IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TIFFANY GRIFFIN, *individually and on behalf of all others similarly situated*, Plaintiff, v. GSK CONSUMER HEALTH, INC. Defendant.	Case No. _____ **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Tiffany Griffin (hereinafter, "Plaintiff"), individually and on behalf of all other persons similarly situated, by her undersigned attorneys, alleges the following based upon personal knowledge as to herself and her own actions, and, as to all other matters, alleges, upon information and belief and investigation of her counsel, as follows:

NATURE OF THE ACTION

1. This is a consumer class action brought individually by Plaintiff and on behalf of all persons in the below-defined proposed Classes, all of whom purchased GSK Consumer Health, Inc.'s ("Defendant") Benefiber Original Prebiotic Powder and Benefiber Healthy Shape Prebiotic Powder (hereinafter, the "Product" or "Products").

2. Defendant manufactures, sells, and distributes these Products through a marketing and advertising strategy that emphasizes that these Products are "100% Natural," which is a claim that appeals to health-conscious consumers.

3. Defendant's advertising and marketing campaign, however, is false, fraudulent, deceptive, and misleading. Unbeknownst, to Plaintiff and members of the Classes at the time of their purchase, and contrary to the express representations on the labels, these Products contain wheat

dextrin, which is a non-natural synthetic ingredient.

4. As a result of Defendant's unlawful and highly deceptive conduct, Plaintiff and Members of the Classes have been and continue to be harmed by purchasing a product under false pretenses. Furthermore, Plaintiff and Members of the Classes paid a premium for the Products based on the misrepresentation made by Defendant that the Products were "100% Natural." Accordingly, Plaintiff and Members of the Classes paid more for the Products than they otherwise would have, if at all, and suffered an injury in the amount of the premium paid.

5. Plaintiffs and the Classes thus bring claims for consumer fraud, common law fraud, and unjust enrichment and seek damages, injunctive and declaratory relief, interest, costs, and reasonable attorneys' fees.

PARTIES

6. Plaintiff Tiffany Griffin is a citizen of the State of Texas residing in the City of Desoto and is a member of the Class defined herein. Her current residence is 812 Princeton Drive, Desoto, Texas. She purchased the Products for her own use many times preceding the filing of this Complaint. She most recently made a purchase on May 3, 2020. Plaintiff and members of the Classes suffered an injury in fact caused by the false, fraudulent, unfair, deceptive, and misleading practices of Defendant set forth in this Complaint. Plaintiff and members of the Classes would not have purchased the Products had they been accurately labeled.

7. Defendant, GSK Consumer Health, Inc., is a corporation with its principal place of business in Warren, New Jersey. Defendant's corporate headquarters is located at 184 Liberty Corner Road, Warren, New Jersey. Defendant manufactures, markets, distributes, and advertises the Products throughout the United States. Defendant developed and/or authorized the false, fraudulent, misleading, and deceptive advertisements and labeling of the Products from its New Jersey headquarters.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005 (hereinafter referred to as "CAFA") codified as 28 U.S.C. § 1332(d)(2) because the claims of the proposed Class members exceed $5,000,000 and because Defendant is a citizen of a different state than most Class members.

9. The Court has personal jurisdiction over Defendant because it is headquartered in this District, regularly conducts business in this District, and/or under the stream of commerce doctrine by causing its products to be disseminated in this District.

10. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant is headquartered here and conducts substantial business in this District.

FACTUAL ALLEGATIONS

A "100% Natural" Representation is Material to Consumers

11. The use of the term "natural," let alone "100% Natural," is a powerful statement that is important to consumers.

12. A study conducted by Consumer Reports[1] in 2014 found that about two-thirds of consumers believe that Products that are "natural" do not contain any "artificial ingredients, pesticides, or genetically modified organisms" and that 80% of consumers believe it should mean that.[2]

[1] Consumer Reports (CR), founded in 1936, is "an independent, nonprofit member organization that works side by side with consumers for truth, transparency, and fairness in the marketplace." https://www.consumerreports.org/cro/about-us/what-we-do/index.html (last visited Nov. 20, 2020). It has six million members and tests tens of thousands of products annually to provide consumers with product reviews. *See id*. CR has a Survey Research department that conducts more than one hundred surveys per year. Its surveys are not commissioned or financed by industry. *See* https://www.consumerreports.org/cro/about-us/what-we-do/research-and-testing/index.html (last visited Nov. 20, 2020).

[2] Deborah Pike Olsen, *Say No to 'Natural' on Food Labels*, Consumer Reports (June 16, 2014, 6:00 AM), https://www.consumerreports.org/cro/news/2014/06/say-no-to-natural-on-food-labels/index.htm.

13. According to one study, nearly three-quarters (73 percent) of global consumers believe it is important their groceries are one hundred percent natural.[3]

14. The shift in consumers actively looking for more natural products is associated with consumer preferences regarding health.[4]

15. A 2015 Consumer Reports survey found that 62% of consumers purchase "natural" products, and that 87% of those purchasers are willing to pay more for products called "natural" that meet their expectations regarding what "natural" means.[5]

16. A 2016 survey found the number of consumers who purchase "natural" products to be as high as 73%.[6]

17. Reflecting this trend, in 2011, the natural products industry was valued at approximately $91 billion.[7]

18. Merely four years later the natural products industry had almost doubled in value to $180 billion.[8]

19. Thus, seeking to capitalize on the booming natural products industry, Defendant

---

[3] Will Cowling, *Consumers Continue to Seek Products with Natural Ingredients*, Candy Industry (Jan. 22, 2020), https://www.candyindustry.com/articles/88953-consumers-continue-to-seek-products-with-natural-ingredients#:~:text=The%20research%20firm%20found%2036,of%20artificial%20and%20synthetic%20ingredients.&text=Nearly%20three%2Dquarters%20(73%20percent,groceries%20are%20100%20percent%20natural.

[4] *Id.*

[5] Andrea Rock, *Peeling Back the 'Natural' Food Label*, Consumer Reports (last updated: Jan. 27, 2016), https://www.consumerreports.org/food-safety/peeling-back-the-natural-food-label/.

[6] *Consumer Reports Survey Show 73 Percent of Consumers Look for 'Natural' Labels at Grocery Stores- and Many are Unwittingly Misled*, Consumer Reports, (May 10, 2016) https://www.consumerreports.org/media-room/press-releases/2016/05/consumer-reports-survey-show-73-percent-of-consumers-misled-by-natural-labels-at-the-grocery-store/.

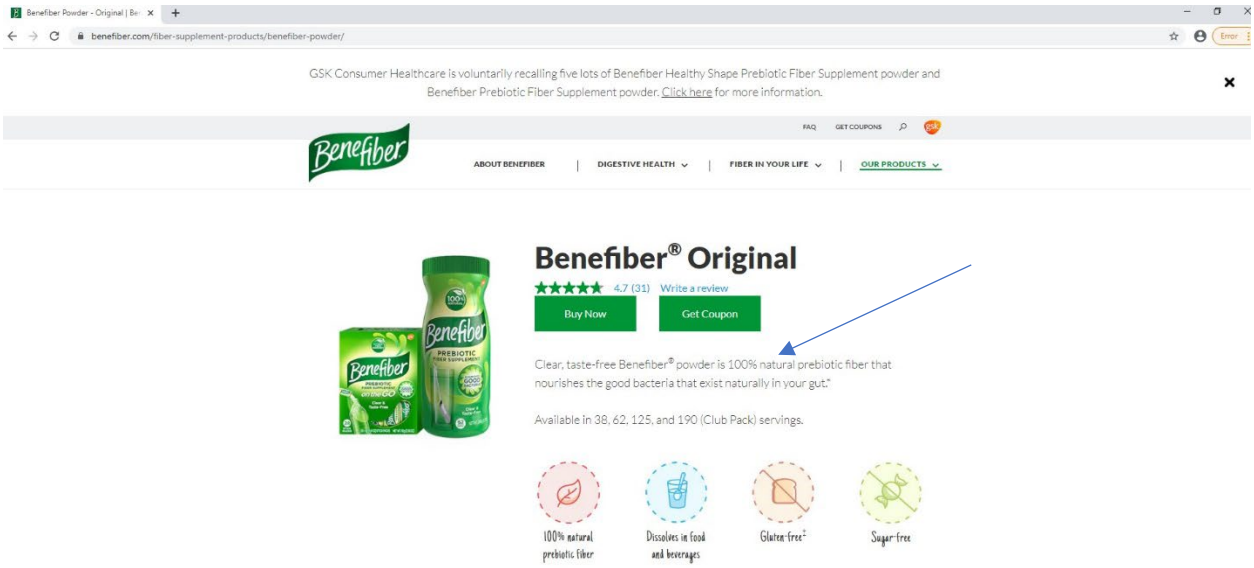
[7] Nancy Wagner, *Size of the Natural Products Industry*, Chron, https://smallbusiness.chron.com/size-natural-products-industry-71266.html (last visited Nov. 19, 2020).

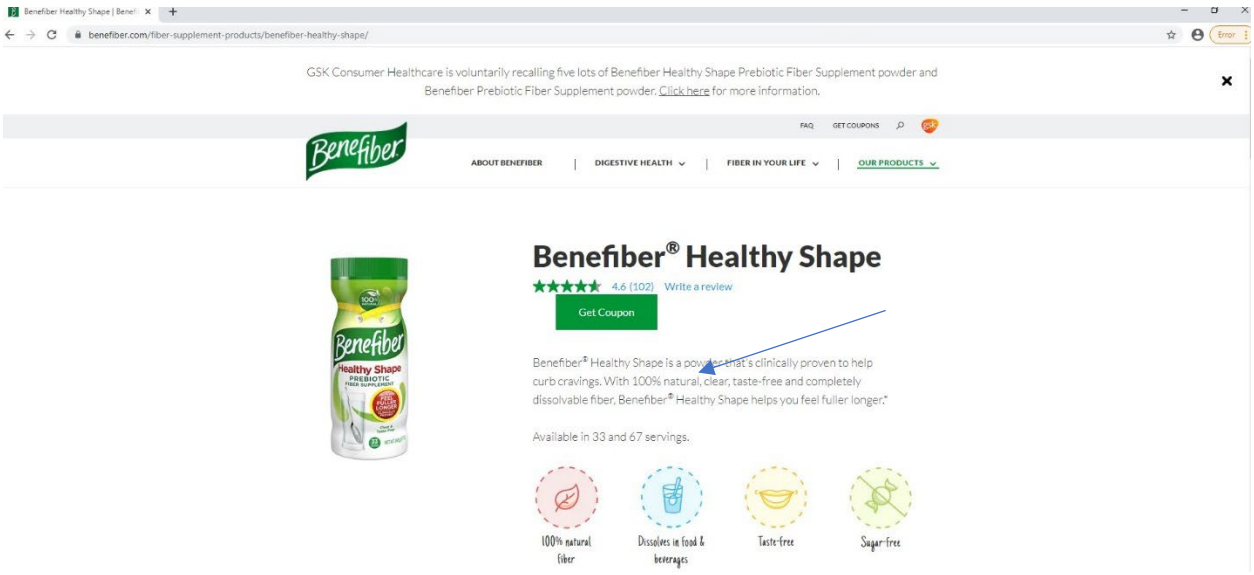
[8] *Natural Products Industry Sales up 9.5% to $180bn Says NBJ,* FOOD NAVIGATOR, http://www.foodnavigator-usa.com/Markets/EXPO-WEST-trendspotting-organics-natural-claims/(page)/6

marketed, advertised and labeled its Products as "100% Natural".

GSK Falsely Markets the Products as 100% Natural

20. As shown below, Defendant prominently marketed and labeled the Products as "100% Natural[.]"





21. Defendant directs the "100% Natural" representation to consumers, like Plaintiff

and the members of the Classes, and Defendant intends that Plaintiff and members of the Classes read and rely on its representations.

22. However, contrary to the representations made through marketing, advertisements and on each bottle of the Products, the Products actually contain wheat dextrin, a synthetic ingredient, which means that they are not "100% Natural[.]"

23. Because Defendant falsely marketed, advertised and labeled the Products as "100% Natural," Defendant's competitor Procter & Gamble brought a case before the National Advertising Division—the advertising industry's self-regulatory body—challenging Defendant's assertion that the Products are "100% Natural[.]"

24. Upon concluding its review of the matter, on May 14, 2020 the NAD concluded that Defendant deceptively labeled and misrepresented the Products.[9] The NAD asserted that Defendants' "100% Natural" representation on the Products was "inconsistent with the reasonable consumer takeaway" of what that "100% Natural" means.[10] This decision was based on the NAD finding that wheat dextrin is actually a synthetic ingredient due to the complex chemical process required to produce it.

25. The NAD made its determination by reviewing the complex chemical process used to produce the wheat dextrin in the Products. This process is explained below:[11]

> The process of manufacturing Benefiber is largely undisputed. It begins with wheat starch, a carbohydrate derived from wheat, which both parties agree is a natural ingredient. Wheat starch is digestible in the gut, contains no dietary fiber and no reducing sugars. Next, food-grade hydrochloric acid is added to the wheat starch, which aids in hydrolysis. Hydrolysis is the reaction of water with a substance, which causes water to split the bonds within that

[9] NAD's Ruling is attached hereto and cited hereinafter as Exhibit A. *See* Exhibit A, at p. 7.

[10] *Id.*

[11] *Id.* at p. 2.

> substance. In food production, hydrolysis is induced when heat is applied to certain ingredients.
>
> After hydrochloric acid is combined with wheat starch, the starch is then heated to a high temperature, which creates new bonds between the glucose sugars. More specifically, new nondigestible bonds are created (bonds not found in wheat starch), the polysaccharide chain lengths are altered and their molecular weight is lowered, which increases the product's solubility and creates less viscosity, so Benefiber is dissolved when mixed with water. This process also forms reducing sugars, which add sweetness to the Benefiber product. Next, an enzyme, α-amylase, is added to the mixture, which further reduces the molecular weight of the polymer chains. After the enzyme is added, the preferred polymers are selected, collected from the mixture, filtered to remove impurities, then concentrated to remove water and increase the concentration of polysaccharides to transform the solution into a dry powder.
>
> Next, the substance is subjected to chromatography. Chromatography allows the manufacture to select specific polysaccharides by molecular weight to alter the weight distribution of the mixture, which impacts its overall viscosity. Chromatography also allows for the removal of small sugar molecules, which further increases the fiber content of the mixture. Finally, the product is purified by ion exchange, evaporated and then spray dried to product the final wheat starch ingredient found in Benefiber.

26. The process commences with wheat starch, a carbohydrate derived from wheat. High-grade hydrochloric acid is then added to the wheat starch. The starch is then heated to a high temperature, which creates new bonds between the glucose sugars. Next, an enzyme, α- amylase, is added to the mixture, which further reduces the molecular weight of the polymer chains. After the enzyme is added, the preferred polymers are selected, collected from the mixture, filtered to remove impurities, then concentrated to remove water and increase the concentration of polysaccharides to transform the solution into a dry powder. Then, the substance is subjected to chromatography which allows the manufacturer to select specific polysaccharides by molecular weight to alter the weight distribution of the mixture and allows for the removal of small sugar molecules, which further increases the fiber content of the mixture. Finally, the product is purified

by ion exchange, evaporated and then spray dried to produce the final wheat starch ingredient found in the Products.

27. In its ruling, the NAD stated, "the process of manufacturing Benefiber transforms the source ingredient – wheat starch – which is digestible and has 0% dietary fiber, into a new ingredient – wheat dextrin – which is non-digestible and has 85% dietary fiber."[12]

28. Based on this, the NAD determined that a reasonable consumer would not deem Defendants' Products to be "100% Natural" because "ingredients that are derived from nature and undergo significant chemical alterations are often not 'natural' in the way that consumers expect them to be."[13]

29. Though a reasonable consumer likely understands many products undergo some degree of processing, claiming the Products are "100% Natural" conveys to consumers minimal or even no processing.

30. This would not be accurate with Defendants' Products as the creation of wheat dextrin in the Products involve significant processing that changes the biological properties of the natural ingredient.[14]

31. Moreover, this complex process to create wheat dextrin is essential to providing the Products' benefits and characteristics, including its high fiber content, viscosity, solubility, and sweetness.[15]

32. The NAD similarly rejected Defendant's argument that wheat dextrin is "natural"

[12] *Id.*

[13] *Id.* at p. 3.

[14] *Id.* at p. 4.

[15] *Id.* at p. 5.

according to the FDA and Federal Trade Commission ("FTC").[16] In particular, the NAD cited the FDA's *Review of the Scientific Evidence on the Physiological Effects of Certain Non- Digestible Carbohydrates* which expressly calls wheat dextrin a "synthetic" non-digestible carbohydrate.[17]

33. Furthermore, the conclusion made by the NAD, that wheat dextrin is synthetic, is validated by U.S. Department of Agriculture ("USDA") guidance.

34. A 2016 document produced by the USDA, titled "Draft Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic," outlines how to determine whether a substance is synthetic or natural.

35. According to the USDA, a substance is classified as natural based upon the following guidelines: (a) it is produced or extracted from a natural source; (b) it has not undergone a chemical change that chemically or structurally altered it to be different than how it naturally occurs in the source material; or (c) the chemical change was created by a "naturally occurring biological process such as composting, fermentation, or enzymatic digestion or by heating or burning biological matter."[18]

36. In addition, Congress has also defined what "synthetic" means. According to Congress, synthetic is "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plants, animals, or mineral sources." 7 U.S.C. § 6502 (21).

37. Based on this analysis, the NAD recommended that Defendant discontinue its claim

[16] *Id.*

[17] *Id.*

[18] *See* Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, Agriculture Marketing Service, USDA (Dec. 2, 2016), https://www.ams.usda.gov/sites/default/files/media/NOP-Synthetic-NonSynthetic-DecisionTree.pdf.

of "100% Natural" on the Products.[19]

38. Defendant knew or should have known that the "100% Natural Claim" prominently featured on the front of the label of the Products was not accurate and that the labeling, advertising and/or marketing was false and misleading.

39. Nevertheless, Defendant falsely and misleadingly marketed, advertised, packaged and/or sold the Products to the general public as a "100 % Natural[.]"

40. The only conceivable purpose for falsely and deceptively making these claims about the Products is to stimulate sales and enhance Defendant's profits based on the booming natural products industry.

41. Consumers are particularly vulnerable to these kinds of false and deceptive labeling and marketing practices. Most consumers are unable to verify that products such as Defendant's Products are accurately labeled.

42. As set forth above, the decision to purchase a product that is 100% Natural is material to consumers.

43. The difference between the Products promised and the Products sold is significant.

44. As set forth above, consumers willingly pay more for products that are labeled "100 % Natural" such as Defendant's Products.

45. Because of Defendant's deceptive advertising practices, consumers were and continue to be fraudulently induced to purchase and pay a premium for the Products.

Plaintiff Relied Upon the Products' Label to Purchase the Products

46. Plaintiff was herself a victim of Defendants' mislabeling of the Products. On several occasions, she purchased one of the products, Benefiber Original Prebiotic Powder, most

[19] *See* Exhibit A at p. 7.

recently in May of 2020 at a Walgreens in City of Desoto, Texas.

47. Prior to each purchase of the Product, Plaintiff viewed the "100% Natural" representation prominently featured on the Product's label.

48. Plaintiff chose to purchase the Product over cheaper alternatives because the Product was prominently labeled and advertised as "100% Natural".

49. Plaintiff purchased the Product believing they were "100% Natural."

50. Plaintiff would not have purchased and consumed the Product had she known they were not "100% Natural" and instead contained synthetic ingredients.

51. Plaintiff is in the same Class as all other consumers who purchased Defendant's Products during the relevant time period. Plaintiff and the Class Members were in fact misled by Defendant's misrepresentations with respect to the Products. Plaintiff and Class Members would have purchased other nutritional supplements, if any at all, if they had not been deceived by the misleading and deceptive labeling and advertising of the Products by Defendant.

GSK's Marketing and Sale of the Products Violates Federal Law

52. Section 5(a) of the Federal Trade Commission ("FTC") Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

53. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

54. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, the Products are either "foods" or "drugs" as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. §§ 55(b), (c). Under these provisions, companies must have a

reasonable basis for making objective product claims.

55. As alleged herein, Defendant has represented the Products as "100% Natural." However, these representations are false, deceptive, and misleading as the Product contains wheat dextrin, a synthetic ingredient. The making of such misrepresentations by Defendant constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

New Jersey's Substantive Law Applies to the Proposed Class

56. New Jersey's substantive laws should apply to the proposed nationwide class. New Jersey's substantive laws may be constitutionally applied to the claims of Plaintiff and the nationwide class under the Due Process Clause, 14th Amend., § 1, and the Full Faith and Credit Clause, art. IV., § 1, of the U.S. Constitution.

57. New Jersey has significant contact, or significant aggregation of contacts, to the claims asserted by Plaintiff and Members of the Class. Defendant's principal place of business is located in New Jersey and Defendant also owns property and conducts substantial business in New Jersey. New Jersey has an interest in regulating Defendant's conduct under its laws. These considerable state interests ensure that applying New Jersey state law is not unfair or arbitrary. Further, Defendant's decision to reside in New Jersey and avail itself of New Jersey's laws renders the application of New Jersey law to the claims herein constitutionally permissible.

58. Defendant's misconduct emanated from New Jersey because Defendant's marketing and any testing efforts relating to the deceptive Products, were likely undertaken and orchestrated from its headquarters in New Jersey.

59. Due to its choice-of-law rules, interest in applying its own laws, and considerable contacts to the claims of the Plaintiff and the Members of the Class, New Jersey law is appropriate

and should be applied in this case.

CLASS ACTION ALLEGATIONS

60. Plaintiff brings this action individually and on behalf of all other persons similarly situated pursuant to Federal Rule of Civil Procedure 23. The class definition(s) may depend on the information obtained throughout discovery. Notwithstanding, at this time, Plaintiffs bring this action and seek certification of the following Classes:

> **National Class:** All persons within the United States who purchased the Products labeled as "100% Natural" for personal consumption from the beginning of any applicable limitations period through the date of class certification (the "National Class" or the "Class").
>
> **Texas Sub-Class:** All persons within the State of Texas who purchased the Products labeled as "100% Natural" for personal consumption from the beginning of any applicable limitations period through the date of class certification (the "Texas Sub-Class").

61. Excluded from the Classes are the Defendant, and any entities in which the Defendant has a controlling interest, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and Plaintiff's counsel, their staff members, and their immediate family.

62. Plaintiff reserves the right to amend the Class definitions or add a Class if further information and discovery indicate that the Class definitions should be narrowed, expanded, or otherwise modified.

63. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of her claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

64. **Numerosity** – Federal Rule of Civil Procedure 23(a)(1). The members of the Classes are so numerous that their individual joinder herein is impracticable. On information and belief, members of the Classes number in the thousands to hundreds of thousands. The number of members of the Classes is presently unknown to Plaintiff but may be ascertained from Defendant's books and records. Members of the Classes may be notified of the pendency of this action by mail, email, Internet postings, and/or publication.

65. **Commonality and Predominance** – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3). Common questions of law and fact exist as to all members of the Classes and predominate over questions affecting only individual members of the Classes. Such common questions of law or fact include, but are not limited to, the following:

a. Whether the Products are "100% Natural," as claimed on the labels;

b. Whether Defendant had a reasonable basis for claiming that the Products are "100% Natural";

c. Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Product are deceptive;

e. Whether Defendant's actions violate the state consumer fraud statute invoked below;

f. Whether Defendant's actions constitute common law fraud;

g. Whether Plaintiff and the members of the Classes were damaged by Defendant's conduct;

h. Whether Defendant was unjustly enriched at the expense of Plaintiff and Class Members; and

i. Whether Plaintiff and Class Members are entitled to injunctive relief.

66. Defendant engaged in a common course of conduct giving rise to the legal rights Plaintiff seeks to enforce, on behalf of herself and the other Members of the Classes. Similar or identical statutory and common law violations, business practices, and injuries are involved. Individual questions, if any, pale in comparison, in both quality and quantity, to the numerous common questions that dominate this action.

67. **Typicality** – Federal Rule of Civil Procedure 23(a)(3). Plaintiff's claims are typical of the claims of the other Members of the Classes because, among other things, all Members of the Classes were comparably injured through Defendant's uniform misconduct described above. Further, there are no defenses available to Defendant that are unique to Plaintiff or to any particular Members of the Classes.

68. **Adequacy of Representation** – Federal Rule of Civil Procedure 23(a)(4). Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the other Members of the Classes she seeks to represent; she has retained counsel competent and experienced in complex class action litigation; and she will prosecute this action vigorously. The Classes' interests will be fairly and adequately protected by Plaintiff and undersigned counsel.

69. **Insufficiency of Separate Actions** – Federal Rule of Civil Procedure 23(b)(1). Absent a representative class action, Members of the Classes would continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual consumers, the resulting multiplicity of lawsuits would cause undue burden and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated purchasers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendant. The proposed Classes thus satisfy the requirements of Fed. R.

Civ. P. 23(b)(1).

70. **Declaratory and Injunctive Relief** – Federal Rule of Civil Procedure 23(b)(2). Defendant has acted or refused to act on grounds generally applicable to Plaintiff and the other Members of the Classes, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to the members of the Classes as a whole. In particular, Plaintiff seeks to certify a Class to enjoin Defendant from selling or otherwise distributing the Products as labeled until such time that Defendant can demonstrate to the Court's satisfaction that the Products confer the advertised health or medicinal benefits.

71. **Superiority** – Federal Rule of Civil Procedure 23(b)(3). A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other Members of the Classes are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendant, so it would be impracticable for Members of the Classes to individually seek redress for Defendant's wrongful conduct. Even if Members of the Classes could afford individual litigation, the court system could not. Individualized litigation would create a potential for inconsistent or contradictory judgments and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

CAUSES OF ACTION

Count I

Violations of New Jersey Consumer Fraud Act ("CFA") N.J.S.A. § 56:8-1, *et seq.* (On Behalf of the National Class)

72. Plaintiff, individually and on behalf of the Members of the Class, incorporates by reference all of the foregoing paragraphs of this Complaint, as if fully alleged herein.

73. The CFA was enacted and designed to protect consumers against unfair, deceptive and fraudulent business practices. N.J. Stat. Ann. §56:8-1, *et seq.*

74. N.J. Stat. Ann. §56:8-2 provides:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice . . . .

75. Plaintiff, other members of the Class, and Defendant are "persons" within the meaning of the CFA.

76. The mislabeled Product sold by Defendant is "merchandise" within the meaning of the CFA, and Plaintiffs and other members of the Class are "consumers" within the meaning of the CFA and, thus, are entitled to the statutory remedies made available in the CFA.

77. Defendant, through its advertisements and labeling, used unconscionable commercial practices, deception, fraud, concealment, false promises, and misrepresentations, in violation of the CFA, in connection with the marketing and sale of the Products.

78. Further, Defendant knowingly concealed and omitted material facts to the Plaintiff and Members of the Class regarding the ingredients in the Products. These deceptive acts and omissions caused Plaintiff and Members of the Class to sustain damages in an amount to be proven at trial.

Count II

Common Law Fraud

(On behalf of the National Class and, alternatively, the Texas Sub-Class)

79. Plaintiff incorporates by reference all of the foregoing paragraphs of this Complaint as if fully stated herein.

80. Plaintiff brings this claim against Defendant on behalf of himself and the other Members of the National Class and, alternatively, the Texas Sub-Class (the "Classes").

81. Defendant made false statements and omissions of material facts, including, but not limited to Defendant's claim that the Products are "100% Natural".

82. Defendant's false statements and omissions of material facts were made to Plaintiff and the members of the Classes at least each time that Plaintiff and the members of the Classes purchased the Products.

83. Defendant knew or should have known that these statements were false and that the omissions were material. In the alternative, Defendant made these false statements and/or omissions without having any reasonable basis to believe they were true.

84. Defendant intended that its false statements and omissions of material facts would induce Plaintiff and each of the members of the Classes to purchase the Products.

85. Plaintiff and the members of the Classes relied on the false statements and omissions of material facts of Defendant.

86. Plaintiff and members of the Classes would not have purchased the Products had they been accurately marketed, advertised, packaged and/or sold.

87. Plaintiff and Members of the Classes have been directly and proximately damaged by Defendant's false statements and omissions of material facts.

88. As a result of Defendant's false statements and omissions of material facts, Plaintiff

and each of the Members of the Classes have sustained damages in an amount to be proven at trial.

89. In addition, Defendant's conduct showed malice, motive, and a reckless disregard of the truth such that an award of punitive damages is appropriate.

Count III

Unjust Enrichment

(On Behalf of the National Class and, alternatively, the Texas Sub-Class)

90. Plaintiff incorporates by reference all of the foregoing paragraphs of this Complaint as if fully stated herein.

91. Plaintiff brings this claim against Defendant on behalf of herself and the other Members of the National Class and, alternatively, the Texas Sub-Class (the "Classes").

92. Plaintiff and the other Members of the Classes conferred benefits on Defendant by purchasing the Products.

93. Defendant received benefits in the form of revenues from purchases of the Products to the detriment of Plaintiff and the other Members of the Classes because Plaintiff and the other Members of the Class purchased a mislabeled product that is not what they bargained for and was not "100% Natural," as claimed.

94. Defendant has been unjustly enriched in retaining the revenues derived from the purchases of the Products by Plaintiff and the other Members of the Classes. Retention of those monies under these circumstances is unjust and inequitable because Defendant's labeling of the Products was misleading to consumers, which caused injuries to Plaintiff and the other Members of the Classes, because they would have not purchased the Products had they known the true facts.

95. Because Defendant's retention of the non-gratuitous benefits conferred on it by Plaintiff and the other Members of the Classes is unjust and inequitable, Defendant must pay restitution to Plaintiff and the other Members of the Classes for its unjust enrichment, as ordered

by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the other Members of the Class, respectfully requests that the Court enter judgment as follows:

A. Declaring that this action is a proper class action, certifying the Classes as requested herein, designating Plaintiff as Class Representative, and appointing the undersigned counsel as Class Counsel for the Classes;

B. Enjoining Defendant from engaging in the unlawful conduct set forth herein;

C. Ordering Defendant to pay actual damages to Plaintiff and the other members of the Classes;

D. Ordering Defendant to pay punitive damages, as allowable by law, to Plaintiffs and the other members of the Classes;

E. Ordering Defendant to pay statutory damages, as provided by the applicable state consumer protection statutes invoked herein, to Plaintiff and the other Members of the Class;

F. Ordering Defendant to pay reasonable attorneys' fees and litigation costs, as allowable by law, to Plaintiff and the other members of the Classes;

G. Ordering Defendant to pay restitution to Plaintiff and the other Members of the Classes;

H. Ordering Defendant to pay both pre- and post-judgment interest, as allowable by law, on any amounts awarded; and

I. Ordering such other and further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury of all claims in this Complaint so triable. Plaintiff also respectfully requests leave to amend this Complaint to conform to the evidence, if such amendment is needed for trial.

Dated: November 23, 2020

Respectfully Submitted,

/s/ David C. Magagna Jr.
David C. Magagna Jr.
Charles E. Schaffer
LEVIN SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Phone: 215-592-1500
dmagagna@lfsblaw.com
cschaffer@lfsblaw.com

Gary M. Klinger
MASON LIETZ & KLINGER LLP
227 W. Monroe Street, Ste. 2100
Chicago, Illinois 60606
Phone: 202.640.1160
Fax: 202.429.2294
gklinger@masonllp.com

Gary E. Mason
David K. Lietz
MASON LIETZ & KLINGER LLP
5101 Wisconsin Ave. NW Ste. 305
Washington DC 20016
Phone: 202.640.1160
Fax: 202.429.2294
gmason@masonllp.com
dlietz@masonllp.com

Attorneys for Plaintiffs and the Class

EXHIBIT A

Case #6366 (05/14/2020)
GlaxoSmithKline Consumer Healthcare, LLC
Benefiber Original and Benefiber Healthy Shape
Challenger: The Procter & Gamble Company
Product Type: Dietary Supplements
Issues: Establishment Claims; Express Claims; Health & Safety claims; Ingredient/Content/Nutrition; Performance Claims
Disposition: Modified/Discontinued

- **When assessing whether a "natural" claim is supported, NAD may broadly consider whether the processing of a naturally derived ingredient alters the ingredient in a manner that is inconsistent with a consumer's reasonable understanding of a "natural" product.**

- **To be consumer meaningful, a study must show effectiveness in the relevant population; results that are not consumer meaningful are inadequate to substantiate advertising claims.**

Basis of Inquiry: Claims made by GlaxoSmithKline ("GSK" or "the advertiser") on product packaging and website advertising for its Benefiber Original and Benefiber Healthy Shape (together, "Benefiber") fiber supplements were challenged by The Procter & Gamble Company ("P&G" or "the challenger"), manufacturer of Metamucil daily fiber supplement and laxative products. The following claims served as the basis for NAD's inquiry:

Express Claims:

"100% Natural"

"Clinically proven to curb cravings"

"Helps you Feel Fuller Longer" **Evidence**

Presented:

In support of its claims, the advertiser provided:

- Detailed information on the process for manufacturing Benefiber.
- Seven in-vivo studies which it contended collectively demonstrate that the consumption of wheat dextrin induces satiety and decreases caloric intake.
- Supportive and rebuttal expert declarations.

The challenger provided:

- The FDA Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates.
- The Benefiber Patent and Generally Recognized as Safe Notification.
- Two in-vivo studies which it contended show that NUTRIOSE has no consumer relevant effect on hunger or satiety.
- Supportive and rebuttal expert declarations.

Decision:

I "100% Natural" Claim

The advertiser claims that Benefiber is "100% Natural." The sole ingredient in Benefiber is wheat dextrin. The challenger argued that the wheat dextrin in Benefiber is extensively processed in a manner that involves significant chemical and structural transformations to yield a compound not found in nature. The advertiser disputed this contention, explaining that the marketing of Benefiber as a "natural" product is truthful and accurate because the wheat dextrin in Benefiber is derived entirely from wheat and does not contain any artificial or synthetic additives. The advertiser also asserted that the production of Benefiber relies on an "incredibly basic" and common process that results in minor changes to the bonds in wheat starch and no changes to the underlying glucose sugars.

A. Production of Benefiber

The process of manufacturing Benefiber is largely undisputed. It begins with wheat starch, a carbohydrate derived from wheat, which both parties agree is a natural ingredient. Wheat starch is digestible in the gut, contains no dietary fiber and no reducing sugars. Next, food-grade hydrochloric acid is added to the wheat starch, which aids in hydrolysis. Hydrolysis is the reaction of water with a substance, which causes water to split the bonds within that substance. In food production, hydrolysis is induced when heat is applied to certain ingredients.

After hydrochloric acid is combined with wheat starch, the starch is then heated to a high temperature, which creates new bonds between the glucose sugars. More specifically, new non-digestible bonds are created (bonds not found in wheat starch), the polysaccharide chain lengths are altered and their molecular weight is lowered, which increases the product's solubility and creates less viscosity, so Benefiber is dissolved when mixed with water. This process also forms reducing sugars, which add sweetness to the Benefiber product. Next, an enzyme, α-amylase, is added to the mixture, which further reduces the molecular weight of the polymer chains. After the enzyme is added, the preferred polymers are selected, collected from the mixture, filtered to remove impurities, then concentrated to remove water and increase the concentration of polysaccharides to transform the solution into a dry powder.

Next, the substance is subjected to chromatography. Chromatography allows the manufacture to select specific polysaccharides by molecular weight to alter the weight distribution of the mixture, which impacts its overall viscosity. Chromatography also allows for the removal of small sugar molecules, which further increases the fiber content of the mixture. Finally, the product is purified by ion exchange, evaporated and then spray dried to product the final wheat starch ingredient found in Benefiber.

Importantly, the process of manufacturing Benefiber transforms the source ingredient – wheat starch – which is digestible and has 0% dietary fiber, into a new ingredient – wheat dextrin – which is non-digestible and has 85% dietary fiber.

B. Applicable Substantiation Standard

As a general rule, ingredients that are derived from nature and undergo significant chemical alterations are often not "natural" in the way that consumers expect them to be.[1] NAD has previously considered cases involving "natural" claims where a product's ingredients were derived from nature but were chemically processed to make the final product.[2] For example, NAD has considered whether Olean, a fat substitute derived from soybean oil and sugar, was a natural product. NAD determined that although Olean may start off with soybean oil and sugar, the oil molecules and sugar molecules were chemically broken apart and then recombined (one part of an oil molecule is combined with one part of a sugar molecule) to form a new molecule not found in nature; accordingly, NAD found the natural claim to be inaccurate.[3] While the Olean case involved the chemical processing of soybean oil and sugar to form a new molecule not found in nature, this is simply a subset of products that are, as a general rule, not "natural" in the way that consumers expect them to be.[4] When assessing whether a "natural" claim is supported, NAD may broadly consider whether the processing of a naturally derived ingredient alters the ingredient in a manner that is inconsistent with a consumer's reasonable understanding of a "natural" product.

C. Benefiber is Not "100% Natural" Consistent with a Consumer's Reasonable Understanding of the Claim

After carefully reviewing the evidence and arguments set forth by both parties, NAD determined that the processing of wheat starch to yield the wheat dextrin found in Benefiber represents a significant alteration of the source ingredient that is inconsistent with a consumer's reasonable understanding of a product that claims to be "100% Natural."

The advertiser rejected the notion that Benefiber is extensively processed and characterized the process of manufacturing Benefiber as minor and "incredibly basic." As an initial matter, the advertiser argued that consumers do not view "natural" ingredients as only raw, unprocessed substances that are taken straight from the ground and placed into a package, but instead argued that consumers understand that there is "some degree" of processing that occurs before food

---

[1] The Colgate Palmolive Company (Tom's of Maine "Naturally Dry" Antiperspirant), Report #6001, *NAD/CARU Case Reports* (September 2016) (naturally sourced ingredient does not meet consumer expectation of "natural" where final ingredient is "significantly processed and does not resemble [ingredient] as it is found in nature"); see also Aspire Beverage Company (Aspire Sports Drink), Report #5861, *NAD/CARU Case Reports* (July 2015).

[2] See Procter & Gamble (Olean Fat Substitute), Report #3499, *NAD/CARU Case Reports* (October 1998).

[3] Id.; See also, e.g., Alde Associates, LLC (daniPro Nail Polish), Report #5565, *NAD/CARU Case Reports* (March 2013) (NAD recommended discontinuing claim that nail polish was "natural" because an ingredient was produced by "breaking carbon bonds under pressure, a chemical alteration of castor oil"); Tom's of Maine (Tom's of Maine Natural Mouthwash), Report #3470, *NAD/CARU Case Reports* (June 1998) (a "natural" ingredient does not include one that, while "literally sourced in nature (as is every chemical substance) . . . is, nevertheless subject to extensive processing before metamorphosing into the [ingredient] that is included in the final product").

[4] Another subset of these cases is covered by the NAD and FDA's determination that "nothing artificial, synthetic (including color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." See Gerber Products Company (Gerber Baby Foods), Report #5409, *NAD/CARU Case Reports* (January 2012).

reaches consumers. With that said, the advertiser also claims that Benefiber is "100% Natural." NAD has recognized that quantified claims have a strong impact on consumers and that the use of the numerical "100%" conveys a message of completeness and certainty that vaguer language may not.[5] Due to its mathematical nature, a claim of "100%" speaks with dispassionate and objective certainty of comprehensive performance and delivery of the promised benefit.[6] Accordingly, "100% Natural" is a powerful claim that promises to deliver a substance that is entirely natural. Even assuming that consumers understand that many foods undergo some degree of processing before reaching them, a "100% Natural" claim reasonably conveys that the product is entirely natural and, if any processing is required to bring the product to market, such processing is minimal.

Here, the production of Benefiber involves a multi-step process that utilizes hydrochloric acid, added enzymes and a tailored, highly controlled method, which selects for biological properties that resist digestion, increases fiber content, enhances solubility, lowers viscosity and adds sweetness to the product marketed to consumers. This process transforms the digestible, 0% fiber wheat starch ingredient into the non-digestible, 85% fiber wheat dextrin ingredient touted to consumers. Accordingly, NAD determined that the "100% Natural" claim is inconsistent with the level of processing required to make Benefiber.

Additional evidence in the record supports NAD's finding that Benefiber's processing is not minimal and is inconsistent with a consumer's reasonable understanding of the "100% Natural" claim. For instance, Benefiber (NUTRIOSE) is the subject of a patent, which states that the purpose of the usage of heat during the patented process is "to obtain a significant transformation of the structure of the product." Moreover, the advertiser's own Generally Recognized as Safe (GRAS) Notification submitted to the Food and Drug Administration (FDA) also details the degree of processing and transformation of the wheat dextrin in Benefiber. The GRAS Notification states that NUTRIOSE:

> [I]s a specialty dextrin that is produced using a highly controlled process of starch dextrinization followed by enzymatic treatment and column chromatography. This process produces a highly indigestible, soluble dextrin, with a higher fiber content and a desired narrower molecular weight distribution.

The GRAS further explains: "Dextrins are partially hydrolyzed starches (glucose polymers) produced by heating starch in the presence of small amounts of food-grade acid. Dextrinization results in a drastically reduced molecular weight and the introduction of new glucoside linkages. Unlike starches and maltodextrins which contain only "digestible" α-(1,4) and α- (1,6) glucosidic linkages, dextrins also contain "nondigestible" (1,2) and (1,3)-glucosidic linkages." The GRAS Notification goes on to detail the significant differences between wheat starch and NUTRIOSE,[7]

---

[5] See e.g., MSD Consumer Care, Inc. (Coppertone Sunscreens 15+ SPF), Report #5403, *NAD/CARU Case Reports* (December 2011).
[6] Id.
[7] For instance, Table 1 shows that NUTRIOSE has reducing sugars that are nonexistent in wheat starch, that the molecular weight of NUTRIOSE is drastically reduced as compared to wheat starch, that NUTRIOSE contains on

all of which suggests the processing of the wheat dextrin in Benefiber is not consistent with a consumer's reasonable takeaway from the "100% Natural" claim.

While the advertiser maintained that Benefiber's processing is "incredibly basic," it also suggested that the steps of Benefiber's manufacturing process responsible for the creation of resistant dextrin – the heating of wheat starch under low water conditions – are the only steps that should be considered when assessing the naturalness of the product. According to the advertiser, none of the other steps are "critical drivers" for the formation of resistant dextrin. Specifically, the advertiser contended that the hydrochloric acid used in the production of Benefiber is food-grade, does not remain in the final Benefiber product, and has no bearing on whether resistant or non-resistant dextrin is formed. Likewise, the advertiser discounted the "additional steps" that occur after the resistant wheat dextrin is formed – the use of enzymes, chromatography, carbon filtering, etc. – as having no effect on the digestion-resistant nature of the product, as not "result[ing] in an alteration" of Benefiber, and as being done merely to remove impurities.

Despite the advertiser's insistence that the use of hydrochloric acid and the "additional steps" following the application of heat to the wheat starch are superfluous to the production of Benefiber, these steps are used to manufacture Benefiber. Importantly, these various processing steps help to confer the benefits consumers receive from Benefiber – including its high fiber content, viscosity, solubility, and sweetness – and are relevant to the assessment of whether the product's processing is consistent with consumers' expectation of a product that is "100% Natural." Moreover, as noted above, the GRAS Notification states that Benefiber "is a specialty dextrin that is produced using a highly controlled process of starch dextrinization followed by enzymatic treatment and column chromatography. This process produces a highly indigestible, soluble dextrin, with a higher fiber content and a desired narrower molecular weight distribution." This language contradicts the advertiser's suggestion that, besides the heating of wheat starch in low water conditions, the remaining steps are irrelevant to the production of Benefiber.[8]

The advertiser next argued that Benefiber is a "100% Natural" product because wheat dextrin is found in nature – in wheat seedlings, when the human body digests starches and when wheat starch is cooked, such as during the making of breakfast cereals or wheat bread. The relevant issue here, however, is not whether wheat dextrin can be found in nature, the human stomach or in bread. Instead, at issue here is how the wheat dextrin *in Benefiber* is made and whether the processing of the ingredient is consistent with consumers' understanding of a product touted as "100% Natural." Thus, the advertiser's argument that Benefiber is natural because wheat dextrin can, theoretically, be found in nature or when baking bread, largely ignores the specific processing required to transform the wheat starch source ingredient into the wheat dextrin found in Benefiber. Similarly,

---

average 85% dietary fibers but wheat starch contains 0%, and that NUTRIOSE has 50% (1,4), 30% (1,6), 10% (1,2) and 10% (1,3) glucosidic linkages, whereas wheat starch has 95% (1,4), 5% (1,6), 0% (1,2) and 0% (1,3) glucosidic linkages.

[8] To the extent the advertiser argues that chromatography merely removes impurities, the GRAS Notification suggests otherwise. It states: "NUTRIOSE 6 [the NUTRIOSE form found in Benefiber] involves partitioning chromatography and additional purification to remove any additional impurities that may have resulted from the chromatographic process."

the advertiser maintained that the creation of Benefiber utilizes a common reaction akin to roasting coffee, making ceviche, brewing beer or making cheese, but, indisputably, none of the examples provided involve the additional steps required to make Benefiber.

The advertiser also argued that wheat dextrin is a "natural" product under FDA and Federal Trade Commission (FTC) precedent,[9] but the FDA has not promulgated a definition of natural and instead has made clear that the informal guidance on which GSK relies does not establish the contours of an advertiser's non-misleading use of the term.[10] Moreover, as NAD has articulated in prior cases, simply because federal regulations do not explicitly prohibit labeling a product as "natural" does not mean such claims will meet the standards imposed by advertising law (i.e., that they be truthful, accurate and not misleading).[11]

Notably, there was evidence in the record suggesting that the FDA considers the wheat dextrin in Benefiber to be a synthetic fiber. The FDA's *Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates* ("FDA Review")[12] expressly calls wheat dextrin a "synthetic" non-digestible carbohydrate. The advertiser rejected this contention, maintaining that the FDA Review in no way determines whether resistant dextrin can be advertised or labeled as natural, and does not stand for the proposition that Benefiber is not a "natural" product. Although the FDA Review may not have been intended to provide guidance as to whether or not wheat dextrin can be advertised or labeled as natural, the very fact this FDA documents calls the main ingredient in Benefiber a "synthetic" fiber casts doubt on whether Benefiber is a natural product, let alone "100% Natural." In addition, the FTC has expressly declined to establish generalized guidance on "natural" claims and has repeatedly cautioned marketers using the term "natural" that they must substantiate any and all claims they are conveying to reasonable consumers.[13]

The advertiser further argued that NAD has explicitly found in two different cases that maltodextrin, a form of wheat dextrin, is a natural product.[14] NAD disagreed, noting that these cases do not stand for the proposition that the form of wheat dextrin found in Benefiber is a "natural" product. Regardless, NAD was unconvinced of the relevance of maltodextrin to this proceeding. While the advertiser claimed that maltodextrin is formed using heat, acid and enzymes, the same elements used during the production of Benefiber, it is unclear why the

---

[9] Citing FDA's statement that FDA "has considered the term 'natural' to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food."

[10] Further, FDA expressly emphasized that "this policy was not intended to address food production methods . . . nor did it explicitly address food processing or manufacturing methods . . ." *Use of the Term "Natural" in the Labeling of Human Food Products Request for Information and Comments*, 80 Fed. Reg. 69905, 69906 (Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101).

[11] See e.g., Swiss Research, Inc. (Shugr Sweetener), Report #4442, *NAD/CARU Case Reports* (January 2006).

[12] FDA, *Scientific Evaluation of Evidence on the Beneficial Physiological Effects of Certain Non-Digestible Carbohydrates* (June 2018).

[13] FTC, *Guide for the Use of Environmental Marketing Claims*, 75 Fed. Reg. 63552, 63586 (Oct. 15, 2010) (to be codified at 16 C.F.R. pt. 260).

[14] Swiss Research, Inc. (Shugr Sweetener), Report #4442, *NAD/CARU Case Reports* (January 2006); Heartland Sweeteners, LLC (Ideal), Report #5125, *NAD/CARU Case Reports* (December 2009).

advertiser categorized these dextrin types as "virtually identical." One key difference between maltodextrin and the wheat dextrin in Benefiber is that maltodextrin has 0% dietary fiber content.

Finally, the advertiser maintained that although the bonds between glucose molecules change in the production of Benefiber, the chemical formula for Benefiber ($C_6H_{10}O_5$) does not change. Based on this, the advertiser concluded there has only been a "structural" alteration to the wheat starch source ingredient (i.e., the bonds between the molecules have changed), not a compositional alteration to the source ingredient (i.e., the creation of a brand-new molecule). Consumers, however, are unlikely to distinguish between "compositional" and "structural" chemical alterations when they consider a "100% Natural" claim. Even if the source and final ingredients have the same molecular formula, consumers viewing a "100% Natural" claim are more likely to take away a message about the extent to which the naturally derived source ingredient has been processed and transformed. Here, the processing of Benefiber – which transforms a digestible, non-fiber ingredient into a non-digestible, 85% fiber ingredient, yielding the very benefits Benefiber touts to consumers – is inconsistent with the reasonable consumer takeaway of a product claiming to be "100% Natural."

Based on the foregoing, NAD recommended that the advertiser's "100% Natural" claim be discontinued.

I "Clinically Proven to Curb Cravings" and "Helps you Feel Fuller Longer" Claims

A. Applicable Substantiation Standard

The challenged advertising makes the establishment claim that Benefiber is "clinically proven to curb cravings," and the health-related satiety claim that Benefiber "helps you feel fuller longer." Establishment claims, such as the "clinically proven" claim at issue here, are traditionally held to a high standard of scientific proof because they are, in essence, a promise that there is scientific evidence that "establishes" the truth of an advertiser's claims.[15] Both establishment claims and health-related claims must be supported by reliable, competent scientific evidence.[16]

Competent and reliable scientific evidence, as defined by the FTC, includes, "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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."[17] The features of a sound methodological study are well-known and generally agreed upon by the scientific community. The study's objectives should be clearly described, and the methodology

[15] Wink Naturals, LLC (Zen Drops), Report #6291, *NAD/CARU Case Reports* (June 2019).

[16] Molekule Inc. (Molekule MH1 Air Purifier), Report #6314, *NAD/CARU Case Reports* (October 2019); Triumph Pharmaceuticals Inc. (SmartMouth Dry Mouth Products), Report #6190, *NAD/CARU Case Reports* (June 2018); Good Health Naturally, LLC (Serranol Supplements), Report # 5441, *NAD/CARU Case Reports* (March 2012); Nature's Cure, Inc. (2-Part Acne Treatment), Report #4797, *NAD/CARU Case Reports* (February 2008).

[17] FTC Guide, *Dietary Supplements: An Advertising Guide for Industry,* www.business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry; Molekule Inc. (Molekule MH1 Air Purifier), Report #6314, *NAD/CARU Case Reports* (October 2019).

must be appropriate for obtaining the objectives posed by the study. The study's duration should be sufficient to detect an effect on the outcome and the sample size should be large enough to provide sufficient statistical power, with the study population representative of the target population to which the claim is targeted.[18] Generally, competent and reliable scientific evidence consists of human clinical trials that are methodologically sound and statistically significant to the 95% confidence level.[19]

Importantly, competent and reliable scientific evidence must also demonstrate that the results will be meaningful to consumers.[20] To be consumer meaningful, a study must show effectiveness in the relevant population; results that are not consumer meaningful are inadequate to substantiate advertising claims.[21] Here, to demonstrate a consumer meaningful result, the advertiser would be required to demonstrate that the labeled dose in Benefiber Healthy Shape (7.4 grams of wheat dextrin twice daily (14.8 grams per day)) "curbs cravings" in U.S. customers, and helps them "feel fuller longer."

In an NAD proceeding the advertiser bears the initial burden of providing a reasonable basis for its claims,[22] both express and those reasonably conveyed by its advertisement. If NAD finds that an advertiser has provided a reasonable basis for its claim, the burden shifts to the challenger to show either that the advertiser's evidence is fatally flawed or that the challenger possesses stronger, more persuasive evidence reaching a different result.[23]

With these standards in mind, NAD reviewed and evaluated the evidence offered by the advertiser to determine whether it reached the level of competent and reliable scientific evidence necessary to support the challenged claims. In support, the advertiser submitted general evidence on the link between fiber and satiety, seven human clinical trials, and accompanying expert reports which, according to advertiser, collectively demonstrate that the consumption of wheat dextrin induces satiety.

---

[18] Id; See also, Good Health Naturally, LLC (Serranol Supplements), Report # 5441, *NAD/CARU Case Reports* (March 2012).

[19] Molekule Inc. (Molekule MH1 Air Purifier), Report #6314, supra; InterHealth Nutraceuticals, Inc. (Zychrome), Report #5569, *NAD/CARU Case Reports* (April 2013); Syntratech Corp. (Syntra-5 Total Body Solution), Report #5150, *NAD/CARU Case Reports* (March 2010); Nature's Healthy Supplements, Inc. (Best Prostate), Report #4982, *NAD/CARU Case Reports* (March 2009).

[20] See e.g., Molekule Inc. (Molekule MH1 Air Purifier), Report #6314, supra; InterHealth Nutraceuticals, Inc. (Zychrome), Report #5569, supra; Novartis Consumer Health, Inc. (Extra Strength Excedrin), Report #4973, *NAD/CARU Case Reports* (February 2009), NARB Panel #152, September 16, 2009.

[21] See The Procter & Gamble Company (Crest Sensitivity Treatment & Protection Toothpaste), Report #5386, *NAD/CARU Case Reports* (September 2011); Alcon Laboratories, Inc. (CLEAR CARE® PLUS), Report #6136, *NAD/CARU Case Reports* (November 2017) (NAD recommended discontinuation of claim of superior comfort for contact lenses based on lack of "clinically meaningful" evidence).

[22] See Molekule Inc. (Molekule MH1 Air Purifier), Report #6314, *NAD/CARU Case Reports* (October 2019); Mead Johnson (Enfamil NeuroPro Infant Formulas), Report #6260, *NAD/CARU Case Reports* (March 2019).

[23] Id.

B. General Evidence on Fiber and Satiety is Not Sufficient to Support Claims About the Wheat Dextrin Fiber Found in Benefiber

The advertiser first argued that fiber generally confers a satiety benefit. Specifically, the advertiser asserted that "[i]t is well established that fiber consumption increases satiety and reduces hunger." In reaching this conclusion, the advertiser and its expert, Dr. Slavin, pointed to studies of "dietary fibers," which is a type fiber that occurs naturally in fruits and vegetables. As the challenger noted, however, these studies are not relevant to this inquiry because "dietary fibers" are different from the "isolated fibers" found in fiber supplements like Benefiber. Dr. Slavin also opined that "[r]esearch demonstrates that [lower body weights and prevention of weight gain] are likely due to enhanced satiety or decreased hunger after fiber consumption." Yet, Dr. Slavin's broad conclusion that fiber increases satiety is contradicted by her own research, which states that "blanket statements between fiber and satiety should be made with caution" and should be "specific to a particular fiber type and dose."

In response, Dr. Slavin disclaimed the latter statements as cherry picked and outdated, asserting in her supplemental submission that "it is now well-established that the consumption of dietary fibers, including isolated fibers such as wheat dextrin, is linked to health benefits, such as weight and BMI, and has a positive impact on satiety." NAD observed, however, that Dr. Slavin did not provide evidence to support the broad assertion that there is a scientific consensus that all fibers are linked to health benefits. An expert's conclusory statement that a particular health outcome is well- established is of little value to assessing the reliability of that opinion.[24] Expert opinions are most reliable – and therefore most effective at NAD – when the expert's opinion is coupled with competent and reliable evidence demonstrating scientific consensus on an issue.[25] Here, as recently as 2018, Dr. Slavin's own statements observe that "[p]ractical amounts of fructan fiber types …do not affect satiety." Additionally, the Fibersol Study submitted by the advertiser, discussed more fully below, also explicitly states that "not all fiber products have the same effects on satiety." As a result, NAD found that there was insufficient evidence to conclude that fiber supplements generally increase satiety and reduce hunger.

As such, the advertiser should demonstrate that the specific fiber found in Benefiber – wheat dextrin – is "clinically proven to curb cravings" and "helps you feel fuller longer." To that point, NAD next considered the seven clinical trials submitted by the advertiser. The studies were double-

[24] Generally, scientific consensus on an issue is more valuable than the opinion of one individual scientist. The FDA, in its guidance to industry on health-related claim substantiation, asserts that "the opinion of a single scientist or small group of scientists is probably not adequate substantiation for [a health-related] claim." U.S. Food & Drug Administration, *FDA Guidance for Industry Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (2009) (example question 3). Thus, expert opinions and reports alone are not a substitute for competent and reliable scientific evidence. This is in accordance with the FTC's decades- old standard of review that "where the opinions voiced by experts are not adequately supported we ordinarily give them little weight." See CEBRIA, LLC (Cebria Supplements), Report #6142, *NAD/CARU Case Reports* (December 2017) (citing *In re Thompson Medical Company, Inc.* 104 FTC 786, 790, and fn 11 (1984); *Thompson Medical Company vs. FTC*, 791 F.2d 189 (1986) (Petition to review FTC order denied by the United States Court of Appeals, District of Columbia Circuit). NAD further noted a similar principle was articulated in *Daubert vs. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 592-595, 597 (1993), where the United States Supreme Court held that expert testimony, to be admissible, must rest on a reliable scientific foundation.

[25] Id.

blinded, randomized and placebo-controlled, ranging from three to twelve weeks in duration. NAD was concerned, however, that the studies were not a good fit for the advertiser's "helps you feel fuller longer" and "clinically proven to curb cravings" claims, which target a U.S. population with virtually limitless food options, who are generally able to eat as much or as often as needed or desired. After careful review, NAD determined that the advertiser's studies lacked consumer relevance because they were: (1) conducted on non-U.S populations with a different or unknown dietary fiber intake in conditions that were not relevant to U.S. consumers; (2) conducted on study populations whose health status were not representative of the healthy, general population targeted by the challenged advertising; (3) conducted on a fiber type different than found in Benefiber; and (4) evaluated clinical outcomes that are unrelated to the challenged claims. Further, one study was only provided in abstract form and did not provide enough information to assess its results.

C. Non-U.S. Study Sample Population in Non-Consumer Relevant Conditions: The Deremaux Studies

The advertiser submitted three clinical studies (the "Deremaux Studies"), all of which were conducted in China on factory workers who lived and worked full time at a manufacturing plant seven days a week. Two of the Deremaux Studies measured the impact of wheat dextrin on satiety (or hunger)[26] as per validated scales recognized by experts in the industry.[27] The results showed that the treatment groups experienced statistically significant increases in feelings of satiety. The third Deremaux Study ("Deremaux 3") measured the impact of wheat dextrin on caloric intake, body weight, BMI and body fat, but failed to measure hunger or satiety outcomes, and therefore, did not directly show that Benefiber confers a satiety or reduced hunger benefit. While the advertiser stated there is "a correlation between increased feelings of satiety and decreases in BMI, body weight, and energy consumption," it is well-known that correlation does not imply causation. Without competent and reliable evidence demonstrating that these ancillary measures are reliable indicators of satiety and/or cravings, Deremaux 3 cannot support claims that Benefiber "curbs cravings" or "helps you feel fuller longer."

With respect to the remaining Deremaux Studies that demonstrated increased satiety or reduced hunger in participants who lived, worked and ate at a Chinese manufacturing plant 7 days per week, NAD was concerned about extrapolating these results to U.S. consumers given that the study

[26] The parties had no material dispute over the difference between measuring feeling less hungry versus more sated as clinical outcome measures.

[27] In the first Deremaux Study ("Deremaux 1"), 120 overweight Chinese men age 20-35 were given either 17 grams of wheat dextrin or a placebo twice daily for twelve weeks. Subjects ate their usual meals at the same time in the same place each day. Body weight, body mass index (BMI) and body fat percentages were measured every four weeks while hunger (using a six-point Likert scale) and energy intake were assessed every three days. Over the course of the study, subjects who consumed wheat dextrin exhibited increased weight loss and reduced BMI and body fat percentage. Moreover, starting at day six of treatment, a statistically significant difference in hunger and energy intake was observed in those who consumed wheat dextrin and this significant difference continued throughout the duration of the twelve-week study. The second of the Deremaux Studies ("Deremaux 2") involved 100 healthy overweight male and female subjects. In addition to their standard meals, subjects received either a placebo or 8, 14, 18 or 24 grams per day of wheat dextrin for three weeks. Satiety was measured at regular intervals using a standardized Visual Analog Scale (VAS), whereas hunger was once again assessed using the Likert scale. Deremaux 2 found a statistically significant promotion of satiety, which increased with dose and time.

population's diet, as well as the conditions under which study was conducted, were not particularly relevant to U.S. consumers.[28] More specifically, the challenger argued that the Deremaux Studies were unreliable because of significant differences between the Chinese and U.S. diets, which impact satiety outcomes. In contrast, the advertiser contended that it is scientifically sound to rely on research from a Chinese test population because the Chinese diet has become similar to the Western diet over the course of the last several decades (i.e., the Chinese diet now includes less fiber). Moreover, the advertiser asserted that even if there were significant differences in the Chinese and U.S. diets, the results of the Deremaux Studies would still be applicable to U.S. consumers because fiber has the same effect on satiety regardless of an individual's diet, and the mechanisms of action by which fiber impacts satiety are not affected by the content of an individual's diet.

Though there was evidence in the record suggesting that the Chinese diet has become increasingly similar to the U.S. diet, there was no evidence in the record demonstrating that the factory workers in the Deremaux Studies consumed a U.S diet. Notably, the Deremaux Studies did not publish information about the participants' diets, including their dietary fiber intake. Nevertheless, the Deremaux authors implicitly acknowledged that the participants ate a more typical, fiber-rich Chinese diet (as compared to a U.S. diet characterized by less fiber) and also emphasized that the amount of fiber in an individual's diet can impact the effect of wheat dextrin on satiety. Specifically, the study authors stated:

> [A] distinct limitation of this trial was that daily fiber intake was not collected. It is possible that because the typical Chinese diet is rich in fiber, the effects of [wheat dextrin] supplementation may have been amplified. Clinical trials that enroll subjects who consume low amounts of fiber may yield a different physiological benefit.

Thus, the Deremaux authors themselves recognized that the effects of wheat dextrin on satiety were potentially exaggerated in their high fiber study population, as compared to populations that eat lower amounts of fiber, like the U.S.

Critically, the FDA's guidance on the interaction between diet, fiber, and satiety is in lockstep with the conclusions set forth by the Deremaux authors. The FDA maintained that the amount of dietary fiber in the individual's diet is relevant to the assessment of the physiological effects of non-digestible carbohydrates (like the wheat dextrin in Benefiber), and stated that in evaluating human intervention studies:

---

[28] As NAD has previously noted, advertisers should not rely on research based on a specific test population for claims targeted at the general population absent additional competent and reliable evidence demonstrating that it is scientifically sound to make such extrapolations. Cerebral Success (SmartX Premium Brain Supplement, Now with Cognizin), Report #5761, *NAD/CARU Case Reports* (September 2014) See also, truDermA (Mangodrin XTREME Formula and Mangodrin Stimulant Free Dietary Supplements), Report #6201, *NAD/CARU Case Reports* (July 2018) (rejecting study using a diet different from a "typical American diet"); Ampersand Industries, LLC (Trimedisyn Prenatal Vitamins), Report #5539, *NAD/CARU Case Report*s (December 2012) (NAD concerned with "extrapolat[ing] results mostly from populations with different diets . . . than the U.S. population to which the advertised product is being marketed).

> [I]t may be difficult . . . to draw scientific conclusions about the physiological effects of an added non-digestible carbohydrate in a population that consumes much higher or much lower amounts of dietary fiber, or other nutrients, that have an effect on the physiological endpoint.[29]

Likewise, the FTC's Guidance for Dietary Supplements concurs, requiring that the study population "reflect the characteristics and lifestyle of the population targeted by [an] ad [.]"[30]

Despite this guidance, an advertiser's expert concluded that the mechanism of action by which fiber impacts satiety is not affected by the content of an individual's diet.[31] NAD determined, however, that the weight of the evidence – including statements by the Deremaux Studies' authors, the FDA and FTC – strongly indicates that differences in the amounts of dietary fiber consumed by a population can impact satiety outcomes.[32] Therefore, the advertiser has not met its burden of showing that dietary differences between the studied population and the U.S population targeted by the challenged advertising have no impact on satiety outcomes; as a result, NAD found that the Deremaux Studies lacked consumer relevance.

In addition to the dietary concerns, NAD was also concerned that the Deremaux Studies conditions were not relevant to the characteristics and lifestyle of the U.S. consumers targeted by the challenged advertising. At least one reasonable takeaway from the "curbs cravings" and "feels fuller longer" claims is that U.S. consumers – who can access vast and nearly limitless types and amounts of foods throughout the day – will be able to resist the urge to snack on or overeat desirous food items because the Benefiber product inhibits their cravings and makes them feel full. Yet, the Deremaux sample population lived and worked in a "highly standardized environment" where subjects did not have to access to foods between meals. As one of the studies stated, while the subjects had "free access to food in the canteen," during mealtimes, with "breakfast provided at 7am, lunch at noon, and dinner at 6:30pm," "[s]ubjects worked from 7 AM to 6:30 PM each day and had no access to additional food during this period." Without access to additional food items outside of what was provided at the canteen during scheduled mealtimes, it is unclear whether the study participants had the ability to snack on or overeat desirous food items. Likewise, there was

---

[29] U.S. Food & Drug Administration, *Scientific Evaluation of Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition* (21 CFR 10.30); *Guidance for Industry* (Feb. 2018), at 14. NAD did not agree with the advertiser's assertion that this FDA guidance is focused solely on incidences of malnutrition. A full reading of the cited paragraph indicates that malnutrition is but one example of ways in which differences in nutrition and diet between the U.S. and the country where a study was conducted may mean that the study results cannot be extrapolated to the U.S. population. Another example is when one population consumes much higher or lower amounts of dietary fiber.

[30] FTC Guide, *Dietary Supplements: An Advertising Guide for Industry* at 16.

[31] Supra, fn. 24.

[32] The advertiser noted that in another NAD matter between the same parties, the challenger's expert, Dr. McRorie, opined that the effects of a fiber supplement will actually be exaggerated if a population's diet is low in fiber. Thus, according to the advertiser, this rationale would lead to the conclusion that the results of the Deremaux Studies would be even more pronounced in a U.S. population. However, NAD notes that this conclusion is contrary to the statement of the Deremaux authors which noted that "because the typical Chinese diet is rich in fiber, the effects of NUTRIOSE supplementation may have been amplified." Moreover, there is insufficient evidence in the record for NAD to reach a finding that populations that consume low amounts of fiber will have a more pronounced result.

no information given about the types or amounts of foods available for consumption during the meal periods, making it difficult to assess whether participants had the opportunity to resist cravings or overeat. Overall, the Deremaux authors said it best themselves:

> a limitation of the clinical trial is implementation in a single-center manufacturing plant in China, *which may limit the ability to generalize outcomes to the population at large*. The population selected in this study lived in a highly standardized environment Yet this study can be considered as an exploratory study allowing
> the choice of an effective dosage. *Larger prospective studies are needed to confirm our findings in other ethnic populations."* (emphasis added)

After carefully considering the parties' arguments, NAD determined that the Deremaux Studies, collectively, were a not a good fit for the advertiser's claims that Benefiber "curbs cravings" and "helps you feel fuller longer" because the underlying diet of the sample population and the condition under which the participants' satiety levels were studied were not relevant to U.S. consumers.

D. Irrelevant Clinical Outcomes and Fiber Types: The Aliasgharzadeh, Fibersol and Curtin Studies

NAD was also concerned that three of the advertiser's studies did not measure clinical outcomes related to the advertiser's claims that Benefiber is "clinically proven to curb cravings" or "helps you feel fuller longer," and/or did not measure the satiety effect of a fiber-type relevant to Benefiber. As such, NAD determined that the Aliasgharzadeh, Fibersol and Curtin studies were not a good fit for the challenged claims.

1. Clinical Outcomes

First, the Aliasgharzadeh Study did not measure satiety.[33] The test group and control group consumed 10 grams per day of wheat dextrin and maltodextrin, respectively, and researchers evaluated and compared energy intake, body weight, and BMI, as well as measures of insulin resistance and inflammation. While the study may have been reliably conducted, like Deremaux 3 discussed above, none of the clinical outcomes studied here directly measure (or have been competently and reliably shown to demonstrate) whether the women felt "fuller longer" or experienced "curb[ed] cravings." Moreover, the study suffered from the same non-U.S. population concerns as the Deremaux Studies, and was conducted only on women with diabetes, which does not match the general, healthy U.S. population targeted by the challenged advertising. Therefore, NAD determined that the Aliasgharzadeh study was not a good fit for the advertiser's claims regarding satiety and cravings.

[33] The Aliasgharzadeh Study (2015) was conducted on 55 Iranian women with type-2 diabetes. In this study, the test group and control group consumed 10 grams per day of wheat dextrin and maltodextrin, respectively, over the course of eight weeks. Researchers evaluated and compared energy intake, body weight, and BMI, as well as measures of insulin resistance and inflammation. Participants treated with the wheat dextrin exhibited statistically significant reductions in energy intake, body weight, and BMI.

2. Fiber-Type

NAD came to a similar conclusion with regards to the Fibersol and Curtin Studies, which both measured characteristics that were not relevant to the advertiser's satiety claims. In particular, the Fibersol and Curtin trials did not measure the effect of wheat dextrin, the fiber found in Benefiber. When submitted for claim support, the underlying study must be conducted with the same type and amount of the main ingredient as found in the product it purports to support.[34]

In the Fibersol study, participants who consumed 10 grams of Fibersol demonstrated statistically significant delays in hunger and increased satiety as compared to placebo.[35] However, the Fibersol Study did not evaluate wheat dextrin, instead evaluating resistant maltodextrin (Fibersol -2), a soluble corn fiber. The challenger contended that the Fibersol satiety results could not be extrapolated to the Benefiber wheat dextrin product because the two fibers are different. The advertiser, on the other hand, argued that the results of the Fibersol Study prove that wheat dextrin provides a satiety benefit because Benefiber and Fibersol are both resistant dextrins produced from food grade starches using similar processes to produce indigestible soluble dietary fibers and, as a result, are functionally identical.

The evidence in the record raises questions as to whether Benefiber and Fibersol are, in fact, functionally identical such that the advertiser can rely on the Fibersol Study to substantiate its satiety claims.[36] First, Fibersol and wheat dextrin in Benefiber (NUTRIOSE) do not undergo the same processing. For example, unlike NUTRIOSE which is heated for a short amount of time (1- 10 minutes), Fibersol is heated for a much longer time (1-3 hours), which causes more reactions to occur and would result in even more branching in the polysaccharide chains, and the chains would be broken down into even smaller pieces. Further, the two substances are chemically distinct, with Fibersol containing 90% dietary fiber by weight and NUTRIOSE containing no more than 85% dietary fiber. Although the FDA has placed wheat dextrin in the same dietary fiber classification as Fibersol, there is no evidence that such a classification means that the two are

---

[34] Prescription Vitamins, LLC (Statinzyme Cholesterol Lowering Medication Supplement), Report #5662, *NAD/CARU Case Reports* (December 2013).

[35] In the Fibersol study, nineteen participants were fed a controlled meal in the evening, and the following morning they were again fed a controlled meal with either 0. 5, or 1 0 grams of Fibersol. assigned test product (they drank one of three beverages containing either 0, 5 or 10 grams of Fibersol). Participants who consumed 10 grams of Fibersol experienced significant delays in hunger and satiety for up to two hours after treatment compared to the participants who drank beverages with 0 or 5 grams of Fibersol. Additionally, participants who drank beverages with 10 grams of Fibersol had decreased hunger AUC (i.e. decreased hunger cravings) and increased satiety AUC compared to those drinking 0 or 5 grams of Fibersol. The study also found that the subjects who consumed 10 grams of Fibersol had increased biochemical indicators of satiety.

[36] Novartis Consumer Health, Inc. (Benefiber Fiber Supplement), Report #5873, *NAD/CARU Case Reports* (August 2015). In the Novartis decision, NAD determined that, based on the evidence presented, for the purposes of its review, resistant dextrins made through the same process from different source starches were functionally identical. Thus, in Novartis, NAD reviewed studies conducted on resistant maltodextrin assessing the regularity benefits of such fibers because these could be used to substantiate regularity claims for the advertiser's wheat dextrin product, Benefiber. NAD's conclusion in Novartis was based on that particular case record and the impact of fiber on regularity. It does not support a finding in the instant case that all soluble corn fibers are functionally equivalent to wheat dextrin or have the same impact on satiety.

functionally identical with respect to a satiety benefit. Indeed, as the NARB as previously noted in evaluating fibers for regularity benefits, "FDA's grouping of fibers in making a safety determination does not establish that all of the fibers are functionally equivalent or impact regularity in the same way."[37] Finally, the Fibersol authors themselves have noted that "not all dietary fibers have the same effects on satiety" and "dose, as well as type of dietary fiber, deserves further study with respect to satiety."

Even if Fibersol was deemed functionally equivalent to NUTRIOSE, the Fibersol Study fails to confirm that the Fibersol product conferred a satiety benefit. As noted by the challenger, with regard to subjective appetite measurements, the Fibersol authors concluded that "[h]unger AUC decreased and satiety AUC increased" with 10g Fibersol compared to placebo. The study reported that the data shows "a distinct delay in increasing hunger" and prolonged satiety for the group that consumed 10 grams of Fibersol as compared to those who consumed 0 to 5 grams. However, this conclusion was based on the results of only two measures – "how much do you think you can eat" and "how satisfied do you feel?" – but largely ignored contradictory results that showed *no significant differences* on other relevant measures of satiety like "how hungry do you feel" and "how full do you feel?"[38] Further, with regard to cravings, the study authors also surveyed participants as to their "desires to eat sweet, salty, savory, and fatty foods," but none of these results differed across the three groups for four hours after meal intake. Therefore, NAD determined that the results of the Fibersol Study did not support the "clinically proven to curb cravings" or "helps you feel fuller longer" claims.[39]

Turning to the Curtin Study, the purpose of the study was to compare the satiety efficacy of a proprietary fiber, PolyGlycopleX ("PGX"), against wheat dextrin, which was tested as a negative control.[40] No actual placebo treatment was administered, and neither PGX nor wheat dextrin were compared to placebo. Although NAD acknowledged the advertiser's point that the results show that the "mean fullness scores" resulting from satiety testing on PGX and wheat dextrin followed a similar trend at every point in the two-hour testing process, simply showing a *potentially* positive impact on satiety is not the same as showing that wheat dextrin had a statistically significant impact on satiety as compared to a placebo. In fact, the wheat dextrin tested as a negative control here did not perform as well as PGX, with the PGX group reporting statistically significant higher satiety scores as compared to the wheat dextrin group. Consequently, NAD determined the Curtin Study

[37] NARB Panel #206, *NAD/CARU Case Reports* (December 2015).

[38] See Interhealth Nutraceuticals, Report #5569, *NAD/CARU Case Reports* (April 2013) ("advertiser's [clinically proven] claims must also closely reflect the test results upon which they are based").

[39] Although the challenger offered several additional critiques of the methodology of the Fibersol Study, such as the lack of reported baseline data and post-hoc analyses to report a "positive" result, having determined that the study is fatally flawed for other reasons, NAD did not address these arguments.

[40] This randomized crossover trial was composed of 14 healthy male and female Australians. At each of six satiety sessions, participants consumed a standard test meal plus 5 grams of PGX, a soluble dietary fiber, or 5 grams of wheat dextrin (negative control). Participants rated their sensation of fullness at 15, 30, 45, 60, 90 and 120 minutes after eating using a validated magnitude scale. Following each satiety time point, participants' blood samples were taken and tested for blood glucose levels. Participants who consumed wheat dextrin negative control reported increased satiety and lower blood glucose levels. According to the advertiser, these trends mirrored the PolyGlycopleX (active comparator) results with a lower degree of magnitude.

does not rise to the level of competent and reliable scientific evidence necessary to support the challenged claims.

For all the foregoing reasons, NAD determined that the Aliasgharzadeh, Fibersol and Curtin studies were not a good fit for the advertiser's claims that Benefiber is "clinically proven to curb cravings" and "helps you feel fuller longer."

3. Abstracts Do Not Provide Enough Information to Make a Reliability Determination: The University of Reading Study

The advertiser provided an abstract of the University of Reading Study, a recently completed randomized, double-blind, placebo-controlled crossover study that examined the impact of wheat dextrin on satiety. From the abstract, NAD could determine that it was a small study comprised of 36 normal and overweight men and women from the United Kingdom, who supplemented with wheat dextrin or energy-matched placebo for 28-days. Participants attended study visits at 0, 14, and 28 days of treatment and completed VAS questionnaires regarding satiety at thirty-minute internals throughout the day. The reported results stated that participants who consumed wheat dextrin had statistically significant increases in fasting satiety, post-meal satiety and post-meal fullness responses as compared to placebo ($p<0.05$). Moreover, at day 28, the blood concentration of GLP-1, a biomarker of satiety, also increased significantly ($p<0.05$).

As noted, the Reading Study was only submitted in abstract form. Typically, abstracts and informal summaries do not impart enough information for NAD to properly evaluate whether they constitute competent and reliable scientific evidence.[41] According to the FDA Guidance for Industry: Substantiation for Dietary Supplement Claims:

> 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.

Moreover, without access to the full publication (or even a draft of the full publication), NAD was unable to properly assess the methodology. For example, the abstract did not include key information about the methodology, such as: What was the distribution of men and women in the study population? What were the exclusion criteria for the subjects? What was the statistical plan for measuring results?

In addition, the challenger's expert took issue with the conclusions of the University of Reading Study, arguing that its satiety conclusions are based on a biased interpretation of only 7 of the 23 satiety measurements taken over 600 minutes (i.e., the authors only drew attention to Minute 0,

---

[41] Creekside Natural Therapeutics, LLC (Focused Mind Jr. Supplements), Report #6334, *NAD/CARU Case Reports* (December 2019).

when patients were in a fasted state, and Minutes 150-270, after subjects had consumed their morning test drink). Although the advertiser maintained that the challenger's assessments do not undercut the study's finding that wheat dextrin has a positive impact on satiety, NAD agreed with the challenger's expert that analysis of all 23 measurement points indicates that NUTRIOSE provided intermittent and inconsistent satiety benefits. Specifically, the authors ignore that on day 14, NUTRIOSE had better satiety effects than placebo on only 12 out of 23 measurement times. They also ignore that on day 28, NUTRIOSE and placebo had identical results, each providing better satiety effects on 11 of 23 of the measurement times. In fact, in the afternoon on day 28, the placebo group provided a better satiety effect than NUTRIOSE. Consequently, NAD determined that the Reading Study abstract and accompanying materials are not sufficient to support the advertiser's establishment and health-related satiety claims.[42]

For all of these reasons, NAD determined that the evidence in the record did not provide a reasonable basis for the advertiser's establishment claim that Benefiber is "clinically proven to curb cravings," and the health-related satiety claim that Benefiber "helps you feel fuller longer."[43]

Reviewing the totality of the advertiser's evidence regarding satiety, NAD determined the studies submitted were either not consumer relevant in terms of population and the conditions under which the data was collected (Deremaux 1 and 2); measured outcomes or fiber-types that were not relevant to the challenged Benefiber claims (Deremaux 3, Aliasgharzadeh, Fibersol, and Curtin), or did not provide critical information that would permit NAD to assess the reliability of the study (University of Reading). In short, even studies that are, arguably, reliably conducted, cannot support claims for which they are not a good fit. For all these reasons, NAD demined that the advertiser had not provided evidence sufficient to provide a reasonable basis for the challenged "clinically proven to curb cravings" and "helps you feel fuller longer" claims.

Conclusion:

NAD determined that the processing of wheat starch to yield the wheat dextrin found in Benefiber represents a significant alteration of the source ingredient that is inconsistent with a consumer's reasonable understanding of a product that claims to be "100% Natural" and recommended that the claim be discontinued.

---

[42] The Reading and Fibersol Studies also reported improvement in biomarkers of satiety. For example, the Reading Study found that the blood concentration of GLP-1 increased significantly at day 28. The Fibersol Study reported that subjects who consumed 10 grams of Fibersol had increases in PYY and GLP-1; the Fibersol study explains that PYY mediates satiety and body-weight regulation and that GLP-1 promotes satiety and insulin secretion. However, the advertiser's "clinically proven to curbs cravings" and "feel fuller longer" claims are claims of human perception that generally cannot be supported by biomarkers alone. For example, in Reckitt Benckiser LLC (Mucinex), Report #5728, *NAD/CARU Case Reports* (June 2014), NAD found that the challenged claims reasonably conveyed a message that consumers taking the Mucinex bi-layer tablet will experience perceptible symptom relief in 8 minutes. The NARB agreed with NAD that evidence that Mucinex was absorbed into the blood stream in eight minutes was insufficient to support a claim of perceptible symptom relief.

[43] Having determined that the advertiser did not provide a reasonable basis for its claims, NAD did not review the rebuttal evidence offered by the challenger in the form of two studies which it contended show that NUTRIOSE has no consumer relevant effect on hunger or satiety, the 2004 Netherlands Study and the 2006 Netherlands Study.

GlaxoSmithKline Consumer Healthcare, LLC Benefiber Original and Benefiber Healthy Shape Page: 18

NAD determined that the evidence in the record did not provide a reasonable basis for the advertiser's establishment claim that Benefiber is "clinically proven to curb cravings," as well as the health-related satiety claim that Benefiber "helps you feel fuller longer," and recommended that the claims be discontinued.

Advertiser's Statement:

GlaxoSmithKline ("GSK") respectfully disagrees with the NAD's findings and will appeal the decision in its entirety. GSK firmly believes that the challenged claims are supported and that the NAD's decision is inconsistent with the evidence in the record and NAD precedent. GSK appreciates the opportunity to participate in the self-regulatory process and looks forward to resolving this matter with the National Advertising Review Board. **(#6366 RL, closed 05/14/2020)**