DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0572]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 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 Animal Generic Drug User Fee Cover Sheet Form FDA 3728 that further implements certain provisions of the Animal Generic Drug User Fee Act of 2008 (AGDUFA).

DATES: Submit written or electronic comments on the collection of information by May 11, 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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Implementation of the Animal Generic Drug User Fee Act of 2008; User Fee Cover Sheet Form FDA 3728—21 U.S.C. 379j-21—(OMB Control Number 0910–0632)—Extension

This collection of information is currently approved under the emergency processing provisions of the PRA of 1995 for 90 days. FDA is now seeking a 3-year clearance.

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

Dated: March 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5107 Filed 3–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0462]

Determination of Regulatory Review Period for Purposes of Patent Extension; CERENIA INJECTABLE SOLUTION

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CERENIA INJECTABLE SOLUTION and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.