



Noramco Public Workshop: Air Permit Presentation

Oct 24, 2023



Noramco at a Glance



Global provider of **active ingredients** for regulated Rx only therapies

We supply no finished drug products (e.g. tablets, capsules, liquids etc)

Company

Started 44 years ago by Johnson & Johnson to make ingredients for Tylenol®

Currently we employ about 190 employees and contractors in the Delaware area and another 40 in Athens GA.

Experience

Our products are used in more than 350 pharmaceuticals sold in 30+ countries

Strategic supplier to top ten brand and generic pharmaceutical companies

Our products are used to treat a variety of indications including ADHD, pain, addiction treatment, opioid overdose and nausea

Quality

FDA, EMEA, UK MHRA, Health Canada, OSHA, and DEA inspected

Our products must meet the highest purity standards



Wilmington, Delaware
Manufacturing and Headquarters



Athens, Georgia
Purisy HQ, Global R&D, and Manufacturing

Manufacturing and Headquarters in Wilmington, DE



World Class Environmental and Security Infrastructure – Continuously Staffed

Products supplied to over 30 countries

Comprehensive controlled substance capabilities

Facility Size:

- 81,000 sq ft.

Location:

- Approximately 30 minutes from Philadelphia Airport
- Located in Wilmington, DE

~190 Skilled Personnel

- 24 hours x 7 day Operation
- Continuously staffed
- Extensive Security

Capabilities

- GMP chemical processing
- DEA licensed manufacturing
- Secured storage
- R&D capabilities
- Commercial scale reactors
- Multiple dryer technologies
- Milling & custom packaging

Regulatory Profile

- FDA, EDQM, DEA, EPA, OSHA, Health Canada, Homeland Security
- Industry leading technical support and API characterization
- Recent 2022 FDA inspection with no observations
- Routine customer approvals with no FDA comment

- Biden-Harris Administration directive to revitalize American manufacturing and secure critical supply chains¹
- Key recommendation from the experts: [On-shore production](#) ²
- Ensures the most reliable supply for US patients
- Post COVID global logistics have become more costly and unreliable
- As a priority project we are on-shoring production of the intermediates (D8/D9) for [Marinol® generics](#)

INDICATIONS AND USAGE

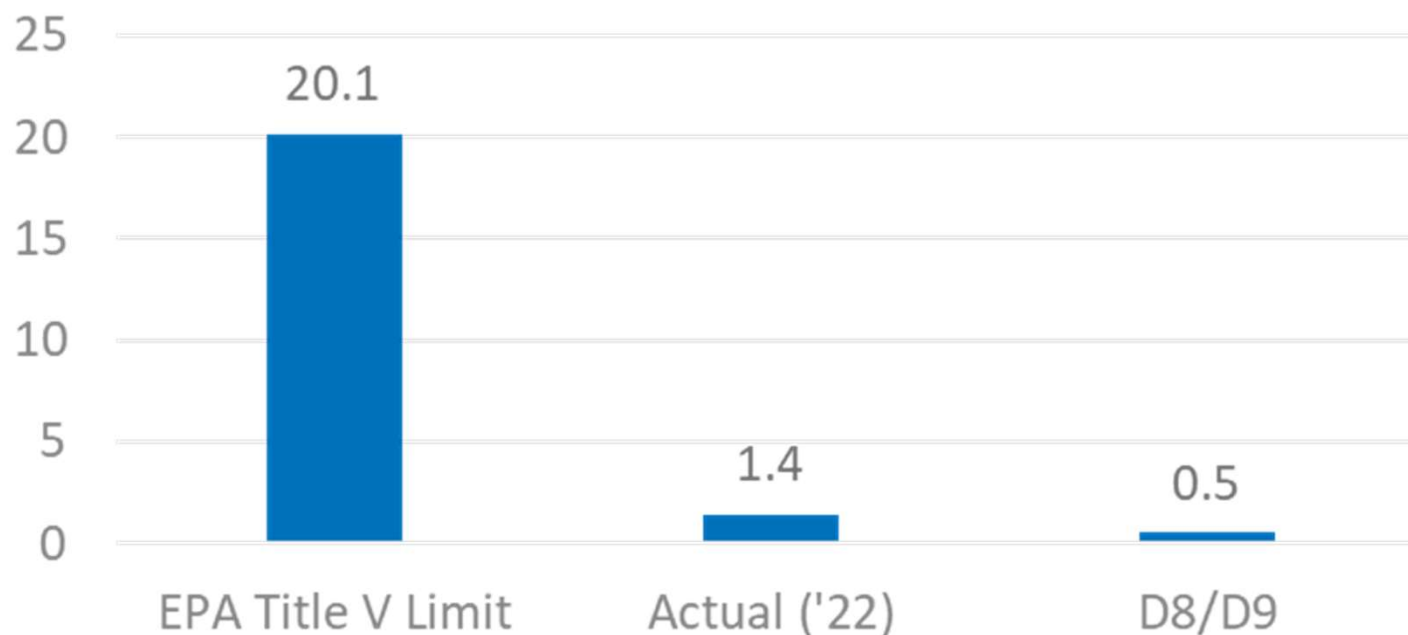
MARINOL® (Dronabinol) Capsules is indicated for the treatment of:

1. anorexia associated with **weight loss in patients with AIDS**; and
2. **nausea and vomiting associated with cancer chemotherapy** in patients who have failed to respond adequately to conventional antiemetic treatments.

Note 1: <https://aspr.hhs.gov/ibx/Pages/EssentialMedicines-2022.aspx>

Note 2: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>

Noramco VOC Emissions Tons Per Year



- Noramco is currently emitting < 7% of it's allowed VOC emissions
- With the addition of D8/D9 VOCs, Noramco will be at 10% of it's allowed VOC emissions
- Annual VOC emissions for the new D8/D9 process will be equivalent to 3 cars driving 12,000 miles each per year.

Overview of Project

Scope:

1. New process transfer piping, instrumentation, and associated safety controls automation for a total cost of \$1,400,000
2. New vacuum pump and associated automation safety controls for the various vacuum distillation steps in the D8/D9 process.

Schedule:

1. Non-permit required construction: August 2023 to December 2023.
2. Permit required construction: On hold until the requested air permit is approved by DNREC; desired completion January 2024.

New Vacuum Pump



Proposed Vacuum Pump Location



Changes to the existing emission permit result in all values being “Far Below The Health-Based Standard”

2022 Emissions and Requested Emissions			
Pollutant	Noramco 2022 Emissions (tons)	Requested Emissions (ton/yr)	Percentage of DNREC's Health-Based Standard~
Ethanol*	0.09	0.015	0.006%
Ethyl Acetate*	0.003	0.13	0.017%
Methanol*†	0.02	0.08	5.033%
n-Butanol*†	0.001	0.0006	0.015%
Tetrahydrofuran*†	N/A	0.015	0.272%
Toluene*†	0.85	0.13	0.253%
Triethylamine*†	0	0.001	0.007%
Acetone*	0	0.11	0.051%
4Hydrogen Chloride†	0.01	0.0007	0.001%
Total VOC*	0.97	0.5	-
Total HAP†	0.88	0.22	-
Facility Wide Actual Total VOC Emissions	1.48	-	-
Facility Wide Actual Total HAP Emissions	0.88	-	-

* Indicates that pollutant is a VOC

† Indicates that pollutant is a HAP

Date for which Noramco's most recent emissions data is available

+ Not shown is tetrahydrofuran, an organic solvent, which is not currently used at the facility, but is being added as part of this permit application up to a limit of 15 kg or about 33 lbs/year.

~ Based upon ACGIH Threshold Limit Values www.acgih.org/science/tlv-bei-guidelines/tlv-chemical-substances-introduction/.

Anything above 100% would be considered unhealthy. **Everything in green above is far below the standard.**

Community Involvement and Economic Contribution

Wilmington payroll and related taxes are about \$20 million

City of Wilmington property taxes of over \$100,000.

Noramco Wilmington purchases over \$5 million in goods and services in Delaware and the surrounding states each year.

The Wilmington site has contributed over \$100,000 annually to local charities and community organizations, through monetary contributions, supplies, services, and volunteerism.

American Cancer Society

Blood Bank of Delaware

Children's Hospital of Philadelphia

Christiana Conservancy

Christina River Cleanup

Delaware Nature Society

Easter Seals

Engineers without Borders

Habitat for Humanity

Junior Achievement

Kalmar Nyckel Foundation

Latin America Community Center

Movember – Prostate Cancer Fundraiser

Southbridge Neighborhood House

Toys for Tots

United Way

City of Wilmington LEPC

City of Wilmington Police

City of Wilmington Fire Department

YWCA Homelife Management Center