The Generic Drug Review Dashboard

January 2016

This is the first publication of the Generic Drug Review Dashboard. The Office of Generic Drugs (OGD) is providing this update to improve transparency and communication as we continue to implement the Generic Drug User Fee Amendments of 2012 (GDUFA). OGD's implementation of GDUFA is part of our 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 Calendar Year 2015 (CY2015) (Figure 3)
- ANDA Prior Approval Supplements - Total Agency Actions for Calendar Year 2015 (CY2015) (Figure 4)

This information is designed to provide industry and the public with clearer insight into the:

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

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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 applicant (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

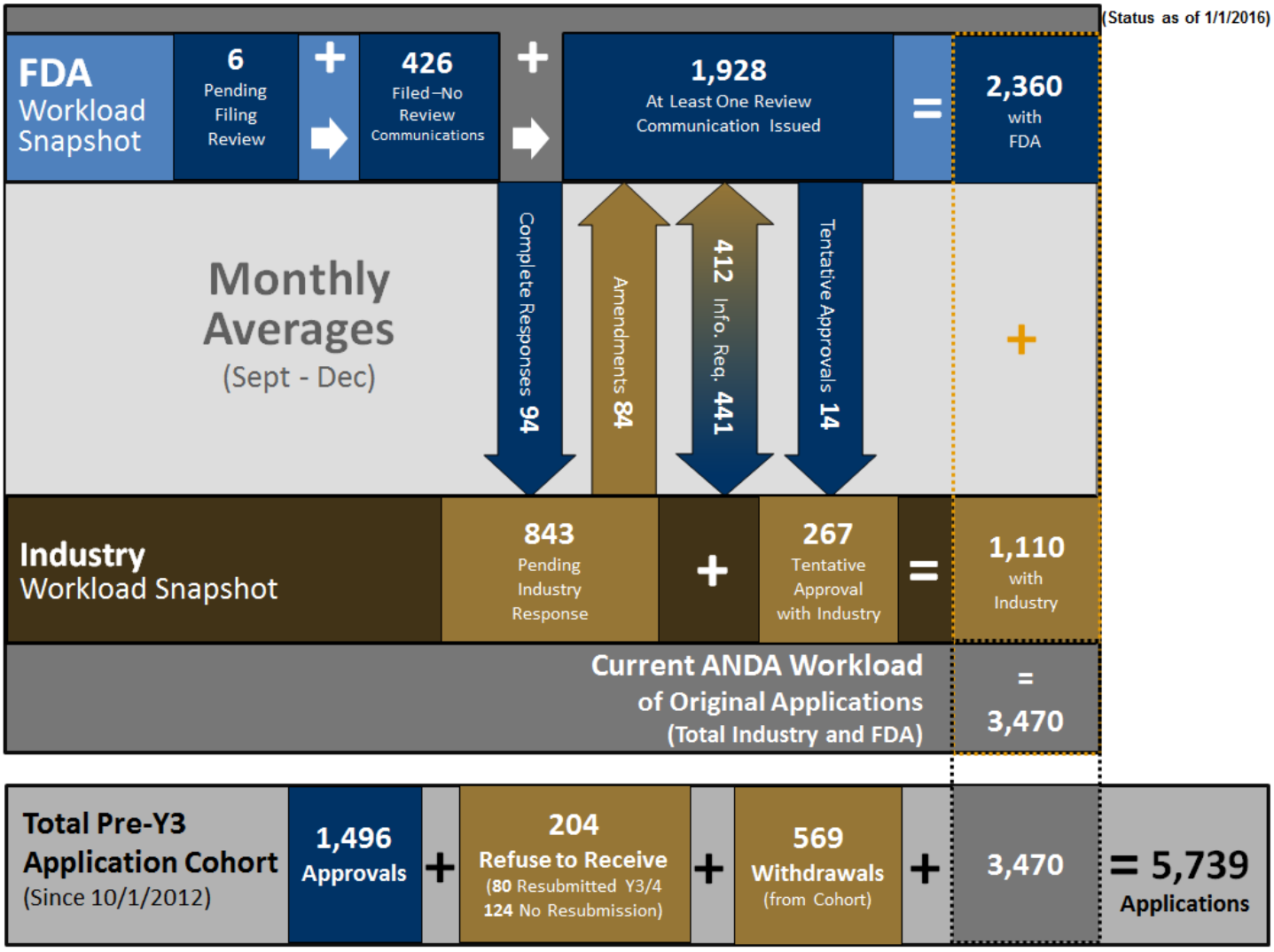
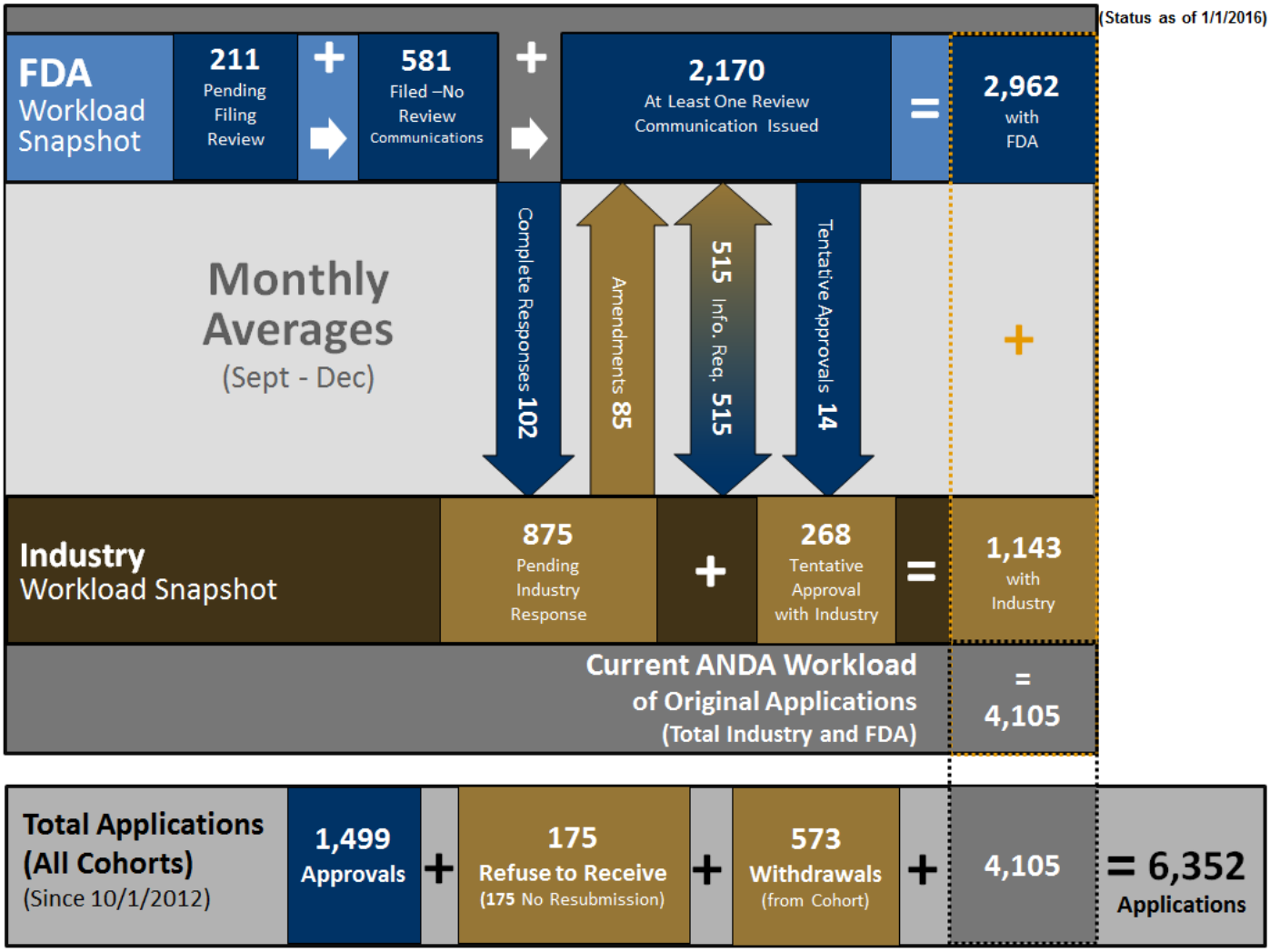


Figure 2. Total Original ANDA Workload Activity for All Unapproved Applications



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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 to PASs demonstrate 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 Calendar Year 2015 (CY2015)

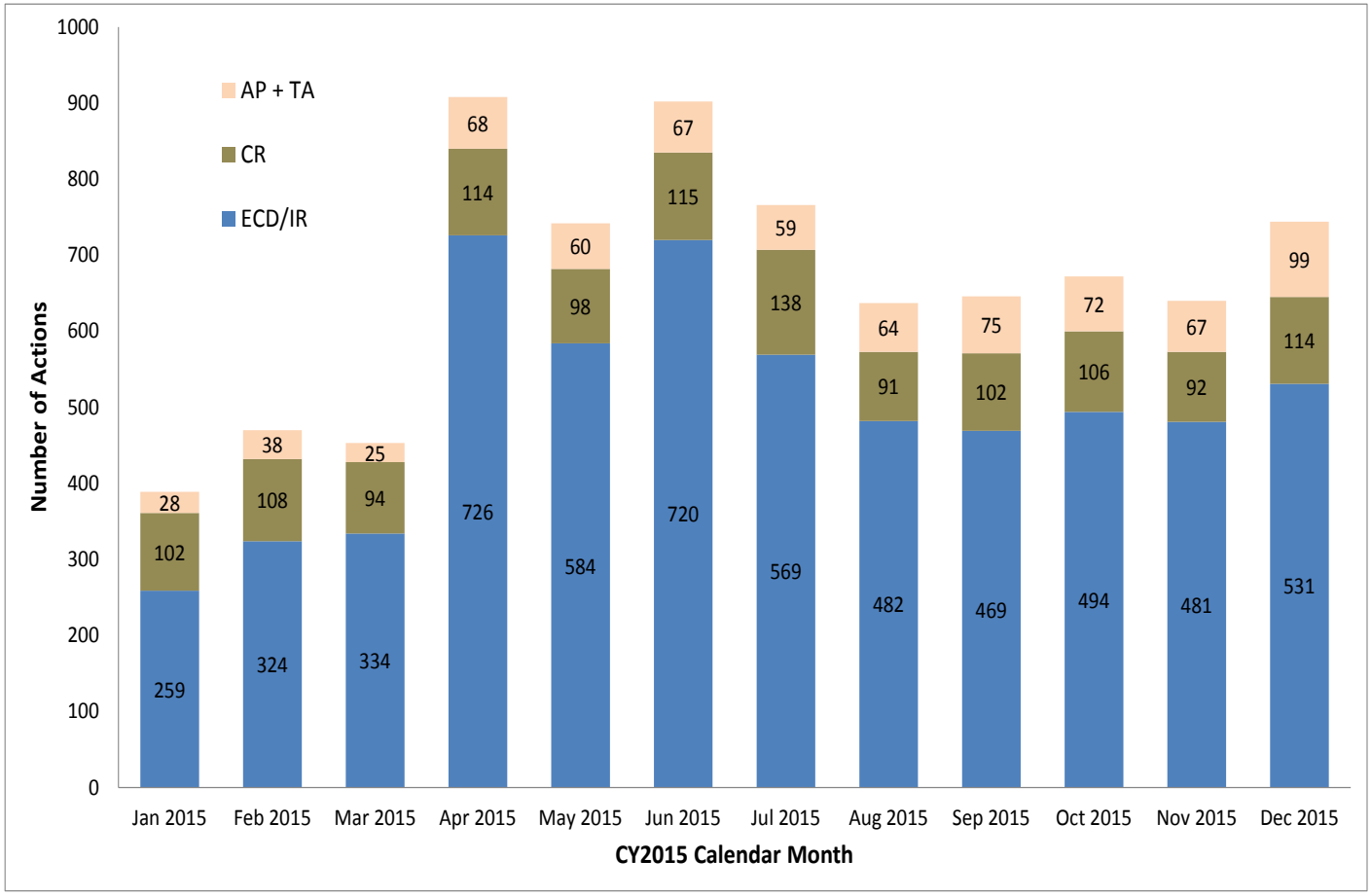

Figure Legend: AP + TA = approval + tentative approval; CR = complete response; ECD/IR = easily correctible deficiency/information request.[1]

[1] Numbers reflect current data at the time of posting 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.

Figure 4. ANDA Prior Approval Supplements - Total Agency Actions for Calendar Year 2015 (CY2015)

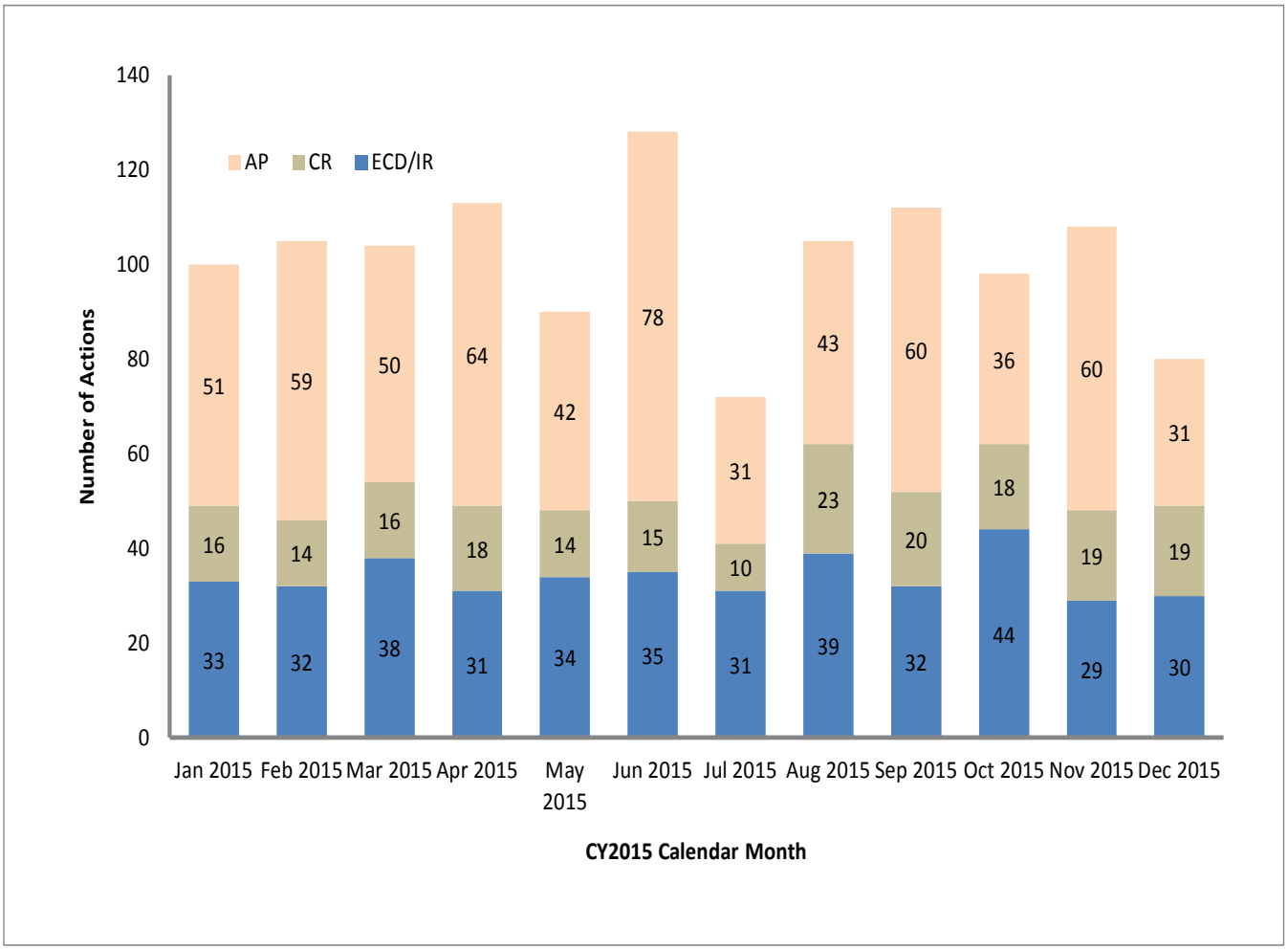

Figure Legend: AP = approval; CR = complete response; ECD/IR = easily correctible deficiency/information request.[2]

[2] Numbers reflect current data at the time of posting 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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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[3] (CR) or Tentative Approval (TA) to a pending ANDA. Industry may have responded to the communication.
Current Original ANDA Workload: Unapproved ANDAs either pending FDA review or pending industry (i.e., the applicant's) response to a review communications.
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.
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 of a pending ANDA.
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.

[3] Includes CRs with and without inspections.