

binomial names of botanical ingredients of dietary supplements. By convention, we treat the option of taking no action as the baseline for defining the costs and benefits of the other options. Therefore, we discuss the impacts of this option indirectly via the costs and benefits of the other options.

For this direct final rule, we include as part of the baseline costs for Option One (take no action) the cost of section 10806 of the Farm Bill, which restricts the use of the term "ginseng" in the labeling of dietary supplements as discussed under section II, Direct Final Rule, of this document. This is because the requirements of the Farm Bill are already in effect and are not dependent upon this rule for implementation.

2. Option Two: Take the Direct Final Rule Action

a. *Costs of option two.* The direct final rule would generate two basic types of costs: (1) Costs associated with changing certain dietary supplement labels and (2) potential one-time increases in product search costs for some consumers.

We estimate the first type of cost by using a model developed for that purpose by Research Triangle Institute (RTI) under contract to us (Ref. 5). This model estimates the total cost to change product labels by estimating and then adding together the following types of costs: (1) Internal administrative, (2) graphic design, (3) pre-press, (4) plate or cylinder engraving or etching, and (5) inventory disposal. The first four costs depend, in part, on the number of stockkeeping units (SKUs) involved. According to this model, dietary supplements are associated with 29,514 SKUs (Ref. 5).

The direct final rule would not affect all of these SKUs, only those associated with dietary supplements containing botanicals. We do not have direct estimates of the number of SKUs associated specifically with dietary supplements containing botanicals. However, a 1999 report by RTI on the economic characteristics of the dietary supplement industry found that herbals and botanicals made up 28 percent of sales in the dietary supplement market (Ref. 6). A statement submitted to us by the American Herbal Products Association (AHPA) noted that the *Nutrition Business Journal* "has consistently stated that herbal products represent approximately 25 percent of the sales of all supplements" (Ref. 7). In the following analysis, we use the 28 percent figure rather than the 25 percent figure because it is better documented and because the 28 percent figure is consistent with the phrase

"approximately 25 percent." In the absence of other information, we assume that the share of SKUs associated with products containing botanicals is similar to the share of sales associated with such products; that is, we assume that 28 percent of the total number of SKUs associated with dietary supplements is associated with dietary supplements containing botanicals. Therefore, we assume that approximately 8,300 SKUs ($29,514 \text{ SKUs} \times 28 \text{ percent}$) are associated with dietary supplements containing botanicals.

In addition, the direct final rule would only affect dietary supplements containing the following botanicals: (1) Any of the 1,500 additional botanicals for which the 2000 edition of *Herbs of Commerce* establishes standardized common names, if the labels of those products do not already list those botanicals under those names, (2) any of the 140 botanicals that the 2000 edition of *Herbs of Commerce* lists under a different standardized common name than in the 1992 edition, and (3) any botanical that the 2000 edition of the *Herbs of Commerce* does not list and for which using the naming conventions in the 2000 edition of the *International Code of Botanical Nomenclature* would result in a different Latin binomial name or author citation than using the naming conventions in the 1994 edition.

We do not know how many Latin binomial names the 2000 edition of the *International Code of Botanical Nomenclature* has changed, because that reference contains naming conventions rather than a list of names that we could compare with another list of names. Firms may need to change the labels of products containing botanicals that were listed under the same standardized common names in both the 1992 and 2000 editions of *Herbs of Commerce*, if the firms voluntarily listed the Latin binomial names of those botanicals and the 2000 edition of the *International Code of Botanical Nomenclature* has changed those names.

We do not have information on the number of dietary supplements this direct final rule would likely affect. AHPA reportedly reviewed the labels of several hundred dietary supplements containing botanicals and found that 85 percent fully conformed to the 2000 edition of *Herbs of Commerce* (Ref. 7). Additional samples might find higher or lower rates of compliance. In addition, labels that are already in compliance with the 2000 edition of *Herbs of Commerce* might not be in compliance with the 2000 edition of the *International Code of Botanical*

Nomenclature. To better reflect the uncertainty about the number of dietary supplements this direct final rule would be likely to affect, we assume it would affect between 10 and 20 percent of the 8,300 SKUs associated with botanical supplements or from 830 SKUs ($8,300 \text{ SKUs} \times 10 \text{ percent}$) to 1,660 SKUs ($8,300 \text{ SKUs} \times 20 \text{ percent}$). This range corresponds to an overall percentage of 3 ($830 \text{ SKUs} \div 29,514 \text{ SKUs}$) to 6 percent ($1,660 \text{ SKUs} \div 29,514 \text{ SKUs}$) of dietary supplement SKUs.

The labeling cost model we use does not base inventory disposal costs specifically on SKUs, but on the types of labels firms generally use for different types of products and assumptions about the amount of inventory remaining under different compliance periods for different types of products. We assume that the direct final rule would generate between 3 and 6 percent of the inventory disposal costs the model estimates for changing all dietary supplement SKUs.

The cost of changing product labels also varies with the amount of time we give firms to change the labels. The effective date for this direct final rule is January 1, 2006, which is the uniform effective date for food labeling regulations published between January 1, 2003, and December 31, 2004. We have chosen the uniform effective date for implementing the direct final rule in part because it provides a compliance period of at least 1 year following the publication of this rule. Under this compliance period, the label cost model estimates that the direct final rule would generate one-time relabeling costs of between \$2 million ($830 \text{ SKUs} \times \$2,400 \text{ per SKU}$) and \$7 million ($1,660 \text{ SKUs} \times \$4,200 \text{ per SKU}$).

In addition, the direct final rule may generate a one-time increase in product search costs for some consumers. Affected consumers would include those who currently identify desired botanical ingredients by: (1) Common or usual names that are different from the 1,500 new standardized common names listed in the 2000 edition of the *Herbs of Commerce*, (2) one of the 140 standardized common names changed by the 2000 edition of the *Herbs of Commerce*, or (3) one of the Latin binomial names changed by the 2000 edition of the *International Code of Botanical Nomenclature*. These consumers would need to learn the new names for desired ingredients. We do not know the number of affected consumers, but approximately 100 million adults (49 percent of adults times 202,493,000 adults ages 18 and older in the United States in 1999) consumed dietary supplements