UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUSAN SWETZ, individually on behalf of herself and all others similarly situated, Plaintiffs, v. GSK Consumer Health, Inc., Defendant.	:	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Susan Swetz (hereinafter "Plaintiff"), individually and on behalf of all others similarly situated, by her attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge:

NATURE OF THE ACTION

1. This action seeks to remedy the deceptive and misleading business practices of GSK Consumer Health, Inc. (hereinafter "Defendant") with respect to the marketing and sales of Defendant's Benefiber Original Prebiotic Powder and Benefiber Healthy Shape Prebiotic Powder ("the Products") throughout the State of New York and throughout the country.

2. Defendant manufactures, sells, and distributes the Products using a marketing and advertising campaign centered around claims that appeal to health-conscious consumers, i.e., that its Products are "100% Natural." However, Defendant's advertising and marketing campaign is

false, deceptive, and misleading because the Products contain wheat dextrin, a non-natural, synthetic ingredient.

3. On May 14, 2020, the National Advertising Division ("NAD"), a Better Business Bureau nonprofit program charged with monitoring and evaluating truth and accuracy in national advertising, conducted an investigation and determined that wheat dextrin, which is created from wheat starch through a multi-step chemical process involving hydrochloric acid, is not a natural ingredient. Accordingly, NAD concluded that Defendant's "100% Natural" label was misleading to a reasonable consumer and should be discontinued. (NAD's Ruling is attached hereto as **Exhibit A**).

4. Plaintiff and those similarly situated ("Class Members") relied on Defendant's misrepresentations that the Products are "100% Natural" when purchasing the Products. Plaintiff and Class Members paid a premium for the Products based upon their "100% Natural" representation. Given that Plaintiff and Class Members paid a premium for the Products based on Defendant's misrepresentations that they are "100% Natural," Plaintiff and Class Members suffered an injury in the amount of the premium paid.

5. Defendant's conduct violated and continues to violate, *inter alia*, New York General Business Law §§ 349 and 350, and the consumer protection statutes of all 50 states Defendant has been and continues to be unjustly enriched. Accordingly, Plaintiff brings this action against Defendant on behalf of herself and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period.)"

FACTUAL BACKGROUND

The Natural Supplements Industry

6. Consumers have become increasingly concerned about the effects of synthetic and chemical ingredients in food and other consumable products. Companies such as Defendant have capitalized on consumers' desire for purportedly "natural" products. Indeed, consumers are willing to pay, and have paid, a premium for products branded "natural" over products that contain synthetic ingredients. In 2015, sales of natural products grew 9.5% to $180 billion.[1] Reasonable consumers, including Plaintiff and Class Members, value natural products for important reasons, including the belief that they are safer and healthier than alternative products that are not represented as natural.

7. The nutritional supplements industry in particular is big business. In 2019, there were more than 5,500 vitamin and dietary supplement launches globally[2] and the global supplements market was valued at $80.3 billion USD.[3] Products focused on digestive health are among the most popular supplements, with global sales of $7.11 billion USD.[4] American

[1] *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; *see also* Shoshanna Delventhal, *Study Shows Surge in Demand for "Natural" Products*, INVESTOPEDIA (February 22, 2017), http://www.investopedia.com/articles/investing/022217/study-shows-surge-demand-natural-products.asp (Study by Kline Research indicated that in 2016, the personal care market reached 9% growth in the U.S. and 8% in the U.K. The trend-driven natural and organic personal care industry is on track to be worth $25.1 million by 2025); *Natural living: The next frontier for growth? [NEXT Forecast 2017]*, NEW HOPE NTWORK (December 20, 2016), http://www.newhope.com/beauty-and-lifestyle/natural-living-next-frontier-growth-next-forecast-2017.

[2] Wellmune White Paper, available at https://explore.kerry.com/rs/117-TLU-222/images/Finding-the-right-format-2020.pdf?mkt_tok=eyJpIjoiTkROb U4yRmxObUkxWkROaSIsInQiOiJiS2pDZ3B1M3JPQmhXUndUT3lobWJ2UUYyMDVnNWxrWHgwS0ZrT3MzeW5SczB6M3NjMVl3Z2RJK0FHRzhOVVpSSFRcL2F2UStpVzJtQmdlQWV4M3JLK3RId0JhUzdZRDZ3TzVXMGRxVTVEWkw2NDNpb2RpQUNJSk5ScFwvd1wvVmQ0cyJ9

[3] *Id*.

[4] *Id*.

consumers are particularly health-conscious and are increasingly turning to supplements to prevent and treat illness.[5] In 2019, dietary supplement sales throughout the United States totaled more than $39 billion.[6]

8. Conditions in the industry have created the perfect storm for unscrupulous supplement makers, like Defendant, to take advantage of consumers. The reasonable consumer lacks the equipment and specialized knowledge and training necessary to test supplement makers' claims and to evaluate the safety of their products. The U.S. Food and Drug Administration ("FDA") lacks the resources to enforce its laws against most supplement makers. Thus, companies drawn to the industry by increasingly attractive sales numbers are able to gain market share and increase their profits by misleading consumers about the quality and benefits of consuming their product(s).[7] Defendant's deceptive acts and practices and false advertising exemplify this ongoing epidemic that has plagued consumers throughout the country.

9. Despite the Products containing wheat dextrin, a synthetic ingredient, Defendant markets the Products as being "100% Natural." The Products' labeling is depicted below:

[5] Ng, Serena and Rockoff, Jonathan D., *With Top Lines Drooping, Firms Reach for Vitamins*, WALL STREET JOURNAL (Mar. 31, 2013, 7:25 PM), http://www.wsj.com/articles/SB10001424127887324392804578362073624344816.

[6] https://www.statista.com/statistics/828481/total-dietary-supplements-market-size-in-the-us/

[7] *The Dangers of Dietary and Nutritional Supplements Investigated What You Don't Know About These 12 Ingredients Could Hurt You*, CONSUMER REPORTS (last updated Sept. 2010), http://www.consumerreports.org/cro/2012/05/dangerous-supplements/index.htm; Harmon, Katherine, *Herbal Supplement Sellers Dispense Dangerous Advice, False Claims*, SCIENTIFIC AMERICAN (May, 28, 2010), http://www.scientificamerican.com/article/herbal-supplement-dangers/.

Benefiber Original Prebiotic Powder

Synthetic Ingredient:

Wheat Dextrin

Benefiber Healthy Shape Prebiotic Powder

Synthetic Ingredient:

Wheat Dextrin

10. Defendant's representations that the Products are "100% Natural" is false, misleading, and deceptive because the Products contain wheat dextrin, a synthetic ingredient.

11. Whether Defendant's labeling of the Products as natural is deceptive is judged by whether it would deceive or mislead a reasonable person. To assist in ascertaining what a reasonable consumer believes the term natural means, one can look to the regulatory agencies for their guidance.

12. Earlier this year, Defendant's competitor Procter & Gamble brought a case before the NAD. On May 14, 2020, NAD issued a ruling concluding that the chemical process used to produce the wheat dextrin found in the Products was "inconsistent with the reasonable consumer takeaway" of the "100% Natural" representation on the Products.[8]

13. NAD reached this conclusion by reviewing the complex chemical process used to produce the wheat dextrin in the Products.[9] The process begins with wheat starch, a carbohydrate derived from wheat. Hydrochloric acid is added to the wheat starch and 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

[8] Exhibit A, p. 7.
[9] *Id*. at p. 2.

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 product the final wheat starch ingredient found in Benefiber.

14. As NAD noted, "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."[10]

15. Upon consideration of the chemical process used to create wheat dextrin, NAD concluded that reasonable consumers would not consider the 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."[11] This is especially true of products that are labeled as "100% Natural" because "'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."[12] The creation of the wheat dextrin in Benefiber does not involve "minimal processing" but rather "a multi-step process that utilizes hydrochloric acid, added enzymes and a tailored, highly controlled method, which selects for

[10] *Id*.
[11] *Id.* at p. 3.
[12] *Id* at p. 4.

biological properties that resist digestion, increases fiber content, enhances solubility, lowers viscosity and adds sweetness to the product marketed to consumers."[13]

16. Moreover, Benefiber 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." And, Defendant's own Generally Recognized as Safe ("GRAS") Notification submitted to the FDA also details the degree of processing and transformation of the wheat dextrin in Benefiber: "[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."[14]

17. The complex chemical process used to create the wheat dextrin in the Products is not superfluous. Rather it is integral to conferring the benefits that consumers desire including its high fiber content, viscosity, solubility, and sweetness.[15]

18. NAD also rejected Defendant's argument that wheat dextrin is "natural" under FDA or Federal Trade Commission ("FTC") precedent.[16] Specifically, NAD noted that "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. 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

[13] *Id*.
[14] *Id*.
[15] *Id*. at p. 5.
[16] *Id*. at p. 6.

imposed by advertising law (i.e., that they be truthful, accurate and not misleading)." Moreover, The FDA's *Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates* expressly calls wheat dextrin a "synthetic" non-digestible carbohydrate.[17]

19. Based on this analysis, NAD recommended that the advertiser's "100% Natural" claim be discontinued.[18]

20. NAD's determination that wheat dextrin is synthetic is supported by guidance provided by the U.S. Department of Agriculture ("USDA"). In 2013, the USDA issued a Draft Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic (Natural). In accordance with this decision tree, a substance is natural—as opposed to synthetic—if: (a) it is manufactured, produced, or extracted from a natural source (i.e. naturally occurring mineral or biological matter); (b) it has not undergone a chemical change (i.e. a process whereby a substance is transformed into one or more other distinct substances) so that it is chemically or structurally 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. **(Exhibit B).**

21. Congress has defined "synthetic" to mean "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).

[17] *Id*.
[18] *Id*. at p. 7.

22. A Technical Evaluation Report of "Dextrin" Compiled by the Technical Services Branch for the USDA National Organic Program ("the Report")[19] describes dextrin as "partially hydrolyzed starch produced by a chemical process called hydrolysis."

23. The Report further describes the multi-step chemical process for creating dextrin:

> It is prepared by using dry heating or roasting unmodified starch with or without an acid or alkaline catalyst. The acid catalysts include hydrochloric, phosphoric, and nitric acid; the alkali catalysts include sodium hydroxide and hydrolysable salts of weak acids, such as carbonates, hydrogen carbonates, perchlorates, and hypochlorites
>
> Unmodified starch is usually acidified with small amounts of acid and placed in heated, agitated vessels called reactors or roasters. The temperature is increased at a controlled rate and then maintained at a maximum temperature for varying lengths of time. The resulting product is cooled, blended, and sometimes aged.
>
> A fluid bed technique can also be used. Unmodified starch is placed in a reactor and suspended or fluidized in a stream of heated air. The starch is then acidified and, as in the conventional or "roaster" process, heated under controlled conditions of time and temperature until the desired end product is attained. With the several degrees of freedom possible in such processes, a range of dextrin with widely varying properties is produced.
>
> In some cases, starch is heated with acid and followed by enzymatic (amylase) treatment to form indigestible polysaccharides called resistant dextrin (including maltodextrin). Resistant dextrin is a class of soluble fiber.[20]

24. Consumers lack the meaningful ability to test or independently ascertain or verify whether a product is natural, especially at the point of sale. Consumers would not know the true nature of the ingredients merely by reading the ingredients label.

[19] Available at www.ams.usda.gov/sites/default/files/media/Dextrin%202010%20TR.pdf
[20] *Id*. (internal citations omitted).

25. Discovering that wheat dextrin not natural and are actually synthetic requires a scientific investigation and knowledge of chemistry beyond that of the average consumer. That is why, even though the wheat dextrin is identified on the back of the Products' packaging in the ingredients listed, the reasonable consumer would not understand – nor are they expected to understand - that this ingredient is synthetic.

26. Moreover, the reasonable consumer is not expected or required to scour the ingredients list on the back of the Products in order to confirm or debunk Defendant's prominent claims and representations that the Products are "100% Natural."

27. Defendant did not disclose that wheat dextrin is a synthetic ingredient. A reasonable consumer understands Defendant's "100% Natural" claims to mean that the Products are "100% Natural" and do not contain synthetic ingredients.

28. Defendant has thus violated, *inter alia*, NY General Business Law § 392-b by: a) putting upon an article of merchandise, bottle, wrapper, package, label or other thing, containing or covering such an article, or with which such an article is intended to be sold, or is sold, a false description or other indication of or respecting the kind of such article or any part thereof; and b) selling or offering for sale an article, which to its knowledge is falsely described or indicated upon any such package, or vessel containing the same, or label thereupon, in any of the particulars specified.

29. Consumers rely on label representations and information in making purchasing decisions.

30. The marketing of the Products as "100% Natural" in a prominent location on the labels of all of the Products, throughout the Class Period, evidences Defendant's awareness that "100% Natural" claims are material to consumers.

31. Defendant's deceptive representations and omissions are material in that a reasonable person would attach importance to such information and would be induced to act upon such information in making purchase decisions.

32. Plaintiff and the Class members reasonably relied to their detriment on Defendant's misleading representations and omissions.

33. Defendant's false, misleading, and deceptive misrepresentations and omissions are likely to continue to deceive and mislead reasonable consumers and the general public, as they have already deceived and misled Plaintiff and the Class members.

34. In making the false, misleading, and deceptive representations and omissions described herein, Defendant knew and intended that consumers would pay a premium for Products labeled as being "100% Natural" over comparable products not so labeled.

35. As an immediate, direct, and proximate result of Defendant's false, misleading, and deceptive representations and omissions, Defendant injured Plaintiff and the Class members in that they:

a. Paid a sum of money for Products that were not what Defendant represented;

b. Paid a premium price for Products that were not what Defendant represented;

c. Were deprived of the benefit of the bargain because the Products they purchased had less value than what Defendant represented;

d. Ingested a substance that was of a different quality than what Defendant promised; and

e. Were denied the benefit of the beneficial properties of the natural foods Defendant promised.

36. Had Defendant not made the false, misleading, and deceptive representations and omissions, Plaintiff and the Class members would not have been willing to pay the same amount for the Products they purchased.

37. Plaintiff and the Class members paid for Products that are "100% Natural" but received Products that are not "100% Natural." The Products Plaintiff and the Class members received were worth less than the Products for which they paid.

38. Plaintiff and the Class members all paid money for the Products. However, Plaintiff and the Class members did not obtain the full value of the advertised Products due to Defendant's misrepresentations and omissions. Plaintiff and the Class members purchased, purchased more of, and/or paid more for, the Products than they would have had they known the truth about the Products. Consequently, Plaintiff and the Class members have suffered injury in fact and lost money as a result of Defendant's wrongful conduct.

JURISDICTION AND VENUE

39. This Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. section 1332(d) in that: (1) this is a class action involving more than 100 class members; (2) Plaintiff is a citizen of the State of New York, Defendant GSK Consumer Health, Inc. is a citizen of the State of New Jersey; and (3) the amount in controversy is in excess of $5,000,000, exclusive of interests and costs.

40. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the State of New York, contracts to supply goods within the State of New York, and supplies goods within the State of New York.

41. Venue is proper because Plaintiff and many Class Members reside in the Southern District of New York, and throughout the State of New York. A substantial part of the events or omissions giving rise to the classes' claims occurred in this District.

PARTIES

Plaintiff

42. Plaintiff is an individual consumer who, at all times material hereto, was a citizen of New York State. Plaintiff purchased the Products during the Class Period. The packaging of the Products Plaintiff purchased contained the representation that they were "100% Natural." Plaintiff believes that products that are labeled as "100% Natural" do not contain synthetic ingredients. Plaintiff believes a synthetic ingredient is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources. If the Products actually were "100% Natural," as represented on the Products' label, Plaintiff would purchase the Products in the immediate future.

43. Had Defendant not made the false, misleading, and deceptive representation that the Products were "100% Natural," Plaintiff would not have been willing to pay the same amount for the Products, and, consequently, would not have been willing to purchase the Products. Plaintiff purchased, purchased more of, and/or paid more for, the Products than she would have had she known the truth about the Products. The Products Plaintiff received were worth less than the

Products for which she paid. Plaintiff was injured in fact and lost money as a result of Defendant's improper conduct.

Defendant

44. Defendant GSK Consumer Health, Inc. is a corporation with its principal place of business in Warren, New Jersey. Defendant manufactures, markets, advertises and distributes the Products throughout the United States. Defendant created and/or authorized the false, misleading and deceptive advertisements, packaging and labeling for the Products.

CLASS ALLEGATIONS

45. Plaintiff brings this matter on behalf of herself and those similarly situated. As detailed at length in this Complaint, Defendant orchestrated deceptive marketing and labeling practices. Defendant's customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution, including injunctive relief.

46. The Class is defined as all consumers who purchased the Products anywhere in the United States during the Class Period (the "Class").

47. Plaintiff also seeks certification, to the extent necessary or appropriate, of a subclass of individuals who purchased the Products in the State of New York at any time during the Class Period (the "New York Subclass").

48. The Class and New York Subclass shall be referred to collectively throughout the Complaint as the Class.

49. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

50. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of consumers who are Class Members described above who have been damaged by Defendant's deceptive and misleading practices.

51. Commonality: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

a. Whether Defendant are responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;
b. Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of its Products;
c. Whether Defendant made false and/or misleading statements to the Class and the public concerning the contents of its Products;
d. Whether Defendant's false and misleading statements concerning its Products were likely to deceive the public;
e. Whether Plaintiff and the Class are entitled to injunctive relief;
f. Whether Plaintiff and the Class are entitled to money damages under the same causes of action as the other Class Members.

52. Typicality: Plaintiff is a member of the Class. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased Defendant's Products. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

53. Adequacy: Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the Class Members she seeks to represent; her consumer fraud claims are common to all members of the Class and she has a strong interest in vindicating her rights; she has retained counsel competent and experienced in complex class action litigation and they intend to vigorously prosecute this action.

54. Predominance: Pursuant to Rule 23(b)(3), common issues of law and fact identified above predominate over any other questions affecting only individual members of the Class. The Class issues fully predominate over any individual issue because no inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendant's deceptive and misleading marketing and labeling practices.

55. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a. The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly

burdensome, and expensive—if not totally impossible—to justify individual actions;

c. When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;

e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;

f. This class action will assure uniformity of decisions among Class Members;

g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation;

h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by single class action; and

i. It would be desirable to concentrate in this single venue the litigation of all plaintiffs who were induced by Defendant's uniform false advertising to purchase its Products as "100% Natural."

56. Accordingly, this Class is properly brought and should be maintained as a class action under Rule 23(b)(3) because questions of law or fact common to Class Members

predominate over any questions affecting only individual members, and because a class action is superior to other available methods for fairly and efficiently adjudicating this controversy.

INJUNCTIVE CLASS RELIEF

57. Rules 23(b)(1) and (2) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, Defendant has engaged in conduct resulting in misleading consumers about ingredients in its Products. Since Defendant's conduct has been uniformly directed at all consumers in the United States, and the conduct continues presently, injunctive relief on a class-wide basis is a viable and suitable solution to remedy Defendant's continuing misconduct. Plaintiff would purchase the Products again if the ingredients were changed so that they indeed were "100% Natural."

58. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the injunctive Class Members would be wholly impracticable. Defendant's Products have been purchased by thousands of people throughout the United States;

b. Commonality: Questions of law and fact are common to members of the Class. Defendant's misconduct was uniformly directed at all consumers. Thus, all members of the Class have a common cause against Defendant to stop its misleading conduct through an injunction. Since the issues presented by this injunctive Class deal exclusively with Defendant's misconduct, resolution of these

questions would necessarily be common to the entire Class. Moreover, there are common questions of law and fact inherent in the resolution of the proposed injunctive class, including, *inter alia*:

i. Resolution of the issues presented in the 23(b)(3) class;

ii. Whether members of the Class will continue to suffer harm by virtue of Defendant's deceptive product marketing and labeling; and

iii. Whether, on equitable grounds, Defendant should be prevented from continuing to deceptively mislabel its Products as "100% Natural."

c. Typicality: Plaintiff's claims are typical of the claims of the injunctive Class because her claims arise from the same course of conduct (i.e. Defendant's deceptive and misleading marketing, labeling, and advertising practices). Plaintiff is a typical representative of the Class because, like all members of the injunctive Class, she purchased Defendant's Products which were sold unfairly and deceptively to consumers throughout the United States.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the injunctive Class. Her consumer protection claims are common to all members of the injunctive Class and she has a strong interest in vindicating her rights. In addition, Plaintiff and the Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

59. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(b)(2) because Plaintiff seeks injunctive relief on behalf of the Class Members on

grounds generally applicable to the entire injunctive Class. Certification under Rule 23(b)(2) is appropriate because Defendant has acted or refused to act in a manner that applies generally to the injunctive Class (i.e. Defendant has marketed its Products using the same misleading and deceptive labeling to all of the Class Members). Any final injunctive relief or declaratory relief would benefit the entire injunctive Class as Defendant would be prevented from continuing its misleading and deceptive marketing practices and would be required to honestly disclose to consumers the nature of the contents of its Products. Plaintiff would purchase the Products again if the ingredients were changed so that they indeed are "100% Natural."

FIRST CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 349
(On Behalf of Plaintiff and New York Subclass Members)

60. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

61. New York General Business Law Section 349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state."

62. The conduct of Defendant alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and the New York Subclass Members seek monetary damages and the entry of preliminary and permanent injunctive relief against Defendant, enjoining them from inaccurately describing, labeling, marketing, and promoting the Products.

63. There is no adequate remedy at law.

64. Defendant misleadingly, inaccurately, and deceptively advertise and market its Products to consumers.

65. Defendant's improper consumer-oriented conduct—including labeling and advertising the Products as being "100% Natural"—is misleading in a material way in that it, *inter alia*, induced Plaintiff and the New York Subclass Members to purchase and pay a premium for Defendant's Products and to use the Products when they otherwise would not have. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

66. Plaintiff and the New York Subclass Members have been injured inasmuch as they paid a premium for products that were—contrary to Defendant's representations—not "100% Natural." Accordingly, Plaintiff and the New York Subclass Members received less than what they bargained and/or paid for.

67. Defendant's advertising and Products' packaging and labeling induced Plaintiff and the New York Subclass Members to buy Defendant's Products and to pay a premium price for them.

68. Defendant's deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law §349(a) and Plaintiff and the New York Subclass Members have been damaged thereby.

69. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and the New York Subclass Members are entitled to monetary, compensatory, treble and

punitive damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

SECOND CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 350
(On Behalf of Plaintiff and the New York Subclass Members)

70. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

71. N.Y. Gen. Bus. Law § 350 provides, in part, as follows:

> False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful.

72. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

> The term 'false advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual . . .

73. Defendant's labeling and advertisements contain untrue and materially misleading statements concerning Defendant's Products inasmuch as they misrepresent that the Products are "100% Natural."

74. Plaintiff and the New York Subclass Members have been injured inasmuch as they relied upon the labeling, packaging and advertising and paid a premium for the Products which

were—contrary to Defendant's representations—not "100% Natural." Accordingly, Plaintiff and the New York Subclass Members received less than what they bargained and/or paid for.

75. Defendant's advertising, packaging and Products' labeling induced Plaintiff and the New York Subclass Members to buy Defendant's Products.

76. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

77. Defendant's conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

78. Defendant made the material misrepresentations described in this Complaint in Defendant's advertising, and on the Products' packaging and labeling.

79. Defendant's material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the Products were and continue to be exposed to Defendant's material misrepresentations.

80. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and New York Subclass Members are entitled to monetary, compensatory, treble and punitive damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

THIRD CAUSE OF ACTION
COMMON LAW UNJUST ENRICHMENT
(On Behalf of Plaintiff and All Class Members in the Alternative)

81. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

82. Plaintiff, on behalf of herself and consumers nationwide, bring a common law claim for unjust enrichment.

83. Defendant's conduct violated, inter alia, state and federal law by manufacturing, advertising, marketing, and selling its Products while misrepresenting and omitting material facts.

84. Defendant's unlawful conduct as described in this Complaint allowed Defendant to knowingly realize substantial revenues from selling its Products at the expense of, and to the detriment or impoverishment of, Plaintiff and Class Members, and to Defendant's benefit and enrichment. Defendant has thereby violated fundamental principles of justice, equity, and good conscience.

85. Plaintiff and Class Members conferred significant financial benefits and paid substantial compensation to Defendant for the Products, which were not as Defendant represented them to be.

86. Under New York's common law principles of unjust enrichment, it is inequitable for Defendant to retain the benefits conferred by Plaintiff's and Class Members' overpayments.

87. Plaintiff and Class Members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiff and Class Members may seek restitution.

JURY DEMAND

Plaintiff demands a trial by jury on all issues.

WHEREFORE, Plaintiff, on behalf of herself and the Class, pray for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class under Rule 23 of the FRCP;

(b) Entering preliminary and permanent injunctive relief against Defendant, directing Defendant to correct its practices and to comply with consumer protection statutes nationwide, including New York consumer protection laws;

(c) Awarding monetary damages, including treble damages;

(d) Awarding punitive damages;

(e) Awarding Plaintiff and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys and experts, and reimbursement of Plaintiff's expenses; and

(f) Granting such other and further relief as the Court may deem just and proper.

Dated: June 19, 2020

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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

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[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]

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[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,

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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

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[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.

II. "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

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[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.

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[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:

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[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

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[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

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[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

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[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.

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[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.

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.

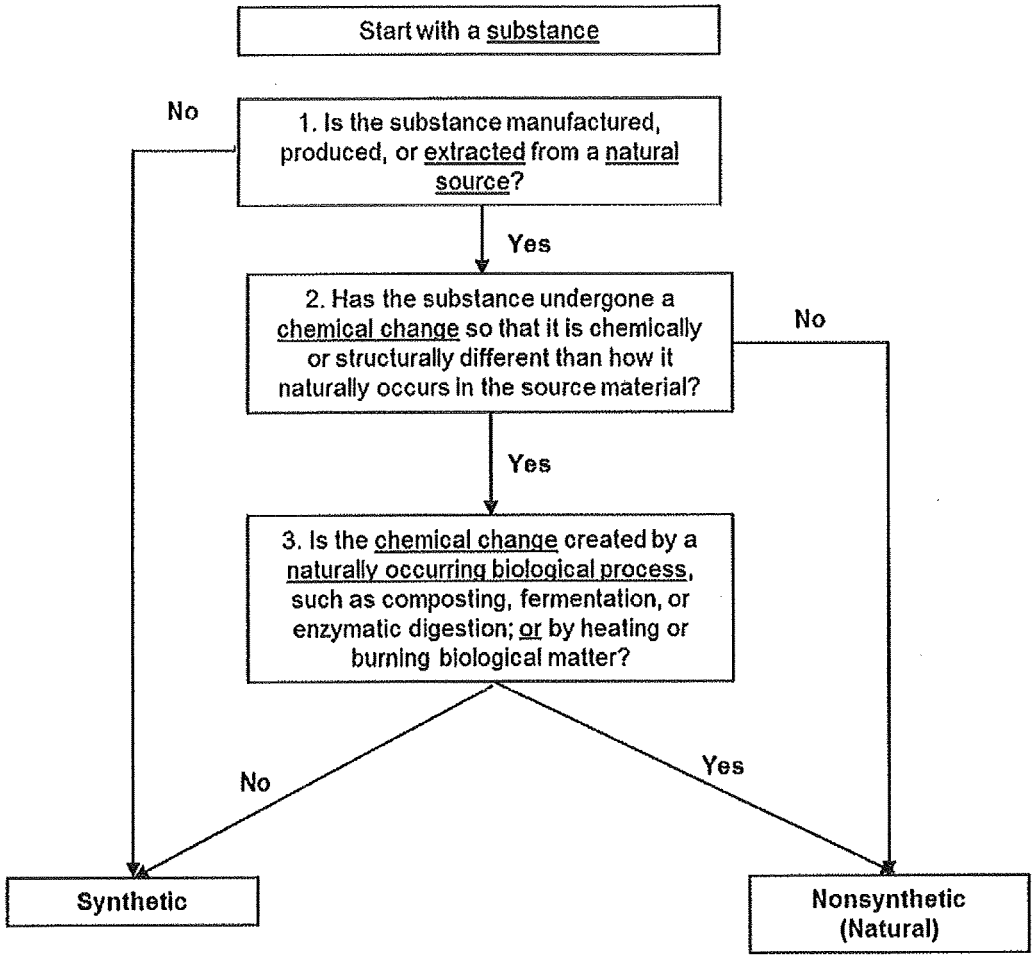
Advertiser's Statement:

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)**

EXHIBIT B

Draft Guidance
Decision Tree for Classification of Materials as Synthetic or Nonsynthetic

Underlined terms defined on page 2



Definitions (bolded terms in 7 CFR 205.2)

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

Chemical change. A process (i.e. chemical reaction) whereby a substance is transformed into one or more other distinct substances.

Extract. To separate, withdraw, or obtain one or more constituents of an organism, substance, or mixture by use of solvents (dissolution), acid-base extraction, or mechanical or physical methods.

Formulate. To combine different materials according to a recipe or formula.

Generic. The common and familiar non-proprietary name.

Manufacture. To make a substance from raw materials.

Natural source. Naturally occurring mineral or biological matter.

Naturally occurring biological process. A process that occurs due to the action of biological organisms or subcomponents of biological organisms, such as enzymes. Examples of naturally occurring biological processes include, but are not limited to, fermentation, composting, manure production, enzymatic processes, and anaerobic digestion.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Substance. A generic type of material, such as an element, molecular species, or chemical compound, that possesses a distinct identity (e.g. having a separate Chemical Abstracts Service

(CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Table 1. Classification examples of inputs:

Substance	Classification	Explanation
Ash (burned wood)	Nonsynthetic	Substance is created by burning biological matter.
Calcium carbonate (limestone)	Nonsynthetic	Substance is produced from a natural source (mined mineral) and does not undergo chemical change.
Calcium oxide (quicklime)	Synthetic	Substance is produced from a natural source (mined mineral), but undergoes chemical change caused by heating the mineral.
Citric acid	Nonsynthetic	Substance is created from a naturally occurring biological process (microbial fermentation of carbohydrate substances).
Enzymes, without synthetic additional ingredients	Nonsynthetic	Substance is extracted from a natural source and is not formulated with synthetic ingredients
Gibberellic acid	Nonsynthetic	Substance is extracted from a natural source without further chemical change
Liquid fish products – pH adjusted with phosphoric acid	Synthetic	Substance is derived from a natural source, but is treated with synthetic acids for pH adjustment.
Molasses	Nonsynthetic	Substance is derived from a natural source and chemical change is due to heating or naturally occurring biological processes.
Newspaper	Synthetic	Substance is manufactured via a chemical process.
Raw manure	Nonsynthetic	Substance is from a natural source and used without further processing.
Rosemary oil	Nonsynthetic	Substance is extracted from a natural source.