† The toxicity data for agent T is inadequate for setting exposure limits. The very low vapor pressure for agent T precludes it as a vapor hazard under normal ambient conditions. For sulfur mustard and T mixtures, air monitoring for sulfur mustard alone should be sufficient under most circumstances to prevent exposure to T.

‡ To be evaluated with near-real-time instrument using shortest practicable analytic cycle time. No more than one exposure per work-shift.

§ The 30-minute period is not meant to imply that workers should stay in the work environment any longer than necessary; in fact, they should make every effort to exit immediately. IDLH conditions require highly reliable dermal and respiratory protection.

§§ Historic monitoring typically is used for time-weighted average (TWA) monitoring where the sample analyzed represents an extended time period, *e.g.*, 8 or 12 hours. Results are not known until laboratory analysis is completed after the sampling event. AELs using historic monitoring are set at levels at which health effects are not expected to occur for most workers. Exposures above the WPL–8, but below the STEL, likewise are not expected to result in significant health effects unless such exposures occur continuously for long periods.

References

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[FR Doc. 04–9946 Filed 4–30–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0185]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the animal drug user fee cover sheet.

DATES: Submit written or electronic comments on the collection of information by July 2, 2004.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug User Fee Cover Sheet; FDA Form 3547 (OMB Control Number 0910–0539)—Extension

Under section 740 of the act, as amended by the Animal Drug User Fee Act (ADUFA) (21 U.S.C. 379j-12), FDA has the authority to assess and collect certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Under the new statutory provisions (section 740(e) of the act, as amended by ADUFA), animal drug applications and supplemental animal drug applications for which the required fee has not been paid are considered incomplete and are not to be accepted for review by the agency. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 3546, is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made, is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected, to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

Inability to collect this information would delay the review process and would also delay receipt of revenue that is to be used to fund the review of animal drug applications during the current fiscal year. Respondents to this collection of information are new animal drug applicants or manufacturers.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING[1]

Section of the act as Amended by ADUFA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(a)(1) FDA Form 3547 (Cover Sheet)	69	1 time for each application	69	1	69

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

Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2003. FDA's Center for Veterinary Medicine estimates 69 annual responses that include 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per responses are based on past FDA experience with the various submissions and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: April 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0186]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fees and Fee Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the animal drug user fees and fee waivers and reductions.

DATES: Submit written or electronic comments on the collection of information by July 2, 2004.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDAs estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug User Fees and Fee Waivers and Reductions (OMB Control Number 0910–0540)—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (ADUFA) (Public Law 108–130) amended the Federal Food, Drug, and Cosmetic Act (the act) and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from, or a reduction of those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.'' This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions; what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA's process for reviewing requests. Respondents to this collection of information are new animal drug sponsors. Requests for waivers or