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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LIZA GERSHMAN, On Behalf of Herself and All Others Similarly Situated, Plaintiff, v. BAYER HEALTHCARE, LLC, a Delaware Limited Liability Company, Defendant.	Case No.: **CLASS ACTION COMPLAINT FOR:** 1. VIOLATION OF THE UNFAIR COMPETITION LAW, Business and Professions Code §17200 *et seq.*; and 2. VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, Civil Code §1750 *et seq.* DEMAND FOR JURY TRIAL

Plaintiff Liza Gershman brings this action on behalf of herself and all others similarly situated against Defendant Bayer Healthcare, LLC ("Bayer" or "Defendant") and states:

NATURE OF ACTION

1. In or around August 2013, Bayer began manufacturing, marketing, selling and distributing Flintstones Healthy Brain Support, a gummy-chewable Omega-3 DHA dietary supplement made with Life's DHA ("the Product"). The Product is not a multivitamin. The Product's sole represented benefits are to provide brain function benefits and brain support benefits. The Product is for adults and children two years and older.

2. Through an extensive, widespread, comprehensive and uniform nationwide marketing campaign, Bayer claims that consuming the Product will "Support[] Healthy Brain Function". On each and every package immediately under the Product name it states "Healthy" above the phrase "BRAIN SUPPORT" (the latter being in a much larger font). In a separate box below this quoted language is the representation that "Omega-3 DHA Supports Healthy Brain Function."[1]

3. Experts in the field determine whether a substance provides brain function benefits by performing randomized controlled clinical trials ("RCTs") and measuring whether, in comparison to placebo, it provides improved cognitive function.

4. Here, the only ingredient in the Product that purportedly provides any brain health benefits is the 50mg-100mg of Omega-3 DHA in each daily dose.[2] Thus, whether Flintstones Healthy Brain Support supports brain function is to be determined by the results of RCTs that have tested Omega-3 DHA. As more fully set forth below, RCTs have conclusively shown that algal Omega-3 DHA

[1] The other ingredients are sugars and a miniscule amount of vitamin C – 2% of the minimum daily value.

[2] 50 mg is the recommended daily dose for children 2 and 3 years of age and 100mg is the recommended daily dose for those 4 years of age and older.

supplements such as the Flintstones Healthy Brain Support supplements sold by Defendant, do not improve cognitive development. And, the scientific evidence is clear that Omega-3 DHA supplementation does not provide any brain function benefits.

5. By law, the FDA does not and cannot regulate the pre-market approval of health benefit statements about dietary supplements such as Flintstones Healthy Brain Support. Instead, it is the manufacturer's responsibility to ensure that the statement "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function…." and that the manufacturer "has substantiation that such statement is truthful and not misleading." 21 U.S.C. §343(r). As more fully set forth herein, the brain function and brain support representations do not have a "documented mechanism by which" the algal Omega-3 DHA in the Product acts to provide these benefits. Moreover, rather than having adequate substantiation for its brain function and brain support representations, the scientific evidence is clear that algal Omega-3 DHA supplementation does not provide brain function or brain support benefits.

6. The Flintstones Healthy Brain Support label – in smaller print – on the side of the bottle – carries a required "disclaimer" that the Product is not "intended to diagnose, treat, cure or prevent any disease." This disclaimer language is required when a dietary supplement manufacturer makes a "structure/function" claim, such as Defendant has made here.

7. This disease disclaimer has no impact on the representations being challenged. The FDA regulations distinguish between "structure/function claims" – such as the brain support/function claims Bayer makes – and "disease claims" which require pre-market approval from the FDA. *See* FDA, Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInfo

rmation/ucm103340.htm.

8. As more fully set forth below, the results from five RCTs involving the *same* algal Omega-3 DHA as is in the Product show that Omega-3 DHA algal oil supplementation performs no better than placebo with regard to brain function. This was so even though several of these RCTs were funded by the manufacturer of the Life's DHA which is used in the Product and even though the studies evaluated much higher doses of DHA than that found in the Product (at least eight times the amount of DHA as the recommended dosage of the Product for children 2-3 years old and 4 times the amount in the recommended dosage for adults and children 4 years and older).

9. Further, it makes no difference that the studies did not employ DHA delivered in a gummy as opposed to a pill. Once digested, the DHA that remains is the same from either delivery vehicle.

10. Equally important to the results of the five RCTs finding no brain function benefits from algal DHA supplementation, is the fact that the algal oil derived DHA in the Product is superfluous as it is not used by the body once consumed, making it useless for any brain function or brain support benefit. In this regard, the scientific evidence shows that the body manufactures DHA from other readily available fatty acids derived from a variety of dietary sources. Thus, American children and adults, who are the target market for the Product, consume adequate amounts of DHA in their diet. There is no need for anyone to take a DHA supplement - their bodies make the needed amounts of DHA.

11. For example, the Institute of Medicine ("IOM")—the health arm of the National Academies—has issued a report stating that it does not recognize a dietary requirement for DHA as there is no DHA deficiency in adults or children in the United States. *See* Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients): The National

Academies Press; 2005 at 5-6, 11, 469.

12. On April 22, 2014, the FDA embraced the IOM finding by publishing a Final Rule that acted on and expressly rejected Martek Biosciences Corp.'s (the maker of the Life's DHA in Bayer's Product) request that the FDA recognize a daily requirement for DHA. *See* http://www.gpo.gov/fdsys/pkg/FR-2014-04-28/pdf/2014-09492.pdf. In doing so, the FDA acknowledged that there is no dietary requirement for DHA as it is not an essential nutrient. *Id*. That is why there is no daily value listed on the Product label.

13. Moreover, only a trivial amount of the DHA in the Product ever enters the brain after it is consumed. The brain contains about 5000 mg of DHA. A daily dose of the Product would only provide about .000005% and .00001% of the brain's DHA content in children 2-3 years of age and adults and children over 4, respectively. This amount is so trivial that experts in the field can conclude, on this basis alone, that the DHA contained in the Product cannot and does not support the brain or its functioning in any manner.

14. Thus, the overwhelming weight of scientific evidence is that DHA supplementation does not provide brain function benefits and does not provide brain support. The only ingredient in the Product represented as providing brain support or function is the DHA. Thus, Bayer's brain function and brain support representations are false, misleading, and reasonably likely to deceive the public.

15. Defendant's brain support and brain function representations are also unlawful. Flintstones Healthy Brain Support is a dietary supplement. 21 U.S.C. § 321(g)(d). Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). Manufacturers are not required to get FDA approval before producing or selling a dietary supplement. However, manufacturers must make sure that all health benefit claims on the product package and label are truthful and not misleading. With regard to each of the representations Defendant

makes about Flintstones Healthy Brain Support, this means that Defendant is required to make sure the they are truthful and not misleading.

16. In order to be truthful and not misleading, dietary supplement health benefit claims must be substantiated by competent and reliable scientific evidence. 21 U.S.C. § 321(r)(6)(b); Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act, ("FDA Guidance of Industry"), Ex. A.

17. Under DSHEA, competent and reliable scientific evidence is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FDA Guidance of Industry, Ex. A.

18. Experts in the field, as well as experts in other fields that concern substances that purport to provide human health benefits, deem the only credible scientific evidence to substantiate human health benefit claims, such as those at issue here, is evidence from RCTs (hereafter "competent and reliable evidence"). No such RCTs exist to substantiate the brain support and brain function representations made by Defendant about Flintstones Healthy Brain Support.

19. Because there is no competent and reliable evidence that Flintstones Healthy Brain Support provides brain support or brain function benefits, Defendant is selling a dietary supplement in violation of federal law, DSHEA, and California's Sherman Act.

20. Bayer has employed numerous methods to convey its uniform, deceptive brain function and brain support representations to consumers including the name of the Product and the front of the Product's packaging and labeling where they cannot be missed by consumers.

21. As a result of Bayer's deceptive brain function and brain support representations, consumers—including Plaintiff and members of the proposed Class—have purchased the Product, which does not perform as advertised. The only reason a consumer would purchase the Product is to obtain the advertised brain function and brain support benefits because these are the only stated benefits of the Product.

22. Plaintiff brings this action on behalf of herself and other similarly situated consumers who have purchased Flintstones Healthy Brain Support to halt the dissemination of these false, misleading and deceptive advertising messages, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased the Product. Based on violations of state unfair competition laws (detailed below), Plaintiff seeks injunctive and monetary relief for consumers who purchased the Product.

23. Plaintiff also brings this action on behalf of herself and other similarly situated California consumers who have purchased Flintstones Healthy Brain Support, under the "unlawful" prong of the UCL. Plaintiff seeks to halt Defendant's unlawful sale of Flintstones Healthy Brain Support in violation of applicable FDA law and regulations and California's Sherman Act and also seeks full restitution of Plaintiff's and other California consumers' full purchase price.

JURISDICTION AND VENUE

24. 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 there are in excess of 100 class members and Class members are citizens of a state different from Defendant.

25. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct and does conduct business in California. Defendant has marketed, promoted, distributed, and sold the Product in California and Defendant

has sufficient minimum contacts with this State and/or sufficiently availed itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

26. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to Plaintiff Gershman's claims occurred while she resided in this judicial district. Venue is also proper because Defendant transacts substantial business in this District.

PARTIES

27. Plaintiff Liza Gershman is a citizen of California and resides in San Francisco, California. In or around the summer/spring of 2014, Plaintiff Gershman purchased one bottle of Flintstones Healthy Brain Support from Walgreens in San Francisco, California. Prior to purchasing the Product, Plaintiff Gershman was exposed to and saw Bayer's brain function and brain support representations by reading the Product's label. Plaintiff Gershman purchased the Product in reliance on Bayer's brain function and brain support representations. Plaintiff paid approximately $15.00 for the Product. The Product Plaintiff Gershman purchased has been proven to not support healthy brain function and the scientific evidence is that taking Defendant's DHA supplement does not provide brain support. As a result, Plaintiff Gershman suffered injury in fact and lost money at the point when she purchased the Product. Had Plaintiff Gershman known the truth about Bayer's misrepresentations, she would not have purchased the Product.

28. Defendant Bayer Healthcare, LLC is a Delaware limited liability company with its principal place of business in Whippany, New Jersey. The sole member of Bayer Healthcare, LLC is Bayer Corporation. Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Defendant is therefore a citizen of Delaware, Indiana and Pennsylvania.

29. At all relevant times, Defendant manufactured, distributed, marketed

and sold the Product and created the deceptive brain function and brain support representations, which it caused to be disseminated to consumers throughout the United States, including California.

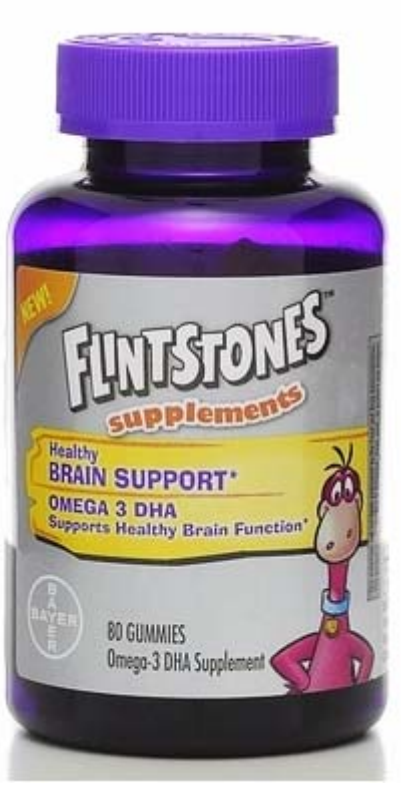
FACTUAL ALLEGATIONS

Flintstones Healthy Brain Support

30. Since at least August 2013, Bayer has manufactured, distributed, marketed and sold the Product throughout the United States, including California. The Product is marketed as a supplement with the singular purpose of providing brain function benefits and brain support benefits. The Product is sold in virtually every major food, drug, and mass retail outlet in the country, and retails for approximately $13-$16 for 80 gummies. Each gummy contains 50 mg of DHA - children ages 2-3 are directed to take 1 gummy daily (*i.e.*, 50 mg DHA daily) and adults and children ages 4 and older are directed to take 2 gummies daily (*i.e.*, 100 mg DHA daily).

31. Since the Product's launch, Bayer has consistently conveyed the message to consumers throughout the United States, including California, that the Product provides "Healthy Brain Support" and "Supports Healthy Brain Function." Bayer's brain function and brain support representations are false, misleading and deceptive.

32. Each and every consumer who purchases the Product is exposed to Bayer's deceptive brain function and brain support representations, which are the only represented Product benefits and appear prominently and conspicuously on the front of the Product's packaging, as follows:



The Product Does Not Provide Healthy Brain Support and Does Not Support Healthy Brain Function

33. DHA is a long-chain Omega-3 fatty acid typically found in cold water fish. The DHA in Bayer's Product is not derived from fish. Instead, the Life's DHA in the Product -- manufactured by Martek Biosciences -- is from algae. Contrary to Bayer's representations made on each and every Product package, DHA algal oil does not support healthy brain function or provide brain support.

34. The results from several RCTs, regarded by experts in the field as the "gold standard" of scientific evidence, show that the DHA in the Product provides no brain function benefits, even though these studies involved far higher amounts of DHA supplementation.

35. For example, a 2008 RCT funded by Martek Biosciences, the manufacturer of the Life's DHA in the Product – examined algal DHA supplementation (400mg) in 4-year old children for 16 weeks and reported no effect

of DHA on 4 measures of cognitive function in children: "[t]he results did not demonstrate statistically significant improvements in cognitive measures." *See* Ryan, A., et al., *Assessing The Effect Of Docosahexaemoic Acid On Cognitive Functions In Healthy Preschool Children*, 47(4) Clin. Pediatr. 355-62 (2008). Indeed, the authors acknowledged "the primary end points[3] of the study were not met." This is so even though the amount administered was 400mg or 4 times the daily dose of the Product for persons over four years of age. Furthermore, in attempting to explain away the negative results, the authors noted that perhaps an even "larger dose" of DHA might be required to possibly see any results.

36. *Ryan et al.*, also included the results of a secondary analysis where they ran regression analyses of the test results against DHA levels in the blood. The report states that this was done with regard to both the DHA group and the placebo group as to all four tests. But the results for only one test, the PPVT test, and one group, the DHA group, were reported. There is no explanation why the results from the regression analyses for the other tests for both the DHA group and placebo group were not reported. Nor, is there any explanation why the results for both the placebo group and the PPVT test were not reported in order for a comparison between placebo and DHA groups for this test.

37. As a threshold matter, the use of regression analyses, such as the one performed in *Ryan et al.*, are not considered the type of statistical analysis that is acceptable for reaching any cause and effect conclusions. This is particularly true with regard to DHA blood levels, which can vary widely from individual to individual over time.

38. Yet, as reported in *Ryan et al.*, for one group, the DHA group who gave

[3] The primary outcome measured attention, memory, processing, speed and error rate. *Id.* at 2.

blood samples at both the beginning and end of the study,[4] with regard to one of the four tests used to measure cognitive performance, there was a positive correlation between DHA blood levels and test results. While the authors stated that they were going to perform this analysis on all four tests, the results of the blood level regression analysis with the three other tests were not reported. Thus, it is safe to assume that these results were null or negative, since, while stating that they ran regressions for blood levels for all four of the tests, *Ryan et al*. does not report these other results.

39. The study's authors stated that this secondary analysis was preplanned ("The relationship between blood DHA levels and the efficacy end points were considered preplanned secondary outcomes."). However, at clinicaltrials.gov, where the protocol of this study was registered,[5] this particular secondary analysis was not described. Instead, the secondary endpoints are safety and a simple measurement of DHA blood levels before and after DHA supplementation without any mention of a regression analysis being performed.

40. Under accepted scientific conventions, unless an endpoint, be it primary or secondary, is described in the registration, it is not deemed an endpoint from which any conclusions can be drawn.

41. Further, nowhere in their registration do the authors describe an intention to perform a regression analysis solely on the DHA treatment group.

42. Moreover, the number of subjects within the DHA blood level study group are internally inconsistent and raise considerable doubt about the accuracy of this, albeit, secondary and exploratory analysis. First, there are 46 subjects described as being in the DHA blood level group. The authors then excluded, albeit for an

[4] As the report notes, because of some children's unwillingness to have their fingers stuck with a pin to draw blood, this was a smaller subset than the subjects who merely took placebo or 400mg of DHA and took the tests.

[5] Most studies that are conducted with the intention of potential publication in a peer-reviewed journal register the protocol of the study and its general progress to completion. The registration for this study can be found at https://clinicaltrials.gov/ct2/show/NCT00351624?term=Docosahexaenoic+and+ryan&rank=1.

improper reason, four subjects in the DHA blood level group.[6] And then, in figure 1 in the study report, which purports to depict the results of the regression analysis, there are only 40 points plotted on the graph, reflecting yet another inexplicable exclusion of two more subjects. Putting aside all of the other irregularities with regard to this secondary analysis, these numerical inconsistencies, on their own, cause whatever conclusions that might have been drawn from this secondary/exploratory analysis to be suspect and not reliable to reach any cause and effect conclusions.

43. This secondary analysis only shows results for the DHA group. Yet, only analyses that compare results between an active ingredient and placebo group can result in cause and effect conclusions. Here, this secondary analysis was merely a within group comparison of DHA blood levels and test scores within one group, the DHA group.

44. Even if a comparison of regression analyses within groups had been performed, correlations of the sort that were performed in this secondary analysis cannot be used to reach cause and effect conclusions. At best, such correlation analyses can produce hypotheses that require subsequent testing through RCTs.

45. Moreover, even if this correlation could be deemed a positive result, which it cannot, it is an accepted convention among experts in the field that in interpreting the results of a study such as this one, where multiple tests/measures/endpoints are employed, the existence of one positive result within numerous negative results still means that the results of study have shown that the substance being studied is no better than placebo. In other words, it is improper, under accepted scientific conventions in interpreting results of clinical studies such as this one where multiple tests are employed, to cherry pick individual results and,

[6] They state that these subjects were excluded because their DHA levels did not go up even though they were taking the supplement. This is not a valid reason to exclude these subjects in the intent to treat design that the authors claimed that they were following.

instead, one must view the results of each study as a whole.

46. Furthermore, under standard scientific conventions of interpreting results from RCTs, this one secondary analysis (if it even was pre-planned, which it was not), must be read in the context of the results of the primary endpoints in which it was clearly found that DHA was no better than placebo with regard to cognitive function. Under accepted scientific conventions, experts in the field would deem the results of this study to show that DHA supplementation of 400mg per day was no better than placebo in supporting brain function and this, in fact, is the conclusion of the authors where they state: "For each test, results indicated that changes from baseline to end of treatment were not statistically significantly different between the docosahexaenoic acid group and the placebo group."

47. Even the authors of the *Ryan et al*. study, whose lead investigator was employed by Martek, were constrained about the conclusions to be drawn from this secondary analysis on blood levels and only stated: "That healthy children *may* benefit from DHA supplementation is promising" (emphasis added). In other words, this secondary analysis could not be relied upon to reach the conclusion that DHA was proven to and *did* provide a benefit to healthy children.

48. As a result, following accepted conventions of study result interpretation, these Martek employed authors were constrained to conclude "further studies are needed to further elucidate the effects of DHA supplementation on cognitive function in healthy children." This is because even though this regression analysis may have found a correlation between high DHA levels and test results in the DHA group, the fact still remains that the test scores of the DHA group were no better than the placebo group (the primary endpoint of the study).

49. Thus, this secondary analysis, at best, under accepted scientific principles, was an exploratory analysis and could not and should not be deemed one upon which cause and effect conclusions can be made.

50. In a 2009 RCT, David Kennedy and colleagues examined the effects of 400 or 1000 mg[7] of DHA per day compared to placebo on a battery of cognitive tests in children ages 10 to 12. *See* Kennedy, DO, et al., *Cognitive And Mood Effects Of 8 Weeks' Supplementation With 400 Mg Or 1000 Mg Of The Omega-3 Essential Fatty Acid Docosahexaenoic Acid (DHA) In Healthy Children Aged 10–12 Years*, 12 Nutr. Neurosci. 48-56 (2009). At a dose of 400 mg per day, scores on 1 of 35 measures improved while 1 score out of 35 was worse upon 1000 mg per day, and no effect was observed on 68 other measures. *Id.* Because so many tests were conducted, with regard to the one positive and the one negative finding the authors appropriately concluded that these two outlier results were due to chance and that the 34 results that showed no effect by their sheer weight were not due to chance and demonstrated a lack of efficacy. *Id.* Thus, the authors concluded: "The results here do not suggest that supplementation with these doses of DHA for 8 weeks has any beneficial effect on brain function in cognitively intact children." *Id.*[8]

51. Similarly, a RCT reported by McNamara, RK, et al., *Docosahexaenoic Acid Supplementation Increases Prefrontal Cortex Activation During Sustained Attention In Healthy Boys; A Placebo-Controlled, Dose-Ranging, Functional Magnetic Resonance Imaging Study*, 91 Am. J. Clin. Nutr., 1060-7 (2010), examined the effect of 400 or 1200[9] mg DHA per day compared to placebo on attention scores in healthy boys. For the one primary registered endpoint "performance on sustained attention task"[10] (that was measured four ways), McNamara and colleagues reported

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[7] Four to ten times the recommended daily dose of the Product.

[8] The *Kennedy* study also examined whether DHA supplementation had any consistent or meaningful effect on mood in children ages 10-12. The study's authors concluded that it did not. *Id.* at 54, 55-56.

[9] Four times and twelve times the daily recommended dose of the Product.

[10] See https://clinicaltrials.gov/ct2/show/NCT00662142?term=mcnamara+and+martek&rank=1. As noted above, every clinical trial that is registered at clinicaltrial.gov, must set forth, among other things, the endpoints that the study is designed to examine. Under universally accepted scientific protocols, conclusions can only be drawn from the results of the registered endpoints.

no effects of DHA on all 4 measures at either the 400mg or 1200mg doses.

52. The study also measured whether DHA supplementation increased brain activation. The results showed for the DHA group as compared to the placebo group increased activation in the dorsal lateral prefrontal cortex and pre-central gyrus, but decreases in the bilateral occipital cortex. While this may have been an observed effect, it is of no meaning in the context of whether DHA provides any brain health benefits because, notwithstanding this reported increased activation, the subjects taking DHA did not perform any better on the cognitive testing than did those given placebo.

53. Finally, in a 2012 RCT, Alexandra Richardson and colleagues examined placebo or 600 mg[11] of DHA per day for 16 weeks in school children ages 7 to 9 who were under the 33rd percentile in reading scores. *See* Richardson, AJ, et al., *Docosahexaenoic Acid For Reading, Cognition And Behavior In Children Aged 7–9 Years: A Randomized, Controlled Trial (The DOLAB Study)*, PLoS One, 7:e43909 (2012). As set forth in the study report, the original protocol for the study was to select children in the twentieth or below percentile in reading, but because they could not recruit enough subjects for the study to be adequately powered, they raised the inclusion criteria to the 33% percentile or below. The results of the study, as registered and designed by its authors, concluded that there were no differences between DHA and placebo on reading scores, reading age, two working memory scores or 14 behavior scores whether rated by parents, teachers or using intent-to-treat (all subjects) or per protocol design (only those who completed the study). *Id.* Thus, this study showed no efficacy.

54. The report proffers a purported secondary analysis on results for those subjects that were in the twentieth percentile or below. This analysis was not a registered endpoint with clinicaltrials.gov and thus, cannot be deemed an endpoint

[11] Six times the recommended daily dose of the Product for adults and children 4 and older.

upon which cause and effect conclusions can be reached. Further, the authors did not find sufficient subjects in the twentieth percentile to conduct an adequately powered study – a requirement for drawing any cause and effect conclusions. As a result, any conclusions derived from the subset of twentieth percentile or below subjects can only be deemed hypotheses for further study and cannot serve as a basis for cause and effect conclusions. This is due to the fact that when a study or subgroup analysis is not adequately powered, it is accepted by experts in the field that any such results can also be due to chance.

55. As noted above, all of the RCTs using the DHA in the Product, while in far larger doses, showed no brain function benefits. Furthermore, while all of these studies that showed no effect were on healthy children, the results of these studies can be and are used to extrapolate to healthy adults by experts in the field. This is due to the fact that adults are no longer accreting DHA in their brains, and the scientific evidence is that as humans age their need for DHA decreases over time (e.g., pre-natal and up to age 2 DHA has been shown to provide brain health benefits, but no effects have been shown after the age of 2).

56. These scientific studies establish that there is no cause and effect relationship between intake of DHA dietary supplements like the DHA in Bayer's product and brain function. Thus, Bayer's brain function representations are false and misleading and reasonably likely to deceive the consumer.

57. In addition to, and separately from, the evidence from RCTs, the Product cannot support brain function or brain support because: (1) a trivial and meaningless amount of DHA is provided to the brain by the Product; and (2) American children and adults get sufficient DHA in their daily diet.

58. While *molecular* DHA does play a role in the brain, this does not mean *supplemental* DHA supports brain function. Much as the brain needs oxygen to function, humans do not need to supplement their diets with oxygen; nor do humans

need DHA supplementation. In fact, there is only one reported case of Omega-3 deficiency in the United States in the last thirty years and it involved a girl on an intravenous diet.

59. In this regard, it should also be understood that the human body produces DHA from other Omega-3 fatty acids that are consumed on a daily basis. As result, the target population for this Product produces sufficient amounts of DHA from a variety of dietary sources, even if they do not consume dietary DHA from such foods as fish rich in DHA.

60. Furthermore, a trivial amount of the DHA in a daily dose of the Product actually enters the brain – so small that experts in the field deem this amount as incapable of providing any brain function or brain support benefit. Based on the amount of DHA available to the brain in the plasma pool and the amount of DHA the brain uptakes from this plasma pool, it is estimated that approximately 0.0005% of an oral dosage enters the brain in 24 hours. And, because the brain contains about 5000 mg of DHA, a daily dose of the Product would only replace about .000005% and .00001% of the brain's DHA content in children 2-3 years of age and adults and children over 4, respectively, on a daily basis. While these estimates may vary as much as 10-100 times in either direction, even at the highest point in the estimate range (e.g. 100 x .00001% or .00100%), experts in the field deem this amount of DHA to be trivial and that it cannot contribute to brain function or brain support.

61. In this vein, the IOM—the health arm of the National Academies—has issued a report stating that it does not recognize a dietary requirement for DHA as there is no DHA deficiency in adults or children in the United States. *See* Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients): The National Academies Press; 2005 at 5-6, 11, 469. Specifically, the IOM concluded that Americans consume sufficient amounts of alpha-linolenic acid (ALA), a dietary precursor to DHA, in their daily

diet. ALA is converted to DHA by a series of enzymes, largely in the liver. Thus, the algal oil derived DHA in the Product has no effect on brain function or brain support as it is not an essential nutrient and American adults and children are already producing adequate amounts of DHA from its dietary precursor ALA.

62. Likewise, on April 22, 2014, the FDA, citing the 2005 IOM report, published a Final Rule that acted on and expressly rejected Martek Biosciences Corp.'s (the maker of the DHA in Bayer's Product) request that the FDA recognize a daily requirement for DHA.[12] *See* 79 Fed. Reg. 23262 *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-04-28/pdf/2014-09492.pdf. In doing so, the FDA acknowledged that there is no dietary requirement for DHA as it is not an essential nutrient. *Id.* The FDA's ruling applies to the entire U.S. population, including adults and children ages 2 years and older – Bayer's target market for the Product.

63. In sum, the DHA in the Product is superfluous and does not provide brain function or brain support benefits because: a) DHA is not an essential nutrient; b) Americans already get plenty of DHA in their diet; c) there are virtually no reported cases of a DHA deficiency in the United States; d) basic chemistry and biology show that the human body makes sufficient DHA by converting a different substance, ALA, into DHA; and e) the amount of DHA in Flintstones Healthy Brain Support is trivial and incapable of supporting brain function or brain support

64. Thus, the overwhelming weight of scientific evidence is that the DHA in a daily dose of Defendant's Product does not support brain function or provide brain support in U.S. consumers aged 2 and older.

Defendant is Unlawfully Selling Flintstones Healthy Brain Support in Violation of Federal and State Law

[12] The Martek notification proposed the following exact wording for these claims: "'Excellent source of DHA.' ('High in DHA,' 'Rich in DHA') contains ___ mg of DHA per serving, which is ___ % of the 160 mg daily value for DHA." 79 Fed. Reg. at 23263 n.3.

65. Flintstones Healthy Brain Support is a dietary supplement and governed by DSHEA.

66. DSHEA permits the makers of dietary supplements to make claims as to how their supplement affects the structure or function of the body without obtaining prior FDA approval provided certain requirements are met. 21 U.S.C. §§342, 343. One of these requirements is that the manufacturer must have substantiation that the claims are truthful and not misleading. 21 U.S.C. §343(r)(6)(B).

67. California's Sherman Food, Drug, and Cosmetic Law ("Sherman FD&C") (California's Health & Safety Code §§109875, et. seq.), parallels the FDCA in material part and adopts the Federal requirements for dietary supplements, including that dietary supplement claims be made in accordance with Section 403(r)(6) of the FDCA. Cal. Health & Safety Code § 110100(a).

68. The FDA has adopted the FTC's substantiation standard of "competent and reliable scientific evidence" for dietary supplements as described above.

69. Competent and reliable scientific evidence is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FDA Guidance of Industry, Ex. A. For products such as Flintstones Healthy Brain Support, adequate substantiation as required by experts in the relevant area consists of high quality RCTs.

70. There are no reliable or high quality RCTs substantiating any of the representations made by Defendant about Flintstones Healthy Brain Support.

71. By selling Flintstones Healthy Brain Support without the prerequisite competent and reliable scientific evidence/substantiation for these representations, Defendant has violated DSHEA and the Sherman Law.

The Impact of Bayer's Wrongful Conduct

72. Even though the DHA in the Product is trivial in amount, superfluous, and proven to not support healthy brain function, Bayer continues to unequivocally claim that its Product provides "brain support" and "Supports Healthy Brain Function" in children ages 2 and older, as well as adults.

73. Plaintiff and Class members have been and will continue to be deceived or misled by Bayer's deceptive brain function and brain support representations. Plaintiff purchased the Product during the relevant time period and in doing so, read and considered the Product label and based her decision to buy the Product on the brain function and brain support representations. Bayer's brain function and brain support representations were a material factor in influencing Plaintiff's decision to purchase the Product. Plaintiff would not have purchased the Product had she known that Bayer's brain function and brain support representations were false and misleading.

74. As a result, Plaintiff and the Class members have been damaged in their purchases of the Product and have been deceived into purchasing a Product that they believed, based on Bayer's representations, provides brain function benefits and brain support benefits, when, in fact, it does not.

CLASS DEFINITION AND ALLEGATIONS

75. Plaintiff Gershman brings this action on behalf of herself and all other similarly situated Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendants for violations of California state laws and/or similar laws in other states:

> **Multi-State Class Action**
> All Consumers who, within the applicable statute of limitations period, purchased Flintstones Healthy Brain Support in California, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington until the date notice is disseminated.

> Excluded from this class are Defendant and its officers, directors, and employees and those who purchased Flintstones Healthy Brain Support for re-sale.

76. Alternatively, Plaintiff Gershman brings this action on behalf of herself and all other similarly situated California consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class:

> **California-Only Class Action**
> All California consumers who, within the applicable statute of limitations, purchased Flintstones Healthy Brain Support until the date notice is disseminated.
>
> Excluded from this Class are Defendant and its officers, directors and employees, and those who purchased Flintstones Healthy Brain Support for the purpose of resale.

77. **Numerosity.** The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class contains thousands of purchasers of Flintstones Healthy Brain Support who have been damaged by Bayer's conduct as alleged herein. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery.

78. **Existence and Predominance of Common Questions of Law and Fact**. This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the claims discussed above are false, or are misleading, or likely to deceive;

(b) whether Bayer's alleged conduct violates public policy;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Bayer engaged in false or misleading advertising; and

(e) whether Plaintiff and Class members are entitled to other appropriate remedies, including corrective advertising and injunctive relief.

79. ***Typicality.*** Plaintiff's claims are typical of the claims of the members of the Class because, *inter alia*, all Class members were injured through the uniform misconduct described above and were subject to Bayer's deceptive brain function/support representations that accompanied each and every bottle of Flintstones Healthy Brain Support. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class.

80. ***Adequacy of Representation***. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel 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 Class.

81. ***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 Bayer. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain effective redress for the wrongs done to them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances here.

82. 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 Class members.

83. Unless a Class-wide injunction is issued, Bayer will continue to commit the violations alleged, and the members of the Class and the general public will continue to be deceived.

84. 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
Violation of Business & Professions Code §17200, *et seq.*
(On Behalf of the California-Only Class)

85. Plaintiff Gershman repeats and re-alleges the allegations contained in the paragraphs above, as if fully set forth herein.

86. Plaintiff Gershman brings this claim individually and on behalf of the California-only Class.

87. The Unfair Competition Law, Business & Professions Code §17200, et seq. ("UCL"), prohibits any "unlawful" business act or practice.

88. As alleged herein, Defendant engaged in illegal conduct by unlawfully making the representations set forth above. Because Defendant did not have adequate substantiation that these representations were truthful and not misleading Defendant has committed unlawful business practices by violating California's Sherman Food, Drug and Cosmetic Law, California's Health & Safety Code §§ 109875, et seq. and the Food Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq. Plaintiff and the California-only Class reserve the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

89. Plaintiff and the California-only Class suffered "injury in fact"/economic loss by spending money on a Product that, but for Defendant's illegal conduct, would not have been on the market.

90. The FDA and Sherman Act misbranding/consumer protections are intended to ensure that any claims made about dietary supplements, as defined under the FDA law and regulations, to the consuming public (e.g., sold to Plaintiff and the Class), are truthful and not misleading.

91. The UCL unlawful prong is intended to hold a defendant who violates this prong accountable for its violations by, among other things, paying full compensation to purchasers who have purchased the illegally sold products.

92. But for Defendant unlawfully selling Flintstones Healthy Brain Support, Plaintiff and the California-Only Class would never have purchased this illegal Product. As result of Defendant's illegal conduct, Plaintiff and the California-Only Class have suffered injury/economic loss and are entitled to a full refund of their purchase price. Unless restrained and enjoined, Defendant will continue to engage in the illegal sale of the Product. Accordingly, injunctive relief is appropriate

93. Plaintiff, on behalf of herself, all other similarly situated California consumers, and the general public, seeks restitution of all money they paid for Defendant's illegally sold Product, an injunction prohibiting Defendant from continuing to sell the Product with the false representations set forth above, corrective advertising and all other relief this Court deems appropriate, consistent with Business & Professions Code §17203.

COUNT II
Violations of the Consumers Legal Remedies Act – Civil Code §1750 *et seq.*
(On Behalf of the Multi-State or California-Only Class)

94. Plaintiff Gershman repeats and re-alleges the allegations contained in the paragraphs above, as if fully set forth herein.

95. Plaintiff Gershman brings this claim individually and on behalf of the

Class.

96. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code §1750, et seq. (the "Act"). Similar statutes, identical in their material respects, are in effect in all states that are a part of the alleged Multi–State Class.

97. Plaintiff Gershman is a consumer as defined by California Civil Code §1761(d). Defendant's Flintstones Healthy Brain Support is a "good" within the meaning of the Act.

98. Defendant violated and continues to violate the Act by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiff Gershman and the Class which were intended to result in, and did result in, the sale of Flintstones Healthy Brain Support:

> (5) Representing that [Flintstones Healthy Brain Support has] . . . approval, characteristics, . . . uses [and] benefits . . . which [it does] not have . . . .
>
> * * *
>
> (7) Representing that [Flintstones Healthy Brain Support is] of a particular standard, quality or grade . . . if [it is] of another.
>
> * * *
>
> (9) Advertising goods . . . with intent not to sell them as advertised.
>
> * * *
>
> (16) Representing that [Flintstones Healthy Brain Support has] been supplied in accordance with a previous representation when [it has] not.

99. Defendant violated the Act by misrepresenting material facts on the Flintstones Healthy Brain Support labeling and packaging and associated advertising, as described above, when the representations were false and misleading.

100. As alleged herein, Plaintiff has suffered injury in fact and lost money or property as a result of Defendant's conduct because she purchased Flintstones

Healthy Brain Support in reliance on Defendant's false representations.

101. Plaintiff and other members of the Class have in fact been deceived as a result of their reliance on Defendant's material false representations described above. This reliance has caused harm to Plaintiff and other members of the Class who each purchased Flintstones Healthy Brain Support. Plaintiff and the other Class members have suffered injury in fact and lost money as a result of these deceptive and fraudulent practices.

102. Pursuant to California Civil Code §1782(d), Plaintiff Gershman and the Class seek a Court order enjoining the above-described wrongful acts and practices of Defendant and for restitution and disgorgement.

103. Pursuant to §1782 of the Act, Plaintiff Gershman notified Defendant in writing by certified mail of the particular violations of §1770 of the Act and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendant's intent to so act. A copy of the letter is attached hereto as Exhibit B.

104. If Defendant fails to rectify or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act, Plaintiff Gershman will amend this Complaint to add claims for actual, punitive and statutory damages, as appropriate.

105. Pursuant to §1780(d) of the Act, attached hereto as Exhibit C is the affidavit showing that this action has been commenced in the proper forum.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

A. Certifying the Class as requested herein;

B. Awarding restitution and disgorgement of Defendant's revenues to Plaintiff and the proposed Class members;

C. Awarding injunctive relief as permitted by law or equity, including: enjoining Defendant in California from continuing the unlawful practices as set forth herein;

D. Ordering Defendant to engage in a corrective advertising campaign;

E. Awarding attorneys' fees and costs; and

F. Providing such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial of her claims by jury to the extent authorized by law.

Dated: December 4, 2014

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.

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EXHIBIT A

Food

Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act

Contains Nonbinding Recommendations

December 2008

Additional copies are available from:
Office of Nutrition, Labeling, and Dietary Supplements
HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2375 (Updated phone: 240-402-2375)
http://www.cfsan.fda.gov/guidance.html

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov[1]. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
December 2008

OMB Control No. 0910-0626
Expiration Date: 08/31/2011
See additional PRA statements in Section III of this guidance

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Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Guidance for Industry[(1)]
Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

A. *What Does This Guidance Document Address?*

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim[(2)] have substantiation that the claim is truthful and not misleading.[(3)]

This guidance document is intended to describe the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403(r) (6) of the Act. This guidance document is limited to issues pertaining to substantiation under section 403(r)(6) of the Act; it does not extend to substantiation issues that may exist in other sections of the Act.[(4)]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

B. *Why Is Guidance on Substantiation Helpful?*

The Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and the legislative history accompanying DSHEA do not define "substantiation." For this guidance, we drew upon our own expertise with respect to the regulations and case law regarding substantiation of various statements that may be made in the labeling of dietary supplements, conventional foods, and drug products (recognizing that conventional foods and drugs are regulated differently from dietary supplements), the Federal Trade Commission's (FTC) experience with its policy on substantiating claims made for dietary supplements in advertising, and recommendations from the Commission on Dietary Supplement Labels.

The Commission on Dietary Supplement Labels (the Commission), a seven-member body that was established under DSHEA to "provide recommendations for...the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims," held public meetings around the United States from 1996 through 1997. During these meetings, several manufacturers asked the Commission to provide guidance regarding the type of information that manufacturers should have in hand to substantiate a statement of nutritional support.[(5)]

Under the Act, FDA has exclusive jurisdiction over the safety, and primary jurisdiction over the labeling, of dietary supplements. The FTC has primary jurisdiction over advertisements for dietary supplements. Given these jurisdictional assignments, we and the FTC share an interest in providing guidance on what "substantiation" means. In April 2001, FTC issued a guidance document entitled, "Dietary Supplements: An Advertising Guide for Industry."[(6)] Our guidance document is modeled on, and complements, the FTC guidance document.

Dietary supplement manufacturers should be familiar with the requirements under both DSHEA and the Federal Trade Commission Act that they have substantiation that labeling and advertising claims are truthful and not misleading. Our approach provides manufacturers flexibility in the precise amount and type of evidence that constitutes adequate substantiation. Providing a standard for substantiation may also help to preserve consumer confidence in these products. To ensure compliance with the Act, we recommend that dietary supplement manufacturers carefully draft their labeling claims and carefully review the support for each claim to make sure that the support relates to the specific product and claim, is scientifically sound, and is adequate in the context of the surrounding body of evidence.

The FTC has typically applied a substantiation standard of "competent and reliable scientific evidence" to claims about the benefits and safety of dietary supplements and other health-related products. FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach. This guidance document, using examples of claims that might be made for a dietary supplement, describes criteria to be considered in evaluating the nature of the claim and the amount, type, and quality of evidence in support of the claim.

II. Discussion

A. *What is the Substantiation Standard?*

The FTC standard of competent and reliable scientific evidence has been defined in FTC case law as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[(7)]

Although there is no pre-established formula as to how many or what type of studies are needed to substantiate a claim, we, like the FTC, will consider what the accepted norms are in the relevant

research fields and consult experts from various disciplines. If there is an existing standard for substantiation developed by a government agency or other authoritative body, we may accord some deference to that standard.

In determining whether the substantiation standard has been met with competent and reliable scientific evidence, we recommend that firms consider the following issues in their assessment:

1. The meaning of the claim(s) being made;
2. The relationship of the evidence to the claim;
3. The quality of the evidence; and
4. The totality of the evidence.

Each of these issues is discussed further in this guidance.

B. *Identifying the Meaning of the Claim*

The first step in determining what information is needed to substantiate a claim for a dietary supplement is to understand the meaning of the claim and to clearly identify each implied and express claim. When a claim may have more than one reasonable interpretation, we recommend that a firm have substantiation for each interpretation. Consumer testing may be useful to determine consumer understanding of each claim, in context. We recommend that firms not only focus on individual statements or phrases, but also on what expected effect or benefit are being promoted when all of the statements being made for the product are considered together. Although it is important that individual statements be substantiated, it is equally important to substantiate the overall "message" contained when the claims are considered together.

Example 1: The label of a dietary supplement containing "X" uses the following claims: "The amino acid 'X' is the chemical precursor to nitric oxide. Blood vessel cells contain enzymes that produce nitric oxide. Nitric oxide is important in maintaining blood vessel tone." Assuming this statement were supported by sound science so that each individual statement was substantiated, the "message" conveyed by the claims, when considered together, is that taking oral "X" will affect nitric oxide production and blood vessel tone. Therefore, we recommend in this case that the dietary supplement manufacturer have substantiation that taking the amount of "X" provided by the product affect nitric oxide production and blood vessel tone under the product's recommended conditions of use.

The firm's clear understanding of the meaning of the claim is useful in ensuring that the evidentiary basis for substantiation is appropriate for the claim. Understanding the claim's meaning will help identify the appropriate study hypotheses and measurable endpoints, which can be used to ensure that the firm has appropriate studies to substantiate the claim. For example, a firm making a claim that a dietary supplement "helps maintain blood vessel tone" or "supports healthy immune system" should have a clear understanding of the claim's meaning to develop endpoints that could be measured and replicated in studies used as a basis for substantiation.

Example 2: The labeling of a dietary supplement includes the statement "promotes weight loss." The dietary supplement contains various vitamins and minerals and a botanical extract. The manufacturer relies on a randomized controlled double blind clinical study showing that subjects who took the botanical extract had a small but significant increase in metabolism over subjects taking a placebo over a 24 hour period. The study did not examine the effect of the extract on subjects' weight and there is no research showing that a short term increase in metabolism will translate into any measurable weight loss. The weight loss claim would likely not be adequately substantiated.

Example 3: The labeling for a dietary supplement contains a statement saying, "Recommended by Scientists," in connection with the product's claim. The statement gives consumers the impression that there is a body of scientists, qualified experts, who believe that the claim being made is supported by evidence. Consumers might also reasonably interpret the statement as meaning that there is general scientific agreement or consensus regarding the claim. If the manufacturer does not possess evidence to demonstrate such a consensus, the claim may not be substantiated. The opinion of a single scientist or small group of scientists is probably not adequate substantiation for such a claim.

Example 4: The labeling states, in connection with the product's claim, that the dietary supplement has been "studied for years" in a particular country or region and is the subject of clinical or "university" research. Here, the labeling conveys the impression that the product has been studied and also conveys the impression that there is a substantial body of competently conducted scientific research supporting the claim. We recommend that manufacturers possess evidence to substantiate both the express statements and their implied meaning.

C. *The Relationship of the Evidence to the Claim*

Whether studies or evidence have a relationship to the specific claim being made or to the dietary

supplement product itself is an important consideration in determining if a claim is substantiated. The following are some threshold questions in determining this relationship:

- *Have the studies specified and measured the dietary supplement that is the subject of the claim?* We recommend that the studies being used as substantiation for dietary supplement claims identify a specific dietary supplement or ingredient and serving size and that the conditions of use in the studies are similar to the labeling conditions of the dietary supplement product. Factors that would tend to indicate a stronger relationship between a substance that is the subject of a study and the substance that is the subject of the dietary supplement claim includes similarities in formulation, serving size, route of administration, total length of exposure, and frequency of exposure. Manufacturers should be aware that other substances involved in the study or included in the dietary supplement product itself might also affect the dietary supplement's performance or the study results.

Example 5: To illustrate this issue, assume that a firm has high quality studies that are also consistent with the totality of the scientific evidence. The firm would like to use these studies to substantiate a claim that its dietary supplement has a particular effect on the human body, but the studies involved the impact of a specific ingredient in foods on the human body, and did not involve the dietary supplement product itself. In this instance, although the studies might be of high quality, the results of these studies of conventional foods are not applicable to the specific dietary supplement product.[(8)]

- *Have the studies appropriately specified and measured the nutritional deficiency, structure/function, or general well-being that is the subject of the claim?* We recommend that the studies clearly identify the endpoints that are to be used to substantiate the claimed effect.
- *Were the studies based on a population that is similar to that which will be consuming the dietary supplement product?* For example, if the study involved young adults, but the product's claims involve conditions seen only in the elderly, the study might not be applicable to the claims.
- *Does the claim accurately convey to consumers the extent, nature, or permanence of the effect achieved in the relevant studies and the level of scientific certainty for that effect?*

A note on foreign research: Foreign research could be sufficient to substantiate a claim as long as the design and implementation of the foreign research are scientifically sound and the foreign research pertains to the dietary supplement at issue. In evaluating data from studies conducted in a foreign population, care should be taken in extending the results to what might be expected in consumers in the United States who will use the product. Differences between the two populations, such as differences in diets, general health, or patterns of use, could confound the results. Also, it is important to make sure that the study examined the same dietary ingredient about which the claim is being made since there may be instances where, due to provincial or regional differences in custom, language, or dialect, the same name is given to different substances or different names to the same substance.

Example 6: A firm claims that its dietary supplement contains an ingredient shown to promote claim Y. The firm conducts a literature search and finds several references for carefully conducted, well-controlled studies demonstrating that the substance appears to be helpful in persons with claim Y associated with aging when the substance is applied topically to the affected area. However, there is no information provided concerning the effect of the substance when taken orally. Although the evidence may demonstrate that the product is effective when used topically, this information would generally not be useful to substantiate a claim for a dietary supplement (by definition, a product that is intended for ingestion (section 201(ff)(2)(A) of the Act (21 U.S.C. 321(ff)(1)(A))).

Example 7: A dietary supplement firm wants to promote an amino acid product to improve blood circulation and improve sexual performance. The firm conducts a literature search and finds many abstracts and articles about the amino acid's effect on biological mediators of circulation and a few animal and human studies designed to study the effect of the amino acid on blood flow. The firm intends to use this list of studies as substantiation for its claim.

Although the firm appears to have a significant amount of information for its claim, the list is likely not adequate because the firm has not demonstrated that the information is directly related to the claim being made. For example, in this situation we would recommend that the firm provide information to clarify the meaning of "improves blood circulation" and "improves sexual performance." We would also recommend that the firm determine whether the studies examined a dosage of product similar to the firm's product and whether any study measured outcomes (i.e., improved sexual performance) other than blood flow/blood circulation. Until the firm has reviewed the underlying studies, it should not assume that merely finding studies testing the same substance necessarily constitutes adequate substantiation.

Example 8: A firm wishes to market its mineral supplement by using a claim that "studies show that the mineral supplement promotes "Z." The firm has the results of a randomized, double blind, placebo-

controlled study conducted in a foreign country showing that a similar product did, in fact, promote "Z," although the study indicates that the foreign study subjects had low blood levels of the mineral at the start of the study. The general U.S. population does not have such a mineral deficiency. Although this study is a high quality study, it may not be adequate to substantiate a claim about the product's use intended for consumers in the United States because it is confounded by the initial abnormal blood levels of the mineral. Since the study is not designed to answer the question of whether the effect would be expected to occur in subjects with normal blood levels of the mineral, the study may not be adequate evidence to substantiate the claim.

Example 9: A firm is marketing a product specifically to reduce nervousness during stressful everyday situations, such as public speaking. The firm has results from several small studies demonstrating that the product will raise blood levels of a chemical that is well known to relax people in stressful situations. The firm also has two small, randomized, placebo-controlled studies showing that its product positively affected measurable indices of anxiety in people placed in stressful situations, including public speaking. These studies may be adequate evidence to support the product claims. Although the studies may be small in terms of the numbers of subjects tested, they are well-designed studies that resulted in statistically significant positive results that are consistent with the larger body of scientific evidence related to stress anxiety in public situations.

Example 10: A firm has developed a product to improve memory and cognitive ability and intends to market the product to parents for their school-aged children. The firm has several high quality clinical studies that examined the ingredient's effect in elderly people with diagnosed, age-related memory problems. These studies alone would likely not be adequate substantiation for a claim about memory improvement in young children because the patient population (elderly people with memory problems) is completely different from the intended population (children) in the claim.

Example 11: A dietary supplement firm is marketing an iron dietary supplement with the claim that the dietary supplement is to correct iron-deficiency anemia in the 10% of menstruating women with menorrhagia. The firm has not studied the product in this population of women directly, but has assembled and carefully reviewed the scientific literature of studies that have investigated the oral dosage and intestinal absorption of the type of iron used in its product, both in the population in general, and in women that match the target consumer of the product. Using this information, the firm has formulated its product to provide the amount of bioavailable iron needed by this population of women. Even though the firm did not test its product directly, it has examined the existing scientific literature and has formulated the product in a manner to meet the standards of products shown effective in well-controlled studies. There is, therefore, a basis to conclude that the existing literature is applicable to the product in the target population in which it is intended. Thus, the firm's claim that the product will be useful in correcting iron-deficiency anemia would likely be adequately substantiated.

Example 12: A firm claims that its multi-vitamin, multi-mineral product "provides the vitamins and minerals needed to promote good health and wellness." In this case, the firm's claim is likely substantiated by the substantial scientific evidence showing that certain vitamins and minerals are essential nutrients that are needed to maintain good health, even though the firm does not have data from specific scientific studies to show that its product results in any measurable outcome. Scientific evidence studying the firm's particular product formulation probably would not be needed for this claim unless the firm were to make claims that its formulation is different or superior to other formulations or confers benefits above and beyond the benefits demonstrated to be associated with adequate intake of vitamins and minerals.

D. *The Quality of the Evidence*

In deciding whether studies substantiate a claim, an important consideration is the scientific quality of studies. Scientific quality is based on several criteria including study population, study design and conduct (e.g., presence of a placebo control), data collection (e.g., dietary assessment method), statistical analysis, and outcome measures. For example, if the scientific study adequately addressed all or most of the above criteria, it could be considered of high quality. Generally accepted scientific and statistical principles should be used to determine the quality of the studies used as evidence to substantiate a claim. The "gold" standard is randomized, double blind, placebo-controlled trial design. However, trials of this type may not always be possible, practical, or ethical. There are several systems available to rate scientific information.[(9)] Firms making claims are encouraged to refer to these systems when developing substantiation for claims or relying on existing information. The following provides some commonly accepted scientific principles in evaluating the quality of scientific evidence.

What Are the Types of Evidence that May Substantiate a Claim?

As a general principle, one should think about the type of evidence that would be sufficient to substantiate a claim in terms of what experts in the relevant area of study would consider to be

competent and reliable. Competent and reliable scientific evidence adequate to substantiate a claim would consist of information derived primarily from human studies.

Human studies can be divided into two types: *intervention* studies and *observational* studies.[10] Of these types of studies, intervention studies can provide causal evidence to substantiate the effect of a dietary supplement in humans because they can evaluate the product's direct effect in the human body. Observational studies have a more limited ability than intervention studies to distinguish relationships between a substance and the outcomes being evaluated and cannot provide causal evidence.

- *Intervention studies*

  In intervention studies, an investigator controls whether the subjects receive the treatment or intervention of interest in order to test whether the intervention or treatment supports a pre-determined hypothesis. Firms should determine the hypothesis that should be supported or tested prior to identifying supportive documentation or developing a study protocol. Randomized, double blind, parallel group, placebo-controlled trials offer the greatest assessment of a relationship between a dietary supplement and an outcome. Although intervention studies are the most reliable studies for determining a cause-and-effect relationship, generalizing from such evidence on selected populations to different populations may not be scientifically valid. For example, as described in *Example 10* above, if there is evidence to demonstrate a relationship in a specific population (elderly patients with diagnosed age-related memory problems), then such evidence should not be extrapolated to a different population (children).

- *Observational studies*

  In observational studies, the investigator does not have control over the exposure to the treatment or intervention of interest. In prospective observational studies, investigators recruit subjects and observe them before a particular outcome occurs. In retrospective observational studies, investigators review the records of subjects and interview subjects after the outcome has occurred. Retrospective studies are usually considered to be more vulnerable to recall bias (error that occurs when subjects are asked to remember past behaviors) and measurement error, but are less likely to require large sample size, cost, or encounter the ethical problems that may occur in prospective studies. Types of observational studies include:

  - Case reports, which describe observations of a single subject or a small number of subjects.
  - Case-series studies, which are a descriptive account of a series of "outcomes" observed over time and reported for a group of subjects. No control group is described.
  - Case-control studies, which compare subjects with a condition (cases) to subjects who do not have the same condition (controls). Subjects are enrolled based on their outcome rather than based on their exposure.
  - Cohort studies, which compare the outcome of subjects who have been exposed to the substance to the outcome of subjects who have not been exposed.
  - Cross-sectional (prevalence) studies, which compare, at a single point in time, the number of individuals with a condition who have been exposed to a substance to the number of individuals without the condition who were not exposed to the substance.
  - Time-series studies, which compare outcomes during different time periods, e.g., whether the rate of occurrence of a particular outcome during one five-year period changed during a subsequent five-year period.
  - Epidemiological studies, which compare the rate of a condition across different populations.

What types of information are useful as background to support a claim?

The following additional types of information would generally be considered background information, but alone may not be adequate to substantiate a claim.

- *Animal studies* - Animal studies may provide useful background on the biological effects of a substance. However, they often have limited or unknown value in predicting the effect of the substance in humans. Care should be exercised in extrapolating results obtained in animal research directly to the human condition. The strongest animal evidence is based on data from studies in appropriate animal models, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship. Without any data from human studies, the results of animal studies alone are not sufficient to substantiate a claim.
- *In vitro studies* are studies that are done outside a living body. For example, such studies might examine a product's effect on isolated cells or tissues. These studies are of limited value in predicting the effect of a substance when consumed by humans. The strongest in vitro evidence

would be based on data that have been reproduced in different laboratories, but this evidence alone would not substantiate a claim.

- *Testimonials and other anecdotal evidence* - This type of evidence includes descriptions of experiences of individuals using a dietary supplement product or ingredient. It might also include descriptions of the use of the product or ingredient by others, for example, by other cultures in the past or present. It might consist of an opinion or statement of an expert or someone who endorses the product. Anecdotal evidence generally would not be sufficient to substantiate claims regarding a dietary supplement's effect because each individual's experience might be attributable to factors other than the dietary supplement itself. For example, a person might have experienced a placebo or coincidental effect, rather than an effect attributable to the dietary supplement itself. Additionally, the "honest opinion" of a consumer testimonial or an expert endorsement would not be enough to substantiate a claim; rather, the endorsement should also be supported by competent and reliable scientific evidence.
- *Meta-analysis* is the process of systematically combining and evaluating the results of clinical trials that have been completed or terminated. Meta-analysis may identify relevant reports, which may provide substantiation for the claim.
- *Review articles* summarize the findings of primary reports. Review articles may identify relevant primary reports, which may provide substantiation for the claim. Review articles may also provide background information that is useful to understand the scientific issues about the relationship between the substance and the claimed effect.
- *Comments and Letters to the Editor* usually focus on a particular issue or issues from a study, presentation at a meeting etc. Comments generally do not present the results of a study. Comments and letters to the editor may identify relevant primary reports, which may provide substantiation for the claim. Comments and letters to the editor may also provide background information that is useful to understand the scientific issues about the relationship between the substance and the claimed effect.
- *Product monographs* are prepared by the manufacturer to convey specific information about a product such as its specifications. Product monographs may provide background information that is useful to understand the scientific issues about the relationship between the substance and the claimed effect.

Example 13: A dietary supplement claim states, "Data suggest that including Substance X in the diet may promote brain neuron health in healthy individuals." The firm cites a study in which rats were fed diets containing Substance X and the brains of all rats were examined for ischemia-induced brain damage. The study does not provide a basis that Substance X would have the same effect on brain health in otherwise healthy humans. This study alone likely would not provide adequate substantiation of the claim being made because it relies solely on animal data.

Example 14: A dietary supplement claim states, "Grain Y has been used effectively for centuries to promote gastrointestinal health." The firm has no clinical studies in humans, but has an industry monograph that relies only on historical descriptions of grain Y use by pre-modern civilizations. Although the monograph may be an accurate review of the historical use of grain Y, it would likely not constitute competent and reliable evidence to support the claim because it is not based on objective scientific evidence. Rather, it is largely anecdotal evidence that cannot be objectively evaluated to determine if it applies to the consumers who would use the product.

Example 15: A dietary supplement label claims that, in laboratory tests (i.e., in vitro tests), the enzymes in the supplement can digest up to 20 grams of protein and 15 grams of dietary fat, and the firm is promoting the supplement to assist in breaking down protein and fat that its users eat. The firm has not tested its product or the ingredients in the supplement in humans. Although this evidence may be accurate, it would generally not be adequate substantiation for the claimed effects on dietary components because it is insufficient for reaching a conclusion on whether the enzymes, when consumed, would behave equivalently in the human body. Corroborating evidence from some human studies would likely be needed to determine if the in vitro findings reflect the outcomes of the product when consumed by humans.

Example 16: A botanical product label uses the claim "improves vitality." The substantiation that the firm is relying upon consists of testimonial experience it has collected from consumers and descriptions of the botanical product's traditional use. Although the firm may have testimonial experience to back up the basic claim being made, the claimed benefit would likely not be adequately substantiated because neither source is based on scientific evidence. If the firm wants to make a claim of this type, we recommend that it have scientific evidence that some measurable outcome(s) associated with the general conditions cited in the claim is (are) significantly improved.

What Design Factors Affect the Quality of a Study?

Multiple factors should be considered in study design. These include, but are not limited to:

- *Bias, confounders, and other limitations* - Potential sources of bias include lack of appropriate randomization and blinding, the number of subjects called for in the protocol vs. the number of subjects who actually participated in the trial, demographics, adequacy of primary variables, compliance, control agent, drop-outs, statistical procedures, subgroup analysis, safety issues, and reproducibility of results. Confounders are factors that are associated with the outcome in question and the intervention and prevent the measured outcome from being attributed unequivocally to the intervention. Potential confounders include variability in the quantity of the dietary supplement being administered or the presence of other dietary ingredients that may have their own independent effects. These factors can limit the reliability of the study.
- *Quality assessment criteria* - Factors that contribute to higher quality studies include:
  - Adequacy and clarity of the design
    - The questions to be answered by the study are clearly described at the outset.
    - The methodology used in the study is clearly described and appropriate for answering the questions posed by the study.
    - The duration of the study intervention or follow-up period is sufficient to detect an effect on the outcome of interest.
    - Potential confounding factors are identified, assessed, and/or controlled.
    - Subject attrition (subjects leaving the study before the study is completed) is assessed, explained, and reasonable.
  - *Population studied*
    - The sample size is large enough to provide sufficient statistical power to detect a significant effect. (If the study is underpowered, it may be impossible to conclude that the absence of an effect is not due to chance.)
    - The study population is representative (with respect to factors such as age, gender distribution, race, socioeconomic status, geographic location, family history, health status, and motivation) of the population to which the claim will be targeted.
    - The criteria for inclusion and exclusion of study subjects were clearly stated and appropriate.
    - The study used recruitment procedures that minimized selection bias.
    - For controlled interventions, the subjects were randomized. If matching was employed to assign the subjects to control and treatment groups, appropriate demographic characteristics and other variables were used for the matching. The randomization was successful in producing similar control and intervention groups.
- *Assessment of intervention or exposure and outcomes*
  - The analytical methodology and quality control procedures to assess dietary intake are adequate.
  - The dietary supplement serving size is well defined and appropriately measured.
  - The background diets to which the dietary supplement was added, or the control and interventional diets, are adequately described, measured, and suitable.
  - In studies with cross-over designs, the "wash-out" period (the period during which subjects do not receive an intervention) between dietary supplement exposures is appropriate. Lack of a sufficient wash-out period between interventions may lead to confusion as to which intervention produced the health outcome.
  - The form and setting of the intervention are representative of the way the product will be normally used.
  - Other possible, concurrent changes in diet or health-related behavior (weight loss, exercise, alcohol intake, and smoking cessation) present during the study that could account for the outcome identified are assessed and/or controlled.
  - The study's outcomes are well defined and appropriately measured
  - Efforts were made to detect harmful as well as beneficial effects.
- *Data Analysis and Assessment*
  - Appropriate statistical analyses were applied to the data.

- "Statistical significance" was interpreted appropriately.
- Relative and absolute effects were distinguished.

- *Peer Review* - The nature and quality of the written report of the research are also important. Although studies or evidence used to substantiate a claim do not have to be published in a peer-reviewed journal or publication, such publications do give some level of assurance that qualified experts have reviewed the research and found it to be of sufficient quality and validity to merit publication. In contrast, an abstract or informal summary of an article is less reliable, because such documents usually do not give the reader enough insight into how the research was conducted or how the data were analyzed to objectively evaluate the quality of the research data and the conclusions drawn by the authors. Moreover, the mere fact that the study was published does not necessarily mean that the research is competent and reliable evidence adequate to substantiate a particular claim.

Example 17: A dietary supplement label claims, "Randomized, double blind, placebo-controlled studies demonstrate that herbal extract 'Z' is beneficial in relieving menopausal symptoms." The firm is relying on the results of more than one randomized, double blind, placebo-controlled intervention study using menopausal women as subjects, and the results of those studies are in general agreement. The claim would likely be substantiated because it relies on high quality studies in humans that directly addressed conditions described in the claim.

E. *Consider the Totality of the Evidence*

How Well Does the Totality of Evidence Support the Claims?

In determining whether there is adequate evidence to substantiate a claim, one should consider the strength of the entire body of evidence, including criteria such as quality, quantity (number of various types of studies and sample sizes), relevance of exposure, and consistency and replication of the findings.

To determine whether the available scientific evidence is adequate to substantiate a claim, it is important to consider all relevant research, both favorable and unfavorable. Ideally, the evidence used to substantiate a claim agrees with the surrounding body of evidence. Conflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated. If conflicts or inconsistencies exist in the scientific evidence, one should determine whether there are plausible explanations for such conflicts or inconsistencies. For example, an inconsistency between two studies might be attributable to different concentrations of the dietary supplement, different test methodologies, different study populations,[(11)] or other factors.

There is no general rule for how many studies, or what combination of types of evidence, is sufficient to support a claim. However, the replication of research results in independently conducted studies makes it more likely that the totality of the evidence will support a claim.

Although the quality of individual pieces of evidence is important, each piece should be considered in the context of all available information; that is, the strength of the total body of scientific evidence is the critical factor in assessing whether a claim is substantiated.

Example 18: A firm intends to promote an herbal product "X" to "help maintain cognitive performance" of people who are fatigued. The firm has researched the scientific literature and found many studies that demonstrate that the botanical ingredient is effective. However, there are some studies that demonstrate no effect. Still other studies examined the botanical ingredient combined with other ingredients, typically caffeine, which demonstrated mixed positive and negative results. Many reports do not adequately describe the study participants and products examined. Consequently, it is not possible to explain the disparate results. However, the firm's review suggests that either the botanical and/or caffeine are the most likely dietary ingredients that act to maintain better cognition test results in fatigued study participants. As a result, the firm conducts a large, randomized, placebo-controlled study to compare the botanical ingredient against caffeine in the treatment of cognitive performance deficits associated with fatigue. The results demonstrate that caffeine improved cognition test results in all of the fatigued subjects that received caffeine, while test performance was unaffected in all subjects receiving the botanical ingredient. The study cannot explain the results reported in the earlier studies; however, it demonstrates that the botanical ingredient studied is most likely ineffective for improving or maintaining cognitive performance in fatigued people.

Example 19: A firm plans to promote its herbal product "to effectively relieve occasional, nocturnal leg cramps." The firm has one study demonstrating the product to be effective in ameliorating nocturnal leg cramps. The firm is also aware of several other randomized controlled trials that do not show a benefit. All these studies are of equal quality and used similar patient populations and test materials. When considered as a whole, even though some evidence to support the claim exists, the totality of the

evidence does not support the proposed claim. If no plausible explanation can be found to explain the disparate results, the available evidence would probably not be considered adequate to substantiate the claim.

Example 20: An herbal product is promoted "to help you get to sleep when you have difficulty falling asleep." The firm has one randomized, placebo-controlled study in volunteers who had trouble falling asleep. The study showed that those who used the product decreased the amount of time needed time to fall asleep. There are several other high-quality studies, however, that found that the herbal ingredient used in the product did not consistently help people get to sleep. It is not clear whether the different results of the various studies are a consequence of differences in product formulation or dosage or some other factor. Even though the firm's single study is positive, it may not provide adequate substantiation because the totality of existing evidence suggests that the herbal ingredient does not decrease time to fall asleep in persons who have trouble falling asleep. Given the contrary evidence against the claim, it is unlikely that this sleep-related claim would be substantiated for this product.

Example 21: A company plans to promote its product containing ingredient X to athletes "to improve endurance performance." There are some well-designed published studies demonstrating that other products containing ingredient X are effective, but other well-designed studies show no effect for certain products containing ingredient X. The firm sponsored a randomized, blinded, six-month study comparing its product to four other products containing ingredient X in a dose (serving size)-response fashion. The findings demonstrate that the firm's product and two other products that provided the highest amount of ingredient X per day produced substantial, statistically significant improvements in athletic endurance. When the firm compared the results of this study to prior studies, the firm concluded that the explanation for previous conflicting study results is that when the serving size of ingredient X is below a certain amount, there is no measurable benefit. Taken together, the positive results from their study, and the identification of a plausible explanation to explain why some studies showed no positive effects, would likely provide evidence to substantiate adequately the endurance performance claim for the dietary supplement.

F. *Conclusion*

Section 403(r)(6) of the Act requires dietary supplement manufacturers to have substantiation that structure/function, nutrient deficiency, and general well-being claims on a dietary supplement product's labeling are truthful and not misleading. To meet this statutory requirement, we recommend that manufacturers possess adequate substantiation for each reasonable interpretation of the claims. We intend to apply a standard that is consistent with the FTC standard of "competent and reliable scientific evidence" to substantiate a claim. We consider the following factors important to establish whether information would constitute "competent and reliable scientific evidence:"

- Does each study or piece of evidence bear a relationship to the specific claim(s)?
- What are the individual study's or evidence's strengths and weaknesses? Consider the type of study, the design of the study, analysis of the results, and peer review.
- If multiple studies exist, do the studies that have the most reliable methodologies suggest a particular outcome?
- If multiple studies exist, what do most studies suggest or find? Does the totality of the evidence agree with the claim(s)?

III. Paperwork Reduction Act of 1995

This guidance contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to range from 44 to 120 hours per response, depending on the nature of the claim, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Nutrition, Labeling, and Dietary Supplements, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0626 (expires 08/31/2011).

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(1) The Office of Nutrition, Labeling, and Dietary Supplements in FDA's Center for Food Safety and Applied Nutrition prepared this guidance document.

(2) Under section 403(r)(6)(A) of the Act (21 U.S.C. 343(r)(6)(A)), such a statement is one that "claims a benefit related to a classical nutritional deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient...."

(3) Comments to the Draft Guidance published November 9, 2004 (69 FR 64942), questioned the constitutionality, under the First Amendment, of the substantiation requirement in section 403(r)(6), as interpreted by the Draft Guidance. This Guidance offers FDA's non-binding interpretation of what constitutes substantiation and does not change the statutory or Constitutional requirement in any way. We believe the statutory substantiation requirement in section 403(r)(6) is constitutional under the Supreme Court's analysis governing commercial speech in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York (447 U.S. 557 (1980)). Claims made under section 403(r)(6) are misleading when made without substantiation. The misleading nature of a claim made under section 403(r)(6) that is not substantiated cannot be cured by a disclaimer stating that the claim lacks support. For example, a product cannot claim "to promote the structure and function of the skeletal system" and then attempt to cure the misleading nature of the claim with a statement "no evidence exists that this product promotes the structure and function of the skeletal system." However, nothing in this Guidance addresses the circumstances under which a claim made under section 403(r)(6) that includes qualifying language may be substantiated.

(4) This guidance does not discuss the criteria to determine whether a statement about a dietary supplement is a structure/function claim under section 403(r)(6) of the Act or a disease claim. Please see the *Federal Register* of January 6, 2000 (65 FR 1000, codified at 21 CFR 101.93) (www.cfsan.fda.gov/~lrd/fr000106.html) for the final rule defining structure/function claims for dietary supplements and the January 9, 2002 Small Entity Compliance Guide for structure/function claims (www.cfsan.fda.gov/~dms/sclmguid.html)(Updated web reference: Structure/Function Claims; Small Entity Compliance Guide[2]).

(5) See Report of the Commission on Dietary Supplement Labels, November 1997, at page 42. The Commission's recommendations on substantiation are at pages 42 through 45 of the report.

(6) See Bureau of Consumer Protection, Federal Trade Commission, "Dietary Supplements: An Advertising Guide for Industry," April 2001 (hereinafter referred to as "FTC Advertising Guide"), available at www.ftc.gov.

(7) *See, e.g. Vital Basics, Inc.,* C-4107 (Consent April 26, 2004); *see also In Re Schering Corp.,* 118 F.T.C. 1030, 1123 (1994).

(8) For example, a study using a conventional food or a multi-nutrient supplement would not substantiate a single ingredient dietary supplement claim. When the substance studied contains many nutrients and substances, it is difficult to study the nutrient or food components in isolation (Sempos, et al., 1999). It is not possible to accurately determine whether any observed effects of the substance were due to: 1) the substance alone; 2) interactions between the substance and other nutrients; 3) other nutrients acting alone or together; or 4) decreased consumption of other nutrients or substances contained in foods displaced from the diet by the increased intake of foods rich in the substance at issue. Furthermore, although epidemiological studies based on the recorded dietary intake of conventional foods have indicated a benefit for a particular nutrient, it has been subsequently demonstrated in an intervention study that the single ingredient nutrient-containing dietary supplement did not confer a benefit or actually was harmful. See Lichtenstein and Russell, 2005. We note that the D.C. Circuit Court in *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) indicated that FDA had "logically determined" that the consumption of a dietary supplement containing antioxidants could not be scientifically proven to reduce the risk of cancer where the existing research had examined only foods containing antioxidants as the effect of those foods on reducing the risk of cancer may have resulted from other substances. The court, however, concluded that FDA's concern with granting antioxidant vitamins a qualified health claim could be accommodated by simply adding a prominent disclaimer noting that the evidence for such a claim was inconclusive given that the studies supporting the claim were based on foods containing other substances that might actually be responsible for reducing the risk of cancer. Id. The court noted that FDA did not assert that the dietary supplements at issue would "threaten consumer's health and safety." Id. at 656. As the agency has stated in the context of qualified health claims, that is, claims regarding the relationship between a substance and the reduced risk of a disease, there is a more fundamental problem with allowing qualified health claims for nutrients in dietary supplements based solely on studies of foods containing those nutrients than the problem the D.C. Circuit held could be cured with a disclaimer. As noted in endnote 3, even if the effect of the specific component of the food constituting the dietary supplement could be determined with certainty, recent scientific studies have shown that nutrients in food do not necessarily have the same beneficial effect when taken in the form of a dietary supplement. Such studies established either that there was no benefit when the nutrients are taken as a supplement and some studies even showed

an increased risk for the very disease the nutrients were predicted to prevent. We would expect similar issues with structure/functions claims made under § 403(r)(6). Thus, an observational study based on food does not provide competent and reliable scientific evidence for a dietary supplement and, and therefore, cannot substantiate a claim made under § 403(r)(6).

(9) See "Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment Number 47, "Agency for Healthcare Research and Quality and Research (AHRQ), Publication No. 02-E016, April 2002.

(10) See Spilker, B. *Guide to Clinical Trials*. Raven Press, New York, 1991.

(11) For example, with respect to human drug products, it is fairly well known that children and the elderly may experience different drug effects compared to those seen in the adult population. These differences may be due to physiological differences (such as hormonal differences, differences in kidney function, etc.) between children, adults, and the elderly.

This document supercedes the previous (draft) version, issued November 2004.

Page Last Updated: 07/07/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.regulations.gov
2. /Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm103340.htm

EXHIBIT B

BONNETT FAIRBOURN
FRIEDMAN & BALINT PC

WILLIAM G. FAIRBOURN
VAN BUNCH[9]
ELAINE A. RYAN[8]
KATHRYN A. HONECKER[3]
GUY A. HANSON
MANFRED P. MUECKE[5]
T. BRENT JORDAN[7]
LINDSEY M. GOMEZ-GRAY
BARRETT N. LINDSEY
AUDRA E. PETROLLE[11]

ANDREW S. FRIEDMAN
ROBERT J. SPURLOCK
WENDY J. HARRISON[2]
PATRICIA N. SYVERSON[2]
KIMBERLY C. PAGE[4]
WILLIAM F. KING
ANDREW M. EVANS
KEVIN R. HANGER
KENDALL K. WILSON

FRANCIS J. BALINT, JR.[10]
C. KEVIN DYKSTRA
ANDREW Q. EVERROAD
JONATHAN S. WALLACK
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TY D. FRANKEL
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JERRY C. BONNETT,[1] Of Counsel
MICHAEL N. WIDENER, Of Counsel

[1]Admitted Also in Colorado
[2]Admitted Also in California
[3]Admitted Also in Illinois
[4]Admitted Also in Alabama and Georgia
[5]Admitted Only in California
[6]Admitted Only in California, Kansas, Missouri and Oregon (located in Oregon)
[7]Admitted Only in Pennsylvania
[8]Admitted Also in Colorado, Idaho, Kansas, Missouri, Texas, Utah and Washington
[9]Admitted Also in Tennessee and West Virginia
[10]Admitted Also in Massachusetts and Virginia
[11]Admitted Also in New Jersey and New York

December 4, 2014

VIA CERTIFIED MAIL
(RECEIPT NO. 7012 3460 0000 7080 8561)

Bayer Healthcare, LLC
General Counsel
100 Bayer Boulevard
Whippany, NJ 07981 09762

Re: *Gershman v. Bayer Healthcare, LLC*

Dear Sir or Madam:

Our law firm together with Stewart M. Weltman, LLC and Siprut PC represent Liza Gershman and all other consumers similarly situated in an action against Bayer Healthcare, LLC, arising out of, *inter alia*, misrepresentations by Defendant to consumers that the Flintstones Healthy Brain Support provides "Healthy Brain Support" and "Supports Healthy Brain Function."

Ms. Gershman and others similarly situated purchased Flintstones Healthy Brain Support unaware that the overwhelming weight of scientific evidence is that DHA supplementation does not provide brain function benefits and does not provide brain support. The only ingredient in the Product represented as providing brain support or function is the DHA. Thus, Bayer's brain function and brain support representations are false, misleading, and reasonably likely to deceive the public. The full claims, including the facts and circumstances surrounding these claims, are detailed in the Class Action Complaint, a copy of which is enclosed and incorporated by this reference.

Defendant's brain support and brain function representations are false and misleading and constitute unfair methods of competition and unlawful, unfair, and fraudulent acts or practices, undertaken by Defendant with the intent to induce the consuming public to purchase Flintstones Healthy Brain Support. The brain support and brain function representations do not assist consumers; they simply mislead them.

Defendant's brain support and brain function representations violate California Civil Code §1770(a) under, *inter alia,* the following subdivisions:

(5) Representing that [Flintstones Healthy Brain Support has] . . . characteristics, . . . uses [or] benefits. . . which [it does] not have.

* * *

(7) Representing that [Flintstones Healthy Brain Support is] of a particular standard, quality or grade, . . . if [it is] of another.

* * *

(9) Advertising goods . . . with the intent not to sell them as advertised.

* * *

(16) Representing that [Flintstones Healthy Brain Support has] been supplied in accordance with a previous representation when [it has] not.

California Civil Code §1770(a)(5)-(16).

Defendant's brain support and brain function representations also constitute violations of California Business and Professions Code §17200, *et seq.*

While the Complaint constitutes sufficient notice of the claims asserted, pursuant to California Civil Code §1782, we hereby demand on behalf of our client and all others similarly situated that Defendant immediately correct and rectify this violation of California Civil Code §1770 by ceasing the misleading marketing campaign and ceasing dissemination of false and misleading information as described in the enclosed Complaint. In addition, Defendant should offer to refund the purchase price to all consumer purchasers of Flintstones Healthy Brain Support, plus reimbursement for interest, costs, and fees.

Plaintiff will, after 30 days from the date of this letter, amend the Complaint without leave of Court, as permitted by California Civil Code §1782, to include claims for actual and punitive damages (as may be appropriate) if a full and adequate response to this letter is not received. These damage claims also would include claims under the Consumers Legal Remedies Act. Thus, to avoid further litigation, it is in the interest of all parties concerned that Defendant address these violations immediately.

Defendant must undertake all of the following actions to satisfy the requirements of California Civil Code §1782(c):

1. Identify or make a reasonable attempt to identify purchasers of Flintstones Healthy Brain Support;

2. Notify all such purchasers so identified that upon their request, Defendant will offer an appropriate remedy for its wrongful conduct, which can include a full refund of the purchase price paid for Flintstones Healthy Brain Support, plus interest, costs and fees;

3. Undertake (or promise to undertake within a reasonable time if it cannot be done immediately) the actions described above for all Flintstones Healthy Brain Support purchasers who so request; and

4. Cease from representing to consumers that Flintstones Healthy Brain Support provides brain support and brain function benefits, when there is no reasonable basis for so claiming, as more fully described in the enclosed Complaint.

We await your response.

Very truly yours,

for

Patricia N. Syverson
For the Firm

PNS:lmg
Enclosures

EXHIBIT C

BONNETT, FAIRBOURN, FRIEDMAN
& BALINT, P.C.
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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LIZA GERSHMAN, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

BAYER HEALTHCARE, LLC, a Delaware Limited Liability Company,

Defendant.

Case No.:

CLASS ACTION

DECLARATION OF PATRICIA N. SYVERSON PURSUANT TO CALIFORNIA CIVIL CODE §1780(d)

I, Patricia N. Syverson, declare as follows:

1. I am an attorney duly licensed to practice before all of the courts of the State of California. I am a shareholder of the law firm of Bonnett, Fairbourn, Friedman & Balint, P.C., the counsel of record for plaintiff in the above-entitled action.

2. Defendant Bayer Healthcare, LLC has done and is doing business in the Northern District of California. Such business includes the distributing, marketing, labeling, packaging and sale of Flintstones Healthy Brain Support. Furthermore, Plaintiff Gershman purchased Flintstones Healthy Brain Support in San Francisco, California.

3. I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 4th day of December 2014, at Phoenix, Arizona.

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.

s/*Patricia N. Syverson*
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JS 44 (Rev. 12/12) cand rev (1/15/13)

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 NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

LIZA GERSHMAN, on behalf of herself and all others similarly situated

(b) County of Residence of First Listed Plaintiff San Francisco
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Patricia N. Syverson, Bonnett Fairbourn Friedman & Balint PC, 2325 E Camelback Rd., #300, Phoenix, AZ 85016, 602-274-1100

DEFENDANTS

Bayer Healthcare, LLC

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 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 (Excludes 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
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 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
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. §1332

Brief description of cause:
Violation of Civil Code §1750, Business & Professional Code §17200

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
12/04/2014

SIGNATURE OF ATTORNEY OF RECORD
s/Patricia N. Syverson

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) ☑ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA

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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 filed. The attorney 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.Cv.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**; NOTE: 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 clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six 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.

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.** Example: 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 actual dollar amount 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.

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