

botanical names on dietary supplement labels that are not identical to those required by the new rule, which amends the existing § 101.4(h) to incorporate by reference *Herbs of Commerce* (2000) and the *International Code of Botanical Nomenclature (Tokyo Code) 2000*, and to incorporate new Federal legislative restrictions on the use of the term "ginseng" in dietary supplement labeling.

Section 403A(a)(2) to (a)(3) of the act displaces both State legislative requirements and State common-law duties (*Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548–49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part)). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements, including State tort-law imposed requirements, that are not identical to the requirements of this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(e) of the Executive order states that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." Similarly, section 6(c) of the Executive order states that:

* * * to the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts state law, unless the agency, prior to the formal promulgation of the regulation * * * consulted with State and local officials early in the process of developing the proposed regulation. This requirement, that FDA provide the States with an opportunity for appropriate participation in this rulemaking, has been met. This rule updates and makes minor changes to a rule that was first proposed through full notice-and-comment rulemaking procedures in 1995 and finalized in 1997. During the comment period prior to the issuance of the 1997 final rule, and after the publication of the final rule, the agency received no comments, correspondence, or other communications from any State or local government concerning preemption of an existing legislative or common-law requirement. In its consultation with

states prior to the publication of this direct final rule, FDA was not informed about any State requirements that would be in conflict with the Federal requirements in this rule, and no States expressed concerns over the rule's preemptive effect. Moreover, FDA is providing an opportunity for State and local officials to comment through this rulemaking, and intends to withdraw the direct final rule if significant adverse comments are received.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order, and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

X. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. This comment period runs concurrently with that for the companion proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received on either this direct final rule or the companion proposed rule to be comments received on both rules.

XI. Effective Date

FDA periodically establishes, by final rule in the **Federal Register**, uniform effective dates for compliance with food labeling regulations (see, e.g., the **Federal Register** of December 31, 2002 (67 FR 79851), designating the effective date of January 1, 2006, for food labeling regulations issued between January 1, 2003, and December 31, 2004). FDA intends to make this direct final rule effective on January 1, 2006, the uniform effective date for compliance with food labeling regulations published between January 1, 2003, and December 31, 2004. FDA will publish a document in the **Federal Register** to confirm the effective date of this direct final rule, if FDA receives no significant adverse comments on it or its companion proposed rule.

XII. References

Copies of the following references have been placed on display and may be

seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday at the Division of Dockets Management (see ADDRESSES). FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Foster, Steven, editor, *Herbs of Commerce*, American Herbal Products Association, Austin, TX, 1992.
2. Greuter, W., editor (chairman), *International Code of Botanical Nomenclature (Tokyo Code) 1994*, adopted by the 15th International Botanical Congress, Koeltz Scientific Books, D-61453 Königstein, Germany, 1994.
3. McGuffin, Michael, managing editor, *Herbs of Commerce, 2nd Edition*, American Herbal Products Association, Silver Spring, MD, 2000.
4. Greuter, W., editor (chairman), *International Code of Botanical Nomenclature (Saint Louis Code) 2000*, adopted by the 16th International Botanical Congress, Koeltz Scientific Books, D-61453 Königstein, Germany, 2000.
5. *FDA Labeling Cost Model: Final Report*, Research Triangle Institute (RTI) International, April 2002, Revised.
6. *Economic Characterization of the Dietary Supplement Industry*, Research Triangle Institute (RTI), March 1999, p. 5–1.
7. Letter from Michael McGuffin, President, American Herbal Products Association, to Rhonda R. Kane, Consumer Safety Officer, FDA, May 13, 2002, pp. 1–6 with 3 attachments.
8. "Consumer Use of Dietary Supplements," Prevention Magazine Survey, Table A, *Prevention Magazine*, 2000, p. 13.
9. *Statistical Abstract of the United States: 2000*, Table Number 13—Resident Population by Sex and Age: 1999, U.S. Census Bureau, Washington, DC, p. 14. Obtained data at the Internet site <http://www.census.gov/prod/2001pubs/statab/sec01.pdf> on June 19, 2002.
10. *National Employment, Hours, and Earnings*, Bureau of Labor Statistics, U.S. Department of Labor, Washington, DC. Obtained data from the Internet site <http://data.bls.gov/cgi-bin/srgate> on August 14, 2002. To view the data used, enter the number EES00510006 in the series id window, select the year 2001–2002 in the years to report window, and select the button "retrieve data."
11. "The Power of Persuasion at the Moment of Truth," *Drug Store News*, 19(20):3–8, 22, and 24, December 8, 1997.
12. Robinson, J. P. and G. Godbey, *Time for Life: The Surprising Ways Americans Use Their Time*, Second Edition, The Pennsylvania State University Press, University Park, PA, 1997, Appendix A, 1985 column, categories 30 to 39, pp. 355 and 356.
13. Guthrie, J. F., K. M. Koehler, and R. A. Scharff, *Trends in the Consumption of Dietary Supplements 1994–2000*, Table 11—Growth in Market Size and Per Capita Consumption of Dietary Supplements, 1994–2000, Panel A, Unpublished document, Center for Food Safety and Applied Nutrition, FDA, Washington, DC, July 12, 2000, p. 29.