

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Robert Pitofsky, Chairman
Janet D. Steiger
Mary L. Azcuenaga
Roscoe B. Starek, III
Christine A. Varney

In the Matter of)	DOCKET NO. C-3636
)	
JOHNSON & JOHNSON)	
CONSUMER PRODUCTS INC.,)	
)	DECISION AND ORDER
a corporation.)	

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent and its parent corporation, Johnson & Johnson, having been furnished thereafter with a copy of a draft of complaint which the San Francisco Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its parent corporation, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent and its parent corporation of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent or its parent corporation that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, pursuant to

§ 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Johnson & Johnson Consumer Products, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at 1999 Grandview Road, in the City of Skillman, State of New Jersey.

Johnson & Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at One Johnson & Johnson Plaza, in the City of New Brunswick, State of New Jersey.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent and the parent corporation, and the proceeding is in the public interest.

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 on January 18, 2016, 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.

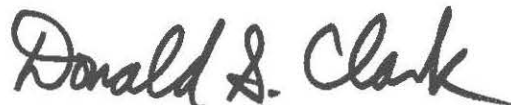
VIII.

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.

By the Commission.



Donald S. Clark
Secretary

ISSUED: January 18, 1996

Attachment: Statement of Commissioner Azcuenaga