Sheet can be mailed to: Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195–3877.

If payment is made by wire transfer, send payment to: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding additional fees.

If you prefer to send a check by a courier such as Federal Express (FEDEX) or United Parcel Service (UPS), the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4821. This telephone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources click "The Animal Drug User Fee Cover Sheet" and then click "Create ADUFA User Fee Cover Sheet." For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are 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 PIN.

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

Step Four—Please submit your application and a copy of the completed Animal 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, Establishment, and Sponsor Fees

By December 31, 2010, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2011 using this Fee Schedule. Payment will be due and payable within 30 days of issuance of the invoice. FDA will issue invoices in November 2011 for any products, establishments, 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. 2010–19037 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–N–0340]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2011 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Generic Drug User Fee Act of 2008 (AGDUFA), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, on certain generic new animal drug products, and on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2011.

For FY 2011, the generic animal drug user fee rates are: $92,600 for each abbreviated application for a generic new animal drug; $5,440 for each generic new animal drug product; $55,950 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $41,963 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $27,975 for a generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2011 product and sponsor fees by December 31, 2010. These fees will be due and payable within 30 days of the issuance of the invoices.

The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2010, and will remain in effect through September 30, 2011. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm* or contact Bryan Walsh, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9730. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the act (21 U.S.C. 379j–21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2009 through FY 2013, the act establishes aggregate yearly base revenue amounts for each of these fee

categories. Base revenue amounts established for years after FY 2009 may be adjusted for workload. Fees for applications, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for workload.

II. Revenue Amount for FY 2011

A. Statutory Fee Revenue Amounts

AGDUFA (Title II of Public Law 110–316 signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2011 for abbreviated application fees is $1,619,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $1,889,000 each, before any adjustment for workload is made (see 21 U.S.C. 379j–21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA for each year for FY 2009 through FY 2013 include an inflation adjustment, so no inflation adjustment is required.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning after FY 2009, AGDUFA provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j–21(c)(1)).

FDA calculated the average number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period ended on September 30, 2008 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended on June 30, 2010.

The results of these calculations are presented in the first two columns of table 1 of this document. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 of table 1 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of negative 24.47 percent for FY 2011. This is the workload adjuster for FY 2011.

TABLE 1—WORKLOAD ADJUSTER CALCULATION

Application Type	Column 1 5-Year Avg. 2004–2008 (Base Years)	Column 2 Latest 5-Year Avg. (thru June 30, 2010)	Column 3 Percent Change	Column 4 Weighting Factor	Colum 5 Weighted Percent Change
Abbreviated New Animal Drug Applications (ANADAs)	44.2	30.2	-32%	56%	-17.74%
Manufacturing Supplements ANADAs[1]	114.6	102.6	-10%	19%	-1.99%
Generic Investigational Study Submissions[2]	17.4	17.4	0%	10%	0.00%
Generic Investigational Protocol Submissions	21.6	15.2	-30%	16%	-4.74%
FY 2011 AGDUFA Workload Adjuster					-24.47%

[1] This number is slightly lower than the 114.8 shown in last year's notice because FDA refused to file some applications.
[2] This number is slightly lower than the 18 shown in last years notice because FDA refused to accept some submissions.

AGDUFA specifies that the workload adjuster may not result in fees for a fiscal year that are less than the statutory revenue amount (21 U.S.C. 379j–21(c)(1)(B)) for that fiscal year. Because applying the workload adjuster for FY 2011 would result in fees less than the statutory amount, the workload adjustment will not be applied in FY 2011. As a result, the statutory revenue amount for each category of fees for FY 2011 ($1,619,000 for application fees and $1,889,000 for both product and sponsor fees) becomes the revenue target for the fees in FY 2011, for a total fee revenue target in FY 2011 of $5,397,000 for fees from all three categories.

III. Abbreviated Application Fee Calculations for FY 2011

The term "abbreviated application for a generic new animal drug" is defined in 21 U.S.C. 379j–21(k)(1).

A. Application Fee Revenues and Numbers of Fee-Paying Applications

The application fee must be paid for abbreviated applications for a generic new animal drug that is subject to fees under AGDUFA and that is submitted on or after July 1, 2008. The application fees are to be set so that they will generate $1,619,000 in fee revenue for FY 2011. This is the amount set out in the statute.

To set fees for abbreviated applications for generic new animal drugs to realize $1,619,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2011.

The agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. FDA is making estimates and applying different assumptions for two types of submissions: Original submissions of abbreviated applications for generic new animal drugs and "reactivated" submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed

fees (21 U.S.C. 379j–21(a)(1)(A)). Some of these nonfee paying submissions were later resubmitted after July 1 because the initial submission was not approved by FDA (i.e. FDA marked the submission as incomplete and requested additional nonadministrative information) or because the original submission was withdrawn by the sponsor. Because these abbreviated applications for generic new animal drugs are resubmitted after July 1, 2008, they are assessed fees. In this notice, FDA refers to these resubmitted applications as "reactivated" applications.

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications that will pay fees in FY 2011 will equal 30 percent less than the average number of submissions over the 5 most recent years. This 30-percent reduction is made because of the anticipated impact of fees on the number on submissions. During FY 2010, FDA estimates it will receive only 6 original submissions of abbreviated applications for generic new animal drugs, compared to average receipts of 14.4 per year over the latest 5 years, including our FY 2010 estimate. Applying a 30-percent reduction to the 14.4 average, the estimate for original submissions of abbreviated applications for generic new animal drugs for FY 2011 is 10.1. (If the number of original submissions of abbreviated applications for generic new animal drugs does not increase over the next year, a higher percent reduction will have to be applied a year from now when fees are set for FY 2012.)

Regarding reactivated submissions of abbreviated applications for generic new animal drugs, FDA is applying a 50-percent reduction based on the FDA's experience with these types of submissions during the third year of other user fee programs. This assumption is based on the fact that there were a limited number of original submissions of abbreviated applications for generic new animal drugs received by FDA before July 1, 2008, and which were not assessed fees. For these original submissions that were not approved before July 1, 2008, resubmission to FDA would trigger an application fee (21 U.S.C. 379j–21(a)(1)(A)). Once these initial original submissions of abbreviated applications for generic new animal drugs received by FDA before July 1, 2008, have either been withdrawn or resubmitted, "reactivation submissions" will cease completely. This reduction is consistent with estimates made when this user fee program was in the development process. During FY 2010, FDA estimates it will receive only 9 reactivated submissions of abbreviated applications for generic new animal drugs, compared to average receipts of 14.8 per year average over the most recent 5 years, including our estimate for FY 2010. Applying a 50-percent reduction to the 14.8 average, the estimate for reactivated submissions of abbreviated applications for generic new animal drugs for FY 2011 is 7.4. These reductions may not fully account for possible year to year fluctuations in numbers of fee-paying applications, but FDA believes that this is a reasonable approach after about 7 years of experience with a similar user fee program.

Based on the previous assumptions, FDA is estimating that it will receive a total of 17.5 fee paying generic new animal drug applications in FY 2011 (10.1 original applications and 7.4 reactivations).

B. Fee Rates for FY 2011

FDA must set the fee rates for FY 2011 so that the estimated 17.5 abbreviated applications that pay the fee will generate a total of $1,619,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be $92,600.

IV. Generic New Animal Drug Product Fee Calculations for FY 2011

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an abbreviated new animal drug application or supplemental abbreviated application for generic new animal drugs for an animal drug product submitted for listing under section 510 of the act (21 U.S.C. 360), and who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term "generic new animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $1,889,000 in fee revenue for FY 2011. This is the amount set out in the statute and no further adjustments are required for FY 2011.

To set generic new animal drug product fees to realize $1,889,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2011. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the act, and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. FDA estimates a total of 386 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 386 products will be subject to this fee in FY 2011. The number of products has dropped substantially from the numbers in last year's **Federal Register** fee notice because a number of products were de-listed and are no longer subject to fee. That also causes the fee per product to increase.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2011, FDA is assuming that 10 percent of the products invoiced, or 38.6, will not pay fees in FY 2011 due to fee waivers and reductions. Based on experience with other user fee programs and the first 2 years of AGDUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2011.

Accordingly, the agency estimates that a total of 347.4 (386 minus 38.6) products will be subject to product fees in FY 2011.

B. Product Fee Rates for FY 2011

FDA must set the fee rates for FY 2011 so that the estimated 347.4 products that pay fees will generate a total of $1,889,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest five dollars, to be $5,440.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2011

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an

abbreviated application for a new generic animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive; and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3)). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(B)). Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee, applicants with 2 to 6 approved abbreviated applications will pay 75 percent of the sponsor fee, and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(B)). The sponsor fees are to be set so that they will generate $1,889,000 in fee revenue for FY 2011. This is the amount set out in the statute and no adjustments are required for FY 2011.

To set generic new animal drug sponsor fees to realize $1,889,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2011. Based on the number of firms that meet this definition, FDA estimates that in FY 2011, 12 sponsors will pay 100 percent fees, 12 sponsors will pay 75 percent fees, and 33 sponsors will pay 50 percent fees. That totals the equivalent of 37.5 full sponsor fees (12 times 100 percent or 12, plus 12 times 75 percent or 9, plus 33 times 50 percent or 16.5).

FDA estimates that about 10 percent of all of these sponsors, or 3.75, may qualify for a minor use/minor species waiver.

Accordingly, the agency estimates that the equivalent of 33.75 full sponsor fees (37.5 minus 3.75) are likely to be paid in FY 2011.

B. Sponsor Fee Rates for FY 2011

FDA must set the fee rates for FY 2011 so that the estimated equivalent of 33.75 full sponsor fees will generate a total of $1,889,000. To generate this amount will require the 100-percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $55,950. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $41,963, and the fee for those paying 50 percent of the full sponsor fee will be $27,795.

VI. Fee Schedule for FY 2011

The fee rates for FY 2011 are summarized in table 2 of this document.

TABLE 2—FY 2011 FEE RATES

Generic New Animal Drug User Fee Category	Fee Rate for FY 2011
Abbreviated Application Fee for Generic New Animal Drug Application	$92,600
Generic New Animal Drug Product Fee	5,440
100 Percent Generic New Animal Drug Sponsor Fee[1]	55,950
75 Percent Generic New Animal Drug Sponsor Fee [1]	41,963
50 Percent Generic New Animal Drug Sponsor Fee [1]	27,975

[1] An animal drug sponsor is subject to only one fee each fiscal year.

VII. Procedures for Paying FY 2011 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2011 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA that is submitted on or after October 1, 2010. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or by automatic clearing house (ACH) using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the "Pay Now" button). On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters "AG", from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (PO Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195–3877.

If payment is made via wire transfer, send payment to U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, Routing Number: 021030004, Swift Number: FRNYUS33. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding the amount of the fees that need to be paid in addition to the wire transfer amount.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the check and printed copy of the cover sheet to: US Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, Missouri 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the US Bank at 314–418–4821. This phone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by FDA's Center for Veterinary Medicine, or the date US Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. US Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link "Create AGDUFA User Fee Cover Sheet." Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are

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