

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2011, TO JUNE 30, 2011

IN THE MATTER OF

NESTLÉ HEALTHCARE NUTRITION, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4312; File No. 092 3087
Complaint, January 12, 2011 – Decision, January 12, 2011*

This consent order relates to allegations that Nestlé Healthcare Nutrition, Inc. (“Nestlé HCN”), a subsidiary of Nestlé S.A., the world’s largest food and nutrition company, made deceptive advertising claims about the health benefits of its BOOST Kid Essentials fortified drink product (“BOOST”), in violation of Sections 5 and 12 of the FTC Act. According to the complaint, respondent made false and unsubstantiated claims regarding the health benefits of BOOST for children. The order prohibits respondent Nestlé HCN from claiming that BOOST will reduce the risk of colds, flu, and other upper respiratory tract infections unless the claim is supported by the Food and Drug Administration. The order further prohibits respondent from claiming that BOOST will reduce a child’s sick-day absences and the duration of acute diarrhea in children under age 13, unless the claims are true and backed by at least two well-designed human clinical studies. The order also prohibits respondent from making any claims about the health benefits, performance, or efficacy of any probiotic or nutritionally complete drinks that it sells at retail, unless the claims are true and backed by competent and reliable scientific evidence, and bars respondent from misrepresenting any tests or studies.

Participants

For the Commission: *Richard Cleland, Christine DeLorme, Mary K. Engle, Karen Mandel, Janis K. Pappalardo, and Margaret Patterson.*

For the Respondent: *Lewis Rose and Dana Rosenfeld, Kelley Drye & Warren, LLP.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Nestlé HealthCare Nutrition, Inc., 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 Nestlé HealthCare Nutrition, Inc. is a Delaware corporation with its principal office or place of business at 12 Vreeland Road, Florham Park, New Jersey 07932-0697.

2. Respondent has labeled, advertised, promoted, offered for sale, sold, and distributed BOOST Kid Essentials to consumers.

3. BOOST Kid Essentials is a “food” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of respondent, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

5. Respondent has disseminated or caused to be disseminated advertisements for BOOST Kid Essentials, including but not limited to the attached Exhibits A through E. These advertisements contain the following statements and depictions, among others:

- a. **Television Advertisement:** “Straw Power” (Complaint Exhibits A1 (Storyboard) and A2 (Video))

(A girl pops into frame and takes a big enjoyable sip of Kid Essentials.)

Female Announcer: Introducing NEW Boost Kid Essentials, the only nutritionally complete drink that gives kids the power of immune strengthening probiotics.

ON SCREEN: *L. reuteri Protectis* has been clinically shown to help strengthen the immune system when consumed daily. For more information about clinical trials involving *L. reuteri Protectis*, go to

Complaint

www.kidessentials.com.

(The girl runs along playfully as the straw twirls around her. She encounters a boy who sneezes. The straw quickly forms a protective barrier around her. The girl continues on her way and as she approaches a basketball net, the straw forms stairs for her to step up on.)

ON SCREEN: muscle-building protein

Female Announcer: Plus the power to grow strong – with muscle-building protein and 25 vitamins and minerals.

(She takes a shot and hits a perfect swoosh.)

ON SCREEN: 25 vitamins & minerals

(Cut to straw popping back into drink box. The vortex of wellness swirls around the box, highlighting product attributes.)

ON SCREEN: Immunity strengthening probiotics/7 g protein/25 vitamins & minerals

Female Announcer: NEW Boost Kid Essentials: complete nutrition for your child's healthy growth, and probiotics clinically shown to help strengthen the immune system.

(The straw bends forwards, and probiotics titles emerge, followed by animated probiotic bubbles and a twirling arrow.)

ON SCREEN: Probiotic straw/Clinically shown to help strengthen the immune system

(Close up of the girl grabbing the drink box and enjoying another sip)

Female Announcer: And that means the power to do anything is possible every day.

(She finishes her sip, turns and skips out of frame.)

Complaint

**ON SCREEN: Boost Kid Essentials Nutritionally
Complete Drink KidEssentials.com....****b. Product Packaging (Exhibit B)****Front Panel:**

BOOST®

Kid Essentials

Nutritionally Complete Drink

Immunity Protection*

Patented PROBIOTIC straw

**Nutritionally Complete Drink with PROBIOTICS to
Help Keep Kids
Healthy...***Side Panel:**

Complete, Balanced Nutrition for Your Child's

Healthy Growth and Strong Immune System!BOOST® Kid Essentials provides complete, balanced
nutrition for kids 1-13.Only BOOST Kid Essentials has the vitamins and
minerals kids need plus immune-supporting
probiotics and antioxidants to help keep them
healthy!...Talk to your pediatrician about using BOOST Kid
Essentials as a supplement with a meal or as a snack. To
learn more about immunity, probiotics, and antioxidants,
visit www.kidessentials.com...**c. Internet Website www.kidessentials.com (excerpt)
(Exhibit C)****FAQ:**

Q: What exactly do probiotics protect my kids from?

A: Probiotics are healthy bacteria that must be consumed in order to build up in our digestive system - in the lining of the GI tract. While they occur throughout nature, they are less likely to be

Complaint

present in large numbers in our own GI tract, and therefore need to be consumed to derive a benefit. They help balance and keep the levels of bad bacteria in check. Most importantly, they help keep our immune system healthy by increasing disease-fighting antibodies.^{1,2}

References:

1. Tuohy KM *et al.* Using probiotics and prebiotics to improve gut health. *DDT* 2003;8(15):692-700.
2. Isolauri E *et al.* Probiotics: effects on immunity. *Am J Clin Nutr* 2001;73(suppl):440S-50S.

Q: Are probiotics effective against viruses?

A: Yes, certain probiotics have been shown to help fight viruses such as Rotaviral diarrhea.¹ *Lactobacillus reuteri* *Protectis* (the probiotic found in BOOST Kid Essentials Drink) has been shown to reduce the duration of diarrheal illness in children³ and reduce the number of days that infants miss daycare due to illness.²

References:

1. Szajewska H *et al.* Probiotics in gastrointestinal diseases in children: hard and not-so-hard evidence of efficacy. *J Pediatr Gastroenterol Nutr* 2006;42 (5):454-75.
2. Weizman Z *et al.* Effect of a probiotic infant formula on infections in child care centers: comparison of two probiotic agents. *Pediatrics* 2005;115;5-9.
3. Shornikova AV *et al.* Bacteriotherapy with *Lactobacillus reuteri* in rotavirus gastroenteritis. *Pediatr Infect Dis J.* 1997;16:1103-7.

Q: Are probiotics safe for my young child?

A: Absolutely. The safety and efficacy of probiotic use has been documented for 100 years all around the world. Probiotic supplemented infant formula has been available for over 15 years, in over 30 countries. *Lactobacillus reuteri* *Protectis* specifically has been thoroughly tested in infants, children and adults and has shown to be safe and effective.

Complaint

d. **Pamphlet Advertisement to Health Care Practitioners** (Exhibit D)**Front Cover:**

The essential facts: a comparison of **BOOST® Kid Essentials Nutritionally Complete Drink** with probiotic immunity protection vs. **PediaSure®.***

Only BOOST Kid Essentials Drink provides immune-supporting probiotics in its patented straw to help keep kids healthy....

Inside Pamphlet:

....**The immunity support every kid needs.**

Only BOOST® Kids Essentials Nutritionally Complete Drink delivers **immunity-supporting probiotics**. PediaSure® does not.

Clinical studies of *L. reuteri Protectis* showed the following:

Faster Resolution of Acute Diarrhea In Young Children

[Depiction of a bar graph showing that 81% of patients in a control group had watery diarrhea compared with 26% of patients in the treatment group on day 2 of treatment]

Adapted from Shornikova *et al.*¹

Fewer Absences Among Infants From Child Care

[Depiction of a graph showing a 67% relative risk reduction of absences among infants from child care]

Adapted from Weizman *et al.*²

Fewer Days with Fever Among Infants

[Depiction of a graph showing a 79% relative risk reduction of days of fever among infants]

Adapted from Weizman *et al.*²...

Back Cover:

Strong growth and immunity protection every child deserves....

Only BOOST Kid Essentials Drink's patented straw offers the immune support of the probiotic *L. reuteri Protectis*.

Complaint

Studies in *L. reuteri* *Protectis* demonstrate the ability to support the body's defenses, resulting in reduced sick days, fever, and the duration of diarrhea.^{1,2}...

1. Shornikova A *et al.* *Lactobacillus reuteri* as a therapeutic agent in acute diarrhea in young children. *JPGN* 1997;24(4):399-404.
2. Weizman Z *et al.* Effect of a Probiotic Infant Formula on Infections in Child Care Centers: Comparison of Two Probiotic Agnes. *Pediatrics* 2005;115(1):5-9.

e. **People Magazine Advertisement (Exhibit E)****First Page:**

Do your kids
have the
power?

[Depiction of Boost Kid Essentials package with the probiotic straw,
which reads:

NEW!

BOOST

Kid Essentials

Nutritionally Complete Drink

Immunity Protection*

Patented PROBIOTIC Straw

*Nutritionally Complete Drink

with PROBIOTICS to Help

Keep Kids Healthy]

Second Page:

The power of immune-strengthening
probiotics^{1, 2}

Probiotic straw to help keep kids healthy

[Depiction of the probiotic straw (continued from the previous page) forming a complete circle around a girl, while a boy sneezes in her direction]

1. Weizman Z *et al.* Effect of a Probiotic Infant Formula on Infection in Child Care Centers: Comparison of Two Probiotic Agents. *Pediatrics* 2005; 115(1) 5-9.

2. Shornikova AV *et al.* *Lactobacillus reuteri* as a therapeutic agent in acute diarrhea in young children. *JPGN* 1997;24(4):399-404.

Third Page:

The power to grow strong

Complaint

25 vitamins & minerals
7g of muscle-building protein

[Depiction of the probiotic straw (continued from the previous page) forming stairs for the girl to climb, as she tosses a basketball into a basketball hoop]

Fourth Page:

The power
to do anything!
Every day.

NEW BOOST® Kid Essentials
Nutritionally Complete Drink:

- Immune-strengthening probiotics in the straw
- 25 vitamins & minerals + 7g of protein to support healthy growth
- Kid preferred taste vs. Pediasure®...

6. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through E, among others, respondent has represented, expressly or by implication, that drinking BOOST Kid Essentials:

- a. Prevents upper respiratory tract infections in children;
- b. Strengthens the immune system, thereby providing protection against cold and flubviruses; and
- c. Reduces absences from daycare or school due to illness.

7. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through E, among others, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6 at the time the representations were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made. Therefore,

Complaint

the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A, C, and D, among others, respondent has represented, expressly or by implication, that clinical studies prove that drinking BOOST Kid Essentials:

- a. Reduces the general incidence of illness in children, including upper respiratory tract infections;
- b. Reduces the duration of acute diarrhea in children up to the age of thirteen; and
- c. Strengthens the immune system, thereby providing protection against cold and flu viruses.

10. In truth and in fact, clinical studies do not prove that drinking BOOST Kid Essentials reduces the general incidence of illness in children, including upper respiratory tract infections, reduces the duration of acute diarrhea in children up to the age of thirteen, or strengthens the immune system, thereby providing protection against cold and flu viruses. Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

11. 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 twelfth day of January, 2011, has issued this complaint against respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than 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 had reason to believe that the respondent has violated the Act, and that a 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 thirty (30) days for the receipt and consideration of public comment, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

Decision and Order

1. Respondent Nestlé HealthCare Nutrition, Inc. (“Nestlé HCN”) is a Delaware corporation with its principal office or place of business at 12 Vreeland Road, Florham Park, New Jersey 07932-0697.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent and this proceeding is in the public interest.

ORDER**DEFINITIONS**

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

1. Unless otherwise specified, “respondent” means Nestlé HealthCare Nutrition, Inc., a corporation, its successors and assigns and their officers, and each of the above’s agents, representatives, and employees.
2. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. “Adequate and well-controlled human clinical study” means a human clinical study conducted by persons qualified by training and experience to conduct such study. Such study shall be randomized, and, unless it can be demonstrated that blinding or placebo control cannot be effectively or ethically implemented given the nature of the intervention, shall be double-blind and placebo-controlled.
4. “Covered product” means BOOST Kid Essentials, any drink product containing probiotics, or any nutritionally complete drink, other than infant formula, medical foods, and any product not sold primarily through conventional retail channels.

Decision and Order

5. “Essentially equivalent product” means a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, inactive binders, flavors, preservatives, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), as the covered product; provided that the covered product may contain additional ingredients or other differences in formulation to affect taste, texture, or nutritional value (so long as the other differences do not change the form of the product or involve the ingredients from which the functional benefit is derived), if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount of additional ingredients, combination of additional ingredients, and any other differences in formulation are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
6. “Dosage” means the quantity of the substance taken in or absorbed over a specified, biologically relevant time period to achieve the intended effect.
7. The term “including” in this order means “without limitation.”
8. 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 respondent, 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 represent, in any manner, expressly or by implication, including through the use of a

Decision and Order

product name, endorsement, depiction, or illustration, that such product prevents or reduces the risk of upper respiratory tract infections, including, but not limited to, cold or flu viruses, unless the representation 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.

II.

IT IS FURTHER ORDERED that respondent, 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 represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product:

- A. Reduces the duration of acute diarrhea in children up to the age of thirteen; or
- B. Reduces absences from daycare or school due to illness;

unless the representation is non-misleading and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Respondent shall have the burden of proving that a product satisfies the definition of essentially equivalent product.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent, 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 product name, endorsement, depiction, or illustration, other than representations covered under Parts I or II of this order, about the health benefits, performance, or efficacy of any covered product, unless the representation is non-misleading, and, at the time of making such representation, the respondent possesses and relies 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, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that respondent, 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.

V.

Decision and Order

IT IS FURTHER ORDERED that 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.

VI.

IT IS FURTHER ORDERED that respondent Nestlé HCN, 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 reasonable notice 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 their 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.

VII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and other employees having primary 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. Respondent Nestlé HCN, and its successors and assigns, shall deliver this order to current personnel within thirty (30) days after

Decision and Order

the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, 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, 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 Nestlé HCN, and its successors and assigns, learn less than thirty (30) days prior to the date such action is to take place, respondent Nestlé HCN, and its successors and assigns, 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, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall, within sixty (60) days after service of this order file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports.

Decision and Order

X.

This order will terminate on January 12, 2031, 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 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.

By the Commission.

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

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Nestlé HealthCare Nutrition, Inc. (“respondent”). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) 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.

This matter involves the advertising and promotion of BOOST Kid Essentials, a children’s nutritional drink that also delivers probiotics via an attached straw. According to the FTC complaint, respondent represented, in various advertisements, that BOOST Kid Essentials prevents upper respiratory tract infections in children; strengthens the immune system, thereby providing protection against cold and flu viruses; and reduces absences from daycare or school due to illness. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act.

The FTC complaint further charges that respondent represented that clinical studies prove that BOOST Kid Essentials reduces the general incidence of illness in children, including upper respiratory tract infections; reduces the duration of acute diarrhea in children up to age thirteen (the age group for which the product is marketed); and strengthens the immune system, thereby providing protection against cold and flu viruses. The complaint alleges that these claims are false and thus violate the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. The order covers representations made in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting

Analysis to Aid Public Comment

commerce. The order defines a covered product as BOOST Kid Essentials, any drink product containing probiotics, or any nutritionally complete drink, other than infant formula, medical foods, and any product not sold primarily through conventional retail channels.

Part I of the consent order is designed to address the complaint allegations concerning respondent's allegedly unsubstantiated representations that its products prevent upper respiratory tract infections (URTIs). Part I prohibits respondent from making representations that a covered product prevents or reduces the risk of URTIs, including, but not limited to, cold or flu viruses, unless the representation is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration (FDA) pursuant to the Nutrition Labeling and Education Act of 1990 (NLEA). Under this provision, therefore, respondent cannot make a claim of URTI risk reduction unless the FDA has issued a regulation authorizing the claim based on a finding that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, considering the totality of publicly available scientific evidence. As noted in the Commission's Enforcement Policy Statement on Food Advertising, "[t]he Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim." Enforcement Policy Statement on Food Advertising (1994), *available at* <http://www.ftc.gov/bcp/policystmt/ad-food.shtm>. Thus, although the Enforcement Policy Statement does not say that the only way a food advertiser can adequately substantiate a disease risk-reduction claim is through FDA authorization, the Commission has determined that requiring FDA pre-approval before respondent makes a URTI risk-reduction claim for its covered products will facilitate compliance with the order and is reasonably related to the enforcement of this order.

Respondent may decide to make an advertising claim

characterizing limited scientific evidence supporting the relationship between a covered product and URTIs. However, if the net impression is that a covered product prevents or reduces the risk of URTIs, and not merely that there is limited scientific evidence supporting the claim, the advertisement would be covered under Part I. The Commission notes that its experience and research show that it is very difficult to adequately qualify a disease risk-reduction claim in advertising to indicate that the science supporting the claimed effect is limited. In other words, reasonable consumers may interpret an advertisement to mean that the product will prevent or reduce the risk of URTIs, even if respondent includes language indicating that the science supporting the effect is limited in some way. However, if respondent possesses reliable empirical testing demonstrating that the net impression of an advertisement making a qualified claim for a covered product does not convey that it will prevent or reduce the risk of URTIs, then that claim would be covered under the relevant subsequent parts of the order.

Although Part I requires FDA approval before respondent can make claims that a covered product prevents or reduces the risk of URTIs, the Commission does not intend Part I to limit respondent to using the precise language specified in an FDA-approved health claim. To the contrary, if the FDA has approved a claim that a covered product can prevent or reduce the risk of URTIs, respondent may use a variety of words and images to communicate that claim in its advertising. Likewise, regardless of the particular words or images used, if the net impression of an advertisement is that a covered product prevents or reduces the risk of URTIs, then for the ad to comply with the order, the FDA must have authorized a health claim based on significant scientific agreement that such product provides such a benefit.

Part II of the consent order prohibits respondent from making representations that a covered product reduces the duration of acute diarrhea in children up to the age of thirteen, or reduces absences from daycare or school due to illness, unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable

Analysis to Aid Public Comment

scientific evidence that substantiates that the representation is true. For purposes of Part II, competent and reliable scientific evidence means at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. For purposes of the order, essentially equivalent product means a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, inactive binders, flavors, preservatives, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), as the covered product; provided that the covered product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.

Part III of the consent order prohibits respondent from making representations, other than representations covered under Parts I or II, about the health benefits, performance, or efficacy of any covered product, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies 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 Part III, competent and reliable scientific evidence means tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the consent order prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Analysis to Aid Public Comment

Part V of the consent order provides that nothing in the 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 FDA pursuant to the NLEA.

Parts VI, VII, VIII, and IX of the consent order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

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 their terms in any way.

Complaint

**IN THE MATTER OF
SIMON PROPERTY GROUP, INC.****CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT**

*Docket No. C-4307; File No. 101 0061
Filed November 10, 2010 – Decision January 13, 2011*

This consent order addresses the acquisition of Prime Outlets Acquisition Company (“Prime”) by Simon Property Group, Inc. (“Simon”). According to the Complaint, the proposed acquisition of Prime’s outlet centers, valued at approximately \$2.3 billion, would substantially lessen competition in the provision of retail space at outlet centers in the Southwest Ohio; Chicago, Illinois; and Orlando, Florida areas. The order requires Simon to divest either its Cincinnati Premium Outlets or Prime’s Outlets-Jeffersonville, both located in Southwest Ohio. In order to ensure the divestiture is successful, the order requires Simon to maintain the Southwest Ohio outlet centers at full economic viability, marketability, and competitiveness until the divestiture to a Commission-approved acquirer is complete. The order also prohibits Simon from enforcing any radius restriction with respect to any lease with any tenant in either the Chicago or Orlando metropolitan areas. The order also allows all tenants in Prime Outlets Orlando, Prime Outlets Orlando Marketplace, and Orlando Premium Outlets to opt unilaterally to extend any lease under its existing terms, without penalty, until January 1, 2015.

Participants

For the Commission: *Joseph Lipinsky and Robert Schroeder.*

For the Respondent: *Bernard A. Nigro, Jr., Esq., Fried,
Frank, Harris, Shriver & Jacobson LLP.*

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that Respondent, Simon Property Group, Inc. (“Simon”), a real estate investment trust (“REIT”) subject to the jurisdiction of the Commission, has agreed to acquire Prime Outlets Acquisition Company LLC (“Prime”), a Delaware limited liability company subject to the jurisdiction of the Commission, in violation of Section