Federal Register document of January 15, 2016 (81 FR 2212) (FRL–9940–82). In that document, EPA opened a comment period for a draft pollinator-only ecological risk assessment for the registration review of imidacloprid. EPA is hereby extending the comment period, which was set to end on March 15, 2016, to April 14, 2016.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of January 15, 2016. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: February 29, 2016.

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation, Office of Pesticide Programs.

[FR Doc. 2016–05033 Filed 3–4–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL TRADE COMMISSION

[File No. 151 0198]

Hikma Pharmaceuticals PLC; 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 draft 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 March 29, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/hikmaroxaneconsent* 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 Hikma Pharmaceuticals PLC,—Consent Agreement; File No. 151–0198'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/hikmaroxaneconsent* by following the instructions on the Web-based form. If you prefer to file your comment on paper, write ''In the Matter of Hikma Pharmaceuticals PLC,—Consent Agreement; File No. 151–0198'' 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: Jacqueline Mendel (202–326–2603), 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 a consent order 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 February 26, 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 March 29, 2016. Write ''In the Matter of Hikma Pharmaceuticals PLC,—Consent Agreement; File No. 151–0198'' 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/hikmaroxaneconsent* 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 Hikma Pharmaceuticals PLC,—Consent Agreement; File No. 151–0198'' 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. 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 March 29, 2016. You can find

[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).

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 Hikma Pharmaceuticals PLC (''Hikma'') that is designed to remedy the anticompetitive effects resulting from Hikma's acquisition of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, ''Roxane'') from Boehringer Ingelheim Corporation (''BI''). Under the terms of the proposed Consent Agreement, Hikma must divest all of its rights and assets related to 5 mg, 10 mg, and 20 mg generic prednisone tablets and to generic lithium carbonate capsules to Renaissance Acquisition Holdings LLC (''Renaissance''), and to divest all marketing rights and ownership interests in generic flecainide tablets to Unimark Remedies Ltd (''Unimark'').

The Commission has placed the proposed Consent Agreement 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 Stock Purchase Agreement dated July 28, 2015, Hikma proposed to acquire 100% of the issued and outstanding shares of Roxane for approximately $2.65 billion. On February 10, 2016, the purchase price was reduced to approximately $2 billion (the ''Proposed Acquisition''). 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 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsules market, and future competition in the market for generic flecainide tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that the Proposed Acquisition would otherwise eliminate.

I. The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of current suppliers in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and for generic lithium carbonate capsules, and reduce the number of future suppliers in the market for generic flecainide tablets.

Prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. Prednisone is also prescribed as an immunosuppressant medication. Generic prednisone is available in six tablet strengths: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, and 50 mg. Hikma and Roxane both market three of the six tablet strengths: 5 mg, 10 mg, and 20 mg. In addition to Hikma and Roxane, Endo International plc, Allergan, Inc., and Jubilant Cadista Pharmaceuticals, Inc. also offer 5 mg, 10 mg, and 20 mg generic prednisone tablets in the United States.

Lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. Lithium therapy reduces the frequency of manic episodes and diminishes the intensity of episodes when they occur. In addition to Hikma and Roxane, two other firms currently supply generic lithium carbonate capsules in the United States: Glenmark Pharmaceuticals Ltd. and Camber Pharmaceuticals Inc.

Flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. Four firms currently market generic flecainide tablets: Roxane, Amneal Pharmaceuticals, ANI Pharmaceuticals, Inc., and Citron Pharma. Hikma owns the U.S. marketing rights to a generic flecainide in development at Unimark Remedies Ltd. Hikma is one of few suppliers that can enter the United States market in the near future.

II. Entry

Entry into the 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 current competition between Hikma and Roxane in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsule market. Market participants characterize both generic prednisone tablets and generic lithium carbonate capsules as commodity products, and prices are typically 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 five companies offering the 5 mg, 10 mg, and 20 mg strengths of generic prednisone tablets, and two of four firms offering generic lithium carbonate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisition likely would harm consumers by eliminating future generic competition that would otherwise have occurred in the generic flecainide market if Hikma and Roxane remained independent. The Proposed Acquisition would likely harm competition by eliminating an additional independent entrant in the market for generic flecainide. Customers view the price of this pharmaceutical product as less competitive than it would be in a market with more participants, including Hikma. Thus, absent a remedy, the Proposed Acquisition would likely cause U.S. consumers to pay significantly higher prices for generic flecainide tablets.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition by requiring Hikma to divest all its rights and assets relating to 5 mg, 10 mg, and 20 mg generic prednisone and those relating to generic lithium carbonate capsules to Renaissance. Established in 2010 and based in Newtown, Pennsylvania, Renaissance is a privately held pharmaceutical company that manufactures and markets both generic and branded prescription drugs in the United States. In addition, the proposed Consent Agreement requires Hikma to return its rights to market generic flecainide tablets in the United States to Unimark, along with its equity interest in Unimark.

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 Renaissance is not an acceptable acquirer, or that the manner

of the divestitures is not acceptable, the proposed Order requires Hikma to unwind the sale of rights to Renaissance 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 should 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 Hikma supply Renaissance with 5 mg, 10 mg, and 20 mg generic prednisone tablets and with generic lithium carbonate capsules for eighteen months while Hikma transfers the manufacturing technology to Renaissance's facility. The proposed Order also requires Hikma to provide a back-up supply of active pharmaceutical ingredient for generic prednisone tablets should the need for it arise. To ensure the success of these divestitures, the proposed Order requires Hikma to provide transitional services to assist Renaissance 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 Hikma, and advice and training from knowledgeable employees of the parties. In addition, to ensure that Hikma complies with the terms of the Consent Agreement, the Commission has appointed Owen Richards of Quantic Regulatory Services, LLC as the Interim Monitor.

To remedy competitive concerns raised by the acquisition in the market for generic flecainide tablets, the proposed Order requires Hikma to divest its approximately 23% ownership interest in Unimark and to return to Unimark all rights it has to commercialize generic flecainide tablets in the United States. Unimark has selected another firm, Bion Pharma, of Princeton, New Jersey, to market generic flecainide tablets in the United States upon the product's approval by the FDA.

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. 2016–04884 Filed 3–4–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0077; Docket 2016–0053; Sequence 13]

Information Collection; Quality Assurance Requirements

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning quality assurance requirements.

DATES: Submit comments on or before May 6, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0077, Quality Assurance Requirements, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0077, Quality Assurance Requirements''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0077, Quality Assurance Requirements'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0077, Quality Assurance Requirements.

Instructions: Please submit comments only and cite Information Collection 9000–0077, Quality Assurance Requirements, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, at 202–501–1448 or email *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Supplies and services acquired under Government contracts must conform to the contract's quality and quantity requirements. FAR Part 46 prescribes inspection, acceptance, warranty, and other measures associated with quality requirements. Standard clauses related to inspection require the contractor to provide and maintain an inspection system that is acceptable to the Government; gives the Government the right to make inspections and test while work is in process; and requires the contractor to keep complete, and make available to the Government, records of its inspection work.

B. Annual Reporting Burden

Respondents: 138,292.

Responses Per Respondent: 1.03226.

Total Responses: 142,753.

Hours Per Response: .83511.

Total Burden hours: 119,214.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0077, Quality Assurance Requirements, in all correspondence.