TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Sections and Parts	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital, Operating, and Maintenance Costs
101.70	3	1	3	80	240	$400,000
101.79(c)(2)(ii)(D)	1,000	1	1,000	0.25	250	0
101.79(c)(2)(iv)	100	1	100	0.25	25	0
101.100(d)	1,000	1	1,000	1	1,000	0
101.105 and 101.100(h)	17,000	1.03	17,500	0.5	8,750	0
101.108	0	0	0	40	0	0
Total					996,869	$16,800,000

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Sections and Parts	No. of Recordkeepers	Annual Frequency per Recordkeepers	Total Annual Records	Hours per Record	Total Hours
101.12(e)	25	1	25	1	25
101.13(q)(5)	265,000	1.5	397,500	0.75	298,125
101.14(d)(2)	265,000	1.5	397,500	0.75	298,125
101.22(i)(4)	25	1	25	1	25
101.100(d)(2)	1,000	1	1,000	1	1,000
101.105(t)	100	1	100	1	100
Total					597,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of January 6, 1993 (58 FR 2927), FDA published a document based on these estimates entitled ''Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations,'' which is the agency's most recent comprehensive review of food labeling costs. The estimates are also based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E4–303 Filed 2–17–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Animal Drug User Fee Rates for Applications for Fiscal Year 2004 and Payment Procedures

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for application fees for fiscal year (FY) 2004 and payment procedures for those fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), Public Law 108–130, authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This document establishes the application fee rates for FY 2004. A

separate document will be published in the **Federal Register** establishing fee rates and payment procedures for annual product, establishment, and sponsor fees for FY 2004.

The application fee rates are $61,000 for an animal drug application and $30,500 for a supplemental animal drug application for which safety or effectiveness data are required. (In this document, supplemental animal drug applications are referred to as ''supplements''; animal drug applications and supplemental animal drug applications are collectively referred to as ''applications''.) These rates are effective for applications submitted on or after September 1, 2003, and will remain in effect through September 30, 2004. FDA may begin to collect these fees now since the President signed Public Law 108–199, appropriating FY 2004 animal drug user fee revenues, on January 23, 2004. FDA will issue invoices for all fees payable for applications submitted between September 1, 2003, and March 31, 2004. Those invoices will be due and payable within 30 days of issuance. Subsequently, fees for animal drug applications and supplemental animal drug applications received on or after April 1, 2004, must be paid at the time the applications are submitted. Applications will not be accepted for review until full payment of all fees owed is received. Payment instructions and answers to anticipated questions are also provided in this document.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/oc/adufa* or contact Robert Miller, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 301–827–5436. For general questions, you may also e-mail the Center for Veterinary Medicine at: *cvmadufa@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the act (21 U.S.C. 379j–12), establishes four different kinds of user fees: (1) Fees for certain types of animal drug applications and supplements, (2) annual fees for certain animal drug products, (3) annual fees for certain establishments where such products are made, and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. (See 21 U.S.C. 379j–12(a).) When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2004 through FY 2008, the act establishes aggregate yearly revenue amounts for each of these fee categories. Revenue amounts established for years after FY 2004 are subject to adjustment for inflation and workload. Fees for applications, establishments, 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 inflation and workload.

This document establishes fee rates for FY 2004 for application fees. These fees are effective on September 1, 2003, and will remain in effect through September 30, 2004. A separate document will be published in the **Federal Register** providing rates and payment procedures for product, establishment, and sponsor fees.

II. Application Fee Calculations for FY 2004

ADUFA specifies that the aggregate revenue amount for FY 2004 for animal drug application fees and supplemental animal drug application fees is $1,250,000, before any adjustments are made. (See 21 U.S.C. 379j–12(b)(1).) The terms animal drug applications and supplemental animal drug applications are defined in 21 U.S.C. 379j–11(1) and (2). Since FY 2004 is the first year of the program, there are no adjustments for workload or inflation; however, these adjustments are made to the statutory revenue amounts each year after FY 2004. (See 21 U.S.C. 379j–12(c)(1) and (2).)

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

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be established so that they will generate the fee revenue amounts specified in the statute—$1,250,000 in FY 2004, $2,000,000 in FY 2005, and $2,500,000 in FYs 2006, 2007, and 2008. (See 21 U.S.C. 379j–12(b)(1).) The fee for a supplemental animal drug application for which safety or effectiveness data are required is to be set at 50 percent of the animal drug application fee. (See 21 U.S.C. 379j–12(a)(1)(A)(ii).)

To set animal drug application fees and supplemental animal drug application fees to realize $1,250,000, FDA must make some assumptions about the number of fee-paying applications it will receive in FY 2004.

The agency knows the number of applications that have been submitted in previous years, but that number fluctuates significantly from year to year. Further, it is possible that the user fee program will affect the number of applications submitted in FY 2004, exacerbating the fluctuation that is normally experienced. In addition, the agency does not have data on the number of waivers and reductions that will be granted, though this number will reduce the revenues that the agency will realize. For these reasons, in estimating the application fee for FY 2004, FDA is assuming that the number of applications that will pay fees in FY 2004 will be 70 percent of the lower of the average number of applications submitted over the past 3 years or the number submitted in the most recent year, whichever is lower. This should account both for the effect of fluctuations in the numbers of applications submitted and for the effect of fee waivers or reductions that FDA estimates will be granted. Based on experience with other application user fee programs, FDA believes that this is a reasonable basis for estimating the number of fee-paying applications in the first year of this program.

Over the past 3 years, the average number of animal drug applications that would have been subject to the full fee was 23.3, and the number for the most recent year was 27. Over this same period, the average number of supplements that would have been subject to half of the full fee was 18.3, and the number for the most recent year was 12.

Thus, for FY 2004, FDA estimates that it will receive 16.3 fee-paying animal drug applications (70 percent of the 3-year average of 23.3) and 8.4 fee-paying supplemental animal drug applications (70 percent of the 12 for the most recent year).

B. Fee Rates for FY 2004

FDA must set the fee rates for FY 2004 so that the estimated 16.3 animal drug applications that pay the full fee and the estimated 8.4 supplements that pay half of the full fee will generate a total of $1,250,000. To generate this amount will require that the fee for an animal drug application, rounded to the nearest hundred dollars, will be $61,000, and the fee for a supplemental animal drug application for which safety or effectiveness data are required will be $30,500.

C. Adjustment for Excess Collections

Under the provisions of ADUFA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce the adjusted aggregate revenue amount in a subsequent year by that excess amount (21 U.S.C. 379j–12(g)(4)). No

adjustments under this provision are required for fees assessed in FY 2004.

III. Procedures for Paying Application Fees

FDA requests that you follow the listed steps, on or after April 1, 2004, before submitting an animal drug application or supplement that is subject to a fee. Please pay close attention to these procedures to ensure that FDA associates the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Create a User Account and Password

For security reasons, each firm submitting an application will be assigned an organization identification number, and users will also be required to set up a user account and password the first time they use this Web site. To create a new account, log onto the ADUFA Web site at *http://www.fda.gov/oc/adufa* and, under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' Online instructions will walk you through this process. It may take a day or two to get the organization number and have the user account and password established.

B. 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 that shows your unique payment identification number.

C. Step Three—Mail Payment and a Copy of the Printed Animal Drug User Fee Cover Sheet to the Following St. Louis Address

•Payment will only be accepted in U. S. currency by check, bank draft, or U.S. postal money order payable to FDA. (The tax identification number of FDA is 53–0196965, should your accounting department need this information.)

•On your check, bank draft, or U.S. postal money order, please write your application's unique payment identification number, beginning with the letters AD followed by the number from the upper right-hand corner of your completed animal drug user fee cover sheet.

•Mail the payment and a copy of the completed animal drug user fee cover sheet to the following address:

Food and Drug Administration, P.O. Box 953877, St. Louis, MO 63195–3877.

If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to the following address:

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.)

It is helpful if the fee arrives at the U.S. Bank at least 2 days before the application arrives at FDA's Center for Veterinary Medicine (CMV). FDA records the official application receipt date as the later of the following information:

• The date the application was received by FDA's CVM, or

• The date U.S. Bank notifies FDA that your check in the full amount of the payment due has been received. U.S. Bank is required to notify FDA within 1 working day, using the payment identification number described in the previous paragraphs.

D. Step Four—Submit Your Application to FDA With a Copy of the Completed Animal Drug User Fee Cover Sheet

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.

IV. Are All Animal Drug Applications and Supplements Subject to Fees?

No. The following are examples of applications and submissions that do not require an application fee:

• Any type of investigational animal drug submission, as that term is defined in 21 U.S.C. 379j–11(5).

• Abbreviated new animal drug applications submitted under 21 U.S.C. 360b(b)(2).

• Supplemental new animal drug applications for which safety or effectiveness data are not required. (See 21 U.S.C. 379j–12(a)(1)(A)(ii).)

• A resubmitted animal drug application or supplement, for the same product submitted by the same person, for which an application was previously filed and for which a fee was paid, but which was not approved or was withdrawn without waiver or refund, as provided by 21 U.S.C. 379j–12(a)(1)(C).

• Annual (or other periodic) reports required under an approved new animal drug application.

If you are unsure of whether a planned application or submission will be subject to an ADUFA user fee, see **FOR FURTHER INFORMATION** section of this document.

V. May Some Animal Drug Application or Supplement Fees Be Waived or Reduced? How Do I Apply For Such Waivers or Reductions?

FDA will grant a waiver or reduction of one or more fees when the agency finds that:

• The assessment of the fee would present a significant barrier to innovation because of limited resources or other circumstances. (See 21 U.S.C. 379j–12(d)(1)(A).)

• Fees exceed the costs (both anticipated present and future costs of reviewing animal drug applications. (See 21 U.S.C. 379j–12(d)(1)(B).)

• The animal drug is intended solely for use in either a type C free-choice medicated feed or a type B medicated feed intended for use in the manufacture of type C free choice medicated feeds. (See 21 U.S.C. 379j–12(d)(1)(C).)

• The animal drug application or supplement is intended solely to provide for a minor use or minor species indication. (See 21 U.S.C. 379j–12(d)(1)(D).)

• The animal drug application is the first ever submitted by a small business. (See 21 U.S.C. 379j–12(d)(1)(E) and 21 U.S.C. 379j–12(d)(3).)

Note that all of the previously mentioned situations require the applicant to submit a written request to the agency for a waiver or reduction not later than 180 days after the fee is due. (See 21 U.S.C. 379j–12(i).) Also note that the application fee must be paid in full before the application is submitted or the application will not be accepted for filing. (See 21 U.S.C. 379j–12(a)(1)(C) and 21 U.S.C 379 j–12(e).) If FDA grants a waiver or reduction before you have submitted the application, then you should submit a copy of the document granting the waiver or reduction both with the application and, if applicable, with the check for a reduced amount sent separately to the bank. If FDA grants a waiver or reduction after you have submitted the application and paid its associated fee, FDA would make the appropriate refund. FDA will provide information on how to apply for any of the previously stated waivers or reductions on ADUFA's Web site at *http://www.fda.gov/oc/adufa*, under the ''Fee Waivers and Reductions'' link.

VI. When Do I Submit a Fee For an Application I Submitted On or After September 1, 2003, and Before April 1, 2004?

You must pay a fee for any animal drug application or supplemental animal drug application subject to a fee that you submitted on or after September 1, 2003 (21 U.S.C. 379j–12(a)(1)(A)). FDA will issue invoices to all applicants who submitted animal drug applications and supplemental animal drug applications on or after September 1, 2003, and through March 31, 2004. FDA will issue those invoices during April 2004, and payment will be due within 30 days of issuance date. FDA will include detailed payment instructions with the invoices. Please include the invoice numbers on all payments submitted in response to these invoices.

VII. When Do I Submit the Fee for Applications Submitted On or After April 1, 2004?

If you submit an animal drug application or supplemental animal drug application subject to fees on or after April 1, 2004, you must pay the fee for the application at or before the time the application is submitted. If you have not paid all ADUFA user fees owed, FDA will consider the application incomplete and will not accept it for review (21 U.S.C. 379j–12(e)).

VIII. Product, Establishment, and Sponsor Fees to be Established Soon

A separate document will be published in the **Federal Register** providing the rates and payment procedures for establishment, product, and sponsor fees. After that document has been published in the **Federal Register**, invoices will be issued for the FY 2004 establishment, product, and sponsor fees.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3410 Filed 2–17–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0047]

Determination That Chlorthalidone Tablets and Seven Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the eight drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or, (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in table 1 of this document have informed FDA that the drug products have been withdrawn from sale. (As requested by the applicants, FDA withdrew approval of NDA 17–503 for COMBIPRES and ANDA 60–462 for GARAMYCIN in the **Federal Register** of August 18, 2003 (68 FR 49481)).

TABLE 1

Application No.	Drug	Applicant
12–283	HYGROTON (chlorthalidone) Tablets, 25 and 50 milligrams (mg).	Aventis Pharmaceuticals, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807–2854.
17–503	COMBIPRES (clonidine hydrochloride (HCl); chlorthalidone) Tablets, 0.1 mg/15 mg, 0.2 mg/15 mg and 0.3 mg/15 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368.