

SHIRE HUMAN GENETIC THERAPIES, INC.

FACT SHEET – March 10, 2021

Who they are:

Shire Human Genetic Therapies, Inc. (Shire) is a global biotechnology company focused on serving people with rare diseases and other highly specialized conditions. Shire operates a Facility that includes multiple buildings including 200 Shire Way, 300 Shire Way, 400 Shire Way, 500 Shire Way, and 125 Spring Street in Lexington, Massachusetts.

What they manufacture:

Shire manufactures a variety of biological pharmaceutical products. Most of the Facility's emissions come from the use of surface disinfectants, including isopropyl alcohol (IPA), to disinfect surfaces of clean rooms and equipment for manufacturing. In addition to manufacturing operations, the Facility conducts research and development (R&D), quality assurance/quality control (QA/QC) laboratories, and office/administrative areas that support local and global functions.

Environmental Compliance History:

On February 12, 2021, the Office of Attorney General and Massachusetts Department of Environmental Protection announced that Shire entered into a settlement to limit its emissions of air pollutants and to settle allegations that it violated the Massachusetts Clean Air Act and regulations at its Lexington Facility. The settlement establishes strict emission limits for the Facility's operations and requires Shire to obtain a new air permit. Additionally, Shire agreed to fund a project being conducted by GreenRoots, Inc., a community-based organization dedicated to improving and enhancing the urban environment and public health in Chelsea and surrounding communities.

Current and Proposed Operations:

Process emissions at the Facility include volatile organic compound (VOC) emissions associated with surface disinfection, manufacturing, R&D, and QA/QC laboratory activities. The Shire air application proposes a limit of 18 tons per year for all process VOC emissions. Shire has proposed, all monitoring, testing, record-keeping, and reporting requirements necessary to ensure that the Facility will operate in compliance with applicable regulations and approval requirements.

MassDEP Air Quality Permitting Process and Public Comment Opportunity:

MassDEP is in the process of reviewing Shire's application and will issue a proposed decision, and a Public Notice, when the agency's review is completed. At that time, a 30-day public comment period will begin, during which the public is invited to submit comments to MassDEP on the proposed decision. The Public Notice will include Information for submitting comments. After the 30-day public comment

period, MassDEP will consider and address any comments received about MassDEP’s proposed decision. When MassDEP issues the Approval or Denial of Shire’s application, a 21-day appeal period will begin. During the appeal period, an adjudicatory hearing may be requested by those individuals or groups that have standing. MassDEP will notify interested stakeholders of the start of the public comment period. If you wish to be notified of the start of the public comment period, please contact the MassDEP Northeast Region’s Air Quality Permit Chief at edward.braczyk@mass.gov.

Location of Draft Permit & Application Materials:

Online at MassDEP website: (<https://eeaonline.eea.state.ma.us/EEA/PublicApp/>), then search by “Shire Human Genetic Therapies, Inc.”

Environmental Justice (EJ):

Shire is located at 125 Spring Street and multiple buildings at Shire Way in Lexington. The Facility is located in an EJ community.

Figure 1: Shire Facility Location and Designated Environmental Justice Area

