

- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
- d. Any claim under the Equal Access to Justice Act.

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 of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent and its parent corporation, 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 the proposed respondent or its parent corporation of facts, other than jurisdictional facts, or of violations of law as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to the proposed respondent or its parent corporation, (a) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (b) make information public in respect thereto. When so entered, the order to cease and desist 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 by the U.S. Postal Service of the complaint and decision containing the agreed-to order to the proposed respondent's address and to its parent corporation's address as stated in this agreement shall constitute service. The proposed respondent and its parent corporation waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. The proposed respondent and its parent corporation have read the proposed complaint and order contemplated hereby. The proposed respondent and its parent corporation understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. The proposed respondent and its parent corporation further understand that

they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

I.

IT IS ORDERED that respondent, Johnson & Johnson Consumer Products, Inc., a corporation, its parent corporation, Johnson & Johnson, and all the other subsidiaries of Johnson & Johnson, their successors and assigns (hereinafter collectively "the companies"), and the companies' officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of K-Y Plus Nonoxynol-9 Spermicidal Lubricant, or any other personal lubricant and/or spermicide, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, relating to:

- A. The failure rate of any method of contraception due to defects, misuse, or any other cause;
- B. Any such product's ability to provide protection against the development of tiny holes in condoms during use;
- C. Any such product's ability to provide protection against HIV and other viruses; or
- D. The health-related benefits of any such product;

unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation. For the purposes of this Order, "competent and reliable scientific evidence" shall mean those tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have 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.

II.

IT IS FURTHER ORDERED that the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any "food," "drug" or "device," as those terms are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, the efficacy of any over-the-

counter product as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease, unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation.

III.

IT IS FURTHER ORDERED that the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

IT IS FURTHER ORDERED that for five (5) years after the last date of dissemination of any representation covered by this Order, the companies shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All materials that were relied upon in disseminating such representation; and
- B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V.

IT IS FURTHER ORDERED that the companies notify the Commission at least thirty (30) days prior to any proposed change in the companies such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED (1) that respondent Johnson & Johnson Consumer Products, Inc., shall, within ten (10) days from the date of service of this Order upon it, distribute a copy of this Order to each of its operating divisions, to each of its managerial employees, and to each of its officers, agents, representatives or employees engaged in

the preparation, review or placement of advertising or other materials covered by this Order, and (2) that the parent corporation, Johnson & Johnson, shall, within ten (10) days from the date of service of this Order upon it, distribute a copy of this Order to each of its and of its subsidiaries' officers, agents, representatives or employees engaged in the preparation, review or placement of advertising of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

VII.

IT IS FURTHER ORDERED that this Order will terminate twenty years from the date of its issuance, or twenty 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; **provided, however,** that the filing of such a complaint will not affect the duration of:

- A. Any paragraph in this Order that terminates in less than twenty 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 paragraph.

Provided further, 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 paragraph as though the complaint was never 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.

VIII.

IT IS FURTHER ORDERED that the companies shall, within sixty (60) days from the date of service of this Order upon them, and at such other times as the 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.

IX.

IT IS FURTHER ORDERED that nothing in this Order shall prohibit the companies from making any representation for any drug that is permitted in labeling for any 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.

Signed this _____ day of _____, 19____.

JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.

By _____

JOHNSON & JOHNSON

By _____

FEDERAL TRADE COMMISSION

By _____
LINDA K. BADGER
MATTHEW D. GOLD

APPROVED:

JEFFREY KLURFELD, Director
San Francisco Regional Office