

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; Extension of Application and Comment Deadlines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice to extend application and comment deadlines.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension in the deadlines for submitting requests to participate in and comment on a pilot program involving the submission of chemistry, manufacturing, and controls (CMC) information consistent with the new pharmaceutical quality assessment system.

DATES: Submit written requests to participate in the pilot program by March 31, 2006. Submit eligible new drug applications (NDAs) by March 31, 2007. Submit written or electronic comments on the pilot program by March 31, 2007.

ADDRESSES: Submit written requests to participate in the pilot program and comments on the pilot 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 in and comments on the pilot program 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

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 14, 2005 (70 FR 40719), FDA announced that it is seeking pharmaceutical companies to participate in a pilot program involving the submission of CMC information consistent with a new pharmaceutical quality assessment system. 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, “ONDC’s New Risk-Based Pharmaceutical Quality Assessment System” (http://www.fda.gov/cder/gmp/gmp2004/ondc_reorg.htm). The pilot program will provide additional information for ONDC to use in implementing the new quality assessment system. The pilot program will provide participating pharmaceutical companies 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 at the time of submission of an NDA. The pilot program will also enable the public and regulated industry to provide feedback that will assist FDA in developing guidance for industry on the new quality assessment system.

The July 14, 2005 (70 FR 40719), notice provided deadlines related to the submission of certain information related to the pilot program. To ensure inclusive and relevant results from the pilot program, this notice extends the deadlines as follows: Requests to participate in the pilot program to March 31, 2006, from October 31, 2005, and submission of eligible New Drug

Applications (NDA) to March 31, 2007, from December 31, 2006. This notice also extends the comment period on the pilot program to March 31, 2007, from December 31, 2006. See the process section (II.B) in the July 14, 2005 (70 FR 40719) notice for instructions on submitting requests to participate in the pilot program. All requests to participate in the pilot program, both written and electronic, should be marked confidential.

II. 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. 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: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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