including policies involving food derived from biotechnology.

Advises Center officials on regulatory approaches and manages the development of periodic plans for the Center's regulation development activities.

Develops legislative proposals related to food and cosmetic safety and defense; coordinates the Center's review of bills and proposed legislation, upon request; and coordinates the Center's technical assistance to Congressional or FDA Office of Legislation staff developing bills related to food and cosmetics, upon request.

Manages the Center's compliance with the Information Quality Act, including responses to request for correction and reconsideration submitted under the Act.

Advises Center staff concerning the administrative procedures for rulemaking, guidelines, guidance documents, and other policy documents, hearings and delegations of authority.

Leads the Center's evaluation of existing regulations to determine whether they are efficiently or effectively accomplishing their intended purpose.

Provides Center-level leadership and coordination regarding briefings with other parts of the Agency or Federal Government with clearance responsibility regarding CFSAN regulations and guidance documents, and other CFSAN documents subject to the Paperwork Reduction Act, in coordination with the Executive Operations Staff.

Directs and manages Center programs involving the use of external scientific advisors, consultants, and committees.

Counsels and coordinates with Center managers on the use of external scientific experts and resources.

N. OFFICE OF NUTRITION, LABELING, AND DIETARY SUPPLEMENTS (DHK). The Office of Nutrition, Labeling, and Dietary Supplements (ONLDS):

Primary responsibility for policy development and management of food and nutrition labeling, food standards, conventional foods, dietary supplements, and special nutritional (including infant formula and medical foods) food.

Provides expert advice to the Center Director, other Deputy Directors, and other senior managers, and directs major Agency and Department nutrition and labeling initiatives and is the Delegate to national and international forums and conferences.

Primary responsibility for policy and regulatory development and management of the food labeling program, including Nutrition Labeling and Education Act, Food Allergen Labeling and Consumer Protection Act and other Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act labeling requirements.

Provides scientific and technical review of and response to petitions and notifications related to all aspects of conventional food labeling. With the Office of Compliance, determines compliance with existing food standards and common or usual name regulations and issues temporary marketing permits to allow manufacturers to test market new foods. In addition, conducts scientific and technical review of enforcement and compliance materials including inspection reports, analytical reports and other pertinent records, and provides policy decisions on misbranding charges for all domestic and import actions, including infant formula and medical food manufacturers.

Provides expert guidance for other Agency units and Federal and State officials and industry concerning regulatory requirements and compliance policies on food labeling (including infant formula and medical foods) and reviews proposed enforcement/compliance actions referred by other agency units.

Provides expert technical advice for participation in international forums.

Reviews food product labeling (including infant formula, medical foods and nutrition labels) for adherence to regulations and appropriateness of claims and manages the Small Business Nutrition Labeling Exemption Notification Program.

Provides scientific review and analysis of policies, regulations, research priorities, position papers, and advisory opinions on issues related to nutrition and nutrition labeling, and dietary guidance recommendations, and related nutrition science issues.

Responsible for scientific and regulatory review of health claim petitions, qualified health claim petitions, nutrient content claim petitions, and FDA Modernization Act notifications for health claims and nutrient content claims.

Provides expert advice and assistance to key officials and coordinates with other domestic and international scientific bodies on efforts related to nutrition and health.

Identifies program priorities for, provides content design input to, and analysis of large-scale databases of food consumption, food composition, food ingredients, sales of processed packaged food products and product label information. Develops methods for monitoring US populations and special subgroups relative to use and safety of conventional foods and dietary supplements.

Provides management and scientific review on issues related to infant formula, medical foods, and dietary supplements including petitions and notifications, and provides advice to key Agency components as well as international bodies.

Responsible for the development of regulations, guidance, policy, programs, position papers and advisory opinions, and recommends research priorities for the management of the dietary supplement program, which includes safety assessments for the New Dietary Ingredient Notification Program, structure-function notifications, Certificates of Export, safety assessment for dietary supplement policy, responses to petitions and industry-related notifications, post-market adverse event evaluations, and issues related to dietary supplement safety and nutrition.

III. Delegations of Authority. Pending further delegation, directives, or orders by the Commissioner of the Food and Drugs, all delegations or re-delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: December 20, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–6257 Filed 12–31–07; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0492]

Guidance for Industry and Food and Drug Administration; Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements.'' The purpose of this guidance document is to recommend an

interactive premarket review process for these submissions that is designed to expedite FDA's review of device applications while continuing to assure device safety and effectiveness, in accordance with the goals of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidelines are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Samie Allen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013.

SUPPLEMENTARY INFORMATION:

I. Background

In the letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate setting out the goals of the Medical Device User Fee Amendments of 2007 (MDUFA) (see section 201(c) of FDAAA), dated September 27, 2007, FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. While FDA committed to developing an interactive review process only for premarket notification submissions (510(k)s), premarket approval applications (PMAs), and PMA supplements, the agency believes that medical device Biologic License Applications (BLAs) could also benefit from such a process. Therefore, the guidance document also applies to medical device BLAs and BLA supplements.

The goal of the interactive review process is to improve the timeliness of the review process for 510(k)s, PMAs, PMA supplements, BLAs and BLA supplements. FDA expects that the interactive review process will result in prompter approvals and clearances of medical devices and thereby improve the public health. FDA intends to reassess the interactive review process on a regular basis to determine whether it is meeting its intended objectives. When necessary, changes will be implemented to improve the efficiency of this process.

FDA is making this guidance document immediately in effect because prior public participation was not feasible or appropriate. In the letter described in section 201(c) of FDAAA that sets out the goals of MDUFA, FDA committed to developing, within 3 months of the date of FDAAA's enactment, a guidance document that describes an interactive review process. The interactive review process supports a less burdensome approach to the premarket review process that is consistent with public health.

II. Significance of Guidance

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 the interactive review process for premarket medical device submissions. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1655 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions [including lists of approved applications and manufacturers' addresses], small manufacturer's assistance, information on video conferencing and electronic 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 Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 PRA). 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, subpart B, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 601, subpart A, 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 in January 2008, the FDA website is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–6268 Filed 12–27–07; 3:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D– 0496]

Draft Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection 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 ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' This draft guidance is intended to assist industry in complying with the labeling requirements for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application established by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on labeling requirements for dietary supplements, is announced elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by March 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, addressStreet5630 Fishers Lane, rm. 1061, placeCityRockville, StateMD PostalCode20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5488, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The draft guidance document contains questions and answers relating to the new labeling requirements under Public Law 109–462 for OTC drugs marketed without an approved application.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 requirement 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 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 in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (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(c) 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 publishing notice of the proposed collection of information set forth as follows.

With respect to the following collection of information, FDA invites comment on the following: (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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act for Nonprescription Drug Products Marketed Without an Approved Application.