



References

Articles Cited by FDA

1. The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group. The effect of vitamin E and beta carotene on the incidence of lung cancer and other cancers in male smokers. *New England Journal of Medicine*. 1994;330:1029-1035.
2. Asplin, J.R., F.L. Coe, and M.J. Favus. Nephrolithiasis. In Harrison's Principles of Internal Medicine, A.S. Fauci, E. Braunwald, K.J. Isselbacher, J.D. Wilson, J.B. Martin, D.L. Kasper, S.L. Hauser, and D.I. Longo, eds. (New York: McGraw-Hill Health Professions Division), 1998, pp. 1569-1575.
3. Bihl, G. and A. Meyers. Recurrent renal stone disease-advances in pathogenesis and clinical management. *Lancet* 2001;358: 651-656.
4. Curhan, G.C., W.C. Willett, E.L. Knight, and M.J. Stampfer. Dietary factors and the risk of incident kidney stones in younger women: Nurses' Health Study II. *Archives of Internal Medicine*. 2004;164:885-891.
5. Dawson-Hughes, B., D.T. Stern, C.C. Shipp, and H.M. Rasmussen. Effect of lowering dietary calcium intake on fractional whole body calcium retention. *Journal of Clinical Endocrinology and Metabolism*. 1988;67:62-68.
6. Dorland's Illustrated Medical Dictionary. (2002). (Philadelphia, Pennsylvania: W.B. Saunders and Company). p. 273.
7. Federal Judicial Center. Reference Manual on Scientific Evidence, Second Edition. p. 93. 2000.
8. Heller, H.J., M.F. Doerner, L.J. Brinkley, B. Adams-Huet, and C.Y. Pak. Effect of dietary calcium on stone forming propensity. *Journal of Urology*. 2003;169:470-474.
9. Institute of Medicine, Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride, (Washington, D.C.: National Academy Press, 1997), p. 1 – 20 “Summary,” p 71-145 “Calcium,” and p 314 – 324 “Uses of Dietary Reference Intakes.”
10. Institute of Medicine, Dietary Supplements: A Framework for Evaluating Safety. (Washington, D.C.: National Academy Press, 2005), Chapter 7, “Categories of Scientific Evidence – *In Vitro* Data”.
11. Lichtenstein, A.H. and R.M. Russell. Essential Nutrients: Food or Supplements? *Journal of American Medical Association*. 2005;294:351-358.

12. Omenn, G.S., G.E. Goodman, M.D. Thornquist, J. Balmes, M.R. Cullen, A. Glass, J.P. Keogh, F. L. Meyskens, B. Valanis, J.H. Williams, S. Barnhart, and S. Hammer. Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. *New England Journal of Medicine*. 1996;334:1150-1155.
13. Peto, R., R. Doll, J.D. Buckley, M.B. Sporn. Can dietary beta-carotene materially reduce human cancer rates? *Nature*. 1981;290:201-208.
14. Sakhaee, K., S. Baker, J. Zerwekh, J. Poindexter, P.A. Garcia-Hernandez, and C.Y. Pak. Limited risk of kidney stone formation during long-term calcium citrate supplementation in nonstone forming subjects. *Journal of Urology*. 1994;152:324-327.
15. Sempos, C.T., K. Liu, and N.D. Ernst. Food and nutrient exposures: what to consider when evaluating epidemiologic evidence. *American Journal of Clinical Nutrition*. 1999;69:1330S-1338S.
16. Spilker, B. (1991). *Guide to Clinical Studies*. (New York, New York: Raven Press).
17. Szklo, M. and F. J. Nieto. (2000). *Epidemiology. Beyond the Basics*. (Gaithersburg, Maryland; Aspen Publishers).
18. Taylor, E.N. and G.C. Curhan. Role of nutrition in the formation of calcium-containing kidney stones. *Nephron Physiology*. 2004;98:55-63.
19. Taylor, E.N., M.J. Stampfer, and G.C. Curhan. Dietary factors and the risk of incident kidney stones in men: new insights after 14 years of follow-up. *Journal of the American Society of Nephrology*. 2004;15:3225-3232.
20. Willett, W.C. (1990). Overview of nutritional epidemiology. In *Nutritional Epidemiology*, (Oxford, United Kingdom: Oxford University Press), pp. 16-17.
21. Willett, W.C. (1998). Issues in analysis and presentation of dietary data. In *Nutritional Epidemiology, Second Edition*, (Oxford, United Kingdom: Oxford University Press), pp. 339-340.
22. Zerwekh, J.E., T.I. Hwang, J. Poindexter, K. Hill, G. Wendell, and C.Y. Pak. Modulation by calcium of the inhibitor activity of naturally occurring urinary inhibitors. *Kidney International*. 1988;33:1005-1008.

Articles Cited in Petition (Document Nos. QHC1 of Docket No. 2004Q-0102)

Adams, N.D., R.W. Gray, and J. Lemann, Jr. The effects of oral CaCO₃ loading and dietary calcium deprivation on plasma 1, 25-dihydroxyvitamin D concentrations in

healthy adults. *Journal of Clinical Endocrinology and Metabolism*. 1979;48:1008-1016. (Petition Reference No. 68)

Burtis, W.J., L. Gay, K.L. Insogna, A. Ellison, and A.E. Broadus. Dietary hypercalciuria in patients with calcium oxalate kidney stones. *American Journal of Clinical Nutrition*. 1994;60:424-429. (Petition Reference No. 31)

Curhan, G.C., E.B. Rimm, W.C. Willett, and M.J. Stampfer. Regional variation in nephrolithiasis incidence and prevalence among United States men. *Journal of Urology*. 1994;151:838-841. (Petition Reference No. 32)

Curhan, G.C., W.C. Willett, E.B. Rimm, and M.J. Stampfer. A prospective study of dietary calcium and other nutrients and the risk of symptomatic kidney stones. *The New England Journal of Medicine*. 1993;328:833-838. (Petition Reference No. 46)

Curhan, G.C., W.C. Willett, F.E. Speizer, D. Spiegelman, and M.J. Stampfer. Comparison of dietary calcium with supplemental calcium and other nutrients as factors affecting the risk for kidney stones in women. *Annals of Internal Medicine*. 1997;126:497-504. (Petition Reference No. 47)

Dawson-Hughes, B., S. Harris, C. Kramich, G. Dallal, and H.M. Rasmussen. Calcium retention and hormone levels in black and white women on high- and low-calcium diets. *Journal of Bone and Mineral Research*. 1993;8:779-787. (Petition Reference No. 21)

Domrongkitchaiporn, S., B. Ongphiphadhanakul, W. Stitchantrakul, S. Chansirikarn, G. Puavilai, and R. Rajatanavin. Risk of calcium oxalate nephrolithiasis in postmenopausal women supplemented with calcium or combined calcium and estrogen. *Maturitas*. 2002;41:149-156. (Petition Reference No. 51)

Domrongkitchaiporn, S., B. Ongphiphadhanakul, W. Stitchantrakul, N. Piaseu, S. Chansirikarn, G. Puavilai, and R. Rajatanavin. Risk of calcium oxalate nephrolithiasis after calcium or combined calcium and calcitriol supplementation in postmenopausal women. *Osteoporosis International*. 2000;11:486-492. (Petition Reference No. 52)

Ettinger, B. Recurrence of nephrolithiasis. A six-year prospective study. *American Journal of Medicine*. 1979;67:245-248. (Petition Reference No. 33)

Heaney, R.P., S.D. Dowell, J. Bierman, C.A. Hale, and A. Bendich. Absorbability and cost effectiveness in calcium supplementation. *Journal of the American College of Nutrition*. 2001;20:239-246. (Petition Reference No. 55)

Iguchi, M., K. Kataoka, K. Kohri, S. Yachiku, and T. Kurita. Nutritional risk factors in calcium stone disease in Japan. *Urologia Internationalis*. 1984;39:32-35. (Petition Reference No. 43)

Ireland, P. and J.S. Fordtran. Effect of dietary calcium and age on jejunal calcium absorption in humans studied by intestinal perfusion. *Journal of Clinical Investigation*. 1973;52:2672-2681. (Petition Reference No. 7)

Jackman, L.A., S.S. Millane, B.R. Martin, O.B. Wood, G.P. McCabe, M. Peacock, and C.M. Weaver. Calcium retention in relation to calcium intake and postmenarcheal age in adolescent females. *American Journal of Clinical Nutrition*. 1997;66:327-333. (Petition Reference No. 28)

Lemann, J., Jr., J.A. Pleuss, E.M. Worcester, L. Hornick, D. Schrab, and R.G. Hoffmann. Urinary oxalate excretion increases with body size and decreases with increasing dietary calcium intake among healthy adults. *Kidney International*. 1996;49:200-208. (Petition Reference No. 48)

Leonetti, F., B. Dussol, P. Berthezene, X. Thirion, and Y. Berland. Dietary and urinary risk factors for stones in idiopathic calcium stone formers compared with healthy subjects. *Nephrology, Dialysis, Transplantation*. 1998;13:617-622. (Petition Reference No. 53)

Martini, L. and R.J. Wood. Relative bioavailability of calcium-rich dietary sources in the elderly. *American Journal of Clinical Nutrition*. 2002;76:1345-1350. (Petition Reference No. 56)

Nishiura, J.L., L.A. Martini, C.O. Mendonca, N. Schor, and I.P. Heilberg. Effect of calcium intake on urinary oxalate excretion in calcium stone-forming patients. *Brazilian Journal of Medical and Biological Research*. 2002;35:669-675. (Petition Reference No. 49)

Robertson, W.G., M. Peacock, and A. Hodgkinson. Dietary changes and the incidence of urinary calculi in the U.K. between 1958 and 1976. *Journal of Chronic Diseases*. 1979;32: 469-476. (Petition Reference No. 54)

Serio, A. and A. Fraioli. Epidemiology of nephrolithiasis. *Nephron*. 1999;81 Suppl 1:26-30., 26-30. (Petition Reference No. 40)

Spencer, H., L. Kramer, M. Lesniak, M. De Bartolo, C. Norris, and D. Osis. Calcium requirements in humans. Report of original data and a review. *Clinical Orthopaedics and Related Research*. 1984;184:270-280. (Petition Reference No. 27)