Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Exploration of Low-Income Couples' Decision-Making (CDM) Processes study. This project will gather important information that will be useful for improving social services delivery approaches for working with individuals in couple relationships. The proposed collection will consist of two elements: (1) Focus groups with low-income couples; and (2) a telephone survey and observation of low-income couples. These data collection efforts will examine sources of conflict and assess decision-making processes among low-income couples—especially in relation to issues directly addressed by social service programs (e.g., employment, housing).

Respondents: Low-income couples.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Focus Group Discussion	16	1	2	32
Telephone Survey	80	1	.333333	27
Home Visit Setup and Administration of Oral History Interview and Decision Payoff Ratings	80	1	.666666	53
Paper Tower Task	80	1	.5	40
Economic Decision Task—Revealed Differences	80	1	.25	20
Interpersonal Conflict Discussion	80	1	.25	20
Video Recall Task	80	1	.83	66

Estimated Total Annual Burden Hours: 258.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 12, 2008.

Brendan C. Kelly,

Reports Clearance Officer.

[FR Doc. 08–777 Filed 2–20–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0082]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the agency) is publishing proposed recommendations for the reauthorization of the Animal Drug User Fee Act of 2003 (ADUFA) for fiscal years (FY) 2009 to 2013. These proposed recommendations were developed after a public meeting with stakeholders and discussions with regulated industry. ADUFA, enacted November 18, 2003, directs FDA to publish these proposed recommendations in the **Federal Register**; hold a meeting at which the public may present its views on such recommendations; and provide a period of 30 days for the public to provide written comments on such recommendations.

Dates and Time: The public meeting will be held on March 11, 2008, from 1 p.m. to 3:30 p.m.

Location: The public meeting will be held at 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. There is parking near the building. Photo identification is required to clear building security.

Contact Person: Roxanne Schweitzer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9705, FAX: 240–276–9744, e-mail: *Roxanne.Schweitzer@fda.hhs.gov*.

Registration: To ensure there is sufficient room we ask that you pre-register. Furthermore, to assist us in scheduling, we ask that you notify us through the registration process if you wish to make a public comment at the meeting. To register, please send an electronic mail message to *roxanne.schweitzer@fda.hhs.gov* by March 4, 2008. Your e-mail should include the following information: Name, Company, Company Address, Company Telephone Number, and E-mail Address. You will receive a confirmation within 2 business days.

FDA also will accept walk-in registration at the meeting site, but space is limited, and the agency will close registration when maximum seating capacity (approximately 500) is reached. FDA will try to accommodate all persons who wish to make a public comment at the meeting, including those who register at the meeting site, however, the time allotted for public comments may depend on the number of persons who wish to speak.

Additionally, please notify FDA (see *Contact Person*) if you need any special accommodations (such as wheelchair access or a sign language interpreter) at least 7 days in advance.

Comments: To ensure consideration of your comments regarding these proposed recommendations, you should

submit comments by April 14, 2008. Interested persons may submit written or electronic comments 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.regulations.gov*. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4 of ADUFA, enacted in 2003 (Public Law 108–130, November 18, 2003), authorized FDA to collect user fees from regulated industry that were to be dedicated to expediting the review of animal drug applications in accordance with certain performance goals identified in letters dated November 13, 2003, from the Secretary of Health and Human Services to the Chairman and Ranking Minority Member of the Energy and Commerce Committee of the House of Representatives and the Chairman and Ranking Minority Member of the Health, Education, Labor and Pensions Committee of the Senate.

Before ADUFA, FDA's animal drug review process was unpredictable and slow. Since the implementation of ADUFA there has been a significant improvement in FDA funding for the process for review of new animal drug applications (NADA), including significant investments in infrastructure and support. ADUFA has enabled FDA to increase the staff dedicated to the process of reviewing animal drug applications since 2003 by about 30 percent. As a result, the process for review of NADAs has become more predictable and faster.

Under ADUFA, the industry provides user fees that are available to FDA, in addition to appropriated funds, to spend on the animal drug review process. Moreover, FDA authority to collect user fees is ''triggered'' only when a base amount of appropriated funds, adjusted for inflation, is spent.

As part of ADUFA, FDA established review performance goals that have been phased in over a 5 year period. These performance goals run from FY 2004 through FY 2008 and are intended to achieve progressive, yearly improvements in the time for review of animal drug applications. FDA agreed to review and act on submissions within shorter periods of time each fiscal year. With the fifth and final year of ADUFA ending on September 30, 2008, FDA has agreed to review and act on 90 percent of the following submission types within specified times:

- Animal drug applications and reactivations of such applications within 180 days after submission date.
- Non-manufacturing supplemental animal drug applications (that is, supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after submission date.
- Investigational animal drug study submissions within 180 days after submission date.
- Investigational animal drug submissions consisting of protocols, that FDA and the sponsor consider to be an essential part of making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data, within 60 days after submission date.
- Administrative animal drug applications submitted after all scientific decisions have been made in the investigational animal drug process (that is, prior to submission of the animal drug application) within 60 days after submission date.

We began public consultation on ADUFA reauthorization with a public meeting held on April 24, 2007. The meeting included presentations by FDA and four speakers from the public. FDA presented information on ADUFA's successful performance and financial outcomes. The public participants represented different stakeholder groups, including consumer groups and regulated industry. The stakeholders were asked to respond to the following questions: (1) What is your assessment of the overall performance of the ADUFA program thus far and (2) What suggestions or changes would you make relative to the reauthorization of ADUFA? There was general agreement among the responding stakeholders that ADUFA should be reauthorized. In preparing proposed recommendations for ADUFA reauthorization (ADUFA II), FDA has also conducted technical discussions with regulated industry.

Congress also directed FDA to: (1) Publish in the **Federal Register** the proposed recommendations developed through this process after negotiations with the regulated industry, (2) present the proposed recommendations to the congressional committees specified in the statute, (3) hold a public meeting at which the public can present its views on the proposed recommendations, and (4) provide a period of 30 days for the public to provide written comment on the proposed recommendations.

We have now concluded discussions with industry and other stakeholders regarding reauthorization of ADUFA. The purpose of this document is to publish the recommendations FDA intends to propose to Congress and announce the dates for the upcoming public meeting and written comment period. After the public meeting and the close of the 30-day comment period, FDA plans to undertake a careful review of all public comments on these proposed recommendations.

II. What FDA is Proposing to Recommend for ADUFA II

For ADUFA II, as described in the following paragraphs, FDA plans to carry forward the performance goals from ADUFA and to propose additional goals related to proposed enhancements to the program. Proposed recommendations fall into three categories:

A. Proposals to Ensure Sound Financial Footing for the Animal Drug Review Program

B. Proposals to Enhance the Process for Review of Animal Drug Applications and

C. Improving the Information Technology (IT) Infrastructure for Animal Drug Review

A. Proposed Recommendations to Ensure Sound Financial Footing

Although user fees have provided substantial resources to FDA since the beginning of the program, user fees have not kept up with the increasing costs of the program associated with inflation in pay and benefit costs to the agency, and rent and rent-related costs. FDA has experienced an increase in costs of pay and benefits averaging 5.9 percent per year over the most recent 5 years. Non-salary costs, including the costs of rent and contract support, have also increased at the same rate. FDA is proposing changes to the financial provisions of ADUFA to address these shortcomings and place the program on sound financial footing so FDA can

continue with the program and enhance it.

1. The Proposals Set the Total Fee Revenue Amounts in Section 740(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379j–12(b)) to Assure That the Amounts Grow Sufficiently Each Year to Cover FDA's Anticipated Change in Costs Each Year

Based on an analysis of FDA's recent costs history and anticipated costs over the next 5 years, FDA expects the trend of increasing costs to continue. FDA's proposed recommendation to Congress, after consultation with regulated industry, is that the total fee revenue estimate for each of the 5 fiscal years of ADUFA II be the amounts set out in table 1 of this document.

TABLE 1.— ADUFA II FEE REVENUE TARGETS FOR EACH YEAR BEGINNING FY 2009

Fiscal Year	2009	2010	2011	2012	2013	Total
Total Revenue Target	$15,260,000	$17,280,000	$19,448,000	$21,768,000	$24,244,000	$98,000,000

With this level of proposed funding, FDA can have confidence that it will have a stable review workforce over the 5 years to be covered by ADUFA II. That assurance of a stable animal drug review workforce enables FDA to commit to a continuation of the FY 2008 performance goals, and to some additional performance goals.

2. Proposed Elimination of the Inflation Adjustment Applied to User Fees

Because the proposed total fee revenue amounts already have the costs of inflation built into them, there is no need for the inflation adjustment that was applied to the total revenue amounts that were in ADUFA. Accordingly, FDA proposes to eliminate the inflation adjustment provisions for the fee revenue amounts.

3. Technical Changes to Increase Administrative Efficiency of the User Fee Program

FDA is proposing several technical changes to ADUFA to clarify the original intent of several ADUFA definitions and to remove potential ambiguity. FDA's analysis of the impact of these changes indicates that they would be revenue-neutral and would have a minimal impact on industry fee-payers. These technical proposals include the following:

- Change the date for the calculation of the inflationary adjustment factor so it can be calculated before the President's budget is sent to Congress;
- Amend the definition of ''animal drug sponsor'' to clarify that it includes a holder of an approved application for an animal drug that is not marketed but the application has not been withdrawn;
- Add the definition of ''person'' to include affiliates, which continues the current interpretation of the act and parallels recent changes made to Prescription Drug User Fee Act;
- Change the application fee rate for combination applications subject to the criteria of section 512(d)(4) of act (21 U.S.C. 360b(d)(4)) (Animal Drug Availability Act combinations) to one-half the full application fee rate;
- Delay offsets for collections in excess of appropriations in any year to the final year of the ADUFA program and make offsetting reductions only if cumulative fees collected over the first 4 years exceed cumulative appropriations for fees over the same period; and
- Revise the authorization of appropriations in the act to match the total fee revenue amounts being proposed.

4. Triggers

ADUFA has three triggers. One is tied to appropriations for the process for review of new animal drug applications and two are tied to agency appropriations. FDA is proposing to leave the current triggers unchanged through ADUFA II. The three triggers are as follows:

(1) Fees may not be assessed for a FY beginning after FY 2003 unless appropriations for salaries and expenses of FDA for such FY (excluding the amount of fees appropriated for such FY) are equal to or greater than the amount of appropriations for the salaries and expenses of FDA for FY 2003 (excluding the amount of fees appropriated for such FY) multiplied by the adjustment factor applicable to the FY involved.

(2) The fees authorized shall only be collected and available to defray increases in the cost of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected for FY 2003 multiplied by the adjustment factor.

(3) The fees authorized by this section shall be retained in each FY in an amount not to exceed the amount specified in appropriation acts, or otherwise made available for obligations for such FY.

B. Enhancing the Process for Premarket Review

We are proposing changes to the performance goals that ADUFA established to enhance the process for review of animal drug applications. In addition to the performance goals established by ADUFA for the review of administrative animal drug applications submitted after all scientific decisions have been made in the investigational animal drug process (that is, prior to submission of the animal drug application) and the review of manufacturing supplemental animal drug applications and reactivations of such supplemental applications, FDA has agreed to revised performance goals for the following submission types:

(1) The agency will review and act on 90 percent of non-administrative animal drug applications and reactivations of such applications within:

- 180 days after the submission date (Day 180) if the agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
- 220 days after the submission date if the agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment

to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or

- 345 days after the submission date if the agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.

(2) The agency will review and act on 90 percent of non-manufacturing supplemental animal drug applications (i.e., supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within:

- 180 days after the submission date (Day 180) if the agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
- 220 days after the submission date if the agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or
- 345 days after the submission date if the agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.

(3) The agency will review and act on 90 percent of investigational animal drug study submissions within:

- 180 days after the submission date (Day 180) if the agency determines that the submission is complete or incomplete. A submission is incomplete if it would require substantial data or information to enable the agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission; or
- 220 days after the submission date if the agency determines that the submission of additional non-substantial data or information would likely complete the submission and electronically requests an end-review amendment to the submission on or before Day 180, but the sponsor fails to submit such amendment on or before Day 210. If a sponsor submits an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (270 days) will not apply, and a complete action letter will be issued by Day 220 for the original submission; or
- 270 days after the submission date if the agency electronically requests an end-review amendment to the submission on or before Day 180 and the sponsor submits an end-review amendment on or before Day 210.

(4) Review and act on 90 percent of investigational animal drug submissions consisting of protocols without substantial data, that the agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, within:

- 60 days after the submission date (Day 60) if the agency does not request an end-review amendment to the protocol and the agency determines that the protocol is acceptable, the agency will notify the sponsor of this decision electronically on or before Day 50, followed by a complete action letter; or
- 60 days after the submission date (Day 60) if the agency does not request an end-review amendment to the protocol and the agency determines that a protocol is not acceptable, the agency will notify the sponsor of this decision electronically, providing preliminary broad areas of protocol deficiency, on or before Day 50, with the subsequently issued complete action letter providing the detailed protocol assessment. The sponsor may contact the agency for a brief clarification of these areas of deficiency prior to the issuance of the complete action letter; or
- 75 days after the submission date if the agency electronically requests an end-review amendment to the protocol on or before Day 50, but the sponsor fails to submit such amendment within 10 days of the amendment request date. If a sponsor files an amendment more than 10 days after the amendment request date, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (refer to the following paragraph) will not apply, and a complete action letter will be issued by Day 75 for the original submission; or
- The greater of 60 days after the original protocol is received by the agency or 20 days after the amended protocol is received by the agency if the agency electronically requests an end-review amendment on or before Day 50 and the sponsor submits such amendment within 10 days of the date the amendment is requested.

(5) The following are additional efforts related to the performance goals for all submission types being proposed for ADUFA II to enhance the premarket review of animal drug applications:

- The agency and regulated industry agree to participate in 10 public workshops by the end of FY 2013 on mutually agreed-upon topics;
- To improve the timeliness and predictability of foreign preapproval inspections (PAIs), sponsors may voluntarily submit at the beginning of the calendar year, a list of foreign manufacturing facilities that are subjects of animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and may be subject to foreign PAIs for the following fiscal year;
- If such a list is voluntarily submitted the sponsor should submit a notification 30 days prior to submitting an animal drug application, a supplemental animal drug application, or investigational animal drug submission that informs the agency that the application includes a foreign manufacturing facility; (should any changes to the annual list occur after its submission to the agency, the sponsor may provide the updated information to the agency);
- The agency and the regulated industry agree to explore and discuss the applicable use of pharmacokinetic/pharmacodynamic data in the development and evaluation of new animal drugs

submitted for approval;

- The agency and the regulated industry agree to explore opportunities for exchange of information regarding the characteristics of a new animal drug, and to identify safety and effectiveness issues as early as possible in the drug development process; and
- The agency and regulated industry commit to work together to explore shorter timeframes commensurate with the magnitude of submitted pharmacokinetic/pharmacodynamic and other new animal drug characteristic data/information.

C. Improving the Information Technology (IT) Infrastructure for Animal Drug Review

In the recommended IT performance goals for ADUFA II, FDA will develop an electronic submission tool for industry submissions and online review capability within 24 months of appropriated ADUFA funds for FY 2009. The agency will consult with the sponsors in the development of this tool.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this document, FDA is announcing the convening of a public meeting to hear stakeholder views on the recommendations we propose to provide to Congress on the reauthorization of ADUFA.

FDA will conduct the meeting at 1 p.m. on March 11, 2008, at 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. In general, the meeting format will include presentations by FDA and an open comment period for the public. FDA will also give organizations and individuals an opportunity to submit written comments to the docket after the meeting.

B. Will Meeting Transcripts Be Available?

FDA will prepare a meeting transcript and make it available on the agency's Web site (*www.fda.gov*) after the meeting. FDA anticipates that transcripts will be available approximately 30 business days after the meeting.The transcript will also be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3267 Filed 2–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0081 (formerly Docket No. 2006D–0297)]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes a process for the evaluation and recommendation by the ICH Q4B Expert Working Group (EWG) of selected pharmacopeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions. Following favorable evaluations, ICH will issue topic-specific annexes with information about these texts and their implementation (the Q4B Outcomes). Implementation of the Q4B annexes is intended to avoid redundant testing by industry in favor of a common testing strategy in each ICH regulatory region.

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, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3542, Silver Spring, MD 20993–0002, 301–796–1242;or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.'' In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan,