TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement and labeling requirements, § 801.150(e)</td>
<td>90</td>
<td>20</td>
<td>1,800</td>
<td>4</td>
<td>7,200</td>
</tr>
</tbody>
</table>

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

The authority for AGDUFAs expires September 30, 2018. Without new legislation, FDA will no longer have the authority to collect user fees to fund the generic new animal drug review process. Prior to beginning negotiations with the regulated industry on AGDUFAs, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–13(d)(2)) requires FDA to: (1) Publish a notice in the Federal Register requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization including specific suggestions for changes to the goals referred in section 740A(a) of FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA’s Web site. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of AGDUFAs. 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 AGDUFAs program thus far?
2. What aspects of AGDUFAs should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of AGDUFAs and its current status.

II. Background

The Animal Generic Drug User Fee Act enacted in 2008 (Pub. L. 110–316; hereinafter referred to as “AGDUFAs”) amended the FD&C Act to authorize FDA’s first ever generic new animal drug user fee program. AGDUFAs provided FDA with additional funds to enhance the performance of the generic new animal drug review process. Furthermore, the authorization of AGDUFAs enabled FDA’s continued assurance that generic new animal drug products are safe and effective, and enabled FDA’s continued support for lower-cost alternatives to brand drugs for consumers. Under AGDUFAs, FDA agreed to meet review performance goals for certain submissions over 5 years from fiscal year (FY) 2009 through FY 2013. These review performance goals strive to expedite the review of abbreviated new animal drug applications (ANADAs) and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions.

Under AGDUFAs, the industry agreed to pay user fees that are available to FDA, in addition to appropriated funds, to spend on the generic new animal drug review process. Moreover, FDA’s authority to collect user fees is contingent on a certain level of spending from appropriated funds, as adjusted for inflation.

AGDUFAs established increasingly stringent review performance goals over a 5-year period from FY 2009 through FY 2013. By the 5th and final year of AGDUFAs, FDA agreed to review and act on 90 percent of the following submission types within the specified timeframes:

- Original ANADAs and reactivations within 270 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made during the JINAD process, i.e., prior to the submission of the original ANADAs) within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations within 270 days after the submission date.
- JINAD study submissions within 270 days after the submission date.
- JINAD protocol submissions within 100 days after submission date. JINAD protocol submissions consist of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis to make the decision to approve or not approve an ANADA or supplemental ANADA.

The additional resources provided under AGDUFAs enabled FDA to completely eliminate the backlog of ANADA and JINAD submissions by August 2010.

In 2013, before AGDUFAs expired, Congress passed the Animal Generic Drug User Fee Amendments of 2013 (Pub. L. 113–14; hereinafter referred to as “AGDUFAs II”) which included an extension of AGDUFAs for an additional 5 years (FY 2014 to FY 2018). AGDUFAs II is maintaining the AGDUFAs I performance goals regarding work queue procedures, timely meetings with industry, review of administrative ANADAs, review of protocols without substantial data, and amending similar applications and submissions. In addition, FDA agreed to the following program enhancements to further improve review processes:

- Developing a shortened review time process for certain ANADA and JINAD submissions.
- Permitting certain prior approval manufacturing supplements to be resubmitted as “Supplement-Changes Being Effect in 30 days.”
- Developing guidance for a two-phased Chemistry Manufacturing and Controls technical section submission and review process under the JINAD file.
- Permitting comparability protocols to be submitted as protocols without substantial data in a JINAD file.
- Improving timeliness and predictability of foreign pre-approval inspections.

In general, the meeting format will include presentations by FDA followed by an open public comment period. Registered speakers for the open public comments will be grouped and scheduled in advance of the meeting based on their affiliation (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry) and timing of their registration. FDA presentations are planned from 1 p.m. until 2 p.m. The open public comment portion of the meeting for registered and scheduled speakers is planned to begin at 2 p.m.

An opportunity for additional open public comments from meeting attendees will commence following the registered presentations, if time permits.

FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, not on policy issues.

B. Meeting Questions

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the AGDUFAs program thus far?
2. What aspects of AGDUFAs should be retained, changed, or discontinued to further strengthen and improve the program?
C. Registration

If you wish to attend and/or present at the meeting, please register by email to cvmadgdufa@fda.hhs.gov by May 4, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patients and consumer advocacy groups; or the regulated industry and whether you are requesting a scheduled presentation. Registration is free and available on a first-come, first-served basis. Early registration is recommended since seating is limited. FDA may limit the number of participants from each organization based on space constraints. Registrants will receive confirmation once their registrations are accepted. Onsite registration on the day of the public meeting will be based on space availability. FDA will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you need special accommodations due to a disability, please contact Cassie Ravo (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

D. Transcripts

Please be advised that as soon as the transcript is available, it will be accessible at http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUA/ucm270232.htm. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be made available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency’s Web site at http://www.fda.gov.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–09150 Filed 4–19–16; 8:45 am]