DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0308]

Centers for Medicare and Medicaid Services

[CMS-3180-N3]

Pilot Program for Parallel Review of Medical Products; Extension of the Duration of the Program

AGENCIES: Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) (the Agencies) are announcing the extension of the "Pilot Program for Parallel Review of Medical Products." The Agencies have decided to continue the program as currently designed for an additional period of 2 years from the date of publication of this notice.

DATES: This notice is effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: John Burke, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5460, Silver Spring, MD 20993-0002, 301-796-5738, John.Burke@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the Federal Register of October 11, 2011 (76 FR 62808), the Agencies announced the procedures and guiding principles for the Parallel Review Pilot Program and solicited nominations for the pilot. To date, there has been significant interest in the pilot and the Agencies are currently working through the parallel review process with the approved pilot program participants. We believe that interest in the pilot has also facilitated mutually informative discussions between additional sponsors and the Agencies.

In the October 11, 2011 (76 FR 62808), Parallel Review Pilot Program notice, the Agencies stated their intent to accept requests for a 2-year period, followed by an announcement in the Federal Register as to the future of the pilot. The Agencies have decided to continue the program as currently designed for an additional 2 years from the date of publication of this

notice.

Once a representative group of participants have completed the pilot process the Agencies will formally evaluate the program for best practices and will announce any future revisions and/or enhancements in a future Federal Register notice.

Dated: December 5, 2013.

Marilyn Tavenner,
Administrator,
Centers for Medicare & Medicaid Services.

[BILLING CODE: 4120-01-P]

Dated: December 6, 2013.

Margaret A. Hamburg,
Commissioner of Food and Drugs.

[BILLING CODE: 4160-01-P]

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