

detailed information to distinguish the size of this benefit from that of Option Two, so we again estimate the benefits to be between \$3 and \$10 million per year, except that they must be the same or less than the benefits of Option Two because the source of benefits under Option Three is a subset of the sources of benefits under Option Two.

We cannot compare the net benefits of Option Three to those of Option Two because the costs and benefits of Option Three are both lower, and we do not know the relative size of the changes in costs and benefits. If, however, the costs and benefits of Option Three were below those of Option Two by the same proportion, then Option Three would probably have lower net benefits than Option Two.

VI. Regulatory Flexibility Analysis

FDA has examined the economic implications of this direct final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would minimize the economic effect of the rule on small entities. We find that this direct final rule will have a significant economic impact on a substantial number of small entities.

A. Regulatory Options

In the preceding preliminary regulatory impact analysis under section V.A, Regulatory Options, of this document, we 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. We request comments on these and any other plausible alternatives.

B. Impacts of Regulatory Options

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.

Taking no additional action beyond the current regulatory regime that we described in the previous paragraphs would have no effect on small entities relative to the status quo.

2. Option Two: Take the Direct Final Rule Action

The direct final rule action is to 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).

The direct final rule would cause some small businesses to change product labels as described in the preceding regulatory impact analysis. It would not affect any other class of small entities. RTI developed a Dietary Supplement Enhanced Establishment Database (DS-EED) under contract to us. RTI based the DS-EED on our official establishment inventory and supplemented it with information from trade organizations, trade shows, and electronic databases (Ref. 6). According to these data, approximately 350 to 1,260 establishments might manufacture, repackage, or relabel supplements containing botanicals.

The Small Business Administration (SBA) defines a small business in the dietary supplement industry as a business having 500 or fewer employees. RTI traced the establishments to the parent company to determine how many establishments belonged to small firms. Based on that study, between 60 and 90 percent of the 1,260 establishments belong to small firms, or between approximately 700 and 1,200 establishments. However, the RTI study did not provide information on the total number of firms associated with those establishments.

In a letter to FDA, AHPA claims that between 600 and 1,100 firms produce at least one dietary supplement product containing an herbal ingredient and are also involved in labeling products (Ref. 7). The letter also states that the editor of the *Nutrition Business Journal* told AHPA that between 95 and 96 percent of dietary supplement companies have 500 or fewer employees. This information appears consistent with the information on establishments provided by RTI. We do not know how many of these firms would actually need to revise their labels. Therefore, we estimate that the direct final rule would affect between 0 and 1,045 small firms.

We assume that these firms would face 96 percent of the maximum total labeling costs for all firms we estimated in this document’s preceding section V.B.2.a, Costs of Option Two, which were \$2 to \$7 million. Therefore, we estimate that this direct final rule would generate one-time costs for small firms