

We again assume that 49 percent of this amount was spent by adults who consumed dietary supplements containing botanicals. Based upon this study and the stated assumptions, we estimate that consumers spend about 33 minutes per year $[(\$4.8 \text{ billion} \div \$711 \text{ billion} \times 0.49)] \times 46 \text{ minutes per week} \times 52 \text{ weeks per year}$ shopping for dietary supplements containing botanical ingredients.

All of the estimates of search costs are imprecise. None of these studies looks at product search activity that does not involve shopping, such as looking up material in books or on the Internet. The grocery store and use of time studies both addressed shopping time, which includes activities other than reading product labels. Nevertheless, in the absence of additional information, we estimate that this rule could reduce one's shopping time by a maximum of about 33 minutes (0.55 hours) per year. Applying this time savings to the estimated 3 to 6 million affected consumers and the average value of time of \$15.66 gives maximum search cost savings of between \$26 million (0.55 hours per year \times 3 million \times \$15.66 per hour) and \$52 million (0.55 hours per year \times 6 million \times \$15.66 per hour) per year. The proposed rule, however, would not eliminate all search costs associated with dietary supplements containing botanical ingredients for consumers interested in the affected products. To reflect this fact, we tentatively assume that this proposed rule would eliminate between 10 and 20 percent of those search costs, which would result in a range of search cost savings of \$3 to \$10 million per year (\$2.6 million \times 10 percent to \$52 million \times 20 percent). These benefits would recur annually because they would apply whenever a consumer actively searched for products containing the relevant ingredients, unlike the one-time increases in search costs that some consumers might face because the proposed rule would change existing botanical ingredient names.

Based on the preceding discussion, we estimate this proposed rule would generate net costs in the first year of between \$15 to \$51 million, and net benefits of \$3 to \$10 million every year after the first year. Under a discount rate of 7 percent, the present value of an infinite stream of benefits of \$3 million per year is \$43 million ($\$3 \text{ million} \div 7 \text{ percent}$), and the present value of an infinite stream of benefits of \$10 million per year is \$143 million ($\$10 \text{ million} \div 7 \text{ percent}$). Therefore, over time, this option would generate net benefits of negative \$8 million (\$43 million - \$51 million) to \$128 million (\$143 million -

\$15 million). The stream of benefits that would exactly offset the maximum estimated cost of \$51 million to give zero net costs is \$4 million ($\$4 \text{ million} \div 7 \text{ percent} = \57 million) per year out of the potential range of \$3 to \$10 million per year. Therefore, this rule would probably generate net benefits.

3. Option Three: Take an Alternative Action (as described under section V.A, Regulatory Options, of this document)

As discussed under section I, Background, of this document, in addition to standardized common names and Latin binomial names, the 2000 edition of *Herbs of Commerce* includes up to four other categories of names (i.e., botanical synonyms, Ayurvedic names, pinyin names and other common names) for each plant listed, when applicable. In order to reduce the number of label and name changes that we would require under Option Two, we could allow firms using any of the 1,500 botanicals that were not listed in the 1992 edition of *Herbs of Commerce*, but that are listed in the 2000 edition, to continue to label their products as they do now, as long as the name used for a botanical ingredient meets one of the following requirements: (1) Is among the names for the respective botanical listed in the 2000 edition and complies with the Farm Bill requirement concerning the use of the term "ginseng" and (2) is accompanied by the corresponding Latin binomial name, stated to conform to the naming conventions of the 2000 edition of the *International Code of Botanical Nomenclature*, including the author citation when needed for a positive identification of the botanical.

a. *Costs of option three.* This option would generate the same labeling costs as Option Two, except that some firms manufacturing or labeling dietary supplements containing one or more of the 1,500 botanical ingredients for which the 2000 edition of *Herbs of Commerce* establishes new standardized common names would not need to revise the labels of those products. The product whose labels would not need to be revised are with some exceptions, those that currently list botanical ingredients by any one of their corresponding names found in the 2000 edition of *Herbs of Commerce*. The exceptions, whose labels would nonetheless need to be revised, are those with names that conflict with the Farm Bill restriction on the use of the term "ginseng," or that do not state the correct Latin binomial names in accordance with the naming conventions of the 2000 edition of the *International Code of Botanical*

Nomenclature and include the author citations when needed for a positive identification of the botanicals. We do not know the number of such products. Using the cost estimated for Option Two, we estimate that the label change costs for Option Three would also be between \$2 and \$7 million, except that the cost of this option must be the same or less than the costs of Option Two.

Option Three would also generate the same short-term increases in product search costs as Option Two, except that some consumers who currently use one of the other names listed in the 2000 edition of *Herbs of Commerce* to identify botanical ingredients would be able to continue to use those names to identify those ingredients. We do not know the number of such consumers. Using the cost estimated for Option Two, we estimate that the increase of search costs under Option Three would also be between \$23 and \$47 million, except that these costs must be the same or less than the corresponding costs of Option Two, because the consumers affected by this cost under Option Three are a subset of the consumers affected by this cost under Option Two.

b. *Benefits of option three.* This option would generate the same reduction in long-term search costs as Option Two, except that fewer consumers who currently shop for dietary supplements using nonstandardized names would instead be able to use standardized common names to more easily identify those ingredients in other supplements. Again, we do not have sufficiently 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 this option were below those of Option Two by the same proportion, then this option would probably have lower net benefits than Option Two.

VI. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a