



STATE OF DELAWARE
**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**

RICHARDSON & ROBBINS BUILDING
89 KINGS HIGHWAY
DOVER, DELAWARE 19901

OFFICE OF THE
SECRETARY

PHONE
(302) 739-9000

Secretary's Order No: 2024-A-0010

**RE: Application of Noramco Inc. for a Natural Minor Construction
Permit**

Date of Issuance: March 12, 2024

Effective Date: March 12, 2024

Under the authority vested in the Secretary of the Department of Natural Resources and Environmental Control ("Department," "DNREC") pursuant to 7 *Del.C.* §§6003, 6004, 6006(4), and all other relevant statutory authority, the Department issues this Order, approving the revised application submitted by Noramco Inc. ("Applicant") for a Natural Minor Construction Permit to install a new vacuum pump and add a new production line for two new products at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County ("Application") in accordance with 7 DE Admin. Code 1102 - Permits ("Regulation"). The following findings of fact based on the record, reasons and conclusions are entered as an Order of the Secretary in the above-referenced Natural Minor Construction Permit application proceeding.

Background, Procedural History and Findings of Fact

Pursuant to 7 *Del.C.* Ch. 60, the Department's Division of Air Quality ("DAQ") received the initial Application submitted by Noramco on April 13, 2023, to install a new production line to manufacture two new products. The Applicant's facility is a pharmaceutical manufacturing plant that specializes in producing batches of pharmaceutical intermediates that serve as active ingredients for various medications to treat a medical condition including ADHD, pain, addiction treatment, opioid overdose, and nausea.

Noramco currently operates under a Facility-Wide Title V Permit, Permit #AQM-003/00324 – Renewal (1) Revision (2) and is considered a major source facility. A major source facility emits or has the potential to emit criteria pollutant or hazardous air pollutant ("HAP") at levels equal to or greater than the Major Source Thresholds ("MST") set in the *Clean Air Act*. The New Castle County MST for volatile organic compounds ("VOC") and HAPs is 25 tons per year for each the emissions, and 10 tons per year for individual HAPs. Noramco's Title V Permit limits their annual rolling 12-month total emissions to 20.1 tons per year of VOC, 10.7 tons per year of combined HAPs, and 9.9 tons per year of individual HAPs.

Subsequent to receiving the initial Application, the Department received a revised Application on July 17, 2023, and then additional revisions on August 14, 2023. The revised Application added the installation of a new vacuum pump to support the new production line. In addition to receiving the revised Application, the Applicant submitted a request for confidentiality of records to safeguard propriety information and trade secrets contained within the Application. In accordance with Section 6.0 of 8 DE Admin Code 900, the Applicant's proposed pharmaceutical intermediates are referred to, herein, as "D8" and "D9".

The Applicant proposes to install a new production line and vacuum pump at their New Castle County facility to manufacture two new pharmaceutical intermediates, D8 and D9. Pharmaceutical intermediates are chemical compounds generated during the synthesis or manufacturing process of drugs, serving as crucial components for final drug products. The manufacturing of D8 and D9 intermediates produce VOCs and HAPs that contribute to the emissions regulated by the Title V permit. The individual VOCs and HAPs emitted include Ethanol, Ethyl Acetate, Methanol, n-Butanol, Tetrahydrofuran, Toluene, Triethylamine, Acetone, and Hydrogen Chloride. The Applicant calculated the potential emissions (without using control devices) and controlled emissions (using control devices) of these VOCs and HAPs.

The Applicant proposes to use one of two control devices, a Caustic Scrubber or a VARA Carbon Adsorber, to reduce the pollutants that enter the atmosphere when manufacturing of D8 and D9. The Caustic Scrubber has a 93% (emission) destruction efficiency and the VARA Carbon Adsorber that has a 95% (emission) destruction efficiency. Without the use of the control device, the Applicant calculated the total potential emissions from the manufacturing process of both D8 and D9 to be approximately 4.9 tons/ year of VOCs and 2.6 tons/year of combined HAPs. The controlled emissions, using one of the two devices, is calculated to measure 0.50 tons/year of VOCs and 0.22 tons/year of combined HAPs, for both D8 and D9 combined.

The Applicant's total emissions for facility-wide production were calculated at 1.5 tons of VOCs and 0.55 HAPs in 2021, and 1.48 tons of VOCs and 0.88 HAPs in 2022. The actual emissions for both years were lower than their Title V Permit limits (20.1 tons per year of VOC, 10.7 tons per year of combined HAPs.) As a part of the Application review process the Department confirmed these calculations and concluded that manufacturing D8 and D9 do not pose a risk of exceeding the Title V emissions limits. Additionally, the Department also performed an AERSCREEN Dispersion Modeling analysis.

The AERSCREEN Dispersion Modeling analysis estimates a maximum downwind concentration (“MDC”) of a pollutant from a source. The MDC value is then compared to an established threshold limit value (“TLV”) exposure limit. A TLV represents the airborne concentrations of pollutants that individuals are exposed without experiencing adverse health effects. The Department applies a safety factor of 100 to account for different ages, health conditions, genders, and body types. To ensure public health, safety, and welfare are not negatively affected by the proposed project, the ratio of TLV to MDC should exceed 100:1. The Department concluded that the emissions of individual VOCs and HAPs resulting from the manufacturing D8 and D9 are above the 100:1 threshold. Therefore, it is presumed that the emissions will not adversely impact public health, safety, and welfare.

The Department placed the revised application on public notice and received a request for a public hearing. To that, the Department issued a legal notice of the public hearing scheduled for November 7, 2023, and offered a Community Information Session. The Community Information Session was scheduled for Tuesday, October 24, 2023, from 6:00 PM to 7:00 PM at 1113 E 7th St., Wilmington, DE 19801 and offered both in person and virtual attendance to the event, as noticed in the Wilmington News Journal and Delaware State News on October 1, 2023. The purpose of the meeting was to provide the public an opportunity to ask questions about the proposed project and for the Department and Applicant to respond. At the conclusion of the meeting, the Department offered the public various ways to submit comment for the record being generated in this matter.

On November 7, 2023, a virtual public hearing was held by the Department. The Department's staff from the DAQ, primarily responsible for reviewing this Application, developed the hearing record (“Record”) with the relevant documents in the Department's files. The Applicant’s Representative provided an overview of company and provided a presentation which was marked into the Record at the time of the virtual public hearing. There were seventeen (17) members of the public in attendance at the hearing. At the conclusion of the virtual public hearing, the Record remained open for 15 days and comment was received through November 22, 2023.

Following the close of record, and at the request of Hearing Officer Theresa Smith, the technical experts in the DAQ prepared a Technical Response Memorandum (“TRM”) to: (1) address the concerns associated with this pending revised Application, as set forth in the public comment received by the Department; (2) provide a formal regulatory review of the Applicant’s proposed project; and (3) offer the DAQ conclusions and recommendations with regard to the Applicant’s pending revised Application for the benefit of the Record generated in this matter.

The Department’s DAQ technical experts addressed the public health and environmental impact concerns raised by the public. The Department concluded that the public health, safety, and welfare are presumed to not be adversely impacted by the emissions, as the TLV-to-MDC ratios are above 100:1 and it is presumed that the emissions will not negatively impact public health, safety, and welfare. In addition, the Department referred to the cancer and non-cancer risk data developed by Environmental Protection Agency’s (“EPA”) Air Toxics Screening Assessment for the area Noramco is located. The location shows that the risk is considered lower (30 in 1,000,000) than the EPA’s upper limit of acceptable risk (100 in 1,000,000.)

Moreover, in accordance with the Title V Permit # AQM-003/00324 (Renewal 1) (Revision 2.), Condition 3(c)(2) the facility is required to report any discharge of more than the permitted limits to the Department’s 24-hour Environmental Emergency Notification and Complaint line. In addition, Noramco is subject to Tier II Emergency Planning and Community Right-To-Know requirements, as well as the regulations governing hazardous waste.

Finally, DNREC places a high priority on engaging with stakeholders in Delaware communities in a transparent and public engagement process. The Department is particularly interested in hearing concerns from residents who live in communities potentially impacted by Environmental Justice issues. In the present matter, DNREC conducted a Community Information Session with Noramco, Division of Air Quality, and the members of the public. In addition, the Department heard from Environmental Justice advocates regarding concerns about this proposed Application and the potential impact of air quality related to emissions of the proposed Application. The Department amended the proposed permit to include stipulations for the Applicant to form a “Community Advisory Board,” and hold regular meetings to communicate with key stakeholders and members of the public.

The mission of DNREC is to engage stakeholders to ensure the wise management, conservation, and enhancement of the State’s natural resources; protect public health and the environment; provide quality outdoor recreation; improve quality of life; lead energy policy and climate preparedness; and educate the public on historic, cultural, and natural resource use, requirements, and issues. Furthermore, it is the policy of DNREC that no person shall, on the grounds of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance, as provided by Title VI of the Civil Rights Act of 1964, the Rehabilitation Act of 1973, the Civil Rights Restoration Act of 1987, and all other related nondiscrimination laws and requirements.

The Record generated in this matter reflects that the Department’s subject matter experts in the DAQ have reviewed the Record in light of potential Environmental Justice issues existing in the area surrounding the proposed Application and have determined that the same is consistent with the Department’s Environmental Justice policy. The Department has provided the public with multiple avenues and ample opportunities to offer comment regarding this proposed Application, including pre-registration to offer live comment at the time of the public hearing, links to obtain further information on the Department’s website, and the issuance of several Legal Notices advising the community of the ability to review the proposed Application, attend the Community Information Session and the public hearing.

The Department's presiding Hearing Officer, Theresa Smith, prepared a Hearing Officer's Report dated February 28, 2024 ("Report"). Ms. Smith's Report set forth the procedural history, summarized and established the record of information ("Record") relied on in the Report, and provided findings of fact, reasons, and conclusions that recommend the Department approve this revised Application, subject to the conditions set forth in the revised draft permit. The Report concluded that the revised draft Natural Minor Construction Permit is protective of human health and the environment while being consistent with applicable zoning requirements and federal and state air pollution control laws and regulations.

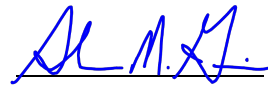
Reasons and Conclusions

Based on the Record developed by the Department's experts and established by the Hearing Officer's Report, I find and conclude that the Record developed in this matter supports approval of the Applicant's revised Application for a Natural Minor Construction Permit, consistent with 7 DE Admin. Code 1102 - *Permits*. Therefore, the recommendations of the Hearing Officer are hereby adopted, and I direct that a Natural Minor Construction Permit be issued to the Applicant to install a new vacuum pump and add a new production line for two new products, D8 and D9, at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County.

I further direct that the following reasons and conclusions are entered:

1. The Department has jurisdiction under 7 *Del. C.* §§6003, 6004, 6006(4) and all other relevant statutory authority, to make a final determination of the Application after holding a public hearing, considering the public comments, and reviewing all information contained in the Record generated in this matter;
2. The Department provided proper public notice of the revised Application submitted by Noramco Inc. and of the public hearing held on November 7, 2023. Further, the Department held said hearing to consider all public comment that may be offered on the revised Application, in a manner required by the law and regulations;

3. The Department has consulted with DNREC's Environmental Justice Coordinator throughout this permitting process, has reviewed the Record generated in this matter in the light of potential Environmental Justice issues existing in the area surrounding Noramco's facility located at 500 Swedes Landing Road, Wilmington, DE, and has determined that the finalization of the revised Application is consistent with the Department's Environmental Justice policy;
4. The Department has carefully considered the factors required to be weighed in issuing the Natural Minor Construction Permit required by this revised Application, and finds that the Record supports approval of the revised Application and the issuance of the Natural Minor Construction Permit associated with the same;
5. The Department shall issue the Natural Minor Construction Permit to the Applicant, Noramco Inc., to install a new vacuum pump and add a new production line for two new products, D8 and D9, at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County, consistent with the Record developed in this matter. Furthermore, said permit shall include all conditions as set forth in the Department's revised draft permit, to ensure that Delaware's environment and public health will be protected from harm;
6. The Department has an adequate Record for its decision, and no further public hearing is appropriate or necessary; and
7. The Department shall serve and publish its Order on its internet site, and shall provide legal notice of the Order in the same manner that the Department provided legal notice of the Application.



Shawn M. Garvin
Secretary