

**Section 520(m)(6)(A)(iii) of the FD&C Act**

(<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/ChapterV/DrugsandDevices/default.htm>) provides that an HDE holder immediately notify the Agency if the number of devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may

petition to modify the ADN if additional information arises.

On August 5, 2008, FDA issued a guidance entitled “Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers” (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf>). The guidance was developed and issued prior to the enactment of FDASIA, and

certain sections of this guidance may no longer be current as a result of FDASIA. The Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research are currently working on a draft HDE guidance, that when finalized, will represent the FDA’s current thinking on this topic.

FDA is requesting OMB approval for the collection of information required under the statutory mandate of sections 515A (21 U.S.C. 360e–1) and 520(m) of the FD&C Act as amended.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity/section of FD&C Act (as amended) or FDASIA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act .....	6	1	6	100	600
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act .....	3	1	3	50	150
Request for Determination of Eligibility Criteria—613(b) of FDASIA .....	2	1	2	10	20
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act .....	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act .....	5	1	5	100	500
<b>Total</b> .....					<b>1,370</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of original HDE applications received in the period between October 1, 2008, and September 30, 2011. During that time, FDA’s Center for Devices and Radiological Health received 19 original HDE applications, or about 6 per year. FDA estimates that for each year we will receive six HDE applications and that three of these applications will be indicated for pediatric use. The request for determination of eligibility criteria is new under section 613(b) of FDASIA. We estimate that we will receive approximately two such requests per year. Historically, no companies have exceeded the ADN; and under FDASIA the ADN has expanded to a minimum of 4,000. Therefore, FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under

OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A, B, and C, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: December 11, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–30275 Filed 12–14–12; 8:45 am]

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**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:** Connie Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–3130.

**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 (Pub. L. 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0369]

#### Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by February 15, 2013.

**ADDRESSES:** Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kris André, Center for Drug Evaluation and

Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9326.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of September 14, 2012 (77 FR 56851). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

##### II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

- A
  - Abiraterone acetate
  - Albendazole
  - Amlodipine besylate, hydrochlorothiazide, and olmesartan medoxomil
- C
  - Clindamycin phosphate; tretinoin
  - Clorazepate dipotassium
- F
  - Ferumoxytol
- G
  - Gabapentin
- P
  - Piroxicam
- S
  - Sodium Phosphate, dibasic, anhydrous; sodium phosphate, monobasic, monohydrate