

Women from the Southern United States," *Cancer Research*, 44:1216-1222, 1984.

19. McLaughlin, J. K. et al., "Dietary Factors in Oral and Pharyngeal Cancer," *Journal of the National Cancer Institute*, 80:1237-1243, 1988.

20. O'Reilly, P. et al., "Alcohol Content of Proprietary Mouthwashes," *Irish Journal of Medical Science*, 163:178-181, 1994.

21. Kowitz, G. M. et al., "Effects of Mouthwashes on the Oral Soft Tissues," *Journal of Oral Medicine*, 31:47-50, 1976.

22. Bernstein, M. L., "Oral Mucosal White Lesions Associated with Excessive Use of Listerine Mouthwash," *Journal of Oral Surgery*, 46:781-785, 1978.

23. Weaver, A. et al., "Mouthwash Use and Oral Cancer: Carcinogen or Coincidence," *Journal of Oral Surgery*, 37:250-253, 1979.

24. Winn, D. M. et al., "Mouthwash Use and Oral Conditions in the Risk for Oral and Pharyngeal Cancer," *Cancer Research*, 51:3044-3047, 1991.

25. Young, T. B., C. Ford, and J. Brandenburg, "An Epidemiologic Study of Oral Cancer in a Statewide Network," *American Journal of Otolaryngology*, 7:200-208, 1986.

26. Kabat, G. C., J. R. Herbert, and E. L. Wynder, "Risk Factors for Oral Cancer in Women," *Cancer Research*, 49:2803-2806, 1989.

27. Mashberg, A., P. Barsa, and M. L. Grossman, "A Study of the Relationship Between Mouthwash Use and Oral and Pharyngeal Cancer," *Journal of the American Dental Association*, 110:731-734, 1985.

28. Elzay, R. P., "Local Effect of Alcohol in Combination with DMBA on Hamster Cheek Pouch," *Journal of Dental Research*, 45:1788, 1966.

29. Henefer, E. P., "Ethanol, 30 Percent, and Hamster Pouch Carcinogenesis," *Journal of Dental Research*, 45:838-844, 1966.

30. Freedman, A., and G. Schklar, "Alcohol and Hamster Buccal Pouch Carcinogenesis," *Oral Surgery, Oral Medicine, Oral Pathology*, 46(6):794-804, 1978.

31. Tuyns, A. J., "Association of Tobacco and Alcohol in Cancer," *Bul der Schweizerischen Akademie der Medizinischen Wissenschaften*, English abstract, 35:151-158, 1979.

32. Muller, P. et al., "Tissue Damage in the Rabbit Oral Mucosa by Acute and Chronic Direct Toxic Action of Different Alcohol Concentrations," *Experimental Pathology*, 24:171-181, 1983.

33. Autrup, J. L., C. Hansen, and H. Autrup, "Detection of Tobacco Smoke Carcinogen-DNA Adducts in Cultured Rat Buccal Mucosa Cells Following Exposure to Ethanol and Total Cigarette Smoke Condensate or Chewing Tobacco," *Chemico-Biological Interactions*, 85:141-150, 1992.

34. Squier, C. A., P. Cox, and B. K. Hall, "Enhanced Penetration of Nitrosornicotine Across Oral Mucosa in the Presence of Ethanol," *Journal of Oral Pathology*, 15(5):276-279, 1986.

35. Ho, N. F. H., "Biophysical Kinetic Modeling of Buccal Absorption," *Advanced Drug Delivery Reviews*, 12:61-97, 1993.

36. Food and Drug Administration, *Transcript of the June 6, 1996 Dental Plaque Subcommittee Meeting*, OTC Vol. 210480.

37. Cole, P. et al., "Alcohol-Containing Mouthwash and Oropharyngeal Cancer: An Epidemiologic Perspective," unpublished study in OTC Vol. 210476.

38. Thomas, D. B. et al., "Mouthwash and Oral Cancer: Results from the L.E.O. Study in Western Washington State," submission to the Dental Plaque Subcommittee, June 6, 1996, unpublished study in OTC Vol. 210476.

39. Shapiro, S., J. V. Castellana, and J. M. Sprafka, "Reviews and Commentary: Alcohol-Containing Mouthwashes and Oropharyngeal Cancer: A Spurious Association Due to Under Ascertainment of Confounders?," *American Journal of Epidemiology*, 144(12):1091-1095, 1996.

40. Midanik, L., "The Validity of Self-Reported Alcohol Consumption and Alcohol Problems: A Literature Review," *British Journal of Addiction*, 77:357-382, 1982.

41. Babor, T. F. et al., "Verbal Report Methods in Clinical Research on Alcoholism: Response Bias and Its Minimization," *Journal of Studies on Alcohol*, 48:410-424, 1987.

42. Czarnecki, D. M. et al., "Five-Year Reliability of Self-Reported Alcohol Consumption," *Journal of Studies on Alcohol*, 51:68-76, 1990.

43. Liu, S. et al., "Reliability of Alcohol Intake as Recalled from 10 Years in the Past," *American Journal of Epidemiology*, 143:177-186, 1996.

44. Van de Mheen, P. J., and L. J. Gunning-Schepers, "Reported Prevalences of Former Smokers in Survey Data: The Importance of Differential Mortality and Misclassification," *American Journal of Epidemiology*, 140:52-57, 1994.

45. Williams, G. M., "Mechanisms of Alcohol Beverage Consumption in Oral Cancer Risk: Lack of Relevance to Mouthwash Use," unpublished article in OTC Vol. 210476.

46. Organization of Economic Cooperation and Development, *Guidelines for Testing of Chemicals*, ISBN 92-64-12900-6, adopted February 24, 1987.

47. Food and Drug Administration, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives in Food," Redbook I, 1982.

48. Food and Drug Administration, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives in Food," Redbook II (draft), 1993.

49. Yuen, G. J., "Altered Pharmacokinetics in the Elderly," *Clinical Geriatric Medicine*, 6:257-267, 1990.

50. Russell, R. M., "Changes in Gastrointestinal Function Attributed to Aging," *The American Journal of Clinical Nutrition*, Supplement 6, 55:1203S-1207S, 1992.

51. Holt, P. R., and J. A. Balint, "Effects of Aging on Intestinal Lipid Absorption," *American Journal of the Physiological Society*, 264:G1-G6, 1993.

52. Atillasoy, E., and P. R. Holt, "Gastrointestinal Proliferation and Aging," *Journal of Gerontology — Biological Sciences*, 48:B43-B49, 1993.

53. Yamada, H., B. Sacktor, and J. Kinsella, "Age-Associated Changes in Ammoniogenesis in Isolated Rat Renal

Tubule Segments," *American Journal of Physiology*, 262:F600-F605, 1992.

54. Ahronheim, J. C., *Handbook of Prescribing Medications for Geriatric Patients*, Little, Brown and Co., Boston, MA, pp. 1-12, 1992.

55. Draize, J. H., "Dermal Toxicity," in *Appraisal of Safety of Chemicals in Foods, Drugs and Cosmetics*, The Association of Food and Drug Officials of the United States, Austin, TX, pp. 46-59, 1959.

56. Shelanski, H. A., and M. V. Shelanski, "A New Technique of Human Patch Tests," in *Proceedings of Scientific Section*, The Toilet Goods Association, 19:46-49, 1953.

57. Kligman, A. M., "The Identification of Contact Allergens by Human Assay; III. The Maximization Test: A Procedure for Screening and Rating Contact Sensitizers," *Journal of Investigative Dermatology*, 47:393-409, 1966.

58. *The United States Pharmacopeia—23, The National Formulary—18*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 329, 1995.

59. Scheie, A. A., "Modes of Action of Currently Known Chemical Antiplaque Agents Other Than Chlorhexidine," *Journal of Dental Research*, 68:1609-1616, 1989.

60. Smith, R. N., R. N. Anderson, and P. E. Kolenbrander, "Inhibition of Intergeneric Coaggregation Among Oral Bacteria by Cetylpyridinium Chloride, Chlorhexidine Digluconate and Octenidine Dihydrochloride," *Journal of Periodontal Research*, 26:422-428, 1991.

61. Merianos, J. J., "Quaternary Ammonium Antimicrobial Compounds," in *Disinfection, Sterilization and Preservation*, edited by S. S. Block, 4th ed., Lea & Febiger Co., Philadelphia, PA, pp. 225-255, 1991.

62. OTC Vol. 210421.

63. Nelson, J. W., and S. C. Lyster, "The Toxicity of Myristyl-gamma-Picolinium Chloride," *Journal of the American Pharmaceutical Association (Science Edition)*, 35:89-94, 1946.

64. OTC Vol. 210013.

65. "Chronic Toxicity," unpublished studies C.1 and C.2, in OTC Vol. 210421.

66. Lin, G. H. Y., K. A. Voss, and T. J. Davidson, "Acute Inhalation Toxicity of Cetylpyridinium Chloride," *Food and Chemical Toxicology*, 29:851-854, 1991.

67. Margarone, J. et al., "The Effects of Alcohol and Cetylpyridinium Chloride on the Buccal Mucosa of the Hamster," *Journal of Oral Maxillofacial Surgery*, 42:111-113, 1984.

68. Segreto, V. A., "A Clinical Investigation to Assess the Effects on Plaque, Gingivitis, and Staining Potential of an Experimental Mouthrinse—Study 002393," unpublished study in OTC Vol. 210421.

69. Stookey, G. K., "A Clinical Study Assessing the Safety and Efficacy of Two Mouthrinses with Differing Concentrations of An Active Ingredient in Commercially-Available Mouthrinses—Study 005293," unpublished study in OTC Vol. 210421.

70. OTC Vol. 210014.

71. Lobene, R. R. et al., "The Effect of Cetylpyridinium Chloride on Human Plaque Bacteria and Gingivitis," *Pharmacology Therapeutics in Dentistry*, 4:33-47, 1979.