The Generic Drug Review Dashboard

This is the Quarterly Update (data as of October 1, 2016) to the Generic Drug Review Dashboard. The Office of Generic Drugs (OGD) is providing this update to improve transparency as we continue implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA), which is part of OGD's comprehensive and ongoing efforts to make quality, affordable generic medicines available to the American public.

This report includes the **Current Submission Status Snapshot** for:

- Total Original ANDA Workload Activity for Pre-GDUFA Year 3 Application Cohorts *(Figure 1)*
- Total Original ANDA Workload Activity for All Unapproved Applications *(Figure 2)*

The report also includes the **Activity and Review Communications Tracking** for:

- Original ANDAs - Total Agency Actions for the Past 12 months (October 2015 – September 2016) *(Figure 3)*
- ANDA Prior Approval Supplements - Total Agency Actions for the Past 12 months (October 2015 – September 2016) *(Figure 4)*

This information provides industry and the public with clearer insight into the:

- proportion of the ANDA workload that is pending review by FDA from the last report
- proportion of the ANDA workload that is pending response by industry from the last report
- ongoing review communications between FDA and industry

Note: Numbers included in this report reflect current data at the time of report preparation and may change based on refreshed counts in our tracking systems, including application status updates. These numbers are not intended for Congressional reporting purposes or for GDUFA annual reporting.

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Current Submission Status Snapshot

The figures below provide snapshots of the current workload for original ANDAs including applications pending review by FDA and pending response by applicants (referred to below as industry). They also display the portion of the workload that has been completed, including, for example, approved ANDAs. These snapshots capture the flow of ANDAs between FDA and industry through the issuance of and response to review communications (shown as monthly averages below).

Figure 1. Total Original ANDA Workload Activity for Pre-GDUFA Year 3 Application Cohorts

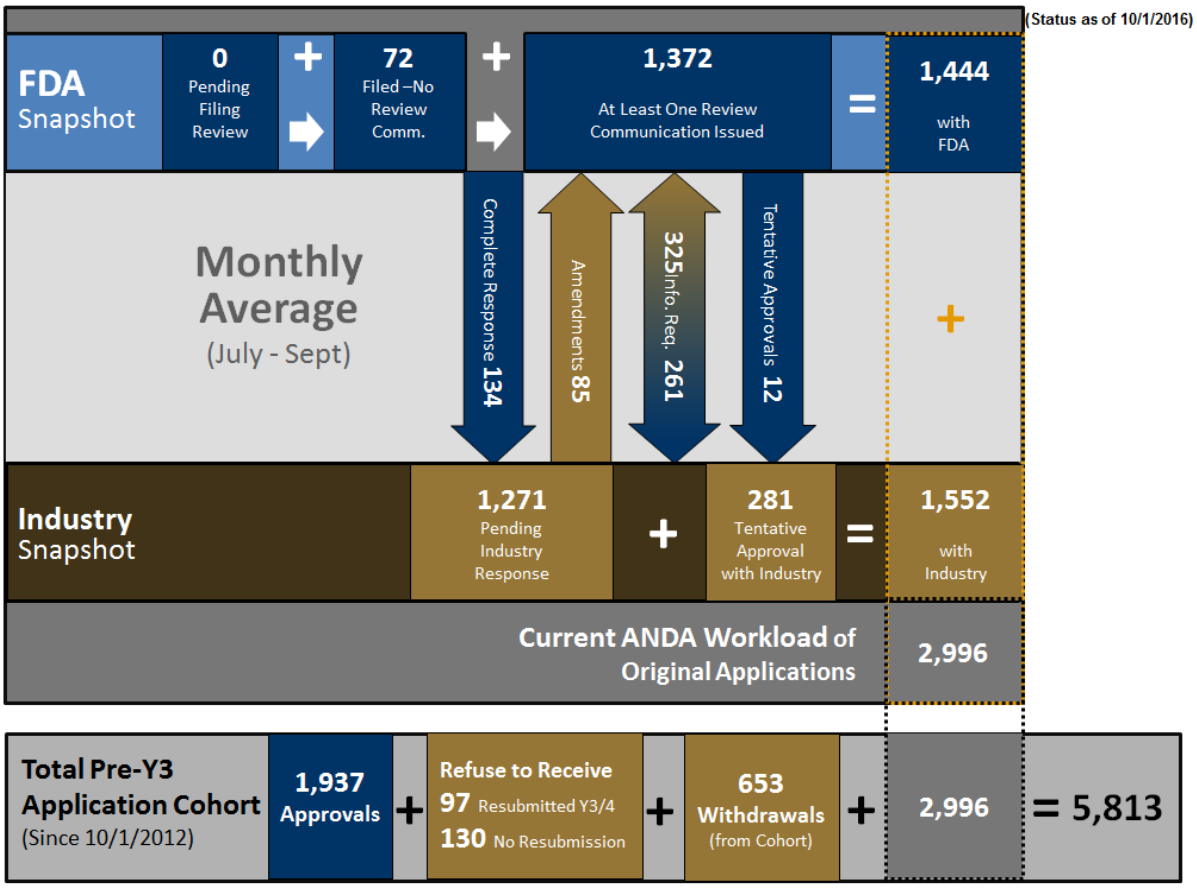

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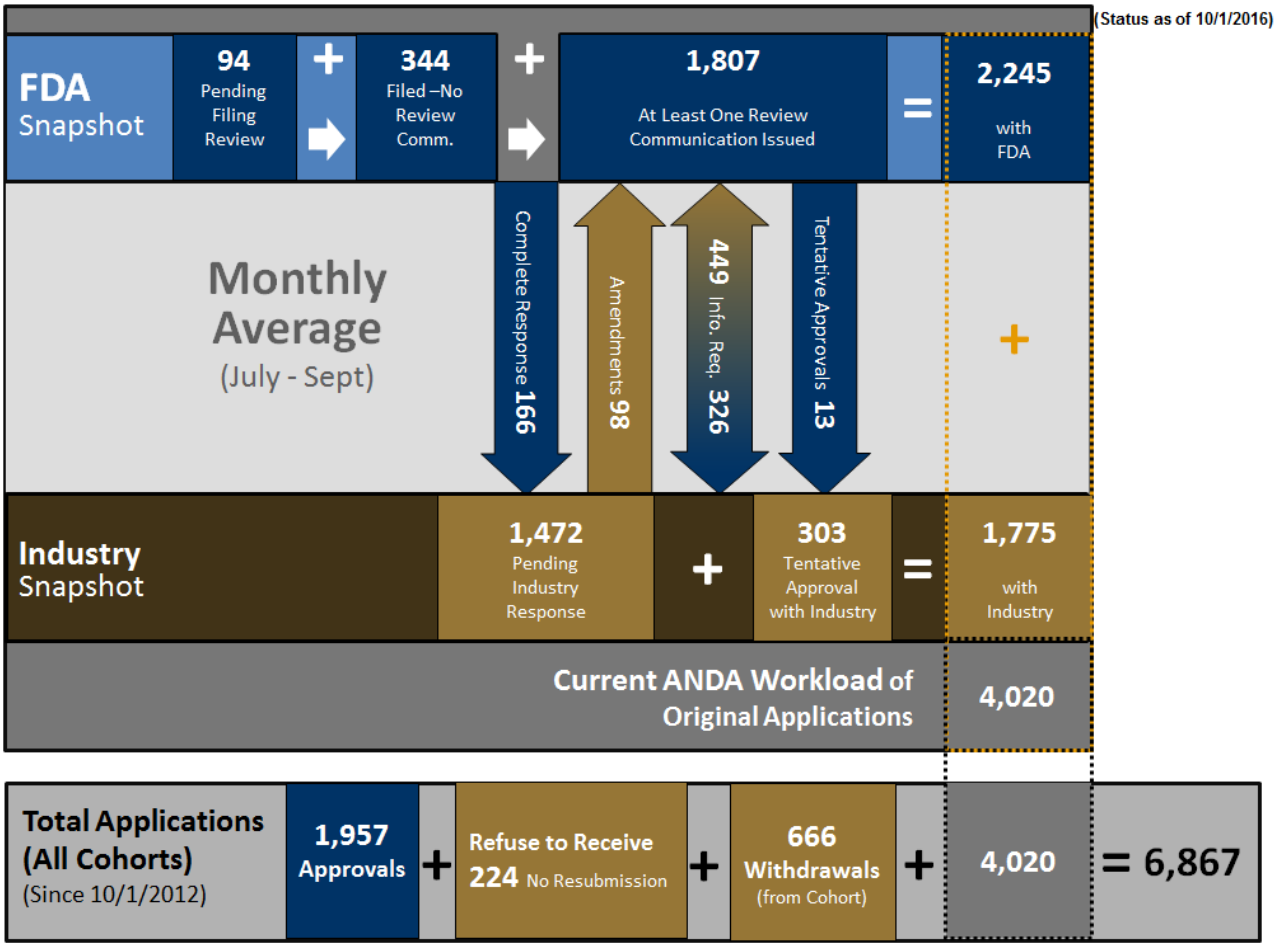
Figure 2. Total Original ANDA Workload Activity for All Unapproved Applications



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Action and Review Communications Tracking

These charts represent 1) original ANDAs and 2) ANDA prior approval supplements (PASs) for which FDA has issued review communications and/or taken an action. The chart showing regulatory actions and review communications issued on PASs demonstrates FDA's workload consistency with these submissions. The increase in ECD/IRs issued demonstrates the Agency's commitment to increasing communications with industry.

Figure 3. Original ANDAs: Total Agency Actions for the Past 12 Months (October 2015 – September 2016)

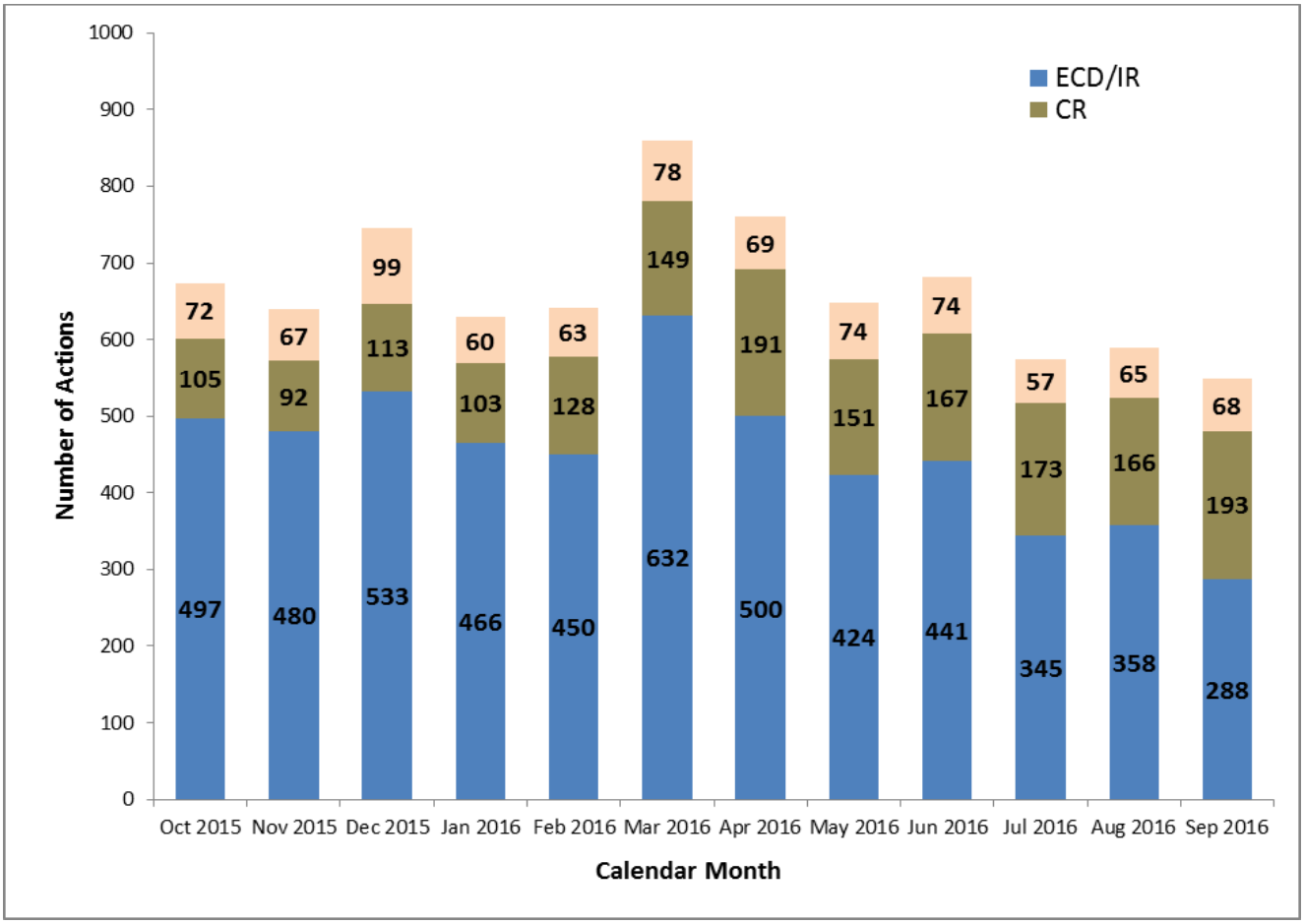

Figure Legend: AP + TA = approval + tentative approval; CR = complete response; ECD/IR = easily correctible deficiency/information request.

Figure 4. ANDA Prior Approval Supplements: Total Agency Actions for the Past 12 Months (October 2015 – September 2016)

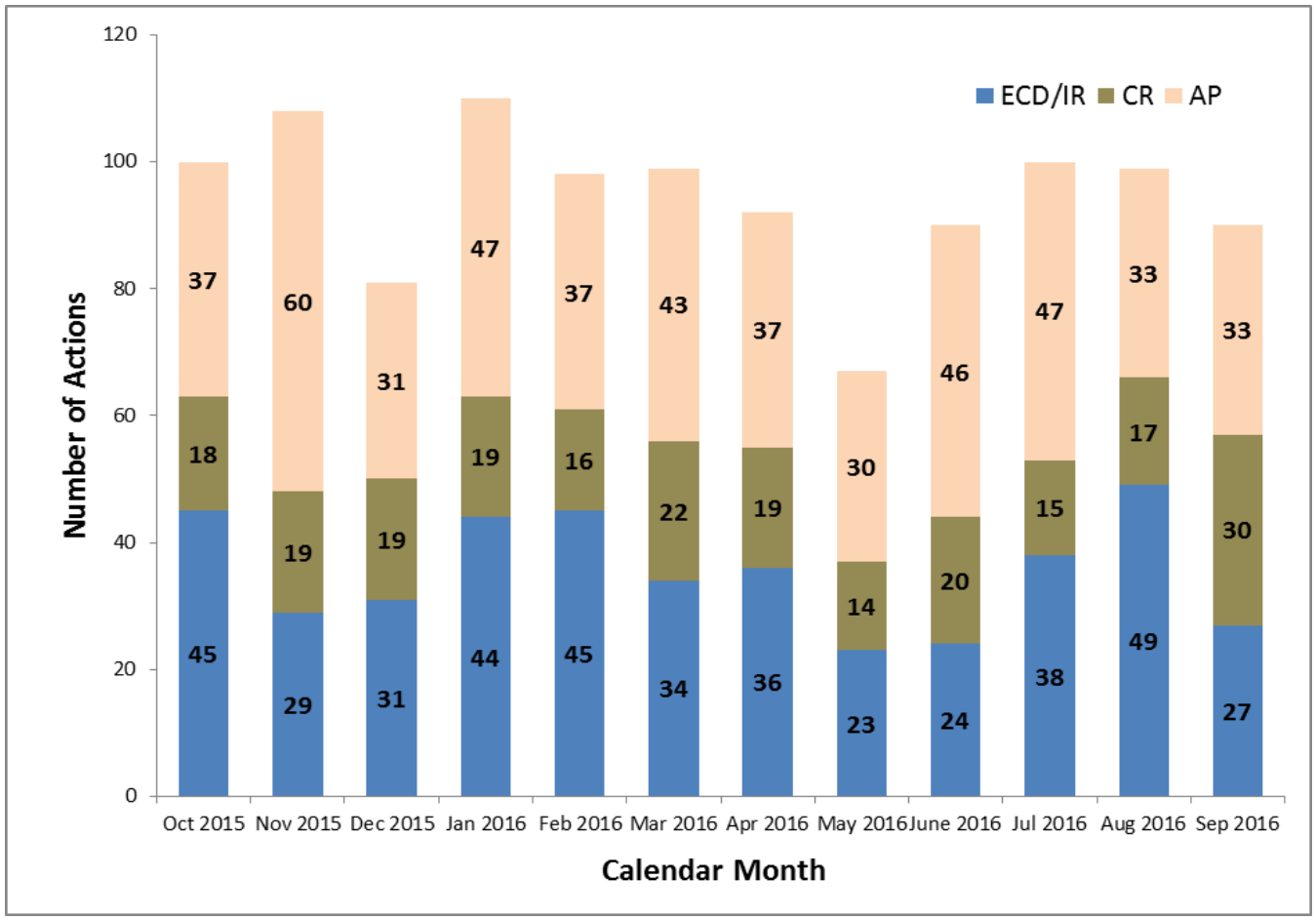

Figure Legend: AP = approval; CR = complete response; ECD/IR = easily correctible deficiency/information request.

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Key Terms

Additional terminology can be found in the GDUFA Glossary.

- **Amendment:** Submission by an applicant to revise existing information or provide additional information to a pending ANDA; can be for more than one review discipline in a given ANDA. Under GDUFA, amendments may be solicited, unsolicited or administrative in nature.
- **At Least One Review Communication Issued:** Indicates that FDA has issued an Information Request (IR), Easily Correctable Deficiency (ECD), Complete Response[1] (CR) or Tentative Approval (TA) to a pending ANDA. Industry may have responded to the communication.
- **Complete Response (CR) letter:** a written communication to an applicant or DMF holder from FDA usually describing all of the deficiencies that the agency has identified in an abbreviated application (including pending amendments) or a DMF that must be satisfactorily addressed before the ANDA can be approved. Complete response letters will reflect a complete review and will require a complete response from industry to restart the clock.[2] When a citizen petition (CP) may impact the approvability of the ANDA, FDA will strive to address, where possible, valid issues raised in a relevant CP in the CR letter. If a CP raises an issue that would delay only part of a CR, a response that addresses all other issues will be considered a CR.
- **Current Original ANDA Workload:** Unapproved ANDAs either pending FDA review or pending industry (i.e., the applicant's) response to a review communication.
- **Easily Correctable Deficiency (ECD):** A request issued to an applicant during review for further information or clarification. The response to an ECD, in FDA's judgment, requires only a modest expenditure of FDA resources. An applicant should be able to respond to an ECD quickly as the applicant should already possess or be able to quickly retrieve the information needed for an adequate response to an ECD.
- **Filed – No Review Communication:** Indicates that an ANDA has been received, but no review communications (e.g., IR, ECD, CR) have been issued to that ANDA applicant.
- **Information Request (IR):** A request issued to an applicant during review for further information or clarification that is needed or would be helpful to allow completion of the discipline review.
- **Pending Filing Review:** Indicates that an ANDA is pending a determination by OGD's Division of Filing Review (DFR) if the ANDA may be received for review (i.e., that the ANDA submission is sufficiently complete to permit a substantive review pursuant to 21 CFR 314.101(b)).
- **Pending Industry Response:** Indicates that FDA issued a review communication to an applicant, but the applicant has not submitted a response to the review communication.
- **Review Communication**: Indicates the issuance by FDA of an IR, ECD, CR letter or TA to the applicant.
- **Tentative Approval (TA) with Industry:** Indicates that FDA has issued a TA to an ANDA. Tentative approval indicates that an ANDA meets the statutory requirements for approval, but cannot be approved because there is a period of unexpired exclusivity for the reference listed drug (RLD) referenced by the ANDA. Tentatively approved ANDAs are considered pending with the applicant for the ANDA workload because the applicant must submit an amendment to the tentatively approved ANDA requesting full approval to FDA; requiring additional review by FDA.
- **Withdrawal (WD):** Indicates that an applicant has withdrawn its ANDA from review and for consideration for approval by FDA.

[1] Includes CRs with and without inspections.

[2] See CFR 314.110 and http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084138.htm.