# State of Rhode Island Department of Environmental Management Office of Air Resources

In re: Proposed revisions to Air Pollution Control Regulation No. 26 "Control of Organic Solvent Emissions from Manufacturers of Synthetic Pharmaceutical Products"

#### **DECISION**

#### Introduction

On September 20, 2018 a notice was posted on the websites of the Rhode Island Department of Environmental Management (RI DEM) and the Rhode Island Office of Secretary of State and was sent to interested parties announcing a public comment period to accept comments on the adoption of proposed revisions to Air Pollution Control Regulation No. 26, Control of Organic Solvent Emissions from Manufacturers of Synthetic Pharmaceutical Products (250-RICR-120-05-26). The notice stated that a public hearing would be held if requested by twenty-five or more people, a governmental agency or subdivisions, or an association having not less than twenty-five members. No requests for a public hearing were received. The public comment period ended at 4:00 PM on October 20, 2018.

The purpose of this regulation is to limit volatile organic compound emissions from the manufacture of synthesized pharmaceutical products. The Department of Environmental Management, Office of Air Resources is proposing to eliminate portions of the regulation that no longer apply. Additionally, the regulation has been updated to current RI Code of Regulations (RICR) format which required the addition of an incorporated materials section. There are no new requirements being proposed.

Written comments were received from the United States Environmental Protection Agency. The following is the Office of Air Resources' responses to the comments received:

## **Response to Comments**

Comment:

EPA has reviewed Rhode Island's proposal and finds that the revised regulation is

generally consistent with EPA guidance.

Response:

No response required.

**Comment:** 

EPA will not be able to approve the "Application" section in this regulation because it states that the "regulation shall be liberally construed to permit the Department to effectuate the purposes of state law, goals and policies." While this provision may be appropriate as a matter of state law, this provision provides Rhode Island with broad discretion, akin to a Director's discretion provision, which is

problematic to approve into the State Implementation Plan (SIP). For example, EPA would be approving language that is not sufficiently defined in a way that EPA or the public could know what the "purposes of state law, goals and policies" happen to be for the individual regulation in question. Therefore, when Rhode Island submits this rule to be approved as part of a SIP revision, the "Application" section should be omitted.

Response:

When DEM submits this regulations to EPA, as a revision to the RI SIP, the "Application" section in the regulation will be stricken.

### **Decision**

It is the decision of the Department to adopt the proposed revisions to Air Pollution Control Regulation, 250-RICR-120-05-26, "Control of Organic Solvent Emissions from Manufacturers of Synthesized Pharmaceutical Products" as proposed. The final amended regulations are appended to this Decision.

Date '

Laurie A. Grandchamp P.E.

Administrator, Environmental Protection