



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

Southeast Regional Office • 20 Riverside Drive, Lakeville MA 02347 • 508-946-2700

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Secretary

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Commissioner

October 13, 2011

Mr. Shawn Cain
Director, Facilities and Plant Engineering
Organogenesis, Inc.
150 Dan Road
Canton, MA 02021

RE: FINAL APPROVAL OF LPA NON-FUEL EMISSIONS:

Application No.: SE-11-022
Transmittal No.: X238970
Facility ID No.: 2521

AT: Organogenesis, Inc.
65 Dan Road
86 Dan Road
150 Dan Road
275 Dan Road
Canton

Dear Mr. Cain:

The Department of Environmental Protection, Bureau of Waste Prevention has determined that the referenced Limited Plan Application (“LPA”), is administratively complete and in conformance with current air pollution control practices. The Department approves LPA No. SE-11-022 for biotechnology manufacturing operations at your Organogenesis, Inc., complex (herein referred to as “facility” or “Organogenesis”), located at 65, 85, 150, and 275 Dan Road, Canton, Massachusetts.

Emissions from the facility include Volatile Organic Compounds (VOCs), and Hazardous Air Pollutants (HAPs). HAPs are as listed in the 1990 Clean Air Act Amendments, Section 112(b).

The LPA was submitted in accordance with 310 CMR 7.02(1), (3), and (4) of the Air Pollution Control Regulations (“Regulations”), 310 CMR 7.00, as adopted pursuant to M.G.L. c.111, sections 142A-142K.

Included as part of the LPA Approval are the following:

- *Stamped approved BWP AQ 01 (LPA-Process) Application Form received August 9, 2011, and updated Application Form received October 5, 2011,*
- *General Conditions for Non-Fuel Emissions LPAs,*
- *Special Conditions, and*
- *Appeal Rights*

Please review the entire LPA Approval carefully as it stipulates the conditions that the facility owner / operator must adhere to for the facility to be constructed / reconstructed / altered and operated in compliance with the Regulations.

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

Should you have any questions concerning this FINAL APPROVAL, please contact Dan Kamieniecki at (508) 946-2717.

Very truly yours,

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.

John K. Winkler, Chief
Permit Section
Bureau of Waste Prevention

Enclosures

ecc: L. Carlson DEP/SERO
J. Winkler DEP/SERO
L. Black DEP/SERO
Y. Tian DEP/Boston
Canton Board of Health
Canton Fire Dept
S. Smits Mabbett & Associates, Inc.

GENERAL CONDITIONS FOR NON-FUEL EMISSION LPAS

1. Operation - No person shall operate a facility constructed, substantially reconstructed, or altered pursuant to 310 CMR 7.02(1), (3), and (4) except in conformance with the requirements established therein and in conformance with the specific written plan approval requirements.
2. Recordkeeping - The facility owner/operator shall establish an on site recording system. All records shall be maintained up-to-date such that year-to-date information is readily available for Department examination. Recordkeeping shall, at a minimum, include:
 - a) The initiation and completion dates for the proposed construction/reconstruction/ alteration.
 - b) Malfunctions - A record of all malfunctions including, at a minimum: the date and time the malfunction occurred; a description of the malfunction and the corrective action taken; the date and time corrective actions were initiated; and the date and time corrective actions were completed and the facility returned to compliance.
 - c) Records shall be maintained documenting the air contaminant emission analysis supporting the response to LPA-Process (BWP AQ 01) Section H.
 - d) All records shall be kept on site for five (5) years from date of record and shall be made available to the Department upon request.
3. The Regional Bureau of Waste Prevention office must be notified by telephone or fax as soon as possible after the occurrence of any upsets or malfunctions to facility equipment, air pollution control equipment, or monitoring equipment that result in an excess emission to the air or a condition of air pollution.
4. The Department must be notified in writing within 30 days of commencement of construction and completion of this approved installation.
5. The Department may revoke, in accordance with 310 CMR 7.02(3)(k), any plan approval if the actual construction has not begun within two years from the date of issuance or if, during the construction, the construction is suspended for the period of one year or more.
6. Reporting - Any construction, substantial reconstruction or alteration, as described in 310 CMR 7.02(1), (3), and (4) at a facility subject to the reporting requirements of 310 CMR 7.12, shall be reported to the Department on the next required source registration.

GENERAL CONDITIONS FOR NON-FUEL EMISSION LPAs

7. This approval may be suspended, modified, or revoked by the Department if, at any time, the Department determines that the facility is violating any condition or part of this LPA Approval. The Department shall be notified in writing before any modification of the facility such as a change in raw materials or an increase in production capacity that may increase emissions.
8. Opacity, exclusive of uncombined water, shall not exceed 10% at all times during all modes of operation, including startups and shutdowns. Visible emissions or opacity that exceeds the limits set forth in this approval shall be reported to the Department in writing or by fax within seven (7) days of the occurrence.
9. Noise from the facility during construction, initial startup and routine operation, including startups and shutdowns, shall not exceed the Department noise guidelines and shall not cause a condition of air pollution as defined in 310 CMR 7.01 and 7.10.
10. The facility shall be constructed and operated in a manner to prevent the occurrence of dust or odor conditions that cause or contribute to a condition of air pollution as defined in 310 CMR 7.01 and 7.09.
11. This Final Approval does not negate the responsibility of owner/operator of the referenced facility to comply with this or any other applicable federal, state, or local regulations now or in the future. Nor does this approval imply compliance with any other applicable federal, state, or local regulations now or in the future.
12. Emission Testing - The Department may, in accordance with Regulation 310 CMR 7.13, require source emission testing ("stack testing"). All emission testing shall be conducted in accordance with the Department's Guidelines for Source Emission Testing and with 310 CMR 7.13.
13. Should asbestos remediation/removal be required because of the approved construction/reconstruction/or alteration of this facility, such asbestos remediation/removal shall be done in accordance with Regulation 310 CMR 7.15 in its entirety and 310 CMR 4.0.

SPECIAL CONDITIONS FOR NON-FUEL EMISSION LPAS

Organogenesis operates an existing biotechnology manufacturing facility located at 150 Dan Road in Canton. On May 27, 2010, the Department approved Limited Plan Application 4P10009, Transmittal No. X231972, pertaining to the design, development, and manufacture of ApligrafTM, a living skin equivalent. The facility was limited to 12.47 tons of VOC process emissions per year.

The current application proposes additional research and development (R&D) labs, quality analysis and control (QA/QC) labs, and manufacturing processes located among 4 properties located on Dan Road. An additional 9.4 tons of VOC process emissions per year is proposed in the current application. MassDEP has determined that for the purpose of compliance with the Air Pollution Control Regulations at 310 CMR 7.00 et seq, that the contiguous Organogenesis complex in Canton, Massachusetts, is comprised of the sum of four street locations/buildings including 65 Dan Road, 85 Dan Road, 150 Dan Road, and 275 Dan Road.

Organogenesis has indicated that the emissions from proposed biotechnology surface disinfection operation in Building 275 and the QA/QC lab operations in building 275 and 65 warehouse will be included in the laboratory, cleaning, and process agents usage and emission limitations.

1. This Final Approval supersedes Approval 4P10009 dated May 27, 2010, and Approval MBR-03-IND-018 dated January 15, 2004, both of which shall be deemed null and void. The underlying application for Approval 4P10009 shall remain valid.
2. To establish "Federal Enforceability," while allowing for maximum operational flexibility, the operational limits below are based on the amount of VOCs and HAPs, as contained in the laboratory, cleaning and process agents used. The corresponding emission limits are based on 100% volatilization of the VOCs and HAPs contained in the laboratory, cleaning and process agents. Organogenesis shall limit the amount of VOCs and HAPs used, as contained in the laboratory, cleaning and process agents, as follows:
 - a. 3.81 tons VOCs per month.
 - b. 21.9 tons VOCs per consecutive 12-month period.
 - c. 0.22 tons HAPs per month.
 - d. 1.29 tons HAPs per consecutive 12-month period.
3. Organogenesis shall limit emissions of VOCs and HAPs from the processes using laboratory, cleaning and process agents as follows:
 - a. 3.81 tons VOCs per month.
 - b. 21.9 tons of VOCs per consecutive 12-month period.
 - c. 0.22 tons of HAPs per month.
 - d. 1.29 tons of HAPs per consecutive 12-month period.

4. Organogenesis shall be permitted to utilize any cleaning, laboratory, or process agent with comparable or lower VOC emissions than those presently in use and described in the Application, as long as these emissions are included in and comply with Special Conditions Nos. 2. and 3. above.
5. Organogenesis shall be permitted to modify the facility, such as an increase in production capacity or addition and/or re-location of the equipment within the facility, as long as the resulting emissions are included in and comply with Special Conditions Nos. 2., 3., and 4. above.
6. Organogenesis may reconcile the VOCs and HAPs contained in any hazardous waste shipped during the month when determining monthly emissions and usage. The facility shall maintain hazardous waste disposal records, Material Safety Data Sheets, and purchase records for VOCs and HAPs containing materials, etc, which support and substantiate the emissions and usage records such that the Department may check these for consistency with plant logs. Such records shall verify the VOCs and HAPs and the quantity present, in the waste being shipped if reconciling monthly emissions and usage.
7. Organogenesis shall store and dispose of VOCs and HAPs in a manner that will minimize evaporation to the atmosphere. Proper storage shall be in a container with a tight fitting cover. Proper disposal shall be in a manner consistent with all applicable regulations.
8. Organogenesis shall take any and all measures necessary to ensure the operation of the equipment approved herein shall not result in visible emissions (i.e. zero percent opacity), exclusive of uncombined water vapor. These measures, as determined by the Department, may include add-on pollution control equipment and/or shutdown of the equipment while corrective actions are being employed. This provision supersedes Proviso No. 8. of the General Conditions contained in this Approval.
9. Organogenesis shall maintain detailed VOC and HAP records on a monthly basis and on a consecutive 12-month period basis (the total from the latest month plus the sum for the eleven months preceding the latest month). These records, including any other "credible evidence," shall document the compliance status of the facility regarding the conditions, provisions, requirements, and limits contained in this Final Approval, and pertain to the laboratory, cleaning, and process agents in the facility. Supporting documentation shall be maintained as appropriate for determining compliance.
10. The facility shall be operated in strict accordance with the application approved herein. Should there be any differences between the aforementioned application and this approval letter, this approval letter shall govern.
11. The facility shall comply with all conditions contained in this Final Approval. Should there be any differences between conditions contained in the "General Conditions" and the conditions contained in the "Special Conditions" of this Final Approval, the "Special Conditions" shall govern.

APPEAL OF APPROVAL

This Approval is an action of the Department. 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 Approval.

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

The hearing request along with a valid check payable to 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

The 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.

The Department 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.