CBSA code	Urban area (constituent counties)	Wage index
	Mahoning County, OH.	
	Trumbull County, OH.	
	Mercer County, PA.	
49700	Yuba City, CA	1.1137
	Sutter County, CA.	
	Yuba County, CA.	
49740	Yuma, AZ	0.9281
	Yuma County, AZ.	

[1] At this time, there are no hospitals in these urban areas on which to base a wage index. Therefore, the urban wage index value is based on the average wage index of all urban areas within the State.

[FR Doc. E8–26142 Filed 10–30–08; 4:15 pm]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0572]

Agency Emergency Processing Under Office of Management and Budget Review; Implementation of the Animal Generic Drug User Fee Act of 2008; User Fee Cover Sheet Form FDA 3728

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the burden hours required for the Animal Generic Drug User Fee Cover Sheet, Form FDA 3728 and the timeframe requirement under the Animal Generic Drug User Fee Act of 2008 (AGDUFA) (21 U.S.C. 379j–21) for implementing the new user fee cover sheet Form FDA 3728.

DATES: Fax written comments on the collection of information by November 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and ''Implementation of the Animal Generic Drug User Fee Act of 2008 (21 U.S.C. 379j–21(a)); User Fee Cover Sheet Form 3728; Emergency Request.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The Federal Food, Drug, and Cosmetic Act (the act), as amended by AGDUFA authorizes FDA to collect user fees: (1) For certain abbreviated applications for a generic new animal drug, (2) on certain generic new animal drug products, and (3) on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs.

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.

Implementation of the Animal Generic Drug User Fee Act of 2008; User Fee Cover Sheet Form FDA 3728 (21 U.S.C. 379j–21); Emergency Request

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. Because the submission of user fees concurrently with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728, the Animal Generic Drug User Fee Cover Sheet, is designed to provide the minimum necessary information in order to: (1) Determine whether a fee is required for review of an application, (2) determine the amount of fee required, and (3) account for and track user fees.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. 379j–21.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3728	20	2	40	.08	3.2

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

Respondents to this collection of information are generic new animal drug applicants. Based on FDA's data base system, there are an estimated 20 sponsors of new animal drugs potentially subject to AGDUFA. The

annual reporting burden estimates in table 1 of this document are based on FDA's previous experience.

Dated: October 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26162 Filed 10–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0565]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

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 information collection contained in the guidance for industry on formal dispute resolution.

DATES: Submit written or electronic comments on the collection of information by January 2, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 of information, 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.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level (OMB Control Number 0910–0430)—Extension

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75) and dispute resolution during the investigational new drug (IND) process (§ 312.48) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§ 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910–0014), 314 (OMB Control No. 0910–0001), and part 601 (21 CFR part 601) (OMB Control No. 0910–0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(11)(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571 - OMB Control No. 0910–0014, and FDA Form 356h - OMB Control No. 0910–0338.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be