

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0499]

DDM

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Certifier D. Hawkins

**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.

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**SUMMARY:** The Food and Drug Administration (FDA) is extending the expiration date of the compliance policy guide (CPG) entitled "Sec. 400.210—Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs" to December 31, 2008.

**FOR FURTHER INFORMATION CONTACT:** Ilisa Bernstein, Office of the Commissioner, Office of Policy, Planning, and Preparedness (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

**SUPPLEMENTARY INFORMATION:** On November 17, 2004, FDA announced the availability of the CPG entitled "Sec. 400.210—Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs." 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.

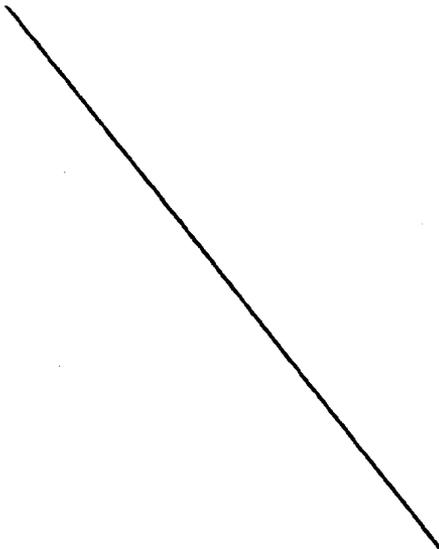
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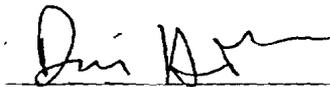
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On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of FDAAA addresses pharmaceutical safety and creates section 505D of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.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

As FDA considers the overlapping and complementary issues raised in the CPG and section 505D of the act, as well as the experience of stakeholders and the agency under the CPG, and whether to amend, revoke, or further extend the CPG, the CPG will remain in effect until December 31, 2008.



Dated: 11/15/07  
November 15, 2007.



David Horowitz,  
Assistant Commissioner for Regulatory Affairs.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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