4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-D-0298; formerly Docket No. 2004D–0499]

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice to Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of compliance policy guide (CPG) Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs" to December 31, 2014.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the Federal Register of November 17, 2004 (69 FR 67360), FDA announced the availability of CPG Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs." Previous extensions of

the expiration date of the CPG were published in 2007, 2008, and 2010 (72 FR 65750, November 23, 2007; 73 FR 78371, December 22, 2008; 75 FR 80827, December 23, 2010). FDA has identified RFID as a promising technology to be used in the various efforts to combat counterfeit drugs. The CPG describes how the Agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA) was signed into law. Section 913 of FDAAA addressed pharmaceutical safety and created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355e). Section 505D(b) of the FD&C Act requires the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) of the FD&C Act states that these new standards must address promising technologies, which may include RFID technology.

In implementing section 505D of the FD&C Act, FDA is currently addressing issues, such as promising technologies, that also are relevant for the CPG. In addition, FDA is considering further the experience of stakeholders and the Agency under the CPG. As we consider all of these issues, the CPG will remain in effect until December 31, 2014.

Dated: December 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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