UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

BONNIE WILMOT, individually and on behalf of all others similarly situated, Plaintiff, - against - RICOLA USA, INC., Defendant	Class Action Complaint Jury Trial Demanded

Plaintiff Bonnie Wilmot ("Plaintiff") alleges upon information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Ricola USA, Inc. ("Defendant") manufactures and sells oral anesthetic lozenges for "Nasal Care," containing the "max strength" of menthol under the Ricola brand ("Product").

I. LEGAL BACKGROUND

2. Research shows that "consumers initially [] rely on extrinsic cues such as visual information on labels and packaging to evaluate [any] product," thereby "develop[ing] sensory expectations" about its attributes and abilities.[1]

3. Consistent with these principles, Congress passed the Federal Food, Drug and Cosmetic Act ("FFDCA") in 1938, which set standards and regulations for what companies were required to tell consumers about over-the-counter ("OTC") medications they sell. 21 U.S.C. § 301 *et seq*.; 21 C.F.R. Parts 200 and 300.

4. This State adopted these laws in their entirety through the Florida Drug and Cosmetic Act ("DCA"). Fla. Stat. § 499.001 et seq.; Fla. Stat. § 499.002(b) ("Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the [FFDCA] and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.").

5. The Florida Administrative Code "adopts and incorporates by reference the labeling requirements for prescription drugs and over-the-counter drugs as set

[1] Lancelot Miltgen et al., "Communicating Sensory Attributes and Innovation through Food Product Labeling," Journal of Food Products Marketing, 22.2 (2016): 219-239; Helena Blackmore et al., "A Taste of Things to Come: The Effect of Extrinsic and Intrinsic Cues on Perceived Properties of Beer Mediated by Expectations," Food Quality and Preference, 94 (2021): 104326; Okamoto and Ippeita, "Extrinsic Information Influences Taste and Flavor Perception: A Review from Psychological and Neuroimaging Perspectives," Seminars in Cell & Developmental Biology, 24.3, Academic Press, 2013.

forth in the federal act at 21 U.S.C. [] 301 et seq. and in Title 21 [C.F.R.].” Fla. Admin. Code R. 61N-1.006(1).

6. These laws consider a drug “misbranded” and misleading if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a); Fla. Stat. § 499.005(1)-(2).

7. OTC products are required to contain specific information. 21 C.F.R. § 201.66(c).

8. This information tells purchasers a product’s purposes and uses. 21 C.F.R. § 201.66(c)(3)-(4).

II. “NASAL” CLAIMS FALSE AND MISLEADING

9. The front label identifies the Product’s active ingredient of menthol and its general pharmacological category as an “Oral Anesthetic.” § M022.52(a).

10. Menthol stimulates receptors for cold, thereby producing the sensation of coldness which temporarily masks pain by depressing the nerves for pain on the skin and mucous membranes.

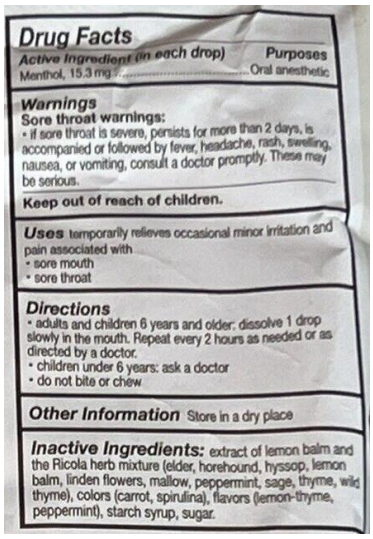
11. In a sense, menthol merely substitutes a cool sensation for the pain sensation.

12. Menthol’s local anesthetic effect has a mean duration of 1.5 minutes and a mean latency period of 0.16 minutes, regardless of the dosage.

13. As an oral anesthetic, menthol provides temporary relief of occasional

minor irritation, pain, sore mouth, and sore throat. § M022.52(b).

14. This is disclosed in the fine print on the back label in the "Uses" section of the Drug Facts, "temporarily relieves occasional minor irritation and pain associated with sore mouth and sore throat."



15. Consumers viewing the label will expect the Product to reduce symptoms of nasal issues, such as congestion and stuffiness.

16. However, the statements of "Nasal Care," "Cools Passage" and "Soothes Nose" and the pictures of the red cross, the universal symbol for care, and vapors passing through a human nose, are misleading for several reasons.

17. First, the "Uses" section on the back label concedes the Product is unable to provide relief to nasal symptoms, because it only lists its ability to temporarily provide relief to minor mouth and throat irritation.

18. Second, menthol provides no benefits to nasal symptoms, which is why the FDA did not authorize it to make these types of claims.

19. Studies have consistently demonstrated that though menthol stimulates cold receptors in nasal mucosa to create an increased sensation of airflow, it is incapable of any nasal decongestant action.[2]

20. No evidence was found in support of any nasal decongestant action for menthol.

21. Third, the Product does not contain any nasal decongestant active ingredients, whether oral or topical. 21 C.F.R. § 341.20(a)-(b).

22. Labeling the Product as having the ability to provide "Nasal Care" is false and misleading, which renders it "misbranded" under federal and identical state law. 21 U.S.C. § 352(a)(1).

23. Labeling the Product as having the ability to provide "Nasal Care" is inconsistent with the format and content requirements for OTC drug product labeling because menthol is not authorized to make claims related to nasal symptoms. 21 C.F.R. § 330.1(c)(1); 21 C.F.R. § 201.66(c).

III. "MAX STRENGTH" CLAIMS MISLEADING

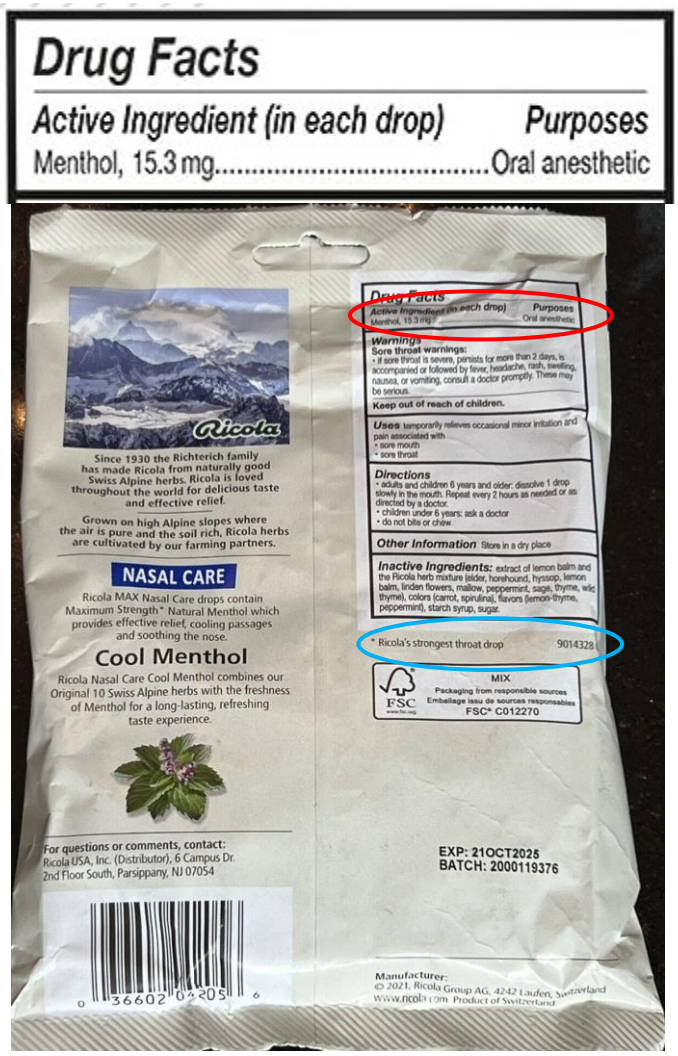
24. The front label statements of "Max Strength*," "Extra Strength Menthol" and "Max" ("Max Strength Claims") are misleading for multiple reasons.

25. First, the maximum strength allowed by the FDA for menthol in a

[2] R. Eccles and A. S. Jones, "The Effect of Menthol in Nasal Resistance to Air Flow," *The Journal of Laryngology & Otology* 97.8 (1983): 705-709.

lozenge is 20 mg.

26. However, the Product only provides 15.3 mg menthol per drop (red circle), which is less than the legally allowed 20 mg, shown in the fine print under the Drug Facts' Active Ingredient section.



27. Second, a small asterisk beneath the Drug Facts box (blue circle) reveals this refers to "Ricola's strongest throat drop."

28. The asterisk apparently is next to the front label "Max Strength" claim but is so small that purchasers do not even notice it.

29. Even if purchasers notice the asterisk, it does not point them to a location on the packaging where its meaning is explained to them.

30. Third, the Max Strength Claims are misleading by alluding to the Product's superiority due to greater potency.

31. No credible or accepted controlled scientific studies or reports indicate 15.3 mg of menthol provides a greater therapeutic benefit than a lozenge containing 10 mg of menthol.

32. Whether the amount of menthol was 10 mg or 15.3 mg, the pharmacological effects would be similarly effective.

33. Moreover, the higher "Max Strength" dosage of menthol may cause more side effects in numerous purchasers due to its greater amount of menthol.

34. There is no justification for claiming that from a therapeutic perspective, 10 mg of menthol is less effective in relieving temporary minor sore throat and mouth pain than 15.3 mg menthol.

35. When the FDA evaluated the dosages for menthol lozenges, it only relied

on studies of 9 mg menthol lozenges, not 20 mg, the maximum amount allowed.

36. However, because the amount of menthol that would be fatal was significantly higher at 2 g, it allowed a maximum concentration of 20 mg, but not based on a showing this concentration was more effective or potent.

JURISDICTION

37. Jurisdiction is based on the Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

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

39. Plaintiff is a citizen of Florida.

40. Defendant is a citizen of New Jersey because it is a corporation formed under the laws of New Jersey with a principal place of business in New Jersey.

41. The class of persons Plaintiff seeks to represent includes persons who are citizens of a different state from which Defendant is a citizen.

42. The members of the proposed class Plaintiff seeks to represent are more than one hundred, because the Product has been sold at thousands of retail stores, including grocery stores, convenience stores, warehouse club stores, big box stores, gas stations, pharmacies and online, throughout this State.

43. The Court has jurisdiction over Defendant because it transacts business within Florida and sells the Product to consumers within Florida from thousands of

retail stores.

VENUE

44. Venue is in this District because a substantial part of the events or omissions giving rise to these claims occurred in Brevard County, which is where Plaintiff's causes of action accrued.

45. Plaintiff purchased, used and/or consumed the Product in reliance on the labeling identified here in Brevard County.

46. Plaintiff first became aware the labeling was false and misleading in Brevard County.

47. Plaintiff resides in Brevard County.

PARTIES

48. Plaintiff Bonnie Wilmot is a citizen of Brevard County, Florida.

49. Defendant Ricola USA, Inc. is a New Jersey corporation with a principal place of business in New Jersey.

50. Defendant is a leading manufacturer and seller of OTC lozenges.

51. The Ricola brand is one of the world's most recognizable and trusted, because its lozenges are based on time-tested formulations, crafted originally in chalets in the shadows of the Swiss Alps.

52. Defendant sells the Product to third parties such as grocery stores, big box stores, warehouse club stores, drug stores, convenience stores, bodegas, and/or

online, where purchasers buy it.

53. Plaintiff purchased the Product between January 2021 and the present, at grocery stores, big box stores, warehouse club stores, drug stores, convenience stores, bodegas, and/or online, in this State.

54. Plaintiff is like most consumers and looks to the large print and images on the front of a product to learn what it is, its contents, and its abilities, relative to itself and other similar products she may buy.

55. Plaintiff read and relied on "Nasal Care," "Cools Passage," "Soothes Nose," and the pictures of the red cross, the universal symbol for care, and vapors passing through a human nose, to believe the Product would alleviate nasal symptoms including congestion and stuffiness, in addition to its functioning as an oral anesthetic.

56. Plaintiff read and relied on "Max Strength*," "Extra Strength Menthol" and "[Ricola] Max" and believed these were statements of the Product's superiority, such that it went beyond a traditional oral anesthetic so it could provide "Nasal Care."

57. Plaintiff read and relied on "Max Strength*," "Extra Strength Menthol" and "[Ricola] Max" to expect the Product contained the maximum amount of menthol allowed by law.

58. Plaintiff read and relied on "Max Strength*," "Extra Strength Menthol"

and "[Ricola] Max" and believed the additional amount of menthol would provide a proven therapeutic benefit above non-max strength oral anesthetic menthol lozenges.

59. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than $5.79 per 34 lozenges, excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

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

61. Plaintiff paid more for the Product than she would have had he known its claims about nasal care and max strength were false and misleading, as she would not have bought it or would have paid less.

62. 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.

CLASS ALLEGATIONS

63. Plaintiff seeks to represent the following class:

> All persons in the State of Florida who purchased the Product in Florida during the statutes of limitations for each cause of action alleged.

64. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and

class members are entitled to damages.

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

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

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

68. 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.

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

CAUSES OF ACTION

COUNT I
Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"),
Fla. Stat. § 501.201, *et seq.*

70. Plaintiff incorporates by reference paragraphs 1-36.

71. Plaintiff believed the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said, "Nasal Care" and was described as "max strength" and (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than

other oral anesthetic lozenges not represented as "max strength."

72. Plaintiff paid more for the Product, would not have purchased it or paid as much if she knew (1) it was unable to provide relief to nasal symptoms such as congestion and stuffiness, (2) it did not contain any active nasal decongestant ingredients, (3) the amount of menthol it contained was less than the maximum amount allowed by law, and (4) the greater amount of menthol provided no therapeutic benefits beyond similar products with the standard dosage of 10 mg of menthol.

73. Plaintiff seeks to recover for economic injury and/or loss she sustained based on the misleading labeling of the Product, a deceptive practice under this State's consumer protection laws, by paying more for it than she otherwise would have.

74. Plaintiff will produce evidence showing how she and consumers paid more than they otherwise would have paid for the Product, relying on Defendant's representations, using statistical and economic analyses, hedonic regression, and other advanced methodologies.

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

COUNT II
False and Misleading Adverting,
Fla. Stat. § 817.41

76. Plaintiff incorporates by reference paragraphs 1-36.

77. Defendant made misrepresentations and omissions of material fact, that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength," through its advertisements and marketing in various forms of media, product packaging and descriptions, and targeted digital advertising.

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

79. Defendant knew these statements were false and/or misleading.

80. Defendant intended for consumers to rely on its false statements and omissions for the purpose of selling the Product.

81. Plaintiff and class members did in fact rely upon these statements.

82. Reliance was reasonable and justified because of Ricola's reputation as a leader in OTC lozenges, honestly marketed to consumers.

83. As a result of Defendant's misrepresentations, Plaintiff and class members suffered damages in the amount paid for the Product and the premium amount paid.

COUNT III
Breach of Express Warranty

84. Plaintiff incorporates by reference paragraphs 1-36.

85. The Product was manufactured, identified, marketed, and sold by Defendant and expressly warranted to Plaintiff and class members that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

86. Defendant directly marketed the Product to Plaintiff and consumers through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, and/or targeted digital advertising.

87. Defendant knew the product attributes that potential customers like Plaintiff were seeking, such as an oral anesthetic lozenge to alleviate minor throat and mouth pain, but one which also provided relief to nasal symptoms such as congestion and stuffiness and developed its marketing and labeling to directly meet those needs and desires.

88. Defendant's representations affirmed and promised that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said, "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

89. Defendant described the Product so Plaintiff and consumers believed it (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength," which became part of the basis of the bargain that it would conform to its affirmations and promises.

90. Plaintiff recently became aware of Defendant's breach of the Product's express warranties.

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

92. Plaintiff hereby provides notice to Defendant that it breached the Product's express warranties.

93. Defendant received notice and should have been aware of these issues

due to complaints by third parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums.

94. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.

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

COUNT IV
Fraud

96. Plaintiff incorporates by reference paragraphs 1-36.

97. Plaintiff satisfied the requirements of fraud by establishing relevant elements with sufficient particularity.

98. WHO: Defendant, Ricola, made material misrepresentations and/or omissions of fact in its advertising and marketing of the Product by representing it (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

99. WHAT: Defendant's conduct was and continues to be fraudulent because it deceives consumers into believing the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was

described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

100. Defendant omitted telling consumers the Product's active ingredient of menthol was unable to reduce or alleviate nasal symptoms such as congestion and stuffiness even though it could function as an oral anesthetic to relieve minor mouth and throat pain.

101. Defendant omitted telling consumers the Product's menthol dosage was not the highest amount allowed by law.

102. Defendant omitted telling consumers that a dosage of menthol beyond the standard 10 mg per lozenge had no therapeutic benefits and could cause side effects.

103. Defendant knew or should have known this information was material to all reasonable consumers and impacts their purchasing decisions.

104. Defendant conducts research on consumer preferences and is aware of consumer demand for (1) multi-functional OTC products, which could alleviate multiple categories of symptoms and (2) higher potency formulations which presumably are more effective than regular versions of a product.

105. The records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive

knowledge of this falsity and deception, through statements and omissions.

106. Yet, Defendant has represented and/or continues to represent that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said, "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

107. WHEN: Defendant made these material misrepresentations and/or omissions detailed herein, continuously throughout the applicable class period and through the filing of this Complaint.

108. WHERE: Defendant's material misrepresentations and omissions, that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength," were made in the advertising and marketing of the Product, on the front of the packaging, which all consumers buying would inevitably see and take notice of.

109. HOW: Defendant made written and visual misrepresentations and omissions in the advertising and marketing of the Product, that it (1) provided relief

to nasal symptoms such as congestion and stuffiness because it said "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength."

110. And as discussed in detail throughout this Complaint, Plaintiff and class members read and relied on Defendant's representations and omissions before purchasing the Product.

111. WHY: Defendant misrepresented that the Product (1) provided relief to nasal symptoms such as congestion and stuffiness because it said, "Nasal Care" and was described as "max strength," (2) contained the maximum amount of menthol allowed by law, and (3) could provide greater therapeutic effects because it contained more menthol than other oral anesthetic lozenges not represented as "max strength," for the express purpose of inducing Plaintiff and class members to purchase the Product at a substantial price premium, in part based on consumer demand for multi-functional OTC products and higher potency versions of regular products.

112. As such, Defendant profited by selling the misrepresented Product to thousands of consumers throughout this State.

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. Awarding monetary damages and interest;
3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and
4. Other and further relief as the Court deems just and proper.

Dated: September 6, 2023

Respectfully submitted,

/s/ William Wright

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