requirements, Supplemental Security Income.

Dated: July 22, 2003.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—[Amended]

■ 2. Add new section 11.00G to section 11.00 in part A of appendix 1 and revise section 11.10 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

11.00 Neurological

* * * * *

G. *Amyotrophic Lateral Sclerosis (ALS).* 1. Amyotrophic lateral sclerosis (ALS), sometimes called Lou Gehrig's disease, is a progressive, invariably fatal neurological disease that attacks the nerve cells (motor neurons) responsible for controlling voluntary muscles. Eventually, all muscles under voluntary control are affected, and individuals with ALS ultimately lose their ability to move their arms and legs, and their capacity to swallow, speak, and breath. Most people with ALS die from respiratory failure. There is currently no cure for ALS, and most treatments are designed only to relieve symptoms and improve the quality of life.

2. Diagnosis of ALS is based on history, neurological findings consistent with the diagnosis of ALS, and electrophysiological and neuroimaging testing to rule out other impairments that may cause similar signs and symptoms. The diagnosis may also be supported by electrophysiological studies (electromyography or nerve conduction studies), but these tests may be negative or only suggestive of the diagnosis. There is no single test that establishes the existence of ALS.

3. For purposes of 11.10, documentation of the diagnosis must be by generally accepted methods consistent with the prevailing state of medical knowledge and clinical practice. The evidence should include documentation of a clinically appropriate medical history, neurological findings consistent with the diagnosis of ALS, and the results of any electrophysiological and neuroimaging testing.

* * * * *

11.10 *Amyotrophic lateral sclerosis* established by clinical and laboratory findings, as described in 11.00G.

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

■ 3. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

■ 4. In § 416.934, revise paragraph (g) and add new paragraph (i) to read as follows:

§ 416.934 Impairments which may warrant a finding of presumptive disability or presumptive blindness.

* * * * *

(g) Allegation of Down syndrome.

* * * * *

(i) Allegation of amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease).

[FR Doc. 03–22016 Filed 8–27–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N–0346]

Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on declaring botanical ingredients in dietary supplements to incorporate by reference the latest editions of two books. Currently, the regulation incorporates by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code) 1994*. FDA is replacing the references to these editions with the 2000 editions of the same books. This action is intended to provide industry with current and more comprehensive references to use in identifying on product labels the common or usual name of each botanical ingredient contained in dietary supplements. In addition, FDA is incorporating new statutory restrictions on the use of the word ''ginseng'' in dietary supplement labeling. Finally, FDA is making minor wording changes in its regulation on declaring botanical ingredients in dietary supplements. These changes are intended to improve the reader's understanding, consistent with the principles of plain English, or to be more technically accurate, consistent with internationally accepted botanical terminology. FDA is issuing a direct final rule for this action because FDA expects there will be no significant adverse comments on the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule through the usual notice-and-comment rulemaking process. If FDA receives significant adverse comment on either rule, FDA intends to withdraw the direct final rule and proceed with the rulemaking. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective January 1, 2006. Submit written or electronic comments on this direct final rule by November 12, 2003. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document in the **Federal Register** confirming the effective date of this direct final rule. If the agency receives any timely significant adverse comments, FDA intends to publish a document in the **Federal Register** withdrawing this direct final rule before its effective date. The Director of the Office of the Federal Register approves the incorporation by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, of certain publications in 21 CFR 101.4(h) as of January 1, 2006.

ADDRESSES: Submit written comments on this direct final rule to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Victoria Lutwak, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

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.

C. Updated Books To Be Incorporated by Reference

Herbs of Commerce, 2nd Edition (2000) establishes a ''standardized common name,'' expressed primarily in English, for each plant used in commerce, including fungi and algae. However, in a few instances, the standardized common name is expressed in another language or is the same as the plant's Latin binomial name (i.e., genus and species) when that name has become common. For example, the Spanish word ''mate'' is the standardized common name for the plant ''*Ilex paraguariensis* A. St.-Hil.,'' and the Latin binomial name ''*Phyllanthus amarus*'' is the standardized common name for the plant ''*Phyllanthus amarus* Schumach.'' The standardized common name generally applies to the whole plant, but in some instances it applies to a plant part. For example, the standardized common names ''mace'' and ''nutmeg'' pertain specifically to the plant parts ''aril'' and ''seed,'' respectively, of the same plant ''*Myristica fragrans* Houtt.''

All standardized common names listed in *Herbs of Commerce, 2nd Edition* (2000) are printed in boldface letters. In this book under ''Section One: Latin Binomials,'' each plant name is listed first alphabetically by its Latin binomial name. The plant's corresponding standardized common name is stated after the acronym ''SCN'' on the first indented line of text underneath its Latin binomial name. Under ''Section Two: Standardized Common Names,'' each plant name is listed first alphabetically by its standardized common name. The plant's corresponding Latin binomial name is stated on the first indented line of text underneath its standardized common name.

In addition to the standardized common name, *Herbs of Commerce, 2nd Edition* (2000) identifies the currently recognized Latin binomial name and four other categories of common names for each of the plants listed, as applicable. These other categories are:

- ''botanical synonym,''
- ''Ayurvedic name,''
- ''pinyin name,'' and
- ''other common name.''

The botanical synonym, if any, represents one or more examples of other Latin binomial names that have been broadly used for the plant in the past. The Ayurvedic name, if any, generally represents the plant's Sanskrit name; however, the Hindi name may be cited if the plant is primarily known by it instead. The pinyin name, if any, may be one or more of the plant's Chinese common names. Other common names, if any, represent any additional names frequently used for the plant.

The ''standardized common name'' is different and distinct from all of the other categories of common names for a plant. There is only one *standardized* common name that is selected for each plant listed in *Herbs of Commerce, 2nd Edition* (2000); however, there may be several names cited within one or more of the other categories of common names that are associated with the same plant.

The *International Code of Botanical Nomenclature (Saint Louis Code) 2000* (the Code) establishes the current internationally accepted rules that govern the scientific naming of plants, including fungi and algae. The scientific name, which identifies the plant's genus and species, is expressed in Latin and applies to the whole plant without exception. The Latin binomial name of a plant is followed by the name(s) of the person(s) who described and published the plant name in accordance with the Code's guidelines. The Code refers to such notation about authors as an ''author citation.''

II. Direct Final Rule

FDA is revising § 101.4(h) to substitute *Herbs of Commerce, 2nd Edition* (2000) for its 1992 edition, and the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* for its 1994 edition, as books incorporated by reference. Requirements on how these references are to be used for dietary supplement labeling purposes remain the same and are not affected by this direct final rule, with one minor exception.

Currently, § 101.4(h)(2) uses the phrase ''such as'' when referring to the *International Code of Botanical Nomenclature* as a reference that industry may use to ensure that any Latin binomial name of a botanical ingredient listed on the label of a dietary supplement conforms to the internationally accepted rules of botanical nomenclature. As presently worded, the regulation could be interpreted to allow other references to be consulted for this purpose. We are revising the language in the Code of Federal Regulations (CFR) to make the *International Code of Botanical Nomenclature* the only reference that may be used on the rules for determining and formatting the Latin binomial name of a botanical ingredient for dietary supplement labeling purposes. This book is internationally recognized by botany experts from nations around the world as the foremost authoritative reference on botanical nomenclature. We are not aware of any comparable reference that comprehensively addresses the rules on the scientific naming of plants and has as broad international support. The *International Code of Botanical Nomenclature* is regulated by the Nomenclature Section of an International Botanical Congress. This group meets under the auspices of the International Union of Biological Sciences, of which the U.S. National Research Council/National Academy of Sciences is a member. The XVI International Botanical Congress brought together more than 4,000 scientists from more than 100 countries at its most recent meeting held in Saint Louis, MO in 1999 when the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* was voted on and adopted. Therefore, to be in harmony with this international cooperation and to be consistent with FDA's science-based philosophy, this direct final rule is incorporating by reference the *International Code of Botanical Nomenclature (Saint Louis Code) 2000* as the one that industry must follow on the rules to determine and format the Latin binomial names of any botanical ingredients stated on dietary supplement labels.

Some dietary supplements may contain a botanical ingredient that is not listed in the 2000 edition of *Herbs of Commerce* and therefore does not have a standardized common name. Like the former regulation, in such cases the direct final rule is requiring that the common or usual name for that botanical ingredient listed on the label be accompanied, in parentheses, by the Latin binomial name of the plant from which it is derived. When needed to positively identify the botanical ingredient, the direct final rule is continuing to require that the Latin binomial name also must include the author citation, stated in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*.

FDA is aware that there may be instances when a botanical ingredient belongs to a subspecies or variety of a species that is not listed in the 2000 edition of *Herbs of Commerce*. In those cases, the Latin binomial name and author citation alone will not identify the subspecies or variety of that species. Although not a requirement, FDA encourages industry to voluntarily state the following on dietary supplement labels directly after the Latin binomial name when needed to positively identify a botanical ingredient below the species level: The name of any

applicable subspecies, variety, or other subdivision and its corresponding author citation, stated in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*.

FDA is further revising § 101.4(h) to incorporate statutory restrictions on the use of the term ''ginseng'' that were imposed by section 10806 of the Farm Bill. Specifically, the direct final rule includes the following statement in § 101.4(h): ''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*.'''

Finally, FDA is making minor wording changes in § 101.4(h) to improve the reader's understanding, consistent with the principles of plain English, or to improve technical accuracy, consistent with internationally accepted botanical terminology. Examples of changes we are making to improve the reader's understanding are using simpler language throughout, substituting the word ''must'' for ''shall,'' and dividing very long sentences into shorter ones. To be more technically accurate, the direct final rule replaces the current wording under § 101.4(h)(2) that refers to the ''designation of the author or author(s) who published the Latin name'' with the term ''author citation'' to refer to the ''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*.'' For technical clarity, the direct final rule also adds the notation ''(i.e., genus and species)'' after the first reference to the term ''Latin binomial name'' under § 101.4(h).

III. Use of the Incorporated References and Implementation of Pertinent Farm Bill Provisions

Over the years, FDA has received several inquiries from representatives of the dietary supplement industry about the use of *Herbs of Commerce* and the *International Code of Botanical Nomenclature*. These books are references for industry to use in determining the common or usual name of each botanical ingredient or to consult on the rules for determining and formatting any required Latin binomial names corresponding to the botanical ingredients declared on dietary supplement labels. The act of ''incorporation by reference,'' however, does not imply that all of the botanicals that have standardized common names listed in *Herbs of Commerce* or that follow the scientific naming rules found in the *International Code of Botanical Nomenclature* are safe for consumption as dietary supplements or other foods by man or other animals. Citation of these books in the CFR is specific and limited to the sole purpose of identifying authoritative references for industry to use to determine the correct plant nomenclature. Neither reference addresses the safety or uses of plants.

This direct final rule focuses only on the naming of botanical ingredients of dietary supplements for labeling purposes. It is the responsibility of manufacturers and distributors to ensure that the particular botanicals they use as ingredients of dietary supplements are safe for human consumption, do not contain contaminants, are properly identified on the label, are legally marketed, and conform to all governing regulations.

In addition, *Herbs of Commerce, 2nd Edition* (2000) does not represent an authoritative compilation of botanical dietary ingredients that were marketed in the United States before October 15, 1994 (i.e., botanicals that are not new dietary ingredients under section 413(c) of the act (21 U.S.C. 350b(c))). The book's disclaimer explains that the publisher did not verify whether or not the companies that submitted botanical information for inclusion in this reference had valid documentation that supported such marketing. The book's disclaimer further states: ''The listing of a particular species of plant in this work is not, therefore, in and of itself, evidence that such species was marketed in the United States prior to October 15, 1994'' (Ref. 3, page xx). This direct final rule does not confer FDA endorsement of *Herbs of Commerce, 2nd Edition* (2000) for any other purpose than to serve as a reference on the common or usual names of botanical ingredients contained in dietary supplements.

In most cases, *Herbs of Commerce, 2nd Edition* (2000) assigns a unique standardized common name to each plant. However, the book indicates that the same standardized common name is given to more than one plant when the plants are used interchangeably in commerce. There are over 100 instances in *Herbs of Commerce, 2nd Edition* (2000) where the same standardized common name applies to two or more different species, subspecies, or varieties of the same genus of plant.

In other cases in *Herbs of Commerce, 2nd Edition* (2000), a name listed under one of the categories of common names (e.g., Pinyin names) for one botanical may be shared by another botanical from a different genus of plants. For example, the botanical *Ammi majus* L. has the standardized common name bishop's weed, whereas bishop's weed is also listed as the other common name for the botanical *Aegopodium podagraria* L. that has the standardized common name ash weed.

Confusion and mistakes in the identity of botanicals can be caused when the ingredients have the same or similar common names. Therefore, it is important that manufacturers know a botanical's true identity, including its Latin binomial name with author citation and its biological and chemical properties, before substituting one botanical for another as an ingredient of a dietary supplement. It is the responsibility of manufacturers and distributors to ensure that any botanical used as an ingredient of a dietary supplement or other food marketed in the United States is safe for consumption and complies with all applicable requirements of the act.

The ''standardized common names'' of botanicals listed in both the 1992 and 2000 editions of *Herbs of Commerce* are consistent with the Farm Bill's definition of the term ''ginseng.'' However, both editions note that the term ''ginseng'' has been used as part of ''other common names'' associated with botanicals from genera other than *Panax*, including blue ginseng, lesser ginseng, prince ginseng, and Siberian ginseng. We remind industry that names that include the term ''ginseng'' may be used as the common or usual name for a botanical ingredient only if the botanical is derived from the plant genus ''*Panax*.''

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

V. Regulatory Impact Analysis

FDA has examined the economic implications of this direct final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The

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

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 SKUs x 28 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 SKUs x 10 percent) to 1,660 SKUs (8,300 SKUs x 20 percent). This range corresponds to an overall percentage of 3 (830 SKUs ÷ 29,514 SKUs) to 6 percent (1,660 SKUs ÷ 29,514 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 SKUs x $2,400 per SKU) and $7 million (1,660 SKUs x $4,200 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

containing botanicals in 1999 (Refs. 8 and 9). Probably only a small percentage of these consumers would be interested in one or more of the botanicals whose names would be affected by this direct final rule. In the absence of other information, we assume that the proportion of consumers using the botanical ingredient names that the direct final rule would change is the same as the proportion of labels bearing those names or 3 to 6 percent. These percentages correspond to 3 to 6 million consumers.

We do not know the amount of time these consumers would need to discover that they cannot locate a product containing a desired botanical ingredient by the name under which they were accustomed to finding it, investigate the cause, and discover the new name. The methods consumers would use to resolve these issues are probably: (1) Asking a salesperson, (2) reading information on current botanical names in books or the Internet, or (3) reading additional product labels or brochures, some of which might voluntarily indicate the relevant name changes. The amount of time particular consumers devote to finding ingredients that have different names will vary with their interest in the ingredient and the number of ingredients involved. Consumers interested in multiple affected ingredients would probably spend the greatest amount of time on the first change they encounter because they could use some of the information they discover about that change to deal with additional changes. For example, they might learn that names have changed and develop a method for finding the new name. We assume that each affected consumer might spend between 0 and 30 minutes to process the name changes. The average value of 1 hour of leisure time should be similar to the average value of 1 hour of working time, which was $15.66 in January 2001 (Ref. 10). Therefore, we estimate a maximum search cost increase of between $23 million (3 million x 0.5 hours x $15.66 per hour) and $47 million (6 million x 0.5 hours x $15.66 per hour). This burden is a one-time cost, because future consumers of these products would not need to switch from the old name to the new name.

Combining the two types of costs, relabeling and search costs, gives a range of total one-time costs of $25 to $54 million.

b. *Benefits of option two.* The direct final rule would reduce product search costs for consumers who currently shop for dietary supplements containing desired botanical ingredients by using Latin binomial names or the nonstandardized names that might appear along with Latin binomial names, but who would be able to use one or more of the 1,500 additional standardized common names in the 2000 edition of the *Herbs of Commerce*. The direct final rule would reduce these consumers' search costs because standardized common names tend to be shorter and more distinctive than Latin binomial names, and the same ingredients would always appear under the same standardized common name.

Other consumers who would benefit from the direct final rule are those who shop for dietary supplements containing botanical ingredients by using the standardized common names listed in the 1992 edition of *Herbs of Commerce*, but who are currently unable to differentiate desired ingredients from undesired ingredients using those standardized names. Some of these consumers might be better able to differentiate these ingredients using the more specific standardized common names in the 2000 edition. As noted previously, the 2000 edition reports that it has changed 140 names to improve specificity, accuracy, or both.

Additional consumers who would benefit are those who shop for dietary supplements containing botanical ingredients using: (a) One or more of the standardized common names that the 2000 edition of *Herbs of Commerce* has changed to improve accuracy or (b) one or more of the Latin binomial names that the 2000 edition of the *International Code of Botanical Nomenclature* has changed due to a better understanding about the taxonomic relationships between plants. These consumers shop for dietary supplements using the botanical ingredient names in the 2000 edition of *Herbs of Commerce* or stated in accordance with the rules in the 2000 edition of the *International Code of Botanical Nomenclature* but sometimes have difficulty finding those dietary supplements because the product labeling may use a name from or stated in accordance with previous editions of those texts. The direct final rule would reduce search costs for these consumers by reducing inconsistencies between the botanical names in the 2000 editions of *Herbs of Commerce* and the *International Code of Botanical Nomenclature* and the names used to refer to those botanicals on dietary supplement labels.

We do not know the number of consumers in each of these categories. Therefore, we again assume that the total number of consumers in all affected categories would be between 3 and 6 percent of the estimated 100 million consumers who used a dietary supplement containing a botanical ingredient in 1999, or 3 to 6 million consumers.

We also do not know the decrease in search costs that the consumers in each of these categories would experience. However, we estimate the possible range of total search cost reductions using three studies on consumer behavior. The first study recorded the amount of time people in drug stores spent looking at an item on the shelf before making a purchase (Ref. 11) and found that customers, on average, spent approximately 4 minutes studying a product before purchasing it. According to data from RTI, adult consumers bought an average of six units of dietary supplements containing a botanical ingredient in 1999. Therefore, this study suggests that consumers of dietary supplements containing botanicals spend an average of 24 minutes per year (six units per year x 4 minutes per unit) looking at these products on shelves before purchasing them.

The second study, called the Americans' Use of Time Project, used time diaries to study how over 3,500 adults spent their time (Ref. 12). This study found that adult Americans spent about 371 minutes per week shopping for personal consumption items in 1985, such as groceries and other household products. This study did not provide information on time spent searching specifically for dietary supplements. To estimate this time, we assume that the share of shopping time devoted to dietary supplements is proportional to the share of consumers' budgets spent on dietary supplements. According to an industry source and FDA projections, consumers spent about $4.8 billion on dietary supplements containing botanical ingredients in 1999 (Ref. 13). Consumers spent $6,250 billion on personal consumption in 1999 (Ref. 14). We do not know the personal consumption expenditures of people who specifically purchase dietary supplements containing botanicals. Therefore, we assume that the personal consumption expenditures of those consumers are 49 percent of the personal consumption expenditures of all consumers. We base this assumption on the estimate that 49 percent of adult consumers used such a supplement in 1999, and the assumption that those consumers spent about the same amount on personal consumption as did other consumers. Under these assumptions, we estimate on the basis of this study that consumers spend an average of 30 minutes per year [($4.8 billion ÷ [$6,250 billion X 0.49]) x 371 minutes per week

x 52 weeks per year] shopping for supplements containing botanicals.

The third study used hidden observers to track and record shopping time in grocery stores (Ref. 15). This study found that people spent an average of about 21 minutes shopping in the grocery store per trip to the grocery store. By combining the estimated time per trip with the Food Marketing Institute's finding that consumers average about 2.2 grocery shopping trips per week, we estimate shopping time for all grocery store purchases to be 46.2 minutes per week (2.2 trips per week x 21 minutes per trip) (Ref. 16). Again, we assume that the proportion of shopping time devoted to dietary supplements equals the proportion of grocery store expenditures on dietary supplements. In 1999, consumers spent approximately $711 billion on grocery store purchases (here defined as food, alcoholic beverages, housekeeping supplies, personal care products, and tobacco products and smoking supplies) (Ref. 17).

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 billion ÷ [$711 billion X 0.49]) x 46 minutes per week x 52 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 direct final 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 x 3 million x $15.66 per hour) and $52 million (0.55 hours per year x 6 million x $15.66 per hour) per year. The direct final 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 assume that this direct final 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 x 10 percent to $52 million x 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 direct final rule would change existing botanical ingredient names.

Based on the preceding discussion, we estimate this direct final 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 million ÷ 7 percent), and the present value of an infinite stream of benefits of $10 million per year is $143 million ($10 million ÷ 7 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 million ÷ 7 percent = $57 million) per year out of the potential range of $3 to $10 million per year. Therefore, this direct final 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 must be stated 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 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 APHA 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

of between $2 and $7 million, after rounding to the nearest million.

3. Option Three: Take an Alternative Action

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

We discussed this option under this document's preceding section V.B.3.a, Costs of Option Three, and concluded that it would generate lower relabeling costs for all firms than the direct final rule action. However, we were unable to estimate the size of the cost reduction and again concluded that labeling costs could be anywhere from $2 to $7 million, except that the costs of this option must be the same or less than the costs of Option Two. These conclusions also hold for small firms, which make up the vast majority of the affected firms. Although Option Three would reduce the impact of the direct final rule on small firms, it would also reduce the benefits by an unknown amount. We have decided not to pursue this option because the potential cost savings for small firms would be modest and we do not know the impact on benefits.

VII. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, these dietary supplement labeling requirements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VIII. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the direct final rule, because the direct final rule is not expected to result in any one-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $112 million.

IX. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to:

> * * * construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.

Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. That section provides that ''no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce'' certain food labeling requirements, unless an exemption is provided by the Secretary of Health and Human Services (and, by delegation, FDA). Relevant to this rule, one such requirement that States and political subdivisions may not adopt is ''any requirement for the labeling of food of the type required by section * * * 403(i)(2) that is not identical to the requirement of such section,'' (section 403A(a)(2) of the act). Another such requirement that States and political subdivisions may not adopt is ''any requirement for the labeling of food of the type required by section * * * 403(i)(1) that is not identical to the requirement of such section,'' (section 403A(a)(3) of the act). Prior to the effective date of this direct final rule, this provision operates to preempt States from imposing requirements concerning the use of botanical names in dietary supplement labeling if the requirements concerning the use of those names are not identical to those contained in § 101.4(h) (incorporating by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code) 1994*). Specifically, the preemptive effect applies to requirements concerning the use of botanical names in the common or usual name on the label of a dietary supplement (section 403(i)(1) of the act) and to requirements for listing individual botanical ingredients on the label of a dietary supplement (section 403(i)(2) of the act). Once this direct final rule becomes effective, States will be preempted from imposing any such requirements concerning the use of

botanical names on dietary supplement labels that are not identical to those required by the new rule, which amends the existing § 101.4(h) to incorporate by reference *Herbs of Commerce* (2000) and the *International Code of Botanical Nomenclature (Tokyo Code) 2000*, and to incorporate new Federal legislative restrictions on the use of the term ''ginseng'' in dietary supplement labeling.

Section 403A(a)(2) to (a)(3) of the act displaces both State legislative requirements and State common-law duties (*Medtronic* v. *Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548–49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part)). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements, including State tort-law imposed requirements, that are not identical to the requirements of this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(e) of the Executive order states that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' Similarly, section 6(c) of the Executive order states that:

> * * * to the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts state law, unless the agency, prior to the formal promulgation of the regulation
> * * * consulted with State and local officials early in the process of developing the proposed regulation.

This requirement, that FDA provide the States with an opportunity for appropriate participation in this rulemaking, has been met. This rule updates and makes minor changes to a rule that was first proposed through full notice-and-comment rulemaking procedures in 1995 and finalized in 1997. During the comment period prior to the issuance of the 1997 final rule, and after the publication of the final rule, the agency received no comments, correspondence, or other communications from any State or local government concerning preemption of an existing legislative or common-law requirement. In its consultation with states prior to the publication of this direct final rule, FDA was not informed about any State requirements that would be in conflict with the Federal requirements in this rule, and no States expressed concerns over the rule's preemptive effect. Moreover, FDA is providing an opportunity for State and local officials to comment through this rulemaking, and intends to withdraw the direct final rule if significant adverse comments are received.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order, and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

X. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with that for the companion proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received on either this direct final rule or the companion proposed rule to be comments received on both rules.

XI. Effective Date

FDA periodically establishes, by final rule in the **Federal Register**, uniform effective dates for compliance with food labeling regulations (see, e.g., the **Federal Register** of December 31, 2002 (67 FR 79851), designating the effective date of January 1, 2006, for food labeling regulations issued between January 1, 2003, and December 31, 2004). FDA intends to make this direct final rule effective on January 1, 2006, the uniform effective date for compliance with food labeling regulations published between January 1, 2003, and December 31, 2004. FDA will publish a document in the **Federal Register** to confirm the effective date of this direct final rule, if FDA receives no significant adverse comments on it or its companion proposed rule.

XII. References

Copies of the following references have been placed on display and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday at the Division of Dockets Management (see **ADDRESSES**). FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Foster, Steven, editor, *Herbs of Commerce*, American Herbal Products Association, Austin, TX, 1992.

2. Greuter, W., editor (chairman), *International Code of Botanical Nomenclature (Tokyo Code) 1994*, adopted by the 15th International Botanical Congress, Koeltz Scientific Books, D–61453 Königstein, Germany, 1994.

3. McGuffin, Michael, managing editor, *Herbs of Commerce, 2nd Edition*, American Herbal Products Association, Silver Spring, MD, 2000.

4. Greuter, W., editor (chairman), *International Code of Botanical Nomenclature (Saint Louis Code) 2000*, adopted by the 16th International Botanical Congress, Koeltz Scientific Books, D–61453 Königstein, Germany, 2000.

5. *FDA Labeling Cost Model: Final Report*, Research Triangle Institute (RTI) International, April 2002, Revised.

6. *Economic Characterization of the Dietary Supplement Industry*, Research Triangle Institute (RTI), March 1999, p. 5–1.

7. Letter from Michael McGuffin, President, American Herbal Products Association, to Rhonda R. Kane, Consumer Safety Officer, FDA, May 13, 2002, pp. 1–6 with 3 attachments.

8. ''Consumer Use of Dietary Supplements,'' Prevention Magazine Survey, Table A, *Prevention Magazine*, 2000, p. 13.

9. *Statistical Abstract of the United States: 2000*, Table Number 13—Resident Population by Sex and Age: 1999, U.S. Census Bureau, Washington, DC, p. 14. Obtained data at the Internet site *http://www.census.gov/prod/2001pubs/statab/sec01.pdf* on June 19, 2002.

10. *National Employment, Hours, and Earnings*, Bureau of Labor Statistics, U.S. Department of Labor, Washington, DC. Obtained data from the Internet site *http://data.bls.gov/cgi-bin/srgate* on August 14, 2002. To view the data used, enter the number EES00510006 in the series id window, select the year 2001–2002 in the years to report window, and select the button ''retrieve data.''

11. ''The Power of Persuasion at the Moment of Truth,'' *Drug Store News*, 19(20):3–8, 22, and 24, December 8, 1997.

12. Robinson, J. P. and G. Godbey, *Time for Life: The Surprising Ways Americans Use Their Time*, Second Edition, The Pennsylvania State University Press, University Park, PA, 1997, Appendix A, 1985 column, categories 30 to 39, pp. 355 and 356.

13. Guthrie, J. F., K. M. Koehler, and R. A. Scharff: *Trends in the Consumption of Dietary Supplements 1994–2000*, Table 11–Growth in Market Size and Per Capita Consumption of Dietary Supplements, 1994–2000, Panel A, Unpublished document, Center for Food Safety and Applied Nutrition, FDA, Washington, DC, July 12, 2000, p. 29.

14. *Economic Report of the President*, Table B–16—Personal Consumption Expenditures, 1959–2001, U.S. Government Printing Office, Washington, DC, February 2002. Obtained data at the Internet site *http://w3.access.gpo.gov/usbudget/fy2003/sheets/b16.xls* on August 14, 2002.

15. ''Customer Behavior: How Consumers Shop,'' *Progressive Grocer*, December 1992, pp. 62–64.

16. ''A Shopping for Health Report, 1998: A Look at the Self-Care Movement,'' *Food Marketing Institute*, Research Department, Washington, DC, and *Prevention Magazine*, Research Department, Emmaus PA, 1998, p. 2.

17. *Consumer Expenditures in 1999*, Report 949, Table A—Average Annual Expenditures of All Consumer Units and Percent Changes, Consumer Expenditure Survey, 1997–99, Bureau of Labor Statistics, U.S. Department of Labor, Washington, DC, May 2001, p. 3. Obtained data from the Internet site *http://stats.bls.gov/cex/csxann99.pdf* on July 25, 2002.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.4 is amended by revising paragraph (h) to read as follows:

§ 101.4 Food; designation of ingredients.

* * * * *

(h) The common or usual name of a botanical ingredient (including fungi and algae) listed on the label of a dietary supplement must be consistent with the ''standardized common name'' listed in *Herbs of Commerce, 2nd Edition* (2000) for the plant from which the ingredient is derived. 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*.'' *Herbs of Commerce, 2nd Edition* (2000) is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this book may be obtained from the American Herbal Products Association, 8484 Georgia Ave., suite 370, Silver Spring, MD 20910, 301–588–1171, FAX: 301–588–1174, e-mail: *ahpa@ahpa.org*. Copies also may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) The listing of the common or usual name on the label must be followed by statements of:

(i) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., ''Garlic bulb'' or ''Garlic (bulb)''), except that this designation is not required for algae. The name of the part of the plant must be expressed in English (e.g., ''flower'' rather than ''flos''); and

(ii) The Latin binomial name (i.e., genus and species) of the plant from which the botanical ingredient is derived, stated in parentheses, when no ''standardized common name'' for the plant is listed in *Herbs of Commerce, 2nd Edition* (2000). In such cases, this Latin binomial name may be listed before the part of the plant and 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 *International Code of Botanical Nomenclature (Saint Louis Code) 2000*, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this book may be obtained from Koeltz Scientific Books, D–61453 Königstein, Germany; University Bookstore, Southern Illinois University, Carbondale, IL 62901–4422, 618–536–3321, FAX: 618–453–5207, e-mail: *siu@bkstr.com*; and from Lubrecht & Cramer, 18 East Main St., Port Jervis, NY 12771, 800–920–9334, FAX: 800–920–9334, e-mail: books@lubrechtcramer.com. Copies also may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

Dated: August 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–21980 Filed 8–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Etodolac

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of American Cyanamid Co. The supplemental NADA provides for a 500-milligram (mg) tablet size of etodolac for oral use in dogs.

DATES: This rule is effective August 28, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (301) 827–7540, e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 141–108 that provides for a 500-mg tablet size of ETOGESIC (etodolac) Tablets used for the management of pain and inflammation associated with osteoarthritis in dogs. The supplemental application is approved as of May 8, 2003, and the regulations are amended in 21 CFR 520.870 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.