IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
NORTHERN DIVISION

THE UNITED STATES OF AMERICA, and STATE OF MISSOURI Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION NO. 2:13-cv-00027 CONSENT DECREE

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APPENDICES

I. INTRODUCTION

1. Plaintiffs the United States of America, on behalf of the United States Environmental Protection Agency ("EPA"), and the State of Missouri ("State"), have filed a joint complaint in this action alleging that Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), violated the Clean Air Act, 42 U.S.C. §§ 7401-7671q, the Missouri Air Conservation Law, Sections 643.010 to 643.210, RSMo, the Clean Water Act, 33 U.S.C. §§ 1251-1387, the Missouri Clean Water Law, Sections 644.006-644.141, RSMo, the Solid Waste Disposal Act (also known as the Resource Conservation and Recovery Act), 42 U.S.C. §§ 6901-6992k, and the Missouri Hazardous Waste Management Law, §§ 260.350-260.430 RSMo, and the State and Federal regulations promulgated thereunder.

2. The Complaint alleges that between January 2006 and April 2009, Teva discharged excessive amounts of pollutants, including biochemical oxygen demand, total suspended solids, ammonia, acetone, methylene chloride, toluene, and triethylamine from its pharmaceutical manufacturing plant in Mexico, Missouri ("Facility"), to the Publicly Owned Treatment Works ("POTW") owned and operated by the City of Mexico, Missouri ("City"). The Complaint alleges that these discharges violated Sections 301 and 307 of the Clean Water Act ("CWA"), 33 U.S.C. §§ 1311 and 1317 and 40 C.F.R. § 403.5 because they alone, or in combination with other discharges, caused pass-through (*i.e.* caused the City's POTW to violate its CWA permit limits) and interfered with the proper operation of the City's POTW. In addition, the Complaint alleges that numerous discharges violated Sections 301 and 307 of the CWA, 33 U.S.C. §§ 1311 and 1317 and the effluent guidelines and standards promulgated in the Pharmaceutical manufacturing point source category found at 40 C.F.R. Part 439.

3. The Complaint also alleges that Teva violated the requirements of the Clean Air Act, the Missouri Air Conservation Law, Sections 643.010 to 643.210, RSMo, and the National Emissions Standards for Hazardous Air Pollutants applicable to the pharmaceutical manufacturing industry found at 40 C.F.R. Part 63, Subpart GGG ("Subpart GGG"). These violations include failure to control emissions of hazardous air pollutants from its wastewater, failure to comply with test methods and procedures, and failure to properly implement a leak detection and repair program at the Mexico, Missouri facility.

4. The Complaint further alleges that Teva violated the requirements of the Resource Conservation and Recovery Act, the Missouri Hazardous Waste Management Law, and the State and Federal regulations promulgated thereunder, by failing to make hazardous waste determinations, by operating as an illegal Treatment, Storage and/or Disposal Facility without a permit by failing to meet standards applicable to generators of hazardous waste, by failing to comply with Missouri pretransport, containerization, and labeling requirements, and by offering hazardous waste for transport without a manifest.

5. Teva does not admit any liability to the United States or the State arising out of the transactions or occurrences alleged in the Complaint.

6. The Parties recognize, and the Court by entering this Consent Decree finds, that this Consent Decree has been negotiated by the Parties in good faith and will avoid litigation between the Parties and that this Consent Decree is fair, reasonable, and in the public interest.

7. NOW, THEREFORE, before the taking of any testimony, without the adjudication or admission of any issue of fact or law except as provided in Section II (General Provisions), and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED, AND DECREED as follows:

II. GENERAL PROVISIONS

8. Jurisdiction and Venue. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, 33 U.S.C. § 1319(b), and 42 U.S.C. §§ 6928(a) and 7413(b) and over the Parties. Venue lies in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a), 33 U.S.C. § 1319(b), and 42 U.S.C. §§ 6928(a) and 7413(b) because the violations alleged in the Complaint are alleged to have occurred in this District, and the Facility is located in, and Teva conducts business in, this judicial district.

9. Consent to Jurisdiction and Venue. For purposes of this Consent Decree, and any action to enforce this Consent Decree, Teva consents to the Court's jurisdiction over this Consent Decree and any such action and over Teva and consents to venue in this judicial district. For purposes of this Consent Decree, Teva agrees that the Complaint states claims upon which relief may be granted pursuant to 33 U.S.C. § 1319 and 42 U.S.C. §§ 6928(a) and 7413(b).

10. Retention of Jurisdiction. The Court shall retain jurisdiction over this Consent Decree until termination of this Consent Decree, for the purpose of resolving disputes arising under this Consent Decree or entering orders modifying this Consent Decree as provided in Paragraph 19 (Modification), and for effectuating or enforcing compliance with the terms of this Consent Decree.

11. Applicability. The obligations of this Consent Decree apply to and are binding upon the United States, the State, and upon Teva and any successors, assigns, or other entities or persons otherwise bound by law.

12. Transfer of Property.

a. No transfer of ownership or operation of the Facility, whether in compliance with the procedures of this Paragraph or otherwise, shall relieve Teva of its obligation to ensure that the terms of this Consent Decree are implemented.

b. At least thirty (30) Days prior to such transfer, Teva shall provide a copy of this Consent Decree to the proposed transferee and shall promptly provide written notice of the prospective transfer, together with a copy of the proposed written agreement, to the United States Attorney for the Eastern District of Missouri, and the United States and the State in accordance with Paragraph 18 (Notices). Any attempt to transfer ownership or operation of the Facility without complying with this Paragraph constitutes a violation of this Consent Decree.

13. Distribution of Consent Decree. Teva shall provide a copy of this Consent Decree (by hard copy, electronic copy, or by providing online access to it with notice to the affected personnel) to all officers, employees, and agents whose duties would reasonably be expected to include compliance with any provision of this Consent Decree, as well as to any contractor retained by Teva to perform work required under this Consent Decree. Teva shall condition any such contract upon performance of the work in conformity with the terms of this Consent Decree.

14. Responsibility of Teva. In any action to enforce this Consent Decree, Teva shall not raise as a defense the failure by any of its officers, directors, employees, agents, or contractors to take any actions necessary to comply with the provisions of this Consent Decree.

15. Purpose of Consent Decree. It is the express purpose of this Consent Decree to further the objectives of the Clean Water Act, Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, and the

Missouri Hazardous Waste Management Law, as well as regulations and permits issued pursuant to those Acts. All obligations in this Consent Decree shall have the objective of causing Teva to be and remain in full compliance with the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, the Missouri Hazardous Waste Management Law, the regulations and permits issued pursuant to those Acts and Laws, as well as state and local laws, regulations, and permits authorized pursuant to those Acts.

16. Definitions. Terms used in this Consent Decree that are defined in the Clean Water Act, the Missouri Clean Water Law, the Clean Air Act, the Missouri Air Conservation Law, the Resource Conservation and Recovery Act, and the Missouri Hazardous Waste Management Law, or in regulations promulgated pursuant to those Acts and Laws shall have the meanings assigned to them in those Acts and Laws or such regulations, unless otherwise provided in this Consent Decree. Whenever the terms set forth below are used in this Consent Decree, the following definitions shall apply:

a. "Clean Air Act" shall mean the Clean Air Act as amended and codified at 42 U.S.C. §§ 7401-7671q.

b. "Clean Water Act" shall mean the Federal Water Pollution Control Act as amended and codified at 33 U.S.C. §§ 1251-1387.

c. "Complaint" shall mean the complaint filed by the United States and the State in this action.

d. "Consent Decree" shall mean this Consent Decree and all Appendices and plans approved pursuant to this Consent Decree.

e. “Court” shall mean the United States District Court for the Eastern District of Missouri.

f. "Covered Process Units" shall mean pharmaceutical process units at the Facility used for the production of Amoxicillin, Cephalexin, Cefadroxil, and Cefprozil.

g. "Covered Equipment" shall mean all Covered Types of Equipment in all Covered Process Units.

h. "Covered Types of Equipment" shall mean all valves, connectors, pumps, agitators, and Open-Ended Lines in light liquid, heavy liquid, or gas/vapor service that are regulated under a federal, state, or local leak detection and repair program.

i. "Date of Lodging" shall mean the date on which this Consent Decree is filed with this Court.

j. "Day" or “Days” shall mean a calendar day or calendar days unless expressly stated to be a business day. In computing any period of time under this Consent Decree, where the last day would fall on a Saturday, Sunday, or federal holiday, the period shall run to the close of business of the next business day.

k. "Directed Maintenance" shall mean the utilization of concurrent monitoring (or other method that indicates the relative size of the leak) to repair a leaking piece of equipment to achieve the best repair/lowest emission rate possible.

l. "DOR" shall mean Delay of Repair.

m. "Effective Date" shall mean the date upon which this Consent Decree is entered by the Court or a motion to enter the Consent Decree is granted, whichever occurs first, as recorded on the Court’s docket.

n. "ELP" shall mean the Enhanced Leak Detection and Repair Program specified in Paragraphs 58 (Applicability of the ELP) - 68 (Certification of Compliance) of this Consent Decree.

o. "EMS" shall mean Environmental Management System, and shall refer to the integrated system created by the EMS Consultant pursuant to Paragraph 71 (Development of the EMS), meeting the requirements set forth in Appendix A.

p. "EMS Auditor" shall mean the auditor selected pursuant to Paragraph 72 (Selection of EMS Auditor).

q. "EMS Audit Report" shall mean a report prepared pursuant to and meeting the requirements of Paragraph 73 (Duties of the EMS Auditor).

r. "EMS Consultant" shall mean consultant selected pursuant to Paragraph 69 (Selection of EMS Consultant).

s. “EMS Corrective Action Plan” shall mean the Corrective Action Plan required by Paragraph 74 (EMS Corrective Action Plan).

t. "EMS Manual" shall mean the document prepared pursuant to and meeting the requirements of Paragraph 71 (Development of the EMS).

u. "EPA" shall mean the United States Environmental Protection Agency and any of its successor departments or agencies.

v. "Facility" shall mean Teva’s pharmaceutical manufacturing plant located at 5000 Snyder Drive, Mexico, Missouri.

w. "HAP" shall mean any hazardous air pollutant as defined in 40 C.F.R. § 63.2.

x. "Identified Hazardous Waste" shall mean methylene chloride still bottoms that were discharged to Teva's wastewater treatment plant from at least May 2005 through December 2008.

y. "Industrial User Permit" shall mean the permit governing discharges from the Facility to the Mexico POTW issued to Teva by the City of Mexico on October 2, 2006 and any subsequent amendment, revision, or re-issuance.

z. "Initial Review and Evaluation" shall mean an evaluation of Teva's existing environmental management practices and documents to identify where systems or subsystems have not been adequately developed or implemented, or need to be enhanced, or new management systems or subsystems need to be developed to adequately address the elements set forth in Appendix A.

aa. "Interest" shall mean interest at the rate specified in 28 U.S.C. § 1961 as of the Effective Date.

bb. "LDAR" shall mean Leak Detection and Repair.

cc. "LDAR Audit Commencement Date" shall mean the first date that the on-site inspection that accompanies an LDAR audit starts.

dd. "LDAR Audit Completion Date" or "Completion of an LDAR Audit" shall mean one hundred twenty (120) Days after the LDAR Audit Commencement Date.

ee. "LDAR Corrective Action Plan" shall mean the Corrective Action Plan required by Paragraph 67 (LDAR Corrective Action Plan).

ff. "Low Emissions Valve" shall mean either

i. A valve (including its specific packing assembly) for which (A) the manufacturer has issued a written warranty that it will not emit fugitives at greater than 100 parts

per million (ppm), and that, if it does so emit at any time in the first five years, the manufacturer will replace the valve and (B) the valve (including its specific packing assembly) was tested by the manufacturer or a qualified testing firm pursuant to generally-accepted good engineering practices for testing fugitive emissions and the results of the testing reasonably support the warranty; or

ii. A valve (including its specific packing assembly) that has been tested by the manufacturer or a qualified testing firm pursuant to generally-accepted good engineering practices for testing fugitive emissions and that, during the test, at no time leaked at greater than 500 ppm, and on average, leaked at less than 100 ppm.

gg. "Low Emissions Packing" shall mean either

i. A valve packing product, independent of any specific valve, for which (A) the manufacturer has issued a written warranty that the packing will not emit fugitives at greater than 100 ppm, and that, if it does so emit at any time in the first five years, the manufacturer will replace the product and (B) the packing was tested by the manufacturer or a qualified testing firm pursuant to generally-accepted good engineering practices for testing fugitive emissions and the results of the testing reasonably support the warranty; or

ii. A valve packing product, independent of any specific valve, that has been tested by the manufacturer or a qualified testing firm pursuant to generally-accepted good engineering practices for testing fugitive emissions, and that, during the test, at no time leaked at greater than 500 ppm, and on average, leaked at less than 100 ppm.

hh. "Method 21" shall mean the test method found at 40 C.F.R. Part 60, Appendix. A, Method 21.

ii. "Mexico POTW" shall mean the publicly-owned treatment works owned and operated by the City of Mexico, Missouri and located at 1050 North Agricultural Street, Mexico, Audrain County, Missouri.

jj. "Open-Ended Line" or “OEL” shall mean any valve, except pressure relief valves, having one side of the valve seat in contact with process fluid and one side open to the atmosphere, either directly or through open piping.

kk. "Paragraph" shall mean a portion of this Consent Decree identified by an Arabic numeral.

ll. "Parties" shall mean the United States, the State, and Teva.

mm. “Pretreatment Plan” shall mean the plan required to be prepared pursuant to Paragraph 43 (Pretreatment Assessment).

nn. "Pretreatment Regulations" shall mean the General Pretreatment Regulations found at 40 C.F.R. Part 403 and the Categorical Pretreatment Regulations for Pharmaceutical manufacturing point sources found at 40 C.F.R. Part 439.

oo. "Process Unit Shutdown" shall mean either (i) a scheduled maintenance shutdown, (ii) the turnover period following the end of a manufacturing production campaign that lasts longer than fourteen (14) Days, or (iii) any other shutdown that lasts longer than fourteen (14) Days, whichever is sooner.

pp. “Publicly Owned Treatment Works” or “POTW” shall mean the City of Mexico, Missouri’s wastewater treatment plant.

qq. “Resource Conservation and Recovery Act” shall mean the Solid Waste Disposal Act as amended and codified at 42 U.S.C. §§ 6401-6992k.

rr. "Screening Value" shall mean the highest emission level that is recorded at each piece of equipment as it is monitored in compliance with Method 21.

ss. "Section" shall mean a portion of this Consent Decree identified by a Roman numeral.

tt. "State" shall mean the State of Missouri.

uu. "Subpart GGG" shall mean the National Emission Standards for Hazardous Air Pollutants applicable to the pharmaceuticals production source category, currently codified at 40 C.F.R. Part 63, Subpart GGG.

vv. "Teva" shall mean the entity named as the Defendant in the Complaint.

ww. "United States" shall mean the United States of America, acting on behalf of EPA.

xx. "Wastewater Treatment Plant" shall mean the wastewater treatment plant at the Facility.

17. Costs. The Parties shall bear their own costs of this action, including attorneys' fees, except that the United States and the State shall be entitled to collect their costs (including attorneys' fees) incurred in any action necessary to collect any portion of the civil penalty or any stipulated penalties due but not paid by Teva in accordance with this Consent Decree.

18. Notices.

a. Unless otherwise specified herein, whenever notifications, submissions, or communications are required by this Consent Decree, they shall be made in writing and addressed as follows:

To the United States (in addition to the EPA addresses below):

Chief, Environmental Enforcement Section
Environment and Natural Resources Division
U.S. Department of Justice
Box 7611 Ben Franklin Station
Washington, D.C. 20044-7611
Re: DOJ No. 90-5-2-1-09638

To EPA:

Jonathan Meyer
Assistant Regional Counsel
U.S. EPA, Region 7
11201 Renner Boulevard
Lenexa, KS 66219
Phone: (913) 551-7140
Facsimile: (913) 551-9140
Email: meyer.jonathan@epa.gov

and

As to the requirements of Paragraphs 49 (Environmental Mitigation Projects) - 68 (Certification of Compliance):

Leslye Werner
Chief, Air Compliance and Enforcement Section
U.S. EPA, Region 7
11201 Renner Boulevard
Lenexa, KS 66219
Phone: (913) 551-7858
Facsimile: (913) 551-9858
Email: werner.leslye@epa.gov

and

As to the requirements of Paragraph 43 (Pretreatment Assessment) – 44 (Monitoring of Effluent):

Paul Marshall
Environmental Engineer
U.S. EPA, Region 7
11201 Renner Boulevard
Lenexa, KS 66219
Phone: (913) 551-7419

Facsimile: (913) 551-9419
Email: marshall.paul@epa.gov

and

As to the requirements of Paragraphs 45 (Hazardous Waste Accumulation Containers) - 48 (Spent Sulfuric Acid):

Edwin G. Buckner, P.E.
Environmental Engineer
U.S. EPA, Region 7
11201 Renner Boulevard
Lenexa, KS 66219
Phone: (913) 551-7621
Facsimile: (913) 551-9621
Email: buckner.edwin@epa.gov

To the State of Missouri:

Kara L. Valentine
Assistant Attorney General
P.O. Box 899
Jefferson City, MO 65101
Phone: 573-751-3640
Facsimile: 573-751-8796
Email: kara.valentine@ago.mo.gov

and

Aaron Schmidt, P.E.
Acting Deputy Division Director
Division of Environmental Quality
Missouri Department of Natural Resources
P.O. Box 176
Jefferson City, MO 65102
Phone: 573-751-0763
Facsimile: 573-751-9277
Email: aaron.schmidt@dnr.mo.gov

As to the requirements of Paragraphs 45 (Hazardous Waste Accumulation Containers) - 48 (Spent Sulfuric Acid):

Ricardo Jones
Hazardous Waste Program
Missouri Department of Natural Resources

P.O. Box 176
Jefferson City, MO 65102
Phone: 573-526-3214
Facsimile: 573-526-5268
Email: ricardo.jones@dnr.mo.gov

To Teva:

Attention: Plant Manager
Teva Pharmaceuticals USA, Inc.
5000 Snyder Drive
Mexico, MO 65265
Phone: 573-582-6276
Facsimile: 573-581-8085
Email: Carey.Case@tevapharm.com

and

Attention: General Counsel
Teva Pharmaceuticals USA, Inc.
425 Privet Road
Horsham, PA 19044
Phone: 215-293-6402
Facsimile: 215-293-6499
Email: Kirsten.Bauer@tevapharm.com

With a copy to:

Gail S. Port, Esq.
Proskauer Rose LLP
Eleven Times Square
New York, NY 10036
Phone: 212-969-3243
Facsimile: 212-969-2900
Email: gport@proskauer.com

b. Any Party may, by written notice to the other Parties, change its designated notice recipient or notice address provided above. Notices submitted pursuant to this Paragraph shall be deemed submitted upon mailing, unless otherwise provided in this Consent Decree or by mutual agreement of the Parties in writing.

19. Modification.

a. The terms of this Consent Decree, including any attached appendices, may be modified only by a subsequent written agreement signed by all the Parties.

b. Where the modification constitutes a material change to this Consent Decree, it shall be effective only upon approval by the Court.

c. Any disputes concerning modification of this Consent Decree shall be resolved pursuant to Section IX (Dispute Resolution), provided, however, that, instead of the burden of proof provided by Paragraph 100 (Standard of Review), the Party seeking the modification bears the burden of demonstrating that it is entitled to the requested modification in accordance with Federal Rule of Civil Procedure 60(b).

20. Termination.

a. This Consent Decree may be terminated in accordance with the requirements of this Paragraph if the requirements of either of the following subparagraphs are met:

i. Each of the following conditions is met: (1) five years have elapsed since the Effective Date; (2) during that time, Teva has completed the requirements of Section V (Compliance Requirements and Injunctive Relief) of this Consent Decree; (3) Teva has maintained compliance for at least the preceding 12 months with this Consent Decree, and (4) Teva has paid the civil penalty in Section III (Civil Penalty), the cost recovery and damages in Section IV (Cost Recovery and Damages) and any accrued stipulated penalties pursuant to Section VII (Stipulated Penalties) as required by this Consent Decree.

ii. Each of the following conditions is met: (1) Teva has shut down or ceased operations (other than a short term cessation for routine maintenance) and secured the Facility; (2) Teva has disposed of all hazardous waste (including but not limited to cleaning out all contaminated containment system components, contaminated soils, and structures and equipment contaminated with hazardous waste) and closed all waste management units at the Facility in compliance with the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law; (3) Teva is in compliance with all applicable laws and regulations referenced in Paragraph 42, *infra* (Compliance); (4) Teva does not intend to restart manufacturing at the Facility, or to transfer ownership or operation of the Facility to an affiliated entity that intends to restart the manufacturing operations at the Facility; and (5) Teva has paid the civil penalty in Section III (Civil Penalty), the cost recovery and damages in Section IV (Cost Recovery and Damages) and any accrued stipulated penalties pursuant to Section VII (Stipulated Penalties) as required by this Consent Decree.

21. If Teva contends that the requirements of either Paragraph 20.a.i or 20.a.ii have been met, Teva may serve upon the United States and the State in accordance with Paragraph 18 (Notices) a request for termination, signed by an official of Teva, stating that Teva has satisfied those requirements, together with all necessary supporting documentation. The request for termination shall include the following certification:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

a. Following the United States' and the State's receipt of Teva's request for termination, the Parties shall confer informally concerning the request and any disagreement that the Parties may have as to whether Teva has complied with the requirements for termination of this Consent Decree. If the United States and the State agree that the Consent Decree may be terminated, the Parties shall submit, for the Court's approval, a joint stipulation terminating the Consent Decree.

22. Upon receipt of the notice from the United States or the State that they do not agree that the Consent Decree may be terminated, Teva may invoke the dispute resolution procedures of Section IX (Dispute Resolution).

23. Public Participation.

a. This Consent Decree shall be lodged with the Court for a period of not less than thirty (30) Days for public notice and comment in accordance with 28 C.F.R. § 50.7.

b. The United States reserves the right to withdraw or withhold its consent if the comments regarding the Consent Decree disclose facts or considerations indicating that the Consent Decree is inappropriate, improper, or inadequate.

c. Teva consents to entry of this Consent Decree without further notice and agrees not to withdraw from or oppose entry of this Consent Decree by the Court or to challenge

any provision of the Consent Decree, unless the United States has notified Teva in writing that it no longer supports entry of the Consent Decree.

24. Headings. Headings in this Consent Decree are provided for convenience only and shall not affect the substance of any provision.

25. Computation of Time. The computation of any period of time set forth in this Consent Decree shall be governed by Rule 6 of the Federal Rules of Civil Procedure. In computing any period of time under this Consent Decree, where the last Day would fall on a Saturday, Sunday, or Federal holiday, the period shall run until the close of business of the next business Day.

26. Signatories. Each undersigned representative of Teva and the State and the Assistant Attorney General for the Environment and Natural Resources Division of the Department of Justice certifies that he or she is fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind the Party he or she represents to this document.

27. Counterparts. This Consent Decree may be signed in counterparts, and its validity shall not be challenged on that basis.

28. Service. With respect to any action to enforce the terms of this Consent Decree, Teva agrees to accept service of process by mail, in accordance with the notice provisions set forth in Paragraph 18 (Notices) and to waive the formal service requirements set forth in Rules 4 and 5 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons.

29. Integration. This Consent Decree constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the

Consent Decree and supersedes all prior agreements and understandings, whether oral or written, concerning the settlement embodied herein. Other than deliverables that are subsequently submitted and approved pursuant to this Consent Decree, no other document, nor any representation, inducement, agreement, understanding, or promise, constitutes any part of this Consent Decree or the settlement it represents, nor shall it be used in construing the terms of this Consent Decree.

30. Final Judgment. Upon approval and entry of this Consent Decree by the Court, this Consent Decree shall constitute a final judgment of the Court as to the Parties. The Court finds that there is no just reason for delay and therefore enters this judgment as a final judgment under Federal Rules of Civil Procedure 54 and 58.

31. Right of Entry. The United States, the State, and their representatives, including attorneys, contractors, and consultants, shall have the right of entry into the Facility, at all reasonable times, upon presentation of credentials, to:

a. monitor the progress of activities required under this Consent Decree;

b. verify any data or information submitted to the United States or the State in accordance with the terms of this Consent Decree;

c. obtain samples and, upon request, splits of any samples taken by Teva or its representatives, contractors, or consultants;

d. obtain documentary evidence, including photographs and similar data; and

e. assess Teva's compliance with this Consent Decree.

32. Split Samples. Upon prior written request, Teva shall provide EPA, the State, or their authorized representatives splits of any samples taken by Teva pursuant to this Consent Decree.

33. Retention of Information.

a. Until five years after the termination of this Consent Decree, Teva shall retain, and shall instruct its contractors and agents to preserve, all non-identical copies of all documents, records, or other information (including documents, records, or other information in electronic form) in its or its contractors' or agents' possession or control, or that come into its or its contractors' or agents' possession or control, and that relate in any manner to Teva's performance of its obligations under this Consent Decree, including but not limited to all records required by Section V (Compliance Requirements and Injunctive Relief). This information-retention requirement shall apply regardless of any contrary corporate or institutional policies or procedures.

b. At any time during this information-retention period, upon written request by the United States or the State, Teva shall provide copies of any documents, records, or other information required to be maintained under this Paragraph. Any records that are created electronically shall be preserved in their native format and produced in that format upon written request.

c. At the conclusion of the information-retention period provided in this Paragraph, Teva shall notify EPA and the State at least ninety (90) Days prior to the destruction of any documents, records, or other information subject to the requirements of the preceding Paragraph and, upon written request by the EPA or the State, Teva shall deliver any such documents, records, or other information to EPA or the State as requested.

d. Teva may assert that certain documents, records, or other information is privileged under the attorney-client privilege or any other privilege, doctrine, or protection recognized by federal law. If Teva asserts such a privilege, doctrine, or protection, it shall

provide the following: (1) the title of the document, record, or information; (2) the date of the document, record, or information; (3) the name and title of each author of the document, record, or information; (4) the name and title of each addressee and recipient; (5) a description of the subject of the document, record, or information; and (6) the privilege, doctrine, or protection asserted by Teva. However, no documents, records, or other information submitted to the United States, EPA or the State pursuant to or necessary to determine compliance with the requirements of this Consent Decree shall be withheld on grounds of privilege.

e. Teva may also assert that information required to be provided under this Section is protected as Confidential Business Information ("CBI") under 40 C.F.R. Part 2. As to any information that Teva seeks to protect as CBI, Teva shall follow the procedures set forth in 40 C.F.R. Part 2 and 260.430, RSMo.

34. Other Information Gathering Authorities. This Consent Decree in no way limits or affects any right of entry and inspection, or any right to obtain information, held by the United States or the State pursuant to applicable federal or state laws, regulations, or permits, nor does it limit or affect any duty or obligation of Teva to maintain documents, records, or other information imposed by applicable federal or state laws, regulations, or permit.

III. CIVIL PENALTY

35. Civil Penalty. Within sixty (60) Days after the Effective Date of this Consent Decree, Teva shall pay the sum of $2,250,000 as a civil penalty, together with Interest accruing from the Effective Date.

36. Payment of Civil Penalty to the United States. Teva shall pay 50% percent of the civil penalty and Interest due pursuant to Paragraph 35 (Civil Penalty) to the United States by FedWire Electronic Funds Transfer ("EFT") to the U.S. Department of Justice in accordance with

written instructions to be provided to Teva after the Date of Lodging by the Financial Litigation Unit of the U.S. Attorney's Office for the Eastern District of Missouri, Thomas Eagleton U.S. Courthouse, 111 S. 10th Street, 20th Floor, St. Louis, MO 63102. At the time of payment, Teva shall send a copy of the EFT authorization form and the EFT transaction record, together with a transmittal letter, which shall state that the payment is for the civil penalty owed pursuant to the Consent Decree in the above-captioned case, and shall reference the civil action number and DOJ case number 90-5-2-1-09638, to the United States in accordance Paragraph 18 (Notices); by email to acctsreceivable.CINWD@epa.gov; and by mail to:

US Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

37. Payment of Civil Penalty to the State. Teva shall pay 50% percent of the civil penalty and Interest due pursuant to Paragraph 35 (Civil Penalty) to the State of Missouri by check made payable to the "State of Missouri (Audrain County School Fund)." The amount of payment shall be equal to the amount of the EFT payment made to the United States pursuant to Paragraph 36 (Payment of Civil Penalty to the United States). Teva shall mail the check to Collections Specialist, Office of the Attorney General of Missouri, P.O. Box 899, Jefferson City, MO 65102-0899.

38. Tax Treatment. Teva shall not deduct any civil or stipulated penalties paid under this Consent Decree in calculating its federal or state income tax.

IV. COST-RECOVERY AND DAMAGES

39. State Natural Resource Damages. Within sixty (60) Days after the Effective Date, Teva shall pay Natural Resource Damages, including past assessment costs, to the State in the amount of $26,000 for the injuries to the surface water, and other natural resources of the State resulting from the event described in the Complaint. The payment shall be made by check payable to the "Natural Resources Protection Fund -- Damages Subaccount (0555)" and sent to Collections Specialist, Missouri Attorney General's Office, P.O. Box 899, Jefferson City, MO 65102-0899.

40. State Enforcement Costs.

a. Within sixty (60) Days after the Effective Date, Teva shall reimburse the State for its past investigative and enforcement costs in the amount of $59,357. The payment shall be made by check payable to the "State of Missouri" and sent to Collections Specialist, Missouri Attorney General's Office, P.O. Box 899, Jefferson City, MO 65102-0899.

b. During the term of this Consent Decree, the Missouri Department of Natural Resources ("the Department") will incur additional costs of monitoring Teva's compliance with the terms of this Consent Decree. Payment by Teva of these costs shall be subject to an annual cap of $8,750. At intervals not to exceed three months, commencing three months after entry of this Consent Decree, the Department may submit a detailed invoice to Teva for the Department's direct and indirect costs and expenses associated with monitoring and oversight of the terms of this Consent Decree, with a copy to the Attorney General's Office. Within sixty (60) Days after the invoice is sent by the Department to Teva pursuant to Paragraph 18 (Notices), Teva shall make full payment of the Department's oversight costs and expenses described in the invoice, subject to the annual cap. If Teva fails to pay the full amount due

within sixty (60) Days, the Department retains the right to collect the remaining amount due, subject to the annual cap, and the unpaid charges will be included in the Department's subsequent bills until paid in full. The payment shall be made by check payable to the "State of Missouri" and sent to Collections Specialist, Missouri Attorney General's Office, P.O. Box 899, Jefferson City, MO 65102-0899.

41. State Fees and Taxes.

a. Within sixty (60) Days after the Effective Date, Teva shall remit a payment of $65,684.29 to the State for all hazardous waste fees and taxes that would have been required to be paid to the State had Teva disposed of the Identified Hazardous Wastes at a permitted treatment, storage or disposal facility. The payment shall be made by check payable to "the Missouri Department of Natural Resources" and sent to Collections Specialist, Missouri Attorney General's Office, P.O. Box 899, Jefferson City, MO 65102-0899.

b. Within sixty (60) Days after the Effective Date, Teva shall remit a payment of $1,752 to the State for all air emission fees and taxes that would have been required to be paid to the State had Teva accurately calculated the air emissions from Teva's Wastewater Treatment Plant. The payment shall be made by check payable to the "MDNR Air Permit and Emissions Fee Fund (0594)" and sent to Collections Specialist, Missouri Attorney General's Office, P.O. Box 899, Jefferson City, MO 65102-0899.

V. COMPLIANCE ACTIONS AND INJUNCTIVE RELIEF

42. Compliance. Teva shall comply with the pretreatment requirements and standards set forth in the Clean Water Act, the Missouri Clean Water Law, and the permits issued pursuant to those laws with respect to the Facility. Teva shall also comply with the Clean Air Act, the Missouri Air Conservation Law, Sections 643.010 to 643.210, RSMo, and 40 C.F.R. Part 63,

Subpart GGG at the Facility. Teva shall further comply with the Resource Conservation and Recovery Act, the Missouri Hazardous Waste Management Law, and the State and Federal regulations promulgated thereunder at the Facility.

A. Clean Water Act

43. Pretreatment Assessment.

a. No later than one hundred twenty (120) Days after the Effective Date, Teva shall submit to EPA and the State a Pretreatment Plan. The Pretreatment Plan shall:

i. Assess the cause or causes of violations or categories of violations identified on Appendix B.

ii. Recommend those actions necessary to prevent such violations and categories of violations of the Facility's Industrial User Permit, the Pretreatment Regulations, the Missouri Clean Water Law, and the Clean Water Act.

iii. Provide a schedule for implementation of those actions necessary to prevent violations or categories of violations of the Facility's Industrial User Permit, the Pretreatment Regulations, the Missouri Clean Water Law, and the Clean Water Act.

b. Review and implementation of the plan shall be governed by Paragraph 76 (Approval of Deliverables).

44. Monitoring of Effluent. In addition to all other required monitoring, at least once a day Teva shall visually observe its effluent discharge from the Facility to the Mexico POTW. If the discharge exhibits any unsightly color or color that is not reasonably expected to be removed in the City of Mexico treatment process, Teva shall notify the City and take all actions identified by the City, the State or EPA as necessary to prevent pass-through or interference by the colored effluent.

B. Hazardous Waste Management

45. Hazardous Waste Accumulation Containers. In each of the first four quarterly reports submitted pursuant to Paragraph 78 (Quarterly Reports), Teva shall demonstrate that all hazardous waste accumulation containers, both 90-day and satellite, are properly labeled, dated, closed, inspected, and managed in accordance with hazardous waste regulations.

46. Inspection Logs. In each of the first four quarterly reports submitted pursuant to Paragraph 78 (Quarterly Reports), Teva shall submit copies of all hazardous waste inspection logs for containers and tanks prepared during each such quarter.

47. Hazardous Waste Tanks. Within thirty (30) Days after the Effective Date, Teva shall submit to EPA and the State documentation that the following hazardous waste tank standards under 40 C.F.R. Part 265 Subpart J have been met: secondary containment, separation of incompatible wastes, engineer's certification, labeling, inspections, and release detection, for all hazardous waste tanks including, but not limited to, T-013, T-825, T-826, T-827, and T-1403.

48. Spent Sulfuric Acid. In the event that any portion of spent sulfuric acid in tanks and associated equipment, including but not limited to tank T-813, no longer meets the exclusion in 40 C.F.R. § 261.4(a)(7) or is shipped off-site for disposal as a hazardous waste, such tanks and associated equipment shall be in compliance with the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law, and with all implementing regulations including but not limited to 40 C.F.R. Part 265 Subpart J. Within thirty (30) Days of this event, Teva shall submit a written Notification to EPA and the State, pursuant to Paragraph 18 (Notices) that contains the following information:

a. The date that any portion of spent sulfuric acid in tanks and associated equipment no longer met the exclusion in 40 C.F.R. § 261.4(a)(7);

b. The date of the last off-site shipment of spent sulfuric acid for production of virgin sulfuric acid, along with supporting documentation;

c. Documentation, including manifests, associated with each shipment of spent sulfuric acid for off-site disposal within the preceding thirty (30) Days;

d. Identification of the tank(s) at the Facility that contain spent sulfuric acid, the amount of spent sulfuric acid in each tank, and the beginning date of accumulation of spent sulfuric acid in the tank(s); and

e. Documentation that all tanks and associated equipment that contain spent sulfuric acid are in compliance with the requirements of the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law, and with all implementing regulations including but not limited to 40 C.F.R. Part 265 Subpart J.

C. Subpart GGG Environmental Mitigation Projects

49. For the purpose of reducing emissions of HAPs from the Wastewater Treatment Plant, Teva shall implement the two Environmental Mitigation Projects described in paragraphs 50 and 51 according to the schedules set forth in Appendix C (Environmental Mitigation Project Schedule).

50. By no later than sixteen (16) months from the Effective Date of the Consent Decree, Teva shall complete installation and commence operation of the following Environmental Mitigation Project:

a. Vacuum Stripping of Amoxicillin Process Wastewater. Teva shall vacuum strip methylene chloride from the wastewater streams listed below, using a batch

vacuum stripping process operated for a minimum stripping time of 90 minutes and at a minimum vacuum pressure of negative 27.0 inches of mercury.

i. Prior to treatment in the Wastewater Treatment Plant, Teva shall route the following wastewater streams to the vacuum stripper control device:

1. Amoxicillin mother liquor after it has been vacuum stripped in Reactor R-105;

2. Steam condensate from carbon adsorber regeneration;

3. Vacuum pump seal water from vacuum stripping of Amoxicillin mother liquor and wastewater; and

4. Rinse water from the Amoxicillin process vessel rinsing.

ii. Teva shall batch vacuum strip the entire volume of the wastewater streams listed in Paragraph 50.a.i.

51. By no later than eighteen (18) months from the Effective Date of the Consent Decree, Teva shall complete installation and commence operation of the following Environmental Mitigation Project:

a. Wastewater Treatment Plant Optimization to Minimize HAP Stripping. Teva shall minimize evaporation of HAPs in the two existing aeration basins of the Wastewater Treatment Plant to increase the HAP biological destruction efficiency of the Wastewater Treatment Plant, by removing the surface aerators in each basin and by installing an automated diffused aeration rate system to control the diffused aeration rate in the basins. This will include installation of a new cooling system to control the temperature of the aeration basin mixed liquor and installation of a defoamer spray application system.

b. With the exception of periods of time when maintenance is being performed on the diffused aeration system or on other components of the wastewater treatment system, Teva shall continuously operate the automated diffused aeration rate system at all times that wastewater is being discharged from the aeration basins.

52. Teva is responsible for the satisfactory completion of the two Environmental Mitigation Projects under this Section in accordance with the requirements of this Consent Decree and Appendix C (Environmental Mitigation Project Schedule). Teva may use contractors or consultants in planning and implementing the two Environmental Mitigation Projects.

53. Teva shall comply with all applicable federal, state or local laws or regulations and obtain all necessary permits in performance of the two Environmental Mitigation Projects.

54. By signing this Consent Decree, Teva certifies that it is not required to perform or develop either of these two Environmental Mitigation Projects by any federal, state or local law or regulation and is not required to perform or develop the two Environmental Mitigation Projects by agreement, grant, or as injunctive relief awarded in any other action in any forum; that the two Environmental Mitigation Projects are not Environmental Mitigation Projects that Teva was planning or intending to construct, perform, or implement other than in settlement of the claims resolved by this Consent Decree; and that Teva will not receive any reimbursement for any portion of the costs of the two Environmental Mitigation Projects from any other person.

55. Progress Reports. Until the date that the two Environmental Mitigation Projects required by this Section have been fully installed in accordance with Appendix C, Teva shall include in each report required by Paragraph 78 (Quarterly Reports) a status update on the installation of the two Environmental Mitigation Projects required by this Section.

56. Completion Reports. The report required by Paragraph 78 (Quarterly Reports) for the period during which installation of each Environmental Mitigation Project has been completed and operation has commenced shall contain the following information:

a. A detailed description of the Environmental Mitigation Project as installed;

b. A description of any problems encountered in installing the Environmental Mitigation Project and the solutions thereto;

c. An estimate of the pollutant reductions, calculated on an annual basis, associated with each Environmental Mitigation Project; and

d. A certification that the Environmental Mitigation Project has been fully installed pursuant to the provisions of this Consent Decree and Appendix C.

57. Environmental Mitigation Reports. Following completion of the installation and commencement of operation of the two Environmental Mitigation Projects required by this Section, Teva shall include annually, in the Fourth Quarterly Report required under Paragraph 78 (Quarterly Reports), the following information:

a. The annual average control efficiency of the batch vacuum stripper, based on quarterly sampling of the wastewater inlet and outlet of the system;

b. An annual estimated amount of methylene chloride, by mass, removed from each wastewater stream by the vacuum stripper control device during the calendar year covered by the Fourth Quarterly Report;

c. An estimate of the cumulative amount, by mass, of methylene chloride removed by the batch vacuum stripper from the point in time its full-scale operation commences; and

d. A demonstration that the biological treatment process of the Wastewater Treatment Plant is reducing the mass of total soluble and partially soluble HAP sent to the Wastewater Treatment Plant by at least 95%. This demonstration will include an estimate of the mass removal of the Wastewater Treatment Plant without operation of the Environmental Mitigation Projects specified in Paragraphs 50 and 51 above.

D. LDAR Enhanced Leak Detection Program

58. Applicability of the Enhanced Leak Detection Program (ELP). The requirements of the ELP shall apply to all Covered Equipment, except that the requirements of Paragraph 59 (Facility-Wide LDAR Plan) shall apply to all equipment that is: (a) regulated under any federal, state, or local leak detection and repair program; and (b) located at the Facility. The requirements of this ELP are in addition to, and not in lieu of, the requirements of any other LDAR program that may be applicable to a piece of Covered Equipment. In the event any specific requirement set forth in this ELP is more stringent than the applicable LDAR regulation(s) contained in 40 CFR § 63.1255 *et seq.*, the requirements set forth in this ELP shall apply, unless otherwise specified.

59. Facility-Wide LDAR Plan.

a. By no later than ninety (90) Days after the Effective Date, Teva shall develop and submit to EPA and the State a Facility-wide document that describes, at a minimum: (i) its Facility-wide LDAR program (*e.g.*, applicability of regulations to process units and/or specific equipment; leak definitions; monitoring frequencies); (ii) a tracking program (*e.g.*, Management of Change) that ensures that new pieces of equipment added to the Facility for any reason are integrated into the LDAR program and that pieces of equipment that are taken out of service are removed from the LDAR program; (iii) the roles and responsibilities of all employee

and contractor personnel assigned to LDAR functions at the Facility; (iv) how the number of personnel dedicated to LDAR functions is sufficient to satisfy the requirements of the LDAR program; and (v) how the Facility plans to implement the ELP.

b. Teva shall review its Facility-Wide LDAR Plan on an annual basis and update it as needed by no later than December 31 of each year. If the Facility-Wide LDAR Plan is updated, Teva shall submit the updated plan to EPA and the State by no later than December 31 for each year the plan is updated.

60. Monitoring Open Ended Lines. Commencing no later than ninety (90) Days after the Effective Date Teva shall monitor all Open Ended Lines at the closure device quarterly. If the closure device is a valve, monitoring will be done in the same manner as any other valve, but also shall include monitoring at the end of the valve or line that is open to the atmosphere.

61. Leak Repairs.

a. For purposes of this Paragraph, a leak shall be any leak detected at or above the threshold values listed in Table 1 for the category of Covered Equipment identified, regardless of whether the leak is detected during periodic monitoring.

Table 1
Leak Definition by Equipment Type

Equipment Type	**Lower Leak Definition (ppm)**
Valves	250
Connectors	250
Pumps	500
Agitators	1,000
OELs (at the Closure Device)	250

b. Commencing no later than ninety (90) Days after the Effective Date for all Covered Equipment, at any time a leak is detected through audio, visual, or olfactory sensing,

Teva must repair the piece of Covered Equipment in accordance with all applicable regulations and with this Paragraph.

c. Except as explicitly provided in the Equipment Replacement and Improvement Program, by no later than five (5) Days after detecting a leak, Teva shall perform a first attempt at repair. By no later than fifteen (15) Days after detection, Teva shall perform a final attempt at repair or may place the piece of equipment on the DOR list provided that Teva has complied with all applicable regulations and with the requirements of this Paragraph.

d. Except as explicitly provided in the Equipment Replacement and Improvement Program, Teva shall perform Directed Maintenance during all repair attempts.

e. Except as explicitly provided in the Equipment Replacement and Improvement Program, for leaking valves, when other repair attempts have proven ineffective and/or Teva is not able to remove the leaking valve from service, Teva at its option may replace the valve with a Low Emission Valve or may use the drill-and-tap repair method prior to placing the leaking valve on the DOR list unless there is a major safety, mechanical, product quality, or environmental issue with repairing the valve using the drill-and-tap method. Teva shall document the reason or reasons why neither a replacement nor drill-and-tap repair was performed prior to placing any valve on the DOR list. When it selects the drill-and-tap repair method, Teva shall attempt at least two drill-and-tap repairs before placing a valve on the DOR list.

f. Except as explicitly provided in the Equipment Replacement and Improvement Program, for each leak, Teva shall record the following information: (i) the date of all repair attempts; (ii) the repair methods used during each repair attempt; (iii) the date, approximate time, and Screening Values for all re-monitoring events; and, (iv) if relevant, the

information required under Paragraphs 61 (Leak Repairs) and Paragraph 62 (Delay of Repair) for Covered Equipment placed on the DOR list.

g. Nothing in this Paragraph is intended to prevent Teva from taking a leaking piece of Covered Equipment out of service; provided however, that prior to placing the leaking piece of Covered Equipment back in service, Teva must repair the leak or must comply with the requirements of Paragraph 62 (Delay of Repair) to place the piece of Covered Equipment on the DOR list.

h. In connection with leak repairs under this Paragraph 61, Teva shall comply with Method 21 in performing LDAR monitoring, using an instrument attached to a data logger (or an equivalent instrument) which directly electronically records the Screening Value detected at each piece of equipment, the date and time that each Screening Value is taken, and the identification numbers of the monitoring instrument and technician. Teva shall transfer this monitoring data to an electronic database within a week of the actual electronic recording of the measurements for recordkeeping purposes.

62. Delay of Repair. Commencing no later than sixty (60) Days after the Effective Date, for all Covered Equipment placed on the DOR list, Teva shall:

a. Require sign-off from the relevant process unit supervisor or person of similar authority that the piece of Covered Equipment is technically infeasible to repair without a Process Unit Shutdown; and

b. Undertake periodic monitoring, at the frequency required for other pieces of Covered Equipment of that type in the process unit, of the Covered Equipment placed on the DOR list; and

c. Repair the piece of Covered Equipment by the end of the next Process Unit Shutdown.

63. Equipment Replacement and Improvement Program. During each Process Unit Shutdown of a Covered Process Unit commencing with the first Process Unit Shutdown after the Effective Date or during the next annual maintenance shutdown of the Facility in or about July 2013, whichever is sooner, Teva shall implement a program to replace or improve the emissions performance of valves and connectors in the Covered Process Units. The program shall consist of the following elements:

a. Except as provided in Paragraph 63.d. (Equipment Replacement and Improvement Program), Teva shall ensure that each new valve it installs in each Covered Process Unit either is a Low Emission Valve or is fitted with Low Emissions Packing.

b. By no later than two hundred (200) Days after the Effective Date, Teva shall submit to EPA and the State a list of all valves in each Covered Process Unit, broken down by Covered Process Unit, that are in existence as of the Effective Date. The valves on this list shall be the "existing valves" for purposes of Paragraphs 63.c – 63.e (Equipment Replacement and Improvement Program)

c. Teva shall repack or replace all valves that have Screening Values at or above 250 ppm.

i. Except as provided in Paragraph 63.d (Equipment Replacement and Improvement Program), for each existing valve that has a Screening Value at or above 250 ppm during any monitoring event, Teva shall replace or repack the existing valve with a Low Emission Valve or with Low Emissions Packing by no later than thirty (30) Days after the monitoring event that triggers the replacement or repacking requirement, unless the replacement

or repacking requires a Process Unit Shutdown. If the replacement or repacking requires a Process Unit Shutdown, Teva shall undertake the replacement or repacking during the Process Unit Shutdown that follows the monitoring event that triggers the requirement to replace or repack the valve.

ii. Pursuant to Paragraph 63.c.i (Equipment Replacement and Improvement Program), Teva shall meet the repair requirements pending replacements or repacking in Paragraphs 63.c.ii.1– 2 (Equipment and Replacement Program).

1. For each existing valve that has a Screening Value at or above 250 ppm, Teva shall not be required to comply with Paragraph 61 (Leak Repairs) pending replacement or repacking pursuant to Paragraph 63.c.i if Teva completes the replacement or repacking within thirty (30) Days of detecting the leak. If Teva does not complete the replacement or repacking within thirty (30) Days of detecting the leak, or if, at the time of the leak detection, Teva reasonably can anticipate that it might not be able to complete the replacement or repacking within thirty (30) Days of detecting the leak, Teva shall comply with all applicable requirements of Paragraph 61 (Leak Repairs).

2. For each existing valve that has a Screening Value at or above 500 ppm, Teva shall comply with Paragraph 62 (Delay of Repair) and all requirements of any applicable regulation pending replacement or repacking pursuant to Paragraph 63.c.i (Equipment Replacement and Improvement Program).

d. Teva shall repair all valves that have Screening Values greater than or equal to 100 ppm and less than 250 ppm. For such valves, excluding control valves, Teva shall make an initial attempt to repair the valve and eliminate the leak by no later than five (5) Days after detecting the leak. Teva shall perform Directed Maintenance to determine if the repair has

been successful. If, upon Directed Maintenance, the Screening Value is less than 250 ppm, no further actions shall be required. If, upon Directed Maintenance, the Screening Value is greater than or equal to 250 ppm, Teva shall undertake the repair actions required by Paragraph 61 (Leak Repairs) (and all deadlines for such requirements shall be based upon the date of the failed Directed Maintenance), but Teva shall not be required to replace or repack the valve pursuant to Paragraph 63.c. Nothing in this Paragraph shall prevent Teva from electing to replace or repack any valve covered by this subparagraph and, if Teva chooses to replace or repack any such valve, Teva shall not be required to undertake any repairs.

e. Teva shall not be required to utilize a Low Emission Valve or Low Emissions Packing to replace or repack a valve if a Low Emission Valve or Low Emissions Packing is commercially unavailable. Prior to claiming this commercial unavailability exemption, Teva must contact no less than two vendors of valves or valve packing technology (as applicable) and obtain a written representation or equivalent documentation from each vendor that the particular valve or valve packing technology (as applicable) is commercially unavailable either as a Low Emission Valve or with Low Emissions Packing. In its reports submitted pursuant to Paragraph 78 (Quarterly Reports), Teva shall: (i) identify each valve for which it could not comply with the requirement to replace or repack the valve with a Low Emission Valve or Low Emissions Packing; (ii) identify the vendors it contacted to determine the unavailability of such a valve or packing technology; and (iii) include the written representations or documentation that Teva secured from each vendor regarding the unavailability.

f. Prior to installing any Low Emissions Valve or Low Emissions Packing, Teva shall secure from each manufacturer, documentation that demonstrates that the proposed

valve or packing technology meets the definition of "Low Emission Valve" and/or "Low Emissions Packing."

g. For purposes of Paragraphs 63.h – 63.i. (Equipment Replacement and Improvement Program), for each of the following types of connectors, the type of improvement shall apply as shown in Table 2.

Table 2
Connector Type Replacement or Improvement

Connector Type	**Replacement or Improvement Description**
Flanged	Replacement or Improvement of the gasket
Threaded	Replacement of connector with a like kind of connector
Compression	Replacement of connector with a like kind of connector
CamLock	Replacement of the gasket
Quick Connect	Replacement of the gasket, if applicable, or replacement of the connector (with either a like kind connector or other), if there is no gasket
Any type (including any of the above)	Elimination (e.g., through welding, pipe replacement, etc.)

h. In installing any new connector in any Covered Process Unit, Teva shall ensure that each new connector it installs is the best performing connector commercially available for the service and operating conditions for that connector after contacting no less than two vendors (i.e., not likely to leak).

i. Teva shall replace or improve each existing connector that twice in any four consecutive monitoring periods has a Screening Value at or above 250 ppm, in accordance with Table 2. Teva shall use best efforts to install a replacement or improvement that is not likely to leak, using good engineering judgment, for the service and operating conditions for that connector. Teva shall undertake the replacement or improvement within thirty (30) Days after

the monitoring event that triggers the replacement or improvement requirement, except where the replacement or improvement requires a process unit shutdown. If the replacement or improvement requires a process unit shutdown, Teva shall undertake the replacement or improvement during the first Process Unit Shutdown that follows the monitoring event that triggers the requirement to replace or improve the connector.

i. For each connector that has a Screening Value at or above 250 ppm, Teva shall not be required to comply with Paragraph 61 (Leak Repairs) pending replacement or improvement pursuant to this subparagraph, if Teva completes the replacement or improvement within thirty (30) Days of detecting the leak. If Teva does not complete the replacement or improvement within thirty (30) Days, or if, at the time of the leak detection, Teva reasonably can anticipate that it might not be able to complete the replacement or improvement within thirty (30) Days, Teva shall comply with all applicable requirements of Paragraph 61 (Leak Repairs).

ii. For each connector that has a Screening Value at or above 500 ppm, Teva shall comply with Paragraph 62 (Delay of Repair) and all repair requirements of any applicable regulation pending replacement or improvement pursuant to Paragraph 63.i.

j. In each report due under Paragraph 78 (Quarterly Reports), Teva shall include a separate section in the Report that: (i) describes the actions it took to comply with this Paragraph, including identifying each piece of equipment that triggered a requirement in this Paragraph, the Screening Value for that piece of equipment, the type of action taken *(i.e.*, replacement, repacking, improvement, or elimination), and the date when the action was taken; (ii) identifies any required actions that were not taken and explains why; and (iii) identifies the schedule for any known, future replacements, repackings, improvements, or eliminations.

64. Management of Change. Teva shall ensure that each piece of equipment added to or removed from the Facility for any reason, is evaluated to determine if it is or was subject to LDAR requirements and shall integrate into or remove from the LDAR program all such pieces of equipment. In addition, Teva shall incorporate the equipment changes made pursuant to Paragraph 63 (Equipment Replacement and Improvement Program) into the Facility-wide management of change protocol prepared pursuant to Paragraph 59 (Facility-Wide LDAR Plan).

65. Quality Assurance and Quality Control.

a. Commencing no later than one hundred eighty (180) Days after the Effective Date, on each Day that monitoring occurs, Teva shall ensure that each monitoring technician certifies that the data collected accurately represents the monitoring performed for that Day by requiring the monitoring technician to sign a form that includes the following certification:

> On [insert date], I reviewed the monitoring data that I collected today and to the best of my knowledge and belief, the data accurately represents the monitoring that I performed today.

b. Commencing no later than one hundred twenty (120) Days after the Effective Date, at unannounced times, LDAR-trained employee(s) or contractor(s) of Teva, who do not serve on a routine basis as LDAR monitoring technicians, shall undertake the following no less than twice a year of all pharmaceutical manufacturing process units at the Facility:

i. Review whether any pieces of equipment that are required to be in the LDAR program are not being included, and ensure these pieces of equipment are included;

ii. Verify that equipment was monitored at the appropriate frequency;

iii. Verify that proper documentation and sign-offs have been recorded for all equipment placed on the DOR list;

iv. Verify that repairs have been performed in the required periods;

v. Review monitoring data and equipment counts (e.g., number of pieces of equipment monitored per Day) for feasibility and unusual trends;

vi. Verify that proper calibration records and monitoring instrument maintenance information are maintained;

vii. Verify that other LDAR program records are maintained as required; and

viii. Observe each LDAR monitoring technician in the field to verify monitoring is being conducted, as required.

c. Teva shall correct any deficiencies detected or observed as soon as practicable. Teva shall maintain a log that: (i) records the date and time that the reviews, verifications, and observations required by this Paragraph were undertaken; and (ii) describes the nature and timing of any corrective actions taken.

66. LDAR Audits.

a. Within thirty (30) Days of the Effective Date, Teva shall retain a qualified, third-party auditor with experience in conducting LDAR audits. Teva shall confirm that the LDAR Auditor has no direct financial stake in the outcome of the LDAR Audit conducted pursuant to this Consent Decree. Teva shall direct the LDAR Auditor to conduct an LDAR audit to determine whether each Covered Process Unit is in compliance with all applicable LDAR regulations and the requirements of this Consent Decree, including examining each of the items listed in Paragraph 65 (Quality Assurance and Quality Control). Teva shall direct the LDAR auditor to perform such an audit at least once each calendar year until termination of the Consent Decree.

67. LDAR Corrective Action Plan.

a. If the results of an LDAR audit identify any areas of non-compliance, Teva shall develop an LDAR Corrective Action Plan. The LDAR Corrective Action Plan shall describe the actions that Teva shall take to correct the deficiencies and the schedule by which those actions shall be undertaken. Teva shall complete each corrective action as expeditiously as possible.

b. By no later than ninety (90) Days after the LDAR Audit Completion Date, Teva shall submit the LDAR Corrective Action Plan to EPA and the State, together with a certification of the completion of each required corrective action. If Teva asserts that one or more items of corrective action cannot be completed as expeditiously as possible and require more than thirty (30) Days to complete, Teva shall explain the reasons in the LDAR Corrective Action Plan, together with a proposed schedule for completion as expeditiously as practicable.

c. Unless, within thirty (30) Days after receipt of the LDAR Corrective Action Plan, EPA, after consultation with the State, disapproves in writing of all or part of a LDAR Corrective Action Plan's proposed actions and schedules, the LDAR Corrective Action Plan shall be deemed approved.

d. By no later than thirty (30) Days after receipt of the LDAR Corrective Action Plan, after consultation with the State, EPA may disapprove in writing any or all aspects of the LDAR Corrective Action Plan. Each item that is not specifically disapproved in writing shall be deemed approved. Within thirty (30) Days of receipt of any written disapproval from EPA, Teva shall resubmit the LDAR Corrective Action Plan by correcting the deficiencies that EPA identified.

68. Certification of Compliance. Within one hundred eighty (180) Days after the initial LDAR Audit Completion Date, Teva shall certify to EPA and the State that:

a. the Facility is in compliance with all applicable LDAR regulations and the LDAR requirements set forth in this Consent Decree;

b. Teva has completed all corrective actions, if applicable, or is in the process of completing all corrective actions pursuant to an LDAR Corrective Action Plan; and

c. all equipment at the Facility that is regulated under a federal, state, or local leak detection and repair program has been identified and included in the Facility's LDAR program.

E. Environmental Management System

69. Selection of EMS Consultant.

a. No later than forty-five (45) Days after the Effective Date of this Consent Decree, Teva shall submit to EPA and the State a list of two or more proposed consultants to serve as EMS Consultant, along with (a) the name, affiliation, and address of the proposed consultants; (b) information demonstrating how each proposed consultant satisfies the EMS auditor qualification requirements of Table 1 in ISO 19011 (Second edition, 2011-11-15) and has experience in developing and implementing an EMS; (c) information demonstrating that the team proposed to conduct the Initial Review and Evaluation, in composite, has a working process knowledge of the Facility or similar operations, and has a working knowledge of federal and state environmental requirements which apply to the Facility; and (d) descriptions of any previous work contracts, or financial relationships with Teva.

b. EPA, after consultation with the State, shall notify Teva of whether it approves any consultant(s) on the list. If EPA, after consultation with the State, does not

approve any of the proposed consultants on Teva's list, then Teva shall submit another list of proposed consultants to EPA and the State within thirty (30) Days of receipt of EPA's written notice. If EPA does not approve any consultant on Teva's second list, the Parties agree to resolve the selection of the EMS Consultant pursuant to Section IX (Dispute Resolution).

c. No more than forty-five (45) Days after receipt of EPA's approval, Teva shall select one consultant from those approved by EPA and shall enter into a contract with the consultant that requires the EMS Consultant to perform all duties set forth in Paragraph 70 (Duties of the EMS Consultant).

d. If Teva wishes to change the EMS Consultant during the term of this Consent Decree, Teva shall select a consultant from the list of consultants approved pursuant to Paragraph 69.b. If none of the consultants previously approved by EPA is available to perform the duties required under this Consent Decree, Teva shall propose a new consultant that meets the requirements set forth in Paragraph 69.a. Final selection of the substitute EMS Consultant shall be governed by the procedures of Paragraphs 69.b and 69.c.

e. Teva shall bear all costs associated with the EMS Consultant, cooperate fully with the EMS Consultant, and provide the EMS Consultant with access to the Facility and all records, employees, or contractors that the EMS Consultant deems reasonably necessary to effectively perform the duties described in Paragraph 70 (Duties of the EMS Consultant).

70. Duties of the EMS Consultant. Teva's contract with the EMS Consultant shall require the EMS Consultant to conduct and complete an Initial Review and Evaluation for Teva, prepare a report of the results, and provide such report to Teva within sixty (60) Days of the date of the contract. This report shall also be provided to EPA and the State, upon request. The Initial Review and Evaluation shall include, but not be limited to, an evaluation of Teva's

compliance with applicable legal requirements, including the requirements of this Consent Decree.

71. Development of the EMS.

a. Teva shall develop an integrated EMS for the Facility addressing, at a minimum, the twelve key elements in Appendix A and taking into account any areas of concern identified during the Initial Review and Evaluation required by Paragraph 70 (Duties of the EMS Consultant).

b. Within two hundred seventy (270) Days after of the date of the contract between Teva and the first EMS Consultant retained pursuant to Paragraph 69 (Selection of EMS Consultant), Teva shall submit to EPA and the State an EMS Manual. The EMS Manual shall describe and document the EMS for the Facility and contain an implementation schedule for each of the described systems and subsystems not already fully implemented. The EMS Manual shall: (i) describe or contain, as appropriate, overarching policies, procedures, and programs that compose the EMS framework, and respective management systems, subsystems, and tasks for the elements listed in Appendix A; (ii) describe specific procedures for implementing the requirements of this Consent Decree; (iii) provide specifications for the annual training required by Paragraph 75 (Training); and (iv) provide a framework and set of requirements for environmental organizational management and management notification of environmental violations.

c. EPA's review and Teva's implementation of the EMS Manual shall be governed by Paragraph 76 (Approval of Deliverables).

d. Any material revisions to the EMS Manual subsequent to its initial approval must be submitted to EPA and the State for review and approval pursuant to Paragraph 76 (Approval of Deliverables).

72. Selection of EMS Auditor.

a. Within three hundred sixty-five (365) Days of EPA's approval of the EMS Manual, Teva shall propose to EPA and the State for approval the name of two or more proposed EMS Auditors who meet the qualification requirements of Table 1 in ISO 19011 (Second edition, 2011-11-15) and have expertise and competence in the regulatory programs under federal and state environmental laws. The proposed EMS Auditors must have no direct financial stake in the outcome of the EMS Audit conducted pursuant to this Consent Decree. Teva shall disclose to EPA any past or existing contractual or financial relationships with the proposed EMS Auditors when the proposed EMS Auditors are identified.

b. EPA, in consultation with the State, shall notify Teva of whether it approves any auditor(s) on the list. If EPA, after consultation with the State, does not approve any of the proposed EMS Auditors on Teva's list, then Teva shall submit another list of proposed EMS Auditors to EPA and the State within thirty (30) Days of receipt of EPA's written notice. If EPA does not approve any auditor on Teva's second list, the Parties agree to resolve the selection of the EMS Auditor pursuant to Section IX (Dispute Resolution).

c. No more than forty-five (45) Days of the date that EPA notifies Teva of the approval of the proposed EMS Auditor, Teva shall retain the proposed EMS Auditor to perform an EMS Audit as required by Paragraph 73 (Duties of the EMS Auditor).

73. Duties of the EMS Auditor. Teva's contract with the EMS Auditor shall require the EMS Auditor to perform the following duties:

a. Within ninety (90) Days of the date Teva retains the EMS Auditor pursuant to Paragraph 72 (Selection of EMS Auditor), the EMS Auditor shall perform an audit of Teva's EMS. The audit shall evaluate the adequacy of Teva's implementation of its EMS, including whether it has complied with its EMS Manual, and identify areas of concern, from top management down, throughout each major organizational unit with responsibilities related to the Facility under the EMS Manual. The EMS Audit shall be conducted in accordance with ISO 19011 (Second edition, 2011-11-15), and shall determine the following: (i) whether there is a defined system, subsystem, program, or planned task for the respective element of the EMS; (ii) whether and to what extent the system, subsystem, program, or task has been implemented, and is being maintained; (iii) the adequacy of the Facility's internal self-assessment procedures for programs and tasks contained in the EMS; (iv) whether Teva is effectively communicating environmental requirements to affected parts of the organization, or those working on behalf of the organization; (v) whether further improvements should be made to the EMS or EMS Manual; (vi) whether there are deviations from Teva's written requirements or procedures; (vii) each of the items set forth in Paragraph 65 (Quality Assurance and Quality Control); and (viii) whether Teva is in compliance with the requirements of this Consent Decree, the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, and the Missouri Hazardous Waste Management Law, as well as their implementing regulations.

b. Within thirty (30) Days following the completion of the EMS Audit, the EMS Auditor shall develop and submit an EMS Audit Report to Teva, EPA, and the State. The

EMS Audit Report shall contain: (i) a summary of the audit process, including any obstacles encountered; (ii) detailed audit findings, including the basis for each finding and each area of concern identified; (iii) identification of any audit findings corrected or areas of concern addressed during the audit; (iv) recommendations for resolving any area of concern or otherwise achieving full implementation of the EMS Manual; and (v) certification that the EMS Audit was conducted in accordance with the provisions of this Consent Decree.

74. EMS Corrective Action Plan. No later than sixty (60) Days after receiving the EMS audit report required under Paragraph 73 (Duties of the EMS Auditor), Teva shall submit to EPA and the State a report responding to the audit findings and, if any areas of non-conformity, non-compliance or concern are identified in the EMS Audit Report, an EMS Corrective Action Plan. The EMS Corrective Action Plan shall describe the actions that Teva shall take to correct the non-conformity, non-compliance or area of concern and the schedule for completing the actions as expeditiously as possible. The plan shall include the result of any root cause analysis, specific deliverables, responsibility assignments, and an implementation schedule for the identified actions and measures, including those that may have already been completed. Review and implementation of the plan shall be governed by Paragraph 76 (Approval of Deliverables). By no later than fifteen (15) Days after the date the final corrective action is required under the approved EMS Corrective Action Plan, Teva shall submit a certification of the completion of each required corrective action.

75. Training. Teva shall provide and require annual formal training for all individuals with environmental management responsibilities at the Facility with respect to, but not limited to, compliance with the: (i) Clean Water Act and Missouri Clean Water Law; (ii) Resource Conservation and Recovery Act and Missouri Hazardous Waste Law; (iii) Clean Air Act and

Missouri Air Conservation Law; (iv) requirements in the EMS Manual; and (v) obligations in this Consent Decree.

VI. APPROVAL AND IMPLEMENTATION OF PLANS, PERMITS AND REPORTING

76. Approval of Deliverables.

a. Before providing any corrections, directions, disapprovals, or approvals pursuant to this Paragraph, EPA shall consult with the State.

b. After review of any plan, report, or other item that Teva is required to submit pursuant to this Consent Decree, EPA shall, in writing: (i) approve the submission; (ii) approve the submission upon specified conditions; (iii) approve part of the submission and disapprove the remainder; or (iv) disapprove the submission.

c. If EPA approves the submission, Teva shall take all actions required by the plan, report, or other item, in accordance with the schedules and requirements of the plan, report, or other item, as approved.

d. If EPA conditionally approves the submission or approves the submission only in part, Teva shall, upon written direction from EPA, take all actions required by the approved plan, report, or other item that EPA determines are technically severable from any disapproved portions, subject to Teva's right to dispute only the specified conditions or the disapproved portions, under Section IX (Dispute Resolution).

e. If the submission is disapproved in whole or in part:

i. Teva shall, within thirty (30) Days or such other time as the Parties agree to in writing, correct all deficiencies and resubmit the plan, report, or other item, or disapproved portion thereof, for approval, in accordance with Paragraphs 76.a - 76.d. If the resubmission is approved in whole or in part, Teva shall take all actions required by the plan,

report, or other item, in accordance with the schedules and requirements of the plan, report, or other item, as approved.

ii. Any stipulated penalties applicable to the original submission, as provided in Section VII (Stipulated Penalties), shall accrue during the 30-Day period or other specified period, but shall not be payable unless the submission is untimely or EPA disapproves the submission in whole or in part. Notwithstanding the preceding sentence, if EPA determines the original submission was so deficient as to constitute a material breach of Teva's obligations under this Consent Decree, the stipulated penalties applicable to the original submission shall be due and payable notwithstanding any subsequent resubmission.

iii. If a resubmitted plan, report, or other item, or portion thereof, is disapproved in whole or in part, EPA may again direct Teva to correct any deficiencies, in accordance with the preceding subparagraphs, or may itself correct any deficiencies, subject to Teva's right to invoke Dispute Resolution and the right of EPA to seek stipulated penalties.

77. Permits. Where any obligation under this Consent Decree requires Teva to obtain a federal, state, or local permit or approval, Teva shall submit to the appropriate agency timely and complete applications and take all other actions necessary to obtain all such permits or approvals. Teva may seek relief under the provisions of Section VIII (Force Majeure) for any delay in the performance of any such obligation resulting from a failure to obtain, or a delay in obtaining, any permit or approval required to fulfill such obligation, if Teva has submitted timely and complete applications and has taken all other actions necessary to obtain all such permits or approvals.

78. Quarterly Reports. No later than forty-five (45) Days after the end of each calendar-year quarter (*i.e.*, by May 15, August 15, November 15, and February 15) after the

Effective Date, Teva shall submit a report for the preceding quarter to the United States, EPA and the State in accordance with Paragraph 18 (Notices). Unless specified otherwise in this Consent Decree, each report shall include, at a minimum:

a. A written summary of all activities undertaken during the preceding quarter pursuant to this Consent Decree;

b. The information required by Paragraphs 45 (Hazardous Waste Accumulation Containers); 46 (Inspection Logs); 55 (Progress Reports); 56 (Completion Reports); 57 (Environmental Mitigation Reports); and 63 (Equipment Replacement and Improvement Program);

c. A written summary of any discharges to the Mexico POTW during the preceding quarter that exceeded the limits contained in Teva's Industrial User Permit;

d. A description of any non-compliance with the requirements of this Consent Decree during the preceding quarter and an explanation of the likely cause of the non-compliance and of the remedial steps taken, or to be taken, to prevent or minimize such non-compliance;

e. A certification of compliance with the approved EMS manual required by Paragraph 70 (Duties of the EMS Consultant), or, for any noncompliance, an explanation of the cause of the noncompliance and remedial steps taken or to be taken.

79. Additional Reporting. Whenever any violation of this Consent Decree or of any applicable permits or any other event affecting Teva's or its Facility's performance under this Consent Decree, may pose an immediate threat to the public health or welfare or the environment, Teva shall notify EPA and the State orally or by electronic or facsimile transmission as soon as possible, but no later than 24 hours after Teva first knew of the violation

or event. Nothing in this Paragraph relieves Teva of its obligation to provide the notice required by Section VIII (Force Majeure).

80. Certification of Reports. Each report submitted by Teva to EPA and the State under Section VI (Approval and Implementation of Plans, Permits and Reporting) shall be signed by an official of Teva and include the following certification:

> I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

This certification requirement does not apply to emergency or similar notifications where compliance would be impracticable.

81. Effect on Other Reporting Requirements. The reporting requirements of this Consent Decree do not relieve Teva of any reporting obligations required by the Clean Water Act, Clean Air Act, the Solid Waste Disposal Act or its implementing regulations, or by any other federal, state, or local law, regulation, permit, or other requirement.

82. Use of Reports. Any information provided pursuant to this Consent Decree may be used by the United States or the State in any proceeding to enforce the provisions of this Consent Decree and as otherwise permitted by law.

VII. STIPULATED PENALTIES

83. Stipulated Penalties. Teva shall be liable for stipulated penalties to the United States and the State for violations of this Consent Decree as specified below, unless excused under Section VIII (Force Majeure), including any work plan or schedule approved under this

Consent Decree, according to all applicable requirements of this Consent Decree and within the specified time schedules established by or approved under this Consent Decree.

84. Late Payment of Civil Penalty. If Teva fails to pay the civil penalty required to be paid under Section III (Civil Penalty) when due, Teva shall pay a stipulated penalty of $1,000 per Day for each Day that the payment is late.

85. Compliance Milestones. The following stipulated penalties shall accrue per violation per Day for each violation of the requirements of Paragraphs 42 (Compliance) – 77 (Permits):

Penalty Per Violation Per Day	Period of Noncompliance
$500	1st through 14th Day
$1,000	15th through 30th Day
$1,500	31st Day and beyond

86. Deliverable Requirements. The following stipulated penalties shall accrue per violation per Day for each failure to timely submit, modify, or implement, as approved, the reports plans, studies, analyses, protocols, or other deliverables required by this Consent Decree:

Penalty Per Violation Per Day	Period of Noncompliance
$250	1st through 14th Day
$500	15th through 30th Day
$750	31st Day and beyond

87. Accrual of Stipulated Penalties. Stipulated penalties under this Section shall begin to accrue on the Day after performance is due or on the Day a violation occurs, whichever is applicable, and shall continue to accrue until performance is satisfactorily completed or until

the violation ceases. Stipulated penalties shall accrue simultaneously for separate violations of this Consent Decree.

88. Payment of Stipulated Penalties. Teva shall pay any stipulated penalty within sixty (60) Days of receiving the United States' or the State's written demand. Teva shall pay 50% of the stipulated penalties to the United States in the manner set forth and with the confirmation notices required by Paragraph 36 (Payment of Civil Penalty to the United States), except that the transmittal letter shall state that the payment is for stipulated penalties and shall state for which violation(s) the penalties are being paid. Teva shall pay the remaining portion of the stipulated penalties to the State in accordance with the requirements of Paragraph 37 (Payment of Civil Penalty to the State).

89. Effect of Dispute Resolution. Stipulated penalties shall continue to accrue as provided in Paragraph 87 (Accrual of Stipulated Penalties), during any Dispute Resolution, but need not be paid until the following:

a. If the dispute is resolved by agreement or by a decision of EPA pursuant to Paragraph 98.a (Formal Dispute Resolution) that is not appealed to the Court, Teva shall pay accrued penalties determined to be owing, together with Interest, to the United States and the State, in accordance with Paragraph 88, within sixty (60) Days of the effective date of the agreement resolving the dispute or the receipt of EPA's decision or order.

b. If the dispute is appealed to the Court and the United States or the State prevails in whole or in part, Teva shall pay all accrued penalties determined by the Court to be owing, together with Interest, within sixty (60) Days of receiving the Court's decision or order, except as provided in Paragraph 89.c.

c. If any Party appeals the Court's decision, Teva shall pay all accrued penalties determined by the appellate court or the court on remand to be owing, together with Interest, no more than sixty (60) Days of receiving the final appellate court decision.

90. Interest on Unpaid Stipulated Penalties. If Teva fails to pay stipulated penalties according to the terms of this Consent Decree, Teva shall be liable for Interest on such penalties, accruing as of the date payment became due. Nothing in this Paragraph shall be construed to limit the United States or the State from seeking any remedy otherwise provided by law for Teva's failure to pay any stipulated penalties.

91. Reservation of Other Remedies. Subject to the provisions of Section X (Effect of Settlement/Reservation of Rights), the stipulated penalties provided for in this Consent Decree shall be in addition to any other rights, remedies, or sanctions available to the United States or the State for Teva's violation of this Consent Decree or applicable law. Where a violation of this Consent Decree is also a violation of statutory or regulatory requirements, Teva shall be allowed a credit, for any stipulated penalties paid, against any statutory penalties imposed for such violation.

VIII. FORCE MAJEURE

92. Definition of Force Majeure. "Force Majeure," for purposes of this Consent Decree, is defined as any event arising from causes beyond the control of Teva, of any entity controlled by Teva, or of Teva's officers, employees, agents, consultants or contractors, that delays or prevents the performance of any obligation under this Consent Decree despite Teva's best efforts to fulfill the obligation. The requirement that Teva exercise "best efforts to fulfill the obligation" includes using best efforts to anticipate any potential Force Majeure event and best efforts to address the effects of any such event (a) as it is occurring and (b) after it has occurred

to prevent or minimize any resulting delay to the greatest extent possible. "Force Majeure" does not include Teva's financial inability to perform any obligation under this Consent Decree.

93. Notification Requirements. If any event occurs or has occurred that may delay the performance of any obligation under this Consent Decree, whether or not caused by a Force Majeure event, Teva shall provide notice orally or by electronic or facsimile transmission to EPA and the State, within seventy-two (72) hours of when Teva first knew that the event might cause a delay. Within seven (7) Days thereafter, Teva shall provide in writing to EPA and the State an explanation and description of the reasons for the delay; the anticipated duration of the delay; the actions taken or to be taken to prevent or minimize the delay; a schedule for implementation of any measures to be taken to prevent or mitigate the delay or the effect of the delay; Teva's rationale for attributing such delay to a Force Majeure event if it intends to assert such a claim; and a statement as to whether, in the opinion of Teva, such event may cause or contribute to an endangerment to public health, welfare or the environment. Teva shall include with any notice all available documentation supporting the claim that the delay was attributable to a Force Majeure. Failure to comply with the above requirements shall preclude Teva from asserting any claim of Force Majeure for that event for the period of time of such failure to comply, and for any additional delay caused by such failure. Teva shall be deemed to know of any circumstance of which Teva, any entity controlled by Teva, or Teva's contractors knew or should have known.

94. Effect of Force Majeure.

a. If EPA, after consultation with the State, agrees that the delay or anticipated delay is attributable to a Force Majeure event, the time for performance of the obligations under this Consent Decree that are affected by the Force Majeure event will be extended by EPA for such time as is necessary to complete those obligations. An extension of

the time for performance of the obligations affected by the Force Majeure event shall not, of itself, extend the time for performance of any other obligation. EPA will notify Teva in writing of the length of the extension, if any, for performance of the obligations affected by the Force Majeure event.

b. If EPA, after consultation with the State, does not agree that the delay or anticipated delay has been or will be caused by a Force Majeure event, EPA will notify Teva in writing of its decision.

95. Invocation of Dispute Resolution. If Teva elects to invoke the dispute resolution procedures set forth in Section IX (Dispute Resolution), it shall do so no later than fifteen (15) business days after receipt of EPA's written notice. In any such proceeding, Teva shall have the burden of demonstrating by a preponderance of the evidence that the delay or anticipated delay has been or will be caused by a Force Majeure event, that the duration of the delay or the extension sought was or will be warranted under the circumstances, that best efforts were exercised to avoid and mitigate the effects of the delay, and that Teva complied with the requirements of Paragraphs 92 (Definition of Force Majeure) and 93 (Notification Requirements). If Teva carries this burden, the delay at issue shall be deemed not to be a violation by Teva of the affected obligation of this Consent Decree identified to the United States, EPA, the State, and if applicable, the Court.

IX. DISPUTE RESOLUTION

96. Exclusivity of Procedure. Unless otherwise expressly provided for in this Consent Decree, the dispute resolution procedures of this Section shall be the exclusive mechanism to resolve disputes arising under or with respect to this Consent Decree. The procedures set forth in this Section shall not apply to actions by the United States or the State to

enforce obligations of Teva that have not been disputed in accordance with this Section. Teva's failure to seek resolution of a dispute under this Section shall preclude Teva from raising any such issue as a defense to an action by the United States or the State to enforce any obligation of Teva arising under this Consent Decree.

97. Informal Dispute Resolution. Any dispute subject to Dispute Resolution under this Consent Decree shall first be the subject of informal negotiations. The dispute shall be considered to have arisen when Teva sends the United States and the State a written Notice of Dispute. Such Notice of Dispute shall state clearly the matter in dispute. The period of informal negotiations shall not exceed twenty (20) business days from the date the dispute arises, unless that period is modified by written agreement of all Parties. If the Parties cannot resolve a dispute by informal negotiations, then the position advanced by the United States, after consultation with the State, shall be considered binding unless, within twenty (20) business days after the conclusion of the informal negotiation period, Teva invokes formal dispute resolution procedures as set forth below.

98. Formal Dispute Resolution.

a. Teva shall invoke formal dispute resolution procedures, within the time period provided in Paragraph 97 (Informal Dispute Resolution), by serving on the United States and the State a written Statement of Position regarding the matter in dispute. The Statement of Position shall include, but need not be limited to, any factual data, analysis, or opinion supporting Teva's position and any supporting documentation relied upon by Teva.

b. The United States, after consultation with the State, shall serve its Statement of Position within forty-five (45) business days of receipt of Teva's Statement of Position. The United States' Statement of Position shall include, but need not be limited to, any

factual data, analysis, or opinion supporting that position and any supporting documentation relied upon by the United States. The State, after consultation with the United States may serve a separate Statement of Position within forty-five (45) Days of receipt of Teva's Statement of Position. The United States' Statement of Position, and if served, the State's Statement of Position, shall be binding on Teva, unless Teva files a motion, within forty-five (45) business days of receiving the United States' or the State's Statement of Position, requesting judicial review of the dispute in accordance with the following Paragraph.

99. Judicial Review

a. Teva may seek judicial review of the dispute by filing with the Court and serving on the United States and the State, in accordance with Paragraph 18 (Notices), a motion requesting judicial resolution of the dispute. The motion must be filed within ten (10) business days of receipt of the United States' Statement of Position pursuant to Paragraph 98 (Formal Dispute Resolution). The motion shall contain a written statement of Teva's position on the matter in dispute, including any supporting factual data, analysis, opinion, or documentation, and shall set forth the relief requested and any schedule within which the dispute must be resolved for orderly implementation of the Consent Decree.

b. The United States, after consultation with the State, shall respond to Teva's motion within the time period allowed by the Local Rules of this Court. Teva may file a reply memorandum, to the extent permitted by the Local Rules.

100. Standard of Review

a. Except as otherwise provided in this Consent Decree, in any dispute brought under this Section pertaining to EPA's or the State's determination regarding the adequacy or appropriateness of plans, procedures to implement plans, schedules or any other

items requiring approval by EPA and/or the State under this Consent Decree; the adequacy of the performance of work undertaken pursuant to this Consent Decree; and all other disputes that are accorded review on the administrative record under applicable principles of administrative law, Teva shall have the burden of demonstrating, based on the administrative record, that the position of the United States and/or the State is arbitrary and capricious or otherwise not in accordance with law.

b. Except as otherwise provided in this Consent Decree, in any other dispute brought under this Section, Teva shall bear the burden of demonstrating that its position complies with this Consent Decree and better furthers the objectives of the Consent Decree.

101. Effect of Dispute Resolution on Deadlines. The invocation of dispute resolution procedures under this Section IX (Dispute Resolution) shall not, by itself, extend, postpone, or affect in any way any obligation of Teva under this Consent Decree, unless and until final resolution of the dispute so provides. Stipulated penalties with respect to the disputed matter shall continue to accrue from the Day after performance is due or on the first Day of noncompliance, whichever is applicable, but payment shall be stayed pending resolution of the dispute as provided in Paragraph 89 (Effect of Dispute Resolution). If Teva does not prevail on the disputed issue, stipulated penalties shall be assessed and paid as provided in Section VII (Stipulated Penalties).

X. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS

102. Effect of Settlement. This Consent Decree resolves the civil claims of the United States and the State for the violations alleged in the Complaint filed in this action through the Date of Lodging.

103. Reservation of Rights. The United States and the State each reserves all legal and Fequitable remedies available to enforce the provisions of this Consent Decree, except as expressly stated in Paragraph 102 (Effect of Settlement). This Consent Decree shall not be construed to limit the rights of the United States or the State to obtain penalties or injunctive relief under the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, the Missouri Hazardous Waste Management Law or the implementing regulations, or under other federal or state laws, regulations, or permit conditions, except as expressly specified in Paragraph 102 (Effect of Settlement). The United States and the State each further reserve all legal and equitable remedies to address any imminent and substantial endangerment to the public health or welfare or the environment arising at, or posed by, Teva's Facility, whether related to the violations addressed in this Consent Decree or otherwise.

104. Waiver of Certain Defenses. In any subsequent administrative or judicial proceeding initiated by the United States or the State for injunctive relief, civil penalties, other appropriate relief relating to the Facility, Teva shall not assert, and may not maintain, any defense or claim based upon the principles of waiver, res judicata, collateral estoppel, issue preclusion, claim preclusion, claim-splitting, or other defenses based upon any contention that the claims raised by the United States and/or the State in the subsequent proceeding were or should have been brought in the instant case, except with respect to claims that have been specifically resolved pursuant to Paragraph 102 (Effect of Settlement).

105. Limitations on Effect of Decree.

a. This Consent Decree is not a permit, or a modification of any permit, under any federal, State, or local laws or regulations. Teva is responsible for achieving and

maintaining complete compliance with all applicable federal, State, and local laws, regulations, and permits; and Teva's compliance with this Consent Decree shall be no defense to any action commenced pursuant to any such laws, regulations, or permits, except as set forth herein. The United States and the State do not, by their consent to the entry of this Consent Decree, warrant or aver in any manner that Teva's compliance with any aspect of this Consent Decree will result in compliance with provisions of the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, the Missouri Hazardous Waste Management Law or with any other provisions of federal, State, or local laws, regulations, or permits.

b. This Consent Decree does not limit or affect the rights of Teva or of the United States or the State against any third parties, not party to this Consent Decree, nor does it limit the rights of third parties, not party to this Consent Decree, against Teva, except as otherwise provided by law.

c. This Consent Decree shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Consent Decree.

Dated and entered this __ day of _____, ____.

_____

UNITED STATES DISTRICT JUDGE
Eastern District of Missouri

WE HEREBY CONSENT to the entry of the Consent Decree in United States, et al. v. Teva Pharmaceuticals USA, Inc., subject to the public comment requirements of 28 C.F.R. § 50.7.

FOR THE UNITED STATES OF AMERICA:

March 5, 2013
Date

/s/
IGNACIA L. MORENO
Assistant Attorney General
Environment & Natural Resources Division
U.S. Department of Justice
Washington, D.C. 20530

March 14, 2013
Date

JONATHAN W. MEYER
By Special Appointment as a
Department of Justice Attorney
Environment & Natural Resources Division
U.S. Environmental Protection Agency, Region 7
11201 Renner Blvd.
Lenexa, KS 66219
Missouri Bar No. 56669
Telephone: (913) 551-7140

WE HEREBY CONSENT to the entry of the Consent Decree in United States, et al. v. Teva Pharmaceuticals USA, Inc., subject to the public comment requirements of 28 C.F.R. § 50.7.

FOR THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY:

February 26, 2013
Date

_____/s/_____
CYNTHIA GILES
Assistant Administrator
Office of Enforcement & Compliance Assurance
U.S. Environmental Protection Agency

WE HEREBY CONSENT to the entry of the Consent Decree in United States, et al. v. Teva Pharmaceuticals USA, Inc., subject to the public comment requirements of 28 C.F.R. § 50.7.

FOR THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, REGION 7:

January 31, 2013
Date

/s/
Karl Brooks
Regional Administrator, Region VII
United States Environmental Protection Agency
11201 Renner Boulevard
Lenexa, Kansas 66219

January 18, 2013
Date

/s/
David Cozad
Regional Counsel, Region VII
United States Environmental Protection Agency
11201 Renner Boulevard
Lenexa, Kansas 66219

WE HEREBY CONSENT to the entry of the Consent Decree in United States, et al. v. Teva Pharmaceuticals USA, Inc.

FOR THE STATE OF MISSOURI:

December 31, 2012
Date

/s/
KARA L. VALENTINE
Assistant Attorney General
Missouri Attorney General's Office
Missouri Bar No. 40926
P.O. Box 899
Jefferson City, MO 65102-0899
Telephone: (573) 751-3640
Fax: (573) 751-8796
Email: kara.valentine@ago.mo.gov

January 7, 2013
Date

/s/
SARA PARKER PAULEY
Director
Division of Environmental Quality
Department of Natural Resources
P.O. Box 176
Jefferson City, MO 65102-0176

WE HEREBY CONSENT to the entry of the Consent Decree in United States, et al. v. Teva Pharmaceuticals USA, Inc.

FOR TEVA:

December 28, 2012
Date

/s/
Signature

Name: Deborah A. Griffin
Title: VP and CFO
Address: 1090 Horsham Road
North Wales, PA 19454

December 28, 2012
Date

/s/
Signature

Name: Carey Case
Title: Plant Manager
Address: 5000 Snyder Drive
Mexico, MO 65265

APPENDIX A

COMPLIANCE-FOCUSED ENVIRONMENTAL MANAGEMENT SYSTEM ELEMENTS

United States, et al. v. Teva Pharmaceuticals USA, Inc.

1. Environmental Policy

a. This policy, upon which the EMS is based, must clearly communicate management commitment to achieving compliance with applicable federal, state, and local environmental statutes, regulations, enforceable agreements, and permits (hereafter, "environmental requirements"), minimizing risks to the environment from unplanned or unauthorized releases of hazardous or harmful contaminants, and continual improvement in environmental performance. The policy should also state management's intent to provide adequate personnel and other resources for the EMS.

2. Organization, Personnel, and Oversight of EMS

a. Identifies and defines specific duties, roles, responsibilities, and authorities of key environmental staff in implementing and sustaining the EMS (e.g., could include position descriptions and/or performance standards for all environmental department personnel, and excerpts from others having specific environmental duties, and regulatory compliance responsibilities).

b. Includes organization charts that identify units, line management, and other individuals having environmental duties and regulatory compliance responsibilities.

c. Includes ongoing means of communicating environmental issues and information among the various levels and functions of the organization, to include all persons working for or on behalf of the organization (e.g., on-site service providers and contractors who function as *de facto* employees), and for receiving and addressing their concerns.

3. Accountability and Responsibility

a. Specifies accountability and environmental responsibilities of organization's managers, and managers of other organizations acting on its behalf for environmental protection and risk reduction measures, assuring compliance, required reporting to regulatory agencies, and corrective actions implemented in their area(s) of responsibility.

b. Describes incentive programs for managers and employees to perform in accordance with compliance policies, standards, and procedures.

c. Describes potential consequences for departure from specified operating procedures,

including liability for civil/administrative penalties imposed as a result of noncompliance.

4. Environmental Requirements

a. Describes process for identifying potentially applicable environmental requirements; interpreting their applicability to specific operations, emissions, and waste streams; and effectively communicating those applicable environmental requirements to affected persons working for or on behalf of the organization.

b. Describes a process for developing, implementing and maintaining ongoing internal compliance monitoring to ensure that facility activities conform to applicable environmental requirements. Compliance monitoring shall include inspections and measurements, as appropriate.

c. Describes procedures for prospectively identifying and obtaining information about changes and proposed changes in environmental requirements, and incorporating those changes into the EMS (i.e., regulatory "change management").

d. Describes a procedure for communicating with regulatory agencies regarding environmental requirements and regulatory compliance.

5. Assessment, Prevention, and Control

a. Identifies an ongoing process for assessing operations, for the purposes of preventing, controlling, or minimizing reasonably foreseeable releases, environmental process hazards, and risks of noncompliance with environmental requirements. This process shall include identifying operations and waste streams where equipment malfunctions and deterioration, and/or operator errors or deliberate malfeasance, are causing, or have the potential to cause: (1) unplanned or unauthorized releases of hazardous or harmful contaminants to the environment, (2) a threat to human health or the environment, or (3) noncompliance with environmental requirements.

b. Describes process for identifying operations and activities where documented operating criteria, such as standard operating procedures (SOPs), are needed to prevent noncompliance or unplanned/unauthorized releases of hazardous or harmful contaminants, and defines a uniform process for developing, approving and implementing the documented operating criteria.

c. Describes a system for conducting and documenting routine, objective, self-inspections by department supervisors and trained staff, especially at locations identified by the process described in (a) above, to check for malfunctions, deterioration, worker adherence to operating criteria, unusual situations, and unauthorized or unplanned releases.

d. Describes a "management of change" process to ensure identification and consideration of environmental requirements, the environmental aspects/impacts, and potential operator errors or deliberate malfeasance during planning, design, and operation of ongoing, new, and/or changing buildings, processes, equipment, maintenance activities, and products.

6. Environmental Incident and Non-compliance Investigations

a. Describes standard procedures and requirements for internal and external reporting of environmental incidents and noncompliance with environmental requirements.

b. Establishes procedures for investigation, and prompt and appropriate correction of noncompliance. The investigation process includes root-cause analysis of identified problems to aid in developing the corrective actions.

c. Describes a system for development, tracking, and effectiveness verification of corrective and preventative actions.

7. Environmental Training, Awareness, and Competence

a. Identifies specific education and training required for organization personnel or those acting on its behalf, as well as process for documenting training provided

b. Describes program to ensure that organization employees or those acting on its behalf are aware of its environmental policies and procedures, environmental requirements, and their roles and responsibilities within the environmental management system.

c. Describes program for ensuring that personnel responsible for meeting and maintaining compliance with environmental requirements are competent on the basis of appropriate education, training, and/or experience.

d. Identifies training on how to recognize operations and waste streams where equipment malfunctions and deterioration, and/or operator errors or deliberate malfeasance, are causing, or have the potential to cause: (1) unplanned or unauthorized releases of hazardous or harmful contaminants to the environment, (2) a threat to human health or the environment, or (3) noncompliance with environmental requirements.

8. Environmental Planning and Organizational Decision-Making

a. Describes how environmental planning will be integrated into organizational decision-making, including plans and decisions on capital improvements, product and process design, training programs, and maintenance activities.

b. Requires establishing, on an annual basis, written targets, objectives, and action plans for improving environmental performance, by at least each operating organizational subunit with environmental responsibilities, as appropriate, including those for contractor operations conducted at the facility, and how specified actions will be tracked and progress reported. Targets and objectives must include actions that reduce the risk of noncompliance with environmental requirements and minimize the potential for unplanned or unauthorized releases of hazardous or harmful contaminants.

9. Maintenance of Records and Documentation

a. Identifies the types of records developed in support of the EMS (including audits and reviews), who maintains them and, where appropriate, security measures to prevent their unauthorized disclosure, and protocols for responding to inquiries and requests for release of information.

b. Specifies the data management systems for any internal waste tracking, environmental data, and hazardous waste determinations.

c. Specifies document control procedures.

10. Pollution Prevention

a. Describes an internal process or procedure for preventing, reducing, recycling, reusing, and minimizing waste and emissions, including incentives to encourage material substitutions. Also includes mechanisms for identifying candidate materials to be addressed by the pollution prevention program and tracking progress.

11. Continuing Program Evaluation and Improvement

a. Describes program for periodic (at least annually) evaluation of the EMS, which specifies a process for translating assessment results into EMS improvements. The program shall include communicating findings and action plans to affected organization employees or those acting on its behalf.

b. Describes a program for periodic audits (at least annually) of facility compliance with environmental requirements by an independent auditor(s). Audit results are reported to upper management and instances of noncompliance are addressed through the process described in element 6 above.

12. Public Involvement/Community Outreach

a. Describes a program for ongoing community education and involvement in the environmental aspects of the organization's operations and general environmental awareness.

APPENDIX B – Clean Water Act Permit Exceedances

Date	Conventional Pollutants Mass (lbs/d)						Categorical Standards Concentration (mg/l)								Water Quality Standard (Color)
	BOD		TSS		NH3		Acetone		Toluene		Methylene Chloride		Triethylamine		
	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo. Ave	Dmax	Mo. Ave	Dmax	Mo Ave	Dmax	Mo. Ave	
	1125	1125	1125	1125	375	375	20.7	8.2	0.3	0.1	3.0	0.7	255	100	
Jan-06		3891				539		601						620	
¼/2006	3981				438								620		
1/11/2006	4227				544		441								
1/18/2006	3863				450		381								
1/25/2006	3495				723		982								
Feb-06		4220				***720***		375							
2/1/2006	4237				697		562								
2/8/2006	3798				628		297								
2/15/2006	4192				775		221								
2/22/2006	***4653***				781		419								
Mar-06		***5338***				***848***		151						700	
3/1/2006	3153				***589***								700		
3/8/2006	***6899***				***956***		231								
3/15/2006	***7752***				***1084***		128								
3/22/2006	***5762***				***850***		94								
3/29/2006	3125				***760***										
Apr-06		3801				462				3.95					
4/5/2006	***4992***				568				3.95						
4/12/2006	3463				435										
4/19/2006	2827				401										
4/26/2006	3920				446										
May-06		2728				424				1.96					
5/2/2006									1.96						
5/3/2006	3700				398										
5/10/2006	2925				381										

Date	Conventional Pollutants Mass (lbs/d)						Categorical Standards Concentration (mg/l)								Water Quality Standard (Color)
	BOD		TSS		NH3		Acetone		Toluene		Methylene Chloride		Triethylamine		
	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo. Ave	Dmax	Mo. Ave	Dmax	Mo Ave	Dmax	Mo. Ave	
	1125	1125	1125	1125	375	375	20.7	8.2	0.3	0.1	3.0	0.7	255	100	
5/31/2006	***5139***				***679***										
Jun-06		1877				464						94.2			
6/7/2006	2870				552						94.2				
6/14/2006	1346				***594***										
6/21/2006	3241				***702***										
Aug-06															
8/16/2006			1454												
8/30/2006			1211												
Sep-06												5.52			
9/6/2006											5.52				
Oct-06															
10/11/2006			1249												
Dec-06								8.9							
12/13/2006							30.4								
Jan-07															
1/10/2007					527										
1/31/2007					410										
Mar-07				4855		***673***									
3/14/2007					393										
3/21/2007			***9356***		***1641***										
3/28/2007			***8425***												
Apr-07				2624											
4/4/2007			***5768***												
4/11/2007			1822												
4/25/2007			2477												
May-07								31.9							
5/23/2007							158								

Date	Conventional Pollutants Mass (lbs/d)						Categorical Standards Concentration (mg/l)								Water Quality Standard (Color)
	BOD		TSS		NH3		Acetone		Toluene		Methylene Chloride		Triethylamine		
	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo. Ave	Dmax	Mo. Ave	Dmax	Mo Ave	Dmax	Mo. Ave	
	1125	1125	1125	1125	375	375	20.7	8.2	0.3	0.1	3.0	0.7	255	100	
5/30/2007	1251														
Jun-07						***706***									
6/6/2007	2661				***758***										
6/13/2007					574										
6/20/2007					***594***										
6/27/2007					***897***										
Jul-07															
Aug-07						444									
8/8/2007					445										
8/15/2007					400										
8/22/2007					492										
8/29/2007					541										
Sep-07										0.455					
9/5/2007									0.455						
Oct-07						396		9.69							
10/24/2007	1380				571		47.1								
10/31/2007	1444		1245		***809***										
Nov-07		1484		1851				37.66		0.271					
11/7/2007	1221		1313		***684***										
11/15/2007							146								
11/21/2007	2497		2820		387										
11/28/2007	2148		3161		382										
Dec-07		2837		2161				54.6							
12/5/2007	2489		2725												
12/12/2007	2484		2767				33								
12/19/2007	***5016***		1719		547		140								
12/26/2007	1360		1431												

	Conventional Pollutants Mass (lbs/d)						Categorical Standards Concentration (mg/l)								Water Quality Standard (Color)
	BOD		TSS		NH3		Acetone		Toluene		Methylene Chloride		Triethylamine		
	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo. Ave	Dmax	Mo. Ave	Dmax	Mo Ave	Dmax	Mo. Ave	
Date	1125	1125	1125	1125	375	375	20.7	8.2	0.3	0.1	3.0	0.7	255	100	
12/27/2007							30.4								
Jan-08		1645						12.2							
½2008	2699		2253				42.6								
1/9/2008	1219														
1/16/2008	1911														
1/23/2008	1229														
1/30/2008	1165														
Feb-08															
2/6/2008	2079														
2/20/2008					464										
2/27/2008					465										
Mar-08						406				1.29		2.67			
3/5/2008					479				1.29						
3/12/2008					510										
Apr-08												1.42			
May-08										0.149					
Jun-08										0.138					
Jul-08															
7/30/2008	1420														
Aug-08										0.912		0.95			
8/20/2008	1256								2.64						
Sep-08															
9/17/2008					397										
Oct-08										16.74					
10/5/2008									5.82						
10/18/2008									44.4						
Nov-08		1493		1562						0.649					

	Conventional Pollutants Mass (lbs/d)						Categorical Standards Concentration (mg/l)								Water Quality Standard (Color)
	BOD		TSS		NH3		Acetone		Toluene		Methylene Chloride		Triethylamine		
	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo.ave	Dmax	Mo. Ave	Dmax	Mo. Ave	Dmax	Mo Ave	Dmax	Mo. Ave	
Date	1125	1125	1125	1125	375	375	20.7	8.2	0.3	0.1	3.0	0.7	255	100	
11/2/2008	1882		2038						3.66						
11/4/2008	2289		2160		506				1.92						
11/5/2008	1134														
11/9/2008	2028		2431		481										
11/11/2008	2379		2369		482										
11/16/2008	2637		3273		452										
11/18/2008	1184		1481												
11/19/2008															
11/2008-12/2008															
11/26/2008	1335														
Mar-09															
3/31/2009					386										
Apr-09															
4/8/2009					453										

APPENDIX C – ENVIRONMENTAL MITIGATION PROJECT SCHEDULE

Implementation Schedule
WWTP Optimization and MeCl2 Vacuum Stripping HAP Reduction Projects
Teva Pharmaceuticals USA Inc. - Mexico, Missouri

Permanent HAP Mitigation Projects	Anticipated Steps	Completion Schedule from Effective Date of Consent Decree [1]
WWTP Optimization to minimize HAP stripping: 1) Elimination of surface aerators in both basins, with installation of new aeration basin mixed liquor cooling system and defoamer application system to replace current primary functions of the surface aerators in both aeration basins. 2) Automate diffused aeration system serving both aeration basins with a variable frequency drive (VFD) on one blower controlled from dissolved oxygen (DO) sensors in both basins to minimize diffused air rate.	Apply for Industrial User Permit Modification to Cover Proposed Changes to WWTP	1 month
	POTW approval of Industrial User Permit Modification	8 months
	Complete air permit determination, obtain MDNR confirmation that project is exempt from construction permitting	4 months
	Prepare construction permit application if MDNR does not concur with exemption; plus allocation of 3 months for MDNR to develop construction permit	8 months
	Acquire heat exchanger and other ancillary equipment needed to cool aeration basin mixed liquor	14 months
	Acquire VFD for blower, basin DO sensors and other required ancillary equipment	11 months
	Design alternative defoamer application system	4 months
	Install DO sensors and control system to modulate diffused air rate in basins	13 months
	Complete installation of the heat exchanger and required ancillary equipment, and install pumps, piping an nozzles required for new defoamer application system	16 months
	Start-up and shake-down of WWTP optimization systems; remove surface aerators	18 months
Vacuum Stripping of the four targeted Amoxicillin Process wastewater streams to minimize MeCl2 load to the WWTP	Complete air permit determination, verify exemption from construction permitting	4 months
	Prepare construction permit application if MDNR does not concur with exemption; plus allocation of 3 months for MDNR to develop construction permit	8 months
	Design new piping systems to transfer target WW streams to reactor R-306 for stripping	3 months
	Design new vacuum pump system for R-306 to vacuum strip MeCl2 from WW streams	3 months
	Acquire new dry vacuum pump and all associated ancillary equipment to retrofit R-306	12 months
	Install new piping and vacuum pump system for MeCl2 stripping of target WW streams	14 months
	Start-up and shake-down of new R-306 vacuum stripping system	16 months

(1) All time intervals in the schedule run from the Effective Date of the Consent Decree.