enforcement personnel assigned to this facility or otherwise calling (800) CUT-SMOG.

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(C) A written report of such deviations reported pursuant to (B), and any corrective actions or preventative measures taken, shall be submitted to AQMD, in an AQMD approved format, within 14 days of discovery of the deviation.

(D) All other deviations shall be reported with the monitoring report required by condition no. 23. [3004(a)(5)]

23. Unless more frequent reporting of monitoring results are specified in other permit conditions or in regulatory requirements, the operator shall submit reports of any required monitoring to the AQMD at least twice per year. The report shall include a) a statement whether all monitoring required by the permit was conducted; and b) identification of all instances of deviations from permit or regulatory requirements. A report for the first six calendar months of the year is due by August 31 and a report for the last six calendar months of the year is due by February 28. [3004(a)(4)(F)]

24. The operator shall submit to the Executive Officer and to the Environmental Protection Agency (EPA), an annual compliance certification. For RECLAIM facilities, the certification is due when the Annual Permit Emissions Program (APEP) report is due and shall cover the same reporting period. For other facilities, the certification is due on March 1 for the previous calendar year. The certification need not include the period preceding the date the initial Title V permit was issued. Each compliance certification shall include:

(A) Identification of each permit term or condition that is the basis of the certification;

(B) The compliance status during the reporting period;

(C) Whether compliance was continuous or intermittent;

(D) The method(s) used to determine compliance over the reporting period and currently, and

(E) Any other facts specifically required by the Executive Officer to determine compliance.

The EPA copy of the certification shall be sent to: Director of the Air Division Attn: Air-3 USEPA, Region IX 75 Hawthorne St. San Francisco, CA 94105 [3004(a)(10)(E)]

25. All records, reports, and documents required to be submitted by a Title V operator to AQMD or EPA shall contain a certification of accuracy consistent with Rule 3003(c)(7) by a responsible official (as defined in Rule 3000). [3004(a)(12)]

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PERIODIC MONITORING

26. All periodic monitoring required by this permit pursuant to Rule 3004(a)(4)(c) is based on the requirements and justifications in the AQMD document "Periodic Monitoring Guidelines for Title V Facilities" or in case-by-case determinations documented in the Title V application file. [3004(a)(4)]

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FACILITY RULES

This facility is subject to the following rules and regulations:

With the exception of Rule 402, 473, 477, 1118 and Rules 1401 through 1420, the following rules that are designated as non-federally enforceable are pending EPA approval as part of the state implementation plan. Upon the effective date of that approval, the approved rule(s) will become federally enforceable, and any earlier versions of those rules will no longer be federally enforceable.

RULE SOURCE	Adopted/Amended Date	FEDERAL Enforceability
RULE 104	1-9-1976	Federally enforceable
RULE 106	1-9-1976	Federally enforceable
RULE 1113	7-13-2007	Non federally enforceable
RULE 1122	10-1-2004	Federally enforceable
RULE 1146	11-17-2000	Federally enforceable
RULE 1146	9-5-2008	Non federally enforceable
RULE 118	12-7-1995	Non federally enforceable
RULE 1303(a)(1)-BACT	5-10-1996	Federally enforceable
RULE 1303(b)(2)-Offset	5-10-1996	Federally enforceable
RULE 1401	3-7-2008	Non federally enforceable
RULE 1402	3-4-2005	Non federally enforceable
RULE 1404	4-6-1990	Non federally enforceable
RULE 1415	10-14-1994	Non federally enforceable
RULE 202	5-7-1976	Federally enforceable
RULE 204	10-8-1993	Federally enforceable
RULE 206	10-8-1993	Federally enforceable
RULE 207	1-9-1976	Federally enforceable
RULE 209	1-5-1990	Federally enforceable
RULE 217	1-5-1990	Federally enforceable
RULE 219	6-1-2007	Non federally enforceable
RULE 219	9-4-1981	Federally enforceable
RULE 3002	11-14-1997	Federally enforceable
RULE 3003	11-14-1997	Federally enforceable
RULE 3003	3-16-2001	Non federally enforceable
RULE 3004	12-12-1997	Federally enforceable
RULE 3004(a)(4)-Periodic Monitoring	12-12-1997	Federally enforceable
RULE 3007	10-8-1993	Federally enforceable
RULE 304	5-2-2008	Non federally enforceable
RULE 401	11-9-2001	Non federally enforceable

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RULE SOURCE	Adopted/Amended Date	FEDERAL Enforceability
RULE 401	3-2-1984	Federally enforceable
RULE 402	5-7-1976	Non federally enforceable
RULE 404	2-7-1986	Federally enforceable
RULE 405	2-7-1986	Federally enforceable
RULE 407	4-2-1982	Federally enforceable
RULE 408	5-7-1976	Federally enforceable
RULE 409	8-7-1981	Federally enforceable
RULE 429	12-21-1990	Non federally enforceable
RULE 430	7-12-1996	Non federally enforceable
RULE 442	12-15-2000	Federally enforceable
RULE 701	6-13-1997	Federally enforceable
40CFR 82 Subpart F	5-14-1993	Federally enforceable

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APPENDIX B: RULE EMISSION LIMITS [RULE 1113 5-14-1999]

(1) Except as provided in paragraphs (c)(2), (c)(3), (c)(4), and specified coatings averaged under (c)(6) of Rule 1113, the operator shall not supply, sell, offer for sale, manufacture, blend, or repackage any architectural coating for use in the District which, at the time of sale or manufacture, contains more than 250 grams of VOC per liter of coating (2.08 pounds per gallon), less water, less exempt compounds, and less any colorant added to tint bases, and no person shall apply or solicit the application of any architectural coating within the District that exceeds 250 grams of VOC per liter of coating as calculated in this paragraph.

(2) Except as provided in paragraphs (c)(3), (c)(4), and designated coatings averaged under (c)(6) of Rule 1113, the operator shall not supply, sell, offer for sale, manufacture, blend, or repackage, for use within the District, any architectural coating listed in the Table of Standards which contains VOC (excluding any colorant added to tint bases) in excess of the corresponding VOC limit specified in the table, after the effective date specified, and no person shall apply or solicit the application of any architectural coating within the District that exceeds the VOC limit as specified in this paragraph. No person shall apply or solicit the application within the District of any industrial maintenance coatings for residential use; or of any rust-preventative coating for industrial use.

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APPENDIX B: RULE EMISSION LIMITS [RULE 1113 5-14-1999]

TABLE OF STANDARDS
VOC LIMITS

Grams of VOC Per Liter of Coating,
Less Water And Less Exempt Compounds

COATING	Limit*	Effective 1/1/1998	Effective 1/1/1999	Effective 5/14/99	Effective 7/1/2001	Effective 7/1/2002	Effective 1/1/2005	Effective 7/1/2006	Effective 7/1/2008
Bond Breakers	350								
Chemical Storage Tank Coatings	420							100	
Clear Wood Finishes									
Varnish	350								
Sanding Sealers	350								
Lacquer	680	550					275		
Concrete-Curing Compounds	350								
Dry-Fog Coatings	400								
Essential Public Service Coating	420					340		100	
Fire-proofing Exterior Coatings	450		350						
Fire-Retardant Coatings									
Clear	650								
Pigmented	350								
Flats	250				100				50
Floor Coatings	420					100		50	
Graphic Arts (Sign) Coatings	500								
High Temperature Industrial Maintenance Coatings						550		420	
Industrial Maintenance Coatings	420					250		100	
Japans/Faux Finishing Coatings	700		350						
Magnesite Cement Coatings	600		450						
Mastic Coatings	300								
Metallic Pigmented Coatings	500								
Multi-Color Coatings	420	250							
Non-Flat Coatings	250					150		50	
Pigmented Lacquer	680	550					275		
Pre-Treatment Wash Primers	780								
Primers, Sealers, and Undercoaters	350					200		100	
Quick-Dry Enamels	400					250		50	
Quick-Dry Primers, Sealers, and Undercoaters	350**					200		100	
Recycled Coatings				250		250		100	

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APPENDIX B: RULE EMISSION LIMITS [RULE 1113 5-14-1999]

Roof Coatings	300			250					
Bituminous Roof Coatings	300					250			
Rust Preventative Coatings	420			400				100	
Shellac									
Clear	730								
Pigmented	550								
Specialty Primers	350							100	
Stains	350					250			
Swimming Pool Coatings									
Repair	650								
Other	340								
Traffic Coatings	250	150							
Waterproofing Sealers									
Wood	400					250			
Concrete/Masonry	400								
Wood Preservatives									
Below-Ground	350								
Other	350								

* The specified limits remain in effect unless revised limits are listed in subsequent columns in the Table of Standards

** The specified limit applies unless the manufacturer submits a report pursuant to Rule 1113(g)(2).

Grams of VOC Per Liter of Material

COATING	Limit
Low-Solids Coating	120

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 1171 10-8-1999]

Except as otherwise provided in Rule 1171, the operator shall not use a solvent to perform solvent cleaning unless the solvent complies with the applicable requirements set forth below:

	Current limits		Effective 12/1/2001	Effective 7/1/2005
SOLVENT CLEANING ACTIVITY	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)	VOC g/l (lb/gal)	VOC g/l (lb/gal)
(A) Product Cleaning During Manufacturing Process Or Surface Preparation For Coating, Adhesive, Or Ink Application				
(i) General	70 (0.58)		50 (0.42)	25 (0.21)
(ii) Electrical Apparatus Components & Electronic Components	900 (7.5)	33	500 (4.2)	100 (0.83)
(iii) Medical Devices & Pharmaceuticals	900 (7.5)	33	800 (6.7)	800 (6.7)
(B) Repair and Maintenance Cleaning				
(i) General	50 (0.42)		50 (0.42)	25 (0.21)
(ii) Electrical Apparatus Components & Electronic Components	900 (7.5)	20	900 (7.5)	100 (0.83)

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 1171 10-8-1999]

	Current limits		Effective 12/1/2001	Effective 7/1/2005
SOLVENT CLEANING ACTIVITY	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)	VOC g/l (lb/gal)	VOC g/l (lb/gal)
(iii) Medical Devices & Pharmaceuticals	900 (7.5)	33		
(I) Tools, Equipment, & Machinery			800 (6.7)	800 (6.7)
(II)General Work Surfaces			600 (5.0)	600 (5.0)
(C) Cleaning of Coatings, or Adhesives Application Equipment	950 (7.9)	35	550 (4.6)	25 (0.21)
(D) Cleaning of Ink Application Equipment				
(i) General	100 (0.83)	3	50 (0.42)	25 (0.21)
(ii) Flexographic Printing	100 (0.83)	3	50 (0.42)	25 (0.21)
(iii) Gravure Printing				
(I) Publication	900 (7.5)	25	750 (6.3)	100 (0.83)
(II) Packaging	100 (0.83)	3	50 (0.42)	25 (0.21)
(iv) Lithographic or Letter Press Printing				
(I) Roller Wash – Step 1	900	10	600 (5.0)	100 (0.83)

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 1171 10-8-1999]

	Current limits		Effective 12/1/2001	Effective 7/1/2005
SOLVENT CLEANING ACTIVITY	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)	VOC g/l (lb/gal)	VOC g/l (lb/gal)
(II) Roller Wash-Step 2, Blanket Wash, & On-Press Components	900	10	800 (6.7)	100 (0.83)
(III) Removable Press Components			50 (0.42)	25 (0.21)
(v) Screen Printing	1070 (8.9)	5	750 (6.3)	100 (0.83)
(vi) Ultraviolet Ink Application Equipment (except screen printing)	800 (6.7)	33	800 (6.7)	100 (0.83)
(vii) Specialty Flexographic Printing	810 (6.8)	21	600 (5.0)	100 (0.83)
(E) Cleaning of Polyester Resin Application Equipment	50 (0.42)		50 (0.42)	25 (0.21)

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 1171 6-13-1997]

Except as otherwise provided in Rule 1171, the operator shall not use a solvent to perform solvent cleaning unless the solvent complies with the applicable requirements set forth below:

SOLVENT CLEANING ACTIVITY	CURRENT LIMITS		Effective 1/1/1999	
	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)
(A) Product Cleaning During Manufacturing Process Or Surface Preparation For Coating, Adhesive, Or Ink Application				
(i) General	70 (0.58)			
(ii) Electronic Components or Medical Devices	900 (7.5)	33		
(B) Repair and Maintenance Cleaning				
(i) General	900 (7.5)	20	50 (0.42)	
(ii) Electrical Apparatus Components	900 (7.5)	20		
(iii) Medical Devices	900 (7.5)	33		
(C) Cleaning of Coatings, or Adhesives Application Equipment	950 (7.9)	35		
(D) Cleaning of Ink Application Equipment				
(i) General	100 (0.83)	3		
(ii) Flexographic or Gravure Printing	100 (0.83)	3		
(iii) Lithographic or Letter Press Printing	900 (7.5)	25		10
(iv) Screen Printing	1070 (8.9)	5		
(v) Ultraviolet Inks (except screen printing)	800 (6.7)	33		
(vi) Specialty Flexographic Printing	810 (6.8)	21		

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 1171 6-13-1997]

	CURRENT LIMITS		Effective 1/1/1999	
SOLVENT CLEANING ACTIVITY	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)	VOC g/l (lb/gal)	VOC Composite Partial Pressure mm Hg @ 20°C (68°F)
(E) Cleaning of Polyester Resin Application Equipment	50 (0.42)			
or		1		

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 404 2-7-1986]

The operator shall not discharge into the atmosphere from this equipment, particulate matter in excess of the concentration at standard conditions, shown in Table 404(a). Where the volume discharged is between figures listed in the Table, the exact concentration permitted to be discharged shall be determined by linear interpolation.

For the purposes of this rule, emissions shall be averaged over one complete cycle of operation or one hour, whichever is the lesser time period.

TABLE 404(a)

Volume Discharged Calculated as Dry Gas At Standard Conditions		Maximum Concentration of Particulate Matter"Allowed in Discharged Gas Calculated as Dry Gas at Standard Conditions		Volume Discharged Calculated as Dry Gas At Standard Conditions		Maximum Concentration of Particulate Matter Allowed in Discharged Gas Calculated as Dry Gas at Standard Conditions	
Cubic meters Per Minute	Cubic feet Per Minute	Milligrams per Cubic Meter	Grains per Cubic Foot	Cubic meters Per Minute	Cubic feet Per Minute	Milligrams per Cubic Meter	Grains per Cubic Foot
25 or less	883 or less	450	0.196	900	31780	118	0.0515
30	1059	420	.183	1000	35310	113	.0493
35	1236	397	.173	1100	38850	109	.0476
40	1413	377	.165	1200	42380	106	.0463
45	1589	361	.158	1300	45910	102	.0445
50	1766	347	.152	1400	49440	100	.0437
60	2119	324	.141	1500	52970	97	.0424
70	2472	306	.134	1750	61800	92	.0402

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 404 2-7-1986]

Volume Discharged Calculated as Dry Gas At Standard Conditions		Maximum Concentration of Particulate Matter"Allowed in Discharged Gas Calculated as Dry Gas at Standard Conditions		Volume Discharged Calculated as Dry Gas At Standard Conditions		Maximum Concentration of Particulate Matter Allowed in Discharged Gas Calculated as Dry Gas at Standard Conditions	
Cubic meters Per Minute	Cubic feet Per Minute	Milligrams per Cubic Meter	Grains per Cubic Foot	Cubic meters Per Minute	Cubic feet Per Minute	Milligrams per Cubic Meter	Grains per Cubic Foot
80	2825	291	.127	2000	70630	87	.0380
90	3178	279	.122	2250	79460	83	.0362
100	3531	267	.117	2500	88290	80	.0349
125	4414	246	.107	3000	105900	75	.0327
150	5297	230	.100	4000	141300	67	.0293
175	6180	217	.0947	5000	176600	62	.0271
200	7063	206	.0900	6000	211900	58	.0253
250	8829	190	.0830	8000	282500	52	.0227
300	10590	177	.0773	10000	353100	48	.0210
350	12360	167	.0730	15000	529700	41	.0179
400	14130	159	.0694	20000	706300	37	.0162
450	15890	152	.0664	25000	882900	34	.0148
500	17660	146	.0637	30000	1059000	32	.0140
600	21190	137	.0598	40000	1413000	28	.0122
700	24720	129	.0563	50000	1766000	26	.0114
800	28250	123	.0537	70000 or more	2472000 or more	23	.0100

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 405 2-7-1986]

The operator shall not discharge into the atmosphere from this equipment, solid particulate matter including lead and lead compounds in excess of the rate shown in Table 405(a).

Where the process weight per hour is between figures listed in the table, the exact weight of permitted discharge shall be determined by linear interpolation.

For the purposes of this rule, emissions shall be averaged over one complete cycle of operation or one hour, whichever is the lesser time period.

TABLE 405(a)

Process Weight Per Hour		Maximum Discharge Rate Allowed for Solid Particulate Matter (Aggregate Discharged From All Points of Process		Process Weight Per Hour		Maximum Discharge Rate Allowed for Solid Particulate Matter (Aggregate Discharged From All points of Process	
Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour
100 or less	220 or less	0.450	0.99	9000	19840	5.308	11.7
150	331	0.585	1.29	10000	22050	5.440	12.0
200	441	0.703	1.55	12500	27560	5.732	12.6
250	551	0.804	1.77	15000	33070	5.982	13.2
300	661	0.897	1.98	17500	38580	6.202	13.7
350	772	0.983	2.17	20000	44090	6.399	14.1
400	882	1.063	2.34	25000	55120	6.743	14.9
450	992	1.138	2.51	30000	66140	7.037	15.5
500	1102	1.209	2.67	35000	77160	7.296	16.1
600	1323	1.340	2.95	40000	88180	7.527	16.6
700	1543	1.461	3.22	45000	99210	7.738	17.1
800	1764	1.573	3.47	50000	110200	7.931	17.5
900	1984	1.678	3.70	60000	132300	8.277	18.2
1000	2205	1.777	3.92	70000	154300	8.582	18.9

FACILITY PERMIT TO OPERATE

TEVA PARENTERAL MEDICINES, INC

APPENDIX B: RULE EMISSION LIMITS [RULE 405 2-7-1986]

Process Weight Per Hour		Maximum Discharge Rate Allowed for Solid Particulate Matter (Aggregate Discharged From All Points of Process		Process Weight Per Hour		Maximum Discharge Rate Allowed for Solid Particulate Matter (Aggregate Discharged From All points of Process	
Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour	Kilograms Per Hour	Pounds Per Hour
1250	2756	2.003	4.42	80000	176400	8.854	19.5
1500	3307	2.206	4.86	90000	198400	9.102	20.1
1750	3858	2.392	5.27	100000	220500	9.329	20.6
2000	4409	2.563	5.65	125000	275600	9.830	21.7
2250	4960	2.723	6.00	150000	330700	10.26	22.6
2500	5512	2.874	6.34	175000	385800	10.64	23.5
2750	6063	3.016	6.65	200000	440900	10.97	24.2
3000	6614	3.151	6.95	225000	496000	11.28	24.9
3250	7165	3.280	7.23	250000	551200	11.56	25.5
3600	7716	3.404	7.50	275000	606300	11.82	26.1
4000	8818	3.637	8.02	300000	661400	12.07	26.6
4500	9921	3.855	8.50	325000	716500	12.30	27.1
5000	11020	4.059	8.95	350000	771600	12.51	27.6
6000	13230	4.434	9.78	400000	881800	12.91	28.5
7000	15430	4.775	10.5	450000	992100	13.27	29.3
8000	17640	5.089	11.2	500000 or more	1102000 or more	13.60	30.0