

UNITED STATES OF AMERICA  
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**IV.**  
**FDA Approved Claims**

IT IS FURTHER ORDERED that nothing in this order shall prohibit Respondents from making any representation for:

- A. Any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; or
- B. Any product that is specifically permitted in labeling for such product by

- 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 who did not complete the test, and all communications with any participants relating to the test, all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications, including contracts, between any sponsor and the test's researchers.

*Provided, however* the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by any Respondent, or by any person or entity affiliated with or acting on behalf of any Respondent, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with any Respondent ("Respondent's affiliates"), (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to any Respondent, to Respondent's affiliates, or to the product's manufacturer of any ingredient contained in such product.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about

**VIII.**  
**Compliance Notification**

IT IS FURTHER ORDERED that that Respondents shall notify the Commission at least thirty (30) days prior to any change in the corporations 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 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 in the corporation(s) about which Respondents learn less than thirty (30) days prior to the date such action is to take place, 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 (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line i-Health, Inc., FTC File No. 122-3067. 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.**  
**Compliance Reporting**

IT IS FURTHER ORDERED that Respondents within one hundred twenty (120) days after the date of service of this order, shall 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.**  
**Order Termination**

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 Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order,

