

5. Coase, R.H., "The Problem of Social Cost," in H.G. Manne (1975 Ed.), *The Economics of Legal Relationships*, pp. 127-167. St. Paul: West Publishing Company (first published in *The Journal of Law and Economics* 3, pp. 1-44, 1960).
  6. Merrill, R.A., and E.M. Collier, "Like Mother Used to Make, an Analysis of FDA's Food Standards of Identity," *Ill. Columbia Law Review*, Vol. 74:561, p. 592.
  7. *Ibid.*
  8. Akerlof, G.A., "The Market for Lemons, Quality Uncertainty and the Market Mechanism," *The Quarterly Journal of Economics*, 84, 3, pp. 489-508, August 1970.
  9. RTI, *Compliance Costs of Food Labeling Regulations*, FDA Contract #223-87-2097, Project Officer—Richard A. Williams, Jr., December 1990.
  10. National Restaurant Association, "The Food Service Industry: 1989 in Review," 1991.
  11. Commerce Department, "Census of Retail Trade," 1987.
  12. *Tableservice Restaurant Trends: 1991*, National Restaurant Association Research Department, February 1991, Table VIII.
  13. *Tableservice Operator Survey*, National Restaurant Association, 1990.
  14. Memorandum of telephone conversation between Nancy Michalski, NRA, and Edward Puro, FDA, October 11, 1991.
  15. Bender, M., "Status of Nutrition and Sodium Labeling on Processed Foods: 1988," Food Label and Package Survey (FLAPS), Division of Consumer Studies, CFSAN, FDA, July 14, 1989.
  16. Trumboli, W.N., "Who Has Standing in Cost-benefit Analysis," in *Journal of Policy Analysis and Management*, 9(2), pp. 203-218, Spring 1990.
  17. Kass, M., "Build a Better Menu," *R&I*, p. 36, June 27, 1990.
  18. Memorandum of telephone conversation between sales representatives of American Sign and Marketing Systems, Mainstreet Menu Systems, and E. Puro of FDA.
  19. Letter to FDA from Food Marketing Institute, November 16, 1990.
  20. Letter to FDA from the Produce Marketing Association to the FDA, Docket No. 91N-0122, July 31, 1991. Also, letter to FDA from the Food Marketing Institute, Docket No. 91N-0122, August 1, 1991.
  21. Verman, L.C., *Standardization*, Anchor Books, Hamden, CT, 1973.
  22. Ippolito, P.M., and A.D. Mathios, "Health Claims in Food Marketing: Evidence on Knowledge and Behavior in the Cereal Market," Prepared for presentation at the Marketing and Public Policy Workshop: Issues for the 1990's, American Marketing Association, Washington, DC, August 3 and 4, 1990.
  23. Cummings, R.G., D.S. Brookshire, and W.D. Shulze, *Valuing Environmental Goods: An Assessment of the Contingent Valuation Method*, Rowman & Littlefield Publishers, Inc., Savage MD, p. 5, 1986.
  24. RTI, "Estimating Health Benefits of Nutrition Label Changes," April 1991.
  25. Putler, D.S., and E. Frazao, "Assessing the Effects of Diet/Health Awareness on the Consumption and Composition of Fat Intake," *Economics of Food Safety*, Elsevier Science Publishing Co., Inc., pp. 247-70, 1991.
  26. Browner, W.S., J. Tice, and J. Westenhouse, *Model of the Effects of Dietary Fat on Disease Rates of the United States: Computer Program*, Prepared for the Office of Disease Prevention and Health Promotion, Public Health Service, DHHS, 1989.
  27. "Multiple Risk Factor Intervention Trial," Multiple Risk Factor Intervention Trial Research Group, *Journal of the American Medical Association*, 248:1465-7, 1982.
  28. Hegsted, D.M., "Serum Cholesterol Response to Dietary Cholesterol: A Re-Evaluation," *American Journal of Clinical Nutrition*, 44:299-305, 1986.
  29. Gotto, A.M., and D. Phil, "Cholesterol Intake and Serum Cholesterol Level," letter to the *New England Journal of Medicine*, 524 (3), March 28, 1991.
  30. Vaupel, J.W., and J.D. Graham, "Egg in Your Bier," *The Public Interest*, 1980.
  31. Office of Technology Assessment, *The Implications of Cost-Effectiveness Analysis of Medical Technology*, U.S. Congress, Washington, DC, 1980.
  32. Fisher, A., L. Chestnut, and D. Violette, "The Value of Reducing Risk of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, Vol. 8, No. 1, 1989.
  33. Testimony on FDA's 1992 budget request, statement of the American Cancer Society, American Heart Association et al., to the Subcommittee on Agriculture, Rural Development, and Related Agencies, Committee on Appropriations, U.S. Senate, April 10, 1991.
  34. Doll, R., and R. Peto, "The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today," *Journal of the National Cancer Institute*, 66:1192-1308.
  35. Calfee, J.E., and J.K. Pappalardo, "How Should Health Claims for Foods be Regulated? An Economic Perspective," Federal Trade Commission, p. 43, September 1989.
  36. "The Tomato Effect: Rejection of Highly Efficacious Therapies," 251, *Journal of the American Medical Association*, 2387 (1984).
  37. Hile, J.P., "Understanding the Food and Drug Administration's Position on Health Claims," *Food Drug Cosmetic Law Journal*, pp. 101-104, 1986.
  38. Beales, H., R. Craswell, and S.C. Salop, "The Efficient Regulation of Consumer Information," *Journal of Law and Economics*, XXIV, p. 504, December 1981.
  39. Crane, N.T., P.M. Behlen, E.A. Yetley, and J.E. Vanderveen, "Nutrition Labeling of Foods: A Global Perspective," *Nutrition Today*, July/August 1990.
  40. Executive Office of the President, OMB, *Regulatory Program of the United States Government, April 1, 1990 to March 31, 1991*, U.S. Government Printing Office, Washington, DC, S/N 041-001-00354-1.
  41. Harris, T., E.S. Cook, W.B. Kannel, et al., "Proportional Hazards Analysis of Risk Factors for Coronary Heart Disease in Individuals Aged 65 or Older," *Journal of American Geriatric Society*, 36:1023-1028.
- X. Comments**
- Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.
- Dated: November 4, 1991.
- David A. Kessler,  
Commissioner of Food and Drugs.
- Louis W. Sullivan,  
Secretary of Health and Human Services.
- [FR Doc. 91-27171 Filed 11-26-91; 8:45 am]
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- 21 CFR Parts 101, 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169**
- [Docket Nos. 90N-0361 and 80N-0140]
- RIN 0905-AD08 and 0095-AC48
- Food Labeling; Declaration of Ingredients and Food Labeling; Declaration of Ingredients, Common or Usual Name for Nonstandardized Foods, Diluted Juice Beverages**
- AGENCY:** Food and Drug Administration, HHS.
- ACTION:** Proposed rule; delay of statutory effective date.
- SUMMARY:** The Food and Drug Administration (FDA) is announcing changes in the statutory effective date of the ingredient labeling provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in response to an amendment of section 10(c) of the 1990 amendments. FDA published proposed rules to implement the ingredient labeling provisions on June 21, 1991 and July 2, 1991.
- FOR FURTHER INFORMATION CONTACT:** Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202-485-0229.
- SUPPLEMENTARY INFORMATION:** Section 7 of the 1990 amendments modified section 403(i) of the Federal Food, Drug and Cosmetic Act (the act) to require the declaration of all ingredients in standardized foods, the declaration of certified color additives in foods, and the declaration, on the information panel, of the percentage of a fruit or vegetable juice in a food purpo ting to be a beverage containing fruit or

vegetable juice. FDA published proposed regulations to implement these requirements in the *Federal Register* of June 21, 1991 (56 FR 28592) and July 2, 1991 (56 FR 30452), with opportunity for comment through August 5, 1991. Both proposals are part of the Department of Health and Human Services' (DHHS) major initiative to reform the nation's food labeling system and part of DHHS' response to the 1990 amendments.

Although FDA proposed to make the ingredient labeling regulations and percent juice labeling regulations effective on the same date as the mandatory nutrition labeling final rule (i.e., May 8, 1993), the agency pointed out that the 1990 amendments state in section 10(c) that ingredient listing provisions for standardized foods, certified color additives, and percent juice labeling were to take effect 1 year after enactment. Thus, on November 8, 1991, these statutory provisions would be in effect.

In response to the proposals, many comments from the food industry strongly urged FDA to reconsider the effective date for ingredient labeling

regulations and percent juice labeling regulations. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs because present inventory would have to be discarded. The comments strongly urged FDA to establish a uniform effective date to comply with the effective date for section 403(q) of the act (mandatory nutrition labeling) and section 403(r) of the act claims, which were added by the 1990 amendments. Even though FDA agreed with these comments, it had no authority to provide the requested extensions.

A technical amendment was enacted on August 17, 1991, in which Congress amended the 1990 amendments to delay or modify the effective date of the new ingredient and percent juice labeling requirements. To reflect these changes, the agency is giving notice that a food for which a standard of identity has been established, or with one or more colors required to be certified, that bears a label that was printed before July 1, 1991, and that was attached to the food

before May 8, 1993, will not be subject to changes made in section 7(1), which modifies section 403(i) of the act to require that all mandatory as well as optional ingredients in a standardized food be declared, and in section 7(3) of the 1990 amendments, which modify section 403(i) of the act to require the declaration of certified colors. Labels on these foods printed after July 1, 1991 but before the effective date of a final implementing regulation and attached to the food before May 8, 1993, must conform with requirements of the June 21, 1991 proposal. Labels attached to food after May 8, 1993, will be subject to the amended section 403(i) of the act and to FDA's final regulations. Finally, the new ingredient labeling requirements for fruit and vegetable juice beverages will not apply to labels attached to these products before May 8, 1993.

Dated: November 13, 1991.

**Michael R. Taylor,**

*Deputy Commissioner for Policy.*

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