

of between \$2 and \$7 million, after rounding to the nearest million.

3. Option Three: Take an Alternative Action

This option is similar to the direct final rule action. We would still update the incorporation by reference citations under § 101.4(h), but firms would have slightly more flexibility when labeling dietary supplements containing a botanical ingredient. Under this option, the following requirements and provisos apply:

- As in Option Two, if the “standardized common name” for a botanical ingredient has changed from the 1992 to the 2000 edition of *Herbs of Commerce*, firms must use the revised “standardized common name” listed in the 2000 edition of *Herbs of Commerce*.

- If a botanical ingredient listed in the 2000 edition of *Herbs of Commerce* was not previously listed in the 1992 edition of that reference, firms could elect to use any of the names (i.e., botanical synonym, Ayurvedic name, pinyin name, or other common name) listed for that botanical in the 2000 edition as the common or usual name, with the following exception. As in Options One and Two, in accordance with section 10806 of the Farm Bill, the use of the term “ginseng” as a common or usual name (or part thereof) for a dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus “*Panax*.”

- Similar to Options One and Two, if the botanical ingredient is not listed in either the 1992 or 2000 edition of *Herbs of Commerce*, firms could use any appropriately descriptive name as the common or usual name for that ingredient with the following exception. In accordance with section 10806 of the Farm Bill, the use of the term “ginseng” as a common or usual name (or part thereof) for a dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus “*Panax*.”

- As in Option Two, any common or usual name *other than* the “standardized common name” for a botanical ingredient may be used only if the botanical is not listed in *Herbs of Commerce* (2000), and must be accompanied by the Latin binomial name of the plant from which it is derived.

- As in Option Two, the Latin binomial name must be stated in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*.

- As in Option Two, when needed to positively identify the botanical ingredient, the Latin binomial name also must include the author citation (i.e., name(s) of the person(s) who described and published the Latin binomial name in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*).

We discussed this option under this document’s preceding section V.B.3.a, Costs of Option Three, and concluded that it would generate lower relabeling costs for all firms than the direct final rule action. However, we were unable to estimate the size of the cost reduction and again concluded that labeling costs could be anywhere from \$2 to \$7 million, except that the costs of this option must be the same or less than the costs of Option Two. These conclusions also hold for small firms, which make up the vast majority of the affected firms. Although Option Three would reduce the impact of the direct final rule on small firms, it would also reduce the benefits by an unknown amount. We have decided not to pursue this option because the potential cost savings for small firms would be modest and we do not know the impact on benefits.

VII. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, these dietary supplement labeling requirements are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

VIII. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the direct final rule, because the direct final rule is not expected to result in any one-year expenditure that would exceed

\$100 million adjusted for inflation. The current inflation-adjusted statutory threshold is \$112 million.

IX. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to:

* * * construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.

Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. That section provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” certain food labeling requirements, unless an exemption is provided by the Secretary of Health and Human Services (and, by delegation, FDA). Relevant to this rule, one such requirement that States and political subdivisions may not adopt is “any requirement for the labeling of food of the type required by section * * * 403(i)(2) that is not identical to the requirement of such section,” (section 403A(a)(2) of the act). Another such requirement that States and political subdivisions may not adopt is “any requirement for the labeling of food of the type required by section * * * 403(i)(1) that is not identical to the requirement of such section,” (section 403A(a)(3) of the act). Prior to the effective date of this direct final rule, this provision operates to preempt States from imposing requirements concerning the use of botanical names in dietary supplement labeling if the requirements concerning the use of those names are not identical to those contained in § 101.4(h) (incorporating by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code) 1994*). Specifically, the preemptive effect applies to requirements concerning the use of botanical names in the common or usual name on the label of a dietary supplement (section 403(i)(1) of the act) and to requirements for listing individual botanical ingredients on the label of a dietary supplement (section 403(i)(2) of the act). Once this direct final rule becomes effective, States will be preempted from imposing any such requirements concerning the use of