

**SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN DIEGO**

STREET ADDRESS: 330 West Broadway  
MAILING ADDRESS: 330 West Broadway  
CITY AND ZIP CODE: San Diego, CA 92101  
BRANCH NAME: Central  
TELEPHONE NUMBER: (619) 450-7069

PLAINTIFF(S) / PETITIONER(S): Dino Rikos

DEFENDANT(S) / RESPONDENT(S): The Procter &amp; Gamble Company

RIKOS VS. THE PROCTER &amp; GAMBLE COMPANY

**NOTICE OF CASE ASSIGNMENT**

CASE NUMBER:

37-2011-00099818-CU-BT-CTL

Judge: Jeffrey B. Barton

Department: C-69

**COMPLAINT/PETITION FILED: 10/20/2011****ALL CASES MUST COMPLY WITH THE CIVIL REQUIREMENTS LISTED BELOW,  
EXCEPT FOR PARKING TICKETS APPEALS AND CASES ASSIGNED TO THE PROBATE DIVISION.**

IT IS THE DUTY OF EACH PLAINTIFF (AND CROSS-COMPLAINANT) TO SERVE A COPY OF THIS NOTICE WITH THE COMPLAINT (AND CROSS-COMPLAINT), THE ALTERNATIVE DISPUTE RESOLUTION (ADR) INFORMATION FORM (SDSC FORM #CIV-730), A STIPULATION TO USE ALTERNATIVE DISPUTE RESOLUTION (ADR) (SDSC FORM #CIV-359), AND OTHER DOCUMENTS AS SET OUT IN SDSC LOCAL RULE 2.1.5.

ALL COUNSEL WILL BE EXPECTED TO BE FAMILIAR WITH SUPERIOR COURT RULES WHICH HAVE BEEN PUBLISHED AS DIVISION II, AND WILL BE STRICTLY ENFORCED.

**TIME STANDARDS:** The following timeframes apply to general civil cases and must be adhered to unless you have requested and been granted an extension of time. General civil cases consist of all civil cases except: small claims proceedings, civil petitions, unlawful detainer proceedings, probate, guardianship, conservatorship, juvenile, and family law proceedings.

**COMPLAINTS:** Complaints and all other documents listed in SDSC Local Rule 2.1.5 must be served on all named defendants, and a Certificate of Service (SDSC form #CIV-345) filed within 60 days of filing.

**DEFENDANT'S APPEARANCE:** Defendant must generally appear within 30 days of service of the complaint. (Plaintiff may stipulate to no more than 15 day extension which must be in writing and filed with the Court.) (SDSC Local Rule 2.1.6)

**DEFAULT:** If the defendant has not generally appeared and no extension has been granted, the plaintiff must request default within 45 days of the filing of the Certificate of Service. (SDSC Local Rule 2.1.7)

**CASE MANAGEMENT CONFERENCE:** A Case Management Conference will be set within 150 days of filing the complaint.

**ALTERNATIVE DISPUTE RESOLUTION (ADR):** THE COURT ENCOURAGES YOU TO CONSIDER UTILIZING VARIOUS ALTERNATIVES TO TRIAL, INCLUDING MEDIATION AND ARBITRATION, PRIOR TO THE CASE MANAGEMENT CONFERENCE. PARTIES MAY FILE THE ATTACHED STIPULATION TO USE ALTERNATIVE DISPUTE RESOLUTION (SDSC FORM #CIV-359).

YOU MAY ALSO BE ORDERED TO PARTICIPATE IN ARBITRATION. IF THE CASE IS ORDERED TO ARBITRATION PURSUANT TO CODE CIV. PROC. 1411.11, THE COSTS OF ARBITRATION WILL BE PAID BY THE COURT PURSUANT TO CODE CIV. PROC. 1141.28.

FOR MORE INFORMATION, SEE THE ATTACHED ALTERNATIVE DISPUTE RESOLUTION (ADR) INFORMATION FORM (SDSC FORM #CIV-730)

ORIGINAL

BLOOD HURST & O'REARDON, LLP

1 BLOOD HURST & O'REARDON, LLP  
 2 TIMOTHY G. BLOOD (149343)  
 3 LESLIE E. HURST (178432)  
 4 THOMAS J. O'REARDON II (247952)  
 5 600 B Street, Suite 1550  
 6 San Diego, CA 92101  
 Telephone: 619/338-1100  
 619/338-1101 (fax)  
 tblood@bholaw.com  
 lhurst@bholaw.com  
 toreardon@bholaw.com

7 Attorneys for Plaintiff

8 [Additional counsel appear on signature page.]

9

10

SUPERIOR COURT OF THE STATE OF CALIFORNIA

11

COUNTY OF SAN DIEGO

12

DINO RIKOS,

Case No.: **37-2011-00099818-CU-BT-CTL**

13

Plaintiff,

14

v.

COMPLAINT FOR INJUNCTIVE  
AND DECLARATORY RELIEF

15

THE PROCTER & GAMBLE COMPANY  
and DOES 1-10,

16

Defendant.

17

18

19

20

21

22

23

24

25

26

27

28

C. BULLOCK OFFICE 21  
CENTRAL DIVISION

2011 OCT 20 PM 3:47

CLERK-SEAL FOR COURT  
SAN DIEGO COUNTY, CA

2011 OCT 20 PM 3:47

1 Plaintiff Dino Rikos ("plaintiff"), by and through his attorneys, brings this action on  
2 behalf of himself and the general public against The Procter & Gamble Company (which is  
3 collectively referred to, along with the Doe defendants, as "Procter & Gamble" or  
4 "defendant"), and states:

#### 5 NATURE OF THE ACTION

6 1. This is a consumer protection action addressing the advertisements Procter &  
7 Gamble makes about its over-the-counter "digestive care" product called Align®. Through its  
8 advertising and labeling, Procter & Gamble claims that Align provides "digestive care" by  
9 helping to:

- 10 • **Build and maintain** a healthy digestive system
- 11 • **Restore your natural** digestive balance
- 12 • **Protect against** occasional digestive upsets

13 Procter & Gamble claims in its advertising, including the packaging for Align, that these  
14 health benefits result because "Only Align Contains Bifantis®, a Unique, Patented Probiotic,"  
15 that will "**restore your natural balance and bring peace to your digestive system.**" Procter  
16 & Gamble has no support for these claims, even though it states that it does, going so far as to  
17 claim it has clinical proof. Procter & Gamble's representations are false, misleading and  
18 reasonably likely to deceive the public.

19 2. In March 2009, Procter & Gamble began nationally marketing Align.  
20 Prominently placed on its product packaging and in its other advertisements, Procter &  
21 Gamble stated and continues to state that Align contains the unique and patented probiotic  
22 bacteria "Bifantis®." Procter & Gamble advertised and continues to advertise that "Align is  
23 different because only Align contains Bifantis, a patented probiotic strain," that "brings peace  
24 to your digestive system" and provides a "restored natural balance to your digestive system."  
25 For marketing its Align product, Procter & Gamble uses its trademarked phrase "GREAT  
26 DIGESTION THROUGH SCIENCE™."

27 3. In truth, the ingredient matrix found in Align has never been substantiated,  
28 clinically or otherwise, and Procter & Gamble has no legitimate basis to make these claims. In

1 fact, the only purported clinical trial that Procter & Gamble discusses on its website concerns  
2 the effects of Bifantis in treating symptoms of inflammatory bowel disease ("IBS"), rather  
3 than the general population, to whom the advertisements are targeted. Even then, the study  
4 concludes that "[n]o statistically significant differences between [placebo and Bifantis] groups  
5 were observed at any time-point" relating to daily IBS symptom assessments. Results from  
6 this Procter & Gamble funded study are not published in a peer-reviewed scientific journal.

7 4. Two of the other primary studies relied upon by Procter & Gamble as scientific  
8 proof – O'Mahony *et al.* 2005 and Whorwell *et al.* 2006 – fall far short of substantiating the  
9 Align marketing claims. Both are heavily flawed.

10 5. Although it was not launched at nationwide retailers until 2009, Procter &  
11 Gamble's history with Align dates back to 2001 when it began working with a group from  
12 Ireland who formed a for-profit probiotics development company called Alimentary Health  
13 Limited ("Alimentary Health"). In fact, when Procter & Gamble and Alimentary Health  
14 formalized their relationship in 2005, Alimentary Health's CEO boasted that "[t]his deal is the  
15 culmination of a close working partnership with P&G over a number of years and will  
16 transition us into a revenue generating company."<sup>1</sup>

17 6. Procter & Gamble conveyed and continues to convey its deceptive claims about  
18 Align through a variety of media, including the Internet, in-store sampling, point of sale  
19 displays, and on the Align® probiotic supplement's labels and labeling. These representations  
20 appear prominently and conspicuously on every Align container.

21 7. Through this advertising, Procter & Gamble has conveyed one message: Align,  
22 with its probiotic bacteria cultures, provides clinically proven digestive health benefits to the  
23 general public. Attached as Exhibit 1 is a collection of some of the advertisements and  
24 labeling containing the false and deceptive advertising claim.

25 8. Procter & Gamble's advertising and marketing campaign is designed to cause  
26 consumers to buy Align as a result of this deceptive message, and Procter & Gamble has  
27

28 <sup>1</sup> <http://www.alimentaryhealth.ie/cgi-bin/show.cgi?news4> (last visited September 21, 2011)

1 succeeded. Despite being nothing more than a sugared capsule filled with naturally occurring  
2 bacteria, a 28-count package of Align retails for approximately \$30, while a 42-count package  
3 retails for approximately \$40. According to Procter & Gamble, even before its nationwide  
4 retail launch, Align was the No. 1 gastroenterologist-recommended probiotic supplement.

5 9. California consumer protection laws, as well as the consumer protection laws of  
6 the other states, prohibit Procter & Gamble's conduct. Plaintiff seeks injunctive and  
7 declaratory relief to halt Procter & Gamble's ongoing violations of California law.

8 **JURISDICTION AND VENUE**

9 10. Jurisdiction is proper in this Superior Court under California Code of Civil  
10 Procedure ("C.C.P.") §410.10.

11 11. Venue is proper in the County of San Diego under C.C.P. §395.5 because  
12 plaintiff resides in this county, the acts complained of herein have taken place within the City  
13 and County of San Diego, California, and because defendant:

14 (a) is authorized to conduct business in this county and has intentionally  
15 availed itself of the laws and markets within this district through the promotion, marketing,  
16 distribution and sale of its products in this district;

17 (b) does substantial business in this county; and

18 (c) is subject to personal jurisdiction in this county.

19 **PARTIES**

20 12. During the relevant time period, and in this county, plaintiff was exposed to and  
21 saw Procter & Gamble's claims by reading the Align label, thereafter purchased Align in this  
22 county in reliance on these claims, and suffered injury in fact and lost money as a result of the  
23 unfair competition described herein.

24 13. Defendant Procter & Gamble is a global company headquartered in Cincinnati,  
25 Ohio with operations in approximately 80 countries. Procter & Gamble is the self-described  
26 largest consumer packaged goods company in the world. Procter & Gamble designs,  
27 manufactures, markets and sells beauty and grooming, health and well-being, and household  
28

1 care products, including Align. In 2009, Procter & Gamble spent \$7.5 billion on advertising,  
2 and had sales exceeding \$76.7 billion.

3 14. Plaintiff is ignorant of the true names, capacities, relationships and extent of  
4 participation in the conduct alleged herein, of the Defendants sued herein as Does 1 through  
5 10, but is informed and believes that said Defendants are legally responsible for the wrongful  
6 conduct alleged herein and therefore sue these Defendants by such fictitious names. Plaintiff  
7 will amend this complaint to allege the true names and capacities of the Does Defendants  
8 when ascertained.

9 15. Plaintiff is informed and believes that each Defendant acted in all respects  
10 pertinent to this action as the agent of the other Defendants, carried out a joint scheme,  
11 business plan or policy in all respects pertinent hereto, and the acts of each Defendant are  
12 legally attributable to the other Defendants.

#### 13 FACTUAL ALLEGATIONS

14 16. In March 2009, on the heels of very successful marketing launches of  
15 "functional," "probiotic" products by food industry giants, Procter & Gamble announced the  
16 U.S. retail launch of Align. This nationwide launch followed more than two years of a  
17 scripted marketing plan selling Align exclusively through its website, a toll-free number, and  
18 doctors specializing in stomach ailments. According to Align's brand manager at Procter &  
19 Gamble, "People take vitamins on a regular basis to help keep their bodies in shape. This  
20 dietary supplement can help your body, just like a vitamin." The brand manager also stated,  
21 "[w]e know consumers with episodic digestive problems are looking for real solutions, and  
22 Align is a clinically proven option.... Because Align is grounded in real science and meets a  
23 real consumer health need, we expect it to become a cornerstone brand in our personal health  
24 care portfolio."

25 17. Since the launch, Procter & Gamble has consistently conveyed the message to  
26 consumers throughout the United States that Align, with its unique, patented probiotic bacteria  
27 Bifantis, provides probiotic protection and builds and maintains a healthy digestive system.  
28 According to Procter & Gamble, the benefits of Align are backed by clinical proof supporting

1 the "patented probiotic strain exclusively found in Align." These claims are not substantiated  
2 and are factually baseless.

3 18. In 2001, Procter & Gamble and a group of professors and researchers from  
4 University College Cork in Ireland began working together on researching and developing the  
5 bacteria contained in the Align capsules. The College Cork professors formed a for-profit  
6 probiotics development company called Alimentary Health Limited ("Alimentary Health"),  
7 which describes itself as "a development stage specialty biotechnology company focused on  
8 the discovery, development and commercialization of proprietary probiotic-based treatments  
9 for gastrointestinal disorders including irritable bowel syndrome, Crohn's disease, ulcerative  
10 colitis, and C. difficile diarrhea."

11 19. On December 12, 2005, Alimentary Health announced that it signed a  
12 "worldwide licensing agreement" with Procter & Gamble for "Gastrointestinal (GI)  
13 indications."<sup>2</sup>

14 20. According to Alimentary Health, in 2007, Procter & Gamble and Alimentary  
15 Health entered into a "Clinical Studies Agreement," under which Procter & Gamble agreed to  
16 pay "milestone payments based upon clinical performance" of Bifantis to Alimentary Health.<sup>3</sup>  
17 As discussed below, the substantial majority of studies upon which Procter & Gamble relies to  
18 substantiate Align's marketing claims are studies or review articles that were funded by  
19 Procter & Gamble or jointly conducted by Procter & Gamble and Alimentary Health  
20 employees.

21 21. The use of bacteria for probiotic use is in its scientific infancy. In fact,  
22 scientists have yet to settle on a definition of probiotic. The World Health Organization's  
23 definition of probiotics is "Live microorganisms, which, when administered in adequate  
24 amounts, confer a health benefit on the host." The National Center for Complementary and  
25

26  
27 <sup>2</sup> <http://www.alimentaryhealth.ie/cgi-bin/show.cgi?news4> (last visited September 21, 2011).

28 <sup>3</sup> <http://www.alimentaryhealth.ie/cgi-bin/show.cgi?news11> (last visited September 21, 2011).

1 Alternative Medicine ("NCCAM"), one of the centers that makes up the National Institutes of  
2 Health, adds that probiotics have an ultimate goal of prevention and treatment of disease.

3 22. On its packaging and labeling, Procter & Gamble defines probiotics: "What  
4 are probiotics? Simply put, probiotics are good bacteria essential for many vital body  
5 functions, including healthy digestion." On its website, Procter & Gamble provides a  
6 substantially similar definition of probiotics: "What Is a Probiotic? Simply put, probiotics are  
7 good bacteria that confer a health benefit and are essential for many vital body functions,  
8 including healthy digestion."

9 23. Scientists have not yet mapped the tens of thousands of bacteria strains in the  
10 human body's intestinal flora, and do not know whether increasing one type of bacteria  
11 provides health benefits. It is also not known whether increasing one type of bacteria can  
12 prove harmful. The European Food Safety Authority ("EFSA"), established by the European  
13 Union to promote food safety and evaluate advertising claims about food products, reports that  
14 "The numbers/proportions of bacterial groups that would constitute a 'balanced/healthy'  
15 intestinal flora have not been established. Increasing the number of any groups of bacteria is  
16 not in itself considered as beneficial." EFSA states that:

17 The gastrointestinal tract is populated with a large number of microorganisms  
18 and it normally acts as an effective barrier against generalized systemic  
19 infections. It is not possible to provide the exact number of bacterial groups  
20 that would constitute a beneficial microbiota.

21 24. There is almost no scientific support for the notion that healthy people, such as  
22 those targeted by Procter & Gamble, benefit from bacterial supplements, such as the bacteria at  
23 issue. If probiotic bacteria do have any health benefits, they must survive the digestive tract in  
24 sufficient quantities to achieve the possible benefit. However, there is no consensus on the  
25 quantities of probiotics people might need to ingest, or for how long, in order to achieve a  
26 probiotic effect, if probiotics have any such effect in healthy people.

27 25. Using the term as a marketing tool, and without regard to whether it actually  
28 delivers any probiotic benefits, Procter & Gamble calls its product "Align® probiotic



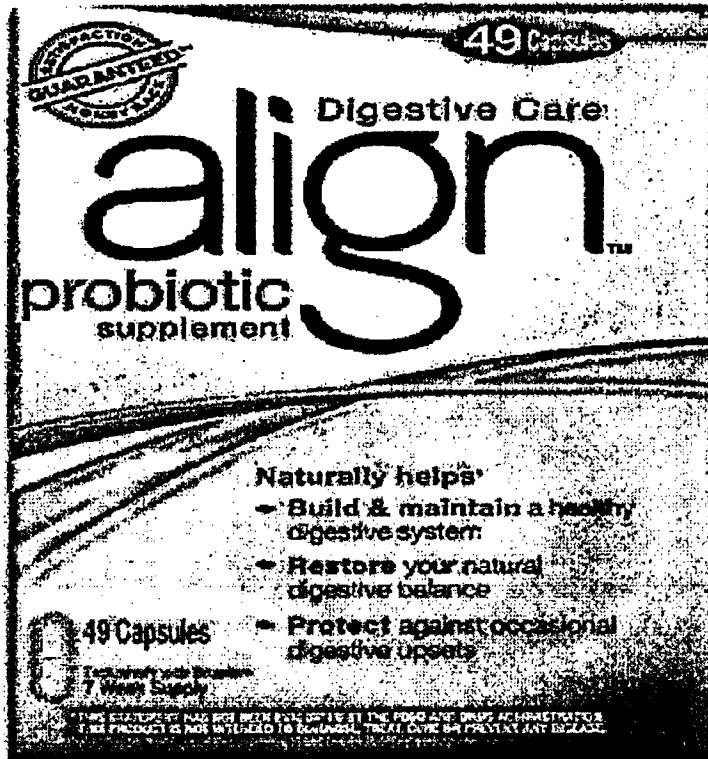
1 supplement." In fact, Procter & Gamble has no legitimate basis to claim that the bacteria with  
2 which it laces Align has any beneficial effects when people consume it, that it helps or  
3 replaces bacteria naturally found in the human body, that it reduces the growth of "harmful"  
4 bacteria, promotes healthy digestion or restores the digestive system.

5 PROCTER & GAMBLE'S CLAIMS ABOUT ALIGN

6 26. Procter & Gamble claims Align, "Naturally helps: Build & maintain a health  
7 digestive system; Restore your natural digestive balance; [and] Protect against occasional  
8 digestive upsets." According to Procter & Gamble, "10 years of research went into the  
9 formulation of Align®, the only probiotic supplement with patented Bifantis®."

10 27. Despite inadequate testing, Procter & Gamble states that Align is beneficial for  
11 healthy and unhealthy people alike; Align is "for people with healthy digestive function who  
12 are looking for help with occasional digestive upsets or who are interesting in promoting their  
13 digestive health."

14 28. Align is described as if it was a medicine. It is characterized as a "capsule."  
15 The label on each package of Align substantially appears as follows:



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

29. On every Align label, Procter & Gamble also prominently claims:

**A few words on good bacteria**

Your body needs beneficial bacteria for a number of things, including healthy digestion. But they're fragile. Common issues, such as diet, antibiotic use, changes in routine, travel and stress can disrupt your natural balance of good bacteria. Bifantis®, only found in Align®, is a probiotic that naturally replenishes your digestive system with healthy bacteria.

**Why take Align®?**

With just one capsule a day each day, Align helps to build and maintain your digestive health with active probiotic bacteria that support your body's own natural defenses, providing ongoing protection against occasional digestive upsets.

**What are probiotics?**

Simply put, probiotics are good bacteria essential for many vital body functions, including health digestion.

**What makes Align Digestive Care special?**

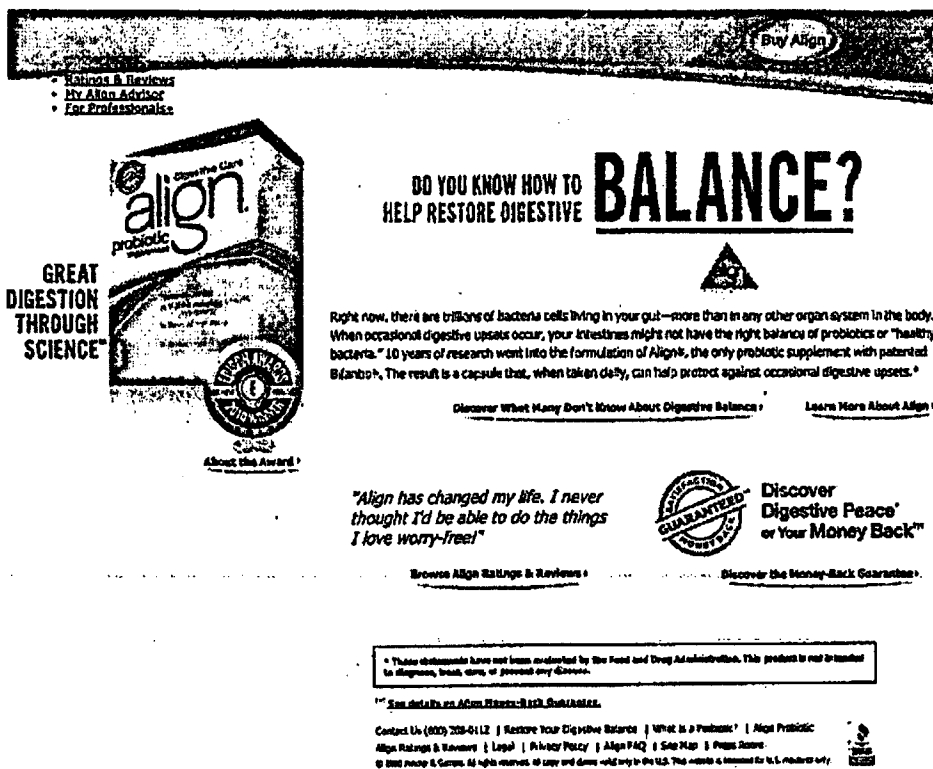
Align contains the patented, pure-strain probiotic bacteria Binfatis® (*Bifidobacterium infantis* 35624), which helps naturally balance your digestive system. Bifantis was developed by Gastroenterologists and, when taken daily, will help your body build and maintain a healthy digestive system.

Procter & Gamble did not and does not have substantiation for these statements, which are false and misleading and reasonably likely to deceive the average consumer.

30. Procter & Gamble deceptively describes Align and Binfantis on its [www.aligngi.com](http://www.aligngi.com) and [www.bifantis.com](http://www.bifantis.com) websites. These websites are available to the general public and Procter & Gamble's advertisements in other media promote these websites. Without sufficient testing or substantiation, Procter & Gamble makes the following similar claims on its websites:

///  
///

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



Align Probiotic packaging and website screenshots. The packaging features the text "align probiotic" and "GREAT DIGESTION THROUGH SCIENCE". The website includes a "Buy Align" button, a testimonial: "Align has changed my life. I never thought I'd be able to do the things I love worry-free!", and a "Money-Back Guarantee" badge. A disclaimer states: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Navigation links include "Browse Align Ratings & Reviews" and "Discover the Money-Back Guarantee".

See also Exhibit 2 attached (additional Align website exemplars as of September 28, 2011).

31. On the Align packaging and websites, Procter & Gamble claims that the bacteria culture in Align was developed by doctors and is supported by clinical proof. The Align advertising statements – conspicuously stated on the product label and websites – include:

- Bifantis was developed by Gastroenterologists and, when taken daily, will help your body build and maintain a healthy digestive system.
- **Proof:** Bifantis has been the subject of several clinical studies and has been featured in peer-reviewed journals. Please see Bifantis.com for full details.
- Recommended by Gastroenterologists
- **GREAT DIGESTION THROUGH SCIENCE™**

32. In addition to making untested and unsubstantiated claims, Procter & Gamble states in its advertising that Align has a "Money-Back Guarantee." However, this is nothing

1 but a marketing gimmick likely to deceitfully induce a placebo effect on consumers,  
2 irrespective of any actual probiotic effect.

3 33. On Align packaging, reprinted below, Procter & Gamble states  
4 "SATISFACTION – GUARANTEED – MONEY BACK."

5 34. On the Align website, Procter & Gamble also promotes the limited "money-  
6 back guarantee":

- 7 • **Find Digestive Peace ...**  
8 **or Your Money Back.**  
9 • **Peace of Mind at Checkout**

10 We proudly stand behind the performance of Align® and believe that our  
11 patented supplement can help you with your occasional digestive upsets.

12 35. The front page of the Align website also contains purported testimonials from  
13 consumers regarding the benefits of Align:

- 14 • *"Align has changed my life. I never thought I'd be able to do the things I love*  
15 *worry-free!"*

16 The Align website has a page entitled "Align Rating & Reviews" where Procter & Gamble  
17 states that "Others have experienced an occasional digestive imbalance and have found Align  
18 to be an effective solution." The Align ratings and testimonials reinforce the deceptive  
19 advertising, misrepresenting Align's ability to combat and ward off digestive system  
20 deficiencies. These statements are not adequately supported by the scientific evidence or  
21 otherwise substantiated.

22 **SUBSTANTIATION FOR THE CLAIMS DOES NOT EXIST**

23 36. According to a June 2006 report on probiotics published by the American  
24 Academy of Microbiology "there is no conclusive evidence that altering the microbiota of a  
25 healthy human adult is beneficial." The report, entitled "Probiotic Microbes: The Scientific  
26 Basis," was prepared by the American Academy of Microbiology, a leadership group of the  
27 American Society of Microbiology, which is the leading professional association of  
28 microbiologists.

1           37. Procter & Gamble deceptively conveys the marketing message that Align has  
2 been clinically tested and proven. For example, the product labeling states "Clinically proven  
3 to naturally defend against 5 signs of digestive imbalance." And on its website, Procter &  
4 Gamble provides purported scientific information and data, including "clinical publications,"  
5 regarding Bifantis.

6           38. There are no proper clinical studies that provide substantiation, clinical or  
7 otherwise, for Align's digestive health claims.

8           39. There is widespread consensus within the legitimate scientific community  
9 concerning the proper research and testing that must be conducted to substantiate a claim made  
10 for a given effect ascribed to a probiotic bacteria. As the American Society for Microbiology  
11 concluded in a symposium focusing on purported probiotic bacteria used in food:

12           There is a pronounced need for large, carefully designed (randomized, placebo  
13 controlled) clinical trials of probiotics that undertake broad sampling of host  
14 microbiota, have clear end points, and have well informed participants who  
15 consent to treatment. Investigations like these are needed to overcome the  
16 placebo effect [of probiotic treatments] and other barriers to the thorough  
17 investigation of probiotic products.<sup>4</sup>

18           40. A properly conducted clinical or scientific trial – e.g., one capable of providing  
19 substantiation for Procter & Gamble's claims – is the well-designed, randomized controlled  
20 trial ("RCT").<sup>5</sup> In RCTs, human study subjects similar to each other are randomly assigned to  
21 receive either the test substance or a placebo. Double-blind RCTs, where neither the patient  
22 nor the administering researcher knows which intervention is placebo, is preferred and  
23 considered more accurate than a single-blind RCT. Procter & Gamble has not so much as  
24 attempted to undertake such a process for Align.

25 <sup>4</sup> R. Walker & M. Buckley, "Probiotic Microbes: The Scientific Basis," at 19 (colloquium  
26 convened before the American Society of Microbiology, Nov. 5-7, 2005).

27 <sup>5</sup> M. Araya, *et al.*, "Guidelines for the Evaluation of Probiotics in Food" (Food and  
28 Agriculture Organization of the United Nations and World Health Organization, Report of  
a Joint Working Group, April 30 and May 1, 2002),  
[http://www.who.int/foodsafety/fs\\_management/en/probiotic\\_guidelines.pdf](http://www.who.int/foodsafety/fs_management/en/probiotic_guidelines.pdf) (last visited  
August 31, 2010).

1           41. According to a leading group of international scientists and researchers, there  
2 should be a proven correlation in human trials when claiming probiotic health benefits in food  
3 products:

4           The principle outcome of efficacy studies on probiotics should be proven  
5 benefits in human trials, such as statistically and biologically significant  
6 improvement in condition, symptoms, signs, well-being or quality of life;  
7 reduced risk of disease or longer time to next occurrence; or faster recovery  
8 from illness. Each should have a proven correlation with the probiotic tested.<sup>6</sup>

9           42. On its bifantis.com website, Procter & Gamble identifies clinical publications  
10 which purportedly substantiate the advertising claims for Align. As explained below, a review  
11 of the studies identified by Procter & Gamble demonstrates the falsity of its claims.

12           43. On its website, Procter & Gamble cites to an unpublished purported "clinical  
13 trial" involving *B. infantis*, which it funded.<sup>7</sup> The cited trial involved persons with IBS  
14 symptoms, not the general health population to whom Procter & Gamble markets Align.  
15 Moreover, the Procter & Gamble trial concluded that the group receiving *B. infantis* did *not*  
16 report greater relief in IBS symptoms. That is, the Procter & Gamble trial concluded that "[n]o  
17 statistically significant differences between [the control group and *B. infantis* group] were  
18 observed at any time-point" relating to daily IBS symptom assessments. Regarding "[w]eekly  
19 IBS symptom assessments" the Procter & Gamble trial concluded that "[n]o statistically  
20 significant differences were observed between groups during any week except for one  
21 parameter at Week 3." And regarding "[m]icrobiology measures," the Procter & Gamble trial  
22 concluded that "[o]nly 1 measure was statistically different in *B. infantis*-IBS subjects at Week  
23 4, Week 8, or Follow-up."

24           44. On its website, Procter & Gamble cites to two "*Bifidobacterium infantis* 35624  
25 Clinical Data Publications." Neither study provides proof, clinical or otherwise, for the Align

---

26 <sup>6</sup> *Id.*

27 <sup>7</sup> A double-blind, randomized, placebo-controlled study of the effects of Bifantis  
28 (*Bifidobacterium infantis* 35624) on fecal microflora and gastrointestinal symptoms in  
adults with irritable bowel syndrome. P&G Study 2005054. Summary available at  
<http://www.bifantis.com/probiotic-scientific-data.php#additional> (last visited August 25,  
2010).

1 claims. Neither of the studies tested *Bifidobacterium infantis* 35624 at amounts (referred to as  
2 "colony-forming units" or "CFUs") different than what is present in Align. Further, both  
3 studies were funded by Procter & Gamble and were conducted by Procter & Gamble and  
4 principles of the company, Alimentary Health, that developed "Bifantis" and sold its exclusive  
5 worldwide licensing rights to Procter & Gamble. The studies also have contradictory results.  
6 The first study (Whorwell, Altringer *et al.* 2006), looked at women who were primary care  
7 IBS patients – not the audience to whom Procter & Gamble markets Align – and tested  
8 endpoints that are irrelevant for purposes of providing substantiation for Procter & Gamble's  
9 advertising claims. The study authors expressly emphasized the variability of results  
10 depending on the amount of CFUs: "The lack of benefits observed with the other dosage levels  
11 of the probiotic highlight the need for clinical data in the final dosage form." The groups  
12 receiving  $1 \times 10^6$  or  $1 \times 10^{10}$  of Bifantis did not experience any significant results over  
13 placebo, but the group receiving  $1 \times 10^8$  did. However, Align contains  $1 \times 10^9$  Bifantis. The  
14 second study (O'Mahony, McCarthy, *et al.* 2005) also fails to provide substantiation for the  
15 claims. Like the first purported clinical data publication, the second study analyzed persons  
16 with IBS, not the population to which Procter & Gamble markets Align. Moreover, the study  
17 improperly analyzed Bifantis infused into a malted milk product, and admits its failure to  
18 properly randomize study arms and its numerous "limitations" including the small study size,  
19 insignificant powering, and a self-assessment tool "subject to recall bias." The only two  
20 objectively measured endpoints in O'Mahony, McCarthy, *et al.* 2005 (bowel movement  
21 frequency and consistency) resulted in no significant differences between the placebo and  
22 "Bifantis" groups.

23 45. Procter & Gamble's website also identifies "preclinical data publications" and  
24 "review articles" as purported substantiation for the marketing claim made on Align's  
25 packaging and labeling. None provide substantiation for the marketing claim:

- 26 • Debonnet, Garrett, *et al.* 2010: Added *B. infantis* to the drinking water of rats  
27 subjected to a "forced swim test" in order to analyze the bacteria's potential  
28 psychiatric benefits as measured by the rats' immobility. Conducted by

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

Alimentary Health employees, and *B. infantis* not analyzed in the amount present in Align. This animal study's forced swim test results conflict with Desbonnet, Garrett, *et al.* 2008.

- McKernan, Fitzgerald, *et al.* 2010: Analyzed effectiveness of *B. infantis* at reducing visceral pain when force-fed in rats. Conducted by Alimentary Health employees.
- Sibartie, O'Hara, *et al.* 2009: Analyzed, in vitro, ability of *B. infantis* to modulate intestinal cells. Conducted by Alimentary Health employees, using Alimentary Health money, and *B. infantis* not analyzed in the amount present in Align.
- Desbonnet, Garrett, *et al.* 2008: Analyzed potential antidepressant properties of *B. infantis* in rats in the "forced swim test," and concluded that the "preliminary" findings indicate there is "encouraging evidence" that the probiotic "may possess antidepressant properties." Probiotic administration had no effect on swim behaviors. Conducted by Alimentary Health employees.
- O'Mahony, Scully, *et al.* 2008: Analyzed cellular interactions in mice infused with *B. infantis* and infected with salmonella. Conducted by Alimentary Health employees, using Alimentary Health money.
- van der Kleij, O'Mahony, *et al.* 2008: Mice induced with acute colitis were given *B. infantis* after undergoing removal of one of their cranial nerves – the vagus nerve. *B. infantis* was more effective in vagotomized mice than ordinary mice. Conducted by Alimentary Health employees.
- O'Hara, O'Regan, *et al.* 2006: Non-clinical analysis of intestinal cells incubated with *B. infantis*. Conducted by Alimentary Health employees, using Alimentary Health money.
- Sheil, MacSharry, *et al.* 2006: The effects of *B. infantis* consumption on colitis in mice prior to onset of chronic inflammation. Conducted by Alimentary Health employees, using Alimentary Health money.



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

- O'Mahony, O'Callaghan, *et al.* 2005: In vivo lymph node cell reaction of humans with inflammatory bowel disease undergoing colectomy or small bowel resection to *B. infantis*. Conducted by Alimentary Health employees, using Alimentary Health grant money. *B. infantis* not analyzed in the amount present in Align.
- Gilman, Cashman 2006: The effect of *B. infantis* on calcium uptake in human intestinal-like cells in culture. Cells exposed to *B. infantis* did not experience calcium uptake. Bacteria supplied by Alimentary Health to the University College, Cork, researchers. *B. infantis* not analyzed in the amount present in Align.
- McCarthy, O'Mahony, *et al.* 2003: Analyzed *B. infantis*' ability to attenuate colitis in mice. Conducted by Alimentary Health employees. Utilized a milk medium for delivering the bacteria, which was present in an amount different than in Align. Acknowledged that human studies were necessary.
- MacConaill, Butler, *et al.* 2003: Analyzed the molecular biology of the *B. infantis* strain. Conducted by Alimentary Health employee.
- Brenner, Moeller, *et al.* 2009: Review article concerning randomized controlled trials involving probiotics in the treatment of IBS.
- Brenner, Chey, 2009: Review article concerning *B. infantis*' reported effects on IBS symptoms.
- Parkes, Brostoff, *et al.* 2008: Review article exploring the role of the gut microbiota in IBS.
- O'Sullivan, O'Halloran *et al.* 2005: Generalized review article concerning probiotics, acknowledging that "[k]nowledge of the normal [gut] flora is still relatively meager" and "controlled clinical trials are necessary to validate the benefit of probiotics." Written by Alimentary Health employees.