Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fees; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA), which authorizes FDA to collect fees and use them for the review of certain generic human drug applications and associated Type II active pharmaceutical ingredient (API) drug master files (DMFs), and for conducting associated inspections for fiscal years (FYs) 2018 through 2022. The legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. Following discussions with the regulated industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) directs FDA to present the recommendations to the relevant Congressional committees, publish the recommendations for the reauthorized program in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on October 21, 2016, from 9 a.m. to 5 p.m. Submit electronic or written comments to the public docket by November 7, 2016.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–N–0882 for ''Generic Drug User Fees; Public Meeting; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at *www.fda.gov/gdufa.*

FOR FURTHER INFORMATION CONTACT: Derek Griffing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993, 240–402–6980, email: *GenericDrugPolicy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations

for the reauthorization of GDUFA, which authorizes FDA to collect user fees related to human generic drugs and use them for the process of the review of certain generic human drug applications and associated submissions, to conduct related inspections, and to engage in other related activities for FYs 2018 to 2022. Without new legislation, FDA will no longer be able to collect user fees to fund the human generic drug review process for future fiscal years. Section 744(C)(d)(4) (21 U.S.C. 379j–43(d)(4)) of the FD&C Act requires that after FDA holds negotiations with regulated industry and periodic consultations with stakeholders, we do the following: (1) Present the recommendations to the relevant Congressional committees, (2) publish such recommendations in the **Federal Register**, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) consider such public views and comments and revise such recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy some of these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the Congressional committees.

II. What is GDUFA and what does it do?

GDUFA is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain DMFs, and certain facilities. It was originally enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) for a period of 5 years.

GDUFA's intent is to provide additional revenues so that FDA can hire more staff, improve systems, and establish a better-managed generic drug review process to improve access to quality, affordable generic medicines. As part of FDA's agreement with industry, the Agency agreed to certain performance goals. Major goals of GDUFA included: (1) Review and act on 90 percent of complete, electronic abbreviated new drug applications (ANDAs) submitted in FY 2017 within 10 months after the date of submission; (2) review and act on 90 percent of all ANDAs, ANDA amendments, and ANDA prior approval supplements (PASs) pending as of October 1, 2012 (*i.e.,* pre-GDUFA ''backlog'' submissions) by the end of FY 2017; (3) achieve risk-based inspection parity with respect to foreign and domestic generic API and generic finished dosage form manufacturers in FY 2017; (4) implement various efficiency enhancements on October 1, 2012; and (5) continue to undertake certain regulatory science initiatives. To date, FDA has met or exceeded all of its GDUFA commitments. The funding provided by GDUFA has enabled FDA to modernize the generic drug review process.

III. Proposed GDUFA II Recommendations

In preparing the proposed recommendations to Congress for GDUFA reauthorization (GDUFA II), we have conducted discussions with the regulated industry, and we have consulted with stakeholders as required by the law. We began the GDUFA reauthorization process with a public meeting held on June 15, 2015 (80 FR 22204, April 21, 2015). The meeting included presentations by FDA and a series of presentations from different stakeholder groups, including patient advocates, consumer groups, regulated industry, health professionals, and academic researchers. The stakeholders were asked to respond to the following questions:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

Following the June 2015 public meeting, FDA conducted negotiations with regulated industry and continued monthly consultations with public stakeholders from October 2015 through August 2016. As directed by Congress, FDA posted minutes of these discussions on its Web site at *http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm* (Under GDUFA **Federal Register** Notices). The proposed enhancements for GDUFA II address many of the top priorities identified by public stakeholders, the top concerns identified by regulated industry, and the most important challenges identified within FDA. These include the new submission review performance goals, review program enhancements, proposals to enhance regulatory science and expedite drug development for complex products, and proposals to enhance facility assessments. The full descriptions of these proposed recommendations can be found in the proposed GDUFA II Commitment Letter (proposed Commitment Letter) which will be posted prior to the public meeting on FDA's Web site at *www.fda.gov/gdufa.*

The enhancements are described below with reference to the section of the draft Commitment Letter where more detailed information can be found.

A. Submission Review Performance Goals

The GDUFA submission review performance goals were very complex. Different cohorts and tiers of submissions received very different review goals. The first cohort was the pre-GDUFA ''backlog.'' FDA agreed to take a first action on 90 percent of ANDAs pending as of the date of enactment (*i.e.,* ANDAs in the pre-GDUFA ''backlog'') by the end of FY 2017. However, none of these individual ANDAs received goal dates; FDA's metric goal applied to the pre-GDUFA ''backlog'' cohort as a whole. Moreover, there were no goals for any subsequent amendments submitted in response to FDA first actions on the backlog ANDAs. The second cohort comprised ANDAs submitted in Years 1 and 2 of the program (FYs 2013 and 2014). They also did not receive goal dates; FDA agreed to maintain pre-GDUFA levels of productivity in Years 1 and 2. The third, fourth, and fifth cohorts were ANDAs submitted in Years 3, 4, and 5 of the program (FYs 2015, 2016, and 2017). They obtained goal dates, which became more rigorous for each FY cohort. There was also, as a practical matter, an effective sixth cohort: In the course of implementing GDUFA, FDA informally committed to assign ''Target Action Dates'' to ''pre-Year 3'' ANDAs and ANDA amendments, which had not obtained formal goal dates under GDUFA. Target Action Dates were aspirational deadlines for action on these submissions.

For GDUFA II, FDA proposes two major changes to the submission review goals: First, all ANDAs and ANDA amendments would fall within a single, consolidated, review goals scheme to simplify and streamline program administration, promote review efficiency, and ensure that ''no submission is left behind.'' Second, GDUFA II would create faster review goals for priority submissions. For an ANDA, standard review would be 10 months from submission and priority review would be 8 months from submission. Priority review would be available for submissions that FDA considers to be public health priorities pursuant to CDER's Manual of Policies and Procedures (MAPP) 5240.3 Rev.2, ''Prioritization of the Review of Original

ANDAs, Amendments and Supplements,'' as revised (the CDER Prioritization MAPP),[1] if the applicant submits a pre-submission facility correspondence 2 months prior to the date of ANDA submission and the pre-submission facility correspondence is found to be complete and accurate and remains unchanged. The purpose of the pre-submission facility correspondence is to give the Agency lead time to conduct planning for a high volume of facility assessments, which frequently impact ANDA approvability. ''Pre-Submission Facility Correspondence'' is defined in section VII(S) of the proposed Commitment Letter.

The proposed submission review performance goals and procedures are set forth in section I of the proposed Commitment Letter.

B. Original ANDA Review Program Enhancements

GDUFA I contained several enhancements of a general nature related to review efficiency and communications transparency, such as the adoption of complete response letters (CRLs) and continuing communication of easily correctible deficiencies. These enhancements, as operationalized, did not meet industry's expectations and were reportedly commercially disruptive. The regulated industry expressed strong concerns. In response, during Years 2 and 3 of GDUFA I, FDA further developed and refined its ANDA review and communications procedures. These newly developed procedures, along with additional procedures developed in GDUFA II discussions with the regulated industry, are set forth in the proposed Commitment Letter. GDUFA II's ANDA review enhancements are substantially more specific and programmatic than corresponding elements of GDUFA I. They would refine and enhance the efficiency of the ANDA review process from start to finish.

The GDUFA II ANDA review program would start with submission of an ANDA. FDA would strive to determine whether to receive an ANDA within 60 days of the date of ANDA submission. The Agency would also issue a MAPP setting forth procedures for filing reviewers on communication of minor technical deficiencies and on deficiencies potentially resolved with information in the ANDA at original submission, in order to provide applicants with an opportunity for resolution within 7 calendar days. If such a deficiency is resolved within 7 calendar days, that deficiency would not be a basis for a refuse-to-receive decision. These ANDA receipt enhancements are set forth in section II(A) of the proposed Commitment Letter.

When FDA has received the ANDA and it is under review, FDA would use information requests (IRs) and/or discipline review letters (DRLs) to communicate review deficiencies beginning at about the mid-point of the review. Following the IR and/or DRL at about the mid-point of the review, IRs and/or DRLs would, as appropriate, continue for each review discipline on a rolling basis. Neither IRs nor DRLs would stop the review clock or add to a GDUFA goal. If an applicant is unable to completely respond within the timeframe requested by FDA, including any extensions that may be granted by FDA, then FDA would generally issue a CRL. FDA would continue to issue IRs and/or DRLs late in the review cycle, until it is no longer feasible, within the current review cycle, for the applicant to develop and FDA to review a complete response to the IR and/or DRL. FDA should continue to work through the goal date if in FDA's judgment continued work would likely result in an imminent tentative approval that could prevent forfeiture of 180-day exclusivity or an imminent approval. FDA would strive to act prior to a goal date when the review is done and there are no longer any outstanding issues. These program enhancements are set forth in sections II(B)(1)–(7). They would result in more opportunities for applicants to address deficiencies within the current review cycle, instead of waiting to receive them in a later-issued CRL. Such ''rolling review'' would promote a more efficient and effective review process and increase the overall rate of ANDA approval.

During the review, to provide transparency concerning review status and the potential timing of FDA action, regulatory project managers would timely provide review status updates upon request of an applicant's authorized representative, notify applicants of certain likely forthcoming major deficiencies, and notify applicants if FDA is likely to miss the goal date for a submission. These program enhancements are set forth in sections II(B)(8)–(10). They would support product launches and other types of business planning that can improve consumer access to generic drugs. ''Review Status Update'' is defined in section VII(W).

To facilitate timely approvals and tentative approvals, GDUFA II would provide that if applicants submit and maintain ANDAs consistent with the statutory requirements for approval under 505(j); respond to IRs and DRLs completely and within the timeframes requested by FDA, and timely submit all required information under 21 CFR parts 314 and 210, including information concerning notice (§ 314.95), litigation status (§ 314.107), and commercial marketing (§ 314.107); then FDA will strive to approve approvable ANDAs in the first review cycle; to approve potential first generics on the earliest lawful approval date, if known to FDA; and to tentatively approve first to file paragraph IV ANDAs so as to avoid forfeiture of 180-day exclusivity. This is set forth in section II(D) of the proposed Commitment Letter.

If the applicant receives a CRL rather than an approval, post-CRL teleconferences would be available. They would enable applicants to seek clarification concerning deficiencies identified in a CRL. FDA would grant appropriate requests for teleconferences concerning first cycle major and subsequent CRLs. There are metric goals for FDA to schedule and conduct post-CRL teleconferences. These program enhancements are set forth in sections II(B)(11)–(12).

With respect to dispute resolution, the proposed Commitment Letter would provide that applicants may review requests for reconsideration at the Division level or original signatory authority, as needed. Following requests for reconsideration, applicants may pursue formal dispute resolution above the Division level. There would be metric goals for FDA to respond to appeals above the Division level. This is set forth in section II(E).

The purpose of the proposed ANDA review transparency and communications enhancements is to improve predictability and transparency, promote the efficiency and effectiveness of the review process, minimize the number of review cycles necessary for approval, increase the overall rate of approval, and facilitate greater consumer access to generic drug products.

C. Pre-ANDA Program and Subsequent Mid-Review Cycle Meetings for Complex Products

The proposed GDUFA II pre-ANDA program for complex products is new. ''Complex Products'' is defined in section VII(I) of the proposed Commitment Letter and would generally include products with complex active

[1] *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf.*

ingredients, formulations, routes of delivery, or dosage forms; complex drug-device combination products; and other products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.

The pre-ANDA program would build an enhanced pathway for complex products, with product development, pre-submission, and mid-review-cycle meetings as set forth in sections III(D)–(F) of the proposed Commitment Letter. FDA would issue a guidance concerning the pathway. A prospective ANDA applicant granted a product development meeting would have the option of a pre-submission meeting and also the option of a mid-review-cycle meeting, subject to policies and procedures to be set forth in the guidance. A product development meeting would involve scientific exchange to discuss specific issues (for example, a proposed study design, alternative approach, or additional study expectations) or questions. In a product development meeting, FDA would provide targeted advice concerning an ongoing ANDA development program. A pre-submission meeting would give an applicant an opportunity to discuss and explain the content and format of an ANDA to be submitted, but would not include substantive review of summary data or full study reports. Post-submission, after the last key discipline has issued its IR and/or DRL, the Agency would schedule a teleconference with the applicant to discuss current concerns with the application and next steps. There would be metric goals for FDA to grant or deny and to conduct product development and pre-submission meetings.

The GDUFA II pre-ANDA program for complex products would also include metric goals for the issuance of product-specific guidance. Specifically, FDA would issue product-specific guidance identifying the methodology for developing drugs and generating evidence needed to support ANDA approval, for 90 percent of new chemical entity new drug applications that are approved on or after October 1, 2017, at least 2 years prior to the earliest lawful approval date. This goal would not apply to complex products. (The pre-ANDA program would have meetings for complex products for which product-specific guidance has not been issued.) FDA would strive to issue product-specific guidance for complex products as soon as scientific recommendations are available. In addition, FDA would continue to develop and issue product-specific guidance based on requests from the regulated industry and public health priorities as set forth in the CDER Prioritization MAPP. These enhancements are set forth in section III.C of the proposed Commitment Letter.

The pre-ANDA program would also include enhancements concerning controlled correspondence, regulatory science, the Inactive Ingredient Database, and safety determination letters. Notably, there would be separate review goals for complex controlled correspondence, to provide answers concerning discrete complex product development questions.

The purpose of the proposed GDUFA II pre-ANDA program for complex products is to clarify regulatory expectations for prospective applicants early in product development, help applicants develop more complete submissions, promote a more efficient and effective review process, and reduce the number of review cycles to obtain ANDA approval of complex products.

D. DMF Review Program Enhancements

GDUFA II also proposes targeted enhancements of current DMF review procedures. DMF review comments submitted to the DMF holder would be issued at least in parallel with the issuance of review comments relating to the DMF for the ANDA. The proposed Commitment Letter would also establish procedures and timelines for teleconferences to clarify DMF first-cycle review deficiencies. Once a DMF has undergone a full scientific review and has no open issues related to the review of the referencing ANDA, FDA would issue a First Adequate Letter. Once the DMF has undergone a complete review and the ANDA referencing it has been approved or tentatively approved, FDA would issue a No Further Comments Letter. By FY 2019, FDA would issue a guidance regarding post-approval changes to a Type II DMF and submission mechanisms for ANDA applicants who reference it. These enhancements are set forth in section IV of the proposed Commitment Letter.

E. Facility Assessment

FDASIA eliminated long-standing minimum inspection frequency requirements and directed FDA instead to inspect drug facilities globally on the basis of risk. Industry sources have asserted that the transition to a new paradigm has been commercially disruptive for the regulated industry, which over time had developed procedures and expectations based on the old model. While facility assessment cuts across multiple FDA drug programs, GDUFA II contains several facility-related enhancements targeted to generic industry-specific challenges.

To mitigate export related challenges identified by U.S.-based API manufacturers, FDA would issue a guidance explaining the risk-based site selection model, undertake outreach to foreign regulators on the risk-based site selection model, and support the export of safe and effective pharmaceutical products by the U.S.-based pharmaceutical industry, including through the issuance of communications conveying the current compliance status of U.S. manufacturing facilities to foreign regulators. These enhancements are set forth in sections V(A)–(D).

To mitigate ANDA sponsor concerns regarding the transparency and speed of facility assessment and its impact on ANDA approvability and product launch, FDA would communicate outstanding facility issues that could prevent approval of an ANDA or PAS through an IR, DRL, or CRL; and communicate to the facility owner final inspection classifications that do not negatively impact approvability of any pending application within 90 days of the end of the inspection. In addition, FDA would provide updates to and seek feedback from industry stakeholders regarding facility assessment. These enhancements would occur in FYs 2018 and 2019. They are described in section V(E).

To enhance transparency concerning the compliance status of GDUFA self-identified facilities and sites, FDA would update its existing, publicly available database beginning in FY 2019. This is described in section V(F).

F. Enhanced Accountability and Reporting

FDA proposes to build internal capacity to enable improved productivity and performance through regular assessment of progress towards GDUFA II goals, consistent methodologies for and timely reporting of GDUFA II metrics, transparent and efficient administration, and allocation and reporting of user fee resources.

FDA would conduct activities to develop a resource management planning function and a modernized time reporting approach to GDUFA II. This is described in section VI(A) of the proposed Commitment Letter.

FDA would also conduct activities to evaluate the financial administration of the GDUFA II program to help identify areas to enhance operational and fiscal efficiency, and to enhance transparency

of how GDUFA program resources are used. This is described in section VI(B).

The Agency would also expand its performance reporting by publishing robust monthly, quarterly and annual program performance metrics, as described in section VI(C). Enhanced performance reporting would enable Congress, the regulated industry, patient and consumer groups, and other stakeholders to better gauge the generic drug program's performance.

G. Enhancements to Fee Structure and Related Mechanisms To Provide Small Business Relief and Increase Predictability, Stability, and Efficiency

The proposed GDUFA II fee structure was designed to provide FDA with predictable, adequate funding for its human generic drug review programs, divide fee responsibilities equitably across different segments of the industry, and provide for small business considerations in a number of ways.

GDUFA II will be funded at a level commensurate with the amount of work associated with incoming ANDAs, since ANDAs are the primary workload driver of GDUFA. In order to provide a more predictable revenue base, GDUFA II will include an annualized ''program fee'' for ANDA holders. This annual fee will help offset the fluctuations in application fees from 1 year to another. An ANDA sponsor will pay a fee based on the total number of approved ANDAs that it and its affiliates own. ANDA sponsors will be split into three tiers based on ANDA ownership. The proposed tier cutoffs were determined by industry and are meant to reflect a firm's size, position in the market, and reliance on the program. With the introduction of the program fee, FDA has eliminated the fee for PASs.

In addition to program fees based on total ANDA ownership, the proposed fee structure includes two other distinct considerations for small businesses. First, under GDUFA I, a facility would pay an annual fee if it was listed in an ANDA, regardless of whether it was listed in any approved ANDAs. As a result, a facility that is listed only in pending applications is charged an annual GDUFA fee even though it has no generic drug revenue stream. Under GDUFA II, no facility or ANDA sponsor would be charged an annual fee until an ANDA in which it is listed is approved. Second, the proposed structure adds a facility category for contract manufacturing organizations (CMOs). CMOs are generally small businesses that are hired by ANDA sponsors to manufacture their generic drugs. Alternatively, some ANDA sponsors manufacture their own drugs. Under the GDUFA II fee structure, CMOs will pay one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.

The full descriptions of these proposed recommendations will be posted prior to the public meeting on FDA's Web site at *www.fda.gov/gdufa*.

IV. Purpose and Scope of the Meeting

If you wish to attend this meeting, please email your registration information to Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) by October 7, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and is on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

The meeting will include a presentation by FDA and a series of invited panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

If you wish to present at the meeting, please include your presentation materials along with your registration information to Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) by October 7, 2016. Early requests for oral presentations are recommended due to possible space and time limitations. FDA will accommodate as many requests for oral presentations as possible and will do so on a first-come, first-served basis. The time allotted for presentations may depend on the number of persons who wish to speak. Those requesting to present will receive confirmation once they have been accepted. Onsite requests for oral presentations on the day of the meeting will be based on time and space availability. If the entire meeting time is not needed, FDA may end the public meeting early.

V. Transcript Request

Please be advised that as soon as a transcript is available, it will be accessible at *www.fda.gov/gdufa* and in this docket at *http://www.regulations.gov*.

It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy 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: September 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23111 Filed 9–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2610]

A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket'' that appeared in the **Federal Register** of September 19, 2016 (81 FR 64177). The document announced the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (such as academic researchers, regulated industries, consortia, and patient groups) on a list of biomarkers that were used as outcomes to develop FDA-approved new molecular entities (NMEs) and New Biological Therapeutics from October 2007 to December 2015. The document was published without an active Web link. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring MD 20993–0002, 301–796–9115, *lisa.granger@fda.hhs.gov*.