undermine competition in the pharmaceutical industry.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18562 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 1623034, Docket No. C–4580]

Very Incognito Technologies, Inc., Doing Business as Vipvape

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: The Commission has approved a final consent order in this matter, settling alleged violations of federal law prohibiting deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the Complaint and the terms of the Decision and Order.

DATES: Issued on June 21, 2016.

SUPPLEMENTARY INFORMATION:

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has approved a final consent order applicable to Very Incognito Technologies, Inc. dba Vipvape (''Vipvape'').

The consent order was placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period became part of the public record. After the public comment period, the Commission reviewed the agreement and the comments received, and determined to make the proposed order final.

This matter concerns allegedly false representations that Vipvape made to consumers concerning its participation in the Asia-Pacific Economic Cooperation (''APEC'') Cross Border Privacy Rules (''CBPR'') system. The APEC CBPR system is a voluntary, enforceable mechanism that certifies a company's compliance with the principles in the CBPR and facilitates privacy-respecting transfers of data amongst APEC member economies. The APEC CBPR system is based on nine data privacy principles: Preventing harm, notice, collection limitation, use choice, integrity, security safeguards, access and correction, and accountability. Companies that seek to participate in the APEC CBPR system must undergo a review by an APEC-recognized Accountability Agent, which certifies companies that meet the standards.

Companies under the FTC's jurisdiction are eligible to apply for APEC CBPR certification. The names of certified companies are posted on a public-facing Web site, *www.cbprs.org.* Companies must re-apply annually in order to retain their status as current participants in the APEC CBPR system. A company that falsely claims APEC CBPR participation may be subject to an enforcement action based on the FTC's deception authority under Section 5 of the FTC Act.

Vipvape makes and distributes hand-held vaporizers. According to the Commission's complaint, Vipvape has set forth on its Web site, *https://www.vipvape.com/content/legal/warranty/privacy*, privacy policies and statements about its practices, including statements related to its participation in the APEC CBPR system.

The Commission's complaint alleges that Vipvape falsely represented that it was a participant in the APEC CBPR system when, in fact, it never sought or obtained certification.

Part I of the order prohibits Vipvape from making misrepresentations about its participation in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including, but not limited to, the APEC CBPR system.

Parts II through VI of the order are reporting and compliance provisions. Part II requires acknowledgment of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that Vipvape submit an initial compliance report to the FTC. Part IV requires Vipvape to retain documents relating to its compliance with the order for a five-year period. Part V mandates that Vipvape make available to the FTC information or subsequent compliance reports, as requested. Part VI is a provision that ''sunsets'' the order on June 21, 2036, with certain exceptions.

The purpose of this analysis, which was placed on the Commission Web site on May 4, 2016, was to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18566 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 161–0102]

Mylan N.V.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christina Perez (202–326–2350), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final

approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 27, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 29, 2016. Write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 29, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Mylan N.V. (''Mylan'') that is designed to remedy the anticompetitive effects resulting from Mylan's acquisition of Meda AB (''Meda''). Under the terms of the proposed Consent Agreement, Mylan is required to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. (''Alvogen''), and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC (''Indicus'') the abbreviated new drug application owner for this product.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed consent Agreement or make final the Decision and Order (''Order'').

Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Mylan intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately $7.2 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

The proposed acquisition would reduce the number of current suppliers in the markets for 400 mg and 600 mg generic felbamate tablets and reduce the number of future suppliers in the market for 250 mg generic carisoprodol tablets.

Generic felbamate tablets treat severe refractory epilepsy and are available in 400 mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration (''FDA'') approval for each strength of generic felbamate tablets, but it is not yet on the market.

Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

II. Entry

Entry into the three relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (''FDA''), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18563 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9098–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2016, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877