satisfied that the data on the cover sheet is accurate and you have finalized the Cover Sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the Payment for your application as described in section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2010, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2011 using this fee schedule. Fees will be due and payable 30 days after the issuance of the invoices. FDA will issue invoices in November 2012 for any products and sponsors subject to fees for FY 2011 that qualify for fees after the December 2010 billing.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19040 Filed 8–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0246]

Draft Guidance for Industry on Residual Drug in Transdermal and Related Drug Delivery Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Residual Drug in Transdermal and Related Drug Delivery Systems." This draft guidance provides recommendations to developers and manufacturers of transdermal drug delivery systems (TDDS), transmucosal drug delivery systems (TMDS), and topical patch products regarding use of an appropriate scientific approach during product design and development—as well as during manufacturing and product lifecycle management—to ensure that the amount of residual drug substance at the end of the labeled use period is minimized. The draft guidance is applicable to investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplemental new drug applications (sNDAs) for TDDS, TMDS, and topical patch products.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance, including comments regarding the proposed collection of information, by November 1, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Terrance Ocheltree, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, rm. 1609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Residual Drug in Transdermal and Related Drug Delivery Systems." This draft guidance provides recommendations to developers and manufacturers of TDDS, TMDS, and topical patch products regarding use of an appropriate scientific approach during product design and development—as well as during manufacturing and product lifecycle management—to ensure that the amount of residual drug substance at the end of the labeled use period is minimized.

Existing TDDS, TMDS, and topical patches contain a larger amount of the drug substance than what is intended to be delivered to the patient. This excess amount of drug substance is needed to facilitate delivery of the intended amount of the drug to the patient and remains as residual drug in the used system. The amount of residual drug substance in TDDS, TMDS, and topical patches has a significant potential to impact the products' quality, safety, and efficacy. Consequently, it is necessary to ensure that an appropriate scientific approach is used to design and develop these products. The approach should ensure that the amount of residual drug substance is minimized consistent with the current state of technology.

Currently marketed TDDS, TMDS, and topical patches may retain 10 to 95 percent of the initial total amount of drug after the intended use period. This raises a potential safety issue not only to the patient, but also to others including family members, caregivers, children, and pets. For example, adverse events due to a patient's failure to remove TDDS at the end of the intended use period have been reported and are generally related to an increased or prolonged pharmacological effect of the drug. Some children have died from inadvertent exposure to discarded TDDS. Reported adverse events resulting from various quality problems pertaining to TDDS have lead to product recalls, withdrawals, and public health advisories.

To reduce some of these risks, we recommend that an enhanced design and development approach—specifically Quality by Design (QbD), as described in the International Conference on Harmonization (ICH) guidance for industry Q8(R2) *Pharmaceutical Development*—be used when developing and manufacturing TDDS, TMDS, and topical patches. We also recommend that sufficient scientific justification to support the amount of residual drug in TDDS, TMDS, or topical patches be included in an application. The level of information in the justification should be sufficient to demonstrate product and process understanding and ensure that a scientific, risk-based approach has been taken to minimize the amount of residual drug in a system after use to the lowest possible level. Furthermore, it is expected that the amount of residual drug in a newly developed system will not exceed that of similar FDA-approved products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on residual drug in transdermal and related drug delivery systems. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Information in an application on the product and process development and justification for the final formulation and system design is approved by OMB under control numbers 0910–0001 and 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19041 Filed 8–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0181]

Guidance for Industry on Label Comprehension Studies for Nonprescription Drug Products; 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 "Label Comprehension Studies for Nonprescription Drug Products." The guidance provides recommendations on the design of label comprehension studies that can be used to assess the extent to which consumers understand the information conveyed by proposed nonprescription drug product labeling. This guidance finalizes the draft guidance published on May 1, 2009.

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

ADDRESSES: Submit written requests for single copies of this guidance 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 guidance document.

Submit electronic comments on the guidance 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: Murewa Oguntimein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5475,Silver Spring, MD 20993–0002, 301–796–4869.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Label Comprehension Studies for Nonprescription Drug Products." This guidance is intended for individuals or organizations involved in the development of label comprehension studies for nonprescription drug products. This guidance discusses general concepts that should be considered in the design and conduct of a label comprehension study. This guidance also incorporates advice obtained from the September 25, 2006, meeting of the Nonprescription Drug Advisory Committee that considered issues related to the analysis and interpretation of consumer studies conducted to support marketing of nonprescription drug products, and comments submitted to the draft guidance published in the **Federal Register** of May 1, 2009 (74 FR 20322).

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 label comprehension studies for nonprescription drug products. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19043 Filed 8–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0363]

Medical Device User Fee Rates for Fiscal Year 2011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the