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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ROBERT WORTHINGTON, on Behalf of Himself and all Others Similarly Situated,

Plaintiff,

V.

BAYER HEALTHCARE, LLC.

Defendant.

Civil Action No.

CLASS ACTION COMPLAINT AND <u>DEMAND FOR JURY TRIAL</u>

Plaintiff Robert Worthington ("Plaintiff"), by his undersigned counsel, brings this action on behalf of himself, all others similarly situated against defendant Bayer HealthCare, LLC ("Defendant" or "Bayer"). Plaintiff alleges, on information and belief, except for information based on his personal knowledge, as follows:

NATURE OF THE ACTION

1. This is a consumer protection class action addressing Bayer's advertisements regarding its over-the-counter "OVERALL DIGESTIVE HEALTH" products called (a) Phillips'

Colon Health Probiotic + Fiber; and (b) Phillips Colon Health Probiotic Caps (collectively, "Phillips' Colon Health").

- 2. Through its advertising and labeling, Bayer claims that Phillips' Colon Health provides "OVERALL DIGESTIVE HEALTH" and "helps defend against" "constipation, diarrhea, [and] gas and bloating" because they contain "3 strains of good bacteria." According to Bayer, Phillips' Colon Health "replenishes the good bacteria when diet and stress cause constipation and upset your natural balance." Bayer's representations are false, misleading, and reasonably likely to deceive the public.
- 3. Bayer claims in its advertising and labeling that these claims of digestive and immune health benefits are based on "scientific evidence" and that Phillips' Colon Health "contains the most common and most studied bacteria for digestive health." However, Bayer's formulation has not been scientifically studied or tested. Bayer began marketing Phillips' Colon Health Probiotic Caps in October 2008 and Phillips' Colon Health Probiotic + Fiber in June 2009. Bayer has made the same health claims throughout the marketing of these products, and has made these uniform claims in prominent and conspicuous package placement and in its marketing and advertisements. These uniform and false representations include Bayer's claim that Phillips' Colon Health "promote[s] overall digestive health," "helps defend against occasional: constipation, diarrhea, [and] gas and bloating," your "digestive system" and "immune system" and that such claims are supported by "scientific evidence".
- 4. In truth, the ingredient matrix found in Phillips' Colon Health has never been tested, clinically or otherwise, and Bayer has no basis to make these claims.
- 5. Bayer conveyed and continues to convey its deceptive claims about Phillips' Colon Health on the Phillips' Colon Health's packages and labels, and through a variety of

media, including the Internet, television advertising, in-store sampling, and point-of-sale displays. These representations appear prominently and conspicuously on every container of Phillips' Colon Health products.

- 6. Through this extensive advertising campaign, Bayer has conveyed one message: Phillips' Colon Health, with its probiotic bacteria cultures, is scientifically proven to provide all consumers with digestive and immune system health benefits.
- 7. Bayer's advertising and marketing campaign is designed to cause consumers to buy Phillips' Colon Health as a result of this deceptive message, and Bayer has succeeded. In an April 2009 article, Hammacher Resource Group, Inc., a retailing strategy group, singled out Phillips' Colon Health as a new probiotic supplement product with high sales in the digestive health category of products. Phillips' Colon Health is sold nationwide in the digestive health sections of drug, grocery, and mass retailers.
- 8. Plaintiff brings this action on behalf of himself and all other similarly-situated consumers to halt the dissemination of this false and misleading advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased Phillips' Colon Health. Plaintiff alleges statutory and common law violations against Bayer arising out of its conduct alleged herein, including Bayer's violations of the New Jersey Consumer Fraud Act, the implied warranty of merchantability, and unjust enrichment.

JURISDICTION AND VENUE

9. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which at least one Class members is a citizen of a state different from

Bayer. Further, more than two-thirds of the Class members reside in states other than the state in which Bayer is a citizen.

- 10. Venue is proper in this Court pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to this action occurred in this District and because Bayer:
- (a) is authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this District through the promotion, marketing, distribution and sale of its products in this District;
 - (b) does substantial business in this District; and
 - (c) is subject to personal jurisdiction in this District.

PARTIES

Plaintiff

11. Robert Worthington is a resident of the State of Alabama. During the Class Period, Plaintiff was exposed to and saw Bayer's claims by reading the product label, purchased Phillips' Colon Health in reliance on these claims, and sustained injury in fact and lost money as a result of the wrongful conduct described herein.

Defendant

12. Bayer Consumer Care, is a wholly-owned division of Defendant Bayer HealthCare, LLC, and maintains its global headquarters in Morristown, New Jersey. Bayer HealthCare, LLC is a subsidiary of Bayer AG. Bayer Consumer Care, which was established as an independent business group in 1994, and is now a division, has businesses in non-prescription medicines and dietary supplements, including Aspirin®, Aleve®, Alka-Seltzer®, and Phillips' Colon Health. Bayer Healthcare, LLC, through its Bayer Consumer Care division, promotes,

markets, distributes and sells Phillips' Colon Health to tens of thousands of consumers throughout the United States.

FACTUAL ALLEGATIONS

- 13. Since the 2008 nationwide launch of its Phillips' Colon Health products, Bayer has consistently conveyed the message to consumers throughout the United States that Phillips' Colon Health, with its three strains of probiotic bacteria, delivers digestive and immune system benefits backed by scientific evidence of the "most studied bacteria for digestive health." These claims are not substantiated and are factually baseless.
- 14. The use of bacteria for probiotic use is in its scientific infancy. In fact, scientists have yet to settle on a definition of what a "probiotic" even is. The World Health Organization's definition of probiotics is "Live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host." The National Center for Complementary and Alternative Medicine ("NCCAM") one of the centers that make up the National Institutes of Health adds that probiotics have an ultimate goal of prevention and treatment of disease.
- 15. In its advertising, Bayer defines "probiotics" as: " live microorganisms that are similar to the good bacteria already inside our bodies. Available to us mainly through dietary supplements and foods, these probiotics can restore intestinal balance by boosting the number of those bacteria that are helpful to us."
- 16. Scientists have not yet mapped the tens of thousands of bacteria strains in the human body's intestinal flora, and do not know whether increasing one type of bacteria provides health benefits. It is also not known whether increasing one type of bacteria can prove harmful.
- 17. The European Food Safety Authority ("EFSA"), established by the European Union to promote food safety and evaluate food claims, reports that "[t]he numbers/proportions

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of bacterial groups that would constitute a 'balanced/healthy' intestinal flora have not been established. Increasing the number of any groups of bacteria is not in itself considered as beneficial." EFSA further states that:

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

- 18. There is almost no scientific support for the notion that healthy people, such as those targeted by Bayer, benefit from bacterial supplements, let alone from the specific formulation of bacteria in the Phillips' Colon Health products at issue here. If probiotic bacteria do have any health benefits, they must survive the digestive tract in sufficient quantities to achieve the possible benefit. There is no consensus, however, on the quantities of probiotics people might need to ingest, or for how long, in order to achieve a probiotic effect, if probiotics have any such effect in healthy people.
- 19. Using the term as a marketing tool, and without regard to whether it actually delivers any probiotic benefits, Bayer stamps "PROBIOTIC" on the label of Phillips' Colon Health. In fact, however, Bayer has no legitimate basis to claim that the bacteria it laces Phillips' Colon Health with have any beneficial effects when people consume Phillip' Colon Health, that those bacteria help or replace bacteria naturally found in the human body, that they reduce the growth of "harmful" bacteria, promote healthy digestion, or support the immune system.

Bayer's Claims About Phillips' Colon Health

20. In its marketing materials, Bayer represents that Phillips' Colon Health promotes "OVERALL DIGESTIVE HEALTH" and "Defend[s] Against Occasional: CONSTIPATION, DIARRHEA, [AND] GAS AND BLOATING." According to Bayer, these digestive and

immune system benefits are the result of Phillips' Colon Health's "proprietary blend" of three of the "most studied" bacteria for digestive health.

- 21. On the Phillips' Colon Health packaging and website, Bayer claims that the bacteria cultures in Phillips' Colon Health are the "most studied bacteria for digestive health" and that there is "scientific evidence that [the bacteria in the product] help relieve gas, diarrhea, constipation and other GI discomforts." Phillips' Colon Health "also supports a health immune system." The Phillips' Colon Health advertising statements conspicuously stated on the product label include:
 - 3 strains of good bacteria to promote

OVERALL DIGESTIVE HEALTH

• Helps Defend Against Occasional:

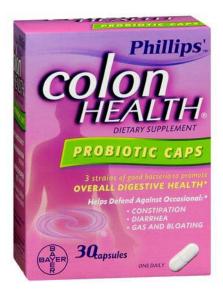
CONSTIPATION

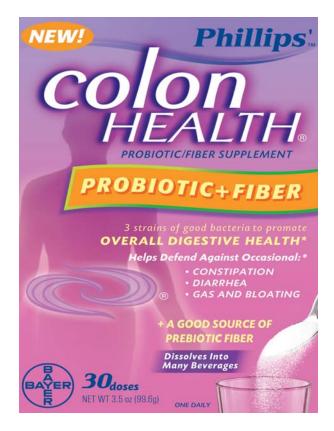
DIARRHEA

GAS AND BLOATING

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

- 22. Phillips' Colon Health is described in a medical manner as coming in a "capsule" form to be consumed "one daily."
- 23. The front label on each package of Phillips' Colon Health substantially appears as follows:





24. The side and back panels of the packaging and labeling for Phillips' Colon Health repeat and reinforce Bayer's same misleading digestive and immune system health benefits claim.

- 25. Despite inadequate evidence to support its representations, Bayer claims that all persons suffering from "irregularity" should take Phillips' Colon Health: "Phillips' Colon Health is right for anyone who suffers from irregularity symptoms and currently treats with an over the counter remedy."
- 26. Bayer's Phillips' Colon Health television commercials convey the same message conveyed by Bayer in other media. A typical Phillips' Colon Health television commercial claims:

Woman 1: You're the colon lady.

Woman 2: Diarrhea, constipation, gas, bloating...that's me.

Woman 1: Can I tell you what a difference Phillips' Colon Health has made.

Woman 2: It's the probiotics. The good bacteria that get your colon back in balance

[hands Woman 1 package of Phillips' Colon Health].

Woman 1: I'm good to go.

Announcer: Phillips' Colon Health [Tag states: "Be good to your colon, and it will be

good to you."]

See http://www.youtube.com/watch?v=iiz42ffF3tY.

27. Bayer repeats its false and deceptive statements on its publicly available Internet website, www.phillipsrelief.com, which appears in Bayer's marketing materials, including Phillips' Colon Health packaging and labeling. Without sufficient testing or substantiation, Bayer makes the following similar claims on its website:

What is Phillips' Colon Health Probiotic Caps?

Phillips' Colon Health Probiotic Caps is a probiotic supplement that helps replenish the good bacteria in your colon. When taken daily, it helps support a healthy immune system and it supports your overall digestive health and helps defend against occasional constipation, diarrhea, gas and bloating.

What is Phillips' Colon Health Probiotic + Fiber?

Phillips' Colon Health Probiotic + Fiber helps promote the health of your colon in 2 ways. Its advanced digestive health formula contains a unique proprietary blend of 3 strains of good bacteria that help promote the colon's natural balance, plus is a good source of soluble prebiotic fiber, inulin, that give the probiotics a boost.

What is Phillips Colon Health?

Phillips' Colon Health is a probiotic supplement that replenishes the good bacteria when diet and stress cause constipation and upset your natural balance causing bloating, gas and diarrhea.

Why take Phillips' Colon Health?

Phillips' Colon Health supports a healthy colon, one of the most important parts of your digestive system. It replenishes the good bacteria when diet and stress cause constipation and upset your natural balance causing bloating, gas and diarrhea. It also supports a healthy immune system.

How does Phillips' Colon Health work?

Phillips' Colon Health contains the most common and most studies bacteria for digestive health (Lactobacillus and Bifidobacterium), which closely resemble your body's natural good bacteria. There is scientific evidence that Lactobacillus and Bifidobacterium help relieve gas, diarrhea, constipation and other GI discomforts.

When should I take Phillips' Colon Health?

When stressed, traveling or using antibiotics, Phillips' Colon Health can help balance your digestive system.

Scientific Substantiation for the Claims Does Not Exist

- 28. On its packaging, labeling, and product website, Bayer deceptively conveys the deceptive marketing message that Phillips' Colon Health's efficacy "contains the most common and most studied bacteria for digestive health," which is substantiated by "scientific evidence."
- 29. There are no studies that provide substantiation, clinical or otherwise, for Phillips' Colon Health's digestive health and immune system claims.

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

There is a pronounced need for large, carefully designed (randomized, placebo controlled) clinical trials of probiotics that undertake broad sampling of host microbiota, have clear end points, and have well informed participants who consent to treatment. Investigations like these are needed to overcome the placebo effect [of probiotic treatments] and other barriers to the thorough investigation of probiotic products.¹

- 31. In 2002, a joint working group of scientists for the Food and Agriculture Organization of the United Nations and the World Health Organization generated guidelines for evaluating probiotics in food, and defined the data necessary to substantiate probiotic health claims.
- 32. The Joint FAO/WHO Working Group Report stated that data generated by *in vitro* tests are "not fully adequate to predict the functionality of probiotic microorganisms in the human body," and that "*in vitro* data for particular [bacteria] strains are not sufficient for describing them as probiotics."
- 33. The Joint FAO/WHO Working Group Report further concluded that "[p]robiotics for human use will require substantiation of efficacy with human trials." The report also emphasized that the human study must utilize appropriate sample sizes, and "[s]tatistically significant differences [between the placebo and test products] must apply to biologically

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

relevant outcomes." And the report recommended that at least a second, independent double-blinded, randomized, placebo-controlled human trials ("DBPC") test confirm the test results.²

- Thus, a properly conducted clinical or scientific trial -e.g., one capable of providing substantiation for Bayer's claims is the well-designed, randomized controlled trial ("RCT").³ In RCTs, human study subjects similar to each other are randomly assigned to receive either the test substance or a placebo. Double-blind RCTs, where neither the patient nor the administering researcher knows which intervention is placebo, is preferred and considered more accurate than a single-blind RCT. *Bayer has never attempted to undertake such a process*.
- 35. According to a leading group of international scientists and researchers, there should be a proven correlation in human trials when claiming probiotic health benefits in food products:

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

- 36. The three strains of bacteria infused in Phillips' Colon Health are *Lactobacillus* gasseri, Bifidobacterium bifidum, and Bifidobacterium longum. On its packaging and website, Bayer describes each of these purportedly probiotic bacteria strains:
 - Lactobacillus gasseri To support nutrient absorption and lactose digestion

M. Araya, *et al.*, "Guidelines for the Evaluation of Probiotics in Food" (Food and 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 (last visited February 2, 2010).

³ *Id.*

⁴ *Id*.

- **Bifidobacterium bifidum** To help guard against occasional intestinal disturbances
- **Bifidobacterium longum** To support digestive and immune health. These bacteria help naturally defend against occasional digestive upsets
- 37. The European Food Safety Authority ("EFSA"), a European Union-funded agency, was set up in January 2002 as an independent source of scientific advice and communication for EU food-related issues.
- 38. In July 2009, EFSA reviewed the scientific substantiation in relation to *Lactobacillus gasseri* and *Lactobacillus coryniformis* and decreasing potentially pathogenic intestinal microorganisms and improvement of intestinal transit.
- 39. EFSA concluded that human intervention studies it reviewed did not show an effect on decreasing potentially pathogenic intestinal microorganisms.
- 40. EFSA also concluded that the data available do not demonstrate a cause and effect relationship between consuming the bacteria and improvement of intestinal transit within the normal range.⁵
- 41. EFSA also analyzed and reviewed the substantiation for the two other strains in Phillips' Colon Health: *Bifidobacterium bifidum*, and *Bifidobacterium longum*.
- 42. In a December 2009 scientific opinion, EFSA found that a cause and effect relationship has not been established between the consumption of the combination of *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium*

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See EFSA Panel on Dietic Production, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to "Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711" and decreasing potentially pathogenic intestinal microorganisms and improvement of intestinal transit (ID 937) pursuant to Article 13 of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9) 1238. Available at www.efsa.europa.eu (last visited October 1, 2010).

longum, and decreasing potentially pathogenic intestinal microorganisms in infants and children aged between 0 and 36 months.⁶

- 43. EFSA also reviewed substantiation for a claim that consuming a bacterial powder containing *Bifidobacterium longum* and two other strains "improve[s] the general immunity by maintaining the microbiological balance." EFSA found that the one unpublished *in vitro* study it was provided did not establish the claimed immune system improvement. According to EFSA, "*In vitro* studies are not sufficient to predict *in vivo* efficacy in humans."⁷
- EFSA also reviewed substantiation for a claim that consuming a bacterial powder containing *Bifidobacterium longum* and two other strains brings back the normal functioning of your digestive system during microflora disturbances. EFSA found that the two clinical studies provided did not constitute substantiation. In one study, those consuming the product containing *Bifidobacterium longum* did not see an improvement in the incidence of diarrhea and only saw a modest reduction in the frequency of daily stools. Likewise, the second study did not provide proof because isolating strain-specific benefits was not possible. And EFSA again rejected the use of *in vitro* studies to predict *in vivo* efficacy in humans.⁸ Based upon this same evidence,

See EFSA Panel on Dietic Production, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to combination of bifidobacteria (Bifidobacterium bifidum, Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium longum) and decreasing pathogenic intestinal microorganisms pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2009; 7(12)1420. Available at www.efsa.europa.eu (last visited October 1, 2010).

See Scientific Opinion of the Panel on Dietic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and improvement of the general immunity. EFSA Journal 2008: 860, 1-8. Available at www.efsa.europa.eu (last visited October 1, 2010).

⁸ See Scientific Opinion of the Panel on Dietic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and normal functioning of the alimentary

EFSA also rejected a claim that the same powder product containing *Bifidobacterium longum* helps protect the digestive system from infectious bacteria.⁹

- 45. Similarly, inulin fiber is not proven to provide the digestive health benefits marketed by Bayer for its Phillips' Colon Health. For example, in a study published in August 2010, analyzing the impact of inulin fiber and/or a probiotic combination on gastrointestinal and immune system endpoints, the authors concluded that "for numerous parameters, inulin and probiotics led to no synergistic but antagonistic interactions."
- 46. Despite inadequate and inapposite testing, Bayer continues to unequivocally claim that with its proprietary blend of three of the most studied bacteria for digestive health, Phillips' Colon Health is proven to deliver digestive and immune benefits, balancing your digestive system and relieving gas, diarrhea, constipation and other GI discomforts.
- 47. Although it is just a tiny "capsule" of natural bacteria, Phillips' Colon Health Probiotic Supplement retails for approximately \$15 for a 30-count package. And Phillips'

tract. EFSA Journal 2008: 861, 1-9. Available at www.efsa.europa.eu (last visited October 1, 2010).

See Scientific Opinion of the Panel on Dietic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and building of the natural intestinal barrier. EFSA Journal 2008: 859, 1-9. Available at www.efsa.europa.eu (last visited October 1, 2010).

See C. Mair, C. Plitzner, et al., Insulin and probiotics in newly weaned piglets: effects on intestinal morphology, mRNA expression levels of inflammatory marker genes and haematology, Arch Anim. Nutr. 2010 Aug; 64(4):304-21.

See www.amazon.com (\$14.95 on April 14, 2011); www.walgreens.com (\$15.99 on April 14, 2011); www.gnc.com (\$21.99 on April 14, 2011), www.cvs.com (\$17.99 on April 14, 2011).

Colon Health Probiotic + Fiber Supplement Power retails for approximately \$26 for a 30-dose package. 12

48. The only reason consumers spend money to purchase Phillips' Colon Health is for the advertised digestive health and immune system benefits claims; claims which are untrue and not substantiated.

CLASS ACTION ALLEGATIONS

49. Plaintiff brings this lawsuit, pursuant to Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of himself and a proposed Class defined as:

All persons in the United States who purchased Phillips' Colon Health products. Excluded from the Class are Defendant's officers, directors, and employees and those who purchased Phillips' Colon Health products for the purpose of resale.

- 50. *Numerosity*. The members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes, and on that basis alleges, that the proposed Class contains thousands of members. The precise number of Class members is presently unknown to Plaintiff, but may be determined from Defendant's books and records.
- 51. Existence and Predominance of Common Questions of Law and Fact.

 Common questions of law or fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and/or factual questions include, but are not limited to, the following:
 - (a) whether Bayer had adequate substantiation for its claims prior to making them;
 - (b) whether Bayer's claims, as alleged herein, are true, or are misleading, or reasonably likely to deceive;
 - (c) whether Bayer's alleged conduct violates public policy;

¹² See www.drugstore.com (\$26.49 on April 14, 2011).

- (d) whether Bayer's alleged conduct constitutes violations of the laws asserted herein;
 - (e) whether Bayer engaged in false or misleading advertising;
- (f) whether Plaintiff and the other Class members have sustained monetary damages and the proper measure of those damages;
- (g) whether Plaintiff and the other Class members are entitled to an award of disgorgement of Bayer's profits;
- (h) whether Plaintiff and the other Class members are entitled to an award of punitive damages; and
- (i) whether Plaintiff and the other Class members are entitled to declaratory and/or injunctive relief.
- 52. *Typicality*. Plaintiff's claims are typical of the claims of the other members of the Class because, among other things, all Class members were comparably injured through the uniform misconduct described above and were subject to Bayer's false and misleading advertisements, in violation of the New Jersey Consumer Fraud Act.
- 53. Adequacy of Representation. Plaintiff will fairly and adequately protect the interests of the other members of the Class. Plaintiff has retained counsel highly experienced in complex consumer class action litigation, and Plaintiff intends to prosecute this action vigorously. Plaintiff has no adverse or antagonistic interests to those of the other Class members.
- 54. **Superiority**. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against the defendant. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done

to them. Further, this action presents no unusual management difficulties under the circumstances here.

- 55. Additionally, the Class may also be certified because:
- (a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for Bayer;
- (b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or
- (c) Bayer has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to Plaintiff and the other members of the Class.
- 56. Adequate notice can be given to Class members directly using information maintained in Bayer's records or through notice by publication.
- 57. Damages may be calculated, in part, from the sales information maintained in Bayer's records, so that the cost of administering a recovery for the Class can be minimized. However, the precise amount of damages available to Plaintiff and the other members of the Class is not a barrier to class certification.
- 58. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Bayer from engaging in the acts described, and requiring Bayer to provide full restitution to Plaintiff and the other Class members.

- 59. Unless a class is certified, Bayer will retain monies received as a result of its conduct that was taken from Plaintiff and the other Class members. Unless a classwide injunction is issued, Bayer will continue to commit the violations alleged, and the members of the Class will continue to be misled.
- 60. Bayer has acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I

(For Violations of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, et seq.)

- 61. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- 62. At all times relevant to this action, there was in full force and effect the New Jersey Consumer Fraud Act (NJCFA), N.J.S.A. 56:8-1 *et seq.*, which was enacted and designed to protect consumers against unfair, deceptive, or fraudulent business practices.
 - 63. N.J.S.A. 56:8-2 provides:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact . . . Whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

- 64. At all relevant times, Plaintiff, the other Class members, and Bayer were "persons" within the meaning of N.J. Rev. Stat. § 56:8-1.
- 65. The Phillips' Colon Health products manufactured, marketed, and sold by Bayer are merchandise within the meaning of the NJCFA, and Plaintiff and the other Class members are consumers within the meaning of the NJCFA and entitled to the statutory remedies made available therein.

- 66. Bayer violated and continues to violate the NJCFA by representing that its Phillips' Colon Health products have characteristics, uses, and benefits which they do not have and advertising its Phillips' Colon Health products to have characteristics, uses, and benefits which Bayer knows the products do not have.
- 67. Bayer violated the NJCFA by representing, through its advertisements and otherwise, that its Phillips' Colon Health products in the manner(s) described above, when it knew, or should have known, that those representations and advertisements were unsubstantiated, false, and/or misleading.
- 68. Bayer intended that Plaintiff and the other members of the Class would rely on its deception by purchasing its Phillips' Colon Health products, unaware of the material facts described above. This conduct constitutes consumer fraud within the meaning of the NJCFA.
- 69. Bayer's conduct, as alleged herein, constitutes unlawful, unfair, and/or deceptive business practices within the meaning of the NJCFA.
- 70. Bayer's conduct is malicious, fraudulent, and wanton, and provides misleading information that can lead to the delayed treatment of serious and life-threatening illness and diseases.
- 71. Bayer's conduct has proximately caused damage to Plaintiff and the other Class members in an amount to be proven at trial.
- 72. As a result of Bayer's violations of the foregoing state consumer protection statutes, Plaintiff and the other members of the Class are entitled to compensatory damages, double damages, treble damages, statutory damages, punitive or exemplary damages, restitution, and/or injunction relief.

COUNT II(Breach of Implied Warranty of Merchantability)

- 73. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- 74. At all times relevant hereto, there was a duty imposed by law which requires that a manufacturer or seller's product be reasonably fit for the purposes for which such products are used, and that produce be acceptable in trade for the product description.
- 75. Notwithstanding the aforementioned duty, at the time of purchase, Bayer's Phillips' Colon Health products sold to Plaintiff and the Class were not merchantable.
- 76. As there is no scientific proof for the efficacy of probiotics products and no testing conducted by Defendant for verification of its claims as discussed above, Defendant was notified that the Phillips' Colon Health products were not merchantable.
- 77. As a result of the non-merchantability of the Phillips' Colon Health products, Plaintiff and the members of the Class sustained a loss or damages.

COUNT III (Unjust Enrichment)

- 78. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- 79. By its deceptive, misleading, bad faith, and unlawful conduct alleged herein, Bayer unjustly received a benefit at the expense of Plaintiff and the other members of the Class.
- 80. It is unjust to allow Bayer to retain the profits from its deceptive, misleading, bad faith, and unlawful conduct alleged herein without providing compensation to Plaintiff and the other members of the Class.

- 81. Bayer acted with conscious disregard for the rights of Plaintiff and the other members of the Class.
- 82. Plaintiff and the members of the Class are entitled to restitution of, disgorgement of, and/or the imposition of a constructive trust upon, all profits, benefits, and other compensation obtained by Bayer from its deceptive, misleading, bad faith, and unlawful conduct.

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, respectfully requests that the Court order relief and enter judgment against Bayer as follows:

- A. An order certifying the proposed Class and appointing Plaintiff as Class Representative and his counsel as Class Counsel;
- B. An order that Bayer be permanently enjoined from its improper and unlawful conduct and practices alleged herein;
- C. A judgment awarding Plaintiff and the other members of the Class their compensatory damages, as appropriate, resulting from damages arising from Bayer's conduct as alleged herein;
- D. A judgment awarding Plaintiff and the other members of the Class exemplary damages for Bayer's knowing, willful, and/or intentional conduct, as alleged herein;
- E. A judgment awarding Plaintiff and the other members of the Class restitution, including, without limitation, disgorgement of all profits and unjust enrichment obtained by Bayer as a result of its unlawful, unfair, and fraudulent business practices and conduct alleged herein;
 - F. Prejudgment and post-judgment interest;
 - G. Ordering Bayer to engage in a corrective advertising campaign;
 - H. Attorneys' fees, expenses, and the costs of this action; and

I. All other and further relief as the Court deems necessary, just, and proper.

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO Attorneys for Plaintiff

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 16, 2011

Jeffrey A. Leon Jamie E. Weiss Julie D. Miller FREED & WEISS LLC 111 West Washington Street, Suite 1331 Chicago, Illinois 60602 (312) 220-0000

Adam J. Levitt John E. Tangren WOLF HALDENSTEIN ADLER FREEMAN & HERZ LLC 55 West Monroe Street, Suite 1111 Chicago, Illinois 60603 (312) 984-0000

Jim S. Calton, Jr. CALTON LEGAL SERVICES, SP 322 South Eufaula Avenue Eufaula, Alabama 36072-0895

Attorneys for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO Attorneys for Plaintiff

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 16, 2011

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Attorneys for Plaintiff

SJS 44 (Rev. 12/07, NJ 5/08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS	DEFENDANTS	EFENDANTS						
Robert Worthington, or Situated	arly	Bayer Healthcare, LLC						
(b) County of Residence of First Listed Plaintiff Barbour County,				County of Residence of First Listed Defendant Mo			Morris County, NJ	
(c) Attorney's (Firm Name, Address, Telephone Number and Email Add				NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED. Attorneys (If Known)				
Carella, Byrne, Cecchi, Olstein, Brody & Agnello 5 Becker Farm Road, Roseland, NJ 07068 (973) 994-1700 jcecchi@carellabyre.com; ltaylor@carellabyrne.com								
II. BASIS OF JURIS	DICTION (Place an "Y"	in One Box Only)	ш ст	TIZENCIUD OE	DDINGID	V DADOVEC		
☐ 1 U.S. Government Plaintiff	U.S. Government		(CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff (For Diversity Cases Only) PTF DEF Citizen of This State				
2 U.S. Government Defendant	M 4 Diversity (Indicate Citizensh	4 Diversity (Indicate Citizenship of Parties in Item III)		of Business		Incorporated and I of Business In .	Principal Place	
				n or Subject of a 6 eign Country	3 0 3	Foreign Nation	□ 6 □ 6	
IV. NATURE OF SUIT (Place an "X" in One Box Only)								
CONTRACT 110 insurance		RTS		RFEITURE/PENALTY		KRUPTCY	OTHER STATUTES	
□ 110 Insurance □ 120 Marine □ 130 Miller Act □ 140 Negotiable Instrument □ 150 Recovery of Overpayment □ Enforcement of Judgment □ 151 Medicare Act □ 152 Recovery of Defaulted Student Loans □ (Excl. Veterans) □ 153 Recovery of Overpayment of Veteran's Benefits □ 160 Stockholders' Suits □ 190 Other Contract □ 195 Contract Product Liability □ 196 Franchise ■ REAL PROPERTY □ 210 Land Condemnation □ 220 Foreclosure □ 230 Rent Lease & Ejectment □ 245 Tort Product Liability □ 290 All Other Real Property	Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability 360 Other Personal Injury CIVIL RIGHTS 441 Voting 442 Employment 443 Housing/ Accommodations 444 Welfare 445 Amer. w/Disabilities - Employment	PERSONAL INJURY 362 Personal Injury - Med. Malpractice 365 Personal Injury - Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERT 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Property Damage 385 Property Damage Product Liability PRISONER PETITIONS 510 Motions to Vacate Sentence Habeas Corpus: 530 General 535 Death Penalty 540 Mandamus & Other 550 Civil Rights 555 Prison Condition	620	O Agriculture O Other Food & Drug O Other Food & Drug For Food & Drug O Drug Related Seizure of Property 21 USC 881 D Liquor Laws O R.R. & Truck O Airline Regs. O Cocupational Safety/Health O Other LABOR Fair Labor Standards Act Labor/Mgmt. Relations Labor/Mgmt. Reporting & Disclosure Act Railway Labor Act Other Labor Litigation Empl. Ret. Inc. Security Act IMMIGRATION Naturalization Application Habeas Corpus - Alien Detainee Other Immigration Actions	□ 422 Appe □ 423 Withor 28 US PROPER □ 820 Copyo □ 830 Paten □ 840 Trade SOCIAL □ 861 HIA (□ 862 Black □ 863 DIWC □ 864 SSID □ 865 RSI (□ FEDERA □ 870 Taxes or De □ 871 IRS— 26 US	al 28 USC 158 drawal SC 157 TTY RIGHTS rights t mark SECURITY 1395ff) Lung (923) //DIWW (405(g)) Title XVI 405(g)) L TAX SUITS (U.S. Plaintiff fendant)	□ 400 State Reapportionment □ 410 Antitrust □ 430 Banks and Banking □ 450 Commerce □ 460 Deportation □ 470 Racketeer Influenced and □ Corrupt Organizations □ 480 Consumer Credit □ 490 Cable/Sat TV □ 810 Selective Service □ 850 Securities/Commodities/ Exchange □ 875 Customer Challenge □ 12 USC 3410 □ 890 Other Statutory Actions □ 891 Agricultural Acts □ 892 Economic Stabilization Act □ 893 Environmental Matters □ 894 Energy Allocation Act □ 895 Freedom of Information Act □ 900Appeal of Fee Determination Under Equal Access to Justice □ 950 Constitutionality of State Statutes	
🕱 1 Original 🗇 2 Re		Remanded from Appellate Court	4 Reinst Reope	accure. Las of constant	ei uistiict	6 Multidistri Litigation	Appeal to District Judge from Magistrate Judgment	
VI. CAUSE OF ACTIO	Brief description of cal	tute under which you are (d)(2) and 28 U.S.						
VII. REQUESTED IN		eeks to stop false and misleading advertising. EMAND \$ CHECK YES only if demanded in complaint:						
COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23			22.	JURY DEMAND:				
VIII. RELATED CASI	(See instructions)	JUDGE				NUMBER	2 .00 2710	
Explanation:		-				***************************************		
DATE ///6///		SIGNATURE OF A	TTORN	EYOF RECORD				

JS 44 Reverse (Rev. 12/07, NJ 1/08)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filing a case should complete the form as follows:

- I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

- III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity.

 U.S. Civil Statute: 47 USC 553
 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases. Provide a brief explanation of why the cases are related.

Date and Attorney Signature. Date and sign the civil cover sheet.