TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
208.20	25	1	25	320	8,000
314.70(b)(3)(ii), 601.12(f)	5	1	5	72	360
208.24(e)	59,000	5,000	295 million	3 minutes	14,750,000
208.26(a)	1	1	1	4	4
Total					14,758,364

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

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32548 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending to January 15, 2013, the comment period for the notice of public meeting; request for public comments that published in the **Federal Register** of September 20, 2011 (76 FR 58279). In that notice, FDA requested comments on the Animal Drug User Fee Act (ADUFA) program to date and solicited suggestions regarding the features FDA should propose for the next ADUFA program. The Agency is taking this action to ensure that interested persons have the option of submitting comments throughout the reauthorization of ADUFA.

DATES: Submit either electronic or written comments by January 15, 2013.

ADDRESSES: Submit electronic comments to: *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donal Parks, Center for Veterinary Medicine (HFV–010), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8688, *ADUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 20, 2011, FDA published a notice of public meeting; request for comments to solicit input from the public on what FDA should consider including in the reauthorization of ADUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

Additional background materials, including the transcript of the public meeting, are available on the FDA's Web site.

The Agency is reopening the comment period to allow members of the general public or of stakeholder groups the opportunity to provide comments throughout the process of reauthorizing ADUFA.

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32567 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0655]

Animal Generic Drug User Fee Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending to January 15, 2013, the comment period for the notice of public meeting; request for public comments, published in the **Federal Register** of September 20, 2011 (76 FR 58277). In that notice, FDA requested comments on the Animal Generic Drug User Fee Act (AGDUFA) program to date and solicited suggestions regarding the features FDA should propose for the next AGDUFA program. The Agency is taking this action to ensure that interested persons have the option of submitting comments throughout the reauthorization of AGDUFA.

DATES: Submit either electronic or written comments by January 15, 2013.

ADDRESSES: Submit electronic comments to: *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donal Parks, Center for Veterinary Medicine (HFV–010), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8688, *AGDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 20, 2011, FDA published a notice of