

and replacement parts for customers that purchased their covered products prior to the date the exclusion order becomes final; and (2) cease and desist orders prohibiting domestic respondents BMC Medical Co., Ltd., 3B Medical, Inc. from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent.

On February 18, 2015, ResMed filed a notice of appeal in the U.S. Court of Appeals for the Federal Circuit, seeking review of the Commission's determination as to the '453 patent (Appeal No. 2015-1360). On April 14, 2015, BMC filed a notice of appeal in the Federal Circuit, seeking review of the Commission's domestic industry determination as well as the Commission's finding that prior art does not render the asserted claims of the '267 patent invalid for obviousness (Appeal No. 2015-1576). The Court consolidated the two appeals on April 23, 2015.

On March 16, 2016, the parties jointly moved to dismiss ResMed's appeal as to the '453 patent. On March 17, 2016, the Commission moved to remand BMC's appeal in light of intervening domestic industry precedent in *Lelo Inc. v. International Trade Commission*, 789 F.3d 879 (Fed. Cir. 2015). On March 29, 2016, the Court granted the motion to dismiss ResMed's appeal. On April 22, 2016, the Court granted the Commission's remand motion.

On May 12, 2016, the Commission issued a notice suspending the remedial orders in place during the pendency of the remand proceedings. 81 FR 31254-55 (May 18, 2016). The Commission also issued an order asking the parties to comment on further proceedings. On June 8, 2016, the parties submitted initial comments. The parties filed responses on July 15, 2016. On August 16, 2016, the Commission issued an order remanding the investigation to the ALJ to: (1) Apply the Federal Circuit's intervening domestic industry precedent in *Lelo* to the existing record (as to the mask patents, the only patents remaining); and (2) issue an RID on remand as to violation.

On November 10, 2016, the ALJ issued the RID finding that ResMed

failed to establish the existence of a domestic industry that practices the mask patents. RID at 1. No petitions for review were received.

Having examined the record of this investigation, the Commission has determined to review in-part the RID for the limited purpose of modifying pages 20-21 and 24 of the RID. The Commission does not adopt the RID's statements that "the amount a complainant spends to purchase components manufactured in the United States is immaterial to the economic prong analysis" (RID at 20-21) or that evidence of payments to domestic suppliers is "*per se* insufficient to include in the quantitative analysis." RID at 24. The Commission has determined to otherwise not review the RID. The Commission has determined to vacate the suspended remedial orders. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 12, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-392]

#### Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before March 20, 2017.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to

exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 12, 2016, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801-4417 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance    | Drug code | Schedule |
|-------------------------|-----------|----------|
| Marihuana .....         | 7360      | I        |
| Codeine-N-oxide .....   | 9053      | I        |
| Dihydromorphine .....   | 9145      | I        |
| Hydromorphanol .....    | 9301      | I        |
| Morphine-N-oxide .....  | 9307      | I        |
| Amphetamine .....       | 1100      | II       |
| Methylphenidate .....   | 1724      | II       |
| Phenylacetone .....     | 8501      | II       |
| Codeine .....           | 9050      | II       |
| Dihydrocodeine .....    | 9120      | II       |
| Oxycodone .....         | 9143      | II       |
| Hydromorphone .....     | 9150      | II       |
| Hydrocodone .....       | 9193      | II       |
| Morphine .....          | 9300      | II       |
| Oripavine .....         | 9330      | II       |
| Thebaine .....          | 9333      | II       |
| Opium extracts .....    | 9610      | II       |
| Opium fluid extract ... | 9620      | II       |
| Opium tincture .....    | 9630      | II       |
| Opium, powdered .....   | 9639      | II       |
| Opium, granulated ....  | 9640      | II       |
| Oxymorphone .....       | 9652      | II       |
| Noroxymorphone .....    | 9668      | II       |
| Tapentadol .....        | 9780      | II       |

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. In reference to drug code 7360, the company plans to manufacture a synthetic version of cannabidiol in bulk for sale to its customers, who are final dosage form manufacturers. No other activity for this drug code is authorized for this registration.

Dated: January 11, 2017.

**Louis J. Milione,**

*Assistant Administrator.*

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**BILLING CODE 4410-09-P**