submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information 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). The collections of information in 21 CFR part 807 subpart E have been approved under OMB Control Number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB Control Number 0910–0231; the collections of information in 21 CFR part 801 and 809 have been approved under OMB Control Number 0910–0485; the collections of information in 21 CFR 820 have been approved under OMB Control Number 0910–0073; and the collections of information in 21 CFR part 601 have been approved under OMB Control Number 0910–0338.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–31319 Filed 1–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0437] (formerly Docket No. 2004D–0549)

Guidance for Industry on Labeling Over-the-Counter Human Drug Products—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products in complying with the agency's regulation on standardized content and format requirements for the labeling of OTC drug products. This guidance primarily discusses labeling questions that have been frequently asked by manufacturers, packers, and distributors relating to these requirements. The labeling examples in this guidance show various format and content features and suggest how OTC drug monograph labeling information finalized before the new requirements can be converted to the new format. This guidance finalizes the draft guidance of the same name published January 13, 2005 (70 FR 2415).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5496, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This is one of several guidances the agency has developed to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (§ 201.66 (21 CFR 201.66)). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format requires revision of all prior labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug application, abbreviated new drug application, or OTC drug monograph (or drug product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquiries from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. To address these inquiries, FDA published a notice in the **Federal Register** of January 13, 2005 (70 FR 2415), announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' That draft guidance summarized the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance discussed those industry inquiries and

provided labeling examples to show various format and content features of the labeling requirements, and suggested how OTC drug monograph labeling finalized before the new regulation was issued can be converted to the new format. The draft guidance also described how to list inactive ingredients that may or may not be contained in the OTC drug product.

The notice invited interested persons to submit comments on the draft guidance by March 14, 2005. FDA did not receive any comments in response to the notice. Therefore, we are announcing the availability of this final guidance with only editorial changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on how OTC drug monograph labeling finalized before or after the new requirements can be converted to the new OTC Drug Facts labeling format. 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 approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–31321 Filed 1–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0303] (formerly Docket No. 2004D–0466)

''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 guidance entitled ''Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.'' The guidance describes the amount, type, and quality of evidence that FDA recommends a manufacturer have to substantiate a claim under this section of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on the guidance 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 guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Nutrition, 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. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1441.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 9, 2004 (69 FR 64962), FDA made available 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'' and gave interested parties an opportunity to submit comments by January 10, 2005. FDA considered received comments as it finalized this guidance.

This guidance describes the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403(r)(6) of the act (21 U.S.C. 343(r)(6)). This final guidance document is limited to issues pertaining to substantiation under section 403(r) of the act; it does not extend to substantiation issues that may exist in other sections of the act.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents FDA's current thinking on the substantiation for dietary supplement claims made 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 approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance 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). The collection of information in the guidance was approved under OMB Control No. 0910–0626.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket