

with review of the application being the primary goal. The process will include appropriate coordination between agency review and inspection staff. Based on experience gained during the pilot program and internal knowledge of manufacturing science, FDA will develop procedures and guidance for implementing the new quality assessment system.

#### A. Scope

This program will be limited to 12 original NDAs to be submitted by December 31, 2006, in the CTD format, paper or electronic. If an applicant believes that a particular CMC supplement would be a good candidate for this pilot program, the applicant is encouraged to first contact ONDC to discuss its acceptability. Acceptance into this program will depend on the soundness of the drug development plan and the potential of the proposed application to affect the development of the new quality assessment system. Every effort will be made to ensure that all pharmaceutical companies have the opportunity to participate and that many different drug product types are included in this pilot program.

This pilot program only affects the CMC section of the NDA. Existing regulations and requirements for the submission of an NDA will not be waived, suspended, or modified for purposes of this pilot program. Participants must submit the NDA, paper or electronic, in accordance with 21 CFR part 314 and other relevant regulations.

#### B. Process

Interested parties should submit to the Division of Dockets Management (see **ADDRESSES**) a written request to participate in the pilot program (identified with the docket number found in brackets in the heading of this document). The request should include the following items: (1) The contact person's name, company name, company address, and telephone number; (2) the name of the drug product and a brief description (e.g., dosage form, indication); (3) a summary of the drug development plan; (4) a statement of the potential of the proposed application to affect the development of the new quality assessment system; and (5) a timeline for end-of-phase-2 and pre-NDA meetings and NDA submission. All pharmaceutical companies requesting participation in the pilot program will be notified of their acceptance in writing by ONDC within 60 days of receipt of the request.

Potential participants are encouraged to discuss their plans to participate in this pilot program with ONDC (e.g., as part of an end-of-phase-2 or pre-NDA meeting). Meeting requests for participating applicants should be submitted in accordance with the CDER guidance for industry on "Formal Meetings With Sponsors and Applicants for PDUFA Products" (<http://www.fda.gov/cder/guidance/2125fnl.htm>). Once agreement is reached on participation in this program, the applicant can meet with ONDC as frequently as needed before the submission and during the review process by submitting requests directly to ONDC.

The quality assessment under this pilot program will be conducted under the direct oversight of the ONDC Office Director by a team of experienced scientists who have a good understanding of the new quality assessment system and a strong scientific background in pharmaceutical development and manufacturing.

A pharmaceutical company may withdraw from participation in the pilot program at any time before the NDA is submitted by notifying ONDC in writing that it wishes to withdraw from the program.

#### III. Comments

Interested persons may submit written comments on this pilot program to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider these comments when developing a guidance on the new pharmaceutical quality assessment system. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. While detailed information on participating NDAs will not be publicly available, names of participating applicants will be made public.

Dated: July 7, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-13829 Filed 7-13-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0133]

#### **"Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;" Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 30, 2005 (70 FR 37863). The document announced the availability of a guidance document entitled "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection." The document published with inadvertent errors. This document corrects those errors.

#### **FOR FURTHER INFORMATION CONTACT:**

Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 05-12960, appearing on page 37863 in the **Federal Register** of Thursday, June 30, 2005, the following correction is made:

1. On page 37864, in the second column, under the section heading "**II. Paperwork Reduction Act of 1995**", the second sentence is corrected to read: "The collection of information in this guidance for 21 CFR 601.12 was approved under OMB control number 0910-0338; § 606.170(b) (21 CFR 606.170(b)) has been approved under OMB control number 0910-0116; and § 606.171 has been approved under OMB control number 0910-0458."

Dated: July 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-13830 Filed 7-13-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4971-N-35]

#### **Notice of Submission of Proposed Information Collection to OMB; Voucher Homeownership Program Implementation Survey**

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

This is a request for approval of a one-time survey to obtain a broad, statistically accurate picture of the Voucher Homeownership Program and how it operates nationwide, based on a sample of 230 PHAs that have implemented the program.

**DATES:** *Comments Due Date:* August 15, 2005.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail [Wayne\\_Eddins@HUD.gov](mailto:Wayne_Eddins@HUD.gov); or Lillian Deitzer at

[Lillian\\_L\\_Deitzer@HUD.gov](mailto:Lillian_L_Deitzer@HUD.gov) or telephone (202) 708-2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms. Deitzer or from HUD's Web site at <http://hlannwp031.hud.gov/po/i/icbts/collectionsearch.cfm>.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses.

This notice also lists the following information:

*Title of Proposal:* Voucher Homeownership Program Implementation Survey.

*OMB Approval Number:* 2528—to be assigned.

*Form Numbers:* None.

*Description of the Need for the Information and Its Proposed Use:* This request is for the clearance of a survey instrument that would provide a broad, statistically accurate picture of the Voucher Homeownership Program and how it operates nationwide, based on a sample of 230 PHAs that have implemented the program. The purpose of the survey is to: (1) Provide an accurate, but general, picture of the program's implementation nationwide and (2) help the Department identify the operational characteristics that contribute to the success of a voucher homeownership program and use the resulting detailed analysis of those operational characteristics to further improve the program.

*Respondents:* Public Housing Authorities operating voucher homeownership programs.

*Frequency of Submission:* One time.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting burden .....	230	230		0.75		172.5

*Total Estimated Burden Hours:* 173.  
*Status:* New collection.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 7, 2005.

**Wayne Eddins,**

*Departmental Paperwork Reduction Act Officer, Office of the Chief Information Officer.*

[FR Doc. E5-3715 Filed 7-13-05; 8:45 am]

**BILLING CODE** 4210-27-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[UT-920-05-1320-EL, UTU-82202]

#### Notice of Invitation To Participate in Coal Exploration License, Utah

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of invitation to participate in Coal Exploration License.

**SUMMARY:** Pursuant to section 2(b) of the Mineral Leasing Act of 1920, as amended by section 4 of the Federal Coal Leasing Amendments Act of 1976, 90 Stat. 1083, 30 U.S.C. 201(b), and to the regulations adopted as 43 CFR 3410, all interested qualified parties, as provided in 43 CFR 3472.1, are hereby invited to participate with Ark Land Company on a *pro rata* cost sharing basis in its program for the exploration of coal deposits owned by the United States of America in the Muddy Canyon Area in the following-described lands of Sanpete and Sevier Counties, Utah:

*T. 20 S., R. 5 E., SLM, Utah*  
Sec. 30, S $\frac{1}{2}$ SE $\frac{1}{4}$ , SE $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
Sec. 31, E $\frac{1}{2}$ , E $\frac{1}{2}$ W $\frac{1}{2}$ ;  
Sec. 32, NW, N $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Containing 840.00 acres.

All of the coal in the above-described land consists of unleased Federal coal within the Uinta-Southwestern Utah Known Coal Production Area. The purpose of the exploration program is to obtain coal quality data to supplement data from previous adjacent coal

exploration programs. The proposed exploration program is fully described and will be conducted pursuant to an exploration plan to be approved by the Bureau of Land Management (BLM).

**ADDRESSES:** Copies of the exploration plan are available for review during normal business hours (serialized under the number of UTU 82202) in the public room of the BLM State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah. The written notice to participate in the exploration program should be sent to both the BLM, Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145, and to Mark Bunnell, Mine Geologist, Canyon Fuel Company, LLC, Skyline Mine, HC 35 Box 380, Helper, Utah 84526.

**FOR FURTHER INFORMATION CONTACT:** Bill Buge, Salt Lake City, Bureau of Land Management, (801) 539-4086.

**SUPPLEMENTARY INFORMATION:** This notice of invitation to participate has been published in the Mt. Pleasant Pyramid and the Richfield Reaper, once each week for two consecutive weeks