UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

)

)

In the Matter of

LONDON INTERNATIONAL GROUP, INC., a corporation.

FILE NO. 962 3004

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission has conducted an investigation of certain acts and practices of London International Group, Inc., a corporation ("proposed respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between London International Group, Inc., by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Proposed respondent London International Group, Inc. is a New Jersey corporation with its principal office or place of business at 3585 Engineering Drive, Norcross, Georgia 30092.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.

- 3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
 - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

This agreement contemplates that, if it is accepted by the 6. Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. It understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

<u>ORDER</u>

DEFINITIONS

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

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. Unless otherwise specified, "respondent" shall mean London International Group, Inc., a corporation, its successors and assigns and its officers, agents, representatives and employees. 3. "In or affecting commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of "Ramses" brand condoms or any other condom in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about:

- A. The comparative or quantifiable strength of any condom;
- B. The comparative or quantifiable risk of breakage of any condom; or
- C. The comparative or quantifiable efficacy of any condom,

unless, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

<u>Provided</u>, that respondent shall not be deemed in violation of Part I of this Order for any representation if the Food and Drug Administration has approved such representation pursuant to 21 U.S.C. § 352 or § 360. <u>Provided, however</u>, that clearance of a report submitted under 21 U.S.C. § 360(k) ("pre-market notification") shall not be deemed an approval of a representation under this paragraph unless the Food and Drug Administration clears such representation based on its review and evaluation of substantiation submitted with such report.

II.

IT IS FURTHER ORDERED that respondent London International Group, Inc. and its successors and assigns 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 Federal Trade Commission for inspection and copying:

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

III.

IT IS FURTHER ORDERED that respondent London International Group, Inc. and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IV.

IT IS FURTHER ORDERED that respondent London International Group, Inc. and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; 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 corporate name or address. <u>Provided, however</u>, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

v.

IT IS FURTHER ORDERED that respondent London International Group, Inc. and its successors and assigns shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

VI.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; <u>provided</u>, <u>however</u>, 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 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.

<u>Provided, further</u>, that if such complaint is dismissed or a federal court rules that the respondent 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.

Signed this _____ day of _____, 19____

London International Group, Inc. By: _____

> GARETH CLARKE President

LINDA K. BADGER

KERRY O'BRIEN Counsel for the Federal Trade Commission

APPROVED:

JEFFREY KLURFELD, Director San Francisco Regional Office UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

DOCKET NO.

LONDON INTERNATIONAL GROUP, INC., a corporation.

COMPLAINT

The Federal Trade Commission, having reason to believe that London International Group, Inc., a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent London International Group, Inc. is a New Jersey corporation with its principal office or place of business at 3585 Engineering Drive, Norcross, Georgia 30092.

2. Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including "Ramses" brand condoms. Ramses brand condoms are "devices," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused to be disseminated advertisements for Ramses brand condoms, including but not necessarily limited to the attached Exhibits A through C. These advertisements contain the following statements and depictions:

A. "it won't give you X-ray vision or bionic strength. but it will make you a hero tonight.

Ramses* gives you the sensitivity and natural feeling you want. and because it's 30% stronger than the leading brand, it performs like a champ. so you can too. Ramses®. a trusted companion.

*Ramses® regular strength condoms."

[The advertisement depicts an individual condom wrapper labeled: "<u>RAMSES</u> CONDOM"] (Exhibit A).

B. "WOMEN PREFER THE STRONG SENSITIVE TYPE.

Ramses provides both strength and sensitivity with that exquisite natural feel. And 30% more strength* than the leading brand. Now all you need to do is learn to cry. **Ramses. A Trusted Companion.**

*Ramses regular strength condoms."

[The advertisement depicts an individual condom wrapper labeled: "durex RAMSES 1 *PREMIUM* CONDOM LATEX"] (Exhibit B).

C. "IT'S TRUE. WOMEN WANT WHAT'S IN YOUR WALLET.

It's not the money they're after. It's the sensitivity. The natural feel. All that added strength* (30% more than the leading brand). An empty wallet can be a beautiful thing. **Ramses. A Trusted Companion.**

*Ramses regular strength condoms."

[The advertisement depicts an individual condom wrapper labeled: "durex RAMSES 1 *PREMIUM* CONDOM LATEX"] (Exhibit C).

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- A. Ramses brand condoms are thirty percent stronger than the leading brand.
- B. Ramses brand condoms break thirty percent less often than the leading brand.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.

7. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. Respondent submitted inadequate data to substantiate its claim that Ramses brand condoms are thirty percent stronger than other condoms. Respondent also submitted inadequate substantiation for the claim that Ramses brand condoms break thirty percent less often than other condoms. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

8. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this day of , has issued this complaint against respondent.

By the Commission.

Donald S. Clark Secretary

[Exhibits A-C attached to paper copies of complaint, but not available in electronic form.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent London International Group, Inc.("London International") a New Jersey corporation.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

London International manufactures and markets various brands of condoms to the public, including Ramses brand condoms. The Commission's complaint charges that respondent's advertising contained unsubstantiated comparative strength representations. Specifically, the complaint alleges that the respondent did not possess adequate substantiation for claims that: (1) Ramses brand condoms are thirty percent stronger than the leading brand; and (2) Ramses brand condoms break thirty percent less often than the leading brand.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future. Part I of the proposed order would prohibit the respondent from making any claim about: (1) the comparative or quantifiable strength of any condom; (2) the comparative or quantifiable risk of breakage of any condom; or (3) the comparative or quantifiable efficacy of any condom, unless at the time of making the claim, it possesses and relies upon competent and reliable evidence.

Part I contains a provision that would permit respondent to make any claim about condoms that is approved by the Food and Drug Administration ("FDA") without violating the settlement. This provision, however, excludes claims that the FDA has permitted through clearing a "premarket notification report," unless the clearance was based on a review and evaluation of the substantiation submitted with the report. The proposed order also requires the respondent to maintain materials relied upon to substantiate claims covered by the order; to provide a copy of the consent agreement to all employees or representatives involved in the preparation and placement of the company's advertisements, as well as to all company executives and marketing and sales managers; to notify the Commission of any changes in corporate structure that might affect compliance with the order; and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.