

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeney

_____)
In the Matter of)
)
FOCUS EDUCATION, LLC,)
a limited liability company,)
)
MICHAEL APSTEIN,)
individually and as an officer of)
FOCUS EDUCATION, LLC,) DOCKET NO. C-4517
)
and)
)
JOHN ABLE,)
individually and as an officer of)
FOCUS EDUCATION, LLC.)
_____)

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondents with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”) that includes: a statement that the agreement is for settlement purposes only and does not constitute an admission 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; 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 has reason to believe that the respondents have violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

- 1.a. Respondent Focus Education, LLC (“Focus Education”) is a Texas limited liability company with its principal office or place of business in Houston, Texas.
- 1.b. Respondent Michael Apstein is the co-founder and Chief Executive Officer of Focus Education. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Focus Education.
- 1.c. Respondent John Able is the co-founder and Chief Financial Officer of Focus Education. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Focus Education.
2. The Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

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

1. Unless otherwise specified, “respondents” shall mean Focus Education, LLC, a limited liability company, its successors and assigns, and officers; Michael Apstein, individually and as an officer of Focus Education, LLC; John Able, individually and as an officer of Focus Education, LLC.
2. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. “Covered Product” shall mean any product, program, device, or service that purports to alter the brain’s structure or function, improve cognitive abilities, behavior or academic performance, or treat or lessen the symptoms of cognitive abnormalities or disorders, including Attention Deficit Hyperactivity Disorder (“ADHD”).
4. “ifocus System” means the Jungle Rangers computer software and any related kits, accessories, or supplies.

5. “Reliably Reported,” for a human clinical test or study (“test”), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.
6. The term “including” in this order shall mean “without limitation.”
7. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS 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 the ifocus System or any substantially similar 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, that such product or component thereof:

- A. improves children’s focus, memory, attention, behavior, and/or school performance, including in children with ADHD; or
- B. causes permanent improvements in children’s focus, memory, attention, behavior, and/or school performance, including in children with ADHD,

unless the representation is non-misleading and, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true.

For purposes of this Part, competent and reliable scientific evidence shall consist of human clinical testing of such product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be (1) randomized, double-blind, and adequately controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of such testing as described in Part IV must be available for inspection and production to the Commission.

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 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 and 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 by: (1) any respondent; (2) any respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any respondent; (4) any person or entity affiliated with or acting on behalf of any respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of 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 respondent Focus Education's size and complexity, the nature and scope of respondent Focus Education's activities, and the sensitivity of the personal information collected from or about the participants.

V.

IT IS FURTHER ORDERED that respondents 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 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. Acknowledgment by electronic mail or similar means will be deemed a signature for purposes of this order. Respondents shall deliver this order to current personnel within thirty (30) days after date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent Focus Education, LLC, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation 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.

Provided, however, 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. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: Focus Education, LLC, FTC File No. 122 3153.

VIII.

IT IS FURTHER ORDERED that respondents John Able and Michael Apstein, for a period of ten (10) years after the date of issuance of the order, shall notify the Commission of the discontinuance of their current business or employment, or of their affiliation with any new business or employment, which may affect their compliance obligations arising under this order. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. 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.

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*, 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.

Provided, further, that if such complaint is dismissed or a federal court rules that respondents 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.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: April 8, 2015