

of Cupertino, CA. The complainant requests that the Commission issue an exclusion order and a cease and desist order.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3190") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic

Filing Procedures.<sup>1</sup>) Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,<sup>2</sup> solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.<sup>3</sup>

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 22, 2016.

**Lisa R. Barton,**

*Secretary to the Commission.*

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<sup>1</sup> Handbook for Electronic Filing Procedures: [https://www.usitc.gov/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf).

<sup>2</sup> All contract personnel will sign appropriate nondisclosure agreements.

<sup>3</sup> Electronic Document Information System (EDIS): <https://edis.usitc.gov>

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-392]

#### Bulk Manufacturer of Controlled Substances Application: Janssen Pharmaceutical, 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 February 27, 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 September 9, 2016, Janssen Pharmaceutical, Inc., Buildings 1-5 & 7-14, 1440 Olympic Drive, Athens, Georgia 30601 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Methylphenidate .....	1724	II
Oxycodone .....	9143	II
Hydromorphone .....	9150	II
Hydrocodone .....	9193	II
Oripavine .....	9330	II
Thebaine .....	9333	II
Oxymorphone .....	9652	II
Tapentadol .....	9780	II
Fentanyl .....	9801	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers.

Dated: December 21, 2016.

**Louis J. Milione,**

*Assistant Administrator.*

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## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Second Partial Consent Decree Under the Clean Air Act

On December 20, 2016, the Department of Justice lodged a proposed Second Partial Consent Decree with the United States District Court for the Northern District of California in the lawsuit entitled *In re: Volkswagen "Clean Diesel" Marketing, Sales Practices, and Products Liability Litigation*, Case No: MDL No. 2672 CRB (JSC), partially resolving Clean Air Act and various California claims (including under the California Health and Safety Code) against Volkswagen AG and others, concerning certain noncompliant 3.0 liter diesel vehicles.

On January 4, 2016, the United States, on behalf of the Environmental Protection Agency ("EPA") filed a complaint against Volkswagen AG, Volkswagen Group of America, Inc., Volkswagen Group of America Chattanooga Operations, LLC, Audi AG, Dr. Ing. h.c. F. Porsche AG, and Porsche Cars North America, Inc. alleging that the defendants violated Sections 203(a)(1), (2), (3)(A), and (3)(B) of the Clean Air Act ("Act"), 42 U.S.C. 7522(a)(1), (2), (3)(A), and (3)(B), with regard to approximately 500,000 model year 2009 to 2015 motor vehicles containing 2.0 liter diesel engines (2.0 Liter Subject Vehicles) and approximately 80,000 model year 2009 to 2016 motor vehicles containing 3.0 liter diesel engines (3.0 Liter Subject Vehicles). An amended complaint was filed on October 7, 2016. The United States' complaint (initial and as amended) alleges that each 2.0 and 3.0 Liter Subject Vehicle contains computer algorithms that are prohibited defeat devices that cause the emissions control system of those vehicles to perform differently during normal vehicle operation and use than during emissions testing. The complaint alleges that the defeat devices cause the vehicles, during normal vehicle operation and use, to emit levels of oxides of nitrogen ("NO<sub>x</sub>") significantly in excess of EPA-compliant levels. The complaint seeks, among other things, injunctive relief to remedy the violations, including mitigation of excess NO<sub>x</sub> emissions, and civil penalties.

On June 27, 2016, People of the State of California ("California"), by and through the California Air Resources Board ("CARB") and the California Attorney General filed a complaint against defendants alleging that defendants violated Cal. Health & Safety Code §§ 43016, 43017, 43151, 43152, 43153, 43205, 43211, and 43212; Cal. Code Regs. tit. 13, §§ 1903, 1961, 1961.2, 1965, 1968.2, and 2037, and 40 CFR Sections incorporated by reference in those California regulations; Cal. Bus. & Prof. Code §§ 17200 *et seq.*, 17500 *et seq.*, and 17580.5; Cal. Civ. Code § 3494; and 12 U.S.C. 5531 *et seq.*, with regard to approximately 71,000 model year 2009 to 2015 motor vehicles containing 2.0 liter diesel engines and approximately 16,000 model year 2009 to 2016 motor vehicles containing 3.0 liter diesel engines, for a total of approximately 87,000 motor vehicles. The California complaint alleges, in relevant part, that the motor vehicles contain prohibited defeat devices and have resulted in, and continue to result in, increased NO<sub>x</sub> emissions from each such vehicle significantly in excess of CARB requirements, that these vehicles have resulted in the creation of a public nuisance, and that defendants engaged in related conduct that violated unfair competition, false advertising, and consumer protection laws.

On June 28, 2016, the United States lodged a Partial Consent Decree, Dkt. No. 1605-1 ("First Partial Consent Decree"), concerning the 2.0 Liter Subject Vehicles, which was entered into by the United States, California, and certain defendants (Volkswagen AG, Audi AG, Volkswagen Group of America, Inc., and Volkswagen Group of America Chattanooga Operations, LLC). The First Partial Consent Decree was entered by this Court on October 25, 2016, Dkt. No. 2103, and may be viewed here: <http://www.cand.uscourts.gov/crb/vwmdl>.

This Second Partial Consent Decree ("Decree") is entered into between the United States, California, and all defendants (collectively, "Volkswagen"). The Decree partially resolves the governments' claims for injunctive relief with respect to the 3.0 Liter Subject Vehicles, by providing remedies for the cars on the road and the environmental harm from the violations. It does not address plaintiffs' claims, *inter alia*, for prospective injunctive relief to prevent future violations of the same type that are alleged in the complaints or claims for civil penalties.

Under the Decree, Volkswagen must perform two vehicle recalls as follows (with all capitalized terms as defined in

Appendix A of the Decree (Buyback, Lease Termination, Vehicle Modification, and Emissions Compliant Recall Program):

First, for Generation 1.x 3.0 Liter Subject Vehicles, Volkswagen must offer all Eligible Owners and Lessees of these vehicles the Buyback or the Lease Termination under terms described in Appendix A. In addition, if approved by EPA/CARB, Volkswagen may, in accordance with the requirements specified in Appendix B of the Decree (Vehicle Recall and Emissions Modification Program for 3.0 Liter Subject Vehicles), offer for Eligible Vehicles the option of a modification to substantially reduce NO<sub>x</sub> emissions in accordance with standards established by EPA/CARB in the Decree.

Second, for Generation 2.x 3.0 Liter Subject Vehicles, if proposed by Volkswagen and approved by EPA/CARB, Volkswagen must offer an Emissions Compliant Recall as set forth in Appendix A to bring these vehicles into compliance with their Certified Exhaust Emission Standards in accordance with the requirements specified in Appendix B. If Volkswagen is unable to effect a recall that meets Certified Exhaust Emission Standards for a particular Test Group or Groups of Generation 2.x 3.0 Liter Subject Vehicles in accordance with the requirements specified in Appendix B, Volkswagen must offer all Eligible Owners and Lessees of such vehicles the Buyback or Lease Termination, under terms described in Appendix A, and may, if proposed by Volkswagen and approved by EPA/CARB, consistent with the provisions in Appendix B, offer to modify such vehicles to substantially reduce their NO<sub>x</sub> emissions in accordance with standards established by EPA/CARB in this Consent Decree. See Decree ¶¶ 9-15; Appendices A and B.

Volkswagen must achieve a recall rate (through the buyback, lease termination, scrapped vehicles, the Emissions Compliant Recall, and any other approved vehicle modification options) of 85% by November 30, 2019 for the Generation 1.x 3.0 Liter Subject Vehicles, and by May 31, 2020 for the Generation 2.x 3.0 Liter Subject Vehicles. If it fails to do so, Volkswagen must augment the mitigation trust fund discussed below by \$5.5 million for each 1% that it falls short of the 85% rate for the Generation 1.x 3.0 Liter Subject Vehicles, and by \$21 million for each 1% that it falls short of the 85% rate for the Generation 2.x 3.0 Liter Subject Vehicles. Volkswagen must also achieve a separate 85% recall rate for vehicles in California, and must pay to