

South Coast Air Quality Management District

Statement of Basis

Proposed Renewal Title V Permit

Facility Name:	Teva Parenteral Medicines, Inc.
Facility ID:	84273
SIC Code:	2834
Equipment Location:	17 - 25 Hughes Ave. Irvine, CA 92618
Application #(s):	461102
Application Submittal Date(s):	10/12/06
AQMD Contact Person:	Hassan Namaki
Phone Number:	(909) 396-2699
E-Mail Address:	hnamaki@aqmd.gov

1. Introduction and Scope of Permit

Title V is a national operating permit program for air pollution sources. Facilities subject to Title V must obtain a Title V permit and comply with specific Title V procedures to modify the permit. This permit replaces the facility's other existing permits. Title V does not necessarily include any new requirements for reducing emissions. It does, however, include new permitting, noticing, recordkeeping, and reporting requirements.

Pursuant to Title V of the federal Clean Air Act and AQMD Rule 3004(f), a Title V permit shall expire five years from the date of issuance unless such permit has been renewed. Accordingly, each facility is required to submit a Title V renewal application and request the AQMD to renew their Title V permit. The proposed permit incorporates updates to the facility information provided in the facility's Title V renewal application and all rules and regulations that are currently applicable to the facility.

The AQMD implements Title V through Regulation XXX – Title V Permits, adopted by the AQMD Governing Board in order to comply with EPA's requirement that local air permitting authorities develop a Title V program. Regulation XXX was developed with the participation of the public and affected facilities through a series of public workshops, working group meetings, public hearings and other meetings.

The Title V major source threshold for a particular pollutant depends on the attainment status of the pollutant. NO₂, SO₂, CO and lead are in attainment with federal standards. The status for PM-10 is serious nonattainment. The status for ozone is currently extreme nonattainment.

A Title V permit is proposed to be issued to cover the operations of Teva Parenteral Medicines, Inc., located at 17 – 25 Hughes Ave., Irvine, CA 92618. This facility is subject to Title V requirements because it is a major source.

2. Facility Description

This is an existing facility applying for a Title V permit renewal that is in the business of manufacturing and packaging injectable drugs. This facility is operating a boiler, a number of mixing/blending tanks, three emergency internal combustion engines, and other supporting equipment. PM10 emissions from mixing/blending tanks are vented to a baghouse.

3. Construction and Permitting History

The facility has been in constant operation since 1991. Numerous permits to construct and permits to operate have been issued to the facility. An initial Title V permit was issued to the facility on 9/18/2002 and subsequent revisions were issued on 8/12/2003, 12/02/2003, and 7/1/2004.

4. Regulatory Applicability Determinations

Applicable legal requirements for which this facility is required to comply are required to be identified in the Title V permit (for example, Section D, E, and H of the proposed Title V permit). Applicability determinations (i.e., determinations made by the District with respect to what legal requirements apply to a specific piece of equipment, process, or operation) can be found in the Engineering Evaluations. This facility is not subject to any NSPS or NESHAP requirements.

5. Monitoring and Operational Requirements

Applicable monitoring and operational requirements for which the facility is required to comply are identified in the Title V permit (for example, Sections D, F, and J and Appendix B of the proposed Title V permit). Discussion of any applicable operational requirements can be found in the Engineering Evaluations. All periodic monitoring requirements were developed using strict adherence to the following applicable guidance documents: SCAQMD Periodic Monitoring Guidelines for Title V Facilities (November 1997); CAPCOA/CARB/EPA Region IX Periodic Monitoring Recommendations for Generally Applicable Requirements in SIP (June 1999); and CAPCOA/CARB/EPA Region IX Recommended Periodic Monitoring for Generally Applicable Grain Loading Standards in the SIP: Combustion Sources (July 2001). This facility has a baghouse to control PM10 emissions. Since the uncontrolled PM10 emission of the APC system does not exceed 70 tons/year, Compliance Assurance Monitoring (CAM) requirements of 40 CFR Part 64 do not apply to any of the permitted emission sources at this facility.

6. Permit Features

Permit Shield

A permit shield is an optional part of a Title V permit that gives the facility an explicit protection from requirements that do not apply to the facility. A permit shield is a provision in a permit that states that compliance with the conditions of the permit shall be deemed compliance with all identified regulatory requirements. To incorporate a permit shield into the Title V permit involves submission of applications for change of conditions for each equipment affected by the permit shield. Permit shields are addressed in Rule 3004 (c). This facility has not applied for a permit shield.

Streamlining Requirements

Some emission units may be subject to multiple requirements which are closely related or redundant. The conditions may be streamlined to simplify the permit conditions and compliance. Emission limits, work practice standards, and monitoring, recordkeeping, and reporting requirements may be streamlined. Compliance with a streamlined condition will be deemed compliance with the underlying requirements whether or not the emission unit is actually in compliance with the specific underlying requirement. This facility has not applied for any streamlined conditions.

7. Summary of Emissions and Health Risks

Criteria Pollutant Emissions (tons/year) Annual Reported Emissions for Reporting Period 2006/2007

Pollutant	Emissions (tons/year)
CO	2.747
NOX	3.276
ROG	32.287
SOX	0.019
PM	0.342

Toxic Air Contaminants Emissions (TAC) Annual Reported Emissions for Reporting Period 2006/2007

The Following TACs Were Reported	Emissions (lbs/yr)
1,3-Butadiene	0.007
2-Methyl naphthalene [PAH, POM]	< 0.001
ACENAPHTHENE	< 0.001
ACENAPHTHYLENE	< 0.001
Ammonia	1176.039
Arsenic	< 0.001
B[GHI] PERYLENE	< 0.001
Benzene	0.434
Benzo[b]fluoranthene	< 0.001
Benzo[e]pyrene [PAH, POM]	< 0.001
Cadmium	< 0.001
Carbon tetrachloride	< 0.001
Chromium (VI)	< 0.001
Chrysene	< 0.001

Ethylene dibromide	< 0.001
Ethylene dichloride	< 0.001
FLUORANTHENE	< 0.001
FLUORENE	< 0.001
Formaldehyde	1.149
Lead (inorganic)	< 0.001
Methylene chloride	< 0.001
Naphthalene	0.020
Nickel	< 0.001
PAHs, total, with components not reported	0.007
PHENANTHRENE	< 0.001
PYRENE	< 0.001
Vinyl chloride	< 0.001

Health Risk from Toxic Air Contaminants

The facility is subject to review by the Air Toxics Information and Assessment Act (AB2588). The AQMD is tracking the status of this facility under AB 2588 requirements.

8. Compliance History

As noted, the facility has been in constant operation since 1991. The facility has been subject to both self-reporting requirements and AQMD inspections. The facility has had no citizen complaints filed in past two years. However, the facility was issued a Notices of Violation by the AQMD in 2007 for facility’s failure to submit semi-annual and certified annual report in a timely manner, and a Notice to Comply in 2008 to provide record for refrigerant use. No other notices have been issued to the facility in past two calendar years. The facility has since corrected the problems and is currently operating in compliance with all applicable rules and regulations.

9. Compliance Certification

By virtue of the Title V permit application and issuance of this permit, the reporting frequency for compliance certification for the facility shall be annual.