



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

One Winter Street Boston, MA 02108 • 617-292-5500

Charles D. Baker
Governor

Karyn E. Polito
Lieutenant Governor

Kathleen A. Theoharides
Secretary

Martin Suuberg
Commissioner

August 28, 2020

Thelma Murphy, Water Permit Branch Chief
US EPA Region 1
5 Post Office Square, Suite 100 (OEP06-1)
Boston, MA 02109-3912

Re: Massachusetts Clean Water Act Section 401 Certification for the Shire Human Genetic Therapies, Inc., Cambridge

Dear Ms. Murphy:

Enclosed please find as Attachment 1 the Commonwealth of Massachusetts' Clean Water Act (CWA) section 401 certification (State Certification) for the proposed 2020 National Pollutant Discharge Elimination System (NPDES) permit for the Shire Human Genetic Therapies, Inc. (MA Permit No. MA0040321). MassDEP proposed a draft State Certification for public notice and comment on July 14, 2020. A copy of the published newspaper notice is enclosed as Attachment 2. The public comment period posted for the draft State Certification closed on August 13, 2020. MassDEP did not receive any public comments during the public comment period. Enclosed please also find as Attachment 3 the Notice of Appeal Rights for the State Certification.

Please contact Ms. Susannah King, MassDEP's NPDES Section Chief, at (617) 556-1147 or susannah.king@mass.gov if you have any questions.

Sincerely,

Lealdon Langley, Director
Division of Watershed Management
Department of Environmental Protection
Commonwealth of Massachusetts

ecc:

Jonathan Tomer, Sr. Environmental Specialist, Shire Human Genetic Therapies, Inc.

This information is available in alternate format. Contact Michelle Waters-Ekanem, Director of Diversity/Civil Rights at 617-292-5751.

TTY# MassRelay Service 1-800-439-2370
MassDEP Website: www.mass.gov/dep

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Dennis Deziel, Regional Administrator, Region 1
Xiaodan Ruan, MassDEP
Nathan Chien, EPA Region 1

Enclosures:

Attachment 1 – State Certification

Attachment 2 – Public Notice

Attachment 3 – Notice of Appeal Rights

FINAL

Clean Water Act Section 401 Certification
For the Proposed 2020 Federal NPDES Permit
For the Shire Human Genetic Therapies, Inc.
MA Permit No. MA0040321

The Massachusetts Department of Environmental Protection (MassDEP), having examined Shire Human Genetic Therapies, Inc.'s National Pollutant Discharge Elimination System (NPDES) permit application for the Shire Human Genetic Therapies, Inc., reviewed the United States Environmental Protection Agency (EPA) – Region 1's draft 2020 Federal NPDES permit (MA Permit No. MA0040321) for the Shire Human Genetic Therapies, Inc. issued July 1, 2020, and considered the public comments received on MassDEP's proposed Clean Water Section 401 Certification for the draft 2020 Federal NPDES Permit for the Shire Human Genetic Therapies, Inc., and in consideration of the relevant water quality considerations, hereby certifies:

1. that the following conditions, together with the terms and conditions contained in the proposed 2020 Federal NPDES permit for the Shire Human Genetic Therapies, Inc., are necessary to assure compliance with the applicable provisions of the Federal Clean Water Act Sections 208(e), 301, 302, 303, 306, and 307 and with appropriate requirements of State law, including, without limitation, the Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26-53 and the Massachusetts Water Quality Standards published at 314 CMR 4.00:
 - a. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, within six (6) months of the effective date of the 2020 Federal NPDES permit, the permittee shall submit to MassDEP an evaluation of whether the facility uses any products containing any per- and polyfluoroalkyl substances (PFAS) and whether use of those products can be reduced or eliminated. The analysis shall be submitted electronically to massdep.npdes@mass.gov.
 - b. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, within six (6) months after EPA's multi-lab validated method for wastewater is made available to the public on EPA's Clean Water Act methods program website¹, or two (2) years from the effective date of the 2020 Federal NPDES permit, whichever is earlier, the permittee shall conduct monitoring of the effluent for PFAS compounds as detailed in the table below. If EPA has not issued a validated test method by twenty (20) months after the effective date of the 2020 Federal NPDES permit, the permittee shall contact MassDEP (massdep.npdes@mass.gov) for guidance on an appropriate analytical method.

¹ See <https://www.epa.gov/cwa-methods/other-clean-water-act-test-methods-chemical> and <https://www.epa.gov/cwa-methods>.

This information is available in alternate format. Contact Michelle Waters-Ekanem, Director of Diversity/Civil Rights at 617-292-5751.

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Effluent (Outfall 001)

Parameter	Units	Measurement Frequency	Sample Type
Perfluorohexanesulfonic acid (PFHxS)	ng/L	Quarterly ²	24-hour Composite
Perfluoroheptanoic acid (PFHpA)	ng/L	Quarterly	24-hour Composite
Perfluorononanoic acid (PFNA)	ng/L	Quarterly	24-hour Composite
Perfluorooctanesulfonic acid (PFOS)	ng/L	Quarterly	24-hour Composite
Perfluorooctanoic acid (PFOA)	ng/L	Quarterly	24-hour Composite
Perfluorodecanoic acid (PFDA)	ng/L	Quarterly	24-hour Composite

Notwithstanding any other provision of the 2020 Federal NPDES permit to the contrary, monitoring results shall be reported to MassDEP electronically (massdep.npdes@mass.gov) within 30 days after they are received. Those results do not need to be reported to EPA through NetDMR, unless EPA establishes a requirement through a future permitting action.

- c. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, after completing one year of monitoring, if four (4) consecutive samples are reported as non-detect for all six (6) PFAS compounds, then the permittee may submit a request to MassDEP to discontinue PFAS monitoring. Any such request shall be made in writing and sent to massdep.npdes@mass.gov. The permittee shall continue such monitoring pending written approval from MassDEP to discontinue it.
2. that there is a reasonable assurance that the activity will be conducted in a manner which will not violate applicable state water quality standards.

To meet the requirements of Massachusetts laws, each of the conditions cited in the draft permit and this certification shall not be made less stringent unless new data or other information is presented and MassDEP determines modification of this certification is appropriate in consideration of the relevant water quality considerations.

If any condition in the draft 2020 Federal NPDES permit for the Shire Human Genetic Therapies, Inc. is changed during EPA's review in any manner inconsistent with this certification, the Department reserves the right to modify this certification in consideration of the relevant water quality considerations. In addition, the Department reserves the right to modify this certification if there is a change in Massachusetts law or regulation upon which this certification is based, or if a court of competent jurisdiction or MassDEP Office of Appeals and Dispute Resolution stays, vacates or remands this certification, as provided by 40 C.F.R. § 124.55.

² Quarters are defined as January to March, April to June, July to September, and October to December. Samples shall be taken during the same month each quarter and shall be taken 3 months apart (e.g., an example sampling schedule could be February, May, August, and November).

Signed this __28th__ day of __August__, 2020.

A handwritten signature in black ink, appearing to read "Lealdon Langley". The signature is fluid and cursive, with a prominent loop at the end.

Lealdon Langley, Director
Massachusetts Department of Environmental Protection
Bureau of Water Resources
Division of Watershed Management

PUBLIC NOTICE

Notice is hereby given that the Massachusetts Department of Environmental Protection (MassDEP), under authority granted by the Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26 – 53, is proposing to: (1) issue a federal Clean Water Act (CWA) section 401 certification for the U.S. Environmental Protection Agency's (EPA) proposed 2020 Draft NPDES Permit (Federal Permit) (MA Permit No. MA0040321) to Shire Human Genetic Therapies, Inc. for their Cambridge facility's pollutant discharges to the Alewife Brook (MA 93-45); and (2) issue the 2020 Draft Massachusetts Permit to Discharge Pollutants to Surface Waters (State Permit) for the same discharge pursuant to the Massachusetts Clean Waters Act. The Shire Human Genetic Therapies, Inc. is located at 205 Alewife Brook Parkway in Cambridge, Massachusetts. The proposed section 401 certification, proposed State Permit, and proposed Federal Permit are all available at <https://www.mass.gov/service-details/massdep-public-hearings-comment-opportunities>. Alternatively a copy of the documents can be obtained by contacting Xiaodan Ruan, MassDEP Surface Water Discharge Program, at 617-654-6517 or xiaodan.ruan@mass.gov. Written comments on both the proposed section 401 certification and the proposed State Permit will be accepted until 5:00 p.m. on Thursday, August 13, 2020. During the state of emergency, MassDEP strongly encourages written comments to be submitted by email to massdep.npdes@mass.gov; subject line: Shire Human Genetic Therapies. If not possible, please send by mail to Xiaodan Ruan, MassDEP Surface Water Discharge Program, Bureau of Water Resources, 1 Winter Street – 5th Floor, Boston 02108.

Following the close of the comment period, MassDEP will issue a final CWA section 401 certification and final State Permit and forward copies to the applicant and each person who has submitted written comments or requested notice.

For special accommodations, please call the MassDEP Diversity Office at 617-292-5751. TTY# MassRelay Service 1-800-439-2370. This information is available in alternate format upon request.

By Order of the Department

Martin Suuberg, Commissioner

NOTICE OF APPEAL RIGHTS
SECTION 401 CERTIFICATION of FEDERAL NPDES PERMIT

Within 21 days of the issuance of MassDEP's decision to grant or deny a water quality certification of EPA's NPDES permit pursuant to § 401 of the federal Clean Water Act, any person aggrieved may request an adjudicatory hearing concerning MassDEP's decision.

How should the request for an adjudicatory hearing be made?

A request for an adjudicatory hearing for DEP's § 401 water quality certification of the federal NPDES permit must be made within 21 days of the issuance of MassDEP's decision to grant or deny the water quality certification, in accordance with 310 CMR 1.01. 310 CMR 1.01(6)(b) establishes the required form and content of the request. Failure to meet the requirements of 310 CMR 1.01 may result in dismissal of the request or the requirement to file a more definite statement.

A person filing a request for an adjudicatory hearing must complete and mail a MassDEP Fee Transmittal Form for the appeal and send it with a valid check to the Commonwealth Master Lockbox, as instructed below, if a fee is required by 310 CMR 4.06. The MassDEP Fee Transmittal Form can be downloaded from:

<http://www.mass.gov/eea/agencies/massdep/service/approvals/transmittal-form-for-payment.html>.

The written notice requesting an adjudicatory hearing shall be delivered to MassDEP's Case Administrator together with (i) a photocopy of the decision being appealed, (ii) a photocopy of the completed MassDEP Fee Transmittal Form, if required, and (iii) a photocopy of the check used to pay any adjudicatory hearing filing fee due for the appeal under 310 CMR 4.06. The notice of claim should be made in writing and sent by email to Caseadmin.OADR@state.ma.us.

Please do not send the original of the completed MassDEP Fee Transmittal Form and check to the Case Administrator. Instead, please follow the instructions below for delivery of the original of the completed Fee Transmittal Form and check to the Commonwealth Master Lockbox.

A \$100 adjudicatory hearing filing fee must be paid, unless (i) a simplified hearing is requested for a reduced fee of \$25, (ii) the person requesting an adjudicatory hearing is a town, a municipal agency, a county or a municipal housing authority, in which case there is no fee, or (iii) the person requesting the hearing is seeking to have MassDEP waive the adjudicatory hearing filing fee because paying the fee will create an undue financial hardship.

A person who believes that payment of the fee would be an undue financial hardship shall file with the request for adjudicatory hearing a request for waiver of the fee together with an affidavit setting forth the facts the appellant believes constitute the undue financial hardship. For more information on the adjudicatory hearing filing fee and the grounds on which the Department may waive the fee, please see 310 CMR 4.06.

If a fee is required, the completed MassDEP Fee Transmittal Form and a valid check made payable to the Commonwealth of Massachusetts for the amount of the fee due must be mailed to:

Mass. Department of Environmental Protection

Commonwealth Master Lockbox
P.O. Box 4062
Boston, Massachusetts 02211

Failure to pay the adjudicatory hearing filing fee, if required, may be grounds for dismissal of the appeal.

In accordance with 314 CMR 2.08(5), any person, other than the permit applicant or permittee, who files a request for an adjudicatory hearing with the Department pursuant to 314 CMR 2.08(2) on an individual permit or general permit coverage, also shall simultaneously send a copy of the request by certified mail, return receipt requested, to the applicant or permittee. Any person who files a request for an adjudicatory hearing with the Department pursuant to 314 CMR 2.08(2) on a general permit also shall simultaneously send a copy of the request by certified mail, return receipt requested, to each permittee covered by the general permit.