

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
WHITE PLAINS DIVISION

HENRY ALEXIS,	:	
	:	
ZANG ANGELFIRE,	:	
	:	
REYES APODACA,	:	Case No.: 7:19-cv-10358
	:	
WILMER ARNOLD,	:	
	:	
SAMUEL BAKER,	:	
	:	
STEPHEN BATEMAN,	:	
	:	
KENNETH BERNARD,	:	
	:	
DAVID BERRIOS,	:	
	:	
PIERRE BIBBS,	:	
	:	
CHESTER BROMBY,	:	Judge:
	:	
MARK BROOKS,	:	
	:	
SIMMIE ANTIONE BROWN,	:	
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RUBEN BUSTILLOS,	:	
	:	
BRYAN CARTER,	:	
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RICHARD CASTIANO,	:	
	:	
MAURICE CHILDS,	:	
	:	
CRUZ CISNEROS,	:	
	:	
JULIO CONCEPCION,	:	COMPLAINT AND JURY DEMAND
	:	
HAYWOOD CRAWFORD,	:	
	:	
DWIGHT CROSBY,	:	
	:	
CREED CULP,	:	
	:	

BILLY CURRY, :
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ARDELL DANIEL, :
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BENJAMIN DAVIS, :
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DARRELL DAVIS. :
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FRANK DAVIS, :
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MARC DAVIS, :
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HECTOR DE LA TORRE, :
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JON DEERY, :
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DENNIS DELANEY, :
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SEAN DEMPSEY, :
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DOUGLAS DIGGS, :
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RICHARD DORR, :
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ANGELO DOURLAS, :
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DENNIS DOUVILLE, :
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LARRY DUSTIN, :
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JOHN FOSTER, :
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MARK FOWLER, :
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TERRENCE FRYE, :
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ANTON GADSDEN, :
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DAVID GAMBLE, :
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STEPHEN GILSTRAP, :
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JOSEPH GLUZ, :
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EVERARDO PARMA GONZALEZ, :

LEON GRAHAM, :
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SAMUEL GRAY, :
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DAVID HALEY, :
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MARK HARPER, :
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MICHAEL HARRIS, :
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DANIEL HARRISON, :
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CHRISTOPHER HAYES, :
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ANDREW HENDERSON, :
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WILLIAM HERON, :
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MICHAEL HOLDEN, :
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MARC HOLLIS, :
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LEONARD HORNE, :
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JEROME JACKSON, :
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MICHAEL HOLDEN, :
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JASON JOHNSON, :
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KEVIN JOHNSTON, :
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ROBERT JONES, :
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WILLIAM JONES, :
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JEFFREY JOYNER, :
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JEFF KALB, :
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EDWARD KEOHOU, :
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JOSEPH KERBER, :
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MICHAEL LANDIE, :
 :

ROBERT LEE, :
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KEVIN LEWIS, :
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CHARLES LITTERAL, :
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KENNETH LUBIC, :
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MARC MARTIN, :
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RONALD MARTINEZ, :
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MARCUS MATTHEWS, :
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SHAWN MATTHEWS, :
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WAYNE MATTHEWS, :
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TOMMY MCBRIDE, :
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CHRIS MCLENDON, :
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WILLIAM MCDONALD, :
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THOMAS MCGINNIS, :
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MICHAEL MCINTOSH, :
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EUGENE MILLER, :
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JAMES MINOR, :
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JOHN MOORE, :
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RICHARD MORRIS, :
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PRESTON MOSLEY, :
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DANIEL MURPHY, :
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CURTIS NELLOMS, :
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STEPHEN NICHOLS, :
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EDWARD PARKER, :
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JUSTIN PARKER, :
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MARK PEREA, :
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JAMES PETTAWAY, :
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ANTHONY PHARR, :
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MYRON PIPES, :
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RICK PIPPIN, :
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JAMES POTTER, :
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MARCUS POWELL, :
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JAMES RAPP, :
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MAURICE RELEFORD, :
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DENNIE RIVERA, :
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ALBERT ROCKY, :
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DAVIAN ROSS, :
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IVAN RUSSELL, :
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ERIC SAMUELS, :
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KYLE SCHIRMER, :
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SAM SHAMES, :
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TYRUS SIMMONS, :
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RONALD SMITH, :
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ELZY SPRUILL, :
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ROY STEWART, :
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RAYMOND STOUT, :
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BRYANT STREET, :

KEVIN SWAN, :
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JOE TAYLOR, :
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DEWAYNE THARPE, :
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RANDY THOMAS, :
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RODNEY THOMAS, :
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HARRY THOMPSON, :
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MICHAEL TOLIVER, :
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JOE TRASK, :
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JAMES TRAYLOR, :
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ROBERT TUCKER, :
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CURTIS TURNER, :
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RICHARD TURNER, :
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SAMUEL UVEGAS, :
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HECTOR VALENTIN, :
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ANTHONY VELLIOS, :
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GEORGE VILLAMIL, :
 :
WILLIAM WAGONER, :
 :
TINEY WARD, :
 :
ANTHONY WHITE, :
 :
DAVID WILLIAMS, :
 :
LEONARD WOLFF, :
 :
and :
 :
SAMUEL YOUNG, :

Plaintiffs, :
 :
v. :
 :
COMBE INCORPORATED :
 :
Defendant. :
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Plaintiffs, by and through counsel, allege as follows:

PARTIES, JURISDICTION, AND VENUE

1. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a), as all Plaintiffs are citizens of states different than Defendant and the amount in controversy alleged by each Plaintiff exceeds the sum of \$75,000, exclusive of interest and costs.
2. Alternatively, the Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 to the extent that any Plaintiff's claims do not exceed \$75,000.
3. Plaintiff, Henry Alexis, citizen of Georgia, suffered personal injury and other damages from use of Just For Men Hair Dye.
4. Plaintiff, Zang Angelfire, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.
5. Plaintiff, Reyes Apodaca, citizen of New Mexico, suffered personal injury and other damages from use of Just For Men Hair Dye.
6. Plaintiff, Wilmer Arnold, citizen of Maryland, suffered personal injury and other damages from use of Just For Men Hair Dye.
7. Plaintiff, Samuel Baker, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

8. Plaintiff, Ruben Bustillos, citizen of Texas, suffered personal injury and other damages from use of Just For Men Hair Dye.

9. Plaintiff, Bryan Carter, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

10. Plaintiff, Richard Castiano, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

11. Plaintiff, Maurice Childs, citizen of Alabama, suffered personal injury and other damages from use of Just For Men Hair Dye.

12. Plaintiff, Cruz Cisneros, citizen of Oklahoma, suffered personal injury and other damages from use of Just For Men Hair Dye.

13. Plaintiff, Julio Concepcion, citizen of Connecticut, suffered personal injury and other damages from use of Just For Men Hair Dye.

14. Plaintiff, Haywood Crawford, citizen of Arizona, suffered personal injury and other damages from use of Just For Men Hair Dye.

15. Plaintiff, Dwight Crosby, citizen of Arizona, suffered personal injury and other damages from use of Just For Men Hair Dye.

16. Plaintiff, Creed Culp, citizen of Oregon, suffered personal injury and other damages from use of Just For Men Hair Dye.

17. Plaintiff, Billy Curry, citizen of Michigan, suffered personal injury and other damages from use of Just For Men Hair Dye.

18. Plaintiff, Ardell Daniel, citizen of Kansas, suffered personal injury and other damages from use of Just For Men Hair Dye.

19. Plaintiff, Benjamin Davis, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

20. Plaintiff, Darrell Davis, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

21. Plaintiff, Frank Davis, citizen of South Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

22. Plaintiff, Marc Davis, citizen of Washington, suffered personal injury and other damages from use of Just For Men Hair Dye.

23. Plaintiff, Hector De La Torre, citizen of Texas, suffered personal injury and other damages from use of Just For Men Hair Dye.

24. Plaintiff, Jon Deery, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

25. Plaintiff, Dennis Delaney, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

26. Plaintiff, Sean Dempsey, citizen of Massachusetts, suffered personal injury and other damages from use of Just For Men Hair Dye.

27. Plaintiff, Douglas Diggs, citizen of Washington D.C., suffered personal injury and other damages from use of Just For Men Hair Dye.

28. Plaintiff, Richard Dorr, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

29. Plaintiff, Angelo Dourlas, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

30. Plaintiff, Dennis Douville, citizen of Washington, suffered personal injury and other damages from use of Just For Men Hair Dye.

31. Plaintiff, Larry Dustin, citizen of Maine, suffered personal injury and other damages from use of Just For Men Hair Dye.

32. Plaintiff, John Foster, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

33. Plaintiff, Mark Fowler, citizen of Georgia, suffered personal injury and other damages from use of Just For Men Hair Dye.

34. Plaintiff, Stephen Bateman, citizen of Missouri, suffered personal injury and other damages from use of Just For Men Hair Dye.

35. Plaintiff, Kenneth Bernard, citizen of Virginia, suffered personal injury and other damages from use of Just For Men Hair Dye.

36. Plaintiff, David Berrios, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

37. Plaintiff, Pierre Bibbs, citizen of Washington, suffered personal injury and other damages from use of Just For Men Hair Dye.

38. Plaintiff, Chester Bromby, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

39. Plaintiff, Mark Brooks, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

40. Plaintiff, Simmie Antione Brown, citizen of Missouri, suffered personal injury and other damages from use of Just For Men Hair Dye.

41. Plaintiff, Terrence Frye, citizen of Alabama, suffered personal injury and other damages from use of Just For Men Hair Dye.
42. Plaintiff, Anton Gadsden, citizen of South Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.
43. Plaintiff, David Gamble, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.
44. Plaintiff, Stephen Gilstrap, citizen of Texas, suffered personal injury and other damages from use of Just For Men Hair Dye.
45. Plaintiff, Joseph Gluz, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.
46. Plaintiff, Everardo Parma Gonzalez, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.
47. Plaintiff, Leon Graham, citizen of Georgia, suffered personal injury and other damages from use of Just For Men Hair Dye.
48. Plaintiff, Samuel Gray, citizen of Alabama, suffered personal injury and other damages from use of Just For Men Hair Dye.
49. Plaintiff, David Haley, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.
50. Plaintiff, Mark Harper, citizen of Massachusetts, suffered personal injury and other damages from use of Just For Men Hair Dye.
51. Plaintiff, Michael Harris, citizen of Minnesota, suffered personal injury and other damages from use of Just For Men Hair Dye.

52. Plaintiff, Daniel Harrison, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

53. Plaintiff, Christopher Hayes, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

54. Plaintiff, Andrew Henderson, citizen of Georgia, suffered personal injury and other damages from use of Just For Men Hair Dye.

55. Plaintiff, William Heron, citizen of Massachusetts, suffered personal injury and other damages from use of Just For Men Hair Dye.

56. Plaintiff, Michael Holden, citizen of Nevada, suffered personal injury and other damages from use of Just For Men Hair Dye.

57. Plaintiff, Marc Hollis, citizen of Michigan, suffered personal injury and other damages from use of Just For Men Hair Dye.

58. Plaintiff, Leonard Horne, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

59. Plaintiff, Jerome Jackson, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

60. Plaintiff, Michael Holden, citizen of Nevada, suffered personal injury and other damages from use of Just For Men Hair Dye.

61. Plaintiff, Jason Johnson, citizen of Indiana, suffered personal injury and other damages from use of Just For Men Hair Dye.

62. Plaintiff, Kevin Johnston, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

63. Plaintiff, Robert Jones, citizen of Michigan, suffered personal injury and other damages from use of Just For Men Hair Dye.

64. Plaintiff, William Jones, citizen of Virginia, suffered personal injury and other damages from use of Just For Men Hair Dye.

65. Plaintiff, Jeffrey Joyner, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

66. Plaintiff, Jeff Kalb, citizen of Nevada, suffered personal injury and other damages from use of Just For Men Hair Dye.

67. Plaintiff, Edward Keohou, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

68. Plaintiff, Joseph Kerber, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

69. Plaintiff, Michael Landie, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

70. Plaintiff, Robert Lee, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

71. Plaintiff, Kevin Lewis, citizen of Colorado, suffered personal injury and other damages from use of Just For Men Hair Dye.

72. Plaintiff, Charles Litteral, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

73. Plaintiff, Kenneth Lubic, citizen of Arizona, suffered personal injury and other damages from use of Just For Men Hair Dye.

74. Plaintiff, Marc Martin, citizen of Washington, suffered personal injury and other damages from use of Just For Men Hair Dye.

75. Plaintiff, Ronald Martinez, citizen of New Mexico suffered personal injury and other damages from use of Just For Men Hair Dye.

76. Plaintiff, Marcus Matthews, citizen of Mississippi, suffered personal injury and other damages from use of Just For Men Hair Dye.

77. Plaintiff, Shawn Matthews, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

78. Plaintiff, Wayne Matthews, citizen of Louisiana, suffered personal injury and other damages from use of Just For Men Hair Dye.

79. Plaintiff, Tommy McBride, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

80. Plaintiff, Chris McLendon, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

81. Plaintiff, William McDonald, citizen of South Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

82. Plaintiff, Thomas McGinnis, citizen of Louisiana, suffered personal injury and other damages from use of Just For Men Hair Dye.

83. Plaintiff, Michael McIntosh, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

84. Plaintiff, Eugene Miller, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

85. Plaintiff, James Minor, citizen of Virginia, suffered personal injury and other damages from use of Just For Men Hair Dye.

86. Plaintiff, John Moore, citizen of Maryland, suffered personal injury and other damages from use of Just For Men Hair Dye.

87. Plaintiff, Richard Morris, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

88. Plaintiff, Preston Mosley, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

89. Plaintiff, Daniel Murphy, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

90. Plaintiff, Curtis Nelloms, citizen of Washington D.C., suffered personal injury and other damages from use of Just For Men Hair Dye.

91. Plaintiff, Stephen Nichols, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

92. Plaintiff, Edward Parker, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

93. Plaintiff, Justin Parker, citizen of Nevada, suffered personal injury and other damages from use of Just For Men Hair Dye.

94. Plaintiff, Mark Perea, citizen of Colorado, suffered personal injury and other damages from use of Just For Men Hair Dye.

95. Plaintiff, James Pettaway, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

96. Plaintiff, Anthony Pharr, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

97. Plaintiff, Myron Pipes, citizen of New Jersey, suffered personal injury and other damages from use of Just For Men Hair Dye.

98. Plaintiff, Rick Pippin, citizen of Kentucky, suffered personal injury and other damages from use of Just For Men Hair Dye.

99. Plaintiff, James Potter, citizen of Alabama, suffered personal injury and other damages from use of Just For Men Hair Dye.

100. Plaintiff, Marcus Powell, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

101. Plaintiff, James Rapp, citizen of New Jersey, suffered personal injury and other damages from use of Just For Men Hair Dye.

102. Plaintiff, Maurice Releford, citizen of Georgia, suffered personal injury and other damages from use of Just For Men Hair Dye.

103. Plaintiff, Dennie Rivera, citizen of Virginia, suffered personal injury and other damages from use of Just For Men Hair Dye.

104. Plaintiff, Albert Rocky, citizen of New Jersey, suffered personal injury and other damages from use of Just For Men Hair Dye.

105. Plaintiff, Davian Ross, citizen of Arizona, suffered personal injury and other damages from use of Just For Men Hair Dye.

106. Plaintiff, Ivan Russell, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

107. Plaintiff, Eric Samuels, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

108. Plaintiff, Kyle Schirmer, citizen of Connecticut, suffered personal injury and other damages from use of Just For Men Hair Dye.

109. Plaintiff, Sam Shames, citizen of Arizona, suffered personal injury and other damages from use of Just For Men Hair Dye.

110. Plaintiff, Tyrus Simmons, citizen of North Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

111. Plaintiff, Ronald Smith, citizen of Idaho, suffered personal injury and other damages from use of Just For Men Hair Dye.

112. Plaintiff, Elzy Spruill, citizen of Texas, suffered personal injury and other damages from use of Just For Men Hair Dye.

113. Plaintiff, Roy Stewart, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

114. Plaintiff, Raymond Stout, citizen of Missouri, suffered personal injury and other damages from use of Just For Men Hair Dye.

115. Plaintiff, Bryant Street, citizen of Idaho, suffered personal injury and other damages from use of Just For Men Hair Dye.

116. Plaintiff, Kevin Swan, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

117. Plaintiff, Joe Taylor, citizen of Wisconsin, suffered personal injury and other damages from use of Just For Men Hair Dye.

118. Plaintiff, Dewayne Tharpe, citizen of Kansas, suffered personal injury and other damages from use of Just For Men Hair Dye.

119. Plaintiff, Randy Thomas, citizen of Colorado, suffered personal injury and other damages from use of Just For Men Hair Dye.

120. Plaintiff, Rodney Thomas, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

121. Plaintiff, Harry Thompson, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

122. Plaintiff, Michael Toliver, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

123. Plaintiff, Joe Trask, citizen of Indiana, suffered personal injury and other damages from use of Just For Men Hair Dye.

124. Plaintiff, James Traylor, citizen of Nevada, suffered personal injury and other damages from use of Just For Men Hair Dye.

125. Plaintiff, Robert Tucker, citizen of South Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

126. Plaintiff, Curtis Turner, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

127. Plaintiff, Richard Turner, citizen of California, suffered personal injury and other damages from use of Just For Men Hair Dye.

128. Plaintiff, Samuel Uvegas, citizen of Florida, suffered personal injury and other damages from use of Just For Men Hair Dye.

129. Plaintiff, Hector Valentin, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

130. Plaintiff, Anthony Vellios, citizen of Pennsylvania, suffered personal injury and other damages from use of Just For Men Hair Dye.

131. Plaintiff, George Villamil, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

132. Plaintiff, William Wagoner, citizen of Virginia, suffered personal injury and other damages from use of Just For Men Hair Dye.

133. Plaintiff, Tiney Ward, citizen of Ohio, suffered personal injury and other damages from use of Just For Men Hair Dye.

134. Plaintiff, Anthony White, citizen of South Carolina, suffered personal injury and other damages from use of Just For Men Hair Dye.

135. Plaintiff, David Williams, citizen of Illinois, suffered personal injury and other damages from use of Just For Men Hair Dye.

136. Plaintiff, Leonard Wolff, citizen of Michigan, suffered personal injury and other damages from use of Just For Men Hair Dye.

137. Plaintiff, Samuel Young, citizen of Maryland, suffered personal injury and other damages from use of Just For Men Hair Dye.

138. Defendant Combe Incorporated is a Delaware corporation, which has its principle place of business at 1101 Westchester Ave., White Plains, New York 10604.

139. At all times relevant hereto, Defendant Combe Incorporated was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Just For Men hair care and dye products.

140. This Court has personal jurisdiction over Defendant because Defendant maintains its principle place of business within the State of New York and this District. Defendant has also regularly and purposefully transacted business and engaged in commercial activities within the State of New York and this District.

141. Venue is proper within this district pursuant to 28 U.S.C. §1391(b)(1) and (d), because Defendant is a resident of the State of New York and has had such contacts within this District that would be sufficient to subject it to personal jurisdiction if this District were a state.

FACTUAL ALLEGATIONS

142. Defendant markets Just For Men® hair dyes (“Just For Men”) not only for application to hair on the scalp, but also for coloring of moustache, beard and side burns.

143. Just For Men hair dyes contain multiple ingredients, including a chemical known as p-phenylenediamine (“PPD”).

144. PPD is characterized as a coal tar dye because it was originally sourced from coal tar, but in modern use is typically derived from petroleum products.

145. According to the National Capital Poison Center,

Even when hair dyes are used as directed, harmful health effects are possible. Up to 25 different ingredients in hair dyes can cause harmful skin effects. One of the main culprits is the primary intermediate PPD. Contact with skin can cause irritation including redness, sores, itching, and burning. Occasionally, allergic reactions occur and involve swelling of the face and neck that causes difficulty breathing. These toxic effects can occur immediately or up to a day after contact with the skin.

146. As referenced above, skin irritation and allergic reactions are distinct. Thus, medical experts recognize irritant contact dermatitis and allergic contact dermatitis as separate diagnoses.

147. According to Mayo Clinic, irritant contact dermatitis is a “non allergic skin reaction [that] occurs when a substance damages your skin’s outer protective layer” which can occur after a single

exposure to strong irritants, or after multiple exposures to mild irritants. Conversely, some people develop tolerance to a skin irritant over time. <https://www.mayoclinic.org/diseases-conditions/contact-dermatitis/symptoms-causes/syc-20352742>. Various solvents, detergents, shampoos, plants, fertilizers and pesticides are identified as causes of skin irritation.

148. By contrast, Mayo Clinic describes allergic contact dermatitis as occurring “when a substance to which you’re sensitive (allergen) triggers an immune reaction in your skin. ... You may become sensitized to a strong allergen such as poison ivy after a single exposure. Weaker allergens may require multiple exposures over several years to trigger an allergy. Once you develop an allergy to a substance, even a small amount can cause a reaction.” *Id.*

149. Common allergens identified by Mayo Clinic includes nickel, medications, balsam of Peru, formaldehyde, plants, airborne substances and personal care products, such as deodorants, body washes and hair dyes.

150. Hair dye dermatitis reactions can vary from mild, localized contact dermatitis and “disseminated generalized dermatitis to severe life-threatening complications such as contact urticaria/angioedema, rhinitis/bronchospasm/asthma and renal toxicity.” Gupta M., et al, “Hair dye dermatitis and p-phenylenediamine contact sensitivity: A preliminary report,” *Indian Dermatology Online Journal* (2015): Jul-Aug; 6;(): 241-246.

151. Scientists have also demonstrated a significant association between vitiligo (destruction of melanocytes resulting in depigmentation of the skin) and contact dermatitis caused by PPD. In fact, an increased rate of vitiligo on the hairline and scalp was observed among vitiligo patients who tested positive for PPD allergy. Lee J-H, et al, “Patch test reactions in patients with the additional diagnosis of vitiligo,” *International Society of Dermatology* (2014); 53:187-191.

152. In 1933 and 1934, medical literature reports in JAMA confirmed serious injuries, including blindness, from the use of eyebrow and eyelash dye containing PPD.

153. With the passage of the Food, Drug and Cosmetic Act in 1938, Congress prohibited the use of coal tar dyes for the eyelashes or eyebrows. However, Congress did allow coal tar products for use as a hair dye, provided that the following information be included in product labeling:

Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.

21 U.S.C. § 361(a).

154. In addition to this minimally required language, 21 U.S.C. § 361(a) further requires that products containing coal tar dyes must also “bear[] adequate directions for such preliminary testing.” A failure to provide such adequate directions renders the product adulterated.

155. Despite the specific requirement in the Food, Drug & Cosmetic Act (FDCA) that products containing coal tar dyes must contain the Caution quoted above, Defendant’s Just For Men products do not comply with this regulation.

156. Instead, Just For Men Products contain altered language which states:

Caution: This product contains ingredients which may cause skin irritation on certain individuals and a preliminary **48 hour skin allergy patch (ALERT)** test according to accompanying directions should be done first. This product must not be used for dyeing the eyelashes or eyebrows - to do so may cause blindness. (emphasis added.)

157. The inclusion of the phrase “48 hour skin allergy patch (ALERT) test” materially alters the requirements contained in 21 U.S.C. § 361 that a test be conducted for “skin irritation.”

158. As described above, unlike skin irritation, allergic contact dermatitis is an immune response to an agent that triggers antibodies called immunoglobulin E (IgE). The IgE antibodies

cause cells to release inflammatory chemicals called histamines, which cause the manifestation of allergy symptoms.

159. Patch tests to detect allergic reactions are articles intended for use in the diagnosis or prevention of a disease.

160. Under the FDCA, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” are drugs. 21 USC § 321(g)(1)(B).

161. By marketing Just For Men hair dyes to be used by consumers with a mandatory 48 hour at home “allergy ALERT patch test” prior to every use, Defendant is promoting Just For Men for use as a drug.

162. Drugs must be approved by FDA prior to introduction to the market. Manufacturers of drugs which are not specifically identified as safe for over the counter use by FDA must submit comprehensive safety and efficacy data to FDA in order to obtain marketing approval.

163. 21 U.S.C. § 355(a) states that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application...is effective with respect to such drug.”

164. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of 21 U.S.C. § 355. *See* 21 U.S.C. § 331(d).

165. Additionally, under federal law, pharmaceutical drugs must be manufactured in accordance with “current Good Manufacturing Practices” (“cGMPs”) to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

166. The FDA’s cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug

product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K).

167. Any drug not manufactured in accordance with cGMPs is deemed “adulterated” and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs’ safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a).

168. A company called SmartPractice Denmark ApS submitted a Biologics License Application for Allergy Patch Testing, which FDA approved in 1994. The product is called T.R.U.E. TEST, which is a Thin-Layer Rapid Use Epicutaneous Patch Test.

169. T.R.U.E. TEST is sold as a prescription drug “for use as an aid in the diagnosis of allergic contact dermatitis in persons 6 years of age and older whose history suggests sensitivity to one or more of the 36 allergens and allergen mixes included on the T.R.U.E. TEST panels.” The T.R.U.E. TEST panels consist of three strips of adhesive panels embedded with pre-measured amounts of potential allergens, as well as a negative control. The panels are removed after 48 hours and the skin is examined for allergic reactions. A second skin examination is conducted at 72 – 96 hours.

170. The Warnings and Precautions for the T.R.U.E. TEST state:

Acute allergic reactions, including anaphylaxis, may occur.

Sensitization to one or more of the allergens may occur with initial or repeat testing.

Extreme positive reactions, excited skin syndrome, tape reactions, irritant contact dermatitis, persistent reactions, and late reactions at the test site may occur.

171. PPD is one of the allergens included on the True Test panels. The PPD ingredient for T.R.U.E. TEST are described as follows:

PPD (purity $\geq 97.5\%$), a blue-black aniline dye, is used to formulate this patch. The gel vehicle is providone. The product is formulated to contain $80 \mu\text{g}/\text{cm}^2$ of PPD, which corresponds to $65 \mu\text{g}$ of PPD per patch. This dye is found most often in permanent and semipermanent hair dyes.

172. After the physician applies the PPD test strips, the patient returns at 48 hours and again at 72 - 96 hours for the physician to evaluate the results. Interpretation instructions to the physicians list 6 possible readings:

- ? (doubtful reaction: faint macular erythema only)
- + (weak positive reaction: non-vesicular with erythema, infiltration, possibly papules)
- ++ (Strong positive reaction: vesicular, erythema, infiltrations papules)
- +++ (extremely positive reaction: bulbous or ulcerative reaction)
- (Negative reaction)

IR (Irritant reaction: Postules as well as patchy follicular or homogenous erythema without infiltrations are usually signs of irritation and do not indicate allergy.)

173. Physicians are specially trained to interpret skin reactions and to distinguish between irritant reaction and allergic reactions as described above, based on published criteria. *See e.g.*, Wilkinson DS, et al, "Terminology of contact dermatitis," *Acta Derm Venereol* 1970;50:287-292. (Establishing the International Contact Dermatitis Research Group standardized readings for distinguishing irritant from allergic reactions.)

174. The T.R.U.E. TEST also indicates that false negatives may occur due to inadequate adhesion of the compound to the test site or premature evaluation, and that false positives may

occur “when an irritant reaction cannot be differentiated from an allergic reaction. A positive test reaction should meet the criteria for an allergic reaction.”

175. Under Warnings and Precautions, physicians administering the T.R.U.E. TEST are advised: “A negative patch test reaction, followed by a positive reaction 10 to 20 days after panel application, may indicate active sensitization. Active sensitization is confirmed upon retesting with a positive reaction occurring at the 72 and/or the 96 hour reading. ... The safety and effectiveness of repetitive testing with T.R.U.E. Test is unknown.”

176. Physicians are also warned about “Persistent Reactions: Positive reactions may persist from 7 days to months after panel application,” and “Late Reactions: Positive reactions may occur 7 to 21 days after application of the panels.”

177. Finally, physicians are warned regarding “Repeat Testing: The safety and efficacy of repetitive testing with T.R.U.E. TEST is unknown. Sensitization or increased reactivity to one or more of the allergens may occur If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of conditions that affect test results.”

178. Physicians are also advised that the impact of a patient’s use of systemic antihistamines or cyclosporins upon test results is unknown, and that use of oral steroids could cause false negative results.

179. Detailed data from ten clinical trials in adults and 2 pediatric studies designed to authenticate the reliability of the T.R.U.E. TEST results are provided in the product labeling for physicians.

180. In contrast to the T.R.U.E. TEST, which is a strictly controlled, carefully administered, well validated allergy patch test approved by FDA as a safe and effective prescription drug to be

administered by a trained physician, the Just For Men “ALERT” skin allergy patch test is an unregulated, uncontrolled, open, random experiment requiring self-administration of strong allergens by untrained consumers for diagnostic purposes.

181. First, the “test” described by Defendant is not actually a patch test. Patch tests are allergy tests in which an allergen is applied directly to the skin and then covered *with a patch* to protect it from deterioration or contamination. The patch is then removed after a specified time period (typically 48 hours) to measure skin reactions, and then recovered and examined again at 72 to 96 hours.

182. Unlike a patch test for allergies, Defendant instructs: “**DO NOT WASH OR COVER TEST AREA FOR 48 HOURS.**”

183. As such, due to the fact that the application area is uncovered, Defendant’s self-described “Patch Test” instead is an “Open Test.” See e.g., Sumanth, K. et al, “Para-phenylenediamine allergy: current perspectives on diagnosis and management,” *Journal of Allergy and Asthma* 2017:10, 9-15 (2017.)

184. Defendant’s Open Test instructs consumers to “mix small, equal parts of the Colour Base and the Colour Developer in the mixing tray with the plastic end of the brush; ... Apply mixture with a cotton ball or swab to a test area the size of a coin on the inside bend of your elbow.”

185. As such, the Just For Men ALERT allergy test instructs consumers to mix up an undefined amount of two products, apply the mixture at an unknown thickness to an area the size of an unspecified coin, and to leave the area uncovered and unwashed, thereby subjecting the site to contamination or deterioration of test product, for 48 hours.

186. Defendant's Open Test thereby exposes consumers to varying, unregulated amounts of strong allergens in Just For Men Hair dyes, including potentially high ranges of exposure to PPD, as well as other allergens and sensitizers.

187. Upon information and belief, some Just For Men Hair dye color base tubes contain more than 3.75% PPD by weight. Even if consumers attempt to combine a "small" sample from the color tube with an "equal" amount of color developer, consumers could be creating a mixture that contains 1.8%, or even more, PPD.

188. Experts recognize that: "PPD 1% patch testing can cause active sensitization." Sumath, "Para-phenylenediamine allergy: current perspectives on diagnosis and management," *Journal of Asthma and Allergy*, 2017:10 9-15. As to open testing with hair dyes prior to application, "it is possible ... that this [open] testing is adding further cutaneous exposure to PPD and may play a part in increasing the risk of PPD sensitization." *Id.*

189. Experts estimate that a consumer self-application of a blob of hair dye in the open test method would expose the individual to approximately 2300 $\mu\text{g}/\text{cm}^2$ PPD, a level which is more than tenfold higher than that used in standardized diagnostic patch tests. In fact, this is 35 times higher than the exposure to PPD in the T.R.U.E. Test.

190. Not only is the amount of allergen applied excessive, but also the frequency of application creates a dramatically increased risk of sensitization. Defendant specifies, in bold, "**You MUST do this test 48 hours ahead of EACH and EVERY use in order to minimize the risk of an allergic reaction.**"

191. There is no scientific basis to support Defendant's assertion that repeat testing minimizes the risk of allergic reaction.

192. To the contrary, the best evidence demonstrates that the cumulative number of exposures is an important factor in determining an individual's risk of having an allergic reaction to a chemical.

193. As such, repeat hair dye testing only increases the risk of sensitization and a resulting allergic reaction by increasing the cumulative number exposures an individual is subjected to.

194. Likewise, repeated full hair dye application would similarly increase an individual's cumulative number of exposures and thus enlarge the ultimate risk of sensitization and resulting reaction.

195. PPD is categorized as a "Category A" allergen, indicating it has a "proven strong contact allergenic effect in humans after short and/or almost negligible exposure." Schlede E., et al, Chemical substances and contact allergy - 244 substances ranked according allergenic potency," *Toxicology* 2003: 193: 219-259.

196. In a PPD sensitization study of healthy subjects conducted by FDA, more than half the participants became sensitized through exposure to samples containing 1% PPD. Marzulli, et al., "The use of graded concentrations in studying skin sensitizers: experimental contact sensitization in man," *Food Cosmet Toxicol* 1974: 12: 219-227.

197. Expert dermatologists conclude that PPD is a strong sensitizer that creates a high risk of allergic response after repeated exposure:

PPD is an extreme sensitizer, and allergy skin testing with this chemical should be carefully performed, owing to the recognized risk of active sensitization. The concentration of PPD in hair dye products is restricted [in Europe] to a maximum of 2% PPD on the head, calculated as free base, but very high exposure concentrations might be applied in the hair dye self-test. Furthermore, other sensitizers, such as PTD (maximum [in Europe] 4% on the head), and several other extreme and potent sensitizers are used in hair-dyes, and may cause sensitization following repeated exposure. Experimental studies have clearly shown that the risk of sensitization increases with allergen dose per unit area, frequency of exposure, duration of exposure, occlusion, the presence of penetration-enhancing factors, and

impairment of skin barrier function, and is related to anatomical site. The hair dye self-test carries a significant risk of sensitization ...

Thyssen JP, et al., "Self-testing for contact sensitization to hair dyes-scientific consideration and clinical concerns of an industry-led screening programme," *Contact Dermatitis* (2012) 66: 300-311.

198. The Thyssen article continues to note that applying a small amount of a skin sensitizer does not reduce the risk of an allergic response. To the contrary, Thyssen explains:

It is important to understand that, as it is the dose of allergen per unit area that is critical for sensitization, application of an allergen to a small skin area does not diminish the risk of sensitization when compared with a larger skin area with the same dose per area. Hence, even though the self-test is applied to a small skin area, it still carries the same risk of sensitization. ... Thus, repeated exposure to low doses of contact sensitizers, as occurs when the hair self-test is performed, may considerably increase the risk of sensitization.

Id.

199. Noting the potential frequent use of hair dye by consumers, Thyssen concludes:

In a worse case scenario, an individual performing the hair dye self-test every fourth week applies up to 2% PPD on the skin each time, in addition to other sensitizers in the product. Such gross exposures strongly contrast with the norms of clinical diagnostic patch testing, when the practice is to attempt to reduce repeated allergen exposures from patch testing, owing to the risk of active sensitization.

Id.

200. An additional risk for sensitization to PPD among consumers is that Just For Men's darker hair dyes contain greater percentages of PPD than the lighter hair dyes. In a study by Dickel, et al., "Comparison of Patch Test Results with a Standard Series Among White and Black Racial Groups," *American Journal of Contact Dermatitis*, Vol. 12, No. 2 (June, 2001) 77-82, the authors reported a PPD sensitization rate of 21.2% among black men tested compared to 4.2% among white males, a highly statistically significant result ($P = 0.00599$.)

201. Dickel and his co-authors concluded: "Our data are in general agreement with the belief that PPD... is one of the most significant contactants in the black population. Higher concentration of PPD... are present in hair colors used by black patients."

202. Because the darker shades of Just For Men dyes contain higher percentages of PPD, consumers using these products for skin testing and/or as a hair dye are at greater risk of sensitization.

203. Moreover, consumers have no training on reading test results, which is a subject upon which physicians are educated, and the results are read only at 48 hours, without the 72 to 96 hour follow-up conducted in physician testing. Further, interpretation of whether skin is red or irritated can be more difficult when a consumer's skin is of a darker complexion.

204. Nonetheless, Defendant instructs consumers:

If you have no reaction on the unwashed patch test site after 48 hours, go ahead with full application of this product. Note: If at any time during the testing, you see redness or rash or feel burning, itching or other irritation, you may be allergic. STOP! Wash area immediately and keep it uncovered. You must not use this product or any other hair colouring.

205. Thus Defendant imposes upon consumers, with no training, no guide for interpretation, no control over the amount, area or actual extent of product exposure, an inadequate observation time, and no negative control for comparison, the responsibility for determining whether they are having a reaction to the product. Further Defendant does not instruct consumers to consult their physician if they experience the listed symptoms during the 48 hour allergy test.

206. Defendant also fails to instruct consumers to discontinue the use of systemic antihistamines, cyclosporines and oral steroids several days prior to conducting the open allergy test because use of these medications could cause a false negative result. Moreover, even if such a warning were made, many consumers are unlikely to recognize whether the drugs they are taking belong to these pharmaceutical classes, or further it may not be safe for them to discontinue these medications.

207. In summary, Defendant's instructions for use are false and misleading in many particulars, inasmuch as the Skin Allergy Patch (ALERT) Test is not a skin irritation test but rather an allergy test, is not a patch test but rather an open test, does not reduce the risk of allergic reaction but rather increases it, provides vague and incomplete instructions, and constitutes an unlawful marketing of hair dye as a drug, (i.e. for the purpose of diagnosing, mitigating or preventing a disease.)

208. In fact, expert dermatologists concur that: "In the hair dye allergy self-test, one must conclude that the hair dyes are used as medicines rather than cosmetics." Thyssen, *Contact Dermatitis*, 66 at 309.

209. As Thyssen states: "Repeated hair dye application on the skin with the consumer self-test may, in its current form, be compared with experimental human sensitization tests." *Id.* at 308.

210. Sensitization to PPD is known to be increasing across populations worldwide. A Saudi Arabia study indicates that PPD was the leading allergen among men undergoing skin patch testing using the T.R.U.E. TEST from 2012 through 2015, at a rate of 37.5%. Further, reactivity to PPD in men and women in Saudi Arabia increased from 5.4% in 1996 to 9.2% in 2012. Shakoor Z., et al, "Screening for skin-sensitizing allergens among patients with clinically suspected dermatitis," *Saudi Med J* 2017: Vol.38 (3) 922-927.

211. The increasing rate of sensitization to PPD is attributed by experts to increased use of hair dyes and tattoos.

212. Defendant exposes consumers to this human experimentation for no confirmed benefit, as they concede in the following Disclaimer: "This test is not a guarantee of avoiding future allergic reaction. For some users, frequent use of haircolouring products can increase the risk of allergic

reaction. This test represents an important precaution. However, be aware that even if a test has been carried out, you may still experience an allergic reaction when you use this product.”

213. Defendant fails to reveal in this Disclaimer that their allergy test itself creates a present, grave risk of sensitization to PPD and other hair dye allergens.

214. Repeated exposure to Just For Men from use as a hair dye and/or in an “allergy patch test” increases the risk of a chronic irritant reaction. Potential irritants in hair dye, such as PPD or other chemicals, can trigger a toxic response from repeated product use and/or from repeated “patch testing.”

215. As confirmed in the published literature, Defendant is aware that consumers are unlikely to conduct the open allergy test (misnamed the allergy patch test) as instructed by Defendant. Instead, Defendant is aware that due to the impracticalities of correctly applying the prescribed open test for allergies, (such as conducting the test 48 hours in advance of hair dye usage; keeping the area dry and uncovered and therefore not bathing for 2 days; mixing and applying the correct amount of product when no amounts are specified and no measuring implements are provided; and interpreting the results with no guide and no training), as well as the lack of understanding by consumers of the seriousness of adverse effects that can result from using Just For Men hair dyes, few consumers will successfully complete the test as described by Defendant.

216. Moreover, Defendant is aware that the prescribed “patch testing” can be futile, providing no protection at all against an allergic or irritant adverse reaction, and in fact could even increase the risk of an adverse response to Just For Men hair dyes.

217. Defendant therefore knows that the instructions for Just For Men do not render the product safe for use, because the instructions are highly impracticable and unlikely to be followed correctly, are flawed and misleading, and even if the prescribed allergy testing is conducted by

consumers, the test in fact provides no assurance that an allergic or other adverse response will be detected or avoided.

218. Defendant is aware that the product has not been rendered safe through its instructions.

219. 21 U.S.C. § 331(a) prohibits the “introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”

220. 21 U.S.C. § 331(g) prohibits the “manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”

221. Defendant’s failure to provide adequate directions for the Just For Men hair dye products rendered the products adulterated under 21 U.S.C. § 361(a).

222. Even if the Just For Men hair dye products’ instructions provided by Defendant were adequate to prevent or reduce the risk of injury, the products’ accompanying warnings fail to adequately appraise consumers of the risks/injuries that may result from use of the product and/or failure to follow the instructions for use.

223. 21 U.S.C. § 362(a) provides that a cosmetic shall be deemed to be misbranded “[i]f its labeling is false or misleading in any particular.”

224. 21 U.S.C. § 331(n) provides that:

[I]n determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

225. Defendant fails to provide consumers with sufficient warnings to appreciate the significance of the medical risks posed by the products. Unlike some trained medical

professionals, lay people do not have the education, training, or expertise to understand the risks of allergic and irritant reactions posed by these products.

226. Defendant is aware that consumers do not fully comprehend the risk that exposure to Just For Men hair dye containing PPD and other allergens/irritants can cause widespread and/or systemic reactions upon initial or any subsequent use, including but not limited to itching, rash, hives, blistering of skin, burning sensation, shortness of breath, restriction of airways or difficulty breathing, edema, sudden drop in blood pressure, flushing, and anaphylactic shock.

227. Consumers have no understanding and no frame of reference (nor are they provided any by Defendant) to appreciate that these reactions can cause permanent, disfiguring scarring on their faces or in other highly visible or widespread areas.

228. As such, consumers are unlikely to understand based upon Defendant's warning that Just For Men hair dye "has been associated with skin depigmentation (skin lightening or loss of skin colour)," that they risk permanent, disfiguring scarring or loss of pigmentation due to use of Just For Men Hair dye.

229. Despite Defendant's awareness of lay consumers' limited knowledge, Defendant failed to provide warnings that could be understood by lay consumers.

230. Notwithstanding Defendant's awareness of lay consumers' limited abilities, impracticalities of the allergy test, and the low number of individuals that successful completion the allergy test, Defendant failed to provide instructions, warnings, or other information concerning the adverse consequences which may result from the use of the Just For Men hair dye products.

231. Defendant fails to warn consumers that a vitiligo reaction triggered by use of Just For Men hair dyes can result in complete and permanent depigmentation of the entire surface area of the

face or scalp in which Just For Men hair dye is applied, such as complete depigmentation of the entire moustache area, or complete depigmentation of the entire beard area.

232. Defendant also fails to disclose that once triggered, a vitiligo response can spread to areas never directly exposed to Just For Men Hair dye.

233. Similarly, Defendant fails to warn consumers that hyperpigmentation, redness, rash or scarring from an allergic reaction to Just For Men can result in large scale, permanent discoloring of facial or other areas, often corresponding with the entire areas in which Just For Men hair dye was applied or contacted the skin, and that such reactions can spread to other areas.

234. Defendant fails to disclose that in addition to allergic reactions to PPD or other components of Just For Men hair dye, consumers may suffer skin irritation reactions, which as previously noted can happen upon initial exposure, or can be exacerbated by chronic exposure to an irritant chemical.

235. Defendant also failed to provide pictorial warnings to convey the risks posed by their products, such as photos of the potential injuries that may result from their use of Just For Men.

236. Defendant's above failures rendered the Just For Men hair dye products misbranded under 21 U.S.C. § 362.

237. The Just For Men hair dyes are more dangerous than an ordinary consumer would expect, due to the highly increased risk of sensitization to allergens in the Just For Men Hair dyes, the potential for serious allergic response and the risk of scarring, vitiligo and other significant permanent injury.

238. The Just For Men hair dyes are more dangerous than an ordinary consumer would expect, because they expose consumers to numerous chemical irritants, creating a significant potential for a skin irritant reaction and the risk of scarring, vitiligo and other significant permanent injury.

239. Other chemicals are available for hair dye that are much less allergenic and much less caustic than the products used in Just For Men. The chemicals 2-methoxymethyl-para-phenylenediamine, paratoluenediamine and henna are among the safer alternatives to PPD.

240. Plaintiffs' claims are not preempted by federal law.

241. By materially altering the minimally required labeling language contained in 21 U.S.C. § 361(a) Defendant and its Just For Men hair dye products are in violation of the federal requirements and therefore Defendant cannot assert that compliance with federal law shields it from state law claims or that federal law prevented it from obeying state law.

242. Additionally, 21 U.S.C. § 379s(d) of the Food, Drug, and Cosmetic Act specifically exempts state law product liability actions involving cosmetics from federal preemption.

243. Further, Plaintiffs' claims assert conduct that both violates the Food Drug and Cosmetic Act and gives rise to recovery under state law in the absence of the Food Drug and Cosmetic Act. The allowance of damages under state law for harm caused by the Defendant's defective, dangerous, misleading, non-conforming, unjust, and/or fraudulent Just For Men hair dye products provides a parallel remedy for the violation of federal standards as described above and does not conflict with the oversight of the federal government.

244. As a direct and proximate result of Plaintiffs' use of the Just For Men hair dye, as manufactured, designed, supplied, marketed and introduced into the stream of commerce by Defendant and/or its failure to comply with federal requirements, Plaintiffs suffered serious physical and psychological injury, harm, damages and economic loss and will continue to suffer such injury, harm, damages and economic loss in the future.

CAUSES OF ACTION

FIRST CAUSE OF ACTION STRICT PRODUCTS LIABILITY DESIGN DEFECT

245. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

246. Defendant is the manufacturer, designer, distributor, seller, and/or supplier of Just For Men hair dyes.

247. The Just For Men hair dyes manufactured and supplied by Defendant were defective in design or formulation in that, when they left the hands of the Defendant, they were more dangerous than an ordinary consumer would expect when used in a foreseeable manner, thereby posing a substantial likelihood of harm to users.

248. Alternatively, the Just For Men hair dyes manufactured and supplied by Defendant were defective in design or formulation in that the foreseeable risks of the products exceeded the benefits associated with their design or formulation.

249. The Just For Men hair dyes used by Plaintiffs were not materially altered prior to their use.

250. Defendant defectively designed Just For Men hair dyes by including the unreasonably dangerous ingredient PPD, an extreme skin sensitizer, rather than using safer chemical alternatives found in other hair dye products.

251. Further, Defendant defectively designed Just For Men hair dyes by including excessively high levels of the unreasonably dangerous ingredient PPD, an extreme sensitizer, rather than using safer, lower levels of PPD found in other hair dye products.

252. Further, Defendant defectively designed Just for Men hair dyes by including multiple other chemicals that increase the likelihood of an adverse reaction to PPD, such as skin sensitizers including lauryl lactate.

253. Defendant defectively designed Just for Men hair dyes by including multiple chemical components that individually or in combination cause skin irritation and allergic reactions.

254. Defendant defectively designed Just for Men hair dyes because the unreasonably high rate of adverse allergic and/or dermatological reactions to the products in the general populace greatly outweighs the cosmetic benefit of hair coloring, which also renders the products more dangerous than an ordinary consumer would expect.

255. The risks of Just for Men hair dyes are even greater among those using darker colors of Just for Men hair dye, which contain higher levels of PPD and other chemicals than lighter colors, creating an even greater outweighing of the risks over the cosmetic benefits of hair coloring, and rendering the products even more dangerous than an ordinary consumer would expect.

256. Just For Men hair dyes are further defectively designed because the patch test as designed and recommended by Defendant is inadequate to prevent harm to consumers, and in fact it increases the risk of an adverse reaction to the products rather than minimizing the risk.

257. Just for Men hair dyes are further defectively designed because the patch test as designed and recommended by Defendant cannot be accurately conducted or interpreted by consumers and therefore it does not adequately mitigate the risk of harm from the products.

258. As a direct and proximate result of their use of Just For Men hair dye products, as defectively designed and marketed by Defendant, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

259. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECT DUE TO INADEQUATE WARNING**

260. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

261. As the manufacturer of Just For Men, Defendant is held to the level of knowledge of an expert in the field of hair dyes.

262. Defendant had a duty to provide adequate warnings and instructions to consumers regarding its Just For Men hair dyes, based upon its superior knowledge of the risks as an expert in hair dyes.

263. The Just For Men dyes manufactured and supplied by Defendant were defective due to inadequate warning or instruction because Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers and it failed to adequately warn consumers of such risks and/or failed to provide adequate and non-misleading instructions to avoid the risk, as previously described.

264. Defendant's inadequate warnings or instructions include but are not limited to the following:

- a. Defendant knew or in the exercise of reasonable care should have known that Just for Men hair dyes marketed to be used repeatedly as a cosmetic hair product created a significant risk of severe allergic and irritant reactions, physical injury and permanent scarring, the magnitude of which ordinary consumers would not understand or appreciate;
- b. Defendant failed to provide the warning that a manufacturer exercising reasonable care would have provided concerning the risk of injuries from use and repeated use of Just For Men, in light of the likelihood that the product would cause the harm suffered by Plaintiffs and in light of the likely seriousness of that harm;

- c. Defendant provided inaccurate and misleading instructions by suggesting that Just For Men hair dye could be used by consumers in a self test for allergic reactions, which constitutes unauthorized sale of the product as a drug (i.e. for medicinal purposes);
- d. Defendant provided inadequate instructions for use in that the recommended “patch test” implied that any safety risks could be mitigated, when in fact the “patch test” was impractical, unrealistic and uncontrolled, increased the risk of harm and created a false sense of safety for users;
- e. Defendant further provided inadequate warnings and instruction by failing to impress upon consumers that any minor allergic or irritation reaction to Just For Men hair dyes could increase upon repeated exposures (including repeated patch tests), thereby placing consumers at greatly increased risk of harm from continual use of Just For Men hair dye products;
- f. Defendant further provided inadequate warning by failing to disclose that darker colored Just For Men hair dyes contained higher levels of active ingredients, including PPD, thus placing persons using darker hair colors, such as African Americans, at greater risk of physical injury.

265. The Just For Men manufactured and supplied by Defendant was defective due to inadequate post-marketing warning or instruction because, after Defendant knew or should have known of the risk of serious bodily harm, as set forth herein, from the use of Just For Men, Defendant failed to provide an adequate warning to consumers of the product, knowing the product could cause serious injury as set forth herein.

266. As a direct and proximate result of their use of Just For Men hair dye products, as

defectively designed and marketed by Defendant due to the failure to provide adequate warnings or instruction, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

267. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**THIRD CAUSE OF ACTION
NEGLIGENCE**

268. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

269. Defendant had a duty to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of Just For Men hair dyes, including a duty to insure that Just For Men did not pose a significantly increased risk of injury to Plaintiffs and other consumers.

270. Defendant failed to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of Just For Men hair dyes.

271. Defendant marketed Just For Men hair dyes to be used on a regular and even continual basis for cosmetic purposes, but Defendant knew or should have known that the products created a significant risk of severe injuries, (including but not limited to anaphylactic reactions, burns, rashes, weeping sores, and permanent scarring), as well as pain and suffering, and that use of the products could result in the need for medical treatment; therefore rendering the products unsafe for use by Plaintiffs.

272. Defendant failed to exercise reasonable care in the manner and method by which it warned

users of the risks associated with use of Just For Men hair dyes, as previously described.

273. Defendant failed to exercise reasonable care by recommending that consumers use the product as an unlicensed drug to perform an allergy “patch test,” and further failed to exercise reasonable care in the instructions as to how to conduct the allergy “patch test,” as previously described.

274. Defendant further failed to exercise reasonable care by failing to provide adequate and appropriate instructions for conducting a “skin irritant test” as required by federal law, and by instructing instead that consumer conduct the “allergy” “patch test” repeatedly with every use, thereby increasing the risk of harm to consumers.

275. Despite the fact that Defendant knew or should have known that Just For Men hair dyes could cause severe reactions in consumers and therefore give rise to physical injury, pain and suffering, and cause the need for medical treatment, Defendant continued to market Just For Men hair dyes as a safe and effective and failed to use ordinary care in providing warnings and instructions to Plaintiffs.

276. As a direct and proximate result of their use of Just For Men hair dye products, as negligently marketed and sold by Defendant, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

277. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY**

278. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

279. At the time Defendant designed, manufactured, tested, marketed, sold, and distributed Just For Men for use by Plaintiffs, Defendant knew of the use for which Just For Men was intended.

280. Defendant expressly warranted that Just For Men was a safe and effective hair dye, and that their products “are backed by over three decades of research and have delivered great results over 50 million times.”

281. Defendant is the manufacturer, designer, distributor, seller and/or supplier of hair care products and dyes including Just For Men and made representations regarding the character or quality of Just For Men, including but not limited to:

- a. Easy brush in application;
- b. Gray is gone in 5 minutes;
- c. Your own natural look is just 5 easy minutes away;
- d. Perfectly matches your natural hair color as well as Just For Men hair color shades;
- e. Keep facial hair looking its best;
- f. Penetrates coarse hair in five easy minutes;
- g. Fool proof way to get rid of gray;
- h. Gentle natural looking results.

282. Defendant further warranted that Just For Men hair dyes were safe for use by consumers to conduct a self-administered allergy “patch test,” while fully aware that its over-the-counter hair dyes were not approved by FDA for use as a drug, that the test described was not a “patch test” but an open test, that the test was impractical, ineffectual and inadequately designed as it could not be accurately conducted or interpreted by a lay person.

283. The Just For Men manufactured and supplied by Defendant was defective in that, when it left the hands of Defendant, it did not conform to representations made by Defendant concerning the product.

284. These material misrepresentations made by the Defendant are false as evidenced by the extensive number of adverse reactions to their Just For Men hair dye products by consumers including but not limited to Plaintiffs.

285. Plaintiffs justifiably relied upon Defendant's representations that Just For Men hair dyes would provide the claimed cosmetic benefits if used in the manner directed by the labeling when Plaintiffs selected Just For Men and used Just For Men as a hair dyes as instructed by the Defendant.

286. As a direct and proximate result of Plaintiffs' use of the Just For Men and their reliance on Defendant's representations regarding the character and quality of Just For Men, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

287. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY**

288. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

289. At the time Defendant designed, manufactured, tested, marketed, sold, and distributed Just For Men hair dyes for use by Plaintiffs, Defendant knew of the use for which Just For Men hair

dyes were intended (their “ordinary use”) and impliedly warranted the products to be of merchantable quality and safe for such use, and further that its design, manufacture, testing, labeling and marketing were sufficient.

290. Defendant further impliedly warranted that Just For Men hair dyes were safe for use by consumers to conduct a self-administered allergy “patch test,” while fully aware that its over-the-counter hair dyes were not approved by FDA for use as a drug, that the test described was not a “patch test” but an open test, that the test was impractical, ineffectual and inadequately designed as it could not be accurately conducted or interpreted by a lay person.

291. Plaintiffs reasonably relied upon the skill and judgment of Defendant as to whether Just For Men hair dyes were of merchantable quality and safe for their intended use and upon Defendant’s implied warranty as to such matters.

292. Contrary to such implied warranty, the Just For Men hair dyes were not of merchantable quality or safe for their intended use, because the products were unreasonably dangerous and defective as described above.

293. As a direct and proximate result of Defendant’s breach of warranty, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

294. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**SIXTH CAUSE OF ACTION
NEGLIGENT REPRESENTATION AND FRAUD**

295. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully

set forth herein and further allege as follows:

296. Defendant made multiple material representations in its marketing, advertisements, or other labeling about Just For Men dyes purchased by Plaintiffs, including but not limited to:

- a. Easy brush in application;
- b. Gray is gone in 5 minutes;
- c. Your own natural look is just 5 easy minutes away;
- d. Perfectly matches your natural hair color as well as Just For Men hair color shades;
- e. Keep facial hair looking its best;
- f. Penetrates coarse hair in five easy minutes;
- g. Fool proof way to get rid of gray;
- h. Gentle natural looking results.

297. Defendant further represented that Just For Men hair dyes were safe for use by consumers to conduct a self-administered allergy “patch test,” while fully aware that its over-the-counter hair dyes were not approved by FDA for use as a drug, that the test described was not a “patch test” but an open test, that the test was impractical, ineffectual and inadequately designed as it could not be accurately conducted or interpreted by a lay person.

298. These material misrepresentations made by the Defendant are false as evidenced by the extreme number of adverse reactions to their Just For Men products by consumers, including but not limited to Plaintiffs.

299. When Defendant made these material representations, it knew that they were false, and Defendant made the material representations recklessly without any knowledge of their truth and a positive assertion.

300. Defendant had actual knowledge based upon studies, published reports and clinical experience that its product, Just For Men, created an unreasonable risk of serious bodily injury yet Defendant negligently misrepresented to Plaintiffs that its hair dyes were safe and met all applicable design and manufacturing requirements.

301. Defendant made these false, material representations with the intention of inducing buyers, including Plaintiffs, to act by purchasing the Just For Men by appealing to the buyers' desire to improve their appearance.

302. Plaintiffs acted in justifiable reliance on these material representations made by Defendant in that they purchased Just For Men specifically under the belief that they would provide the claimed cosmetic benefits if used in the manner directed by the labeling.

303. Defendant further failed to exercise reasonable care by failing to provide adequate and appropriate instructions for conducting a "skin irritant test" as required by federal law, and by instructing instead that consumer conduct the "allergy" "patch test" repeatedly with every use, thereby increasing the risk of harm to consumers.

304. As a direct and proximate result of Defendant's deliberate, systematic, and widespread fraudulent and/or negligent representations and omissions, Plaintiffs have incurred damages, including but not limited to disfiguring permanent injury, other physical injury, mental and emotional distress, medical expenses, lost earnings and other economic loss, and will continue to suffer said damages in the future.

305. Defendant acted and/or failed to act maliciously, wantonly, or with a recklessness suggestive of an improper motive or vindictiveness, so as to warrant the imposition of punitive damages.

**SEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT**

306. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

307. As the intended and expected result of its conscious wrongdoing, Defendant has profited and benefited from the purchase and use of Just For Men by Plaintiffs.

308. Defendant has voluntarily accepted and retained those profits and benefits, derived from Plaintiffs, with full knowledge and awareness that, as a result of Defendant's fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature, or fitness that had been represented by Defendant, or that Plaintiffs, as a reasonable consumers, expected to receive.

309. By virtue of the conscious wrongdoing alleged above, Defendant has been unjustly enriched at the expense of Plaintiffs, who are entitled in equity and hereby seek the disgorgement and restitution of Defendant's wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

**EIGHTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER LAWS**

310. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

311. Defendant markets and sells goods, including Just For Men hair dyes, to consumers throughout the United States and its Territories, including to Plaintiffs. Defendant's acts and omissions regarding Just For Men hair dyes affect trade and commerce across all the United States and its Territories.

312. Plaintiffs are consumers who purchased and used Just For Men hair dye primarily for personal, family and/or household purposes.

313. Defendant has violated state consumer protection laws and or state unfair trade practices acts by engaging in unfair methods of competition and unfair, deceptive, fraudulent, unconscionable and/or unlawful acts or practices, including without limitation, through its defective design and manufacture of Just For Men hair dye as well as misleading marketing, advertising, selling, and warranting of Just For Men hair dye to consumers.

314. Among other things, Defendant made numerous deceptive statements regarding Just For Men hair dyes as previously described.

315. Through its conduct, Defendant has violated the state consumer laws and or unfair trade practices acts which prohibit unfair methods of competition, and unfair, deceptive, unconscionable, fraudulent and/or unlawful acts or practices in the sale of goods.

316. Plaintiffs bring this action to promote the public interests in the provision of truthful, non-deceptive information to allow consumers to make informed purchasing decisions and to protect Plaintiffs and the public from Defendant's unfair methods of competition and unfair, deceptive, fraudulent, unconscionable and/or unlawful practices. Defendant's wrongful conduct has had widespread impact on the public at large and caused serious injuries to Plaintiffs.

317. Defendant has long had notice of Plaintiffs' allegations, claims and demands, including from internal audits, field testing, online complaints, and direct complaints regarding Just For Men hair dye.

318. As a direct and proximate result of Defendant's unfair, deceptive, fraudulent, unconscionable and/or unlawful acts or practices, Plaintiffs have suffered ascertainable losses and injuries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

- 1) Compensatory damages in excess of the jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the trier of fact in this action;
- 2) Economic damages in the form of medical expenses, out of pocket expenses, lost wages, and other economic damages in an amount to be determined at trial of this action;
- 3) Disgorgement of profits, restitution and other forms of equitable relief;
- 4) Punitive damages;
- 5) Attorneys' fees, expenses, and costs of the action; and
- 6) Such further relief as the Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

Respectfully submitted,

/s/ Shane C. Fulton

Shane C. Fulton

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