announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html*.

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/cb/*.

For general questions regarding this announcement please contact: Dr. Margaret Washnitzer, Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Phone: 800–281–9519, E-mail: *OCSGRANTS@acf.hhs.gov*.

Applicants will not be sent acknowledgements of received applications.

Dated: July 8, 2005.

Josephine Robinson,

Director, Office of Community Services.

[FR Doc. 05–13893 Filed 7–13–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0262]

Submission of Chemistry, Manufacturing, and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking pharmaceutical companies to volunteer to participate in a pilot program involving the submission of chemistry, manufacturing, and controls (CMC) information consistent with the new pharmaceutical quality assessment system. The purpose of the pilot program is twofold. First, the pilot program will provide participating pharmaceutical companies with an opportunity to submit critical CMC information that demonstrates their understanding of quality by design, product knowledge, and process understanding of the drug substance and drug product in a new drug application (NDA). Second, the pilot program will enable the public and regulated industry to provide feedback that will assist FDA in developing a guidance for industry on the new quality assessment system.

DATES: Submit written and electronic requests to participate in the pilot program by October 31, 2005. Submit written and electronic comments on this pilot program by December 31, 2006.

ADDRESSES: Submit written requests to participate in the pilot program and written comments on 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 participate and electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael Folkendt, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *folkendtm@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of New Drug Chemistry (ONDC) in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research, is establishing a modern, risk-based pharmaceutical quality assessment system, as described in a September 2004 White Paper entitled ''ONDC's New Risk-Based Pharmaceutical Quality Assessment System'' (*http://www.fda.gov/cder/gmp/gmp2004/ondc_reorg.htm*). This White Paper was published as part of the FDA final report on ''Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach'' (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*).

The new quality assessment system will focus on critical pharmaceutical quality attributes (related to chemistry, formulation, manufacturing process design, and product performance) and their relevance to safety and effectiveness. The principles underlying this new quality assessment system can be found in the February 2005 International Conference on Harmonization (ICH) draft guidance entitled ''Q8 Pharmaceutical Development'' (*http://www.fda.gov/cder/guidance/6672dft.pdf*) and the September 2004 FDA guidance for industry entitled ''PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance'' (*http://www.fda.gov/cder/guidance/6419fnl.htm*). These principles include the following: (1) Ensuring product quality and performance through the design of effective and efficient manufacturing processes; (2) establishing product and process specifications based on a mechanistic understanding of how formulation and process factors affect product performance; and (3) where applicable, continuous ''real time'' quality assurance.

The new quality assessment system is intended to facilitate innovation and improvement throughout the product lifecycle and to provide regulatory flexibility for specification setting and postapproval changes based on scientific knowledge and understanding of product and process by applying quality-by-design principles. To take full advantage of the new quality assessment system, including appropriate regulatory flexibility, applicants should provide information in the CMC section of an NDA that demonstrates their product knowledge and process understanding at the time of submission. A CMC submission under the new system should contain a more comprehensive Quality Overall Summary (Module 2.3 of the ICH Common Technical Document (CTD) ''M4Q: The CTD—Quality'') and a more expansive Pharmaceutical Development section (Module 3.2.P.2, of the CTD). It should also include more relevant information on critical quality attributes and how they relate to clinical safety and effectiveness. The information provided should do the following: (1) Provide an appropriate level of confidence that quality has been built into the product by demonstrating the extent of product knowledge and process understanding at the time of submission, including information explaining critical steps and in-process controls to facilitate setting scientifically sound specifications and acceptance criteria, and (2) identify possible sources of variability in manufacturing by explaining how associated risks can be mitigated. At the same time, there would be less need for information that could be handled through inspectional oversight of current good manufacturing practices (cGMP) requirements (e.g., executed batch record, redundant chromatographic data, standard operating procedures). The pilot is also intended to provide enhanced clarity by distinguishing between information submitted and used in the pharmaceutical assessment process and information that is a condition of approval (e.g., that cannot be modified without further application/supplement review).

II. Description of Pilot Program

The pilot program will provide additional information for ONDC to use in implementing the new quality assessment system. FDA will work with each participant on an individual basis,

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.