(B) Addition of an intended use;

(C) If it is a prescription drug, any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application, unless:

(*1*) The parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted; and

(*2*) Any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(*3*) Prescription drug labeling not requiring an approved supplemental application is submitted in accordance with § 514.80(b)(5)(ii).

(D) Any other changes in labeling, except ones described in paragraph (c)(3) of this section.

(ii) The applicant must obtain approval of the supplement from FDA prior to distribution of the drug. The supplement must contain the following:

(A) A completed Form FDA 356V;

(B) A detailed description of the proposed change;

(C) The drug(s) involved;

(D) The data derived from studies in support of the change; and

(E) Any other information as directed by FDA.

(3) *Labeling changes to be placed into effect prior to receipt of a written notice of approval of a supplemental application.* (i) Labeling changes of the following kinds that increase the assurance of drug safety proposed in supplemental applications must be placed into effect immediately:

(A) The addition to package labeling, promotional labeling, or prescription drug advertising of additional warning, contraindication, adverse reaction, and precaution information;

(B) The deletion from package labeling, promotional labeling, or drug advertising of false, misleading, or unsupported intended uses or claims for effectiveness; and

(C) Any other changes as directed by FDA.

(ii) Labeling changes (for example, design and style) that do not decrease safety of drug use proposed in supplemental applications may be placed into effect prior to written notice of approval from FDA of a supplemental application.

(iii) A supplement submitted under paragraph (c)(3) of this section must include the following information:

(A) A full explanation of the basis for the changes, the date on which such changes are being effected, and plainly marked on the mailing cover and on the supplement, ''Supplement—Labeling Changes Being Effected'';

(B) Two sets of printed copies of any revised labeling to be placed in use, identified with the new animal drug application number; and

(C) A statement by the applicant that all promotional labeling and all drug advertising will promptly be revised consistent with the changes made in the labeling on or within the new animal drug package no later than upon approval of the supplemental application.

(iv) If the supplemental application is not approved and the drug is being distributed with the proposed labeling, FDA may initiate an enforcement action because the drug is misbranded under section 502 of the act and/or adulterated under section 501 of the act. In addition, under section 512(e) of the act, FDA may, after due notice and opportunity for a hearing, issue an order withdrawing approval of the application.

(4) *Changes providing for additional distributors to be reported under Records and reports concerning experience with approved new animal drugs (§ 514.80).* Supplemental applications as described under paragraph (c)(2) of this section will not be required for an additional distributor to distribute a drug that is the subject of an approved new animal drug application or abbreviated new animal drug application if the conditions described under § 514.80(b)(5)(iii) are met.

(d) *Patent information.* The applicant must comply with the patent information requirements under section 512(c)(3) of the act.

(e) *Claimed exclusivity.* If an applicant claims exclusivity under section 512(c)(2)(F) of the act upon approval of a supplemental application for a change in its previously approved drug, the applicant must include such a statement.

(f) *Good laboratory practice for nonclinical laboratory studies.* A supplemental application that contains nonclinical laboratory studies must include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

■ 7. Section 514.106 is amended by removing paragraphs (b)(1)(xiv), and revising paragraphs (b)(1)(vi) and (b)(1)(xiii) to read as follows:

§ 514.106 Approval of supplemental applications.

* * * * *

(b) * * *

(1) * * *

(vi) A change in promotional material for a prescription new animal drug not exempted by § 514.8(c)(2)(i)(C)(*1*) through (c)(2)(i)(C)(*3*).

* * * * *

(xiii) A change permitted in advance of approval as described under § 514.8(b)(3).

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 8. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.5 [Amended]

■ 9. Section 558.5 is amended in paragraph (j) by removing ''514.8(d) and (e)'' and by adding in its place ''514.8(c)(3)''.

Dated: September 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21133 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 1998P–0043] (formerly Docket No. 98P–0043)

Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrition labeling regulations for dietary supplements to provide that the quantitative amount and the percent of Daily Value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis when a recommendation is made on the label that the dietary supplement be consumed more than once per day. This final rule responds to a citizen petition requesting that FDA amend our dietary supplement nutrition labeling regulations to include this provision. FDA is taking this action to give manufacturers of dietary supplements the option to present nutrition information on a ''per day'' basis to consumers.

DATES: The regulation is effective December 13, 2006.

FOR FURTHER INFORMATION CONTACT: Carole L. Adler, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 12, 1999 (64 FR 1765), FDA published a proposed rule entitled ''Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis'' (the proposed rule). The proposed rule was published in response to a citizen petition submitted by the Nutrilite Division of the Amway Corporation (the petitioner) (filed January 23, 1998, Docket No. 98P–0043/CP1). In the citizen petition, the petitioner requested that we amend our nutrition labeling regulations for dietary supplements to permit the option of listing the quantitative amount and percent of Daily Value of dietary ingredients on a ''per day'' basis in addition to the required ''per serving'' basis when the label of the product recommends or instructs that the dietary supplement be consumed more than once per day. The proposed rule described the petitioner's request for ''per day'' labeling, including the petitioner's proposed language for amending § 101.36 (21 CFR 101.36) (64 FR 1765 at 1766 through 1767).

In the proposed rule, FDA explained the relevant background and history of § 101.36, which governs the nutrition labeling of dietary supplements (64 FR 1765 at 1766). Among other statutory provisions, § 101.36 implements section 403(q)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)(5)(F)(ii)), which was added by the Dietary Supplement Health and Education Act of 1994 (DSHEA). Section 403(q)(5)(F)(ii) states that the listing of dietary ingredients in dietary supplement nutrition labeling must include the quantity of each such ingredient (or of a proprietary blend of such ingredients) ''per serving.''

In response to DSHEA, in its December 28, 1995, proposal entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' (the December 28, 1995, proposed rule), FDA proposed that quantitative nutrition information for a dietary supplement be listed on a ''per serving'' basis (60 FR 67194 at 67198 and 67201). This requirement remained unchanged in the September 23, 1997, final rule (62 FR 49826 at 49830) entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide Revocation'' (the September 23, 1997, final rule). The September 23, 1997, final rule established requirements for the nutrition labeling and ingredient labeling of dietary supplements. These regulations state, in relevant part, that, for ''(b)(2)-dietary ingredients'' (i.e., dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in § 101.9(c) (21 CFR 101.9(c))) and their subcomponents (see § 101.36(b)(2)), the declaration of nutrition information on the label and in the labeling of dietary supplements must include the quantitative amount and percent of Daily Value of each dietary ingredient ''per serving'' (§ 101.36(b)(2)(ii) through (b)(2)(iii)). For ''other dietary ingredients'' (i.e., dietary ingredients for which RDIs and DRVs have not been established (see § 101.36(b)(3)), FDA's regulations require a declaration of the quantitative amount of each dietary ingredient ''per serving'' and a symbol (e.g., an asterisk) in the column under the heading ''% Daily Value,'' or following the quantitative amount when such a heading is not used, that refers to the same symbol placed at the bottom of the Supplement Facts label and followed by the statement ''Daily Value not established'' (§ 101.36(b)(3)(ii) and (b)(3)(iv)).

At the manufacturer's option, nutrition labeling for a dietary supplement (i.e., the Supplement Facts label) may also include the quantitative amount and percent of Daily Value of each dietary ingredient on a ''per unit'' basis in addition to the required ''per serving'' basis (§ 101.36(b)(2)(iv)). The petitioner requested that § 101.36 be amended to include a provision that the quantitative amount and percent of Daily Value of a dietary ingredient may also be listed on a ''per day'' basis in addition to the required ''per serving'' basis when a recommendation is made on the label that the dietary supplement be consumed more than once per day.

In response to the petitioner's request, we proposed to amend § 101.36 by adding new paragraph (e)(9) to permit quantitative information by weight (or volume, if permitted) to be declared on a ''per day'' basis in addition to the required ''per serving'' basis. Accordingly, we proposed to remove § 101.36(b)(2)(iv), which provides for the optional listing of quantitative information on a ''per unit'' basis, and to include this provision with the new provision for the optional listing of quantitative information on a ''per day'' basis in new § 101.36(e)(9). These labeling provisions would apply to all dietary ingredients (i.e., paragraph (b)(2) and other dietary ingredients). We further proposed to redesignate existing paragraphs (e)(9), (e)(10), and (e)(11) of § 101.36 as (e)(10), (e)(11), and (e)(12), respectively, and, accordingly, in redesignated paragraph (e)(12), to change the reference to paragraph (e)(10) to (e)(11). Finally, we proposed to provide an example in new § 101.36(e)(11)(viii) of a suggested format for a Supplement Facts label providing information on a ''per serving'' and ''per day'' basis. Interested persons were given until March 29, 1999, to comment on the proposed rule.

II. Summary of Comments and the Agency's Responses

FDA received six letters, each containing one or more comments, in response to the proposed rule. Comments were received from industry (including the petitioner), trade associations, and a consumer advocacy group. All comments supported the proposed rule with two comments requesting additional changes. The latter comments and the agency's responses are discussed in the following paragraphs. Two other comments raised issues regarding the ''Analysis of Impacts'' of the proposed regulation; they are discussed in the ''Analysis of Impacts'' section of this document.

- Two comments responding to the proposed rule's inclusion of a sample Supplement Facts label for ''per serving'' and ''per day'' information recommended additional options for the required format. One comment requested that manufacturers have the option of providing a statement such as ''Recommended Servings Per Day 3 Caplets (multiply per caplet amounts by 3 for per day amount)'' below the ''Serving Size'' declaration. The comment requested that we permit firms to provide the ''per day'' information either in this format or in the proposed rule's column format. The comment stated that the requested optional format gives consumers instructions for calculating the total amount of a dietary supplement and its dietary ingredients consumed per day and that most consumers are able to do this simple calculation. Also, the comment noted that the requested optional format would enable companies to optimize the type size on dietary supplement labels to improve label readability. The comment explained that using a column format to provide ''per day'' information would increase the Supplement Facts label by about 30 percent and that such an increase may drive the choice of type

size to the minimum allowed, rather than larger type. The comment contended that use of the minimum type size to offset the additional space consumed by a larger Supplement Facts label is not necessarily in the public interest.

The other comment requested that we allow a statement such as ''Recommended: Three (3) servings per day'' immediately following the ''Serving Size'' declaration in the Supplement Facts panel when nutrition information is presented on a ''per day'' basis. The comment's sample label provided this statement in conjunction with the column format. The comment stated that the recommendation of a day's consumption in the Supplement Facts label is not confusing and allows for easy readability by the consumer so that the consumer understands the concept of total daily consumption in one place on the label.

We have considered the comments requesting that the agency allow these additional optional statements about servings ''per day'' recommended elsewhere on the label in the Supplement Facts label of a dietary supplement. We believe that permitting a parenthetical statement as part of the ''Serving Size'' declaration in lieu of an additional column would promote larger print and would improve the readability of the Supplement Facts label in some circumstances. We also agree with the comment that permitting manufacturers to include a parenthetical declaration of the servings per day recommended elsewhere on the label after the listed serving size on the Supplement Facts panel would be useful, and would not be confusing, to consumers. Accordingly, we are permitting both types of parenthetical statements with slight modifications.

We disagree with some of the language proposed by both comments. Both comments proposed language for the optional parenthetical statements, and both proposals included the word ''recommended.'' We are not providing for use of the word ''recommended'' in new § 101.36(e)(9) because we believe that the word may cause confusion among consumers if used in the context of the Supplement Facts label. The purpose of the Supplement Facts label is to set out the factual nutritional information for the serving size of the product. To assure that the relevant nutritional information is set out, section 403(q)(5)(F) of the act prescribes information that must be included on the label of the dietary supplement. FDA's nutrition labeling regulations for dietary supplements prescribe both the information in a Supplement Facts label and its presentation, including the format (§ 101.36(b)), the percent of Daily Value of certain dietary ingredients (§§ 101.9(c) and 101.36(b)(2)), the order in which certain dietary ingredients are presented (§ 101.36(b)(2)(i)(B)), the manner in which amounts are to be expressed (§ 101.36(b)(2)(ii)), and the manner in which dietary ingredients are to be listed, even if no RDI or DRV has been established (§ 101.36(d)). Introducing the term ''recommended'' into the Supplement Facts label could suggest to consumers that the recommendation for the number of servings per day comes from some independent source, such as an expert body. FDA believes that permitting the same information to be conveyed without use of the word ''recommended'' would achieve the same result sought by the comments without leading to the potential confusion stemming from use of the word ''recommended'' in the context of the Supplement Facts label. Moreover, manufacturers and distributors remain free to use the term ''recommended'' elsewhere on the label of their dietary supplements, so long as use of the term is not false or misleading (e.g, if it suggests that the recommendation comes from a source other than the manufacturer or distributor when, in fact, it does not) or does not otherwise misbrand the dietary supplement under section 403 of the act.

New § 101.36(e)(9) will now permit a parenthetical statement in the Supplement Facts label that provides directions for calculating the ''per day'' amount when there is a manufacturer's (or distributor's, if the distributor labels the product) recommendation or directions for use in other parts of the label that the dietary supplement be consumed more than once per day. A manufacturer may use such a parenthetical statement as an alternative to the column format for ''per day'' information described in the proposed rule and permitted in new § 101.36(e)(9). For example, a manufacturer could provide a statement such as ''Serving Size: 1 Caplet (Multiply amounts by 3 for total daily amount).'' We are also incorporating a provision for a parenthetical declaration of the servings per day recommended elsewhere on the label into new § 101.36(e)(9). The regulation will now permit such a simple statement following the ''Serving Size'' declaration. FDA believes that a simple declaration of the servings per day recommended on other parts of the label, such as ''Total daily amount: 3 caplets per day,'' on the Supplement Facts label would provide clarity for the consumer when interpreting the column format, which provides the same information in a different way (e.g., ''Per Day (3 Caplets)'').

- One comment asked if continuous bars and lines would be acceptable in place of the non-continuous bars and lines shown in the sample Supplement Facts label in the proposed rule.[1] Specifically, concerning the sample Supplement Facts label, this comment was referring to (1) the non-continuous heavy bar below the ''Serving Size'' declaration, (2) the non-continuous light bar below the ''Per Serving'' (''Per Caplet'' in the proposed sample label) and ''Per Day'' headings, (3) the non-continuous hairlines between the listed dietary ingredients, and (4) the non-continuous heavy bar below the listing of the (b)(2)-dietary ingredients.[2]

The non-continuous lines and bars provided in the proposed sample Supplement Facts label are a means of helping consumers distinguish each column. However, the agency would like to clarify that the sample labels presented in § 101.36(e)(10) (now § 101.36(e)(11)) are included for the purpose of illustration. The non-continuous lines and bars used in the sample Supplement Facts labels are one acceptable way to comply with the regulations, but not the only way. As long as the presentation otherwise complies with § 101.36, deviations from the sample Supplement Facts labels in new § 101.36(e)(11) would not violate the regulation. We believe that a Supplement Facts label using continuous bars and lines to separate multiple pairs of quantitative amounts and percents of Daily Value for dietary ingredients would be acceptable when the information is clearly identified by appropriate column headings.

To clarify the proposed provisions for ''per day'' and ''per unit'' information, and to make the codified language read more clearly and to conform to plain language principles, we are making a number of additional changes to the proposed codified language of new § 101.36(e)(9), both in response to

[1] This comment referred to proposed paragraph § 101.36(e)(9)(vii) for the sample label. However, because there was no § 101.36(e)(9)(vii) in the proposed rule, we presume that the comment intended to refer to the sample label in paragraph § 101.36(e)(11)(viii) of the proposed rule.

[2] This comment referred to the non-continuous nature of the heavy bar below the listing of § 101.36(b)(3) dietary ingredients (i.e., ''other dietary ingredients'') in the proposed sample label. However, because the sample label in the proposed rule did not include other dietary ingredients, we presume that the comment intended to inquire about the non-continuous heavy bar below the listing of (b)(2)-dietary ingredients.

comments, and after our own review of the proposal. We are providing the codified language in two paragraphs: § 101.36(e)(9)(i) and § 101.36(e)(9)(ii). The first two sentences, which pertain to ''per unit'' information are included in § 101.36(e)(9)(i). The remainder of the codified section, which pertains to ''per day'' information is included in § 101.36(e)(9)(ii). In the first sentence of the codified section, after ''Daily Value,'' we are adding ''of each dietary ingredient'' and replacing the last clause of this sentence (i.e., ''as required in paragraph (b)(2)(ii) and (b)(2)(iii) of this section'') with the following: ''required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients.'' After the first sentence, we are adding the following (second) sentence: ''If 'per unit' information is provided, it must be presented in additional columns to the right of the 'per serving' information and be clearly identified by appropriate headings.'' The second sentence in the proposed codified language is now the third sentence in this final rule (the first sentence of § 101.36(e)(9)(ii)), and incorporates changes as follows: (1) We are adding ''by weight (or volume, if permitted)'' following the words ''total quantitative amount'' and (2) following ''Daily Value,'' we are adding ''of each dietary ingredient may be presented on a 'per day' basis in addition to the 'per serving' basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients,'' to be consistent with the first sentence for ''per unit'' information and to avoid potential confusion.

In addition, to clarify the proposed provisions for ''per day'' information, we are adding the following sentences to § 101.36(e)(9)(ii)):

If ''per day'' information is provided, it must be presented in additional columns to the right of the ''per serving'' information and be clearly identified by appropriate headings and/or be presented in a parenthetical statement as part of the ''Serving Size'' declaration. A sample illustration for ''per day'' information in a column format is provided in paragraph (e)(11)(viii) of this section. As illustrated, the additional ''Per Day'' column heading is followed parenthetically by the number of servings recommended per day in other parts of the label (e.g., ''Per Day (3 Caplets)''). When the parenthetical statement format following the ''Serving Size'' declaration is used as an alternative to the column format, the statement must provide no more than simple instructions regarding how to calculate the ''per day'' amount for the number of servings per day recommended in other parts of the label (e.g., ''Serving Size: 1 Caplet (Multiply amounts by 3 for total daily amount)''). When the parenthetical statement format following the ''Serving Size'' declaration is used in addition to the column format, the statement must provide no more than a simple declaration of the number of servings recommended in other parts of the label (e.g., ''Serving Size: 1 Caplet (Total daily amount: 3 caplets per day)'').

We are also changing the word ''shall'' to ''must'' in the second sentence of new § 101.36(e)(12). This change is meant to make the codified language read more clearly and conform to plain language principles.

In sum, we are finalizing the proposed rule as follows: We are removing § 101.36(b)(2)(iv), which provides for the optional listing of quantitative information on a ''per unit'' basis, and including this provision in a new § 101.36(e)(9). We are, therefore, continuing to provide for the optional presentation of the quantitative amount by weight (or volume, if permitted) and the percent of Daily Value on a ''per unit'' basis, in addition to the required ''per serving'' basis. We are also adding a new provision in the new § 101.36(e)(9) to provide for the optional presentation of the quantitative amount by weight (or volume, if permitted) and the percent of Daily Value on a ''per day'' basis, in addition to the required ''per serving'' basis, when the label recommends consumption of the dietary supplement more than once per day.

As proposed, we are also redesignating existing paragraphs (e)(9), (e)(10), and (e)(11) of § 101.36 as (e)(10), (e)(11), and (e)(12), respectively, and accordingly, in redesignated paragraph (e)(12) changing the reference to paragraph (e)(10) to the newly redesignated paragraph (e)(11). Lastly, in new § 101.36(e)(11)(viii), we are providing a sample label for the purpose of illustrating a column format for a Supplement Facts label providing information on a ''per serving'' and ''per day'' basis.

III. Legal Authority

In response to a citizen petition, FDA is amending its food labeling regulations for dietary supplements to provide that the quantitative amount and percent of Daily Value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis when a recommendation is made on the label that the dietary supplement be consumed more than once per day. FDA has authority to take this action under sections 201(n), 403(a)(1) and (q)(5)(F), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1) and (q)(5)(F), 371(a)).

By delegation from the Secretary of Health and Human Services (the Secretary), FDA has authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act. Further, section 403(q)(5)(F) provides that a dietary supplement product must comply with the requirements of sections 403(q)(1) and (q)(2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary (and by delegation, FDA). Sections 403(q)(1) and (q)(2) require that if a food, which includes a dietary supplement, is intended for human consumption and is offered for sale, its label or labeling must bear certain nutrition information. For dietary supplements, this includes nutrition information ''per serving'' about dietary ingredients that are present in significant amounts (21 U.S.C. 343(q)(5)(F)(i)). Under these two sections, FDA has authority to permit the voluntary presentation of ''per day'' nutrition information on a dietary supplement label and provide requirements for such labeling.

This final rule will give dietary supplement manufacturers the option to present nutrition information of dietary supplements on a ''per day'' basis to consumers. When manufacturers choose to include ''per day'' information on a dietary supplement label, in addition to the required ''per serving'' information, consumers will have more information about the daily intake of dietary ingredients from a dietary supplement that is recommended by the manufacturer to be consumed more than once per day. When provided, ''per day'' information about a dietary supplement can assist consumers in making dietary choices about total consumption of dietary ingredients.

IV. Analysis of Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

1. The Need for This Regulation

Current regulations do not permit the voluntary declaration of potentially

useful information on the labels of dietary supplements. Consumers may want information on the amount of nutrition provided by dietary supplements on a ''per day'' basis. Without this rule, manufacturers are precluded from providing consumers with that information in the Supplement Facts label of their dietary supplements.

2. Options

There are primarily four regulatory options available to us.

a. *Option 1.—Take no new regulatory action.* This option would result in no change to the current situation. This option is the baseline for comparison of options and entails no costs or benefits.

b. *Option 2.—Take the regulatory actions as described in the proposed rule.* We proposed allowing the nutrition labeling of dietary supplements to declare the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis when the label recommends that the dietary supplement be consumed more than once per day as long as the information was provided in a column format.

The proposed rule would have caused costs and benefits only to the extent that firms elected to take advantage of the option of presenting information on a ''per day'' basis. No firm would have borne the cost of changing labels unless it believed that the claim would have resulted in increased profits by virtue of increased sales of its products or an increased willingness by consumers to pay more for the product. Interested consumers would have benefited from the additional ''per day'' information.

In response to the proposal, we received one comment that agreed with our analysis and stated that ''[t]he agency accurately notes that the cost impact of this change is inconsequential.'' However, the comment went on to say that, ''FDA should seek ways to balance the potentially conflicting public health needs of the presentation of all of the needed and required information and the limited label space of dietary supplement product labels. * * * The use of a column format would increase the Supplement Facts box by about 30%, thereby potentially driving the choice of type size to the minimum required to offset the additional space consumed by a larger Supplement Facts box. This is not necessarily in the public interest.''

We still believe that finalizing the proposed rule would have been of greater benefit to producers and consumers than continuing to preclude the provision of this information in the Supplement Facts label. However, that benefit would have been mitigated by the potential cost to consumers of having to read the Supplement Facts label in a smaller type size.

c. *Option 3.—Take the regulatory actions described in this final rule.* In this final rule, we are allowing the nutrition labeling of dietary supplements to declare the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis when the label recommends that the dietary supplement be consumed more than once per day. Based on comments (described in section II of this document) we are also permitting this information to be provided in parenthetical notations as an alternative to the column format described in the proposed rule, as detailed in section II of this document. These regulatory actions provide producers of dietary supplements the option to present nutrition information on a ''per day'' basis in the Supplement Facts label with greater flexibility than in the proposed rule.

As under Option 2, the final rule will cause costs and benefits only to the extent that firms elect to take advantage of the option of presenting information on a ''per day'' basis. No firm will bear the cost of changing labels unless it believes that the claim will result in increased profits by virtue of increased sales of its products or an increased willingness by consumers to pay more for the product.

However, this final rule is an improvement over the proposed rule. It gives producers of dietary supplements greater flexibility in how they provide consumers with the ''per day'' information. This potentially decreases the costs to them (in comparison to Option 2) by not requiring the information to be provided in a column format and thereby reducing the potential need for extensive label redesigns.

The increased flexibility and decreased cost to producers of providing the information increases the likelihood (compared to Option 2) that producers will voluntarily provide consumers with ''per day'' information. It also reduces the likelihood (compared to Option 2) that the new ''per day'' information and all of the other information in the Supplement Facts label would be provided in smaller and less legible type.

Therefore, we conclude that this final rule will improve social welfare compared with Options 1 and 2.

d. *Option 4.—Require ''per day'' labeling of dietary supplements.* In response to the proposed rule, one comment stated that we should monitor the costs for manufacturers who use the voluntary ''per day'' labeling and, if the costs are minimal, ''consider making per day labeling mandatory in some future regulation.'' The comment stated the belief ''that the informational benefits of the rule for consumers, both at the time of purchase and of consumption, may be significant enough to warrant a mandatory rule.''

We are not precluding that action in the future. There are at least 62,500 dietary supplement labels for products sold in the United States. Requiring that all labels be changed could impose significant costs on the industry. For example, if we were to require ''per day'' labeling within 2 years of the publication of this final rule, it could cost between as little as $40 million and as much as $100 million, based on data in our labeling cost model. Such significant costs would warrant evidence of at least similarly sized benefits to consumers from information on ''per day'' nutritional information. We currently do not have enough information on the benefit to consumers of ''per day'' labeling to justify mandatory ''per day'' labeling for all dietary supplements. Therefore, we have no evidence that this option is superior for social welfare than this final rule (Option 3).

B. Small Entity Analysis

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule allows voluntary ''per day'' labeling of dietary supplements, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Because ''per day'' labeling will be permitted and not required, a firm, including any small firm, would change its labeling and incur costs only if the expected benefits to it (e.g., increased sales) exceed the expected costs. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and

benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

V. Federalism Analysis

We have analyzed this 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 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. Section 403A(a)(4) of the act 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—* * * (4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * *.''

Before the effective date of this rule, this provision operated to preempt States from permitting ''per day'' nutrition labeling on dietary supplements because no such requirements had been authorized by FDA under section 403(q) of the act. Once this rule becomes effective, States will be preempted from imposing any requirements about ''per day'' nutrition labeling for dietary supplements that are not identical to those permitted by this rule. This preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(4) of the act displaces both State and 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); *Cippollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.); id. at 548–49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part)).

FDA believes that the preemptive effect of the final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides 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.'' FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on January 12, 1999 (64 FR 1765). FDA received no comments from any States on the proposed rulemaking.

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

VI. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions with an estimate of the annual reporting burden is given in the following paragraphs. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis.

Description: Section 403(q)(5)(F) of the act provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. We issued regulations establishing the requirements for nutrition labeling of dietary supplements in § 101.36 in the September 23, 1997, final rule. We are now amending our nutrition labeling regulations for dietary supplements to permit voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These provisions respond to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This rule will provide the option to present nutrition information on a ''per day'' basis to consumers.

Description of Respondents: Suppliers of dietary supplements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours	Total Operating Cost
101.36(e)	125	13	1,625	0.25	406	$151,000

[1] There are no capital or maintenance costs associated with this collection.

The agency estimated in the March 13, 2003, proposed rule entitled ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements'' that there were about 1,250 manufacturers and relabelers of dietary supplements (68 FR 12157 at 12223). Based on data in our labeling cost model each producer has, on average, roughly 50 products. We assume that only 10 percent, or 125, of the dietary supplement suppliers would revise the labels of their products to incorporate ''per day'' information for their products. We also assume that ''per day'' information would generally be placed on, at most, 25 percent, or, at most, 13 of a firm's estimated 50 products, although this number would vary by firm based on the types of products that it produces. The agency also believes that the burden associated with providing nutrition information on a ''per day'' basis for dietary supplements would be a one-time burden for the small number of firms that decide voluntarily to add this additional information to the labels of their products, separate from any other label changes for their products. We estimate that at least 90 percent of firms would coordinate adding ''per day''

information with other changes to their labels. In this case, the voluntary cost of transmitting ''per day'' information to consumers would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 113 firms would be approximately $50 (64 FR 1765 at 1768) per label for 1,469 labels, or about $73,000 total. For the remaining 12 firms that would not coordinate adding ''per day'' information with other labeling changes, we estimate that the cost would be approximately $500 per label (64 FR 1765 at 1768 through 1769) for 156 labels, or $78,000 total. The estimated total operating costs in table 1 of this document are, therefore, $151,000. Respondents are already required to list the quantitative amount and percent of Daily Value of dietary ingredients ''per serving'' as part of the nutrition information for dietary supplements. The ''per day'' information is generated by simple extrapolation from the ''per serving'' information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

The information collection provisions in the proposed rule were approved under OMB control number 0910–0395. This approval was discontinued in November 2004, but is now reinstated and expires on October 31, 2009. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Environmental Impact

We have carefully considered the potential environmental effects of this action. FDA has determined under 21 CFR 25.30(k) that this action is of a type that does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. No new information or comments have been received that would affect this determination.

List of Subjects in 21 CFR Part 101

Food labeling, 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 101.36 is amended by removing paragraph (b)(2)(iv); by redesignating paragraphs (e)(9), (e)(10), and (e)(11) as paragraphs (e)(10), (e)(11), and (e)(12), respectively; by adding new paragraphs (e)(9)(i) and (e)(9)(ii); by adding new paragraph (e)(11)(viii) to newly redesignated paragraph (e)(11); and by revising newly redesignated paragraph (e)(12) to read as follows (The graphic to newly redesignated (e)(12) remains unchanged.):

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(e) * * *

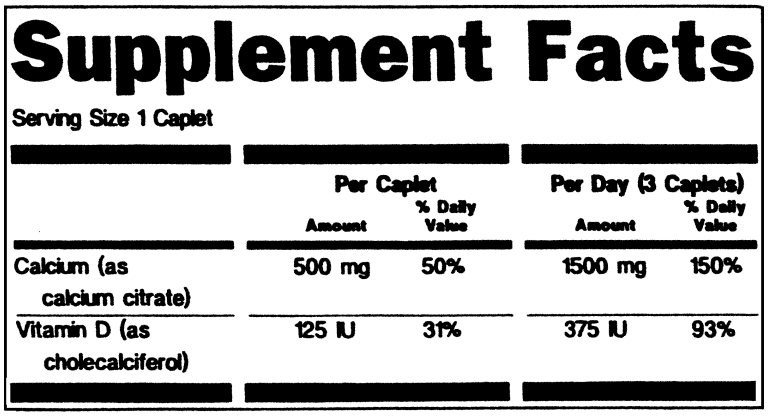
(9)(i) The quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a ''per unit'' basis in addition to the ''per serving'' basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If ''per unit'' information is provided, it must be presented in additional columns to the right of the ''per serving'' information and be clearly identified by appropriate headings.

(ii) Alternatively, if a recommendation is made in other parts of the label that a dietary supplement be consumed more than once per day, the total quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a ''per day'' basis in addition to the ''per serving'' basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If ''per day'' information is provided, it must be presented in additional columns to the right of the ''per serving'' information and be clearly identified by appropriate headings and/or be presented in a parenthetical statement as part of the ''Serving Size'' declaration. A sample illustration for ''per day'' information in a column format is provided in paragraph (e)(11)(viii) of this section. As illustrated, the additional ''Per Day'' column heading is followed parenthetically by the number of servings recommended per day in other parts of the label (e.g., ''Per Day (3 Caplets)''). When the parenthetical statement format following the ''Serving Size'' declaration is used as an alternative to the column format, the statement must provide no more than simple instructions regarding how to calculate the ''per day'' amount for the number of servings per day recommended in other parts of the label (e.g., ''Serving Size: 1 Caplet (Multiply amounts by 3 for total daily amount)''). When the parenthetical statement format following the ''Serving Size'' declaration is used in addition to the column format, the statement must provide no more than a simple declaration of the number of servings recommended in other parts of the label (e.g., ''Serving Size: 1 Caplet (Total daily amount: 3 caplets per day)'').

* * * * *

(11) * * *

(viii) Dietary supplement illustrating ''per serving'' and ''per day'' information:



Supplement Facts

Serving Size 1 Caplet

	Per Caplet		Per Day (3 Caplets)	
	Amount	% Daily Value	Amount	% Daily Value
Calcium (as calcium citrate)	500 mg	50%	1500 mg	150%
Vitamin D (as cholecalciferol)	125 IU	31%	375 IU	93%

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

* * * * *

Dated: November 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–9657 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 96, and 97

[EPA–HQ–OAR–2004–0076; FRL–8254–7]

RIN 2060–AM99

Clean Air Interstate Rule (CAIR) and Federal Implementation Plans for CAIR; Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correcting amendments.

SUMMARY: In this rule, EPA is making minor corrections to the Clean Air Interstate Rule (CAIR) and the Federal Implementation Plans (FIPs) for the CAIR to clarify text that may potentially be misleading. This corrections rule does not change any of CAIR or CAIR FIPs rule requirements or substantively change the rules in any way.

DATES: *Effective Date:* These correcting amendments are effective on December 13, 2006.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2004–0076. Documents related to the CAIR are available in the rulemaking docket under Docket ID No. EPA–HQ–OAR–2003–0053; documents related to the CAIR FIPs are available in the rulemaking docket under Docket ID No. EPA–HQ–OAR–2004–0076. All documents in the dockets are listed on the *http://www.regulations.gov* Web site. Although listed in the indexes, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center (Air Docket), EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744.

Note: The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at *http://www.epa.gov/epahome/dockets.htm* for current information on docket status, locations and telephone numbers.

FOR FURTHER INFORMATION CONTACT: Carla Oldham, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539–04, Research Triangle Park, NC 27711; telephone number (919) 541–3347, e-mail address: *oldham.carla@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 12, 2005, EPA published the Clean Air Interstate Rule (CAIR) in a final rule entitled, ''Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to NO_X SIP Call'' (70 FR 25162). On April 28, 2006, EPA published Federal Implementation Plans for the CAIR as part of a final rule entitled, ''Rulemaking on Section 126 Petition From North Carolina to Reduce Interstate Transport of Fine Particulate Matter and Ozone; Federal Implementation Plans To Reduce Interstate Transport of Fine Particulate Matter and Ozone; Revisions to the Clean Air Interstate Rule; Revisions to the Acid Rain Program'' (71 FR 25328). The CAIR requires States to reduce emissions of nitrogen oxides and sulfur dioxide that contribute significantly to nonattainment and maintenance problems in downwind States with respect to the national ambient air quality standards for fine particulate matter ($PM_{2.5}$) and 8-hour ozone. The CAIR FIPs ensure that the emissions reductions required by the CAIR are achieved on schedule. As the control strategy for the FIPs, EPA adopted the model cap-and-trade programs for power plants that EPA provided in the CAIR as a control option for States, with minor changes to account for Federal, rather than State, implementation. The EPA will withdraw the FIP for any State once that State's own State implementation plan for meeting the CAIR requirements is fully approved. For a detailed description of the CAIR and CAIR FIPs, please see the rulemaking actions which are available on EPA's Web site at *http://www.epa.gov/cair* and in the **Federal Register** at and 70 FR 25162; May 12, 2005 and 71 FR 25328; April 28, 2006.