

I. Background

A. Rulemaking Process

FDA has determined that the subject of this rulemaking is suitable for a direct final rule because it does not involve controversial regulatory changes and FDA does not anticipate receiving any significant adverse comments. This direct final rule has a companion proposed rule addressing the same topic published in the proposed rules section of this issue of the **Federal Register**. The direct final rule and its companion proposed rule are substantively identical. The proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule is withdrawn because FDA receives significant adverse comment.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. A comment recommending additional changes in the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the recommended revision. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

The comment periods for the direct final rule and its companion proposed rule run concurrently. We have identified and discussed the regulatory changes in the preambles to both rules. Any comments received under the direct final rule will be treated as comments regarding the proposed rule and vice versa. FDA is publishing this direct final rule because the rule does not contain controversial changes and FDA does not anticipate receiving significant adverse comments about it. If no significant adverse comments are received in response to either rule, FDA will take no further action on the proposed rule. Instead, after the comment period ends, FDA intends to publish a document in the **Federal**

Register to confirm the January 1, 2006, effective date of the direct final rule. This is the applicable uniform effective date for compliance with food labeling requirements published in the **Federal Register** (see the **Federal Register** of December 31, 2002 (67 FR 79851), designating January 1, 2006, as the effective date for food labeling regulations issued between January 1, 2003, and December 31, 2004). However, if FDA receives significant adverse comment on either rule, FDA will withdraw the direct final rule and will proceed to respond to all comments received on both rules under the companion proposed rule using the usual notice-and-comment procedures. A full description of FDA's policy on direct final rule procedures appears in a guidance document published in the **Federal Register** on November 21, 1997 (62 FR 62466).

B. Current Regulatory and Legislative Requirements Related to Direct Final Rule Amendments

FDA issued a final rule entitled "Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements" in the **Federal Register** on September 23, 1997 (62 FR 49826). This rule incorporated by reference under § 101.4(h) (21 CFR 101.4(h)) the two books entitled *Herbs of Commerce* (1992) (Ref. 1) and *International Code of Botanical Nomenclature (Tokyo Code) 1994* (Ref. 2) for industry's use in identifying on product labels the common or usual name of each botanical ingredient contained in dietary supplements. Both books were incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Section 101.4(h) currently requires that a dietary supplement that contains one or more botanical ingredients (including fungi and algae) state the common or usual name for each of these ingredients on the label. This common or usual name must be consistent with the "standardized common name" listed in *Herbs of Commerce* (1992) for the corresponding plant from which the ingredient is derived. Therefore, the "standardized common name" of each botanical used as an ingredient of a dietary supplement is its common or usual name for labeling purposes.

Current § 101.4(h)(2) also requires that if no standardized common name for a particular botanical ingredient is listed in *Herbs of Commerce* (1992), the label must state the Latin binomial name of the plant from which that ingredient is derived. All names in Latin binomial form must be stated on the label in accordance with internationally

accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature (Tokyo Code) 1994*. Further, the name in Latin binomial form must include the designation of the author or authors who published the Latin name [hereafter referred to as author citation] when a positive identification of the dietary ingredient cannot be made without identifying the author(s).

Since 1997, both of the books incorporated by reference for use by industry in the labeling of dietary supplements that contain botanical ingredients have been updated and now the 2000 editions supersede the earlier ones. *Herbs of Commerce, 2nd Edition* (2000) (Ref. 3) added standardized common names for approximately 1,500 more botanicals than were included in the earlier edition, and changed the standardized common names for approximately 140 botanicals listed in the earlier edition. The *International Code of Botanical Nomenclature (Saint Louis Code) 2000* (Ref. 4) reflects the International Botanical Congress's latest decisions on the rules for the scientific naming of plants. Botanical nomenclature is an evolving science that is influenced by new discoveries and the correction of past misidentifications of plants.

Further, in 2002, Congress passed and the President signed into law the Farm Security and Rural Investment Act of 2002 (Public Law 107-171) [hereafter referred to as the Farm Bill]. Section 10806 of the Farm Bill amended the misbranding provisions in section 403 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343) by adding a new paragraph (u), which states that a dietary supplement is misbranded "[i]f it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus *Panax*." Section 10806(b)(1)(A) of the Farm Bill states that "the term 'ginseng' may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus *Panax*." Section 10806(b)(1)(B) further provides that "only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term 'ginseng'."

The Farm Bill requirements about use of the term "ginseng" are in effect today because the law is self-executing. Congress did not direct FDA to issue regulations in order to implement these new requirements; therefore, industry must comply with them currently.