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.