

Officer) P.O. Box 442, St. Louis, Missouri 63166-2034:

1. *Jerry W. Fuller, individually and acting in concert with Terry R. Fuller and Mary S. Fuller, all as co-executors of the estate of Ray C. Fuller*; all of Poplar Grove, Arkansas, to acquire control of Helena Bancshares, Inc., and thereby indirectly acquire control of Helena National Bank, both of Helena, Arkansas.

Board of Governors of the Federal Reserve System, March 23, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E9-6765 Filed 3-25-09; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day-09-08AX]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Sexually Transmitted Disease (STD) Morbidity Surveillance—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is responsible for the reporting and dissemination of nationally notifiable STD morbidity information for prevention and control purposes in collaboration with state and local health departments. Recent changes in sexually transmitted disease (STD) epidemiology in the United States indicate that the existing passive surveillance for STD does not include all the elements needed in order to control and prevent STDs in the U.S. Towards that end, CDC is proposing a new electronic information collection called STD Morbidity Surveillance that will include information on laboratory confirmation of syphilis infection and risk behaviors of persons infected with

syphilis and other STDs. Physicians and other providers collect demographic, risk, and clinical (including laboratory) information from persons diagnosed with notifiable STDs during a clinical encounter or counseling session. The respondents will submit the information electronically, to the state and local public health departments. Clinical specimens obtained from case-patients are submitted to private or public diagnostic laboratories with laboratory requisition forms which includes information on the provider and case-patient. A subset of the information reported to state health departments from health care providers or laboratories is reported electronically as a case report e-record to CDC's Nationally Notifiable Disease Surveillance System on a weekly basis. CDC estimates that 57 respondents spend 20 minutes each week extracting notifiable STD surveillance information from their electronic information system. CDC staff review STD morbidity data at varying frequencies to identify population subgroups at increased risk for STDs. The target evidence-based intervention strategies, evaluate the impact of ongoing control efforts, thus enhancing our understanding of STD transmission. There is no cost to respondents other than their time. The total estimated annual burden hours are 989.

ESTIMATED ANNUALIZED BURDEN HOURS

Types of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
State Health Departments	Electronic STD Case report	50	52	20/60
Territorial Health Agencies	Electronic STD Case report	5	2	20/60
City and county health departments	Electronic STD Case report	2	52	20/60

Dated: March 19, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9-6631 Filed 3-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0134]

Center for Biologics Evaluation and Research eSubmitter Pilot Evaluation Program for Source Plasma Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation to participate in a pilot evaluation program

for CBER's eSubmitter Program (eSubmitter). CBER's eSubmitter has been customized as an automated biologics license application (BLA) and BLA supplement (BLS) submission system for blood and blood components. Participation in the pilot program is open to blood establishments that collect Source Plasma. The pilot program is intended to provide industry and CBER regulatory review staff the opportunity to evaluate the eSubmitter system and determine if it facilitates the BLA/BLS submission process. The purpose of this notice is to invite blood establishments that collect Source Plasma to submit a request to CBER if they are interested in participating in this pilot program.

DATES: Submit a written or electronic request for participation in this program by April 27, 2009. You should include the following information in your request: contact name, contact phone number, e-mail address, name of the establishment, address, and license number (if applicable).

ADDRESSES: If you are interested in participating in this program, you should submit a request to participate in the program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Lore Fields, Center for Biologics Evaluation and Research (HFM-375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6143, Fax: 301-827-3534, or e-mail: lore.fields@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products, including blood and blood products, and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in the FDA development of a computer-assisted automated BLA/BLS submission program called eSubmitter to improve the process for providing certain regulatory submissions to FDA. The eSubmitter will include programs to submit applications for licensure, supplements to an approved license, and amendments to pending applications or supplements.

II. The eSubmitter Pilot Evaluation Program Expectations

The eSubmitter pilot evaluation program is expected to last approximately 6 months. During this period of time, participants will complete BLA/BLS regulatory submissions using the eSubmitter template developed at CBER for use by Source Plasma establishments. The eSubmitter was developed using the same review criteria for applications for these products as currently used in the BLA/BLS review process at CBER. During the BLA/BLS submission process, the participants will enter the

requested information into the eSubmitter tool and attach requested documents as an Adobe document (pdf format). This information will be saved onto a CD-ROM and mailed to CBER for review. Paper copies of submissions will not be required. CBER will review the information provided on the CD-ROM and the attachments according to current managed review procedures.

During the BLA/BLS submission process, CBER staff will be available to answer any questions or concerns that may arise. As each submission is completed, the users will be asked to comment on the eSubmitter program. These discussions will assist CBER in the final development and release of this electronic tool for use by industry.

III. Requests for Participation

Requests to participate in the eSubmitter pilot are to be identified with the docket number found in brackets in the heading of this document. Once requests for participation are received, FDA will contact interested establishments to discuss the pilot program.

Dated: March 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-6687 Filed 3-25-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0137]

Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated March 2009. The draft guidance document notifies establishments that manufacture Whole Blood and blood components intended for use in

transfusion, and establishments that make eligibility determinations for donors of HCT/Ps about FDA approval of a biologics license application for an enzyme-linked immunosorbent assay (ELISA) test system for the detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*). The draft guidance also notifies establishments that make donor eligibility determinations for HCT/P donors that FDA has determined *T. cruzi* to be a relevant communicable disease under current regulations. In addition, the guidance provides recommendations for using a licensed test for antibodies to *T. cruzi* to test individual human donors, including donors of Whole Blood and blood components for transfusion and HCT/P donors (living and cadaveric (non-heart beating)), for antibodies to *T. cruzi* in plasma and serum samples. The guidance document does not apply to Source Plasma.

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 June 24, 2009. Submit written comments on the information collection burden by May 26, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for