II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: October 28, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–24872 Filed 11–4–04; 8:57 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0562]

Revised Compliance Policy Guide Sec. 110.300—Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised compliance policy guide (CPG) Sec. 110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (registration CPG). The revised CPG provides written guidance to FDA's staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which requires, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

DATES: This revised CPG is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the revised CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revised CPG may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised CPG.

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

FOR FURTHER INFORMATION CONTACT:

Food for human consumption: Judith Gushee, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 301–436–2417.

Food for animal consumption: Isabel Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 301–827–0175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of revised CPG Sec. 110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (registration CPG). This revised CPG outlines for FDA staff the agency's policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation ((68 FR 58894, October 10, 2003); (codified at 21 CFR part 1, subpart H, 1.225 through 1.243)). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must be registered with FDA.

I. Background

On December 19, 2003, FDA issued CPG Sec. 110.300 (the December CPG). The December CPG states that for domestic firms, FDA would initially plan to focus the agency's efforts on educating and otherwise informing the industry on how to comply with the registration of food facilities interim final rule, and that thereafter FDA would enforce the registration provision as appropriate in each situation. We set out in the Regulatory Action Guidance section our enforcement approach.

For foreign facilities, the December CPG referred to the policies set out in CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (the prior notice CPG).

II. Revised CPG Sec. 110.300

FDA is making only one substantive change in the registration CPG. Specifically, the revised CPG provides that, on November 8, 2004, FDA is fully implementing the agency's enforcement policy for domestic food facilities, which was set out in the Regulatory Action Guidance section of the December CPG. For foreign facilities, the registration CPG continues to state that generally, the registration requirement for the facilities of foreign manufacturers and shippers will be enforced in accordance with the policies set out in the prior notice CPG. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for the revision to the prior notice CPG, which is being issued under § 10.115(g)(2) (21 CFR 10.115(g)(2)) as level 1 guidance that is effective November 8, 2004.

FDA is also issuing the revised registration CPG as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115). Revised CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because FDA has determined that prior public participation is not feasible or appropriate. Revision of FDA's prior notice enforcement policy directly affects the agency's enforcement of the registration requirement for foreign manufacturers and shippers. Given this relationship, it is appropriate that FDA coordinate announcement and implementation of the agency's revised enforcement policy for food facilities registration with the agency's comparable actions for the prior notice of imported food requirement.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: November 2, 2004.

Steve M. Niedelman,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–24873 Filed 11–4–04; 8:57 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0466]

Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance describes the amount, type, and quality of evidence that FDA recommends a manufacturer have to substantiate a claim under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (act). FDA is also announcing its decision not to publish additional guidance on applying the structure/function rule at this time.

DATES: Submit written or electronic comments on the draft guidance and the collection of information provisions by January 10, 2005, to ensure adequate consideration in preparation of any final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance document and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Vickey Lutwak, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375, fax: 301–436–2636, e-mail: *Vickey.Lutwak@cfsan.fda.gov*

SUPPLEMENTARY INFORMATION:

I. Background—Substantiation Draft Guidance

Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading.[1]

This draft guidance document is intended to describe the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403(r)(6) of the act. This draft guidance document is limited to issues pertaining to substantiation under section 403(r)(6) of the act; it does not extend to substantiation issues that may exist in other sections of the act.

FDA intends to apply a standard for substantiating claims for dietary supplements that is consistent with the Federal Trade Commission's (FTC's) standard for dietary supplements and other health related products of ''competent and reliable scientific evidence.'' FDA seeks comments on this draft guidance only as they relate to FDA's use and application of the standard and approach that are described in the guidance. We (FDA) are not seeking comment on FTC's application, use, or interpretation of their standard.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance document is being issued as a Level 1 guidance consistent with FDA's GGPs. The draft guidance document represents the agency's current thinking on the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403(r)(6) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of the applicable statutes and regulations.

[1] Under section 403(r)(6)(A) of the act (21 U.S.C. 343(r)(6)(A)), such a statement is one that ''claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient.''

II. Paperwork Reduction Act of 1995—Substantiation Draft Guidance

This draft guidance document 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). Under the PRA, Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is hereby publishing notice of the proposed collection of information set forth in this document.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act; Availability

Section 403(r)(6) of the act requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the statement is truthful and not misleading. This draft guidance document is intended to describe the amount, type, and quality of evidence FDA recommends a dietary supplement manufacturer have to