

AMENDED ENVIRONMENTAL COMPLIANCE APPROVAL

NUMBER 3932-C3SSM5
Issue Date: June 28, 2021

Mylan Pharmaceuticals ULC
85 Advance Road
Etobicoke, Ontario
M8Z 2S6

Site Location: 85 Advance Road
Toronto City
M8Z 2S6

You have applied under section 20.2 of Part II.1 of the Environmental Protection Act, R.S.O. 1990, c. E. 19 (Environmental Protection Act) for approval of:

Description Section

A facility used for conducting QA/QC work on pharmaceutical items which are manufactured elsewhere, consisting of the following processes and support units:

- laboratory fumehoods;
- grinding;
- drying;

including the Equipment and any other ancillary and support processes and activities, operating at a Facility Production Limit of up to 30,000 pharmaceutical tablets per hour, and discharging to the air as described in the Original ESDM Report.

For the purpose of this environmental compliance approval, the following definitions apply:

1. "ACB list" means the document entitled "Air Contaminants Benchmarks (ACB) List: Standards, guidelines and screening levels for assessing point of impingement concentrations of air contaminants", as amended from time to time and published by the Ministry and available on a

Government website;

2. "Acceptable Point of Impingement Concentration" means a concentration accepted by the Ministry as not likely to cause an adverse effect for a Compound of Concern that,
 - a. is not identified in the ACB list, or
 - b. is identified in the ACB list as belonging to the category "Benchmark 2" and has a concentration at a Point of Impingement that exceeds the concentration set out for the contaminant in that document.

With respect to the Original ESDM Report, the Acceptable Point of Impingement Concentration for a Compound of Concern mentioned above is the concentration set out in the Original ESDM Report;

3. "Acoustic Assessment Report" means the report, prepared in accordance with Publication NPC-233 and Appendix A of the Basic Comprehensive User Guide, prepared by Amir Iravani / Dillon Consulting Limited and dated August 2020, submitted in support of the application, that documents all sources of noise emissions and Noise Control Measures present at the Facility, as updated in accordance with Condition 5 of this Approval;
4. "Acoustic Assessment Summary Table" means a table prepared in accordance with the Basic Comprehensive User Guide summarising the results of the Acoustic Assessment Report, as updated in accordance with Condition 5 of this Approval;
5. "Acoustic Audit" means an investigative procedure consisting of measurements and/or acoustic modelling of all sources of noise emissions due to the operation of the Facility, assessed to determine compliance with the Performance Limits for the Facility regarding noise emissions, completed in accordance with the procedures set in Publication NPC-103 and reported in accordance with Publication NPC-233;
6. "Acoustic Audit Report" means a report presenting the results of an Acoustic Audit, prepared in accordance with Publication NPC-233;
7. "Acoustical Consultant" means a person currently active in the field of environmental acoustics and noise/vibration control, who is familiar with Ministry noise guidelines and procedures and has a combination of formal university education, training and experience necessary to assess noise emissions from a Facility;
8. "Approval" means this entire Environmental Compliance Approval and any Schedules to it;
9. "Basic Comprehensive User Guide" means the Ministry document titled "Basic Comprehensive Certificates of Approval (Air) User Guide" dated March 2011, as amended;
10. "Company" means Mylan Pharmaceuticals ULC that is responsible for the construction or operation

- of the Facility and includes any successors and assigns in accordance with section 19 of the EPA;
11. "Compound of Concern" means a contaminant described in paragraph 4 subsection 26 (1) of O. Reg. 419/05, namely, a contaminant that is discharged from the Facility in an amount that is not negligible;
 12. "Description Section" means the section on page one of this Approval describing the Company's operations and the Equipment located at the Facility and specifying the Facility Production Limit for the Facility;
 13. "Director" means a person appointed for the purpose of section 20.3 of the EPA by the Minister pursuant to section 5 of the EPA;
 14. "District Manager" means the District Manager of the appropriate local district office of the Ministry, where the Facility is geographically located;
 15. "Emission Summary Table" means a table described in paragraph 14 of subsection 26 (1) of O. Reg. 419/05;
 16. "Environmental Assessment Act" means the *Environmental Assessment Act*, R.S.O. 1990, c.E.18;
 17. "EPA" means the *Environmental Protection Act*, R.S.O. 1990, c.E.19;
 18. "Equipment" means equipment or processes described in the ESDM Report, this Approval and in the Schedules referred to herein and any other equipment or processes;
 19. "Equipment with Specific Operational Limits" means any Equipment related to the thermal oxidation of waste or waste derived fuels, fume incinerators or any other Equipment that is specifically referenced in any published Ministry document that outlines specific operational guidance that must be considered by the Director in issuing an Approval;
 20. "ESDM Report" means the most current Emission Summary and Dispersion Modelling Report that describes the Facility. The ESDM Report is based on the Original ESDM Report and is updated after the issuance of this Approval in accordance with section 26 of O. Reg. 419/05 and the Procedure Document;
 21. "Facility" means the entire operation located on the property where the Equipment is located;
 22. "Facility Production Limit" means the production limit placed by the Director on the main product(s) or raw materials used by the Facility;
 23. "Independent Acoustical Consultant" means an Acoustical Consultant who is not representing the Company and was not involved in preparing the Acoustic Assessment Report or the design/implementation of Noise Control Measures for the Facility and/or Equipment. The Independent Acoustical Consultant shall not be retained by the Acoustical Consultant involved in the

noise impact assessment or the design/implementation of Noise Control Measures for the Facility and/or Equipment;

24. "Log" means a document that contains a record of each change that is required to be made to the ESDM Report and Acoustic Assessment Report, including the date on which the change occurred. For example, a record would have to be made of a more accurate emission rate for a source of contaminant, more accurate meteorological data, a more accurate value of a parameter that is related to a source of contaminant, a change to a Point of Impingement and all changes to information associated with a Modification to the Facility that satisfies Condition 2;
25. "Minister" means the Minister of the Environment, Conservation and Parks or such other member of the Executive Council as may be assigned the administration of the EPA under the Executive Council Act;
26. "Ministry" means the ministry of the Minister;
27. "Modification" means any construction, alteration, extension or replacement of any plant, structure, equipment, apparatus, mechanism or thing, or alteration of a process or rate of production at the Facility that may discharge or alter the rate or manner of discharge of a Compound of Concern to the air or discharge or alter noise or vibration emissions from the Facility;
28. "Noise Control Measures" means measures to reduce the noise emissions from the Facility and/or Equipment including, but not limited to, silencers, acoustic louvres, enclosures, absorptive treatment, plenums and barriers;
29. "O. Reg. 419/05" means Ontario Regulation 419/05: Air Pollution – Local Air Quality, made under the EPA;
30. "Original ESDM Report" means the Emission Summary and Dispersion Modelling Report which was prepared in accordance with section 26 of O. Reg. 419/05 and the Procedure Document by Dillon Consulting Limited and dated August 21, 2020 submitted in support of the application, and includes any changes to the report made up to the date of issuance of this Approval;
31. "Point of Impingement" has the same meaning as in section 2 of O. Reg. 419/05;
32. "Point of Reception" means Point of Reception as defined by Publication NPC-300;
33. "Procedure Document" means Ministry guidance document titled "Procedure for Preparing an Emission Summary and Dispersion Modelling Report" dated March 2018, as amended;
34. "Processes with Significant Environmental Aspects" means the Equipment which, during regular operation, would discharge one or more contaminants into the air in an amount which is not considered as negligible in accordance with section 26 (1) 4 of O. Reg. 419/05 and the Procedure Document;

35. Publication NPC-103" means the Ministry Publication NPC-103 of the Model Municipal Noise Control By-Law, Final Report, August 1978, published by the Ministry as amended;
36. "Publication NPC-207" means the Ministry draft technical publication "Impulse Vibration in Residential Buildings", November 1983, supplementing the Model Municipal Noise Control By-Law, Final Report, published by the Ministry, August 1978, as amended;
37. "Publication NPC-233" means the Ministry Publication NPC-233, "Information to be Submitted for Approval of Stationary Sources of Sound", October, 1995, as amended;
38. "Publication NPC-300" means the Ministry Publication NPC-300, "Environmental Noise Guideline, Stationary and Transportation Sources – Approval and Planning, Publication NPC-300", August 2013, as amended;
39. "Schedules" means the following schedules attached to this Approval and forming part of this Approval namely:
 - Schedule A - Supporting Documentation
40. "Toxicologist" means a qualified professional currently active in the field of risk assessment and toxicology that has a combination of formal university education, training and experience necessary to assess contaminants; and
41. "Written Summary Form" means the electronic questionnaire form, available on the Ministry website, and supporting documentation, that documents the activities undertaken at the Facility in the previous calendar year.

You are hereby notified that this environmental compliance approval is issued to you subject to the terms and conditions outlined below:

TERMS AND CONDITIONS

1. GENERAL

1. Except as otherwise provided by this Approval, the Facility shall be designed, developed, built, operated and maintained in accordance with the terms and conditions of this Approval and in accordance with the following Schedules attached hereto:
 - Schedule A - Supporting Documentation

2. LIMITED OPERATIONAL FLEXIBILITY

1. Pursuant to section 20.6 (1) of the EPA and subject to Conditions 2.2 and 2.3 of this Approval, future construction, alterations, extensions or replacements are approved in this Approval if the

future construction, alterations, extensions or replacements are Modifications to the Facility that:

- a. are within the scope of the operations of the Facility as described in the Description Section of this Approval;
 - b. do not result in an increase of the Facility Production Limit above the level specified in the Description Section of this Approval; and
 - c. result in compliance with the performance limits as specified in Condition 4.
2. Condition 2.1 does not apply to,
- a. the addition of any new Equipment with Specific Operational Limits or to the Modification of any existing Equipment with Specific Operational Limits at the Facility; and
 - b. Modifications to the Facility that would be subject to the Environmental Assessment Act.
3. Condition 2.1 of this Approval shall expire ten (10) years from the date of this Approval, unless this Approval is revoked prior to the expiry date. The Company may apply for renewal of Condition 2.1 of this Approval by including an ESDM Report and an Acoustic Assessment Report that describes the Facility as of the date of the renewal application.

3. REQUIREMENT TO REQUEST AN ACCEPTABLE POINT OF IMPINGEMENT CONCENTRATION

1. Prior to making a Modification to the Facility that satisfies Condition 2.1.a. and 2.1.b., the Company shall prepare a proposed update to the ESDM Report to reflect the proposed Modification.
2. The Company shall request approval of an Acceptable Point of Impingement Concentration for a Compound of Concern if the Compound of Concern is not identified in the ACB list as belonging to the category “Benchmark 1” and a proposed update to an ESDM Report indicates that one of the following changes with respect to the concentration of the Compound of Concern may occur:
 - a. The Compound of Concern was not a Compound of Concern in the previous version of the ESDM Report and
 - i. the concentration of the Compound of Concern exceeds the concentration set out for the contaminant in the ACB list; or
 - ii. the Compound of Concern is not identified in the ACB list; or
 - b. The concentration of the Compound of Concern in the updated ESDM Report exceeds the

higher of,

- i. the most recent Acceptable Point of Impingement Concentration, and
 - ii. the concentration set out for the contaminant in the ACB list, if the contaminant is identified in that document.
3. The request required by Condition 3.2 shall propose a concentration for the Compound of Concern and shall contain an assessment, performed by a Toxicologist, of the likelihood of the proposed concentration causing an adverse effect at Points of Impingement.
 4. If the request required by Condition 3.2 is a result of a proposed Modification described in Condition 3.1, the Company shall submit the request, in writing, to the Director at least 30 days prior to commencing to make the Modification. The Director shall provide written confirmation of receipt of this request to the Company.
 5. If a request is required to be made under Condition 3.2 in respect of a proposed Modification described in Condition 3.1, the Company shall not make the Modification mentioned in Condition 3.1 unless the request is approved in writing by the Director.
 6. If the Director notifies the Company in writing that the Director does not approve the request, the Company shall,
 - a. revise and resubmit the request; or
 - b. notify the Director that it will not be making the Modification.
 7. The re-submission mentioned in Condition 3.6 shall be deemed a new submission under Condition 3.2.
 8. If the Director approves the request, the Company shall update the ESDM Report to reflect the Modification.
 9. Condition 3 does not apply if Condition 2.1 has expired.

4. PERFORMANCE LIMITS

1. Subject to Condition 4.2, the Company shall not discharge or cause or permit the discharge of a Compound of Concern into the air if,
 - a. the Compound of Concern is identified in the ACB list as belonging to the category "Benchmark 1" and the discharge results in the concentration at a Point of Impingement exceeding the Benchmark 1 concentration; or
 - b. the Compound of Concern is not identified in the ACB list as belonging to the category

“Benchmark 1” and the discharge results in the concentration at a Point of Impingement exceeding the higher of,

- i. if an Acceptable Point of Impingement Concentration exists, the most recent Acceptable Point of Impingement Concentration, and
 - ii. the concentration set out for the contaminant in the ACB list, if the contaminant is identified in that document.
2. Condition 4.1 does not apply if the benchmark set out in the ACB list has a 10-minute averaging period and no ambient monitor indicates an exceedance at a Point of Impingement where human activities regularly occur at a time when those activities regularly occur.
 3. The Company shall, at all times, ensure that the noise emissions from the Facility comply with the limits set out in Ministry Publication NPC-300.
 4. The Company shall, at all times, ensure that the vibration emissions from the Facility comply with the limits set out in Ministry Publication NPC-207.
 5. The Company shall operate any Equipment with Specific Operational Limits approved by this Approval in accordance with the Original ESDM Report.

5. DOCUMENTATION REQUIREMENTS

1. The Company shall maintain an up-to-date Log.
2. No later than March 31 of each year, the Company shall update the Acoustic Assessment Report and shall update the ESDM Report in accordance with section 26 of O. Reg. 419/05 so that the information in the reports is accurate as of December 31 in the previous year.
3. The Company shall make the Emission Summary Table (see section 27 of O. Reg. 419/05) and Acoustic Assessment Summary Table available for examination by any person, without charge, by posting it on the Internet or by making it available during regular business hours at the Facility.
4. The Company shall, within three (3) months after the expiry of Condition 2.1 of this Approval, update the ESDM Report and the Acoustic Assessment Report such that the information in the reports is accurate as of the date that Condition 2.1 of this Approval expired.
5. Conditions 5.1 and 5.2 do not apply if Condition 2.1 has expired.

6. REPORTING REQUIREMENTS

1. Subject to Condition 6.2, the Company shall provide the Director no later than June 30 of each year, a Written Summary Form to be submitted through the Ministry’s website that shall include

the following:

- a. a declaration of whether the Facility was in compliance with section 9 of the EPA, O. Reg. 419/05 and the conditions of this Approval;
 - b. a summary of each Modification satisfying Condition 2.1.a. and 2.1.b. that took place in the previous calendar year that resulted in a change in the previously calculated concentration at a Point of Impingement for any Compound of Concern or resulted in a change in the sound levels reported in the Acoustic Assessment Summary Table at any Point of Reception.
2. Condition 6.1 does not apply if Condition 2.1 has expired.

7. OPERATION AND MAINTENANCE

1. The Company shall prepare and implement, not later than three (3) months from the date of this Approval, operating procedures and maintenance programs for all Processes with Significant Environmental Aspects, which shall specify as a minimum:
 - a. frequency of inspections and scheduled preventative maintenance;
 - b. procedures to prevent upset conditions;
 - c. procedures to minimize all fugitive emissions;
 - d. procedures to prevent and/or minimize odorous emissions;
 - e. procedures to prevent and/or minimize noise emissions; and
 - f. procedures for record keeping activities relating to the operation and maintenance programs.
2. The Company shall ensure that all Processes with Significant Environmental Aspects are operated and maintained in accordance with this Approval, the operating procedures and maintenance programs.

8. COMPLAINTS RECORDING AND REPORTING

1. If at any time, the Company receives an environmental complaint from the public regarding the operation of the Equipment approved by this Approval, the Company shall take the following steps:
 - a. Record and number each complaint, either electronically or in a log book. The record shall include the following information: the time and date of the complaint and incident to which the complaint relates, the nature of the complaint, wind direction at the time and date of the incident to which the complaint relates and, if known, the address of the complainant.

- b. Notify the District Manager of the complaint within two (2) business days after the complaint is received, or in a manner acceptable to the District Manager.
- c. Initiate appropriate steps to determine all possible causes of the complaint, and take the necessary actions to appropriately deal with the cause of the subject matter of the complaint.
- d. Complete and retain on-site a report written within five (5) business days of the complaint date. The report shall list the actions taken to appropriately deal with the cause of the complaint and set out steps to be taken to avoid the recurrence of similar incidents.

9. RECORD KEEPING REQUIREMENTS

1. Any information requested by any employee in or agent of the Ministry concerning the Facility and its operation under this Approval, including, but not limited to, any records required to be kept by this Approval, shall be provided to the employee in or agent of the Ministry, upon request, in a timely manner.
2. Unless otherwise specified in this Approval, the Company shall retain, for a minimum of five (5) years from the date of their creation all reports, records and information described in this Approval, including,
 - a. a copy of the Original ESDM Report and each updated version;
 - b. a copy of each version of the Acoustic Assessment Report;
 - c. supporting information used in the emission rate calculations performed in the ESDM Reports and Acoustic Assessment Reports;
 - d. the records in the Log;
 - e. copies of each Written Summary Form provided to the Ministry under Condition 6.1 of this Approval;
 - f. records of maintenance, repair and inspection of Equipment related to all Processes with Significant Environmental Aspects; and
 - g. all records related to environmental complaints made by the public as required by Condition 8 of this Approval.

10. ACOUSTIC AUDIT

1. The Company shall carry out Acoustic Audit measurements on the actual noise emissions due to the operation of the Facility. The Company:
 - a. shall carry out Acoustic Audit measurements in accordance with the procedures in

Publication NPC-103;

- b. shall submit an Acoustic Audit Report on the results of the Acoustic Audit, prepared by an Independent Acoustical Consultant, in accordance with the requirements of Publication NPC-233, to the District Manager and the Director, not later than twelve (12) months from the date of this Approval.

2. The Director:

- a. may not accept the results of the Acoustic Audit if the requirements of Publication NPC-233 were not followed;
- b. may require the Company to repeat the Acoustic Audit if the results of the Acoustic Audit are found unacceptable to the Director.

11. REVOCATION OF PREVIOUS APPROVALS

1. This Approval replaces and revokes all Certificates of Approval (Air) issued under section 9 EPA and Environmental Compliance Approvals issued under Part II.1 EPA to the Facility in regards to the activities mentioned in subsection 9(1) of the EPA and dated prior to the date of this Approval.

SCHEDULE A

Supporting Documentation

1. Environmental Compliance Approval Application, dated August 5, 2020, signed by Sarah Shannon and submitted by the Company;
2. Emission Summary and Dispersion Modelling Report, prepared by Dillon Consulting Limited and dated August 21, 2020;
3. Acoustic Assessment Report, prepared by Dillon Consulting Limited, dated August 2020 and signed by Amir Irvani; and
4. Additional Information, prepared by Dillon Consulting Limited and dated March 5, 2021 and June 2, 2021.

The reasons for the imposition of these terms and conditions are as follows:

1. GENERAL

Condition No. 1 is included to require the Approval holder to build, operate and maintain the Facility in accordance with the Supporting Documentation in Schedule A considered by the Director in issuing this Approval.

2. LIMITED OPERATIONAL FLEXIBILITY, REQUIREMENT TO REQUEST AN ACCEPTABLE POINT OF IMPINGEMENT CONCENTRATION AND PERFORMANCE LIMITS

Conditions No. 2, 3 and 4 are included to limit and define the Modifications permitted by this Approval, and to set out the circumstances in which the Company shall request approval of an Acceptable Point of Impingement Concentration prior to making Modifications. The holder of the Approval is approved for operational flexibility for the Facility that is consistent with the description of the operations included with the application up to the Facility Production Limit. In return for the operational flexibility, the Approval places performance based limits that cannot be exceeded under the terms of this Approval. Approval holders will still have to obtain other relevant approvals required to operate the Facility, including requirements under other environmental legislation such as the Environmental Assessment Act.

3. DOCUMENTATION REQUIREMENTS

Condition No. 5 is included to require the Company to maintain ongoing documentation that demonstrates compliance with the performance limits as specified in Condition 4 of this Approval and allows the Ministry to monitor on-going compliance with these performance limits. The Company is required to have an up to date ESDM Report and Acoustic Assessment Report that describe the Facility at all times and make the Emission Summary Table and Acoustic Assessment Summary Table from these reports available to the public on an ongoing basis in order to maintain public communication with regard to the emissions from the Facility.

4. REPORTING REQUIREMENTS

Condition No. 6 is included to require the Company to provide a yearly Written Summary Form to the Ministry, to assist the Ministry with the review of the site's compliance with the EPA, the regulations and this Approval.

5. OPERATION AND MAINTENANCE

Condition No. 7 is included to require the Company to properly operate and maintain the Processes with Significant Environmental Aspects to minimize the impact to the environment from these processes.

6. COMPLAINTS RECORDING AND REPORTING PROCEDURE

Condition No. 8 is included to require the Company to respond to any environmental complaints regarding the operation of the Equipment, according to a procedure that includes methods for preventing recurrence of similar incidents and a requirement to prepare and retain a written report.

7. RECORD KEEPING REQUIREMENTS

Condition No. 9 is included to require the Company to retain all documentation related to this Approval and provide access to employees in or agents of the Ministry, upon request, so that the Ministry can determine if a more detailed review of compliance with the performance limits as specified in Condition 4 of this Approval is necessary.

8. ACOUSTIC AUDIT

Condition No. 10 is included to require the Company to gather accurate information and submit an Acoustic Audit Report in accordance with procedures set in the Ministry's noise guidelines, so that the environmental impact and subsequent compliance with this Approval can be verified.

9. REVOCATION OF PREVIOUS APPROVALS

Condition No. 11 is included to identify that this Approval replaces all Section 9 Certificate(s) of Approval and Part II.1 Approvals in regards to the activities mentioned in subsection 9(1) of the EPA and dated prior to the date of this Approval.

**Upon issuance of the environmental compliance approval, I hereby revoke Approval No(s).
2091-9NUNM9 issued on May 25, 2015**

In accordance with Section 139 of the Environmental Protection Act, you may by written Notice served upon me, the Environmental Review Tribunal and in accordance with Section 47 of the Environmental Bill of Rights, 1993, the Minister of the Environment, Conservation and Parks, within 15 days after receipt of this Notice, require a hearing by the Tribunal. The Minister of the Environment, Conservation and Parks will place notice of your appeal on the Environmental Registry. Section 142 of the Environmental Protection Act provides that the Notice requiring the hearing shall state:

- a. The portions of the environmental compliance approval or each term or condition in the environmental compliance approval in respect of which the hearing is required, and;
- b. The grounds on which you intend to rely at the hearing in relation to each portion appealed.

Pursuant to subsection 139(3) of the Environmental Protection Act, a hearing may not be required with respect to any terms and conditions in this environmental compliance approval, if the terms and conditions are substantially the same as those contained in an approval that is amended or revoked by this environmental compliance approval.

The Notice should also include:

1. The name of the appellant;
2. The address of the appellant;
3. The environmental compliance approval number;
4. The date of the environmental compliance approval;
5. The name of the Director, and;
6. The municipality or municipalities within which the project is to be engaged in.

And the Notice should be signed and dated by the appellant.

This Notice must be served upon:

The Secretary*

The Minister of the Environment,

The Director appointed for the purposes of
Part II.1 of the Environmental Protection Act

Environmental Review Tribunal
655 Bay Street, Suite 1500
Toronto, Ontario
M5G 1E5

AND

Conservation and Parks
777 Bay Street, 5th Floor
Toronto, Ontario
M7A 2J3

AND

Ministry of the Environment,
Conservation and Parks
135 St. Clair Avenue West, 1st Floor
Toronto, Ontario
M4V 1P5

*** Further information on the Environmental Review Tribunal's requirements for an appeal can be obtained directly from the Tribunal at: Tel: (416) 212-6349, Fax: (416) 326-5370 or www.ert.gov.on.ca**

This instrument is subject to Section 38 of the Environmental Bill of Rights, 1993, that allows residents of Ontario to seek leave to appeal the decision on this instrument. Residents of Ontario may seek leave to appeal within 15 days from the date this decision is placed on the Environmental Registry. By accessing the Environmental Registry at <https://ero.ontario.ca/>, you can determine when the leave to appeal period ends.

The above noted activity is approved under s.20.3 of Part II.1 of the Environmental Protection Act.

DATED AT TORONTO this 28th day of June, 2021



Neryed Ragbar, P.Eng.

Director

appointed for the purposes of Part II.1 of the
Environmental Protection Act

AB/

c: District Manager, MECP Toronto - District
Amir A. Iravani, Dillon Consulting