Applications for Food and Drug Administration Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Valid or Will Not Be Infringed

OMB Control No. 0910-0513

Justification memorandum for 83-C Change Request

The Food and Drug Administration is requesting a nonmaterial/non-substantive change for OMB Control No. 0910-0513, Patent Declaration Forms FDA 3542 and 3542a.

On November 21, 2016, OMB approved information collection provisions associated with the final rule entitled, "Abbreviated New Drug Applications and 505(b)(2) Applications" under OMB Control No. 0910-0786. As discussed in the final rule and in the agency's supporting statement, to implement certain reporting requirements FDA would need to revise Forms FDA 3542 and 3542a, currently approved under OMB 0910-0513. Accordingly, FDA has revised the patent declaration Forms FDA 3542a and 3542 with modest adjustments to the text of the forms to conform to the regulatory changes made in the final rule. In addition, the layout of the forms has been slightly modified to facilitate electronic completion and submission of the forms. These revisions reflect a minor decrease to the burden associated with the submission of patent information under OMB Control No. 0910-0513.