

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 two hundred thirty thousand dollars (\$230,000) to the Commission to be used for equitable relief, including restitution. The order also requires respondent to administer and bear the costs of the redress program. To facilitate the payment of redress, Part VI of the proposed order requires respondent to provide to the Commission a searchable electronic file containing the name and contact information of all consumers who purchased the garments from respondent from March 20, 2011, through the date of entry of the order.

Part VIII of the proposed order is triggered whenever the human clinical testing requirement in either Part II or Part III applies. Part VIII 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 IX of the proposed order contains recordkeeping requirements for advertisements and substantiation relevant to any representation covered by the proposed order. Parts X, XI and XII 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 XIII 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 and proposed order or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014-23680 Filed 10-3-14; 8:45 am]

BILLING CODE 6750-01-P

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 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/wacoalamericacconsent> 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 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 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 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 Web site. 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

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).

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.

[FR Doc. 2014-23681 Filed 10-3-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Availability of the Report on Carcinogens, Thirteenth Edition

AGENCY: National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Availability of the Report on Carcinogens, Thirteenth Edition (13th RoC).

SUMMARY: The Department of Health and Human Services released the 13th RoC to the public on October 2, 2014. The report is available on the RoC Web site at: <http://ntp.niehs.nih.gov/go/roc13> or electronically from the Office of the RoC (see **ADDRESSES** below).

DATES: The 13th RoC is available to the public on October 2, 2014.

ADDRESSES: Dr. Ruth Lunn, Director, Office of the RoC, NTP, NIEHS, P.O. Box 12233, MD K2-14, Research Triangle Park, NC 27709; telephone: (919) 316-4637; FAX: (301) 480-2970; lunn@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Questions or comments concerning the 13th RoC should be directed to Dr. Ruth Lunn (telephone: (919) 316-4637 or lunn@niehs.nih.gov).

SUPPLEMENTARY INFORMATION:

Background Information on the RoC

The RoC is a congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances") that may pose a hazard to human health by virtue of their carcinogenicity. Substances are listed in the report as either *known* or *reasonably anticipated to be human carcinogens*. The listing of a substance in the RoC indicates a potential hazard, but does not establish the exposure conditions that pose a cancer hazard to individuals in their daily lives. For each listed substance, the RoC provides information from cancer studies that support the listing as well as information about potential sources of exposure and current federal regulations to limit exposures. Each edition of the RoC is cumulative, that is, it lists newly reviewed substances in addition to substances listed in the previous edition. Information about the RoC is available on the RoC Web site (<http://ntp.niehs.nih.gov/go/roc13>) or by contacting Dr. Lunn (see **ADDRESSES** above).

The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. For the 13th RoC, the NTP followed an established, multi-step process with multiple opportunities for public input, and used established criteria to evaluate the scientific evidence on each candidate substance under review (<http://ntp.niehs.nih.gov/go/rocprocess>).

New Listings to the 13th RoC

The 13th RoC contains 243 listings, some of which consist of a class of structurally related chemicals or agents. There are three new listings and one revised listing in this edition. The revised listing is for *ortho*-toluidine, which was previously listed as *reasonably anticipated to be a human carcinogen* and is now listed as *known to be a human carcinogen*. The new listings in the 13th RoC are three substances—1-bromopropane, cumene, and pentachlorophenol and by-products of its synthesis—each listed as *reasonably anticipated to be a human carcinogen*.

Dated: September 26, 2014.

Linda S. Birnbaum,

Director, National Institute of Environmental Health Sciences, and National Toxicology Program.

[FR Doc. 2014-23748 Filed 10-3-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Temporary Assistance for Needy Families/National Directory of New Hires Match Results Report
OMB No.: 0970-0311

Description: Section 453(j)(3) of the Social Security Act (the Act) allows for matching between the National Directory of New Hires (maintained by the Federal Office of Child Support Enforcement (OCSE) and State TANF Agencies for purposes of carrying out responsibilities under programs funded under part A of Title IV of the Act. To assist OCSE and the Office of Family Assistance (OFA) in measuring savings to the TANF program attributable to the use of NDNH data matches, the State TANF Agencies have agreed to provide OCSE with a written description of the performance outputs and outcomes attributable to the State TANF Agency's use of NDNH match results. This information will help OCSE