UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 13-21289-CIV-ALTONAGA/ Simonton

DEMETRI SPENCER, on behalf of himself and others similarly situated, Plaintiffs, vs. NUTRAMAX LABORATORIES, INC., a Maryland corporation, Defendants.	First Amended Class Action Complaint

PLAINTIFF'S FIRST AMENDED CLASS ACTION COMPLAINT

COMES NOW, Plaintiff Demetri Spencer ("Plaintiff"), on behalf of himself and all others similarly situated, filing Plaintiff's First Amended Class Action Complaint against Defendants Nutramax Laboratories, Inc. ("Defendant" or "Nutramax") pursuant to Federal Rule of Civil Procedure Rule 15(a)(1)(B). Plaintiff seeks certification of his claims against Defendant as a class action. Plaintiff alleges, based upon personal knowledge as to Defendant's action and upon information and belief as to all other matters, as follows:

I. PARTIES

1. Plaintiff Demetri Spencer is a Florida citizen residing in Miami, Florida in the Southern District of Florida. Plaintiff suffers from joint pain and has arthritis. During the class period, Plaintiff Demetri Spencer purchased 1 bottle of Cosamin DS from a retailer in Miami-Dade County.

2. Defendant, Nutramax Laboratories, Inc. is a Maryland corporation with its principal place of business at 2208 Lakeside Blvd., Edgewood, Maryland 21236, and can be

served through its registered agent, Mark T. Jensen, Esq., at 29 W. Susquehanna Ave., 6th Floor, Towson, Maryland 21204. At all relevant times, Nutramax Laboratories, Inc. has advertised, marketed, provided, offered, distributed, and/or sold Cosamin DS and Cosamin ASU (collectively, "Cosamin") throughout the United States including to individuals in Florida such as Plaintiff and the Class.

II. JURISDICTION AND VENUE

3. This Court has jurisdiction over Defendant since at all relevant times Defendant has regularly and systematically transacted business within the State of Florida through the marketing, providing, offering, distributing, and selling of Cosamin DS ("Cosamin"). Defendant derives substantial revenue from Florida residents.

4. This Court has subject matter jurisdiction over this class action under the Class Action Fairness Act ("CAFA") because there are more than one-hundred class members, all of the members of the class are citizens of a state (Florida) different from that of Defendant (Maryland), and the aggregate of class members' claims is more than $5 million. 28 U.S.C. § 1332(d). Notably, in addition to FDUTPA claims (which in and of themselves likely reach the $5 million threshold), Plaintiff seeks punitive damages for violations of Florida's Misleading Advertising Law.

5. Venue is proper in this Court because a substantial part of the events or omissions giving rise to the claim occurred in this district and a substantial part of property that is the subject of the action is situated in this district. Plaintiff is a resident of this district; the sale of Cosamin occurred in this district; and Defendant has received substantial compensation from sales in this district.

III. FACTS

A. America's Joint Pain And Arthritis Epidemic

6. According to the Centers for Disease Control and Prevention ("CDC"), an estimated 50 million adults in the United States reported being told by a doctor that they have some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia. One in five adults report having doctor- diagnosed arthritis. So widespread is the problem that arthritis and other rheumatic conditions are the most common cause of disability among U.S. adults and have been for the past 15 years. Centers for Disease Control and Prevention, *Arthritis-Related Statistics*, http://www.cdc.gov/arthritis/data_statistics/arthritis_related_stats.htm.

7. The symptoms of arthritis are "pain and stiffness in and or around one or more joints." Centers for Disease Control and Prevention, *Frequently-Asked Questions- General Public*, http://www.cdc.gov/arthritis/basics/faqs.htm#5.

8. The focus of treatment for arthritis is to control pain and minimize joint damage. Centers for Disease Control and Prevention, *Management*, http://www.cdc.gov/arthritis/basics/management.htm.

9. Arthritis and related conditions cause widespread pain and in many individuals significantly limit their ability to perform vital activities such as walking, kneeling, climbing stairs, or even attending social gatherings. People with doctor-diagnosed arthritis have a significantly worse quality and life than those without arthritis; adults with arthritis report two to four times as many unhealthy days in the past month than those without arthritis. *Id.*

10. In an around 2005, the prevalence of different types of U.S. arthritis patients were as follows: osteoarthritis (27 million), fibromyalgia (5 million), gout (3 million), and rheumatoid arthritis (1.5 million). *Id.*

11. By 2030, an estimated 67 million Americans aged 18 years or older are projected to have doctor-diagnosed arthritis. *Id.*

12. In 2003, the total cost attributed to arthritis and other rheumatic conditions in the United States was $128 billion, up from $86.2 billion in 1997. *Id.*

13. It is no surprise that the arthritis treatment market is big business. In 2005 alone, expenses for the treatment of arthritis totaled $32 billion. Medical Expenditure Panel Survey, *Statistical Brief #222: Arthritis Use and Expenditures among U.S. Adult Noninstitutionalized Population, 2005* (Sep. 2008), http://meps.ahrq.gov/data_files/publications/st222/stat222.pdf.

B. Promotion of Glucosamine And Chondroitin In The Treatment of Arthritis and Joint Pain

14. Glucosamine and chondroitin have been widely promoted as a treatment for Osteoarthritis ("OA"). Glucosamine, an amino sugar, was thought to promote the formation and repair of cartilage. [1] Chondroitin, a carbohydrate, is a cartilage component that is hypothesized to promote water retention and elasticity and to inhibit the enzymes that break down cartilage.

15. Despite its explosion on the national marketplace, the use of glucosamine in the management of arthritis remains unproven, and its purported mechanism of action in arthritis pain and function modification are still unclear. As a result, the American College of Rheumatology ("ACR") [2] and the UK National Institute for Health and Clinical Excellence

[1] This theory that glucosamine could build and repair cartilage was based on the hypothesis that glucosamine supplementation provides the building blocks necessary to promote the formation of healthy cartilage. However, this "over-simplified" hypothesis does not adequately explain the purported mechanism of action of glucosamine, which remains unknown. *See* Herrero-Beaumont, *et al.*, Use of crystalline glucosamine sulfate in osteoarthritis. *Future Rheumatol.* 2006, 1(4): 397-414. As such, at present there is no bonafide medical treatment capable of rebuilding cartilage. The only way to repair damaged cartilage is to surgically remove it and replace it with healthy cartilage.

[2] American College of Rheumatology Subcommittee on Osteoarthritis: Recommendations for

(NICE) have not recommended glucosamine in the management of arthritis symptoms.[3] While at least one source has recommended *glucosamine sulfate* for the management of hip and knee Osteoarthritis,[4] none of the current guidelines have recommended the use of glucosamine hydrochloride (the main ingredient in Cosamin).

16. Nevertheless, Defendant still promotes Cosamin as an over-the-counter supplement that can treat the primary symptom of arthritis: joint pain.

C. Overview Of Defendant's Marketing And Advertising For Cosamin

17. Marketed as a joint health dietary supplement for more than a decade, Defendant claims Cosamin purportedly relieves joint pain through the combination of its two main ingredients: glucosamine hydrochloride and chondroitin sulfate.

18. According to Defendant's website, Cosamin DS works as follows:

> The two main ingredients in Cosamin DS, FCHG49® glucosamine and TRH122® chondroitin sulfate, stimulate the production of

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the medical management of osteoarthritis of the hip and knee: 2000 update. *Arthritis Rheum* 2000, 43:1905-1915.

[3] NICE Clinical Guidelines: The care and management of osteoarthritis in adults, *National Institute for Health and Clinical Evidence* 2008.

[4] *See* W. Zhang, *et al.*, EULAR evidence based recommendations for the management of hip osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis* 2005, 64: 669-681; W. Zhang, *et al.*, EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis* 2003, 62: 1145-1155. Another organization, the Osteoarthritis Research Society International ("OARSI"), originally recommended the use of glucosamine sulfate for the management of knee OA. *See* W. Zhang, *et al.*, OARSI recommendations for the management of hip and knee osteoarthritis, Part I: Critical appraisal of existing treatment guidelines and systematic review of current research evidence. *Osteoarthritis Cartilage* 2010, 18:476-499. However, glucosamine sulfate is no longer recommended in the most recent OARSI guidelines. *See* W. Zhang, *et al.*, OARSI recommendations for the management of hip and knee osteoarthritis: Part III: changes in evidence following systematic cumulative update of research published through January 2009. *Osteoarthritis Cartilage* 2010, 18:476-499.

> cartilage. In younger, healthier individuals cartilage cells would normally accomplish this task. However, as one ages, cartilage cells die off and are not replaced. This starts a cycle of destruction in the cartilage. There are also enzymes present that degrade cartilage. Glucosamine hydrochloride stimulates cartilage production while chondroitin sulfate inhibits enzymes that break down cartilage. Chondroitin sulfate has been shown in clinical trials to slow the progression of cartilage deterioration as well as reduce joint pain.

http://www.nutramaxlabs.com/index.php/your-health-home/joint-health/cosamin-ds (last visited June 25, 2013).

19. As its product packaging demonstrates, Cosamin DS lures consumers to "[p]rotect your cartilage" with "the ONLY BRAND proven to reduce joint pain" (emphasis in original).

20. In its product packaging and elsewhere, Defendant engages in a pervasive marketing scheme to not only tout the purported benefits of Cosamin, but the existence of scientific proof backing those purported benefits. Among Defendant's claims are that Cosamin:

a. "protect[s] your cartilage";

b. is "the ONLY BRAND proven to reduce joint pain";

c. has been "proven effective in controlled published U.S. studies to reduce joint pain";

d. has been "shown in laboratory tests to protect cartilage cells from breakdown";

e. is "THE BEST" product for treating joint pain; and

f. when "compare[d] to other brands", "[c]ontains the FULL CLINICAL STRENGTH of active ingredients".

21. To emphasize those claims, Cosamin packaging features a color image of a red glowing knee joint, further leading consumers to believe that Cosamin will relieve joint pain.

22. Another Nutramax website for Cosamin states the following:

a. "The Cosamin® name on the label is your assurance of the highest quality doctor recommended brand";

b. "Cosamin® is shown effective in peer-reviewed, controlled, published U.S. research";

c. "Don't wait to start feeling better Get Cosamin® Today!";

http://lp.nutramaxlabs.com/WhyCosamin/index.html (last visited June 25, 2013).

23. Defendant has confirmed that, although there are various sizes and varieties of the Cosamin products on the market (tablets, capsules, quantities in the bottle, etc.), the advertising statements on the product labels are substantively identical, regardless of the particular SKU (*See* Dkt. (17).

24. Defendant's television advertisements, commercials and internet advertising campaign further claims the Cosamin products are "the only glucosamine chondroitin brand proven to reduce joint pain" and "anything less just isn't the best."

25. Defendant also makes arthritis-based claims in marketing, advertising and selling the Cosamin products. For example:

a. Nutramax's Facebook page states: "Nutramax Laboratories and Cosamin® Joint Health Supplements are proud to be considered a major donor to the Arthritis National Research Foundation for which 91 cents of every dollar goes to research."

b. On third-party vendor websites, Nutramax states the following regarding the Cosamin products: "Cosamin® DS has been proven effective in controlled clinical studies conducted and published in the U.S. In fact, in

> the new book, *The Arthritis Foundation's Guide to Alternative Therapies*, patients are reminded, "When a supplement has been studied with good results, find out which brand was used in the study, and buy that.""

26. The net impression of Defendant's marketing and advertising (including the packaging) is that Cosamin can treat the symptoms of arthritis: joint pain and discomfort.[5]

27. In short, Defendant engages in a pervasive and widespread marketing campaign to drive sales of its product, luring consumers into purchasing Cosamin by making not only claims as to product efficacy but scientific proof as well.

28. Curiously, Defendant recently began selling another joint health supplement in the Cosamin product line, Cosamin ASU. Defendant now claims "Cosamin DS has served as the premium joint health supplement on the market" but "[b]y combining the exclusive ingredients found in Cosamin DS with ASU, [Defendant] has made the best even better." *See* http://www.nutramaxlabs.com/your-health-home/joint-health/cosamin-asu (last viewed June 27, 2013). Defendant also claims Cosamin ASU is its "maximum strength formula for people with joint discomfort" and that additional ingredients in Cosamin ASU have been shown "to work better than just the combination of glucosamine + chondroitin sulfate" contained in Cosamin DS. *Id.* Defendant's claims about ASU cast additional reasonable suspicion upon the accuracy and truthfulness of Defendant's claims about Cosamin DS.

D. Cosamin Is Not "Proven" To Treat Or Reliev Joint Pain Or Protect Cartilage.

29. The small scale tests conducted on Cosamin and cited by Defendant fail to provide *clinically* significant evidence or proof of joint pain relief.

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[5] Although Defendant markets the Cosamin products for use in animals (calling the product "Cosequin"), this case is only about marketing and advertising for human consumption.

30. In a document on its official website entitled "Cosamin® Clinical and Experimental Studies," Defendant cites to studies which purportedly substantiate its claim that Cosamin DS is "the ONLY BRAND proven to reduce joint pain."[6]

31. These studies are the perfect example of the difference between "statistical significance" and "clinical significance." A determination of statistical significance indicates to investigators the probability that an apparent difference between two or more treatment groups in a study is real and did not occur merely by chance. Accordingly, statistical significance has nothing at all to do with whether or not the hypothesis being tested in a study is true or false, and, thus, it cannot "prove" one's hypothesis. Clinical significance, by comparison, is defined in the scientific community as denoting whether or not an observed treatment effect is of therapeutic importance. Clinical investigators who understand the definition of statistical significance also understand that just because a treatment effect may have attained statistical significance, it does not necessarily mean that clinical significance has been attained.

32. In the studies referenced on Defendant's website, the effects detected as *statistically* significant were, in fact, marginal and barely distinguishable from the response to placebo. For instance, the study conducted by Das and Hammad, the improved pain scores of nearly 5 of every 6 subjects could be accounted for entirely by the placebo response.

33. Accordingly, the findings of these small-scale studies fall well short of *clinical* relevance, and, thus, cannot possibly "prove" that Cosamin reduces joint pain.

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[6] Das AK, Hammad TA. Efficacy of a combination of FCHG49® glucosamine hydrochloride, TRH122® low molecular weight sodium chondroitin sulfate and manganese ascorbate in the management of knee osteoarthritis. *Osteoarthritis and Cartilage* 2000;8(5):343-350; Leffler CT, Philippi AF, Leffler SG, et al. Glucosamine, chondroitin and manganese ascorbate for degenerative joint disease of the knee or low back: a randomized, double-blind, placebo-controlled pilot study. *Military Medicine* 1999;164(2):85-91.

34. Along these lines, any purported "clinical trials" demonstrating the efficacy of glucosamine and chondroitin have been rejected by the medical community. Independent studies evaluating these so-called clinical trials "have shown that trials with methodological flaws, especially inadequate allocation concealment and absence of intent-to-treat approaches are associated with exaggerated estimates of benefit."[7]

E. Glucosamine Hydrochloride (One Of The Primary Ingredients In Cosamin) Is No More Effective Than Placebo

35. As a recent article discussing the body of scientific evidence on glucosamine explained, "***[t]here appears to be consensus that GlcN.HCl [glucosamine hydrochloride] lacks efficacy for the palliation of pain or function in OA [osteoarthritis].***"[8]

36. This "consensus" is reiterated throughout the scientific literature regarding GH:

a. "[T]wo of the major published guidelines recommended glucosamine sulfate in the treatment of OA pain while another integrating more recent data did not consider glucosamine sulfate. At this time, glucosamine hydrochloride cannot be recommended based on the available clinical data."[9]

b. "In other pharmaceutical-grade products, glucosamine is supplied as hydrochloride, that is, a more readily available and easier to manufacture salt that is also present in several dietary supplements available in the

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[7] McAlindon TE *et al.*, *Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis*, *JAMA* 283(11): 1469–75 (Mar. 2000).

[8] Block, *et al.*, The effects of oral glucosamine on joint health: is a change in research approach needed?, *Osteoarthritis and Cartilage* 2010, 18: 5-11.

[9] Henrotin, *et al.*, Is there any scientific evidence for the use of glucosamine in the management of human osteoarthritis?, *Arthritis Research & Therapy* 2012, 14:201.

markets around the world. This salt is often supplied in combination with chondroitin sulfate (CS) and has not proven effective in several trials."[10]

c. "Trials using glucosamine hydrochloride had a very small summary effect size that was statistically indistinguishable from the null. The finding that heterogeneity among these trials was absent suggests that this summary effect is valid. Therefore, we conclude that glucosamine hydrochloride has no effect on pain and that future studies of this preparation are unlikely to yield useful results."[11]

d. "The best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination provide no clinical benefit in patients with primary [Osteoarthritis] of the knee."[12]

37. The lack of effectiveness of GH was demonstrated recently in the Glucosamine/Chondroitin Arthritis Intervention Trial ("GAIT") Study, the lone, large-scale clinical trial to use GH.[13] Under the direction of the National Institutes of Health (NIH), one of

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[10] Roy D Altman, Glucosamine therapy for knee osteoarthritis: pharmacokinetic considerations. *Expert Rev. Clin. Pharmacol.* 2009, 2(4): 359-71.

[11] Vlad, *et al.*, Glucosamine for Pain in Osteoarthritis: Why Do Trial Results Differ? *Arthritis & Rheumatism* 2007, 56(7): 2267-77.

[12] U.S. Department of Health and Human Services – Agency for Healthcare Research and Quality, *Treatment of Primary and Secondary Osteoarthritis of the Knee*, Evidence Report/Technology Assessment No. 157, Sept. 2007, at 106 (systematic review of the scientific literature – including study-level meta-analyses and randomized controlled trials – examining the clinical effectiveness of glucosamine, chondroitin sulfate, and a combination of the two ingredients in relieving joint pain associated with osteoarthritis).

[13] The results of the GAIT study were published in the New England Journal of Medicine. *See* Clegg, D.O. et al, Glucosamine, chondroitin sulfate, and the two in combination for painful knee osteoarthritis, *N Engl J Med* 2006, 354(8): 795-808. Defendant references the GAIT Study in a brochure entitled "Cosamin Clinical and Experimental Studies," which is available on its official website. *See* Exhibit A. Defendant proudly claims that "**[t]he chondroitin sulfate**

the world's foremost medical research centers, 13 highly prestigious research universities in the US performed the GAIT Study, which was a randomized, double-blind, placebo controlled, parallel assignment efficacy study on approximately 1,600 Osteoarthritis sufferers.

38. After six months, researchers reported that, overall, GH and chondroitin sulfate (whether alone, or in the exact combination found in Elations) are no more effective than placebo.[14]

39. When the GAIT Study was published in the New England Journal of Medicine, it was accompanied by an editorial which concluded the following:

> The finding that glucosamine hydrochloride was not more efficacious than placebo is not surprising. Several systematic reviews and meta-analyses have examined the efficacy of glucosamine in the treatment of osteoarthritis of the knee. In the most recent meta-analysis of eight randomized trials in which either glucosamine hydrochloride or glucosamine sulfate not manufactured by Rottapharm was compared with placebo, differences between the groups in the WOMAC[15] scores did not reach significance…. On the basis of the results from GAIT, it

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selected for use in [the GAIT Study] is ONLY found in Cosamin®DS." *Id.* at 6 (emphasis in original). Defendant conveniently fails to mention, however, that the GAIT Study found that chondroitin sulfate, whether alone or in combination with GH, is no more effective than placebo.

[14] The combination of GH and chondroitin sulfate appeared to help a small subset of participants with moderate-to-severe pain. However, because of the small size of the subset, researchers specified that such findings should be considered "preliminary" and could not be confirmed without further testing designed for that purpose. Moreover, the hypothesis that these ingredients may help a subset of the population was undermined by the 2-year ancillary GAIT study and another study utilizing GAIT participants, both of which found that GH and chondroitin sulfate do not provide clinically significant relief from OA pain. *See* Sawitzke, A.D., *et al.*, The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the glucosamine/chondroitin arthritis intervention trial. *Arthritis Rheum*. 2008, 58(10): 3183-91; Sawitzke, A.D., *et al.*, Clinical efficacy and safety over two years use of glucosamine, chondroitin sulfate, their combination, celecoxib or placebo taken to treat osteoarthritis of the knee: a GAIT report, *Ann Rheum Dis.* 2010, 69(8): 1459-64.

[15] WOMAC stands for Western Ontario and McMaster University Osteoarthritis Index, which is a is a set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip.

> seems prudent to tell our patients with symptomatic osteoarthritis of the knee that neither glucosamine hydrochloride nor chondroitin sulfate alone has been shown to be more efficacious than placebo for the treatment of knee pain. If patients choose to take dietary supplements to control their symptoms, they should be advised to take glucosamine sulfate rather than glucosamine hydrochloride and, for those with severe pain, that taking chondroitin sulfate with glucosamine sulfate may have an additive effect.[16]

40. To study whether GH and/or chondroitin sulfate could diminish the structural damage caused by OA, interested GAIT patients were offered the opportunity to continue their original study treatment for 18 more months, for a total of two years.[17] The ancillary study enrolled 572 GAIT participants with moderate or severe knee Osteoarthritis, and the final sample included 357 subjects with Osteoarthritis in one or both knees. Each of these subjects was randomly assigned to receive one of the five treatments used in the first GAIT study.

41. The second GAIT analysis used x-rays to measure the physical effects of these supplements on knee joints. Knee images from the 357 subjects were analyzed to see if daily GH/chondroitin supplements prevented a loss of joint space—the distance between the ends of bones in the joint.

42. Once again, researchers found that there were no meaningful differences among people taking the combination of GH/chondroitin sulfate and a placebo. In fact, researchers observed that loss of joint space width was greater with the combined treatment than with either treatment alone, which raised the possibility that the combination of GH and chondroitin sulfate

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[16] Hochberg, Marc C., Nutritional Supplements for Knee Osteoarthritis – Still No Resolution, *N Engl J Med* 2006, 354(8): 858-60.

[17] Sawitzke, A.D., *et al.*, The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the glucosamine/chondroitin arthritis intervention trial. *Arthritis Rheum*. 2008, 58(10): 3183-91.

(in identical amounts to that found in Osteo Bi-Flex MSM) may actually interfere with absorption.[18]

43. Since the conclusion of the ancillary GAIT study, there was another study conducted involving 662 GAIT participants with moderate-to-severe knee osteoarthritis.[19] This subset continued to receive their randomized treatement: glucosamine HCl (500 mg three times daily), chondroitin sulfate (400 mg three times daily), glucosamine and chondroitin sulfate combined (same doses), celecoxib (Celebrex, 200 mg once daily), or a placebo. Over two years, no treatment achieved a clinically significant difference in WOMAC pain or function as compared with placebo.

44. In addition to the GAIT Study and ancillary GAIT Study, other recent independent and reliable studies failed to detect any benefit of glucosamine supplementation on the treatment of joint pain. Among these is a recent study that concluded that when "[c]ompared with placebo, glucosamine, chondroitin, and their combination do not reduce joint pain or have an impact on narrowing of joint space. Health authorities and health insurers should not cover the costs of these preparations, and new prescriptions to patients who have not received treatment should be discouraged."[20]

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[18] This hypothesis is supported by another recent study establishing that chondroitin sulfate inhibits GH absorption and decreases its bioavailability. *See* Jackson, *et al*., The human pharmacokinetics of oral ingestion of glucosamine and chondroitin sulfate taken separately or in combination. *Osteoarthritis Cartilage* 2010, 18: 297-302.

[19] *See* Sawitzke, A.D., *et al.*, Clinical efficacy and safety over two years use of glucosamine, chondroitin sulfate, their combination, celecoxib or placebo taken to treat osteoarthritis of the knee: a GAIT report, *Ann Rheum Dis.* 2010, 69(8): 1459-64.

[20] Wandel, *et al.*, Effects of glucosamine, chondroitin, or placebo in patients with osteoarthritis of hip or knee: network meta-analysis. *BMJ* 2010, 341:c4675.

45. This study, published in the British Medical Journal, included ten trials and nearly 4,000 subjects. It further employed a Bayesian approach toward network meta-analysis, which "allow[ed] a unified, coherent analysis of data recorded at multiple time points in randomised trials that compare[d] either of these preparations [glucosamine, chondroitin, or their combination] with placebo or head to head."[21] This comprehensive study "showed no clinically relevant effect of chondroitin, glucosamine, or their combination on perceived joint pain. Despite abundant statistical power, none of the pooled estimates crossed the pre-specified boundary of a minimal clinically important difference of -0.9 cm on a 10 cm visual analogue scale at any of the recorded time points."[22]

46. Addressing previous studies, the British Medical Journal noted that "[t]rials that have reported large effects on joint pain were often hampered by poor study quality and small sample sizes, whereas large methodologically sound trials often found only small or no effects."[23]

47. Another 2010 study, published in the Journal of the American Medical Association, further refuted Defendant's claims of both product efficacy and scientific proof.[24] There, researchers concluded that a "6-month treatment with oral glucosamine compared with placebo did not result in reduced pain-related disability after the 6-month intervention and after

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[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *See Wilkens, et al.*, Effect of Glucosamine on Pain-Related Disability in Patients with Chronic Low Back Pain and Degenerative Lumbar Osteoarthritis. *JAMA* 2010, 304(1): 45-52.

1-year follow-up." The study put it bluntly: "[n]o difference was found between glucosamine and placebo in terms of minimal important clinical change[.]"[25]

48. Even after Defendant's claims of efficacy and scientific proof were debunked by the medical community, since at least 2009 Defendant has continued to sell the Cosamin products and continued to make claims regarding its efficacy and scientific proof thereof.

F. Overwhelming Scientific Evidence Establishes Chondroitin Sulfate Is Ineffective

49. As with GH, recent evidence demonstrates that chondroitin sulfate is no more effective than placebo:

a. "Efficacy of chondroitin sulfate over placebo for treating pain in OA was reported in many of the smaller, earlier studies, but the estimates varied considerably from study to study. In recent years, larger-scale trials have reported little to no effect of chondroitin sulfate treatment on the symptoms of OA."[26]

b. "No robust evidence supports the use of chondroitin in osteoarthritis. Large-scale, methodologically sound trials indicate that the symptomatic benefit is minimal to nonexistent. The effect of chondroitin on joint space narrowing was assessed in only a few trials. This effect is likely to be small, and its clinical significance is uncertain. In patients with low-grade osteoarthritis, the use of chondroitin should be restricted to randomized, controlled trials. For patients with advanced osteoarthritis, a clinically

[25] *Id.*

[26] *See* Miller, *et al.*, Glucosamine and Chondroitin Sulfate, *Rheum Dis Clin N Am* 2011, 37: 103-118.

> relevant benefit is unlikely and the use of chondroitin should be discouraged."[27]

50. In touting the efficacy of the active ingredients in Cosamin DS, Defendant simply ignores this scientific evidence which clearly demonstrates that the products cannot work as advertised.

51. Defendant omitted material information in its marketing to consumers regarding the recent studies proving the inefficacy of glucosamine and chondroitin sulfate in reducing or relieving joint pain. Had Plaintiff been aware Defendant omitted this important information and the fact that the claims Defendant made about Cosamin were no longer accurate in light of this information, he would not have purchased Cosamin or paid a premium price for it. All in all, Defendant utilized a deceitful marketing campaign to induce Plaintiff and the Class Members into purchasing a worthless product.

G. Facts as to Demetri Spencer

52. Like many Cosamin consumers, Plaintiff Demetri Spencer suffers from arthritis.

53. For years, Plaintiff Spencer has experienced joint discomfort and pain.

54. Plaintiff Spencer was exposed to the misrepresentations discussed herein (as to product efficacy in reducing joint pain and protecting cartilage and scientific proof thereof), including those contained in Cosamin television commercials, internet advertisements and the packaging for Cosamin DS. In reliance thereon, Plaintiff Spencer purchased Cosamin DS on or around October 2012 for approximately $60.

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[27] *See* Reichenbach, *et al.*, Meta-analysis: Chondroitin for Osteoarthritis of the Knee or Hip, *Ann Intern Med.* 2007, 146: 580 – 590.

55. But for these representations, and further but for the material omissions regarding studies implicating the inefficacy of Defendant's product, Plaintiff Spencer would not have purchased the product or paid nearly as much for it.

56. Plaintiff Spencer consumed the entire bottle of Cosamin DS pills as directed on the product's package, but his joint pain was not reduced, and he did not receive any of the benefits promised.

IV. CLASS ACTION ALLEGATIONS

A. Class Definition

57. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff brings this action for himself and on behalf of a class defined as:

> All natural persons residing in the State of Florida who purchased Cosamin DS for personal use and not for resale since April 12, 2009.

58. Specifically excluded from the Class are: (a) all federal court judges who preside over this case and their spouses; (b) all persons who elect to exclude themselves from the Class; (c) all persons who have previously executed and delivered to Defendant releases of all their claims for all of their Class claims; and (d) Defendant's employees, officers, directors, agents, and representatives and their family members.

B. Rule 23(a) Prerequisites

59. **Numerosity.** The Class is so numerous that joinder of all members is impracticable. At this time, Plaintiff does not know the exact size of the Class. Based on information and belief, the Class is comprised of at least thousands of members so as to render joinder of all Class Members impracticable.

60. **Commonality.** Common questions of law and fact predominate over individual issues. There is a well-defined community of interest in the questions of law and fact involved affecting members of the Class. The questions of law and fact common to the Class predominate over questions affecting only individual Class members, and include, but are not limited to, the following:

a. Whether Defendant's representations about Cosamin' effectiveness are true;

b. Whether Defendant's representations about the scientific proof of Cosamin's effectiveness are true;

c. Whether Defendant's deceptive conduct regarding Cosamin's effectiveness and/or scientific proof would deceive an objective consumer acting reasonably in the circumstances;

d. Whether Defendant's uniform representations and omissions constituted deceptive acts in violation of FDUTPA;

e. Whether Defendant's sale and marketing of Cosamin constituted an unfair practice in violation of FDUTPA;

f. Whether Defendant's uniform advertisements (product packaging and/or television advertisements) violated Florida's Misleading Advertising Law, Fla. Stat. 817.41;

g. Whether Defendant's purported violation of Florida's Misleading Advertising Law constitutes a *per se* violation of FDUTPA;

h. Whether Defendant's products are worthless;

i. Whether Plaintiff and the Class Members are entitled to damages, and what is the proper measure of Plaintiffs' and the Class Members' loss;

j. Whether Plaintiff and the Class Members are entitled to an award of punitive damages; and

k. Whether Plaintiff and the Class Members are entitled to injunctive relief.

61. **Typicality.** Plaintiff's claims are typical of the other Class Members' claims. As described above, Defendant engages in a pervasive advertising scheme, including most

importantly the use of common and uniform product packaging, resulting in substantially uniform misrepresentation and/or omissions regarding the efficacy of Defendant's product (misrepresentation), the scientific proof supporting Defendant's product (misrepresentation), and the failure to disclose studies highlighting the inefficacy of Defendant's product (omission). Further, at all times relevant, Plaintiff has suffered and continues to suffer from conditions resulting in joint pain which as do the typical Cosamin user and Class Member.

62. **Adequacy.** Plaintiff is an adequate representative of the Class because he fits within the class definition and their interests do not conflict with the interests of the members of the Class they seek to represent. Plaintiff will prosecute this action vigorously for the benefit of the entire Class. Plaintiff is represented by experienced and able attorneys. Class counsel have litigated numerous class actions and complex cases, and Plaintiff's counsel intend to prosecute this action vigorously for the benefit of the entire Class. Plaintiff and class counsel can and will fairly and adequately protect the interests of all of the members of the Class.

C. Rule 23(b) Prerequisites

63. Questions of law and fact common to the Class predominate over questions affecting only individual Members, and a class action is superior to other available methods for fair and efficient adjudication of the controversy. The damages sought by each member are such that individual prosecution would prove burdensome and expensive given the complex and extensive litigation necessitated by Defendant's conduct. It would be virtually impossible for the members of the Class to effectively redress the wrongs done to them on an individual basis. Even if the members of the Class themselves could afford such individual litigation, it would be an unnecessary burden on the courts.

64. Furthermore, individualized litigation presents a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and to the court system presented by the legal and factual issues raised by Defendant's conduct. By contrast, the class action device will result in substantial benefits to the litigants and the Court by allowing the Court to resolve numerous individual claims based upon a single set of proof in just one case.

V. CAUSES OF ACTION

A. First Cause of Action: Violations of Florida's Deceptive and Unfair Trade Practices Act

65. Plaintiff incorporates by reference each other allegation set forth in this First Amended Complaint.

66. Plaintiff and the Class are "consumers" within the meaning of Part II of Chapter 501, Florida Statutes, relating to Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

67. Pursuant to FDUTPA, unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful.

68. Within four years prior to the filing of this First Amended Complaint and continuing to the present, Defendant, in the course of trade and commerce, engaged in unconscionable, unfair, and/or deceptive acts or practices harming Plaintiffs and the Class, as described herein.

69. Plaintiff and the Class Members purchased Cosamin as part of consumer transactions.

70. ***Violation One: Deceptive Acts.*** Defendant violated FDUTPA by engaging in deceptive acts against Plaintiff and the Class. Namely:

a. Defendant's representations and omissions regarding product efficacy and/or scientific proof are representations and/or omissions that are likely to mislead consumers acting reasonable in the circumstances, to the consumer's detriment.

b. Clearly, reasonable consumers would, as a result of Defendant's misrepresentations and omissions, be misled and believe that Cosamin is (1) effective in treating joint pain and protecting cartilage (2) has been proven scientifically to do so; neither of which is true.

c. It is highly probable that these representations and omissions (regarding efficacy and proof) are likely to cause injury to a reasonable consumer, and Defendant's misrepresentations and omissions are likely to mislead consumers.

d. In this case, claims of efficacy and scientific proof were the integral part of Defendant's marketing scheme, and the primary reason consumers purchased their product.

71. ***Violation Two: Unfair Practices.*** Defendant further violated FDUTPA by engaging in unfair practices against Plaintiff and the Class. Namely:

a. Given the high cost of Cosamin and that its consumers are seeking relief from joint pain, Defendant's sale of the product (which does not relieve joint pain, because it cannot), especially accompanied by the misrepresentations and omissions described herein, is a practice this is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to consumers. Specifically, Defendant has been preying upon individuals who suffer from joint pain, some of whom have arthritis, and seek a product to help control the pain and/or treat their arthritis symptoms, and charging them a premium price for a product that cannot work as promised.

b. These practices also offend established public policy regarding the protection of consumers against companies, like Defendant, who engage in unfair methods of competition.

c. Defendant's representations in marketing and advertising the efficacy of Cosamin to treat joint pain (as well as purported proof of this efficacy) is likely to mislead consumers acting reasonably under the circumstances, like Plaintiff and members of the Class, to their detriment. For example, Plaintiff and members of the Class spent money on Cosamin, a so-called "premium joint health supplement," because they had joint pain and/or discomfort and Defendant promised that Cosamin was "proven" to treat joint pain and protect cartilage. In reality, relevant and reliable science proves otherwise, a material fact Defendant hid from consumers. Thus, Defendant's false and misleading advertising and material omissions caused Plaintiff to spend money on a product that was worthless.

d. Defendant's conduct, which caused substantial injury to Plaintiff and the Class which could have been avoided, was not outweighed by countervailing benefits to any consumers or competition.

e. The practices complained of herein are not limited to a single instance but is rather done pervasively and uniformly at all times as against Plaintiff and the Class.

72. ***Violation Three: Misleading Advertising.*** Defendant further violated FDUTPA by violating a "statute…which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. 501.203(3)(c). Here, Defendant violated Florida's Misleading Advertising Law (Fla. Stat. 817.41), as described in the "Second Cause of Action" portion of this First Amended Complaint.

73. Defendant's misrepresentations, omissions, deceptive acts, unfair practices, and/or violations of other rules or statutes, as described herein as violating FDUTPA, would deceive an objectively reasonable consumer.

74. As a result of Defendant's misrepresentations, omissions, deceptive acts, unfair practices, and/or violations of other rules or statutes, Plaintiff and the Class Members suffered actual damages by losing money. Defendant's product is worthless and thus Defendant's damages are the purchase price of the product. Plaintiff and the Class paid a premium price for Cosamin.

75. As a result of these FDUTPA violations, Plaintiff and the Class Members are entitled to actual damages, attorney's fees, costs, declaratory relief, and injunctive relief.

B. Second Cause of Action: Misleading Advertising

76. Plaintiff incorporates by reference each other allegation set forth in this First Amended Complaint.

77. Through the misrepresentations and omissions made in Defendant's product packaging and/or television advertising regarding efficacy and scientific proof, Defendant unlawfully disseminated or caused to be made misleading advertisements in Florida, in violation of Fla. Stat. 817.41.

78. Though described above, Plaintiff reiterates the specific circumstances surrounding Defendant's misleading advertising:

a. ***Who.*** Defendant made (or caused to be made) the material misrepresentations and omissions described herein. Plaintiff is unaware, and therefore unable to identify, the true names and identities of those individuals at Nutramax who are responsible for the false or misleading advertisements.

b. ***What.*** Defendant's product packaging made material misrepresentations regarding: (1) the efficacy of Cosamin in treating joint pain (e.g., the product packaging advertised that Cosamin protects cartilage and can reduce joint pain; (2) the scientific proof of same (e.g., the representation that Cosamin was "proven effective in controlled…studies to reduce joint pain" and "shown effective in peer-reviewed, controlled, published U.S. research"). Defendant's television commercials and internet advertising also made these misrepresentations and/or substantially similar misrepresentations. Defendant's advertising was further misleading in that it failed to disclose testing demonstrating the inefficacy of glucosamine hydrochloride and chondroitin sulfate in reducing joint pain. Plaintiff Spencer was exposed to these claims via the product packaging and television advertisements.

c. ***Where.*** The false advertising occurred on Defendant's product packaging and in its television advertising which were (upon information and belief) transmitted and/or displayed throughout the State of Florida.

d. ***When.*** Defendant engaged in the false advertising detailed herein continuously during the Class Period.

e. ***Why.*** Defendant made the false advertisements with the intent to induce Plaintiff to rely upon them and purchase Cosamin.

79. The misrepresentations and omissions as to product efficacy and scientific proof are material to Plaintiff, the Class Members, and the average consumers.

80. Defendant knew or should have known (through the exercise of reasonable care or investigation) that the advertisements were false, untrue, or misleading.

81. Defendant's misrepresentations and omissions were designed and intended, either directly or indirectly, for obtaining money from Plaintiff and the Class Members under false

pretenses by inducing them to purchase Defendant's product. Defendant intended that the representations would induce Plaintiff and the Class Members to rely upon it and purchase Defendant's product.

82. Plaintiff and the Class Members relied to their detriment on Defendant's false advertising, by purchasing an expensive product that they would not otherwise have purchased.

83. Plaintiff and the Class Members suffered injury in justifiable reliance on Defendant's false advertising; namely they lost money by purchasing an expensive product that they would not otherwise (but for the false advertising) have purchased.

84. Pursuant to Fla. Stat. 817.41, Plaintiff and the Class Members are entitled to costs, reasonable attorney's fees, actual damages, and punitive damages

85. Punitive damages are appropriate here, given Defendant knowingly misled consumers including Plaintiff and the Class and engaged in the willful, wanton, and/or reckless conduct described herein. Here, Defendant engaged intentional misconduct (or alternatively, gross negligence) as to the misrepresentations and omissions concerning product efficacy and testing that form the heart of Plaintiff's claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in favor of himself and the Class for the following:

a. That the Court determines that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure; that Plaintiff is a proper class representative; and that the best practicable notice of this action be given to members of the Class represented by Plaintiff;

b. That judgment be entered against Defendant and in favor of Plaintiff and the Class on the Plaintiff's FDUTPA claim, for actual and consequential damages, equitable relief, including restitution and restitutionary disgorgement.

c. That judgment be entered against Defendant and in favor of Plaintiff and the Class on Plaintiff's Misleading Advertising claim, for actual and punitive damages;

d. That Defendant be permanently enjoined from its unfair, fraudulent and deceitful activity.

e. That judgment be entered imposing interest on damages;

f. That judgment be entered imposing litigation costs and attorneys' fees under Plaintiff's FDUTPA and Misleading Advertising claims; and

g. For all other and further relief, including equitable relief, as this Court may deem necessary and appropriate.

JURY TRIAL DEMANDED

July 1, 2013

Respectfully submitted,

KU & MUSSMAN, PA

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by CM/ECF on July 1, 2013 on all counsel or parties of record on the Service List below.

s/ Brian T. Ku
Brian T. Ku, Esq.

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