

Analysis of Proposed Consent Order to Aid Public Comment

In the Matter of Wacoal America, Inc., File No.132-3095

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.