DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245 and 94P–0110]

RIN 0910–AA59

Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; action on petitions for reconsideration.

SUMMARY: The Food and Drug Administration (FDA) is revising its nutrition labeling requirements for dietary supplements that contain liquid extracts to allow the quantity of an extract to be listed on the basis of volume, solvents present to be listed in the ingredient statement, and the optional listing in the nutrition label of the ratio of starting material to the final volume of solvent, and to clarify that the quantity of any constituents of dietary ingredients be listed in the nutrition label in terms of quantitative amount by weight on a ''per serving'' basis. FDA is also eliminating the requirement that a description of a dried extract include the name of the solvent used. This action is in response to four petitions for reconsideration.

EFFECTIVE DATE: These revisions are effective March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5587.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1997 (62 FR 49826), FDA published a final rule entitled ''Food Labeling; Statement of Identity, Nutrition and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation'' (hereinafter identified as ''the September 1997 final rule''). In the September 1997 final rule, FDA amended its food labeling regulations to establish requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA). The September 1997 final rule is to become effective March 23, 1999.

The requirements for the nutrition labeling of dietary supplements are found in § 101.36 (21 CFR 101.36). Specifically, the requirements for liquid and dried extracts are in section § 101.36(b)(3)(ii)(B) and (b)(3)(ii)(C), respectively. Section 101.36(b)(3)(ii)(B) states:

For any dietary ingredient that is a liquid extract from which the solvent has not been removed, the quantity listed shall be the weight of the total extract with information on the concentration of the dietary ingredient, the solvent used, and the condition of the starting material (i.e., whether it is fresh or dried), e.g., ''fresh dandelion root extract, x mg (y:z) in 70% ethanol,'' where x is the number of mg of the entire extract, y is the weight of the starting material and z is the volume (milliliters) of solvent. Where the solvent has been partially removed (not to dryness), the final concentration shall be stated (e.g., if the original extract was 1:5 and 50 percent of the solvent was removed, then the final concentration shall be stated as 1:2.5).

Section 101.36(b)(3)(ii)(C) states:

For a dietary ingredient that is an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract. The dried extract shall be described by an appropriately descriptive term that identifies the solvent used, e.g., ''dried hexane extract of _____'' or ''_____, dried hexane extract.''

II. Petitions for Reconsideration

FDA received four petitions for reconsideration under § 10.33 (21 CFR 10.33) relating to the requirements for the labeling of extracts. A petition for reconsideration from the American Herbal Products Association (AHPA), the Utah Natural Products Alliance, and the National Nutritional Foods Association (Docket Nos. 95N–0245/PRC 4 and 94P–0110/PRC 4) (hereinafter referred to as the ''joint petition''), requested that FDA reconsider the provision on liquid extracts in § 101.36(b)(3)(ii)(B), stay its effective date, and adopt the petition's proposed restatement of this provision. The petitioners stated that, with respect to extracts, FDA had proposed ''For any dietary ingredients that are liquid extracts, the weight shall not include the weight of solvents'' (60 FR 67194 at 67216, December 28, 1995). The petitioners stated that interested parties could not reasonably have anticipated that the final rule would require specifying the solvent used, the ratio, and the condition of the starting material. Thus, they contended that the final rule violated the rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553), because of inadequate provision of notice and opportunity for comment.

The petitioners recommended the adoption of the following technical amendments to this provision: (1) The quantity of a dietary supplement that is a liquid extract be stated in volume, not weight measurements; (2) solvents that have not been removed from a liquid extract be included in the ingredient list; (3) information on the concentration of a liquid extract in the form y:z be optional; and (4) constituents of a liquid extract be stated by weight on a ''per serving'' basis.

Specifically, the petition requested that § 101.36(b)(3)(ii)(B) be amended to read:

For any dietary ingredient that is a liquid extract from which the solvent has not been removed, the quantity listed shall not be the weight but shall instead be the volume of the total extract. If information is included on the concentration of the dietary ingredient in the form y:z, it shall be expressed as a ratio of the weight (in grams) of the starting material to the volume (in milliliters) of solvent. Additionally, the condition of the starting material shall be stated if the starting material is in fresh condition (e.g., ''fresh dandelion root extract (y:z)''), and may be stated if the starting material is in dried condition. If a product contains a dietary ingredient that is a liquid extract from which the solvent has not been removed and is labeled in any manner which quantifies or claims to contain one or more specific contained constituents of a botanical, the constituent shall be quantified on the label by weight on a ''per serving'' basis, in accordance with paragraph (b)(3)(iii) of this section.

The petitioners stated that with these technical amendments the provision would be consistent with the original proposal. The petitioners also stated that they are developing guidelines for manufacturing extracts that they plan to publish in a volume tentatively entitled ''AHPA Extracts Manufacturers Guidelines.''

Another petition for reconsideration, from Wakunaga of America Co., Ltd. (Docket Nos. 95N–0245/PRC 1 and 94P–0110/PRC 1) (hereinafter referred to as the ''Wakunaga petition''), requested that FDA reconsider and revoke the provisions on extracts or revise those provisions to eliminate the requirement to identify the solvent used and the ratio of the botanical to the solvent. The petitioner stated that FDA apparently adopted a suggestion in a comment to describe extracts by the ratio of weight to volume of solvent without any opportunity for other parties to comment on this requirement in violation of the Administrative Procedure Act. The petitioner contended that the disclosure of proprietary information was never addressed by FDA in the proposed or final regulations and that the potential

damages of such disclosure are sufficient grounds to revoke the requirement for such disclosures. The petitioner emphasized that if FDA did not accept either of their requests, it should at least propose the requirements in the final rule to allow opportunity for comment.

Two other petitions for reconsideration were received, one from AHPA (Docket Nos. 95N–0245/PRC 2 and 94P–0110/PRC 2) (hereinafter referred to the ''AHPA petition''), and another from the Council for Responsible Nutrition and Nutrilite Division of Amway Corporation (Docket Nos. 95N–0245/PRC 3 and 94P–0110/PRC 3) (hereinafter referred to as the ''CRN/Amway petition''). Both petitioners requested that FDA reconsider the provision on dried extracts in § 101.36(b)(3)(ii)(B), stay the effective date of the second sentence of this provision, and revoke the sentence. In addition, AHPA further requested that FDA should confer with AHPA and other interested parties regarding the need for, and alternatives to, the revoked requirement.

AHPA included a number of reasons in the statement of grounds for their petition. The petitioners stated that interested parties were deprived of adequate notice and opportunity for comment on solvent identification in violation of the Administrative Procedure Act's rulemaking provisions. AHPA also contended that identifying solvents used in the manufacture of dried extracts is arbitrary. The petitioners stated that the solvent used in the preparation of an extract is only one factor of many factors that are important in the manufacturing process. Moreover, they stated that ''solvents used in food, food additives, and substances generally recognized as safe are not required to be disclosed on labels.''

Furthermore, the petitioners argued that identifying solvents used in the manufacture of dried extracts is potentially misleading. They expressed concern that consumers may assume that solvents remain in the products when, in fact, they do not. Also, they observed that such disclosure may cause some manufacturers to switch to solvents that are less effective because of the fear that consumers may be misled by chemical solvent names.

The CRN/Amway petition contained some of the same reasons as the AHPA petition for revoking the second sentence of the provision on dried extracts. The petitioners stated that interested parties were not given notice and opportunity to comment on this sentence. They stated that this provision should be made the subject of a new notice of proposed rulemaking if FDA wishes to include it in the final regulations.

The CRN/Amway petition also took issue with FDA's statement in the preamble of the September 1997 final rule (62 FR 49826 at 49834) that ''solvent information is needed in the nutrition label of dietary supplements to appropriately describe extracts because dietary ingredients do not have individual regulations, like the regulations for food additives, that specify how they are to be made, and, when needed for identity or safety reasons, what solvent can be used in the processing.'' The petitioners stated that the example that FDA used of a food additive regulation that specifies what solvent can be used (i.e., 21 CFR 172.580(b)) is atypical and, like AHPA, charged that requiring solvent information in the nutrition label of dietary supplements imposes labeling requirements that are inconsistent with conventional foods.

FDA received a comment in support of the AHPA, Wakunaga, and CRN/Amway petitions that stated that it agreed with these petitions.

FDA also received a submission on December 24, 1997, identified by the submitter as comments on the joint petition, a petition for reconsideration, a petition for stay of action, and a petition to amend parts of § 101.36(b)(3)(ii). For the reasons discussed in the following paragraphs, the agency has handled this submission only as a comment on the joint petition. As a comment on the joint petition, it stated general support for the proposed technical amendments to § 101.36(b)(3)(ii)(B) recommended by the joint petition and stated the belief that these amendments could be made administratively, without the need for notice and comment.

Under § 10.33, a petition for reconsideration is to be submitted within 30 days from the date of the decision involved (this can be waived for good cause) and shall contain no new information or views. Because the December 24, 1997, submission was not timely and contains new information and views, FDA has not filed it as a petition for reconsideration.

Likewise, FDA is not handling this submission as a petition for stay of action because, under 21 CFR 10.35, this type of petition must specify the provision for which a stay is requested and be submitted no later that 30 days after the date of the decision involved. FDA finds no mention of a stay in the submission.

Further, the December 24, 1997, submission has not been filed as a petition to amend parts of § 101.36(b)(3)(ii). This submission pointed out specific areas of confusion and expressed the hope that it would stimulate discussion about how best to standardize labeling practices. In addition, the submission suggested adding a new section to define the terms ''extract,'' ''botanical extract,'' and ''native extract.'' The submission also proposed a scheme that would allow for the identification in the nutrition label of the type of solvent used, rather than the specific name of the solvent. Additionally, the submission stated that procedures should be established for expressing the ratio of dried extracts that would clarify whether or not fillers have been taken into consideration. These issues are beyond the scope of reconsideration of the September 1997 final rule, and are therefore not addressed in this final rule. The agency urges industry to consider them in the development of guidelines on extracts, however.

III. Response to Petitions

FDA has fully evaluated the petitions for reconsideration and reviewed the administrative record of the September 1997 final rule to determine if, in light of the arguments raised in the petitions, the agency would have reached a different decision regarding the nutrition labeling of dry and liquid extracts in dietary supplements.

As explained in the following paragraphs, the agency has determined that, based on the administrative record at the time of the publication of the September 1997 final rule, the agency did not make the correct decision.

The joint petition, AHPA petition, and CRN/Amway petition requested that FDA stay the effective date of the provisions of the final regulations pertaining to extracts. The agency is not issuing a stay because the agency believes that a stay is unnecessary. This final rule resolves the issues well enough in advance of March 23, 1999, the effective date for this rule and the September 1997 final rule, to allow firms to meet that effective date.

A. Liquid Extracts

In the agency's December 28, 1995 (60 FR 67194), proposed rule (the December 1995 proposal) on nutrition labeling of dietary supplements entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements,'' the agency proposed that for dietary ingredients for which the Reference Daily Intakes (RDI's) and the Daily

Reference Values (DRV's) have not been established, the supplement facts should include the quantitative amount by weight per serving of the dietary ingredient listed, and not the weight of any component, or the source of, that dietary ingredient. For dietary ingredients that are liquid extracts, the agency proposed that the weight would not include the weight of the solvents.

The comments on the December 1995 proposal convinced the agency that this latter proposal with respect to liquid extracts was unfeasible. The petitions for reconsideration do not question that decision, and the agency stands by it. In the December 1995 proposal's stead, the agency required that the quantity of the entire extract be listed. The petitions for reconsideration have not questioned this provision of the September 1997 final rule.

They do, however, question several other aspects of the final provision on liquid extracts, some of which follow directly from the quantification of the entire extract and others that arise less directly from that decision. The former include whether the volume or the weight should be used to quantify a liquid extract and whether the solvent in the extract should be listed in the nutrition information or in the ingredient list. The latter include whether the ratio of the starting material to the final product should be required. The agency has, therefore, reexamined the administrative record of the September 1997 final rule, in light of the arguments in the petitions for reconsideration, to determine how the agency should have finalized the provision regarding how to quantify liquid extracts.

1. Quantity Listed on the Basis of Volume

The joint petition proposed that the quantity of dietary ingredients in liquid extract form be listed by volume and not by weight. None of the comments of the December 1995 proposal directly requested that the quantity of a liquid extract be listed in terms of its volume rather than its weight. A couple of comments, however, clearly assumed that liquid extracts should be listed by volume and not by weight. For example, one comment suggested that the relative strength of an extract be expressed in a volume to weight ratio that would reflect what volume of liquid extract was equivalent to what weight of herb. For such a ratio to be useful, the quantity of liquid extract would have to be listed by volume. A second comment, portrayed in the September 1997 final rule as agreeing to the listing of the weight of the entire extract (62 FR 49826 at 49833), actually provided several examples using volumes of entire extracts. The agency therefore concludes that the administrative record for the September 1997 final rule supports the use of volume as a means of listing the quantity of a liquid extract.

The joint petition forcefully argues that only volume should be used to list the quantity of a liquid extract. However, the agency received one comment that recommended that liquid extracts should be listed by weight. The agency concludes that it is appropriate for manufacturers to have the option of listing quantity by weight. The agency is, therefore, modifying § 101.36(b)(3)(ii)(B) to require that liquid extracts be quantified either by volume or by weight.

2. Solvent Listed in the Ingredient Statement

In the December 1995 proposal (60 FR 67194 at 67216), FDA proposed that the dry weight of a liquid extract be declared in the nutrition label (proposed § 101.36(b)(3)(ii)) and that the name of any solvent used appear in the ingredient statement (proposed § 101.4(g)) (60 FR 67194 at 67214). In the September 1997 final rule, FDA required that the weight of the total extract be listed in the nutrition label, and that the name of the solvent be included in the description of the liquid extract in the nutrition information. The joint petition requested that solvents that have not been removed from a liquid extract be included in the ingredient list. The Wakunaga petition requested that FDA revoke the provisions on extracts in § 101.36(b)(3)(ii)(B) and (b)(3)(ii)(C) or revise those provisions to eliminate the requirement to identify the solvent used.

FDA has reconsidered this issue. Under section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)), the solvent present in liquid extracts must be identified. The comments on the December 1995 proposal do not directly address the issue of where the solvent should be listed, although it is raised by their suggestion that the quantity of the total extract be listed. On the one hand, FDA continues to believe, as in the September 1997 final rule, that it is appropriate for the name of the solvent to appear in the nutrition label as a part of the description of a liquid extract because the solvent is present in the extract, the entire extract is listed as a dietary ingredient, and the solvent is included in the quantity listed for the extract. Labeling in this manner is truthful and nonmisleading. Those wishing to label solvents in this manner should, therefore, have this option.

On the other hand, the agency is persuaded that it is reasonable to allow manufacturers to list solvents either in the nutrition label or the ingredient list. This approach is consistent with the December 1995 proposal. Moreover, allowing flexibility is consistent with section 403(q)(5)(F) of the act, which allows sources of dietary ingredients to be listed in either the nutrition label or the ingredient list. Therefore, FDA is revising § 101.36(b)(3)(ii)(B) to allow the identity of the solvent in liquid extracts to be listed in either the nutrition label or the ingredient list. The agency points out that if the name of the solvent is not included in the nutrition label, it must be included in the ingredient list in accordance with § 101.4(g), as had been proposed in the December 1995 proposal.

3. Ratio Information Optional

The December 1995 proposal would have required, for dietary ingredients that are liquid extracts, that the weight listed for the dietary ingredient not include the weight of the solvent. The comments pointed out that listing the weight of an extract was not an indication of the concentration or strength of an extract. Some of the comments suggested that a truthful and nonmisleading description of the content of the extract, such as a weight to volume ratio, should be permitted. One of these comments stated that nonstandardized extracts typically are marketed on the basis of a dry botanical to solvent ratio. Other comments suggested that the ratio approach may be useful, but pointed out that the weight of the botanical at the beginning of the extraction process is only one of several factors that affect the concentration of the extract.

As a result of these comments, the agency required in the September 1997 final rule that liquid extracts should be described by a ratio of the weight of the starting material to the volume of the solvent or a description of these values.

The petitions for reconsideration have convinced the agency, however, that it did not adequately consider the comments. In fact, none of the comments requested that ratio information be required, only that it be permitted. Considering this fact, the agency is convinced that, at the time of the September 1997 final rule, it incorrectly required that this information be included in the labeling of dietary supplements. Therefore, FDA is removing the requirement in § 101.36(b)(3)(ii)(B) that ratio information be stated. However, in

recognition of the comment on the December 1995 proposal suggesting that the use of ratio information may provide truthful and nonmisleading information, the agency is not opposed to the optional inclusion of ratio information. Section 101.36(b)(3)(ii)(B) is, therefore, revised accordingly.

In the September 1997 final rule, the agency required that, when listing ratios, the condition of the starting material should be specified, i.e., whether it is fresh or dried. The joint petition stated that the condition should be required only when the starting material is fresh. FDA notes that one of the comments stated that typically the starting material is dried. Additionally, when dried material is used, the amount declared would not include the weight of any water, so consumers would not be misled. Thus, FDA concludes that it unnecessarily required that the condition of dried material be declared. Therefore, FDA is revising § 101.36(b)(3)(ii)(B) to require that the condition of the starting material be required only when it is fresh and may be stated optionally when it is dried.

Having reconsidered the issue of the use of ratios and how they should be stated, when declared, the agency believes that other approaches (such as individual product monographs, good manufacturing practices, or industry guidelines) may provide for better product standardization in the future. These other approaches necessitate further investigation and cooperative research between the agency and the dietary supplement industry. Until such activities can be accomplished, FDA believes that the most appropriate course of action, and the one most useful to consumers, is to proceed to implement the DSHEA by moving ahead with mandatory nutrition labeling in the most truthful, nonmisleading, and flexible manner understood at this time. As experience in this area is gained by all parties, FDA anticipates that the flexibility in this final rule may minimize the need for amendments.

4. Quantification of Constituents of a Liquid Extract Should Be Listed on a ''Per Serving'' Basis.

The agency's December 1995 proposal requested comments on whether constituents of dietary ingredients should be permitted to be listed. The comments favored such listing. The September 1997 final rule, therefore, provided that constituents of a dietary ingredient described in § 101.36(b)(3)(i), which would include constituents of extracts, may be listed, followed by their quantitative amounts by weight.

The joint petition requested clarification that constituents of liquid extracts, when declared, should be listed on a ''per serving'' basis. This petition requested that § 101.36(b)(3)(ii)(B) pertaining to liquid extracts be amended to include the sentence:

> If a product contains a dietary ingredient that is a liquid extract from which the solvent has not been removed and is labeled in any manner which quantifies or claims to contain one or more specific contained constituents of a botanical, the constituent shall be quantified on the label by weight on a 'per serving' basis, in accordance with paragraph (b)(3)(iii) of this section.

The agency points out that the DSHEA specified that quantities in the nutrition label should be listed on a ''per serving'' basis (see section 403(q)(5)(F)(ii) of the act) and FDA implemented this basis for the listing of dietary ingredients in § 101.36. The agency inadvertently did not repeat in § 101.36(b)(3)(iii) that when the quantitative amounts by weight of constituents are listed, they should be reported on a ''per serving'' basis. The agency believes that revising § 101.36(b)(3)(iii) to add the words ''per serving'' is the most direct way of clarifying this issue and points out that this paragraph applies to constituents of all dietary ingredients described in § 101.36(b)(3)(i), not just to constituents of liquid ingredients. Therefore, rather than revising § 101.36(b)(3)(ii)(B) as requested, the agency is modifying § 101.36(b)(3)(iii) to require that the quantitative amount of constituents be declared on a ''per serving'' basis.

B. Dry Extracts

As requested in the AHPA, CRN/Amway, and Wakunaga petitions, FDA has reconsidered the provision on dried extracts in § 101.36(b)(3)(ii)(C). The AHPA petition requested that this provision be reconsidered, revoked, or revised to eliminate the requirement for identification of the solvent. The other petitions requested that FDA reconsider and stay the second sentence of this provision, then revoke it. The second sentence reads ''The dried extract shall be described by an appropriately descriptive term that identifies the solvent used, e.g., 'dried hexane extract of ————' or '————, dried hexane extract.' ''

The September 1997 final rule required that the solvent used to produce a dried extract be identified because the agency had concluded that the solvent used determines the composition of an extract (62 FR 49834). Reconsidering the comments to the December 1995 proposal (which were generally about liquid extracts but which the agency believes apply to dry extracts also), the agency concludes that, although the identity of the solvent contributes significantly to the composition of an extract, other factors also contribute to the composition of an extract. Because these other factors are not currently accounted for in an adequate way by any labeling or other requirements, the agency believes that, at the time of the September 1997 final rule, it was inappropriate to require the identification of the solvent used to produce a dry extract. Therefore, having reconsidered the administrative record of the September 1997 final rule in light of the arguments raised in the petitions for reconsideration, FDA is removing the second sentence in § 101.36(b)(3)(ii)(C) as requested by the petitions.

The agency believes that, given adequate compendial standards or good manufacturing practices, the factors relevant to the concentration and composition of dietary ingredients that are extracts may be accounted for so as to enable the agency, at some future date, to require further information about extracts in the labeling of dietary supplements.

IV. Economic Analysis

A. Benefit/Cost Analysis

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess the 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 effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is neither an economically significant nor a significant regulatory action as defined by Executive Order 12866.

In addition, FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring cost-benefit and other analyses. A significant rule is defined in section 1531(a) of UMRA as ''a 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 (adjusted annually for inflation) in any 1 year.''

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this final rule is not a major rule for the purpose of congressional review.

FDA is publishing these revisions in response to four petitions for reconsideration of the requirements for the labeling of extracts, which are effective March 23, 1999. FDA is making compliance easier by making the requirements for the labeling of extracts more flexible. These revisions will not result in any additional costs.

B. Small Entity Analysis

FDA has examined the impacts of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

These revisions will provide additional flexibility for complying with the requirements for the labeling of extracts. This rule will not cause any additional labels to be changed but will make it easier for small firms to comply with existing requirements by making those requirements more flexible. FDA further notes that small products from certain small firms are exempt from the requirements provided no claims are made.

V. Environmental Impact

The agency 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 environmental assessment nor an environmental impact statement is required.

VI. 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 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time required for reviewing instructions, searching existing data sources, gathering and maintaining any data needed, and completing and reviewing each collection of information.

Title: Requirements for Statement of Identity, Nutrition, and Ingredient Labeling of Dietary Supplements.

Description: This final rule revises the requirements for the declaration of information concerning extracts used in dietary supplements that were established by the September 1997 final rule. In response to four petitions for reconsideration of the September 1997 final rule, FDA is revising the regulations that establish labeling requirements for dietary supplements that contain extracts. This final rule revises the labeling requirements for dietary supplements that contain liquid extracts to allow: (1) The quantity of an extract to be listed on the basis of volume or weight, (2) solvents present to be listed in the ingredient statement or the nutrition label, and (3) the optional listing in the nutrition label of the ratio of starting material to the volume of solvent. FDA is also eliminating the requirement that a description of a dried extract include the name of the solvent used. This final rule does not revise any of the other information collection provisions in the September 1997 final rule, such as the requirements for nutrition labeling of dietary supplements.

As required by section 3506(c)(2)(B) of the PRA (44 U.S.C. 3506(c)(2)(B)), FDA provided an opportunity for public comment under the PRA when the proposed rule was published in December 1995. The information collection provisions of the September 1997 final rule were discussed in that final rule and submitted to OMB for its review and approval (62 FR 49826 at 49845). OMB subsequently approved the information collection provisions of the September 1997 final rule under OMB control number 0910–0351 (see 62 FR 66635, December 19, 1997).

The revisions in this final rule will reduce the information collection burden to producers of dietary supplements that contain extracts. FDA had previously estimated, and OMB had approved, the total annual hour burden for the information collection requirements of the September 1997 final rule at 136,040 hours. FDA now estimates that the total annual hour burden for the information collection requirements of the September 1997 final rule, as revised by this final rule, will be 134,890 hours.

Description of Respondents: Persons and businesses, including small businesses.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours	Total Operating and Maintenance Costs
101.36(b)(2) and (b)(3) (except paragraphs (b)(3)(ii)(B) and (b)(3)(ii)(C)) (disclosure)	850	40	34,000	3.9	132,600	$40,000,000
101.36(b)(3)(ii)(B) and (b)(3)(ii)(C) (disclosure)	250	30	7,500	0.3	2,250	
101.36(f)(2) (reporting)	20	1	20	2	40	
Totals					134,890	$40,000,000

FDA estimated in the September 1997 final rule that there were a maximum of 850 suppliers of dietary supplements and that each supplier had 40 products whose labels required revision. FDA also estimated that there were at least 250 of these firms that produce herbal or botanical products. These are the firms whose products are most likely to contain extracts as ingredients. Based on the agency's knowledge of the dietary supplement marketplace, FDA estimates that approximately 25 percent of these firms' products contain dry extracts. FDA estimates that with elimination of

the requirement for identifying the solvent used for dry extracts, no firms will provide information concerning the identity of the solvent. FDA estimates that firms will provide the ratio of the starting materials to the volume of the solvents used in the production of liquid extracts only when it is in their best interest and that this will occur no more than 10 percent of the time. The other revisions to the regulations should also help reduce the amount of time that a firm must spend to provide the required information. All of the information required by this final rule to be disclosed on the label of dietary supplements that contain liquid extracts is information that a firm would be expected to have in the normal course of its business of producing dietary supplements. Firms should know or have readily available to them information on the amount of the extract by volume or weight that is present in the dietary supplement and the identity of the solvent. The hour burden estimates in Table 1 of this document are for the information collection provisions established by regulation and do not include those that stem solely from the act or the DSHEA.

Although the statement of identity, nutrition, and ingredient labeling regulations for dietary supplements in § 101.36 were approved following publication of the September 1997 final rule (OMB control number 0910–0351), FDA has resubmitted them to OMB for approval of the revised requirements for label disclosure of extract ingredients in this final rule. Prior to the effective date of the regulations, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the revised requirements. 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.

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.

2. Section 101.36 is amended by revising paragraphs (b)(3)(ii)(B), (b)(3)(ii)(C), and (b)(3)(iii) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(B) For any dietary ingredient that is a liquid extract from which the solvent has not been removed, the quantity listed shall be the volume or weight of the total extract. Information on the condition of the starting material shall be indicated when it is fresh and may be indicated when it is dried. Information may be included on the concentration of the dietary ingredient and the solvent used, e.g., ''fresh dandelion root extract, x (y:z) in 70% ethanol,'' where x is the number of milliliters (mL) or mg of the entire extract, y is the weight of the starting material and z is the volume (mL) of solvent. Where the solvent has been partially removed (not to dryness), the final concentration, when indicated, shall be stated (e.g., if the original extract was 1:5 and 50 percent of the solvent was removed, then the final concentration shall be stated as 1:2.5). Where the name of the solvent used is not included in the nutrition label, it is required to be listed in the ingredient statement in accordance with § 101.4(g).

(C) For a dietary ingredient that is an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract.

(iii) The constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section may be listed indented under the dietary ingredient and followed by their quantitative amounts by weight per serving, except that dietary ingredients described in paragraph (b)(2) of this section shall be listed in accordance with that section. When the constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section are listed, all other dietary ingredients shall be declared in a column; however, the constituents themselves may be declared in a column or in a linear display.

* * * * *

Dated: May 29, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–14915 Filed 6–4–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 98N–0294]

Beverages: Bottled Water; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of May 11, 1998 (63 FR 25764). The document lifted the stay of the effective date for the allowable levels in the bottled water quality standard for nine chemical contaminants, i.e., antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8–TCDD (dioxin), that was imposed in a final rule published on March 26, 1996. The document was published with some errors under the **''DATES''** section. This document corrects those errors.

DATES: The regulation published at 63 FR 25764 is effective February 2, 1999. Submit written comments by July 27, 1998. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** no later than August 6, 1998, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule no later than August 6, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631.

SUPPLEMENTARY INFORMATION: FDA published a direct final rule in the **Federal Register** of May 11, 1998 (63 FR 25764), lifting the stay of the effective date for the allowable levels in the bottled water standard for nine chemical contaminants. As published, the dates section is incorrect.

In FR Doc. 98–12381, beginning on page 25764 in the **Federal Register** of Monday, May 11, 1998, the following correction is made:

1. On page 25764, beginning in the second column, the **''DATES''** section is