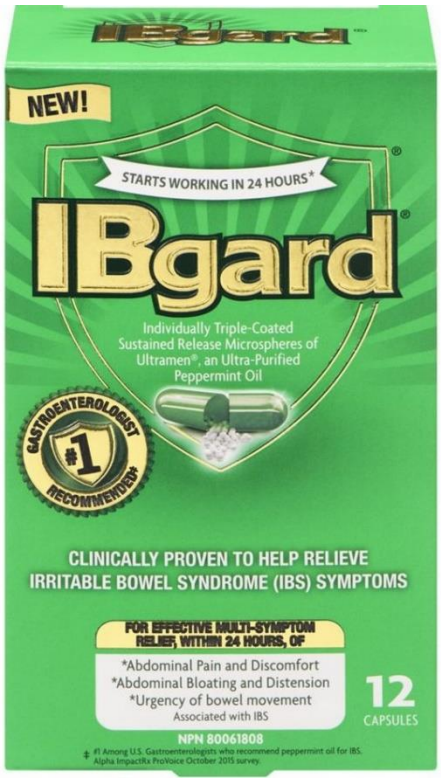
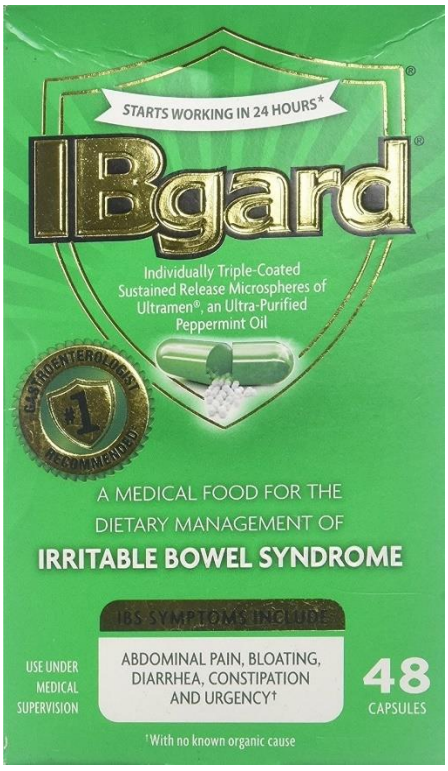
UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

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

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