

exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DIDREX (benzphetamine HCl) Tablets, 25 mg, are the subject of approved NDA 12-427 held by Pharmacia and Upjohn Co., a subsidiary of Pfizer Inc. Benzphetamine HCl 25-mg tablets are indicated in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction. NDA 12-427 was initially approved in 1960. In 1973, under the Drug Efficacy Study Implementation, FDA concluded that benzphetamine HCl 25-mg tablets are effective for the indications described in the **Federal Register** document published on February 12, 1973 (38 FR 4280). Pfizer Inc. ceased manufacturing DIDREX (benzphetamine HCl) Tablets, 25 mg, prior to September 1992. FDA received a citizen petition from Lachman Consultant Services, Inc., dated January 2, 2008, submitted under 21 CFR 10.30. The petition requests that the agency determine whether DIDREX (benzphetamine HCl) Tablets, 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and under § 314.161, has determined that DIDREX (benzphetamine HCl) Tablets, 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DIDREX (benzphetamine HCl) Tablets, 25 mg were withdrawn from sale as a result of safety or effectiveness concerns. FDA’s independent evaluation of relevant information has uncovered no information that would indicate this product was withdrawn for reasons of safety or effectiveness. In addition, DIDREX (benzphetamine HCl) Tablets currently are being marketed in a 50-mg scored tablet. The lower, 25-mg strength of DIDREX (benzphetamine HCl) Tablets is within the effective dosing range (25 to 50 mg, 1 to 3 times daily) and currently can be obtained by breaking in half the scored 50-mg strength tablet.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously, DIDREX (benzphetamine HCl) Tablets, 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DIDREX (benzphetamine HCl) Tablets, 25 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DIDREX (benzphetamine HCl) Tablets, 25 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that the labeling of this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: March 22, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010-6593 Filed 3-24-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0260]

Guidance for Industry on Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled “Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007.” The document provides guidance to the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA), and more specifically, this guidance provides information to the industry on submitting a single reportable food report to FDA covering reportable food located at more than one of a company’s facilities.

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 Food Defense, Communication and Emergency Response (HFS-005), 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.

FOR FURTHER INFORMATION CONTACT: Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85). This law amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry. Section 417 of the act requires the Secretary of Health and Human Services (the Secretary) to establish within FDA a Reportable Food Registry. The congressionally-identified purpose of the Reportable Food Registry is to provide a “reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health” (Section 1005(a)(4) of FDAAA). The Secretary has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the act, including section 417. To further the development of the Reportable Food Registry, section 417 of the act requires FDA to establish an electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. After receipt of reports through the electronic portal, FDA is required to review and assess the information submitted for purposes of identifying reportable food, submitting entries to the Reportable Food Registry, issuing an alert or notification as FDA deems necessary, and exercising other existing food safety authorities under FDAAA to protect the public health. The requirements under the Reportable Food Registry became effective on September 8, 2009.

In the **Federal Register** of June 11, 2009 (74 FR 27803), FDA announced the availability of a draft guidance entitled “Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007” and gave interested parties an opportunity to submit comments by July 27, 2009. The agency reviewed and evaluated these comments and issued a final guidance on September 8, 2009. This document is a related final guidance entitled “Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007” and contains a question and answer addressing the circumstance where reportable food is located at more than one of a company’s facilities.

FDA is issuing this guidance as level 1 guidance. Consistent with FDA’s good guidance practices regulation (§ 10.115 (21 CFR 10.115)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the requirements under the Reportable Food Registry became effective on September 8, 2009. Clarifying the Reportable Food Registry requirements will facilitate compliance and implementation, and will lessen the burden on industry and FDA caused by unnecessary submission of multiple reports when one reportable food situation affects more than one of a company’s facilities. The guidance represents 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 alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in the act. 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 related to submitting reportable food reports to FDA in section 417 of the act have been approved under OMB Control No. 0910–0645.

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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>.

Dated: March 19, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6578 Filed 3–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

Date and Time: April 22, 2010, 8 a.m.–4:30 p.m. EST.

Place: DoubleTree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will work on its ninth report about ways to encourage students into careers in the primary care health professions. Reports are submitted to the Secretary of the Department of Health and Human Services and to Congress.

Agenda: The meeting on Thursday, April 22 will begin with opening comments from the Health Resources and Services Administration, Bureau of Health Professions, Division of Medicine and Dentistry. In the plenary session, the Advisory Committee will continue its work on key report elements and final recommendations for the ninth report on the primary care pipeline. The Advisory Committee will determine next steps in the report preparation process and plan for the next Advisory Committee meeting. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., PhD, Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6190. The Web address for information on the Advisory Committee is <http://bhpr.hrsa.gov/medicine-dentistry/actpcmd>.

Supplementary Information: Requests to make oral comments or to provide written