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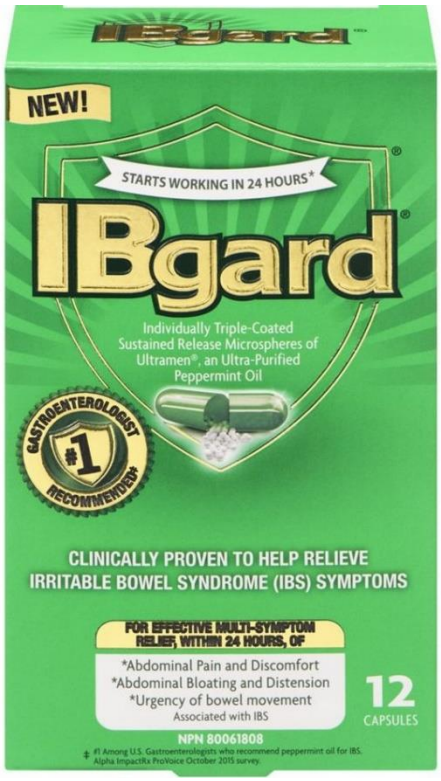
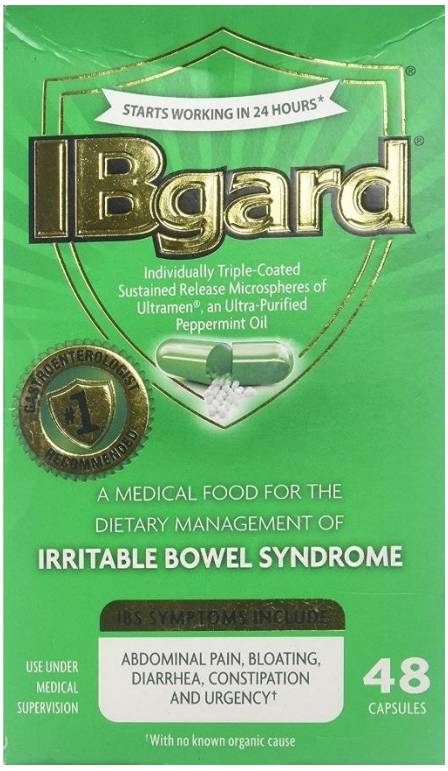
UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

Julie Foster, individually and on behalf of all others similarly situated, Plaintiff, - against - Nestle Health Science US Holdings, Inc., Defendant	1:21-cv-01360 Class Action Complaint Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations pertaining to plaintiff, which are based on personal knowledge:

1. Nestle Health Science US Holdings, Inc. ("Defendant") manufactures, labels, markets, and sells peppermint oil capsules promoted as a treatment for irritable bowel syndrome ("IBS") under the IBgard brand ("Product").





2. The relevant front label representations include "Clinically Proven to Help Relieve Irritable Bowel Syndrome (IBS) Symptoms" (left), "A Medical Food for the Dietary Management of Irritable Bowel Syndrome" (right), and a gold seal relating to the Product's approval by doctors.

3. The representations are misleading.

4. The FDA has established guidance to assist the pharmaceutical industry and investigators who are developing drugs for the treatment of IBS.

5. IBS diagnosis and assessment of clinical status depend mainly on an evaluation of signs and symptoms that are known to the patient.

6. The studies upon which Defendant's claims that the Product is "Clinically Proven" fail to meet the FDA's criteria.

7. This is based on factors which may include the length of the studies, conflicts of interest, sample size, outcome measures, and subsets of IBS considered.

8. No competent or reliable scientific evidence supports the claims that the Product is clinically proven to have the effects promised.

9. Studies have shown that peppermint oil and a placebo both showed clinically meaningful improvement in IBS symptoms, with no significant differences between them.

10. The Product is misleadingly identified as a medical food but does not meet the definition of a medical food. 21 U.S.C. § 360ee(b)(3); 21 C.F.R. § 101.9(j)(8).

11. A "medical food" is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

12. 21 CFR 101.9(j)(8) provides that a food is considered a medical food only if

i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;

ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

iii. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

iv. It is intended to be used under medical supervision; and

v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

13. Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition and must be intended to be used under medical supervision.

14. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.

15. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition's specific dietary

management.

16. Pursuant to 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.

17. The Product is promoted as a medical food for use by persons with irritable bowel syndrome.

18. However, the FDA has stated it is not aware of any distinctive nutritional requirements for individuals with irritable bowel syndrome.

19. Therefore, the Product does not meet the definition of a medical food or the regulatory criteria for a medical food.

20. The Product includes claims that it is intended for use in the cure, mitigation, treatment, or prevention of disease, which are drug claims, and because the products are not generally recognized as safe and effective for treating these conditions, they are considered unapproved new drugs under the FDCA.

21. The Product's gold seal and doctor recommended statements are misleading because these types of representations have been shown to elicit an additional level of trust in the product.

22. However, without uniform standards established by FDA or by industry groups, manufacturers cannot compare the quality of their products or hold each other accountable

23. The Product contains other representations which are misleading.

24. Reasonable consumers must and do rely on a company to honestly identify and describe the components, attributes, and features of a product, relative to itself and other comparable products or alternatives.

25. The value of the Product that plaintiff purchased was materially less than its value as represented by defendant.

26. Defendant sold more of the Product and at higher prices than it would have in the absence of this misconduct, resulting in additional profits at the expense of consumers.

27. Had Plaintiff and proposed class members known the truth, they would not have bought the Product or would have paid less for it.

28. The Product is sold for a price premium compared to other similar products, no less than approximately $7.50 for 12 capsules, a higher price than it would otherwise be sold for, absent the misleading representations and omissions.

Jurisdiction and Venue

29. Jurisdiction is proper pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

30. The aggregate amount in controversy exceeds $5 million, including any statutory damages, exclusive of interest and costs.

31. Plaintiff Julie Foster is a citizen of Illinois.

32. Defendant Nestle Health Science US Holdings, Inc., is a Delaware corporation with a principal place of business in Arlington, Arlington County, Virginia

33. Defendant transacts business within this District through sale of the Product at dozens of stores within this State and District, and online, sold directly to residents of this District.

34. Venue is in this District because plaintiff resides in this district and the actions giving rise to the claims occurred within this district.

35. Venue is in the Peoria Division in this District because a substantial part of the events or omissions giving rise to the claim occurred in McLean County, i.e., Plaintiff's purchase of the

Product and her awareness of the issues described here.

Parties

36. Plaintiff Julie Foster is a citizen of Bloomington, McLean County, Illinois.

37. Defendant Nestle Health Science US Holdings, Inc., is a Delaware corporation with a principal place of business in Arlington, Virginia, Arlington County.

38. Defendant is one of the largest and most trusted food and nutrition companies in the world, which consumers rely upon to supply foods and medical foods to improve their lives.

39. Plaintiff purchased the Product on one or more occasions within the statutes of limitations for each cause of action alleged, at stores within this District between August and September 2021, among other times.

40. Plaintiff bought the Product because she expected it was clinically proven to treat the conditions indicated and was a medical food because that is what the representations said and implied.

41. Plaintiff relied on the words and images on the Product, on the labeling and/or claims made by Defendant in digital and/or social media.

42. Plaintiff bought the Product at or exceeding the above-referenced price.

43. Plaintiff would not have purchased the Product if she knew the representations and omissions were false and misleading or would have paid less for it.

44. Plaintiff chose between Defendant's Product and products represented similarly, but which did not misrepresent their attributes.

45. The Product was worth less than what Plaintiff paid and she would not have paid as much absent Defendant's false and misleading statements and omissions.

46. Plaintiff intends to, seeks to, and will purchase the Product again when she can do so

with the assurance that Product's representations are consistent with its abilities and/or composition.

47. Plaintiff is unable to rely on the labeling of not only this Product, but other similar products, because she is unsure of whether their representations are truthful.

Class Allegations

48. Plaintiff seeks certification under Fed. R. Civ. P. 23(b)(2) and (b)(3) of the following classes:

> **Illinois Class:** All persons in the State of Illinois who purchased the Product during the statutes of limitations for each cause of action alleged.
>
> **Consumer Fraud Multi-State Class**: All persons in the States of Minnesota, Arizona, New Jersey, Rhode Island, Maine, Oregon, Washington, North Dakota, Texas, Iowa, Kansas, Georgia, Ohio, West Virginia, Virginia, North Carolina, Delaware, Montana, Kentucky, Tennessee, New Hampshire, Alaska, South Dakota, Oklahoma, Utah, Nebraska, Maine, and Wyoming, who purchased the Product during the statutes of limitations for each cause of action alleged

49. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiff and class members are entitled to damages.

50. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair and deceptive representations and actions.

51. Plaintiff is an adequate representative because her interests do not conflict with other members.

52. No individual inquiry is necessary since the focus is only on defendant's practices and the class is definable and ascertainable.

53. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

54. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

55. Plaintiff seeks class-wide injunctive relief because the practices continue.

Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1, et seq.

(Consumer Protection Statute)

56. Plaintiff incorporates by reference all preceding paragraphs.

57. Plaintiff and class members desired to purchase a product that was clinically proven to treat the conditions indicated and was a medical food.

58. Defendant's false and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

59. Defendant misrepresented the Product through statements, omissions, ambiguities, half-truths and/or actions.

60. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

61. Defendant misrepresented the Product through statements, omissions, ambiguities, half-truths and/or actions.

62. Plaintiff relied on the representations that the Product was clinically proven to treat the conditions indicated and was a medical food

63. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts

(On Behalf of the Consumer Fraud Multi-State Class)

64. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class prohibit the use of unfair or deceptive business practices in the conduct of trade or commerce.

65. Defendant intended that plaintiff and each of the other members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, and a reasonable person would in fact be misled by this deceptive conduct.

66. As a result of defendant's use or employment of artifice, unfair or deceptive acts or business practices, plaintiff, and each of the other members of the Consumer Fraud Multi-State Class, have sustained damages in an amount to be proven at trial.

67. In addition, defendant's conduct showed motive, and the reckless disregard of the truth such that an award of punitive damages is appropriate.

Breaches of Express Warranty,
Implied Warranty of Merchantability and
Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq*.

68. The Product was manufactured, identified, and sold by defendant and expressly and impliedly warranted to plaintiff and class members that it was clinically proven to treat the conditions indicated and was a medical food.

69. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

70. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high quality products.

71. Plaintiff provided or will provide notice to defendant, its agents, representatives, retailers, and their employees.

72. Defendant received notice and should have been aware of these issues due to complaints by regulators, competitors, and consumers, to its main offices, and by consumers through online forums.

73. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable because it was not fit to pass in the trade as advertised.

74. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

75. Defendant had a duty to truthfully represent the Product, which it breached.

76. This duty is based on defendant's position, holding itself out as having special knowledge and experience in this area, a trusted company known for its high quality products.

77. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in defendant.

78. Plaintiff and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, their purchase of the Product.

79. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

80. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it was clinically proven to treat the conditions indicated and was a medical food.

81. Moreover, the records Defendant is required to maintain, and/or the information

inconspicuously disclosed to consumers, provided it with actual and/or constructive knowledge of the falsity of the representations.

82. Defendant's fraudulent intent is evinced by its knowledge that the Product was not consistent with its representations.

Unjust Enrichment

83. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying plaintiff as representative and the undersigned as counsel for the class;
2. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;
3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages, statutory and/or punitive damages pursuant to any statutory claims and interest pursuant to the common law and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiff's attorneys and experts; and
6. Other and further relief as the Court deems just and proper.

Dated: December 12, 2021

Respectfully submitted,

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