Dated: November 1, 2010.

Christy Thomsen,

Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. 2010–28290 Filed 11–9–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Strengthening Communities Fund (SCF) Evaluation.

OMB No.: New Collection.

Description: This proposed information collection activity is to obtain information from participants in two Strengthening Communities Fund (SCF) programs: The Nonprofit Capacity Building Program and the State, Local, and Tribal Government Capacity Building Program. Both programs are designed to contribute to the economic recovery as authorized in the American Recovery and Reinvestment Act of 2009 (ARRA). The SCF evaluation is an important opportunity to examine outcomes achieved by the Strengthening Communities Fund and progress toward the objective of improving the capacity of organizations served by program grantees to address broad economic recovery issues in their communities.

The evaluation will be designed to assess progress and measure increased organizational capacity of each participating organization. The purpose of this request is to receive approval of the data collection instruments that will be used in this study.

A significant amount of information is already being collected through program-specific OMB-approved PPR forms or is available through secondary sources. Proposed surveys and phone interviews are very brief to reduce the burden on respondents.

Respondents: SCF grantees,and faith-based and Community Organizations (FBCOs).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
An on-line survey of SCF grantees	84	1	0.25	21
Telephone interview of SCF grantees	84	1	1.50	126
On-line survey of faith-based and community organizations (FBCOs) that received capacity building services from the SCF grantees	1,000	1	0.50	500

Estimated Total Annual Burden Hours: 647

In compliance with the requirements of Section 506(c)(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: November 4, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–28304 Filed 11–9–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0273]

Determination That Amphetamine Sulfate, 5 and 10 Milligram Tablets, Was 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 Amphetamine sulfate, 5 and 10 milligram (mg) tablets, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Amphetamine sulfate, 5 mg and 10 mg tablets, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 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 known generally as the "Orange Book." Under FDA regulations, drugs are removed 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.

Amphetamine sulfate, 5 mg and 10 mg tablets, is the subject of ANDA 083901 held by Lannett Company Inc. (Lannett). Amphetamine sulfate is a sympathomimetic amine indicated for treatment of narcolepsy, attention deficit disorder with hyperactivity, and exogenous obesity, as described in the labeling.

In a letter dated April 4, 1994, Lannett notified FDA that Amphetamine sulfate, 5 mg and 10 mg tablets, had been discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services submitted a citizen petition dated June 12, 2009 (Docket No. FDA–2009–P–0273), under 21 CFR 10.30, requesting that the Agency determine whether Amphetamine sulfate, 5 mg and 10 mg tablets, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that Amphetamine sulfate, 5 mg and 10 mg tablets, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Amphetamine sulfate, 5 mg and 10 mg tablets, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Amphetamine sulfate, 5 mg and 10 mg tablets, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Amphetamine sulfate, 5 mg and 10 mg tablets, 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 Amphetamine sulfate, 5 mg and 10 mg tablets, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28358 Filed 11–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0514]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tissue Adhesive With Adjunct Wound Closure Device Intended for the Topical Approximation of Skin; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin." This guidance document describes a means by which tissue adhesives with adjunct wound closure devices intended for the topical approximation of skin may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify tissue adhesive with adjunct wound closure device intended for the topical approximation of skin into class II (special controls). This guidance document is immediately in effect as the special control for tissue adhesive with adjunct wound closure device intended for approximation of skin, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

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

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: George J. Mattamal, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1434, Silver Spring, MD 20993–0002, 301–796–6396.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying tissue adhesive with adjunct wound closure device intended for the topical approximation of skin into class II (special controls), under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the tissue adhesive with adjunct wound closure device intended for the topical approximation of skin device. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III