b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact:

Vel McKleroy, Extramural Co-Project Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E–37, Atlanta Georgia, 30333, Telephone: (404) 639–2982, E-mail: *vmckleroy@cdc.gov.*

OR

Jennifer Galbraith, Extramural Co-Project Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E–37, Atlanta Georgia, 30333, Telephone: (404) 639–8649, E-mail: *jgalbraith@cdc.gov.*

For financial, grants management, or budget assistance, contact:

Brenda Hayes, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2741, E-mail: *bkh4@cdc.gov.*

Dated: August 17, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–19225 Filed 8–20–04; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Computerized Support Enforcement Systems.

OMB No: 0980–0271.

Description: The information being collected is mandated by Section 454(16) of the Social Security Act (the Act) which provides for the establishment and operation by the state agency, in accordance with an initial and annually updated advance planning document (APD) approved under section 452(d) of the Act, of a statewide system meeting the requirements of Section 454A. In addition, 454A(e)(1) requires that states create a State Case Registry (SCR) within their statewide automated child support systems to include information on IV–D cases and non–IV–D orders established or modified in the state on or after October 1, 1998. Section 454A(e)(5) of the Act requires states to regularly update their cases in the SCR.

The data being collected for the APD are a combination of narratives, budgets and schedules which are used to provide funding approvals on an annual basis and to monitor and oversee system development. Child support has separate regulations under 45 CFR 307.15 related to submittal of APDs because the program had supplemental authority for enhanced funding for systems development, and has substantial penalties for non-compliance with the statutory deadline of October 1, 2000. This information collection reflects the fact that 49 states and territories are now certified under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) leaving only five states that are not yet PRWORA systems certified, including one state that has not submitted an implementation APD for compliance with PRWORA automation. States and territories that opted to keep their Annual Planning Documents for child support systems are covered under a separate information collection, OMB No. 0992–0005, for 45 CFR Part 95 Subpart F.

The data being collected for the State Case Registry is used to transmit mandatory data elements to the Federal Case Registry (FCR) where it is used for matching against other data bases for the purposes of location of individuals, assets, employment and other child support related activities.

Respondents: The respondents are 54 state and territorial child support agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
307.15 (APD)	1	1	240	240
307.15 (APD Update)	5	1	60	300
307.11(e)(1)(ii) Collection of non-IV–D data for SCR states	54	25,200	.046	62,597
307.11(e)(1)(ii) Collection of non-IV–D data for SCR courts	3,045	447	.029	39,472
307.11(e)(3)(v) Collection of child data for IV–D cases for SCR courts	3,045	213	.083	53,833
307.11(f)(1) Case data transmitted from SCR to FCR new cases and case updates	54	52	2.82	7,918
Estimated Total Annual Burden Hours:				164,360

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@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: August 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–19256 Filed 8–20–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0346]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Antidiarrheal Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products: *Saccharomyces boulardii* (*S. boulardii*), 250 milligrams (mg) (4.5×10^9 lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg (9.0×10^9 yeast cells), in capsule form as an antidiarrheal ingredient. FDA has reviewed a time and extent application (TEA) for this condition and determined that it is eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether this condition can be generally recognized as safe and effective (GRAS/E) for its proposed OTC use.

DATES: Submit data, information, and general comments by November 22, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that FDA reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) was deleted from the TEA before it was placed on public display.

II. Request for Data and Information

FDA intends to evaluate the condition *S. boulardii*, 250 mg (4.5×10^9 lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg (9.0×10^9 yeast cells), in capsule form for inclusion in the monograph for OTC antidiarrheal drug products (21 CFR part 335). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for FDA to determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use. The TEA did not include an official or proposed United States Pharmacopeia-National Formulary (USP–NF) drug monograph for *S. boulardii*. According to § 330.14(i), an official or proposed USP–NF monograph for *S. boulardii* must be included as part of the safety and effectiveness data for this ingredient. Interested parties should provide an official or proposed USP–NF monograph for evaluation by FDA.

Interested persons should submit comments, data, and information to the Division of Dockets Management. Three copies of all comments, data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.