

the order. In addition, the order enables the Commission to seek civil penalties against Respondent for non-compliance with the order.

The proposed Consent Agreement further requires McCormick to maintain the viability of the assets identified for divestiture. Among other requirements related to maintaining operations of the assets, the proposed Consent Agreement requires McCormick to: (1) maintain the viability, competitiveness, and marketability of the assets to be divested; (2) not cause the wasting or deterioration of the assets to be divested; (3) not sell, transfer, encumber, or otherwise impair the assets' marketability or viability; (4) maintain the assets consistent with past practices; (5) use best efforts to preserve the assets' existing relationships with suppliers, customers, and employees; and (6) keep and maintain the assets at inventory levels consistent with past practices.

The proposed Consent Agreement prohibits McCormick, for ten (10) years, from acquiring, without providing the Commission with prior notice, any other seasoned salt product, or any interest in any other spice blends business. The provisions regarding prior notice are consistent with prior Orders. The proposed Consent Agreement does not restrict McCormick from expanding its line of spices.

McCormick is required to file compliance reports with the Commission, the first of which is due within thirty (30) days of the date on which Respondent signed the proposed Consent Agreement, and every thirty (30) days thereafter until the divestitures are completed, and annually for ten (10) years.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order and the Order to Maintain Assets, or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary of the Commission.

[FR Doc. E8-17868 Filed 8-4-08; 8:45 am]

[BILLING CODE 6750-01-S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Impact of Cultural and Socioeconomic Factors on Post-Treatment Surveillance Among African Americans With Colorectal Cancer, Potential Extramural Project 2008-R-03

Notice of Cancellation: This notice was published in the **Federal Register** on July 22, 2008, Volume 73, Number 141, page 42576. The meeting previously scheduled to convene on August 6, 2008 has been cancelled.

Contact Person for More Information: Linda Shelton, Program Specialist, Coordinating Center for Health and Information Service, Office of the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E21, Atlanta, GA 30333, Telephone (404) 498-1194.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 28, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8-17913 Filed 8-4-08; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request Proposed Projects

Title: Compassion Capital Fund Impact Evaluation.

OMB No.: 0970-0293.

Description: This proposed information collection activity is an extension of the follow-up survey of faith-based and community organizations participating in the Compassion Capital Fund (CCF) Impact Evaluation. The currently approved information collection will expire on December 31, 2008. This information collection request will include the agency's request for an extension of the initial survey instruments for an additional three years.

The CCF evaluation is an important opportunity to examine the effectiveness of the Compassion Capital Fund Demonstration program in meeting its objective of improving the capacity of faith-based and community organizations. The evaluation includes selected CCF-funded intermediary organizations that provide capacity-building services and the faith-based and community organizations that sought those services. The follow-up survey will be used to collect information from the faith-based and community based organizations on various areas of organizational capacity.

The study design includes the random assignment of faith based and community organizations to either a treatment group that receives capacity-building services from a CCF intermediary grantee or to a control group that does not. The impact of the services provided by intermediaries, primarily through sub-awards and/or technical assistance (TA), will be determined by comparing the changes reported through the survey in organizational and service capacity of the recipient organizations with those of the control group.

Respondents: Faith-based and community organizations included in the CCF impact evaluation.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Follow-up Survey	455	1	.42	191
Estimated Total Annual Burden Hours:	191

In compliance with the requirements of section 3506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. *E-mail address:* OPREinfocollection@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: July 29, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8-17721 Filed 8-4-08; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0391]

Draft Guidance for Industry on Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Submission of Documentation in Applications for Parametric Release of Human and

Veterinary Drug Products Terminally Sterilized by Moist Heat Processes." This draft guidance provides recommendations to applicants on information to include in support of parametric release for sterile products terminally sterilized by moist heat when submitting a new drug application (NDA), abbreviated new drug application (ANDA), new animal drug application (NADA), abbreviated new animal drug application (ANADA), or biologics license application (BLA).

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 comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 6, 2008.

ADDRESSES: Submit written requests for single copies of the draft 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; the Communications Staff (HFV-12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855; the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Marla Stevens-Riley, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9310;

Deborah Trout, Center for Biologics Evaluation and Research (HFM-675), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20892, 301-827-3031; or

Mai Huynh, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish

Pl., Rockville, MD 20855, 240-276-8273.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes." The draft guidance addresses the information that should be submitted in an approved new drug application (NDA), abbreviated new drug application (ANDA), new animal drug application (NADA), abbreviated new animal drug application (ANADA), or biologics license application (BLA) in support of parametric release for sterile products terminally sterilized by moist heat.

"Parametric release" is defined as a sterility assurance release program where demonstrated control of the sterilization process enables a firm to use defined critical process controls, in lieu of the sterility test, to fulfill the intent of 21 CFR 211.167(a). Under this strategy, market release of terminally sterilized products can be based upon meeting the defined sterilization parameters and not on performing an approved sterility test. Meeting the requirements of the parametric release process can provide greater assurance that a batch meets the sterility requirement than can be achieved with a sterility test of finished units drawn from the batch.

Parametric release allows manufacturers to replace sterility testing of samples drawn from the finished product as a release criterion with acceptance criteria for the control of identified process parameters. Parametric release of the batch is then based on documented evidence of the control of critical parameters, removing the need for testing of samples drawn from the finished product.

An application to FDA is required to obtain approval for parametric release. The approval of parametric release is based on an assessment of the applicant's proposed critical process parameters and how they are controlled. Demonstrated reliability of the production terminal sterilization cycle, microbiological control and monitoring, and control of production cycle parameters within established validated limits is part of this assessment.

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 inclusion of recommended