



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

Central Regional Office • 627 Main Street, Worcester MA 01608 • 508-792-7650

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October 25, 2012

Mr. George Mwangi
AstraZeneca LP
50 Otis Street
Westborough, MA 01581

RE: Westborough
Transmittal No.: X252153
Application No.: CE-12-022
Class: *NM99*
FMF No.: 130627
AIR QUALITY PLAN APPROVAL

Dear Mr. Mwangi:

The Massachusetts Department of Environmental Protection (“MassDEP”), Bureau of Waste Prevention, has reviewed your Limited Plan Application (“Application”) listed above. This Application concerns the proposed replacement of your existing Non-Major Comprehensive Plan Approval with a Limited Plan Approval at your pharmaceutical facility located at 50 Otis Street in Westborough, Massachusetts (“Facility”).

This Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 “Air Pollution Control” regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-J, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP’s review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner/operator (“Permittee”) must comply in order for the Facility to be operated in compliance with this Plan Approval.

This Plan Approval supersedes Plan Approval Transmittal #W005664 issued May 3, 2000.

1. DESCRIPTION OF FACILITY AND APPLICATION

In 1980 this Facility was constructed and started operation as Astra Pharmaceutical. In 1999 the facility became known as Astra Zeneca, L.P. ("the Permittee") following a merger with Zeneca. In 2000 MassDEP issued a Plan Approval under Transmittal #W005664 to establish federally enforceable limits on the potential to emit volatile organic compounds ("VOC"). At that time, the primary source of the Facility's emissions was the use of isopropyl alcohol ("IPA") in the research and development ("R&D") processes. For the past several years, the R&D activities have either ceased or been relocated to other facilities, leading to reduced VOC emissions. On July 27, 2012, the Permittee submitted the present application in order to revise the Facility emission limits to more accurately reflect current and future operations at this Facility. The Facility-Wide potential to emit of VOC will be lowered from 11.1 tons per year to 8.8 tons per year.

Emissions of VOC are generated from the use of isopropyl alcohol ("IPA") for sanitary wiping of surfaces (sterilizing). There are several minor, incidental uses of VOC associated with a cold cleaner and packaging of pharmaceuticals. All of these uses of VOC are considered Process VOC and grouped under the Facility designation of Emission Unit ("EU") #8. VOC emissions are also generated from the use of VOC containing inks and cleaners for a series (up to 15) of small Videojet printers. The Videojet printers are designated as Facility EU #12. MassDEP has determined that Best Available Control Technology ("BACT") for the VOC emissions is the use of Best Management Practices ("BMP") to control the usage of VOC-containing solvents and emissions therefrom.

Small amounts of VOC are generated from combustion of fuels in fuel burning equipment. Three boilers and two emergency generators, previously approved or certified with MassDEP, are in operation. No fuel burning equipment is being added or affected by this Plan Approval. The total calculated VOC emissions from the fuel burning equipment are included here as part of total facility VOC emissions.

2. EMISSION UNIT (EU) IDENTIFICATION

Each Emission Unit (EU) identified in Table 1 is subject to and regulated by this Plan Approval:

Table 1			
EU#	Description	Design Capacity	Pollution Control Device (PCD)
8	Process VOC (Sanitizing & Sterilization)	n/a	none
12	VideoJet Ink Printers model no. 1610 (15 total)	n/a	none

Table 1			
EU#	Description	Design Capacity	Pollution Control Device (PCD)
Facility Wide Combustion Equipment EU's	All Combustion Sources (Boilers and Emergency Generators)	Various as Detailed in Source Registration/ Emission Statement	none

Table 1 Key:

EU# = Emission Unit Number
 PCD = Pollution Control Device

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION and EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2:

Table 2			
EU#	Operational / Production Limit	Air Contaminant	Emission Limit
8	The Permittee shall restrict the usage of materials as necessary to achieve the emission limits.	VOC (Note 1)	1.25 TPM, 5.0 TPY
		HAP	0.1 TPM, 1.0 TPY
12	The Permittee shall restrict the usage of materials as necessary to achieve the emission limits.	VOC (Note 2)	0.38 TPM, 1.5 TPY
		HAP	0 TPY
Facility-wide Combustion Equipment	The Permittee shall restrict the burning of fuel in the equipment as necessary to achieve the emission limits.	VOC (Note 3)	0.56 TPM, 2.3 TPY
Facility-Wide Total		VOC	2.19 TPM, 8.8 TPY
		HAP	0.1 TPM, 1.0 TPY

Table 2 Footnotes:

1. Based on actual IPA and methanol usage minus VOC in waste.
2. Based on VOC content of ink and actual usage.
3. Based on VOC emission factors contained in USEPA's AP-42.

Table 2 Key:

EU# = Emission Unit Number
 VOC = Volatile Organic Compounds
 HAP = total Hazardous Air Pollutants.
 TPM = tons per month
 TPY = tons per consecutive 12-month period
 USEPA = United States Environmental Protection Agency

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, record keeping, and reporting requirements as contained in Tables 3, 4, and 5:

Table 3	
EU#	Monitoring and Testing Requirements
8 & 12	1. Monitor usage and waste generation of VOC/HAP solvents and inks in order to calculate VOC and HAP emissions.
Fuel Burning EU's	2. Monitor fuel usage in order to calculate VOC emissions from fuel burning.
Facility-wide	3. The Permittee shall monitor all operations to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.
	4. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with USEPA Reference Test Methods and Regulation 310 CMR 7.13

Table 3 Key:

EU# = Emission Unit Number
 VOC = Volatile Organic Compounds
 HAP = total Hazardous Air Pollutants.

Table 4	
EU#	Record Keeping Requirements
Facility-wide	<p>1. The Permittee shall maintain adequate records on-site to demonstrate compliance with all operational, production, and emission limits contained in Table 2 above. Records shall also include the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve-month period (current month plus prior eleven months). These records shall be compiled no later than the 15th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/dep/air/approvals/aqforms.htm#report .</p>
	<p>2. The Permittee shall maintain records of monitoring and testing as required by Table 3.</p>
	<p>3. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date SOMP for the EU(s) approved herein on-site.</p>
	<p>4. The Permittee shall maintain a record of routine maintenance activities performed on the approved EU(s). The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed.</p>
	<p>5. The Permittee shall maintain a record of all malfunctions affecting air contaminant emission rates on the approved EU(s) and monitoring equipment. At a minimum, the records shall include: date and time the malfunction occurred; description of the malfunction; corrective actions taken; the date and time corrective actions were initiated and completed; and the date and time emission rates and monitoring equipment returned to compliant operation.</p>
	<p>6. The Permittee shall maintain records to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.</p>
	<p>7. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years.</p>
	<p>8. The Permittee shall make records required by this Plan Approval available to MassDEP and USEPA personnel upon request.</p>

Table 4 Key:

EU# = Emission Unit Number

SOMP = Standard Operating and Maintenance Procedure

USEPA = United States Environmental Protection Agency

Table 5	
EU#	Reporting Requirements
Facility-wide	1. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a “Responsible Official” as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c).
	2. The Permittee shall notify the Central Regional Office of MassDEP, BWP Permit Chief by telephone: 508-767-2845 , email: CERO.Air@massmail.state.ma.us or fax : 508-792-7621, as soon as possible, but no later than one (1) business day after discovery of an exceedance(s) of Table 2 requirements. A written report shall be submitted to Permit Chief at MassDEP within three (3) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s).
	3. The Permittee shall report every three years to MassDEP, in accordance with 310 CMR 7.12, all information as required by the Source Registration/Emission Statement Form. The Permittee shall note therein any minor changes (under 310 CMR 7.02(2)(e), 7.03, 7.26, etc.), which did not require Plan Approval.
	4. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval within 30-days from MassDEP’s request.
	5. The Permittee shall submit to MassDEP for approval a stack emission pretest protocol, at least 30 days prior to emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements.
	6. The Permittee shall submit to MassDEP a final stack emission test results report, within 45 days after emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements.

Table 5 Key:
 EU# = Emission Unit Number

4. SPECIAL TERMS AND CONDITIONS

The Permittee is subject to, and shall comply with, the following special terms and conditions:

- A. The Permittee is subject to and shall comply with the Special Terms and Conditions as contained in Table 6:

Table 6	
EU#	Special Terms and Conditions
8 & 12	1. BMPs for VOC—The Permittee shall use Best Management Practices ("BMP") to reduce emissions of Volatile Organic Compounds ("VOC") and Hazardous Air Pollutants ("HAP"). BMP will include, but is not limited to, investigating the reduction of usage of VOC containing materials, and limiting their usage consistent with sterilization and quality control standards.

Table 6 Key:

EU# = Emission Unit Number
 VOC = Volatile Organic Compounds
 HAP = total Hazardous Air Pollutants.
 BMP = Best Management Practices

5. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

- A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).
- B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.
- C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.
- D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and / or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.
- E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.

- F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.
- G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.
- H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.
- I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.
- J. The Permittee shall conduct emission testing, if requested by MassDEP, in accordance with USEPA Reference Test Methods and regulation 310 CMR 7.13. If required, a pretest protocol report shall be submitted to MassDEP at least 30 days prior to emission testing and the final test results report shall be submitted within 45 days after emission testing.
- K. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

6. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain “Fail-Safe Provisions,” which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

7. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars (\$100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Enclosed is a stamped approved copy of the application submittal.

Should you have any questions concerning this Plan Approval, please contact Paul Dwiggin by telephone at 508-767-2760, or in writing at the letterhead address.

This final document copy is being provided to you electronically by the Department of Environmental Protection. A signed copy of this document is on file at the DEP office listed on the letterhead.

Roseanna E. Stanley
Acting Permit Chief
Bureau of Waste Prevention

Enclosure

ecc: Westborough Board of Health
Westborough Fire Department
MassDEP/Boston - Yi Tian
P. Kuszpa, AMEC