

**B211223**

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

**In the Matter of  
ABBOTT LABORATORIES,  
a corporation.**

**FILE NO. 962 3069**

**AGREEMENT CONTAINING  
CONSENT ORDER**

The Federal Trade Commission has conducted an investigation of certain acts and practices of Abbott Laboratories, a corporation ("proposed respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

**IT IS HEREBY AGREED** by and between Abbott Laboratories, by its duly authorized officer, and its attorneys, and counsel for the Federal Trade Commission that:

1. Proposed respondent Abbott Laboratories is an Illinois corporation with its principal office or place of business at One Abbott Park Road, Abbott Park, Illinois 60064.
2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
  - a. Any further procedural steps;
  - b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
  - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
4. This agreement shall not become a 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 complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, 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 proposed respondent 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.

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 This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order 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 of the complaint and the decision and order to proposed respondent by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. It understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

## **ORDER**

### DEFINITIONS

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

1. Unless otherwise specified, "respondent" shall mean Abbott Laboratories, a corporation, its successors and assigns, and its officers, agents, representatives and employees.
2. "In or affecting commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

#### **I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Ensure products, any other food, or any other dietary or nutritional supplement in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about:

- A. The extent to which doctors or other professionals recommend such product for healthy adults; or
- B. The recommendation, approval, or endorsement of such product by any person, profession, group, or other entity,

unless, at the time it is made, respondent possesses and relies upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation. For purposes of this order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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 respondent, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Ensure products, or any other product advertised, marketed or sold as a meal replacement or meal supplement for healthy adults, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication:

- A. That one serving of such product provides vitamins in an amount comparable to typical vitamin supplements; or
- B. The absolute or comparative amount of any vitamin or any other nutrient or ingredient contained in or provided by such product.

If any representation covered by this Part either directly or by implication conveys any nutrient content claim defined (for purposes of labeling) by any regulation promulgated by the Food and Drug Administration, compliance with this Part shall be governed by the qualifying amount for such defined claim as set forth in that regulation.

### III.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

### IV.

**IT IS FURTHER ORDERED** that respondent, and its successors and assigns, 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.

### V.

**IT IS FURTHER ORDERED** that respondent, and its successors and assigns, shall:

- A. Within thirty (30) days after the date of service of this order, deliver a copy of this order to all current principals, officers, directors, and managers, and to all current

employees, agents, and representatives having responsibilities with respect to the subject matter of this order; and

- B. For a period of five (5) years after the date of service of this order, deliver a copy of this order to all future principals, officers, directors, and managers, and to all employees, agents, and representatives having responsibilities with respect to the subject matter of this order, within thirty (30) days after the person assumes such position or responsibilities.

## VI.

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

## VII.

**IT IS FURTHER ORDERED** that respondent, and its successors and assigns, shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

## VIII.

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 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 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 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 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.

Signed this 23rd day of December, 1996.

ABBOTT LABORATORIES

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**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

**In the Matter of  
ABBOTT LABORATORIES,  
a corporation.**

**DOCKET NO.**

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Abbott Laboratories, a corporation ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Abbott Laboratories ("Abbott") is an Illinois corporation with its principal office or place of business at One Abbott Park Road, Abbott Park, Illinois 60064.
2. Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed nutritional products to the public, including Ensure products. Ensure products are marketed through Abbott's Ross Products Division and include Ensure, Ensure High Protein, Ensure Plus, Ensure With Fiber, Ensure Pudding, and Ensure Light. These products are "foods" and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
4. Respondent has disseminated or has caused to be disseminated advertisements for Ensure, including but not necessarily limited to the attached Exhibits A through D. These advertisements contain the following statements and depictions:

A.

VIDEO

Close-up of a graduation photograph of man and woman.

Man and woman who appear to be in their middle thirties.

AUDIO

Man: For 15 years, we've taken good care of each other.

Woman: We sure have.



Can of Ensure being poured into glass.

Man and woman jogging in a park.

Cans of Ensure. Super: RECOMMENDED #1 BY DOCTORS.

Man: And to take better care of our health, we started drinking Ensure.

Woman: More than a vitamin supplement, Ensure is a delicious drink with all the nutrients adults need to help stay healthy, active, be energetic.

Man: Drink Ensure as a meal.

Woman: Or in between meals.

Man: Ensure is even recommended number one by doctors as a source of complete balanced nutrition.

Woman: Ensure, to your health honey.

Man: Uh, uh, to our health.

(Exhibit A, television advertisement entitled “Younger Husband/Wife”).

B.

VIDEO

AUDIO

Close-up of black and white photograph of little girl and young father fishing.

Father and adult daughter fishing on dock.

Three cans of Ensure. Super: RECOMMENDED #1 BY DOCTORS.

Can of Ensure being poured into glass.

Father and daughter in boat with father casting.

Woman: When I was young, you and mom made sure I ate right.

Man: Well you were my little girl.

Woman: Well today we’re listening to our doctors and taking better care of our health with Ensure.

Man: Ensure is recommended number one by doctors as a source of complete balanced nutrition.

Woman: More than a vitamin supplement, Ensure has all the nutrients adults need to help stay healthy, active, be energetic.

Man: Drink Ensure as a meal.

Woman: Or in between meals.  
Ensure, to your health dad.

Mother: Uh, uh, to our health.

Three cans of Ensure. Super:  
RECOMMENDED #1 BY DOCTORS.

Announcer: Ensure, doctors  
recommend it number one.

(Exhibit B, television advertisement entitled “Father/Daughter”).

C. Wife: Oh boy, that water felt great!

Husband: Sure did. I always feel so good after a swim.

Wife: For 15 years, we’ve shared a pretty active life.

Husband: I’ve loved every minute.

Wife: And to help make sure we stay active, one thing we’ve done lately is to drink Ensure.

Husband: Hm Hmm. See, our doctor told us that a key to being energetic and in good health is good nutrition.

Wife: Right. And one way to help guarantee that you’re getting the nutrition you need, is by drinking Ensure.

Husband: More than a vitamin supplement, Ensure is a delicious drink that provides complete balanced nutrition.

Wife: It’s got the protein, carbohydrates, minerals and vitamins your body needs everyday to help you stay healthy, active, be energetic.

Husband: Drink Ensure anytime.

Wife: I like it as a delicious meal.

Husband: I like it in between meals. Ensure is even recommended number one by doctors and nutritionists for complete balanced nutrition.

Wife: So make sure the ones you love get the nutrition they need. Ensure. To your health, dear.

Husband: Uh, uh, to our health.

(Exhibit C, radio advertisement entitled “Younger Husband/Wife”).

- D. Depiction: Snapshots of a young man and a young woman. *“Back then we promised to make the most out of life...today we’re enjoying every moment.”*

**DRINK TO YOUR HEALTH WITH ENSURE.**<sup>®</sup> Depiction: Man and woman who appear to be in their thirties holding glasses of Ensure.

### **The #1 Doctor Recommended Source of Nutrition.**

Most doctors will tell you that a key to good health is good nutrition. But even if you’ve improved your diet by eating more lean meats, fruits and vegetables, you still may not be getting the balanced nutrition you need.

So how can you help guarantee that you and the ones you love get the right nutrition?

With Ensure and *New* Ensure High Protein.

Ensure is more than a vitamin supplement. It’s complete balanced nutrition in a delicious ready-to-serve drink that provides an excellent balance of protein, carbohydrate, vitamins, and minerals. In addition, *New* Ensure High Protein is low in cholesterol and low in saturated fat while being high in the nutrients you need everyday to help stay healthy, be energetic and more active. Drink your favorite Ensure anytime. Enjoy it as a healthy meal by itself or as a healthy between-meal snack. Ensure is even recommended #1 by doctors as a complete source of nutrition.

So make sure the ones you love get the right nutrition. Drink Ensure and drink to your health.

(Exhibit D, print advertisement).

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that many doctors recommend Ensure as a meal supplement and as a meal replacement for healthy adults, including those in their thirties and forties.
6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 5, at the time the representation was made.
7. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 5, at the time the representation was made. Among other reasons, a survey of doctors relied upon by respondent was not designed to elicit whether many doctors actually recommend Ensure as a meal supplement or meal replacement for healthy adults, as opposed to for adults who are ill or elderly and may have

nutritional deficiencies. The survey merely asked doctors to assume that they would recommend a supplement for adults who were not ill, and then to select the brand they would most recommend. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

8. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that one serving of Ensure provides vitamins in an amount comparable to typical multivitamin supplements.

9. In truth and in fact, one serving of Ensure does not provide vitamins in an amount comparable to typical multivitamin supplements. While the typical multivitamin supplement provides at least 100% of the recommended daily intake (RDI) of vitamins for which RDIs have been established, at the time the advertisements were first disseminated, one serving of Ensure provided 62% of the RDI of Vitamin C and between 12% and 26% of the RDIs of the other vitamins for which RDIs have been established. Ensure has been reformulated and currently one serving provides 50% of the RDI of Vitamin C and 25% of the RDIs of the other vitamins for which RDIs have been established. Therefore, the representation set forth in Paragraph 8 was, and is, false or misleading.

10. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this        day of                    ,                    ,  
has issued this complaint against respondent.

By the Commission.

Donald S. Clark  
Secretary

SEAL:

[Exhibits A-D attached to paper copies of complaint, but not available in electronic form.]

## **ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission has accepted an agreement to a proposed consent order from Abbott Laboratories. This matter concerns advertising for Ensure nutritional products.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

Ensure is a canned beverage which contains carbohydrates, protein, fat, vitamins and minerals and is formulated so that the very elderly and others who have difficulty obtaining sufficient nutrition from regular food can subsist on it, for example through tube feeding. The Ensure product line includes not only Ensure, but also Ensure High Protein, Ensure Plus, Ensure With Fiber, Ensure Pudding, and Ensure Light.

According to the Commission's complaint, Abbott advertisements made the unsubstantiated representation that many doctors recommend Ensure as a meal supplement and replacement for healthy adults, including those in their thirties and forties. The complaint explains that, among other reasons, this claim is unsubstantiated because a survey of doctors relied upon by Abbott was not designed to elicit whether many doctors actually recommend Ensure as a meal supplement or replacement for healthy adults -- as opposed to adults who are ill or elderly and may have nutritional deficiencies. According to the complaint, the survey merely asked doctors to assume that they would recommend a supplement for adults who were not ill, and then to select the brand they would most recommend.

The complaint also alleges that Abbott misrepresented that one serving of Ensure provides vitamins in an amount comparable to typical multivitamin supplements. According to the complaint, while the typical multivitamin supplement provides at least 100% of the recommended daily intake (RDI) of vitamins, at the time the advertisements challenged in the complaint were first disseminated, one serving of Ensure provided 62% of the RDI of Vitamin C and between 12% and 26% of the RDIs of the other vitamins for which RDIs have been established. The complaint states that, although Ensure has been reformulated, one serving still provides only 50% of the RDI of Vitamin C and 25% of the RDIs of the other vitamins.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent Abbott from engaging in similar acts and practices in the future.

Part I of the order requires Abbott not to make any claim about the extent to which doctors or other professionals recommend any food or dietary or nutritional supplement for healthy adults, or about the recommendation, approval, or endorsement of such products by anyone, unless it possesses competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the claim.

Part II prohibits Abbott from misrepresenting that one serving of any Ensure product, or any other product advertised, marketed or sold as a meal replacement or supplement for healthy adults, provides vitamins in an amount comparable to typical vitamin supplements. It also prohibits Abbott from misrepresenting the absolute or comparative amount of any vitamin or any other nutrient or ingredient provided by such products. Part II also requires that any representation covered by that Part that conveys a nutrient content claim defined for labeling by any regulation of the Food and Drug Administration ("FDA") must comply with the qualifying amount set forth in that regulation.

Part III provides that representations that would be specifically permitted in food labeling, under regulations issued by the FDA pursuant to the Nutrition Labeling and Education Act of 1990, are not prohibited by the order.

The proposed order also requires Abbott to maintain materials relied upon to substantiate the claims covered by the order, to distribute copies of the order to certain current and future officers and employees, to notify the Commission of any changes in corporate structure that might affect compliance with the order, and to file one or more reports detailing compliance with the order. The order also contains a provision stating that it will terminate after twenty (20) years absent the filing in federal court, by either the United States or the FTC, of a complaint against Abbott alleging a violation of the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, or to modify any of their terms.