IN THE MATTER OF
THE DANNON COMPANY, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF SEC. 5(A) AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4313; File No. 082 3158
Filed January 31, 2011 – Decision January 31, 2011

This consent order relates to allegations that The Dannon Company, Inc. ("Dannon") made false and deceptive advertising claims about the health benefits of its DanActive and Activia products in violation of Sections 5(a) and 12 of the Federal Trade Commission Act. According to the complaint, Dannon made false and unsubstantiated claims that drinking DanActive, a probiotic dairy drink, reduces the likelihood of getting a cold or the flu. The complaint also alleges that Dannon made false and unsubstantiated claims that eating one serving of Activia, a probiotic yogurt, relieves temporary irregularity and helps with slow intestinal transit time. The order prohibits Dannon from making representations that any yogurt, dairy drink, or any food or drink that contains a probiotic reduces the likelihood of getting a cold or the flu unless the representation is specifically permitted in labeling by the Food and Drug Administration pursuant to the Nutritional Labeling and Education Act of 1990. The order also prohibits respondent from claiming that eating one serving of Activia yogurt daily relieves temporary irregularity and helps with slow intestinal transit time unless the representation is non-misleading and conveys that eating three servings a day is required to obtain the benefit. The order also prohibits respondent from misrepresenting any tests or studies or from making representations about the health benefits, performance, or efficacy of any yogurt, dairy drink, or any food or drink that contains a probiotic, unless the claims are non-misleading, and backed by competent and reliable scientific evidence.

Participants

For the Commission: *Keith Fentonmiller, Theodore H. Hoppock,* and *Shira D. Modell*.

For the Respondent: *William Baer* and *Randal Shaheen, Arnold & Porter LLP;* and *Thomas B. Leary, Steven B. Steinborn,* and *Robert Winters, HoganLovells.*

COMPLAINT

The Federal Trade Commission, having reason to believe that The Dannon Company, 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 The Dannon Company, Inc., is a Delaware corporation with its principal office or place of business at 100 Hillside Avenue, White Plains, NY, 10603.

2. Respondent has labeled, advertised, promoted, offered for sale, sold, and distributed DanActive and Activia to consumers.

3. DanActive, a probiotic dairy drink, is a "food" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Activia, a yogurt, is also 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.

DANACTIVE

5. Respondent has disseminated or caused to be disseminated advertisements for DanActive, including but not limited to the attached Exhibits A through D. These advertisements contain the following statements and depictions:

a. **Television Advertisement**: "Backpack" (Exhibit A - CDROM and storyboard)

On screen: A boy is shown taking a test in school, playing baseball in the rain, and being thrown to a mat repeatedly in martial arts training.

Female VO:	"Between exams, after-school activities, and tons of homework, my kid never stops."
On screen:	The boy arrives home looking tired; he drops his backpack inside the front door, as his mother kneels down and greets him, and the color drains from his face and body.
Male VO:	"Your kids have a hectic life and don't always eat right, and you don't want their defenses to be weak."
On screen:	Mom's hand reaches into refrigerator and removes a DanActive.
Male VO:	"Delicious DanActive can strengthen them."
On screen:	The boy drinks the DanActive; graphic shows small yellow circles going from the bottle down his throat; the circles are identified as L. casei immunitas.
	Print superscript: As part of a balanced diet and healthy lifestyle. Learn more at DanActive.com.
Male VO:	"Only DanActive has L. casei Immunitas cultures and
On screen:	The yellow circles encircle pink balls, forming a barricade that stops all but one of the fuzzy green, germ-like globs that attempt to penetrate the barricade.
Male VO:	is clinically proven to help strengthen your body's defenses."
On screen:	The boy finishes the DanActive, returns to full color, surrounded by a newly acquired yellow penumbra, and runs out of the house the next morning surrounded by his yellow penumbra,

which then morphs into a yellow DanActive bottle.

Female VO: "And a little strengthening can really help."

On screen: DanActive bottle with tag line "Help strengthen your family's bodies defenses" and "clinically proven" banner

Male VO: "Help strengthen your family's bodies defenses."

On screen: "Dannon."
"Today. For Tomorrow."

b. **Television Advertisement**: "Backpack- New" (Exhibit B - CDROM and storyboard)

On screen: A boy is shown taking a test in school, and being thrown to a mat in martial arts training. He arrives home looking tired, and drops his backpack inside the front door as his mother kneels down and greets him.

Male VO: "Exams, activities, homework; your kids never stop and don't always eat right

On screen: The color drains from the boy's face and body.

Male VO: and you don't want their defenses to be weak."

On screen: A bottle of DanActive rolls toward the viewer.

Male VO: "DanActive can help. How?"

On screen: Dramatization of the body appears, with circles simulating food going down into the gastrointestinal tract. At the bottom of the screen is a yellow band with the question "How are your defenses challenged?"

Male VO: "Unwanted substances enter your body every day, reaching your intestines

On screen:	Visual shows the percentage 70% emerging from the digestive tract in the middle of a sunburst
Male VO:	where about 70% of your immune system is located."
On screen:	Dramatization of the inside of the intestine shows holes appearing, and purple balls entering those holes. At the bottom of screen is the yellow band with the question "How are your defenses challenged?"
Male VO:	"When your defenses are weak, gaps may occur in your intestine wall allowing unwanted substances to pass."
On screen:	The boy drinks the DanActive. Dramatization shows small yellow circles going from the bottle down his throat. Fine print superscript: "When consumed daily as part of a balanced diet and healthy lifestyle"
Male VO:	"DanActive, with L. casei Immunitas works right there
On screen:	Dramatization shifts to inside of the intestine, where the yellow circles, which are identified as L. casei Immunitas, clump together to block the holes in the intestinal wall, so that the purple balls bounce off, instead of penetrate. At the bottom of the screen is the yellow band with the question "How does DanActive help?"
Male VO:	which may help your body close the gaps

On screen:	The boy runs out of the house the next morning. He has returned to full color, and is surrounded by a newly acquired yellow penumbra, which then morphs into a yellow DanActive bottle.
Male VO:	and help strengthen his body's defenses."
On screen:	DanActive bottle with tag line "Help strengthen your family's bodies defenses" and "clinically proven" banner. Print superscript: "Learn more at DanActive.com"
Male VO:	"Which makes you feel good, too."
On screen:	"Dannon." "Today. For Tomorrow."

c. **Print Advertisement (free standing insert)**: (Exhibit C)

DANNON

DanActive™

L. CASEI IMMUNITAS™

IMMUNITY

Helps strengthen your body's defenses.*

CLINICALLY PROVEN

[Depiction of child and mother drinking DanActive and two containers of DanActive with "DanActive, L. Casei

IMMUNITAS™, Helps Strengthen Your Body's Defenses, Immunity" on the labels.]

* as part of a balanced diet and healthy lifestyle

DanActive is a delicious, probiotic-cultured dairy drink that is clinically proven to help strengthen your body's defenses as part of a balanced diet and healthy lifestyle.

d. **Product Packaging**: (Exhibit D)

Appearing on the overwrap for the 8-bottle weekly pack:

DANNON

DanActive™

L. CASEI IMMUNITAS™

IMMUNITY

Helps Strengthen Your
Body's Defenses

7 + 1 Weekly Pack

6. Through the means described in Paragraph 5, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits A through D, among others, respondent has represented, expressly or by implication, that drinking DanActive reduces the likelihood of getting a cold or the flu.

7. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 6, at the time the representation was made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 6, at the time the representation was made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits A through D, among others, respondent has represented, expressly or by implication, that DanActive is clinically proven to reduce the likelihood of getting a cold or the flu.

10. In truth and in fact, DanActive is not clinically proven to reduce the likelihood of getting a cold or the flu. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

ACTIVIA

11. Respondent has disseminated or caused to be disseminated advertisements for Activia, including, but not limited to, the attached Exhibits E through G. These advertisements contain the following statements and depictions:

a. **Television Advertisement**: "Mother & Daughter" (Exhibit E - CDROM and storyboard)

On screen:	A young woman enters an antiques or curios shop, where an older woman is working.
Daughter:	"Hey, mom. All work and no play?"
On screen:	Older woman stands up, walks behind store counter, and gestures toward open boxes of restaurant take-out food.

Mother:	"And too much take-out. I feel irregular. Bloated."
Bird:	"Bloated."
On screen:	Daughter hands her mother a carton of Activia
Daughter:	"Here. Try Dannon Activia."
Mother:	"Activia. . ."
Bird:	"Activia."
On screen:	Strawberries falling into white yogurt.
Female VO:	"Delicious Dannon Activia,
On screen:	Woman's mid-section, on which are super-imposed yellow-green balls moving together in a clump " CLINICALLY PROVEN WITH BIFIDUS REGULARIS" Print superscript: "Scientifically proven to help with slow intestinal transit when consumed daily for two weeks."
Female VO:	with the natural culture Bifidus Regularis,
On Screen:	The yellow-green balls merge into a downward-facing arrow; calendar from which 14 separate pages are torn off in sequence.
Female VO:	it's clinically proven to help regulate your digestive system
On screen:	The arrow moves downward, off the screen.

Female VO: in two weeks."

On screen: Mother tastes Activia.

Mother: "Mmm. Delicious."

Daughter: "Soon you'll be back to your regular self."

Bird: "Regular!"

On screen: overwrap from 4-pack of Activia with tag line "Helps naturally regulate your digestive system in 2 weeks"

Female VO: "Activia" (singing).

On screen: "Dannon."
"Today. For Tomorrow."

b. **Television Advertisement**: "News" (Exhibit F - CDROM and storyboard)

On screen: green screen with Dannon and Activia logos.

On screen: green screen divides horizontally, to show Jamie Lee Curtis (JLC) sitting on couch holding newspaper, with headline that says "87% of Americans Have Occasional Digestive Issues."

JLC: "First the bad news: Eighty-seven percent of this country suffers from digestive issues like occasional irregularity."

On Screen JLC on couch.
Fine print superscript: "Helps relieve temporary symptoms of irregularity."

JLC "No wonder. Our busy lives sometimes force us to eat the wrong things at the wrong time."

On Screen close-up of JLC

JLC "Now the good news. I just discovered a yogurt called Activia that can help."

On screen: Woman's mid-section, on which are super-imposed yellow-green balls moving together in a clump
" CLINICALLY PROVEN WITH BIFIDUS REGULARIS"

Fine print superscript: "Scientifically proven to help with slow intestinal transit when enjoyed daily for two weeks as part of a balanced lifestyle and healthy diet."

Male VO: "With the natural culture, Bifidus Regularis,

On Screen: The yellow-green balls merge into a downward-facing arrow; calendar from which 14 separate pages are torn off in sequence.

Male VO: Activia eaten every day is clinically proven to help regulate your digestive system

On screen: The arrow moves downward, off the screen

Male VO: in two weeks."

On Screen: JLC on couch holding container of Activia, and then tasting spoonful.

JLC "The other good news: Activia tastes great."

On screen: overwraps from 4-packs of Activia and Activia Light, and Activia tub, with tag line "Helps

naturally regulate your digestive system" and "clinically proven" banner

Female VO: "Activia" (singing).

On screen: "Dannon."
"Today. For Tomorrow."

c. **Internet Advertisement**: "Activia by Dannon" (Exhibit G, at p. 1)

Activia with Bifidus Regularis is scientifically proven to help with slow intestinal transit when eaten daily, as part of a balanced diet and healthy lifestyle.
LEARN MORE

12. Activia's webpage, www.activia.us.com, contains a link labeled "For Health Care Professionals" (Exhibit G, at p. 1). Clicking on that link takes the viewer to a page (Exhibit G, at p. 2) that is also entitled "For Health Care Professionals," and that says in part:

Scientific Resources
For health care professionals, who'd like to learn more about Activia and **Bifidus Regularis**, here is a link to a detailed scientific resource that will provide in-depth information about **Bifidus Regularis** and its effect on slow **intestinal transit**

[pdf icon] "Scientific Summary For Health Care Professionals" (1024 kb)

The "Scientific Summary For Health Care Professionals" is a four-page document that includes a discussion entitled "Effects of Activia on total transit time in elderly subjects," which reviews the results of two clinical studies by Meance et al. The reviews refer specifically only to the effects on transit time among elderly subjects given different daily doses of Activia.

The "For Health Care Professionals" page on the Activia website also contains a link labeled "View List of Peer-Reviewed Scientific Summaries," which leads to a two-page document (Exhibit G, at pp. 7-8) entitled "Studies on Bifidobacterium DN-173 010 from Danone." This pdf file contains four summaries of transit time studies, including summaries of the same two studies by Meance et al. The reviews of the Meance et al. studies also refer specifically only to the effects on transit time among elderly subjects given different daily doses of Activia.

13. Neither discussion in Exhibit G of the two studies by Meance et al. discloses that the studies, as conducted, employed a placebo group or that statistical significance was not achieved when the results of the placebo group and the matching active group were compared in both studies. In addition, the document entitled "Studies on Bifidobacterium DN-173 010 from Danone" does not include a summary of a peer-reviewed study by Nishida et al., or summaries of five unpublished studies that measured transit time of subjects consuming Activia or a placebo. Neither the Nishida study nor the five unpublished studies showed a statistically significant improvement in transit time when the Activia group was compared to its respective placebo group.

14. Through the means described in Paragraphs 11 and 12, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits E through G, among others, respondent has represented, expressly or by implication, that eating one serving of Activia daily relieves temporary irregularity and helps with slow intestinal transit time.

15. Through the means described in Paragraphs 11 and 12, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 14, at the time the representation was made.

16. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 14, at the time the representation was made. Therefore, the representation set forth in Paragraph 15 was, and is, false or misleading.

17. Through the means described in Paragraphs 11 and 12, including, but not limited to, the statements and depictions contained in the advertisements attached as Exhibits E through G, among others, respondent has represented, expressly or by implication, that eating one serving of Activia daily is clinically proven to relieve temporary irregularity and help with slow intestinal transit time.

18. In truth and in fact, eating one serving of Activia daily is not clinically proven to relieve temporary irregularity and help with slow intestinal transit time. For example, as described in Paragraphs 12 and 13, (1) the two Meance et al. studies utilized placebo groups but that information was withheld from the scientific journal to which the studies were submitted for publication, thereby concealing the fact that there was no statistically significant difference in transit time between the active and placebo groups, and (2) eight of ten scientific studies conducted on Activia showed no statistically significant effect of Activia on transit time when compared to a placebo. Therefore, the representation set forth in Paragraph 17 was, and is, false or misleading.

19. 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 thirty-first day of January, 2011, has issued this complaint against respondent.

By the Commission.

EXHIBIT A

CODE # 080401233 TIME 06:53 AM
TITLE Boy Taking A Test, Playing Baseball/Vo REV OF # 0803209

ICKING/BELL RINGS)
ANNCR: Between exams
EACHER: Pencils down.

(SFX: CHEERING/CRACK) after-school activities.

(SFX: KARATE PRACTICE SOUN

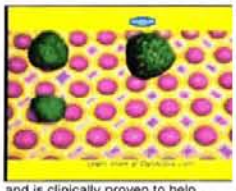
s of homework, my kid never
SFX: THUD)

MALE ANNCR: Your kids have a hectic life and don't always eat right, and you don't want their defenses to be weak.

(MUSIC IN) Delicious DanActive c
help strengthen them.

nActive has

L. casei Immunitas cultures



and is clinically proven to help strengthen your body's defenses.

ANNCR: And a little
ening can really help. (AUDIO
CHILDREN (UNISON):
e.

MALE ANNCR: Help strengthen your family's bodies defenses.

(MUSIC OUT)

EXHIBIT B


vms
CODE # 090301831
TITLE Boy Takes a Test, Karate, Takes Off
TIME 06:12 PM
IALE ANNCR: Exams,
(SFX: THUD) activities, homework; your kid's never stop
and don't always eat right and you don't want their defenses
SFX: POWER DOWN) to be weak.
DanActive can help. How?
(SFX: HISS IN) Unwanted substances enter your body every day
HOW ARE YOUR DEFENSES CHALLENGED ?
aching your intestine where about SFX: HISS OUT)
70 percent of your immune system is located.
70%
When your defenses are weak, (SFX: BOUNCE) gaps may occur in your intestine wall allowing unwanted substances to pass.
USIC IN) DanActive with L. Casei mmunitas
works right there
HOW DOES DANACTIVE HELP ?
which may help your body (SFX: SPRING) close the gaps and help
VIDEO ALSO AVAILABLE IN ANALOG & DIGITAL FORMATS

EXHIBIT B (continued)

vms

PRODUCT Dannon DanActive
MARKET Cincinnati, OH
PROGRAM The King of Queens
CODE # 090301831
TITLE Bcy Takes a Test, Karate, Takes Off

LENGTH :30
STATION WXIX
DATE 03/02/2009
TIME 06:12 PM

(SFX: WHOOSH) strengthen his body's defenses.

(SFX: STAMP) Which makes you feel good too.

CHILDREN (SINGING): DanActive. (MUSIC OUT)

EXHIBIT C


DANNON
DanActive
L.CASEI IMMUNITAS™
IMMUNITY
Helps strengthen your body's defenses.*
CLINICALLY PROVEN
DANNON
DanActive
L.CASEI IMMUNITAS™
Helps Strengthen Your Body's Defenses
IMMUNITY
PROBIOTIC DAIRY DRINK
Strawberry FLAVORED
3.1 FL OZ (93 mL)
DANNON
DanActive Light
L.CASEI IMMUNITAS™
Helps Strengthen Your Body's Defenses
IMMUNITY
PROBIOTIC DAIRY DRINK
Strawberry FLAVORED
NEW Light!
DanActive® Light: 35 calories, 0g Fat; Regular Probiotic Dairy Drink: 90 Calories, 1.5g Fat per 3.1 FL OZ
*as part of a balanced diet and healthy lifestyle
DanActive® is a delicious, probiotic-cultured dairy drink that is clinically proven to help strengthen your body's defenses as part of a balanced diet and
MANUFACTURER'S COUPON
EXPIRES 6/29/08
DO NOT DOUBLE
SAVE $1.00 when you buy any DanActive® or DanActive® Light
21254

Complaint

EXHIBIT D

Complaint

EXHIBIT E

vms

PROGRAM Today
CODE # 060806735
TITLE Daughter Tells Mom To Try It

DATE 08/20/2006
TIME 08:41 AM

IUSIC IN) DAUGHTER: Hey mom!

(SFX: DOOR CLOSING IN & OUT) All work and no play?

MOM: Oh, and too much take out,

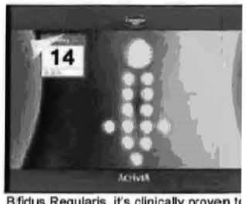
eel irregular, bloated.

PARROT: Hawk! Bloated!

(SFX: DAUGHTER GIGGLES IN & CUT) DAUGHTER: Here, try Dannon Activia. MOM: Activia.

ARROT: Activia!

FEMALE ANNCR: Delicious Dannon Activia, with the natural culture of



Bifidus Regularis, it's clinically proven t help regulate your digestive system in two weeks.

OM: Um! Delicious. DAUGHTER: oon you'll be back to your regular self. ARROT: Regular!

(SFX : LAUGHTER IN & OUT) FEMALE ANNCR: Dannon Activia, help naturally regulate your

digestive system. (MUSIC OUT)

VIDEO ALSO AVAILABLE IN ANALOG & DIGITAL FORMATS

EXHIBIT F

vms

MARKET Huntsville/Decatur/Florence, AL
PROGRAM Comics Unleashed with Byron
CODE # 080215014
TITLE Jamie Lee Curtis: Good & Bad

STATION WAAY
DATE 02-23-2008
TIME 01:03 AM

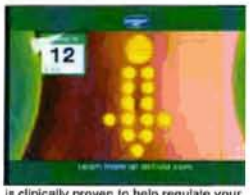
JSIC IN)

JAMIE LEE CURTIS: First the bad news: 87 percent of this country suffers from digestive issues like occasional irregularity.

No wonder. Our busy lives sometimes force us to eat the wrong things at the wrong times.

w the good news: I just discovered a jurt called Activia that can help.

MALE ANNCR: With a natural culture, bifidus regularis, Activia eaten every day



is clinically proven to help regulate your digestive system in two weeks.

MIE LEE CURTIS: The other good vs. Activia tastes great.

FEMALE SINGERS: Activia.

(MUSIC OUT)

EXHIBIT G


DANNON
ACTIVIA
ACTIVIA IN THE NEWS
ESPAÑOL / SPANISH
HOME
ABOUT ACTIVIA
PRODUCTS
ABOUT BIFIDUS REGULARIS
WHAT ARE PROBIOTICS?
MAINTAINING DIGESTIVE HEALTH
FOR HEALTH CARE PROFESSIONALS
TAKE THE CHALLENGE
FAQs
Take the 14 DAY ACTIVIA Challenge
Click for Coupon!
START TODAY
great flavors and sizes
LEARN MORE
clinical proof
Activia with Bifidus Regularis is scientifically proven to help with slow intestinal transit when eaten daily for two weeks, as part of a balanced diet and healthy lifestyle.
LEARN MORE
what are probiotics?
Well-known to nutritionists and health editors for years, these helpful natural cultures are behind a new wave of "functional foods."
LEARN MORE
ACTIVIA IN THE NEWS
Read News
ACTIVIA ON THE AIR
If you haven't seen our latest television commercial, you can watch it here.
Watch now
SEND TO A FRIEND
EMAIL UPDATES
NEWS | DANNON.COM | CONTACT US | PRIVACY INFO | STORE LOCATOR | TV ADS | SITE MAP | ACTIVIA IN OTHER COUNTRIES

EXHIBIT G (continued)

EXHIBIT G (continued)

A lowfat yogurt that helps naturally regulate the digestive system

Presenting—ACTIVIA® by Dannon®

Clinically proven to help regulate the digestive system when eaten daily for two weeks.

- ACTIVIA® is a creamy, blended, probiotic-cultured, lowfat yogurt.
- ACTIVIA® helps with slow intestinal transit and contains a unique culture – *Bifidus Regularis.*™
- ACTIVIA® has the great taste and quality that you expect from Dannon.®

ACTIVIA® helps naturally regulate your digestive system

ACTIVIA® is a probiotic, lowfat yogurt that contains a unique culture, *Bifidus Regularis,*™ clinically proven to survive passage through the gastrointestinal tract and scientifically known as *Bifidobacterium animalis* DN-173 010.

Daily consumption of ACTIVIA® helps with slow intestinal transit, particularly in women and the elderly. ACTIVIA® also possesses the standard nutritional qualities of a dairy product, thanks to the proteins and calcium it contains.

What are probiotics?

Probiotics are living microorganisms that, upon ingestion in sufficient numbers, exert health benefits beyond basic nutrition.

EXHIBIT G (continued)

The gastrointestinal (GI) tract and the intestinal microflora

The GI tract is an extremely complex environment with multiple functions. The small intestine acts as the main site of enzymatic digestion of foods and absorption of nutrients. The colon or large intestine absorbs large quantities of water and electrolytes and allows evacuation of waste matter and toxic substances. The colon also appears to be responsible for regulation of intestinal well-being, particularly through its complex bacterial microflora and maintenance of intestinal balance.

The intestinal microflora of each individual is highly specific and remains remarkably stable over time.[1] However, it develops in stages throughout the individual's lifetime as a result of diet, host health status and environmental conditions. The intestinal tract of an adult human contains microflora comprising approximately 10^{11} microorganisms per gram of stool, with approximately 400 to 500 different bacterial species. The dominant population consists of strict anaerobic bacteria: *Bacteroides, Bifidobacterium, Eubacterium* and *Peptostreptococcus.*[2]

A balanced intestinal microflora rich in bifidobacteria helps ensure optimal functioning of the digestive system.[3,4] Research suggests that when the intestinal microflora is out of balance, it may affect overall health. This balance can be disturbed during physical or psychological stress, with age, in menopause, during drug treatment (e.g., antibiotics) and in the event of acute or chronic intestinal diseases.[5,6,7] The intestinal microflora balance can be temporarily restored by ingestion of certain probiotics.[8]

Intestinal transit

Intestinal transit is the process by which gut intestinal contents pass through the digestive system. The average transit time from mouth to anus in a healthy adult takes under 72 hours and most of this transit time is spent in the colon. Transit time varies significantly between individuals in spite of identical diet and also varies within specific individuals. In addition, it appears that transit time is longer in women than in men and increases with age.[9]

Intestinal transit is affected not only by the quality of the diet and by environmental parameters (e.g., age, stress, etc.), but also by the intestinal microflora.

Slow transit is not necessarily pathological and it corresponds to the upper limit of normal transit time and is between 48 and 72 hours. However, slow intestinal transit is a source of daily discomfort for a large proportion of the population and the physical and physiological consequences on the quality of life should not be underestimated. Bloating, heaviness, difficult and painful defecation are all troublesome symptoms when they become chronic.[10]

A total transit time exceeding 72 hours is considered abnormally long and normally gives rise to a diagnosis of constipation, also involving excessive dehydration of stools. Maintaining a regular intestinal transit is therefore essential for health and general well-being.

Interaction between intestinal microflora and transit

Several studies have attempted to determine the mechanisms by which the intestinal microflora stimulates transit. These studies focus particularly on the effects of products from bacterial fermentation, such as Short-Chain Fatty Acids (SCFA), and on physicochemical modifications induced by the microflora. Various hypotheses, illustrated on the diagram below, have pertained to the effects of the intestinal microflora on transit.[11,12,13,14,15,16]

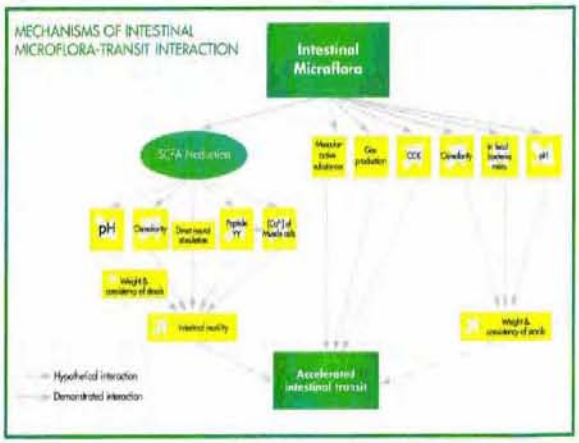


EXHIBIT G (continued)

Since certain strains of probiotics have been identified through their beneficial effect on the endogenous intestinal microflora, it was logical to assess their impact on transit. Bifidobacteria have thus been particularly and closely studied in man.[17] Their effects on transit have been clearly demonstrated through studies performed recently with ACTIVIA® by Dannon® and its specific strain: *Bifidobacterium animalis* DN-173 010.[18,19,20,21] Dannon's *Bifidobacterium animalis* DN-173 010 is an exclusive probiotic culture of food origin, which is found live and in large quantities in ACTIVIA®, and remains stable throughout the product shelf life.

Effects of ACTIVIA® and/or *Bifidobacterium animalis* DN-173 010 on transit time in healthy adults[18]

In a parallel, double-blind study including 72 healthy adult volunteers (mean age 30 years), the ingestion of a fermented milk (3x125 g/day) containing the strain *Bifidobacterium animalis* DN-173 010, for 11 days, significantly reduces total colonic transit time by 21% and sigmoid transit time by 39% compared to an identical fermented milk (3x125 g/day) in which bacteria were killed by heat treatment. The effect was more pronounced in women ($p<0.03$), particularly in those with a long baseline transit time compared to men ($p<0.05$). These beneficial effects were not found with heat-treated product, suggesting that both probiotic survival and metabolic activity are necessary.

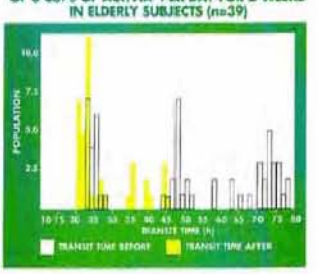
Action of ACTIVIA® on colonic transit time in women[19]

A double-blind, randomized, cross-over study including 36 healthy women (mean age 27 years) compared the efficacy of ACTIVIA® (3x125 g/day) with a fermented milk preparation containing no *Bifidobacterium animalis* DN-173 010 (3x125 g/day) during a consumption period of 10 days. Total colonic and sigmoid transit times were significantly shortened ($p<0.05$) with ACTIVIA® versus control (51.5 +/- 30.2 hours vs. 60.7 +/- 27.1; sigmoid: 21.6 +/- 14.9 hours vs. 26.8 +/- 14.2). In women with a total transit time of more than 40 hours, the sigmoid transit time and total transit time were significantly shorter following consumption of ACTIVIA® versus the baseline values recorded prior to consumption.

Effects of ACTIVIA® on total transit time in elderly subjects[18,21]

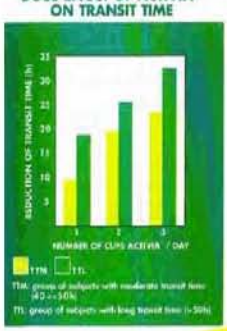
Two randomized studies investigated the efficacy of different doses of ACTIVIA® with *Bifidobacterium animalis* DN-173 010 on transit time by focusing on elderly subjects. The first study (total 100 subjects) showed that consumption of 2x125 g or 3x125 g of ACTIVIA® per day for two weeks significantly reduced intestinal transit time ($p<0.001$). A 10% reduction was found in the groups with a short transit time (less than 40 hours) and a 40% reduction was found in groups with a long transit time (greater than 40 hours). The results were greater in those elderly subjects who had 3x125 g of ACTIVIA® versus 2x125 g ($p<0.05$). Intestinal transit time is shortened in elderly subjects by consumption of two or three cups of ACTIVIA® for two weeks.

TRANSIT TIME BEFORE AND AFTER CONSUMPTION OF 3 CUPS OF ACTIVIA® PER DAY FOR 2 WEEKS IN ELDERLY SUBJECTS (n=39)



A second, large-scale, controlled study evaluated lower doses and the duration of the beneficial effects after discontinuing consumption of the product. The study included 200 elderly, healthy volunteers, aged 50–75 years, divided in two groups—100 with moderate transit time (40–50 hours) and 100 with a longer transit time (50–70 hours), who were randomized to receive either 1x125 g or 2x125 g of ACTIVIA® per day for 2 weeks. Consumption of one or two 125 g cups of ACTIVIA® significantly reduced intestinal transit time, both in subjects with moderate and long transit times ($p<0.05$). However, two servings per day were more effective than one serving per day ($p<0.05$). The action of ACTIVIA® persisted for at least two weeks after the end of consumption of one serving and for at least four weeks after the end of ingestion of two servings of ACTIVIA®.

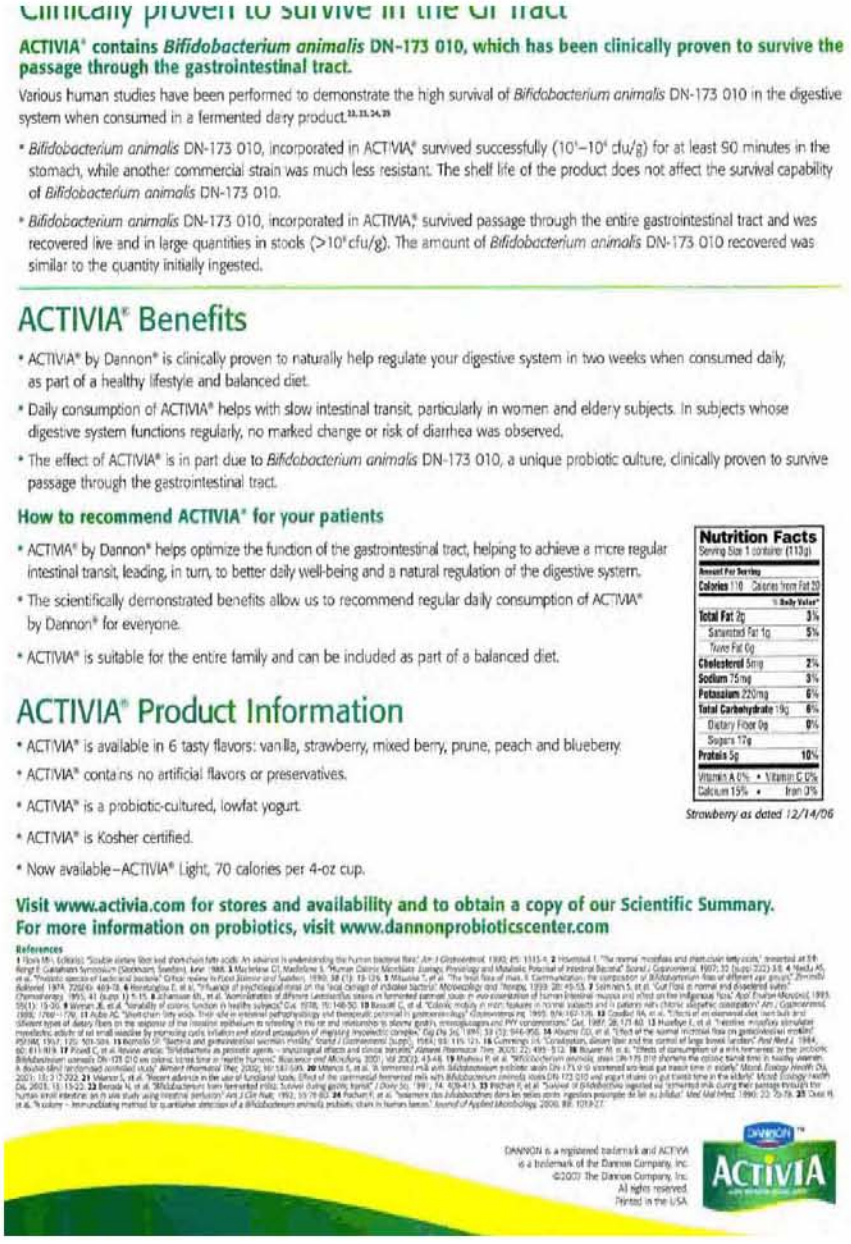
DOSE-EFFECT OF ACTIVIA® ON TRANSIT TIME



In conclusion, these two studies demonstrate the efficacy of ACTIVIA® in reducing transit time in elderly subjects, particularly in those with long transit times. A dose-dependent effect was observed (from 1 to 3 cups).

DANONE
ACTIVIA

EXHIBIT G (continued)



Clinically proven to survive in the GI tract

ACTIVIA® contains *Bifidobacterium animalis* DN-173 010, which has been clinically proven to survive the passage through the gastrointestinal tract.

Various human studies have been performed to demonstrate the high survival of *Bifidobacterium animalis* DN-173 010 in the digestive system when consumed in a fermented dairy product.[22, 23, 24, 25]

- *Bifidobacterium animalis* DN-173 010, incorporated in ACTIVIA,® survived successfully (10^1–10^6 cfu/g) for at least 90 minutes in the stomach, while another commercial strain was much less resistant. The shelf life of the product does not affect the survival capability of *Bifidobacterium animalis* DN-173 010.
- *Bifidobacterium animalis* DN-173 010, incorporated in ACTIVIA,® survived passage through the entire gastrointestinal tract and was recovered live and in large quantities in stools (>10^6 cfu/g). The amount of *Bifidobacterium animalis* DN-173 010 recovered was similar to the quantity initially ingested.

ACTIVIA® Benefits

- ACTIVIA® by Dannon® is clinically proven to naturally help regulate your digestive system in two weeks when consumed daily, as part of a healthy lifestyle and balanced diet.
- Daily consumption of ACTIVIA® helps with slow intestinal transit, particularly in women and elderly subjects. In subjects whose digestive system functions regularly, no marked change or risk of diarrhea was observed.
- The effect of ACTIVIA® is in part due to *Bifidobacterium animalis* DN-173 010, a unique probiotic culture, clinically proven to survive passage through the gastrointestinal tract.

How to recommend ACTIVIA® for your patients

- ACTIVIA® by Dannon® helps optimize the function of the gastrointestinal tract, helping to achieve a more regular intestinal transit, leading, in turn, to better daily well-being and a natural regulation of the digestive system.
- The scientifically demonstrated benefits allow us to recommend regular daily consumption of ACTIVIA® by Dannon® for everyone.
- ACTIVIA® is suitable for the entire family and can be included as part of a balanced diet.

Nutrition Facts
Serving Size 1 container (113g)

Amount Per Serving	
Calories 110 Calories from Fat 20	
	% Daily Value*
Total Fat 2g	3%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 75mg	3%
Potassium 220mg	6%
Total Carbohydrate 19g	6%
Dietary Fiber 0g	0%
Sugars 17g	
Protein 5g	10%
Vitamin A 0% • Vitamin C 0%	
Calcium 15% • Iron 3%	

Strawberry as dated 12/14/06

ACTIVIA® Product Information

- ACTIVIA® is available in 6 tasty flavors: vanilla, strawberry, mixed berry, prune, peach and blueberry.
- ACTIVIA® contains no artificial flavors or preservatives.
- ACTIVIA® is a probiotic-cultured, lowfat yogurt.
- ACTIVIA® is Kosher certified.
- Now available–ACTIVIA® Light, 70 calories per 4-oz cup.

Visit www.activia.com for stores and availability and to obtain a copy of our Scientific Summary.
For more information on probiotics, visit www.dannonprobioticscenter.com

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DANNON™ ACTIVIA

EXHIBIT G (continued)

Studies on *Bifidobacterium* DN-173 010 from Danone

***Bifidobacterium animalis* strain DN-173 010 shortens the colonic transit time in healthy women: a double-blind, randomized, controlled study**

P. Marteau, E. Guillemard, S. Méance, MF. Gerhardt, A. Myara, M. Bouvier, C. Bouley, F. Tondu, G. Bommelaer and JC. Grimaud
Aliment Pharmacol. Ther., 2002; 16: 587-593

Background: A previous study has suggested that *Bifidobacterium animalis* DN-173 010 shortens the colonic transit time in women. Aim: To confirm this effect and to determine whether modifications of the faecal bacterial mass and/or faecal secondary bile acids may be the explanation. Methods: A double-blind, cross-over study was performed. Thirty-six healthy women were divided in four consecutive 10-day periods. During periods 2 and 4, they ingested three 125 g pots per day of a fermented milk which was either a product containing *B. animalis* DN-173 010 or a control without bifidobacteria. Periods 1 and 3 were run-in and washout periods, respectively. The total and segmental colonic transit times were assessed using a plain method. In 13 subjects, all stools were collected and analysed for pH, faecal weight, bacterial mass and bile acids. Results: The total and right colonic transit times were significantly shorter during dosing with *B. animalis* compared to the control ($P < 0.05$). Faecal weight, pH, bacterial mass and bile acids were not significantly affected. Conclusions: *B. animalis* DN-173 010, ingested at 10^11 cfu/day, shortens colonic transit time in healthy women. This effect is not explained by modifications of the faecal bacterial mass or secondary bile acids.

Effect of a fermented milk containing *Bifidobacterium animalis* strain DN-173 010 on the health-related quality of life and symptoms in irritable bowel syndrome in adults in primary care: a multicentre, randomized, double-blind, controlled trial

O. Guyonnet, O. Chassany, P. Ducrotte, C. Picard, M. Mouret, C.-H. Mercier and G. Matuchansky
Aliment Pharmacol. Ther., 2007; 26: 475–486

Summary. Background: Health-related quality of life (HRQoL) has been rarely evaluated as a primary endpoint in the assessment of the effect of probiotics on the irritable bowel syndrome (IBS). Aim: To study the effects of fermented milk containing *Bifidobacterium animalis* DN-173 010 and yogurt strains on the HRQoL in a multicentre, double-blind, controlled trial. Methods: A total of 274 primary care adults with constipation-predominant IBS (Rome II) were randomized to consume for 4 weeks either the test fermented milk or a yogurt-like control, in addition to their usual diet. Digestive symptoms were assessed after 2 and 4 weeks by a questionnaire (at their pace) and a 7-day recording (at 0, 2 and 4 weeks). The HRQoL (Nepean Dyspepsia Index) was assessed at baseline and after 4 weeks. Results: The HRQoL global score was significantly improved in both groups at weeks 2 and 4. The responder rate for this HRQoL discomfort score was higher (63.2 vs. 47.3%, $P = 0.005$) in the active group at week 4 (missing score: 26%; $n = 0.41$ [0.21 vs. 0.20], $P = 0.031$, at week 2; n = the rate ratio, the control group as the reference). Conclusions: This study suggests a beneficial effect of a daily consumption of *Bifidobacterium animalis* DN-173 010 on the HRQoL score and bloating in constipation-predominant IBS, and on stool frequency in subjects with ↺ stool/week.

Review article: Bifidobacteria as probiotic agents – physiological effects and clinical benefits

C. Picard, J. Fioramanti, A. Francois, T. Rojeroon, F. Heurt and C. Matuchansky
Aliment Pharmacol. Ther., 2005; 22: 495–512

Summary. Bifidobacteria, naturally present in the dominant colonic microbiota, represent up to 25% of the cultivable faecal bacteria in adults and 80% in infants. As probiotic agents, bifidobacteria have been studied for their efficacy in the prevention and treatment of a broad spectrum of animal and/or human gastrointestinal disorders, such as colonic transit disorders, intestinal infections, and colonic adenomas and cancer. The aim of this review is to focus on the gastrointestinal effects of bifidobacteria as probiotic agents in animal models and man. The mechanisms of use of bifidobacteria in fermented dairy products and the EFSA's (Generally Recognized As Safe) status of certain strains used in their survey. Some strains, especially *Bifidobacterium animalis* strain DN-173 010 which has long been used in fermented dairy products, show high gastrointestinal survival capacity and exhibit probiotic properties on the colon: resistance to colonization by pathogens, stimulation of the immune system, and ability to prevent or delay infectious diarrhoea through their effects on the mucosal barrier and luminal microbiota. These results underscore the importance of selecting probiotic bifidobacteria that survive gastrointestinal transit and actively protect the host from pathogenic agents of intestinal flora. Bifidobacteria may also exert beneficial actions through various mechanisms, and represent promising advances in the fields of prophylaxis and therapy.

Survival of bifidobacteria ingested via fermented milk during their passage through the human small intestine: an in vivo study using intestinal perfusion

P. Pochart, P. Marteau, V. Bouthilk, I. Goderel, P. Bouvilloux and JC. Rambaud
Am. J. Clin. Nutr., 1992; 55: 78–80

Abstract: The ability of a strain of *Bifidobacterium* sp to survive passage through the upper gastrointestinal tract when ingested in fermented milk was investigated in six healthy healthy adults by using in vivo ileal perfusion. After ingestion of 10.2±5.1 log$_{10}$ bifidobacteria in 400 g fermented milk, ileal flora of bifidobacteria increased significantly and reached a maximum of 8.8±0.2 log$_{10}$ bifidobacteria/g 1.9±0.4 h after ingestion of fermented milk. The average number of bifidobacteria recovered from the terminal ileum during the 8 h after fermented-milk ingestion was 9.8±0.1 log$_{10}$ and considered 12.5±0.4% of the number ingested. These results indicate that in healthy adults *Bifidobacterium* sp survives transit through the gastrointestinal tract when ingested in fermented milk. Further studies are needed to investigate the relevance of these exogenous bacteria in the colonic biotope and to explore their effects on the physiology of the human gastrointestinal tract.

DANONE RESEARCH
CENTRE DANIEL CARASSO

EXHIBIT G (continued)

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 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, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent The Dannon Company, Inc., is a Delaware corporation with its principal office or place of business at 100 Hillside Ave., White Plains, NY, 10603.

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 The Dannon Company, 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: (a) any yogurt, including but not limited to, Activia yogurt; (b) any dairy drink; and (c) any food or drink not covered by the foregoing that contains a probiotic, including, but not limited to, DanActive.

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. "Food" means as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

7. "Endorsement" means as defined in 16 C.F.R. § 255.0.

8. The term "including" in this Order means "without limitation."

9. 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 product name, endorsement, depiction, or illustration, that such product reduces the likelihood of getting a cold or the flu, 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 Activia yogurt, 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 Activia yogurt relieves temporary irregularity or helps with slow intestinal transit time, unless the representation is non-misleading and conveys that eating three servings a day is required to obtain the benefit. *Provided, however*, that nothing in this Part II shall prohibit respondent from representing that such benefit can be achieved from eating less than three servings a day if such claim is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that such representation is true. For purposes of this Part II, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of Activia yogurt, 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.

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 other than Activia yogurt, 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 relieves temporary irregularity or helps with slow intestinal transit time, 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 substantiates that the representation is true. For purposes of this Part III, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the covered 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.

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 make any representation, other than representations covered under Parts I through III of this order, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, 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 this Part IV, competent and reliable scientific evidence means tests, analyses, research, or studies that have been

conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

V.

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, including, but not limited to, any misrepresentation that such product:

A. Is clinically proven to reduce the likelihood of getting a cold or flu; or

B. Is clinically proven to relieve temporary irregularity or help with slow intestinal transit time.

VI.

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.

VII.

IT IS FURTHER ORDERED that respondent The Dannon Company, Inc., 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 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.

VIII.

IT IS FURTHER ORDERED that respondent The Dannon Company, Inc., 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 and its successors and assigns shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IX.

IT IS FURTHER ORDERED that respondent The Dannon Company, Inc., 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 and its successors and assigns learn 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, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondent The Dannon Company, Inc., and its successors and assigns, shall, within sixty (60) days after the date of 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 they have complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent and its successors and assigns shall submit additional true and accurate written reports.

XI.

This order will terminate on January 31, 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 The Dannon Company, 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 DanActive, a probiotic dairy drink, and Activia, a probiotic yogurt. According to the FTC complaint, respondent represented, in various advertisements, that drinking DanActive reduces the likelihood of getting a cold or the flu. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. The complaint also alleges that respondent represented that clinical studies prove that drinking DanActive reduces the likelihood of getting a cold or the flu. The complaint alleges that these claims are false and thus

violate the FTC Act.

With respect to Activia, the complaint alleges that respondent represented, in various advertisements, that eating one serving of Activia daily relieves temporary irregularity and helps with slow intestinal transit time. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. The complaint also alleges that respondent represented that clinical studies prove that eating one serving of Activia daily relieves temporary irregularity and helps with slow intestinal transit time. 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 commerce. The order defines a covered product as: (a) any yogurt, including but not limited to, Activia yogurt; (b) any dairy drink; and (c) any food or drink not covered by the foregoing that contains a probiotic, including, but not limited to, DanActive.

Part I of the consent order is designed to address the complaint allegations concerning respondent's allegedly unsubstantiated representations that drinking DanActive reduces the likelihood of getting a cold or the flu. Part I prohibits respondent from making representations that any covered product reduces the likelihood of getting a cold or the flu 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 claim that a covered product reduces the likelihood of getting a cold or the flu 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 consent order provision requiring FDA pre-approval before respondent makes a reduced cold or flu likelihood claim for its covered products in the future will facilitate compliance with and enforcement of the order and is reasonably related to the violations alleged.

Respondent may decide to make an advertising claim characterizing limited scientific evidence supporting the relationship between a covered product and a reduced likelihood of getting a cold or the flu. However, if the net impression of that advertising is that the covered product reduces the likelihood of getting a cold or the flu, 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 reduce the likelihood of getting a cold or the flu, 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 reduce the likelihood of getting a cold or the flu, then that claim would be covered under Part IV of the order.

Although Part I requires FDA approval before respondent can make claims that a covered product reduces the likelihood of getting a cold or the flu, 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 reduces the likelihood of getting a cold or the flu, respondent may use a variety of words and images to communicate that claim in its advertising. Conversely,

regardless of the particular words or images used, if the net impression of an advertisement is that a covered product reduces the likelihood of getting a cold or the flu, 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 eating one serving of Activia yogurt daily relieves temporary irregularity and helps with slow intestinal transit time unless the representation is non-misleading and it conveys that eating three servings a day is required to obtain the benefit. Part II further provides, however, that the order does not prohibit respondent from representing that the benefit can be achieved from eating less than three servings a day if such claim is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that such 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 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.

Part III of the consent order prohibits respondent from making representations that any covered product other than Activia yogurt

relieves temporary irregularity and helps with slow intestinal transit time unless the representation is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that such representation is true. For purposes of Part III, 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.

Part IV of the consent order prohibits respondent from making representations, other than representations covered under Parts I through III, 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 IV, 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 V of the consent order prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including but not limited to but not limited to, any misrepresentation that a covered product is clinically proven (1) to reduce the likelihood of getting a cold or flu, or (2) to relieve temporary irregularity or help with slow intestinal transit time.

Part VI 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 VII, VIII, IX, and X 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 XI 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.

IN THE MATTER OF

KEYSTONE HOLDINGS, LLC AND COMPAGNIE DE SAINT-GOBAIN, 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-4314; File No. 101 0175
Filed February 7, 2011 – Decision February 7, 2011

This consent order relates to allegations of anticompetitive effects resulting from Keystone Holdings LLC ("Keystone") proposed acquisition of certain Advanced Ceramics Business assets from Compagnie de Saint-Gobain ("Saint-Gobain") in violation of Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act. According to the complaint, in the proposed acquisition, as originally structured, Keystone would have acquired Saint-Gobain's worldwide assets and businesses relating to the manufacture and sale of alumina wear tiles, including Saint-Gobain's North American alumina wear tile business in Latrobe, Pennsylvania. To resolve competitive concerns raised by the proposed acquisition, Keystone and Saint-Gobain re-structured the original transaction to exclude Saint-Gobain's alumina wear tile business in Latrobe. Under the order, Keystone is required for ten years to obtain prior approval from the Commission for the direct or indirect acquisition of Saint-Gobain's alumina wear tile business in Latrobe or certain other assets owned or controlled by Saint-Gobain relating to the alumina wear tile made in North America. The order requires Saint-Gobain for five years to provide advance written notice to the Commission prior to leasing or selling the Latrobe facility or selling substantially all of its interest in the Saint-Gobain alumina wear tile business. The order also requires Saint-Gobain to provide the Commission with advance written notice prior to closing the Latrobe facility, or ceasing production of alumina wear tiles at the facility.

Participants

For the *Commission*: *Melanie Hallas, Victoria Luxardo Jeffries, Victoria Lippincott, Angelike Andrinopoulos Mina, David Morris, Eric M. Sprague,* and *Arthur Strong.*

For the *Respondents*: *Robert Schlossberg* and *Bruce McCulloch, Freshfields Bruckhaus Deringer LLP;* and *Patricia Zeigler* and *Garret Rasmussen, Orrick, Herrington & Sutcliffe LLP.*