

Executive order classifies a regulatory action as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. The Executive order also classifies a regulatory action as significant if it raises novel legal or policy issues. We have determined that this direct final rule is not a significant regulatory action as defined by the Executive order.

#### A. Regulatory Options

We have identified the following major regulatory alternatives or options: (1) Take no action, (2) take the direct final rule action, and (3) take an alternative action. These options are explained in the next section of this document.

##### 1. Option One: Take No Action

The incorporation by reference citations under § 101.4(h) would remain unchanged. Under this option, the following requirements and provisos apply:

- The label of a dietary supplement containing a botanical ingredient must use the “standardized common name” for that botanical ingredient listed in the 1992 edition of *Herbs of Commerce*.

- For a botanical ingredient not listed in the 1992 edition of *Herbs of Commerce*, the label could use any appropriately descriptive name as the common or usual name, 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 any dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus “*Panax*.”

- Any common or usual name *other than* the “standardized common name” for a botanical ingredient may be used only if the botanical ingredient is not listed in *Herbs of Commerce* (1992), and must be accompanied by the Latin binomial name of the plant from which it is derived.

- The Latin binomial name must be stated in accordance with the internationally accepted rules on botanical nomenclature, such as those found in the *International Code of Botanical Nomenclature (Tokyo Code)* 1994.

- The Latin binomial name of a botanical ingredient also must include the designation of the author or authors who published the Latin name, when a positive identification of the botanical cannot be made in its absence.

##### 2. Option Two: Take the Direct Final Rule Action

The direct final rule option would update the incorporation by reference citations under § 101.4(h). Under this option, the following requirements and provisos apply:

- The label of a dietary supplement containing a botanical ingredient must use the “standardized common name” for that botanical ingredient listed in the 2000 edition of *Herbs of Commerce*.

- For a botanical ingredient not listed in the 2000 edition of *Herbs of Commerce*, the label could use any appropriately descriptive name as the common or usual name, with the following exception. As in Option One, 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 any dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus “*Panax*.”

- Any common or usual name other than the “standardized common name” for a botanical ingredient may be used only if the botanical ingredient 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.

- 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.

- 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).

##### 3. Option Three: Take an Alternative Action

This option is similar to the direct final rule option. We would still update the incorporation by reference citations under § 101.4(h), but firms would have slightly more flexibility when labeling 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 ingredient 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).

#### B. Impacts of Regulatory Options

##### 1. Option One: Take No Action

This option would retain the 1992 edition of *Herbs of Commerce* as the source for standardized common names and the 1994 edition of the *International Code of Botanical Nomenclature* as the reference on how to state the Latin