

Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 17, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–21349 Filed 10–25–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0307] (formerly 02D–0307)

Guidance for Industry on Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing.” This guidance document provides recommendations to sponsors of abbreviated new drug applications (ANDAs) on the design of bioequivalence studies for modified-release dosage forms of potassium chloride.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Lizzie Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing.” This guidance is intended to provide information to sponsors of ANDAs on the design of bioequivalence studies for modified-release dosage forms of potassium chloride.

A document entitled “Guidance for In Vivo Bioequivalence Study for Slow-Release Potassium Chloride Tablets/ Capsules” was issued on May 15, 1987 (1987 guidance), and revised on June 6, 1994 (1994 revision). The guidance was further revised to incorporate FDA’s current thinking on the bioequivalence requirements for potassium chloride modified-release products and was issued in draft on August 7, 2002 (2002 draft guidance) (67 FR 51284). Comments were reviewed and incorporated. The most substantive changes made are described in the following paragraphs. Editorial changes were also made and the final guidance is now available.

In the 2002 draft guidance, the agency recommended a three-way crossover design study comparing the reference listed drug (RLD) to both the generic product and a solution of potassium chloride. The 2002 draft guidance also recommended analysis of covariance (ANCOVA) for the pharmacokinetic parameters.

The final guidance provides recommendations for a two-way crossover design comparing the generic

product to the RLD. This design is consistent with the 1994 revision, which stated that the potassium chloride solution mentioned in the 1987 guidance was no longer necessary and recommended the use of a two-treatment, two-period, single-dose, fasting study comparing test product with reference product. The FDA determined that the potassium chloride solution arm is not necessary because the objective of the bioequivalence study is to directly compare the rate and extent of potassium absorption from the test product and the reference product. Therefore, the potassium chloride solution arm is not necessary for the test-versus-reference comparison and adds unnecessary complexity to the statistical bioequivalence analysis.

We also have decided not to recommend the use of ANCOVA in the final guidance. Analysis of variance (ANOVA) with baseline correction is adequate for bioequivalence analysis of pharmacokinetic data obtained following oral administration of potassium chloride drug products. The FDA concluded that using ANCOVA with baseline as a covariate to analyze baseline-uncorrected data was not as sensitive to changes in formulation performance as using ANOVA to analyze baseline-corrected data.

The dissolution testing and criteria for waivers on in vivo testing for lower strengths are revised to reflect the changes outlined in the guidance entitled “Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations,” available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on studies to demonstrate the bioequivalence of potassium chloride modified-release tablets and capsules. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-21347 Filed 10-25-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA-2005-21866]

Extension Agency Information Collection Activity Under OMB Review: Enhanced Security Procedures at Ronald Reagan National Airport (DCA)

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice.

SUMMARY: This notice announces that TSA has forwarded the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 26, 2005, 70 FR 50391.

DATES: Send your comments by November 25, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS-TSA Desk Officer, at (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Katrina Wawer, Information Collection Specialist, Office of Transportation Security Policy, TSA-9, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202-4220.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Enhanced Security Procedures at Ronald Reagan National Airport (DCA).

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652-0035.

Form(s): "Flight Authorization Request Form," "Armed Security Officer Nomination Form," "FBO and Operator Initial Information Survey."

Affected Public: General aviation aircraft operators, crewmembers, and passengers.

Abstract: On July 19, 2005, TSA published an interim final rule (IFR) to restore access to Ronald Reagan National Airport (DCA) for certain aircraft operations while maintaining the security of critical Federal Government and other assets in the Washington, DC metropolitan area. The IFR amended 49 CFR part 1562 by adding a new subpart B entitled Ronald Reagan-Washington National Airport: Enhanced Security Procedures for Certain Operations. The IFR and this information collection apply to all passenger aircraft operations into or out of DCA, except U.S. air carrier operations operating under a full security program required by 49 CFR part 1544 and foreign air carrier operations operating under 49 CFR 1546.101(a) or (b). TSA requires individuals designated as security coordinators by Fixed Based Operators (FBOs) and general aviation aircraft, flight crewmembers who operate general

aviation aircraft into and out of DCA in accordance with the IFR, and armed security officers (ASOs) approved in accordance with the IFR to submit fingerprints and other identifying information. In addition, general aviation aircraft operators are required to provide TSA with identifying information for all individuals onboard each aircraft that operates into and out of DCA. General aviation aircraft operators also are required to provide TSA with the flight plan and registration number of their aircraft that will operate to or from DCA. Finally, aircraft operators and FBOs are required to nominate the individuals they would like to be qualified as ASOs by submitting an ASO Nomination Form to TSA. Once nominated, the ASOs are required to submit identifying information, as well as employment history information, by completing an on-line application.

Number of Respondents: 2,025.

Estimated Annual Burden Hours: An estimated 13,298 hours annually.

Issued in Arlington, Virginia, on October 19, 2005.

Lisa S. Dean,

Privacy Officer.

[FR Doc. 05-21364 Filed 10-25-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2352-05]

RIN 1615-ZA23

Adjustment of the Immigration Benefit Application Fee Schedule; Correction

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice of correction.

SUMMARY: U.S. Citizenship and Immigration Services (USCIS) published a notice in the **Federal Register** on September 26, 2005 at 70 FR 56182 to increase the fees for immigration benefit applications and petitions to account for cost increases due to inflation. In the fee table of the September 26, 2005 notice, USCIS added a footnote "6" next to the new fee for the Form N-600K. Footnote "6" shows an increase in fee from \$200 to \$215 for an application filed on behalf of an adopted child (as compared to the base fee increase from \$240 to \$255). The placement of this footnote and its lack of specificity regarding which "application" it was meant to