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

public meeting; request for comments, to solicit input from the public on what FDA should consider including in the reauthorization of AGDUFA. 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 AGDUFA program thus far?

2. What aspects of AGDUFA 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 AGDUFA.

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. 2011–32565 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–0842]

Gluten in Drug Products; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain information and comments that will assist the Agency in its deliberations about ways to help individuals with celiac disease avoid the presence of gluten in drug products. In particular, FDA is interested in information on ingredients present in human drug products marketed in the United States that are currently derived from wheat, barley, or rye.

DATES: Submit either electronic or written information and comments by March 20, 2012.

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

FOR FURTHER INFORMATION CONTACT: Yana R. Mille, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 4152, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, (301) 796–1577.

SUPPLEMENTARY INFORMATION:

I. Background

A. Celiac Disease

Celiac disease (also known as celiac sprue and gluten-sensitive enteropathy) is an immune-mediated chronic inflammatory disorder affecting primarily the small intestine in genetically susceptible individuals (Refs. 1 and 2). In these individuals, the symptoms of celiac disease are triggered by the ingestion of wheat grain proteins collectively known as glutens (Ref. 3). The consumption of wheat gluten and similar proteins in barley and rye stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response. The resultant immediate inflammatory reaction damages the tiny, fingerlike protrusions called ''villi'' that line the small intestine and absorb nutrients from food (Refs. 4 and 5). In addition, over time, continued dietary exposure to gluten from wheat, barley, or rye can lead to impaired absorption of nutrients and a variety of other serious health problems (Ref. 4). For the purposes of this notice, the phrase ''wheat, barley, or rye'' includes wheat, barley, and rye, as well as the crossbred hybrids of these grains.

The prevalence of celiac disease in the United States is estimated to range from about 0.4 percent to about 1 percent of the population (Refs. 1 and 6). Celiac disease may go undetected in some individuals for years before they develop symptoms that cause them to seek medical attention (Refs. 7 and 8).

The standard treatment of celiac disease is the elimination of gluten-containing products from the diet (Ref. 1). Over time, strict avoidance of gluten from wheat, barley, or rye sources can resolve the symptoms, mitigate and possibly reverse intestinal damage, and reduce the health risks associated with celiac disease (Ref. 4). For some individuals with celiac disease, over time, failure to avoid consumption of gluten from wheat, barley, and rye can lead to severe and sometimes life-threatening complications (Refs. 9 to 11).

B. Gluten and Grains of Concern for Individuals With Celiac Disease

Technically, ''gluten'' is the storage protein of wheat that is composed of alcohol-soluble gliadins and insoluble glutenins (Ref. 2). Gliadins have been most closely studied and have been found to be the main antigen in celiac disease; however, glutenins also have been implicated in the disease (Refs. 12 and 13). The storage proteins of rye (secalins) and barley (hordeins) are similar in amino acid sequence to wheat gluten proteins and may trigger the same inflammatory response. For these reasons, the term ''gluten'' has been adopted to mean any proteins implicated in celiac disease (Ref. 2). In this notice, the term ''gluten'' is used to refer to the antigenic proteins of wheat, barley, and rye implicated in celiac disease.

The grains that contain gluten that can cause harm to individuals who have celiac disease are as follows: Wheat (including durum wheat, spelt wheat, and kamut), barley, rye, and crossbred hybrids of these grains (e.g., triticale, which is a cross between wheat and rye) (Refs. 14 and 15). While there is no general agreement among experts about the extent to which oats may present a hazard for individuals who have celiac disease (Refs. 16 to 18), it is generally believed that moderate amounts of oats can be ingested safely by the majority of individuals with celiac disease (Ref. 4).

C. Determination of Tolerable Daily Intake

The extent of risk posed to celiac patients by ingestion of trace amounts of gluten is uncertain. The majority of current data is from retrospective studies or nonrandomized, prospective, nonblinded studies without a placebo challenge group, limiting the conclusive evidence on safe thresholds for gluten intake. In the context of an ongoing rulemaking to define criteria for voluntary ''gluten-free'' claims on food,