I. Introduction

In the Federal Register of January 6, 2000 (65 FR 1000), FDA published a final rule entitled “Regulations on Statements Made for Dietary Supplements Concerning the Effect on the Structure or Function of the Body” (hereinafter referred to as “the final rule”). In the final rule, FDA established regulations to define the types of statements that may be made without prior FDA review about the effects of dietary supplements on the structure or function of the body (structure/function claims), and to distinguish these claims from claims that a product treats, prevents, cures, diagnoses, or mitigates disease (disease claims).

In the preamble to the final rule, FDA stated that the final rule would become effective on February 7, 2000, approximately 30 days after publication. FDA also stated that any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, would be expected to be in compliance as of the effective date, February 7, 2000. However, small businesses that marketed a product as of January 6, 2000, the date of publication of the final rule, would have an additional 17 months (until July 7, 2001) to bring existing claims (i.e., claims already in the product’s labeling on January 6, 2000) for those products into compliance. For all other products that were on the market as of January 6, 2000, FDA allowed an additional 11 months beyond the effective date (until January 7, 2001) to bring existing claims for those products into compliance.

II. Petitions for Reconsideration and Stay of Action

FDA received one petition under § 10.35 (21 CFR 10.35) for stay of the 30-day effective date and one petition under 21 CFR 10.33 for stay and reconsideration of part of the implementation plan in the final rule. A petition for stay submitted jointly by the Council for Responsible Nutrition (CRN) and the Consumer Healthcare Products Association (CHPA) (Docket No. 99N–0044/PSA1) (Ref. 1) (hereinafter referred to as the “joint petition”) requested that FDA stay its 30-day effective date for “pipeline” products, i.e., products that were labeled, or for which labeling had been printed, but that had not yet been marketed when the final rule was published on January 6, 2000. The joint petition requested that such products be given the 11 or 17 months for compliance afforded to products that were being marketed as of the publication date of the final rule. The joint petition stated that in the nearly 2 years between publication of the proposed and final rules, dietary supplement manufacturers and distributors had relied on the criteria and examples of acceptable structure/function claims in the proposed rule to develop marketing strategies, manufacture products, and design and produce labeling. The petition stated that in many cases, this reliance had involved a significant investment of resources.

The joint petition further stated that the implementation of the final rule will involve, among other things, package redesign, redesign of websites and...
promotional literature, and sometimes, new packaging equipment. The joint petition argued that the short implementation period (30 days for products not yet marketed) would not provide a long enough transition period to enable “pipeline” products to be brought into compliance. Moreover, the joint petition asserted that giving such products the same transition compliance period as products that had actually been marketed by January 6, 2000, would provide a fair and reasonable implementation plan for firms that had invested energy and resources, in good faith, developing a new product with labeling bearing claims based on the proposed rule, but that narrowly missed marketing the product by January 6, 2000.

The petition for stay and reconsideration was submitted by the American Herbal Products Association (Docket No. 98N–0044/PRC4) (Ref. 2). The petition further stated that there is no basis to distinguish the implementation scheme for the final rule from that used to implement the dietary supplement nutrition labeling final regulations published in the Federal Register of September 23, 1997 (62 FR 49826 at 49842), which provided that any product labeled before the effective date did not have to be relabeled to comply after the effective date.

III. Response to Petitions

FDA has fully evaluated the two petitions for stay and reconsideration of the implementation plan in the final rule. FDA agrees that there may be manufacturers acting on the criteria and examples of acceptable structure/function claims in the proposed rule, produced labeling with claims that would have been considered structure/function claims under the proposed rule, but that are classified as disease claims under the final rule. We also agree that the 30-day effective date of the final rule may not have provided a long enough transition period to enable products close to being marketed when the final rule was published to be brought into compliance. Therefore, FDA is announcing a stay of compliance for a limited class of products. Products that were labeled no later than the publication date of the final rule, January 6, 2000, or for which labeling had been printed by that date (hereinafter referred to as “eligible products”) will be eligible for the stay.

To prevent the partial stay from becoming effectively a blanket stay of the 30-day effective date for all products, FDA is requiring that any firm wishing to take advantage of the stay notify FDA of that fact before it markets its eligible products. The notification must: (1) Include the name and complete address of the firm submitting it; (2) identify the eligible products; (3) provide documentation that the eligible products were in fact labeled no later than January 6, 2000, or that labeling for the products had been printed by that date; and (4) include a certification, signed by a responsible individual, that the products are eligible for the stay.

The eligible products must be described in all firms that notify FDA to identify them in the marketplace and distinguish them from other products (including other lots of the same product).

FDA believes that the notification requirement is necessary for effective enforcement of the final rule. Without the notification, the agency would be unable to verify whether individual products are eligible for the stay and therefore would not be able to determine which products in the marketplace bear violative claims and are subject to enforcement action.

Firms must send the required notification to: Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements and Division of Compliance and Enforcement (HFS–810), 200 C St. SW., Washington, DC 20204.

Notifications may be submitted at any time after the effective date of this final rule. It is to a manufacturers’ advantage to submit such notifications as soon as possible, as only products for which FDA has received a notification qualify for the partial stay of compliance.

Small businesses that have eligible products and that submit the required notification to FDA will have 17 months after the effective date of the final rule (until July 7, 2001) to bring their eligible products into compliance, and other firms will have 11 months after the effective date of the final rule (until January 7, 2001) to bring their eligible products into compliance. We believe that this action provides a fair and reasonable implementation plan for firms that made a substantial investment in products that narrowly missed being marketed by the publication date of the final rule.

We are not granting the request in the AHPA petition that FDA allow products labeled before the 11-month or 17-month compliance date to be shipped after that date. In the preamble to the final rule (65 FR 1000 at 1044), FDA concluded that the compliance periods of 11 and 17 months following the effective date of the final rule were reasonable and fair. The agency stated that these compliance periods, uniformly applied, are sufficiently long and that an extension of the time to comply is not needed. The purpose of the compliance period is to give firms time to develop new labels that comply with the requirements of the act and regulation and to ensure a level playing field for dietary supplements. We find no basis to permit some firms to continue to market
products with claims that violate the act and that may give them a competitive advantage over products marketed by firms that have made the investment in time and expense to meet the applicable compliance dates.

Moreover, granting AHPA’s request would create an incentive for manufacturers to perpetuate existing claims that are defined as disease claims under the final rule and, in fact, to label as many products as possible with such claims between now and the applicable compliance date. FDA believes that creating such an incentive would be unwise and that the agency should maintain the policy in the final rule, which was designed to encourage manufacturers to change their labeling in accordance with the final rule as quickly as possible, but no later than the applicable compliance date. Having a date by which all products must comply will reduce consumer confusion and greatly simplify enforcement, as after that date the agency will be able to take action against any product that bears unapproved disease claims, without also having to determine when the product was labeled.

We disagree that the basis for the effective date of the September 23, 1997, final rule implementing the nutrition labeling requirements for dietary supplements is relevant to the current rulemaking. In deciding to base the effective date of the September 23, 1997, final rule on the date of labeling, rather than the date of marketing, FDA relied on language in section 7 of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Section 7 of DSHEA states that dietary supplements “may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and shall be labeled after December 31, 1996, in accordance with such amendments.” The final rule implements section 6 of DSHEA, which does not contain the same language as section 7 and is not subject to section 7. Therefore, the fact that FDA allowed products labeled before the effective date of the September 23, 1997, final rule to be marketed after the effective date of that rule does not compel that the same approach be taken to implement the final rule. For the reasons discussed above, namely, to encourage prompt implementation of the rule and ensure a level playing field after the compliance date, the agency is not staying the compliance dates in the implementation plan for products labeled on or before the applicable compliance date. Consistent with the implementation plan in the final rule (65 FR 1000 at 1044), all products in interstate commerce that are subject to the final rule must be in compliance with the act and regulations by July 7, 2001 (for products marketed by small businesses), or January 7, 2001 (for other products).

Under § 10.35(a) and (d)(1), FDA may stay the effective date of a rule, or any other administrative action, upon a finding that the stay is in the public interest. FDA finds that this partial stay of compliance is in the public interest because it will allow a fair and reasonable transition compliance period for firms that made a substantial investment in dietary supplement products that were close to marketing when the final rule was published.

The Administrative Procedure Act and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B); 21 CFR 10.40(e)(1)). Because this final rule is a stay of compliance, FDA finds that there is good cause to dispense with notice and comment procedures. Notice and comment procedures are unnecessary because this final rule does not change the substantive requirements of the final rule, only the date on which compliance with those requirements is expected for a limited class of products. Further, notice and comment procedures are not in the public interest because the final rule has already become effective, and therefore a prompt response to the petitions for stay and reconsideration is important.

IV. Analysis of Impacts

The economic impact of the final rule was discussed in the Federal Register (65 FR 1000 at 1044 through 1049). A partial stay of compliance for the final rule will provide additional time for companies to relabel products and will reduce label obsolescence, as there will be additional time to use up more existing labeling. Although this rule granting a partial stay of compliance will impose some small administrative costs on those industry members that wish to take advantage of it, these costs are expected to be much smaller than the savings that will be realized from reduced inventory losses. Thus, this final rule granting a partial stay of compliance should reduce the economic impact on industry.

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. 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. This final rule provides a stay of compliance, which will allow manufacturers additional time to use up existing product labeling. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

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

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because this rule is not expected to result in expenditures that would exceed $100 million, adjusted for inflation, in any one year. The current inflation-adjusted statutory threshold is $110 million.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. 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.

With respect to the following collection of information, FDA invites
that the products were labeled before
of the preparation of the letter notifying
have products affected by the partial
rule (65 FR 1000 at 1046). Therefore,
because of the requirements in the final
would be required to change their labels
marketed with structure/function claims
supplement products currently being
percent of the 17,400 dietary
estimated that approximately 4.81
be covered by the final rule. FDA also
dietary supplement products that would
estimated that 1,000 firms manufacture
rule (65 FR 1000 at 1047), FDA
that are eligible for the stay. In the final
to issue regulations for the efficient
claim. Section 701(a) of the act (21
the effect of the product on a disease,
dietary supplements with claims about
commerce of products marketed as
(r)(6)), and 355(a) FDA is responsible
for preventing distribution in interstate
commerce as dietary supplements with claims about
the effect of the product on a disease,
unless the claim is an authorized health
claim. Section 701(a) of the act (21
U.S.C. 371(a)) gives FDA the authority
to issue regulations for the efficient
enforcement of the act. In the final rule
(65 FR 1000), FDA published a
regulation that defined the types of
statements that can be made concerning
the effect of a dietary supplement on the
structure or function of the body. In the
preamble to the final rule, the agency
stated that the final rule would become
effective on February 7, 2000,
approximately 30 days after the date of
the final rule's publication in the
Federal Register. The final rule further
provided that any product that is
marketed for the first time after
publication of the final rule, and any
new claims made for an existing
product for the first time after the
publication of the final rule, would have
to be in compliance as of the effective
date.
In response to two petitions asking
the agency to stay and/or reconsider the
30-day effective date for the final rule,
FDA is granting a partial stay of
compliance with the rule for those
dietary supplement products that were
labeled or for which labeling had been
printed on or before January 6, 2000,
the publication date of the final rule.
A manufacturer that wishes to market
products that are eligible for the stay
would have to notify FDA of the
identity of its eligible products; provide
documentation that the products were
labeled by January 6, 2000, or that
labeling for the products had been
printed by that date; and certify that the
products that are the subject of the
notification meet the eligibility criteria.
Information that is required in the
notification includes: (1) The name and
complete address of the firm submitting
the notification; (2) a description of the
products that are the subject of the
notification. The description must be
sufficient to enable FDA to identify the
firm's qualifying products in the
marketplace and distinguish them from
other products (including other lots of
the same product) that are not eligible
for the stay. For example, the
description might consist of the name of
the product and a unique identifier code
(such as a product identification or lot
code that the manufacturer uses to track
its products); (3) documentation that the
products were labeled by January 6,
2000, or that the labeling for the
products had been printed by that date
(for example, purchase records from a
label manufacturer or production
records that showed that the products
had been labeled by January 6, 2000); and
(4) a certification, signed by a
responsible individual, that the
products are eligible for the stay.
FDA estimates the burden of this
collection of information as follows:

<table>
<thead>
<tr>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
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<tr>
<td>48</td>
<td>1</td>
<td>48</td>
<td>2</td>
<td>96</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the
number of firms that may have products
that are eligible for the stay. In the final
rule (65 FR 1000 at 1047), FDA
estimated that 1,000 firms manufacture
dietary supplement products that would
be covered by the final rule. FDA also
estimated that approximately 4.81
percent of the 17,400 dietary
supplement products currently being
marketed with structure/function claims
would be required to change their labels
because of the requirements in the final
rule (65 FR 1000 at 1046). Therefore,
assuming that products affected by the
final rule are uniformly distributed
throughout the industry, approximately
48 firms (4.8 percent of 1,000 firms) may
have products affected by the partial
stay of compliance.

The notification burden would consist of
the preparation of the letter notifying
FDA and accompanying documentation
that the products were labeled before
January 6, 2000, or that the labeling had
been printed by that date. FDA believes
this burden will be small since firms
already have the information needed to
describe their own products with
specificity. With respect to the
supporting documentation, the firm
would already have identified the
relevant documents as part of
ascertaining which products are eligible
for the stay. Therefore, the firm would
only need to reproduce the relevant
documents to accompany the
notification. The notification is a
one-time action, and all of a firm's eligible
products can be listed in a single
notification. Therefore, FDA anticipates
receiving only one notification per firm.
The information collection provisions
of this final rule have been submitted to
OMB for review. Interested persons may
send comments regarding information
collection by October 10, 2000, to the
Office of Information and Regulatory
Affairs, OMB, New Executive Office
Bldg., 725 17th St. NW., rm. 10235,
Washington, DC 20503, Attn: Desk
Officer for FDA.

FDA has requested expedited
processing of this information collection
request under section 3507(j) of the PRA
and 5 CFR 1320.13. The information to
be collected under this final rule is
needed before clearance could be
obtained under the normal PRA
clearance time periods. Further, the use
of normal PRA clearance procedures is
impracticable and would be likely to
prevent or disrupt the collection of
information because the compliance
periods during which products that
qualify for the partial stay may be
marketed without relabeling would have
ended or would be close to ending.
Prior to the effective date of this final
rule, FDA will publish a notice in the
Federal Register announcing OMB's
decision to approve, modify, or
disapprove the information collection provisions in this final rule. 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.

VI. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the final rule by October 30, 2000, except that comments regarding information collection are to be submitted to OMB (address above) by October 10, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.


William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24960 Filed 9–28–00; 8:45 am]
BILLING CODE 4160–01–F

39 CFR Part 20

Global Express Guaranteed

AGENCY: Postal Service.

ACTION: Amendment to interim rule.

SUMMARY: The Postal Service is amending the interim rule on Priority Mail Global Guaranteed service to establish it as a permanent international mail service, to announce a name change, and to expand the service to include a new classification for non-document (merchandise) shipments. This interim rule will also extend the optional insurance coverage to non-documents and establish and publish rates for the non-document service. This interim rule corrects and amends the interim rule published on August 28, 2000, 65 FR 52023–52028. EFFECTIVE DATE: October 1, 2000. Comments on the amendment to the interim rule must be received on or before October 30, 2000.

ADDRESSES: Written comments should be mailed or delivered to Business

Initiatives, Expedited/Package Services, U.S. Postal Service, 200 E Mansell Court, Suite 300, Roswell GA 30076–4850. Copies of all written comments will be available for public inspection between 9 a.m. and 4 p.m., Monday through Friday, in Business Initiatives, 200 E Mansell Court, Suite 300, Roswell GA.

FOR FURTHER INFORMATION CONTACT: Malcolm E. Hunt, (770) 360–1104.

SUPPLEMENTARY INFORMATION: On April 19, 1999, the Postal Service announced in the Federal Register (64 FR 19039–19042) the introduction of Priority Mail Guaranteed (PMGG) service on an interim basis. With PMGG, the USPS provided customers with a fully featured premium international service for documents with full track and trace capability. This service was initially available from 3,000 retail locations for delivery to a total of 19 countries.

On November 4, 1999, the Postal Service announced in the Federal Register (64 FR 60106–60109) the expansion of PMGG service to permit acceptance at a total of 10,000 retail locations, with destinatining locations being expanded to 65 countries and territories.

On May 26, 2000, the Postal Service announced in the Federal Register (65 FR 34096–34101) the further expansion of PMGG service to a total of 202 destinatining countries and territories. A revised rate structure was also introduced.

On August 28, 2000, the Postal Service announced in the Federal Register (65 FR 52023–52028) a further expansion of PMGG service. The number of retail locations was increased to a total of 20,000, document service rates were adjusted, optional document reconstruction insurance was increased to $2,499, and delivery service was extended to China. An incorrect listing of 3-digit ZIP Codes was included in the list of participating post offices in this rule. The correct list of participating post offices by 3-digit ZIP Code is available from 3,000 retail locations for document service.

Based on the successive and successful expansion of PMGG service, the Postal Service has determined to establish it as a permanent international mail service. To effectuate this change, the Postal Service is changing the name of the service to Global Express Guaranteed (GXG) and completing the expansion to include a new classification for merchandise shipments. GXG will now consist of two classifications for merchandise mail: a. GXG Document service; and b. GXG Non-Docu