and facilitating information exchange among professionals and concerned citizens. A number of vehicles are employed to accomplish these activities, including, but not limited to, Web site hosting, discussions with customers (*e.g.,* phone, live chat, *etc.*), and dissemination of publications (both print and electronic).

The Customer Satisfaction Evaluation was initiated in response to Executive Order 12862 issued on September 11, 1993. The Order calls for putting customers first and striving for a customer-driven government that matches or exceeds the best service available in the private sector. To that end, Information Gateway's evaluation is designed to better understand the kind and quality of services customers want, as well as customers' level of satisfaction with existing services. The proposed data collection activities for the evaluation include customer satisfaction surveys, customer comment cards, selected publication surveys, and focus groups.

Respondents: Child Welfare Information Gateway customers.

ANNUAL BURDEN ESTIMATES

Instrument	Affected public	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Customer Satisfaction Survey (Web site, E-mail, Print, Live Chat, and Phone).	Individuals/Households	1000	1	0.078	78.00
	Private Sector	216	1	0.078	16.84
	State, Local, or Tribal Governments	221	1	0.078	17.24
Publication Survey	Individuals/ Households	88	1	0.052	4.58
	Private Sector	17	1	0.052	0.88
	State, Local, or Tribal Governments	14	1	0.052	0.73
Comment Card (General Web and Conference versions).	Individuals/Households	300	1	0.014	4.20
	Private Sector	41	1	0.014	0.57
	State, Local, or Tribal Governments	67	1	0.014	0.94
Web site Tools Comment Card	Individuals/Households	229	1	0.014	3.21
	Private Sector	30	1	0.014	0.42
	State, Local, or Tribal Governments	28	1	0.014	.39
General Focus Group Guide	Private Sector	12	1	1.0	12.00
	State, Local, or Tribal Governments	12	1	1.0	12.00
	Private Sector	12	1	1.0	12.00
User Input Focus Group Guide	State, Local, or Tribal Governments	12	1	1.0	12.00
User Needs Assessment Focus Guide.	Private Sector	12	1	1.0	12.00
	State, Local, or Tribal Governments				
	State, Local, or Tribal Governments	12	1	1.0	12.00
Total Estimated Annual Burden Hours.					200.00

In compliance with the requirements of Section 3506 (2) (A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 18, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–6469 Filed 3–24–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0215] (formerly Docket No. 2008P–0006)

Determination That DIDREX (Benzphetamine Hydrochloride) Tablets, 25 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DIDREX (benzphetamine hydrochloride (HCl)) Tablets, 25 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for benzphetamine HCl 25 mg tablets, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christine Bina, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6220, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain

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: