

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 obtained from any person and which is privileged or confidential," as provided 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).<sup>3</sup> 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://ftcpublishcommentworks.com/ftc/fraudsurvey2>, 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 "Consumer Fraud Survey, Project No. P105502" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

<sup>3</sup>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).

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 31, 2011. 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>.

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395-5167.

**David C. Shonka,**

*Acting General Counsel.*

[FR Doc. 2011-19367 Filed 7-29-11; 8:45 am]

**BILLING CODE 6750-01-P**

## FEDERAL TRADE COMMISSION

[File No. 111 0083]

### **Perrigo Company and Paddock Laboratories, Inc.; Analysis of Agreement Containing Consent Orders 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 or deceptive acts or practices or 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 order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before August 26, 2011.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section

below. Write "Perrigo Paddock, File No. 111 0083" on your comment, and file your comment online at <https://ftcpublishcommentworks.com/ftc/perrigopaddockconsent>, by following the instructions on the Web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

#### **FOR FURTHER INFORMATION CONTACT:**

Christine Palumbo (202-326-3330), FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 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 July 26, 2011), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 10, 2011. Write "Perrigo Paddock, File No. 111 0083" on your comment. Your comment B including your name and your state B 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 obtained from any person and which is privileged or confidential,” as provided 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).<sup>1</sup> 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://ftcpublishcommentworks.com/ftc/perrigopaddockconsent> 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 “Perrigo Paddock, File No. 111 0083” on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580. 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 26, 2011. 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 Order To Aid Public Comment

### I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Perrigo Company (“Perrigo”) and Paddock Laboratories, Inc. (“Paddock”) that is designed to remedy the anticompetitive effects resulting from Perrigo’s acquisition of Paddock. Under the terms of the proposed Consent Agreement, the companies would be required to divest to Watson Pharmaceuticals, Inc. (“Watson”) Paddock’s rights and assets necessary to manufacture and market generic: (1) Ammonium lactate external cream 12 percent (“ammonium lactate cream”); (2) ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”); (3) ciclopirox shampoo 1 percent (“ciclopirox shampoo”); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”). The proposed Consent Agreement also requires the companies to divest to Watson all of Perrigo’s rights and assets necessary to manufacture and market generic clobetasol propionate spray 0.05 percent (“clobetasol spray”) and diclofenac sodium topical solution 1.5 percent (“diclofenac solution”). Further, the proposed Consent Agreement prohibits the companies from accepting certain payments under a backup supply agreement between Paddock and Abbott Laboratories (“Abbott”) for Androgel, the branded version of testosterone gel 1 percent (“testosterone gel”), and entering into any “pay-for-delay” arrangements with Abbott.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to a Purchase Agreement dated January 20, 2011, Perrigo plans to acquire substantially all of Paddock’s assets for \$540 million. The Commission’s Complaint alleges 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 FTC Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceuticals: (1) Ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the “Products”); and (7) testosterone gel. The proposed Consent Agreement will remedy the alleged violations in each of these markets.

### II. The Products and Structure of the Markets

The proposed acquisition would reduce the number of generic suppliers in six generic drug markets. The number of generic suppliers has a direct and substantial impact on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here and the branded products are substantially more expensive than the generic versions, the branded versions no longer significantly constrain the generics’ pricing.

The proposed acquisition would reduce the number of competitors from three to two in four markets: (1) Ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; and (4) promethazine suppository. The structure of each of these markets is as follows:

- The ammonium lactate cream and lotion products are both prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. In 2010, annual sales of ammonium lactate cream were approximately \$9.7 million, while sales of the ammonium lactate lotion totaled \$19 million. The same firms compete in both markets—Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. (“Taro”), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo leads the market for ammonium lactate cream with a 70 percent share in the United States. Paddock has 17 percent of the market and Taro has 12 percent. In the market for ammonium lactate cream, the combined firm would account for 87 percent after the proposed acquisition. Perrigo and Paddock are the leading U.S. suppliers

<sup>1</sup>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).

of ammonium lactate lotion, with 43 percent and 50 percent of the market, respectively. Taro has only captured a 5 percent market share to date. Post-acquisition, Perrigo's share would increase to 93 percent of the market.

- Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Paddock is the leading supplier in the \$14.5 million market for ciclopirox shampoo, with a share of approximately 83 percent. Perrigo, with a share of 16 percent, and E. Fougera & Co., with a 1 percent share, are the only other U.S. suppliers of the product. The proposed acquisition, therefore, would result in a combined market share of 99 percent.

- Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. Sales of the 12.5 mg and 25 mg strengths were approximately \$7.9 million and \$36.1 million in 2010, respectively. Perrigo, Paddock, and G&W Laboratories, Inc. ("G&W") are the only U.S. suppliers of both strengths. For the 12.5 mg strength, Perrigo has 15 percent of the market, Paddock has 19 percent, and G&W has 66 percent. For the 25 mg strength, Perrigo has 15 percent of the market, Paddock has 20 percent, and G&W has 65 percent. A combined Perrigo and Paddock would possess 34 percent of the 12.5 mg market and 35 percent of the 25 mg market.

Both Perrigo and Paddock also are developing products for two future generic drug markets: (1) Clobetasol spray and (2) diclofenac solution. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are among a limited number of suppliers that are capable of, and interested in, entering these markets in a timely manner. Accordingly, the proposed acquisition would eliminate important future competition in these markets.

Finally, the proposed acquisition also could inhibit important future competition in the testosterone gel market. Testosterone gel, marketed by Abbott under the brand name Androgel, is a prescription gel used to treat adult males with a testosterone deficiency. Perrigo is one of a limited number of suppliers capable of entering this future generic market in a timely manner. Pursuant to an agreement between Par Pharmaceutical Companies, Inc. ("Par"),

Paddock, and Solvay Pharmaceuticals, the former owner of Androgel, Par agreed to delay introducing a generic version of Androgel in exchange for, among other things, payments under a backup supply agreement. That agreement has since been transferred to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product.

### III. Entry

Entry into the markets for the manufacture and sale of the products would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and U.S. Food and Drug Administration ("FDA") drug approval requirements take a minimum of two years. Furthermore, entry would not be likely because many of the relevant markets are small, so the limited sales opportunities available to a new entrant would likely be insufficient to warrant the time and investment necessary to enter.

### IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. The evidence shows that with the entry of each additional competitor, the prices of the generic products at issue have decreased. Customers consistently state that the price of a generic drug decreases with the entry of the second, third, and even fourth competitor. In these markets, the proposed acquisition would eliminate one of only three competitors. The evidence indicates that anticompetitive effects—both unilateral and coordinated—are likely to result from a decrease in the number of independent competitors in these markets, thereby increasing the likelihood that customers will pay higher prices.

The proposed acquisition also eliminates or delays important future competition between Perrigo and Paddock in the U.S. markets for clobetasol spray and diclofenac solution. Perrigo's and Paddock's independent entry into these markets likely would have resulted in lower

prices for customers. The proposed acquisition would deprive customers of the expected price decrease that would occur upon the parties' entry into these markets.

Similarly, the proposed acquisition increases the likelihood and degree of coordinated interaction between Perrigo and Abbott in the U.S. testosterone gel market. Perrigo would become a party to the Par/Paddock backup supply agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product. Perrigo's independent entry into the market likely would result in lower prices for customers. The proposed acquisition could therefore deprive customers of the expected price decrease that would ensue upon Perrigo's timely entry into the market.

### V. The Consent Agreement

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant product markets by requiring a divestiture of the Products to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

The Consent Agreement requires that the parties divest rights and assets related to the Products to Watson. Watson is the third largest generic drug manufacturer in the United States, and well-situated to manufacture and market the acquired products. Watson has extensive experience in the development, manufacturing, and distribution of generic pharmaceuticals, as well as experience transferring assets from other pharmaceutical companies. Watson has approximately 325 active products and an active product development pipeline. Moreover, Watson's acquisition of the divested assets does not in itself present competitive concerns because Watson does not compete, nor does it have plans to independently enter, any of the markets affected by the proposed transaction. With its resources, capabilities, strong reputation, and experience manufacturing and marketing generic products, Watson is well-positioned to replicate the competition that would be lost with the acquisition.

If the Commission ultimately determines that Watson is not an acceptable acquirer of the assets to be divested, or that the manner of the

divestitures to Watson is not acceptable, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Perrigo and Paddock to provide transitional services to enable Watson to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Perrigo and Paddock. In addition, the parties must supply Watson with the Products pursuant to a supply agreement while they transfer the manufacturing technology to a third-party manufacturer of Watson's choice.

The Consent Agreement also preserves competition in the market for testosterone gel by prohibiting the parties from: (1) receiving any payments that accrue after the initial term of the backup supply agreement aside from those for manufacturing the product; and (2) entering into any anticompetitive pay-for-delay arrangements with Abbott regarding the testosterone gel product.

The Commission has appointed F. William Rahe of Quantic Regulatory Services, LLC ("Quantic") as the Interim Monitor to oversee the asset transfer and to ensure Perrigo and Paddock's compliance with the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.

**Richard C. Donohue,**

*Acting Secretary.*

[FR Doc. 2011-19422 Filed 7-29-11; 8:45 am]

**BILLING CODE 6750-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS-0990-New; 60-day Notice]**

### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [Sherrette.funncoleman@hhs.gov](mailto:Sherrette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

**Proposed Project:** Descriptive information of solutions provided to the Federal government in response to Challenge and Competition solicitations posted on *Challenge.gov*.— OMB No. 0990-New-Immediate Office of the Secretary.

**Abstract:** This request is to seek generic clearance for the collection of routine information requested of responders to solicitations the Federal government makes during the issuance of challenges and competitions posted

on the General Service Administration (GSA)'s *Challenge.gov* Web site. Since passage of the America COMPETES Act of 2011, challenge competitions are increasingly being used by Federal agencies to solve complex problems and obtain innovative solutions. In this role, the Federal government places a description of a problem and parameters of the solution on the *Challenge.gov* Web site. The solutions are evaluated by the submitting agency and typically prizes (monetary and non-monetary) are awarded to the winning entries.

This clearance applies to challenges posted on *Challenge.gov* which uses a common platform for the solicitation of challenges from the public. Each agency designs the criteria for its solicitations based on the goals of the challenge and the specific needs of the agency. There is no standard submission format for solution providers to follow.

We anticipate that approximately 100 challenges would be issued each year by HHS, with an average of 15 submissions to each challenge solicitation. It is expected that other federal agencies will issue a similar number of challenges. There is no set schedule for the issuance of challenges; they are developed and issued on an "as needs" basis in response to issues the federal agency wishes to solve. The respondents to the challenges, who are participating voluntarily, are unlikely to reply to more than one or several of the challenges.

Although in recent memoranda the GSA and Office of Management and Budget (OMB) described circumstances whereby OMB approval of a PRA request is not needed, program officials at HHS have identified several sets of information that will typically need to be requested of solution providers to enable the solutions to be adequately evaluated by the federal agency issuing the challenge. These requests for additional information have been suggested to require a PRA review as they represent structured data requests.

There are three types of additional data that will be routinely requested by the federal agencies. These include the following:

**Title of the submission.** Due to the nature of the submission and evaluation processes, it is important that a title be requested and submitted for each submission in order to ensure the solution is correctly identified with its provider.

**Identification of data resources.** In many cases, the solution to a problem will require the solution provider to use data resources. Often, the nature of the data sets will be derived from Federal data resources, such as *data.gov*. Evaluations of solutions will often depend on the understanding of the selection of the data resource(s) used in the solution.