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**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS:

II.

IT IS FURTHER ORDERED that respondents and their officers, agents, representatives, and employees, 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 trade name, product name, endorsement, depiction, illustration, or trademark, other than representations covered under Part I of this order, about the 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, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in Part IV are available for inspection and production to the Commission.

III.

IT IS FURTHER ORDERED that respondents and their officers, agents, representatives, and employees, 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, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or that the benefits of any Covered Product are scientifically proven.

IV.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study (“test”) upon which respondents rely to substantiate any claim covered by this order, respondents shall 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, including, but not necessarily limited to:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants

- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its 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.

VI.

IT IS FURTHER ORDERED that respondents shall, for five (5) years, deliver a copy of this order to all current and future principals, officers, directors, managers, employees, agents, and representatives having 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.

Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondents within sixty (60) days after the date of service 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 own 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 reports.

X.

This order will terminate on April 8, 2035, 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*