[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 132 3095]

Wacoal America, Inc.; 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 or deceptive acts or practices. 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 October 29, 2014.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/wacoalamericaconsent/ 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 Wacoal America, Inc. - Consent Agreement; File No. 132 3095" on your comment. File your comment online at https://ftcpublic.commentworks.com/ftc/wacoalamericaconsent/ by following the instructions on the web-based form. If you prefer to file your comment on paper, 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: David Newman, Western Region – San Francisco, (415) 848-5123, 901 Market Street, Suite 570, San Francisco, CA 94103.

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 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 September 29, 2014), 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 October 29, 2014. Write "In the Matter of Wacoal America, Inc. - Consent Agreement; File No. 132 3095" 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 Website, 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 Website.

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/wacoalamericaconsent/ 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 website.

If you file your comment on paper, write "In the Matter of Wacoal America, Inc. - Consent Agreement; File No. 132 3095" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600

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[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).

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 Website 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 October 29, 2014. 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 Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an Agreement Containing Consent Order from Wacoal America, Inc. ("respondent"). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves the advertising, marketing, and sale by respondent of iPants, women's undergarments that are infused with microencapsulated caffeine and other ingredients. Respondent has marketed the iPants garments to consumers through third-party retailers and

through its website. According to the FTC complaint, respondent claimed the iPants garments would slim and reshape the body and reduce cellulite.

Specifically, the FTC complaint alleges that respondent represented that wearing iPants garments eliminates or substantially reduces cellulite; causes a substantial reduction in the wearer's thigh measurements; and that iPants garments contain caffeine that causes the destruction of fat cells and results in substantial slimming. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. The complaint also alleges that respondent represented that scientific tests prove that most iPant wearers achieve a substantial reduction in thigh measurement and that scientific tests prove that wearing the iPants garments for eight hours a day for 28 days will substantially reduce a wearer's thigh measurement. The complaint alleges that these claims are false and thus violate the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Specifically, Parts I-III address the unsubstantiated claims alleged in the complaint. Part I prohibits respondent from claiming that any Covered Product – i.e., a garment that contains any drug or cosmetic – causes substantial weight or fat loss or a substantial reduction in unclad body size. The Commission has publicly advised that any claim that a product worn on the body causes substantial weight loss is always false.

Part II covers any representation, other than representations covered under Part I, that any Covered Product or any drug or cosmetic causes weight or fat loss or a reduction in unclad body size. Part II prohibits respondent from making such representations unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part II, the proposed order defines "competent and reliable scientific evidence" as at least two randomized, double-blind, placebo-controlled human clinical studies that are conducted by independent, qualified researchers and that conform to acceptable designs and protocols, and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

Part III of the proposed order prohibits respondent from making any representation, other than representations covered under Parts I or II, that use of a Covered Product or a drug or cosmetic reduces or eliminates cellulite, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of Part III, the proposed order defines "competent and reliable scientific evidence" as tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the proposed order addresses the allegedly false claims that scientific tests prove that wearing iPants garments result in reduction of the wearer's thigh measurement. Part IV prohibits respondent, when advertising any product, from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or misrepresenting that the benefits of the product are scientifically proven.

Part V of the proposed order provides a safe harbor for representations that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration ("FDA"), any new drug application approved by the FDA, or FDA regulations

pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Part VII of the proposed order requires respondent to pay one million three hundred thousand dollars ($1,300,000) to the Commission to be used for equitable relief, including restitution, and any attendant expenses for the administration of such equitable relief. To facilitate the payment of redress, Part VI of the proposed order requires Wacoal America to provide to the Commission a searchable electronic file containing the name and contact information of all consumers who purchased the iPants garments directly from respondent from January 1, 2011, through the date of entry of the order. Part VIII of the proposed order requires respondent to comply with the provisions of Appendix A to the order, which sets out the methods for notifying consumers who may be entitled to file a claim for consumer redress.

Part IX of the proposed order is triggered whenever the human clinical testing requirement in either Part II or Part III applies. Part IX of the proposed order requires the company to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test. There is an exception for a "Reliably Reported" test defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by any proposed respondent or supplier. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part X of the proposed order contains recordkeeping requirements for advertisements and substantiation relevant to any representation covered by the proposed order. Parts XI, XII and XIII of the proposed order require respondent to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations

under the order; and to file compliance reports with the Commission. Part XIV provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or and proposed order or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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