UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman Maureen K. Ohlhausen Terrell McSweeny

In the Matter of

POM WONDERFUL LLC and

ROLL GLOBAL LLC,

as successor in interest to Roll

International Corporation,

companies, and

Docket No. 9344

STEWART A. RESNICK,

LYNDA RAE RESNICK, and

MATTHEW TUPPER, individually and
as officers of the companies,

Respondents.

NOTICE

On January 10, 2013, the Commission issued its Opinion and Final Order in this matter, and the Final Order became final and effective on March 25, 2013. On January 30, 2015, the United States Court of Appeals for the District of Columbia Circuit denied the Respondents' petition for review of the Commission Opinion in all respects. The Court of Appeals also modified Part I of the Final Order – to require the Respondents to possess at least one randomized and controlled human clinical trial demonstrating statistically significant results (rather than at least two such trials) "before making disease claims covered by that provision" – and affirmed and enforced the Final Order as modified. The Court of Appeals issued its mandate on June 15, 2015, and on May 2, 2016, the United States Supreme Court denied the Respondents' petition for a writ of *certiorari*.

1 The Respondents and their counsel were served with copies of the Final Order, the Opinion of the Commission, and the Concurring Statements of Commissioner Rosch and Commissioner Ohlhausen on January 22, 2013. The Final Order therefore became final and effective on the sixtieth day thereafter; that is, on March 25, 2013. *See* 15 U.S.C. § 5(g)(2); Commission Rule 3.56(a), 16 C.F.R. § 3.56(a) (2016).

² *POM Wonderful, LLC, et al., Petitioners, v. Federal Trade Commission, Respondent,* No. 13-1060, slip op. at 45, *available at* https://www.ftc.gov/system/files/documents/cases/pom_dc_circuit1_0.pdf.

As required by the Court of Appeals, the second sentence of Part I of the Final Order in this matter has been modified to read as follows:

For purposes of this Part I, competent and reliable scientific evidence shall consist of at least one randomized and controlled human clinical trial (RCT) of the Covered Product that is randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies.

A copy of the Final Order – as modified, affirmed, and enforced by the Court of Appeals – is appended to this Notice.³

Donald S. Clark Secretary

SEAL:

ISSUED: June 14, 2016

³ In order to modify the Final Order as required by the Court of Appeals, the original version of page 2 of the Final Order has been replaced by the modified version – containing the revised version of Part I -- in the attached copy of the Final Order. This modification does not affect the March 25, 2013 date on which the Final Order became final and effective.

UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman

J. Thomas Rosch Edith Ramirez Julie Brill

Maureen K. Ohlhausen

In the Matter of

POM WONDERFUL LLC and

ROLL GLOBAL LLC,
 as successor in interest to Roll International
 Corporation, companies, and

STEWART A. RESNICK,
 LYNDA RAE RESNICK, and
 MATTHEW TUPPER, individually and as officers of the companies,

Respondents.

FINAL ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

- Unless otherwise specified, "Individual Respondents" means Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of POM Wonderful LLC ("POM Wonderful") and Roll Global LLC ("Roll").
- 2. Unless otherwise specified, "Respondents" means POM Wonderful and Roll, their successors and assigns; the Individual Respondents; and each of the above's officers, agents, representatives, and employees.
- 3. "Commerce" means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 4. "Covered Product" means any food, drug, or dietary supplement, including, but not limited to the POM Products.

- 5. "Food" and "drug" means as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 6. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).
- 7. "POM Product" means any food, drug, or dietary supplement containing pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.
- 8. The term "including" in this Order means "without limitation."
- 9. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; treat, prevent or reduce the risk of prostate cancer; or treat, prevent or reduce the risk of erectile dysfunction; unless the representation is non-misleading and, at the time of making such representation, Respondents possess and rely upon competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true. For purposes of this Part I, competent and reliable scientific evidence shall consist of at least one randomized and controlled human clinical trial (RCT) of the Covered Product that is randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies. Such studies shall also yield statistically significant results, and shall be double-blinded unless Respondents can demonstrate that blinding cannot be effectively implemented given the nature of the intervention.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or

illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Respondents possess and rely 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 this Part III, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that:

- A. Nothing in Parts I through III of the Order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and
- B. Nothing in Parts I through III of the Order shall prohibit Respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging, and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation;

- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

VI.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and Individual Respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. *Provided*, however, that, in lieu of overnight courier, notices may be sent by first class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

IT IS FURTHER ORDERED that each Individual Respondent, for a period of ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the Individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his or her duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

IX.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

X.

This Order will terminate on January 10, 2033, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark

Secretary

ISSUED: January 10, 2013

SEAL: