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# Therapeutic Products Directorate

## Drug Submission Performance Quarterly Report

April – June

2018



Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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# OVERVIEW

The Therapeutic Products Directorate's (TPD) Quarterly Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive quarters: from April - June 2017 to April - June 2018. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

## General Information

There are several steps involved in the drug submission review<sup>1</sup> and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

**Submissions Received** are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

**Workload** is the number of submissions “under active review” on the last day of the quarter. **“Backlog”** is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

**Approvals**<sup>2</sup> are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed “on hold” awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

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<sup>1</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

<sup>2</sup> Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further Clarification refer to the [Guidance Document: Notice of Compliance with Conditions \(NOC/c\)](#).



A **review cycle completion**<sup>3</sup> is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set [performance standard](#)<sup>4</sup> which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

**"First Cycle Review" Approvals** are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude “refiled”<sup>5</sup> submissions.

Any questions or comments on this report should be forwarded to:

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101 Tunney's Pasture Driveway, Tunney's Pasture  
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: [hc.osip-bppi.sc@canada.ca](mailto:hc.osip-bppi.sc@canada.ca)

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<sup>3</sup> Review cycles include all types e.g. Review 1, Review 2, Review QN. The total number of “review decisions” may surpass the total number of review cycle completions as they include cancellations/withdrawals that occur while the submission is 'inactive'. For example, a withdrawal can be issued when a company fails to respond to a notice of non-compliance within the allotted time frame. A 'Cancelled by Company' is counted as a review decision when a company sends a cancellation letter after the submission's original materials have been accepted for review.

<sup>4</sup> Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the [Guidance for Industry: Management of Drug Submissions](#). This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

<sup>5</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#)

# ACRONYMS

## Submission Types

ANDS	- Abbreviated New Drug Submission
CTA	- Clinical Trial Application
CTA-A	- Clinical Trial Application-Amendment
DINA	- Application for a Drug Identification Number
DIND	- Application for a Drug Identification Number – Disinfectant Product
DINF	- Application for a Drug Identification Number - Category IV Product – (Labelling Standard)
NDS	- New Drug Submission
NC	- Notifiable Change – New Drug
PDC	- Post-DIN Changes
PRNDS	- Request for Priority Review Status: New Drug Submission
PRSNDS	- Request for Priority Review Status: Supplemental New Drug Submission
SANDS	- Supplemental Abbreviated New Drug Submission
SNDS	- Supplemental New Drug Submission
SNDS-C	- Supplemental New Drug Submission – CONFIRMATORY

## Documents

NOC	- Notice of Compliance
NOC-c	- Notice of Compliance with Conditions
Issuable NOC (Patent)	- NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	- NOC on Hold due to changes (Prescription to Non-Prescription)
NON	- Notice of Non-Compliance
NOD	- Notice of Deficiency
NON Withdrawal	- Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	- Notice of Deficiency Withdrawal Letter

## Fee Categories

Fee Category	Fee Category Description
<b>New Active Substance (NAS)</b>	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
<b>Clinical or Non-Clinical Data and Chemistry and Manufacturing data</b>	Submissions based on clinical or non-clinical data <b>and</b> chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or Non-Clinical Data Only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
<b>Comparative Studies</b>	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
<b>Chemistry and Manufacturing Data Only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
<b>Published Data Only</b>	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
<b>Switch from Prescription to Nonprescription Status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient on the <a href="#">Prescription Drug List</a> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
<b>Labelling Only<sup>6</sup></b>	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
<b>Administrative Submission<sup>7</sup></b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants<sup>8</sup></b>	Submissions and applications that include data in support of a disinfectant.
<b>Drug Identification Number (DIN) - Labelling Standards</b>	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information, please refer to the [Guidance Document - Fees for the Review of Drug Submissions and Applications](#)

<sup>6</sup> For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

<sup>7</sup> For additional information, please consult the ["Changes in Manufacturer and/or Product Name Policy" \(2015\)](#)

<sup>8</sup> The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

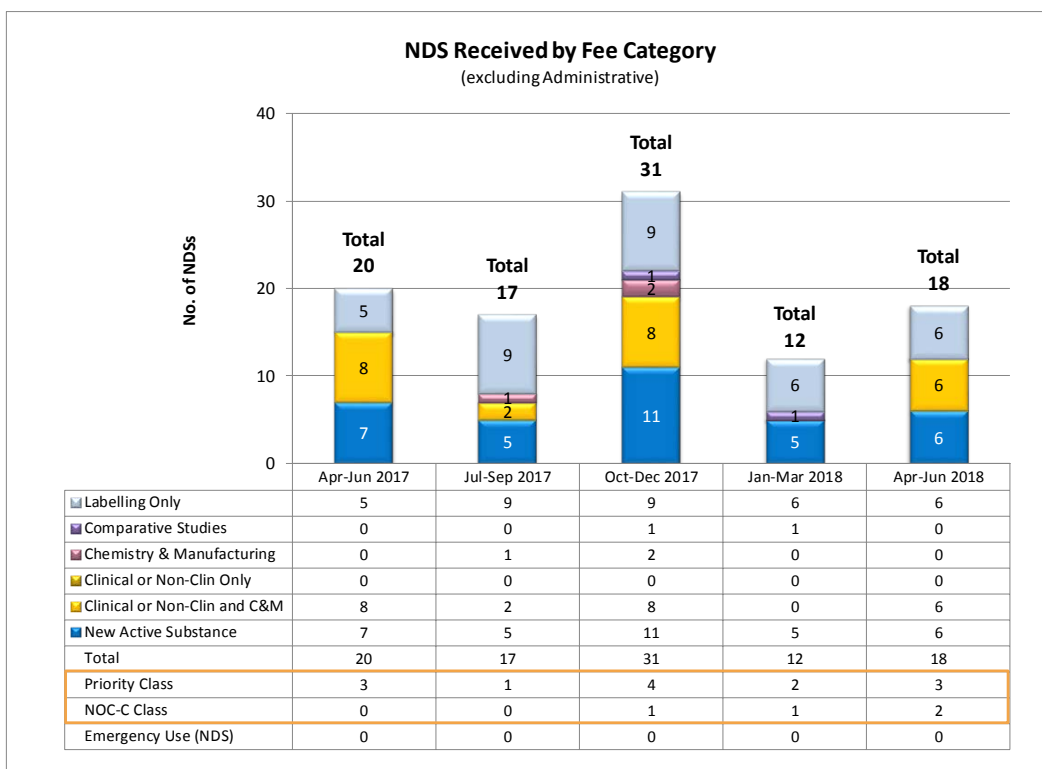
**New Drug Submission  
(NDS)**

**&**

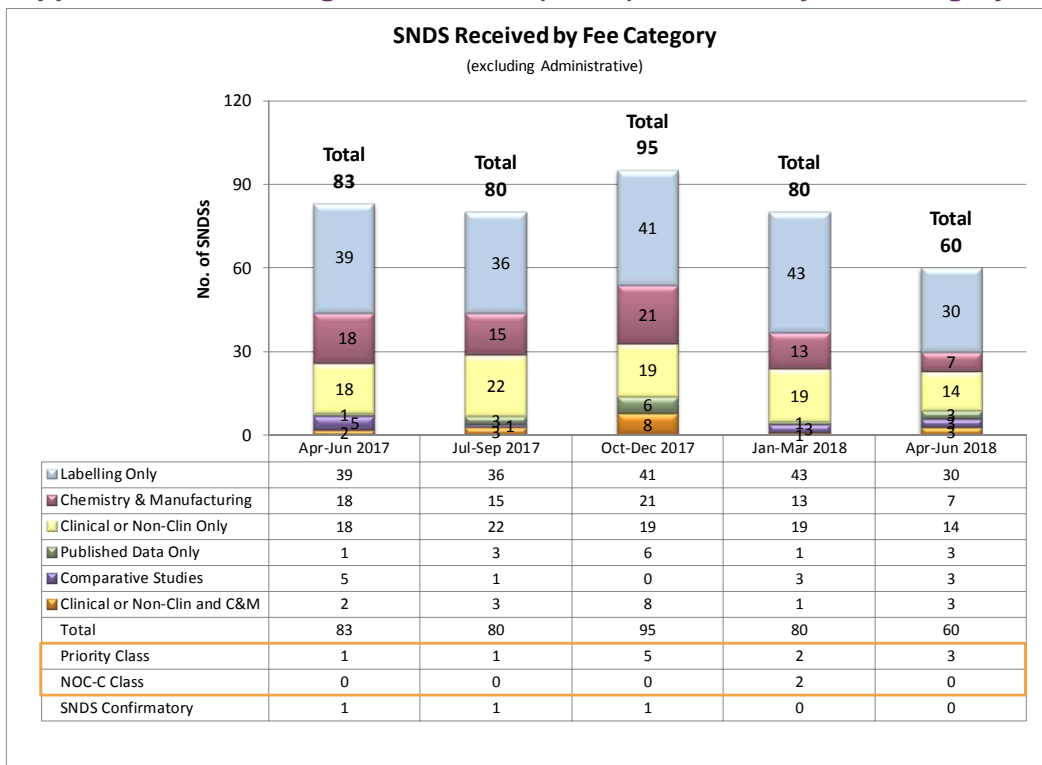
**Supplemental New Drug Submission  
(SNDS)**

## SUBMISSIONS RECEIVED

### New Drug Submissions (NDS) Received by Fee Category



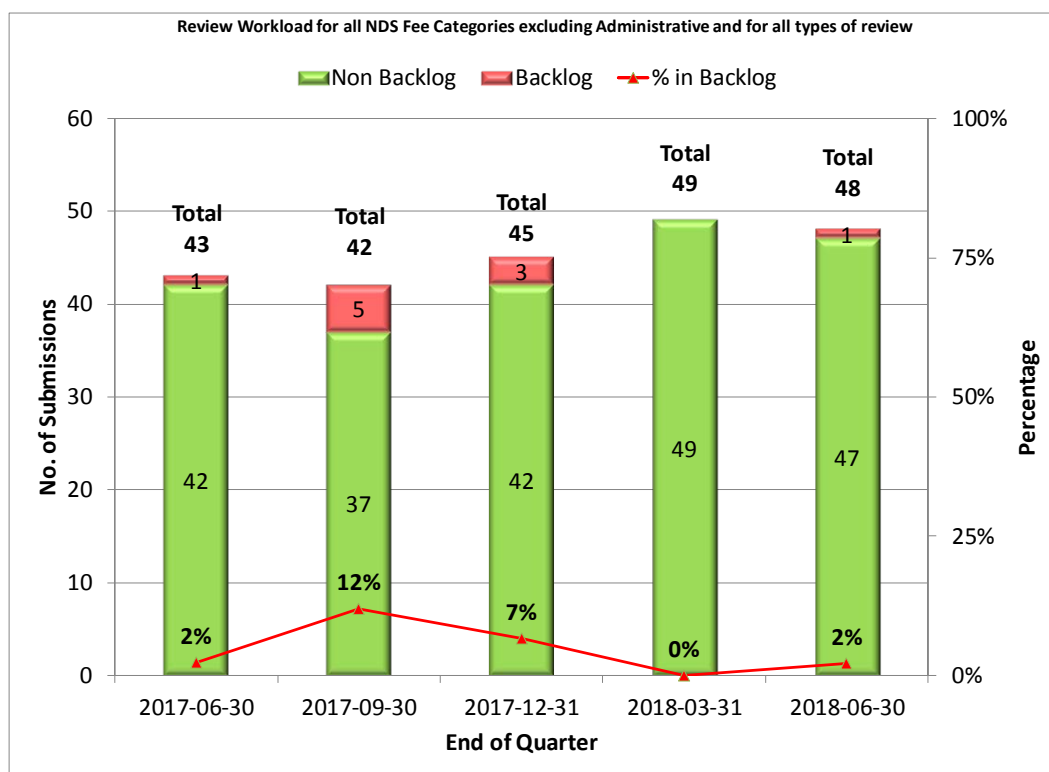
### Supplemental New Drug Submissions (SNDS) Received by Fee Category



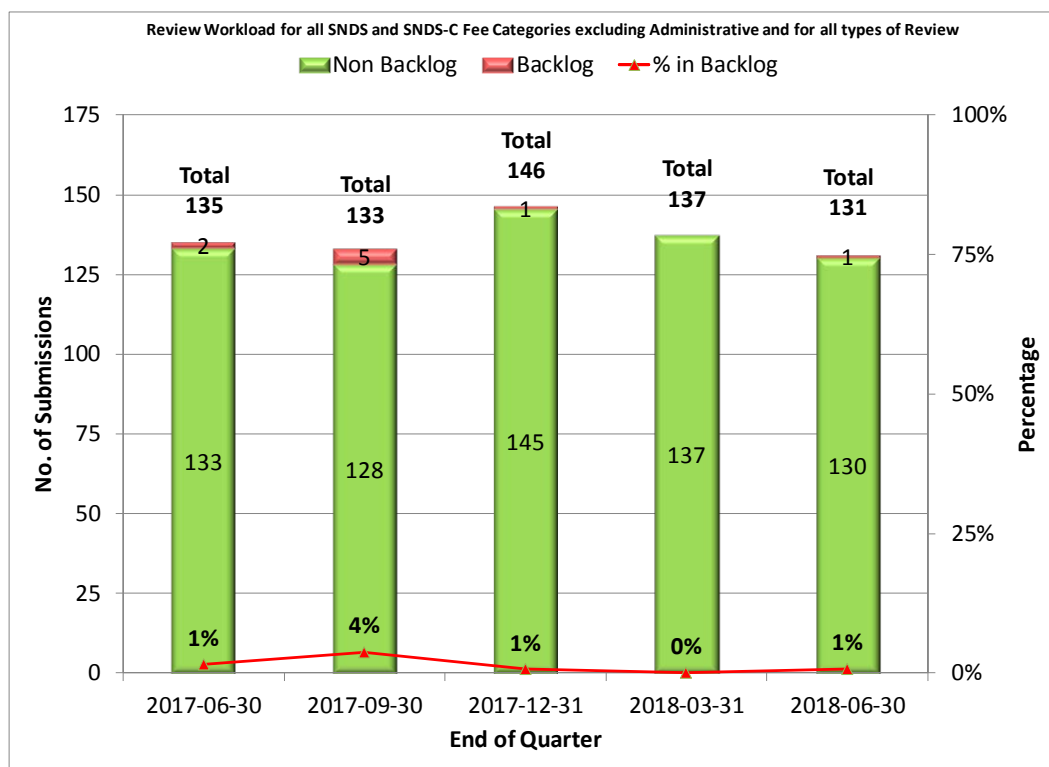
<sup>9</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

## WORKLOAD

### New Drug Submission (NDS) Review Workload / Backlog



### Supplemental New Drug Submission (SNDS) Review Workload / Backlog

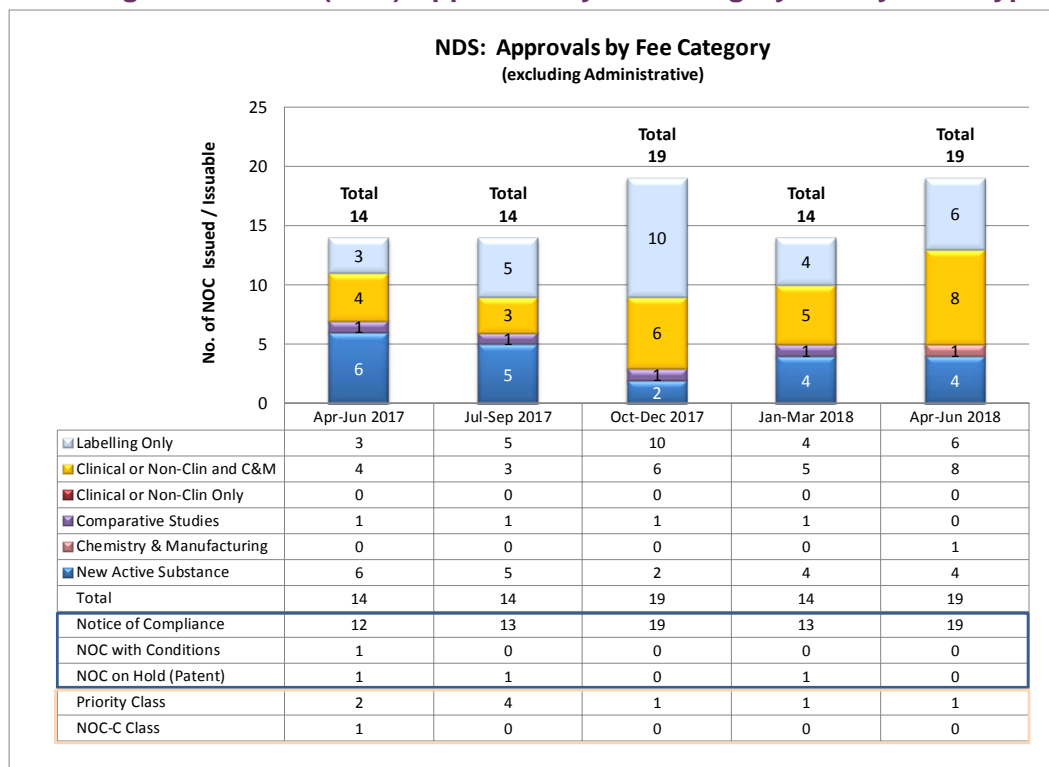
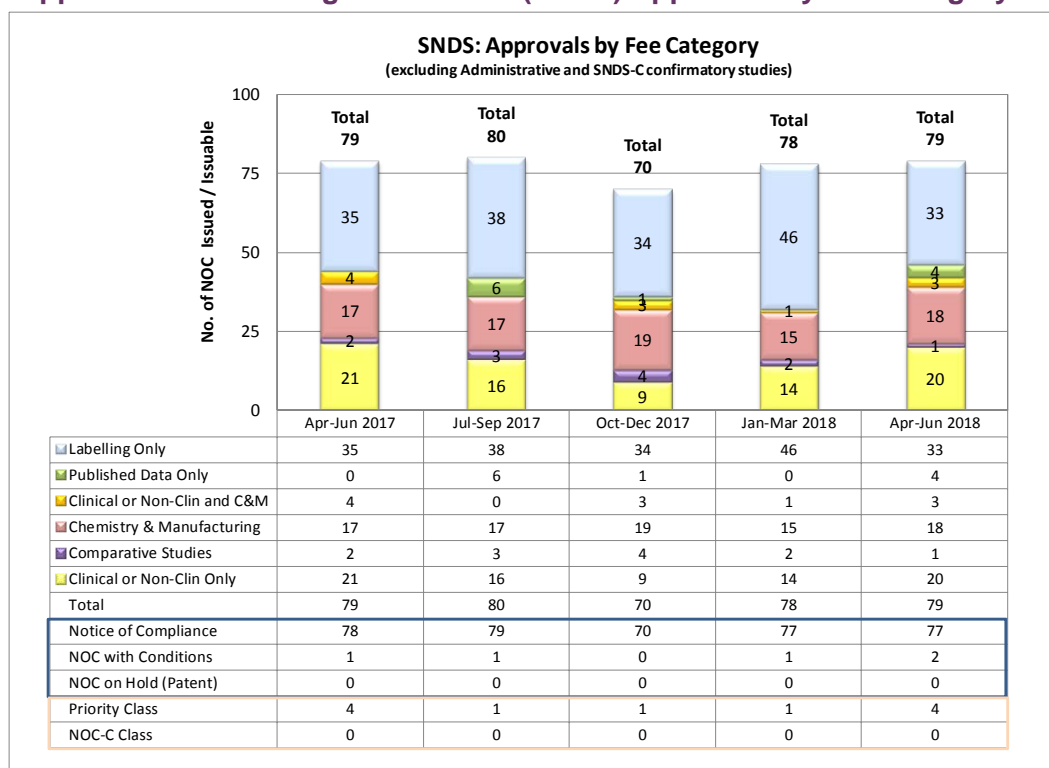


**WORKLOAD****New Drug Submission (NDS) Review Workload by Fee Category**

TPD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Labelling Only</b>	<b>4</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>4</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Comparative Studies</b>	<b>2</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>1</b>
<i>Backlog</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Chemistry &amp; Manufacturing</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Clinical or Non-Clin Only</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Clinical or Non-Clin and C&amp;M</b>	<b>23</b>	<b>24</b>	<b>20</b>	<b>18</b>	<b>16</b>
<i>Backlog</i>	<i>0</i>	<i>3</i>	<i>2</i>	<i>0</i>	<i>0</i>
<b>New Active Substance</b>	<b>14</b>	<b>13</b>	<b>20</b>	<b>25</b>	<b>27</b>
<i>Backlog</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>0</i>	<i>1</i>
<b>Total</b>	<b>43</b>	<b>42</b>	<b>45</b>	<b>49</b>	<b>48</b>
<b>Non Backlog</b>	<b>42</b>	<b>37</b>	<b>42</b>	<b>49</b>	<b>47</b>
<b>Backlog</b>	<b>1</b>	<b>5</b>	<b>3</b>	<b>0</b>	<b>1</b>
<b>% in Backlog</b>	<b>2%</b>	<b>12%</b>	<b>7%</b>	<b>0%</b>	<b>2%</b>
<b>Priority (subset)</b>	<b>5</b>	<b>3</b>	<b>3</b>	<b>6</b>	<b>7</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

**Supplemental New Drug Submission (SNDS) Review Workload by Fee Category**

TPD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Labelling Only</b>	<b>23</b>	<b>23</b>	<b>28</b>	<b>19</b>	<b>15</b>
<i>Backlog</i>	<i>1</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>1</i>
<b>Comparative Studies</b>	<b>7</b>	<b>8</b>	<b>4</b>	<b>4</b>	<b>8</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Chemistry &amp; Manufacturing</b>	<b>37</b>	<b>38</b>	<b>34</b>	<b>30</b>	<b>26</b>
<i>Backlog</i>	<i>0</i>	<i>2</i>	<i>1</i>	<i>0</i>	<i>0</i>
<b>Clinical or Non-Clin Only</b>	<b>55</b>	<b>53</b>	<b>63</b>	<b>63</b>	<b>60</b>
<i>Backlog</i>	<i>1</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Clinical or Non-Clin and C&amp;M</b>	<b>5</b>	<b>6</b>	<b>9</b>	<b>11</b>	<b>13</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Published Data</b>	<b>8</b>	<b>5</b>	<b>8</b>	<b>10</b>	<b>9</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>135</b>	<b>133</b>	<b>146</b>	<b>137</b>	<b>131</b>
<b>Non Backlog</b>	<b>133</b>	<b>128</b>	<b>145</b>	<b>137</b>	<b>130</b>
<b>Backlog</b>	<b>2</b>	<b>5</b>	<b>1</b>	<b>0</b>	<b>1</b>
<b>% in Backlog</b>	<b>1%</b>	<b>4%</b>	<b>1%</b>	<b>0%</b>	<b>1%</b>
<b>Priority (subset)</b>	<b>2</b>	<b>2</b>	<b>5</b>	<b>7</b>	<b>7</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>SNDS-C (Confirmatory)</b>	<b>7</b>	<b>6</b>	<b>5</b>	<b>3</b>	<b>2</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

**APPROVALS<sup>10</sup>****New Drug Submission (NDS) Approvals by Fee Category and by NOC Type****Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type**

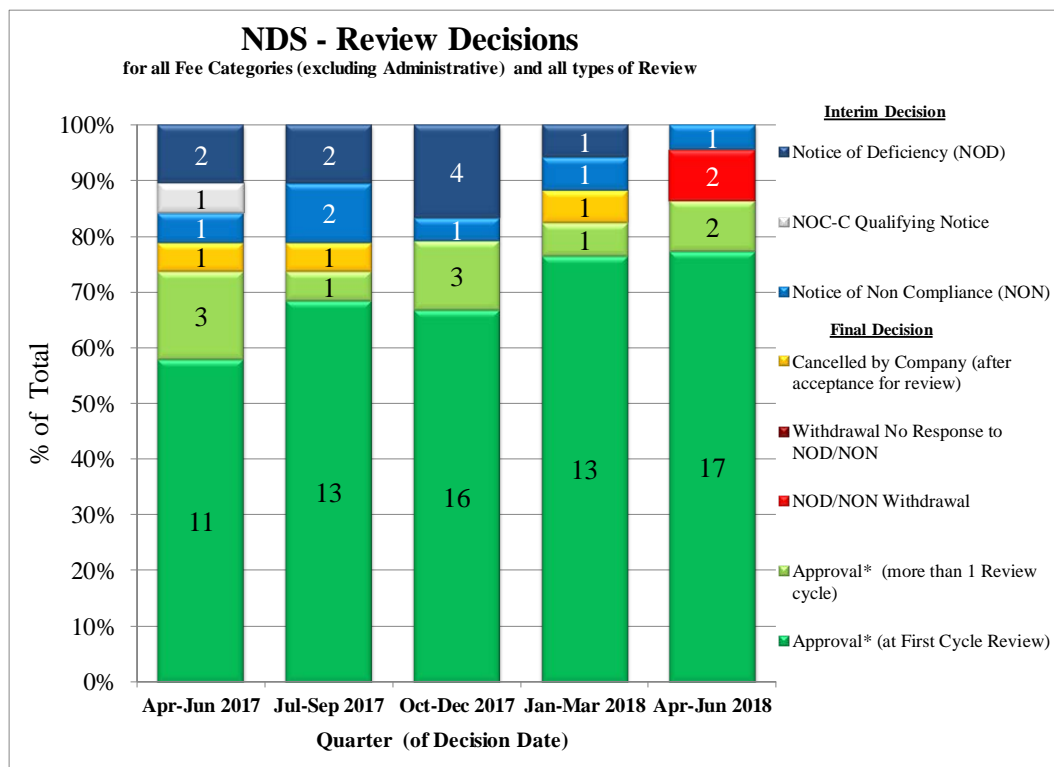
<sup>10</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).



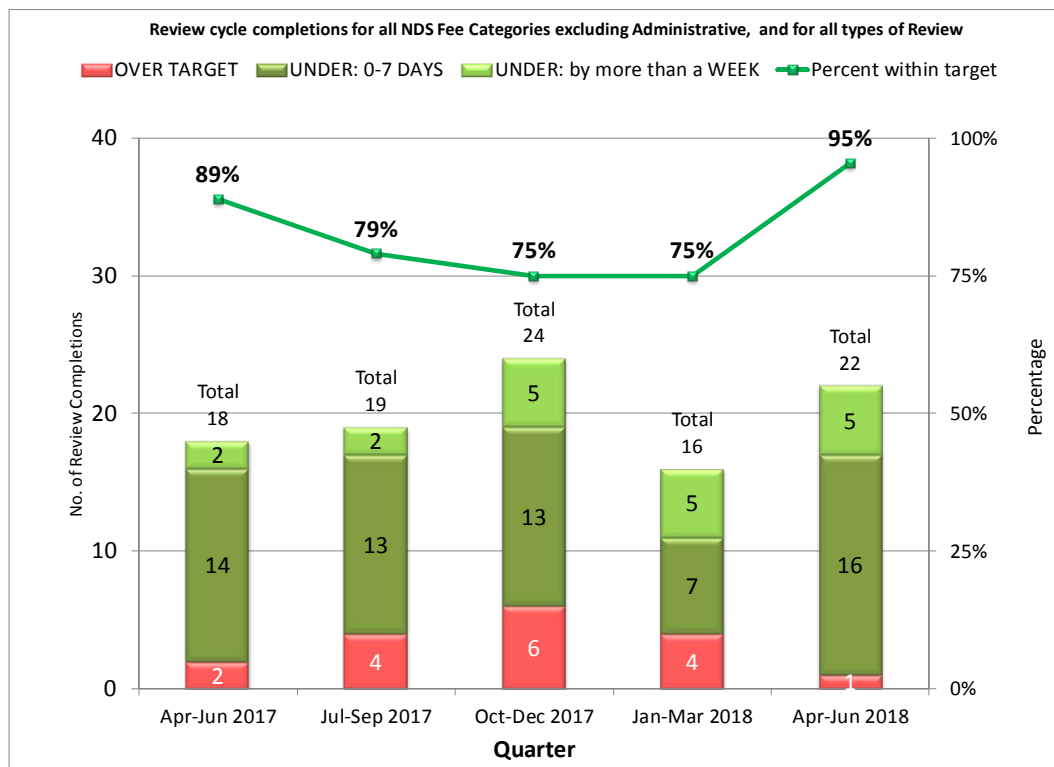
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## REVIEW CYCLE DECISIONS

### New Drug Submission (NDS) Review Decisions

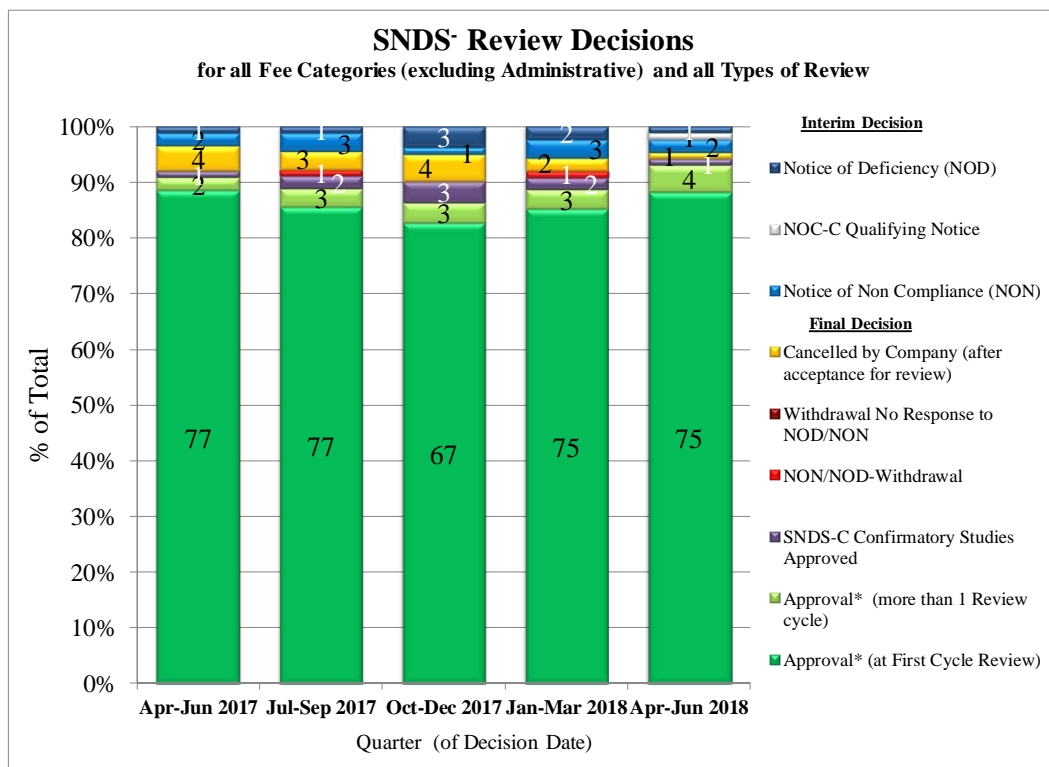


### NDS - Review Cycle Completions Showing Percentage Within Target

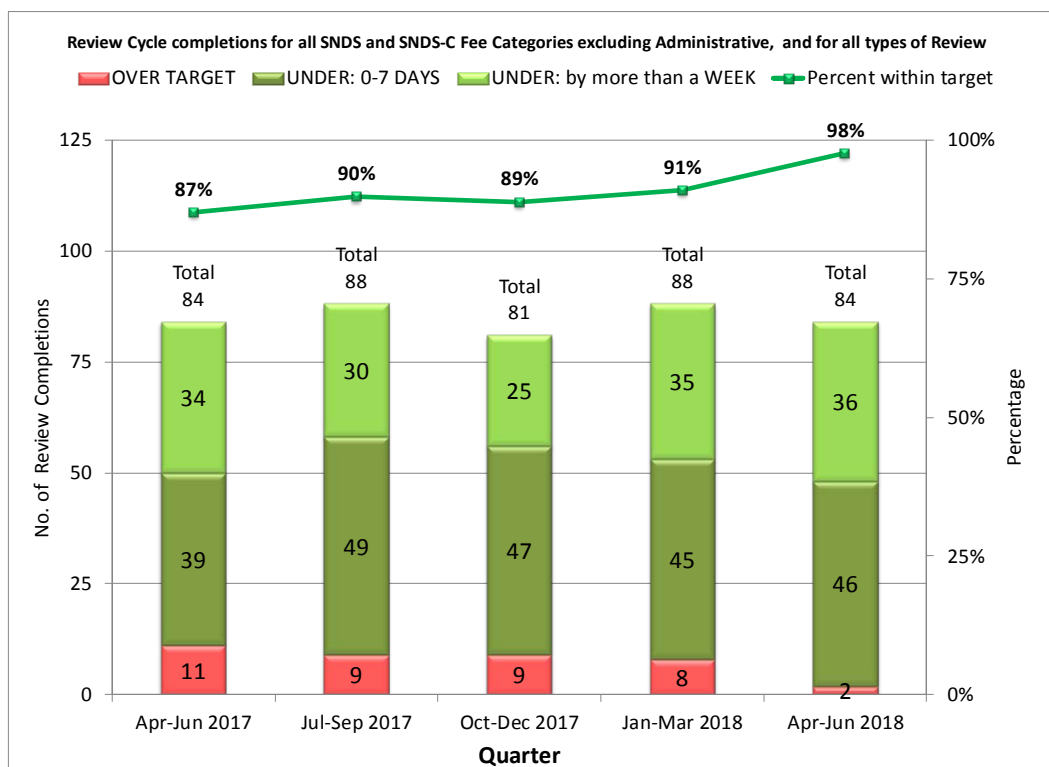


## REVIEW CYCLE DECISIONS

### Supplemental New Drug Submission (SNDS) Review Decisions

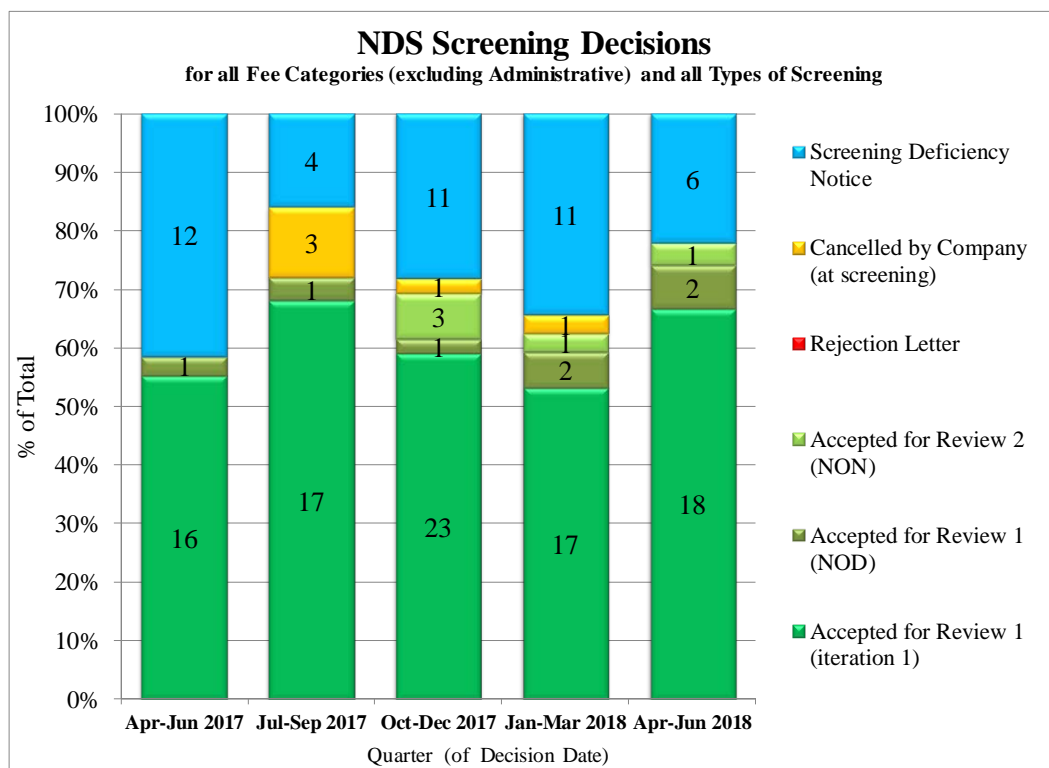


### SNDS - Review Cycle Completions Showing Percentage Within Target

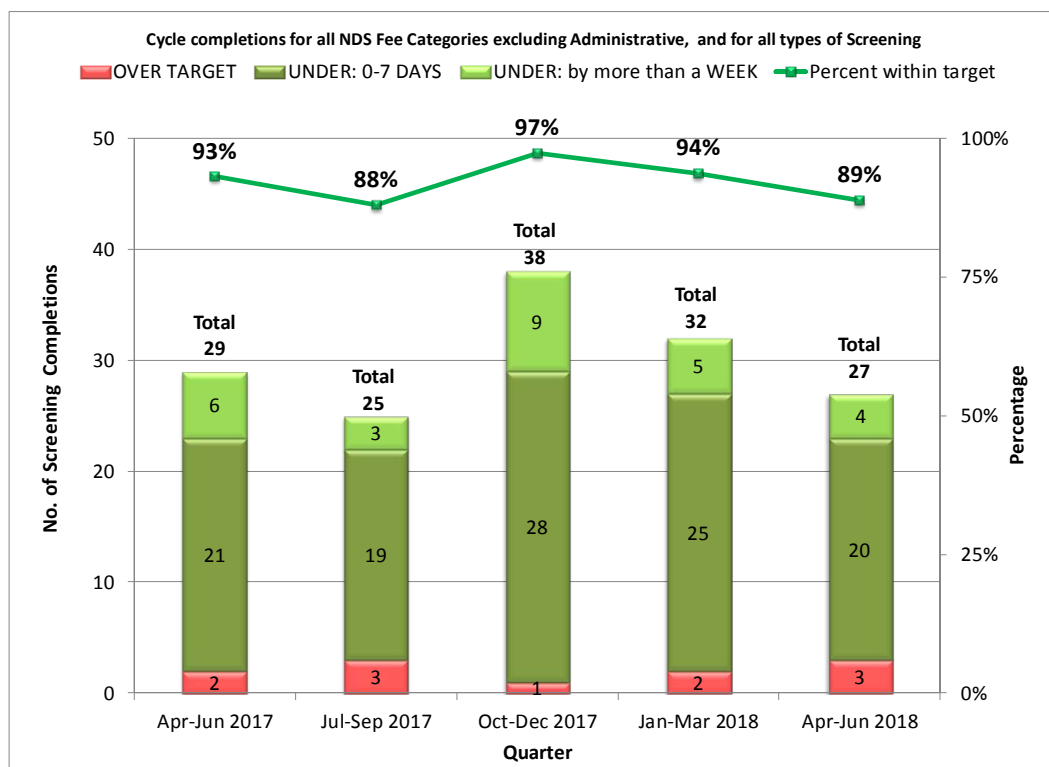


## SCREENING CYCLE DECISIONS

### New Drug Submission (NDS) Screening Decisions

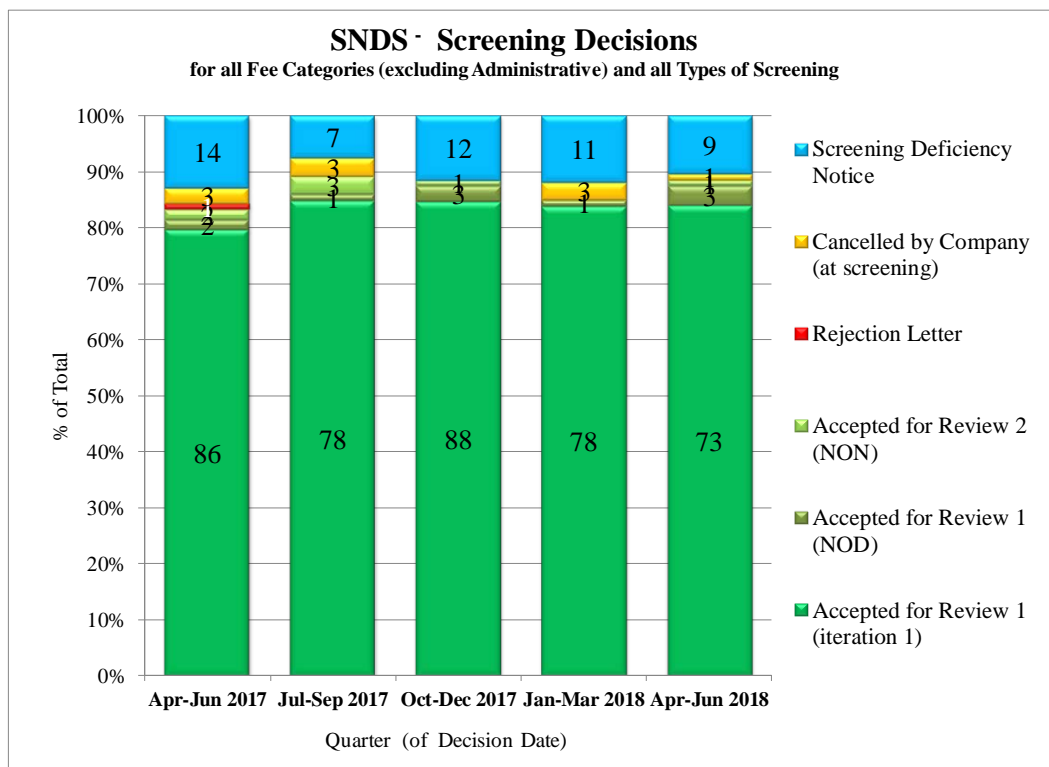


### NDS - Screening Cycle Completions Showing Percentage Within Target

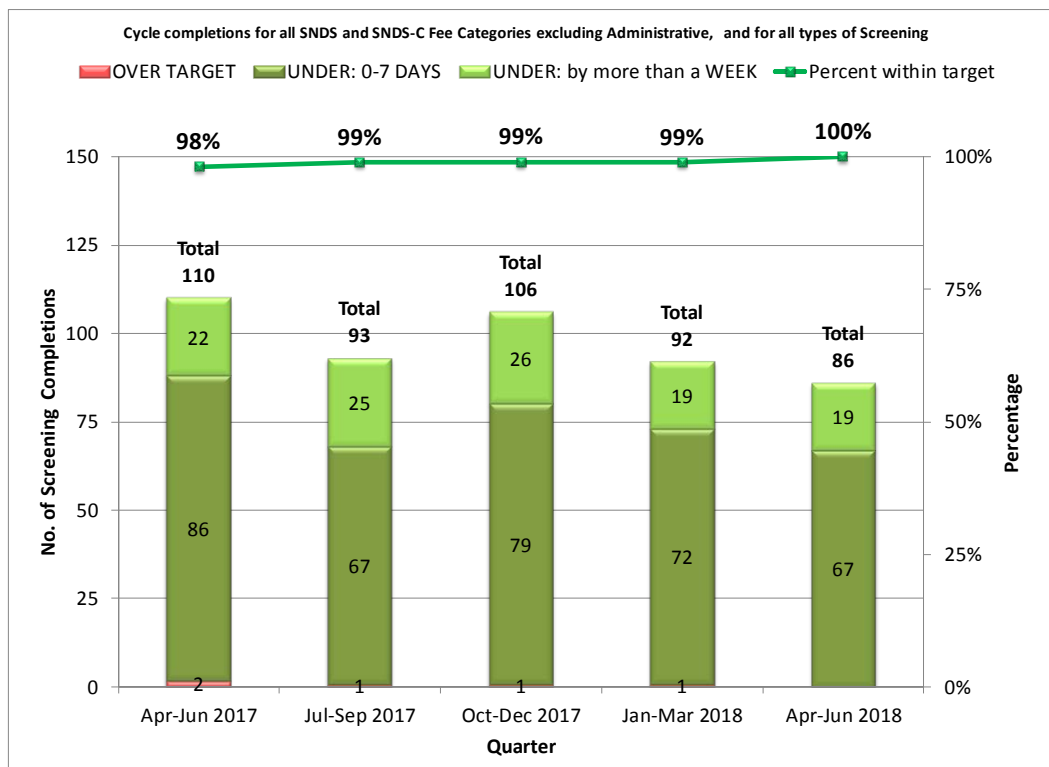


## SCREENING CYCLE DECISIONS

### Supplemental New Drug Submission (SNDS) Screening Decisions



### SNDS - Screening Cycle Completions Showing Percentage Within Target



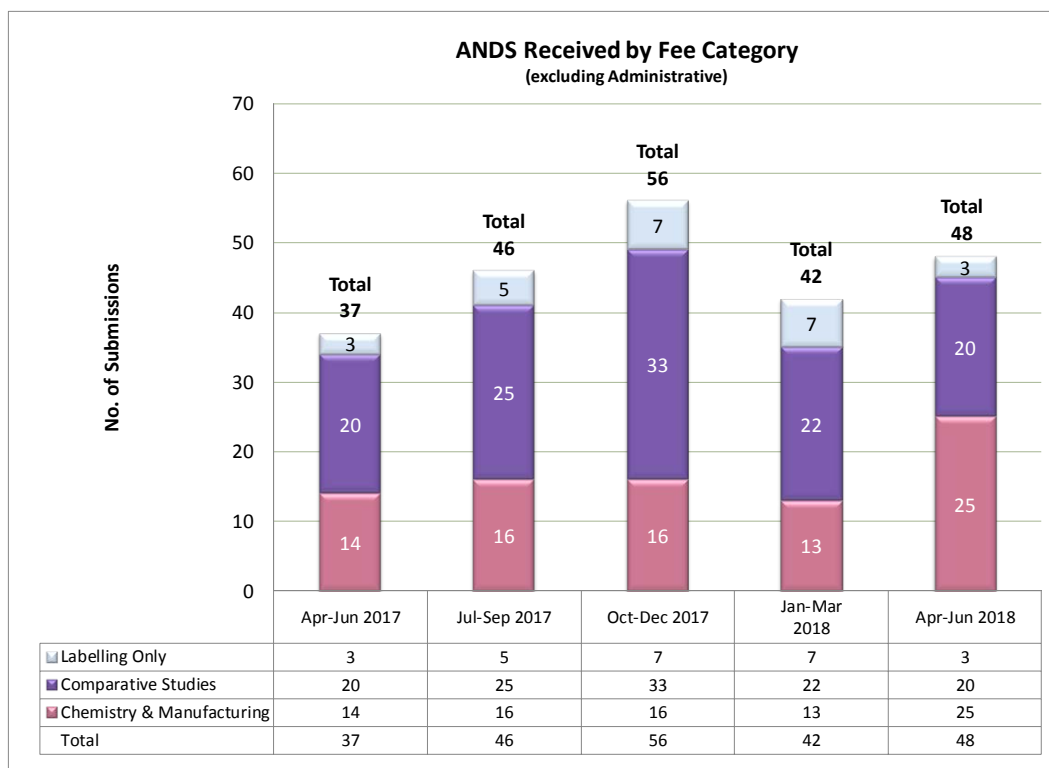
**Abbreviated New Drug Submissions  
(ANDS)**

**&**

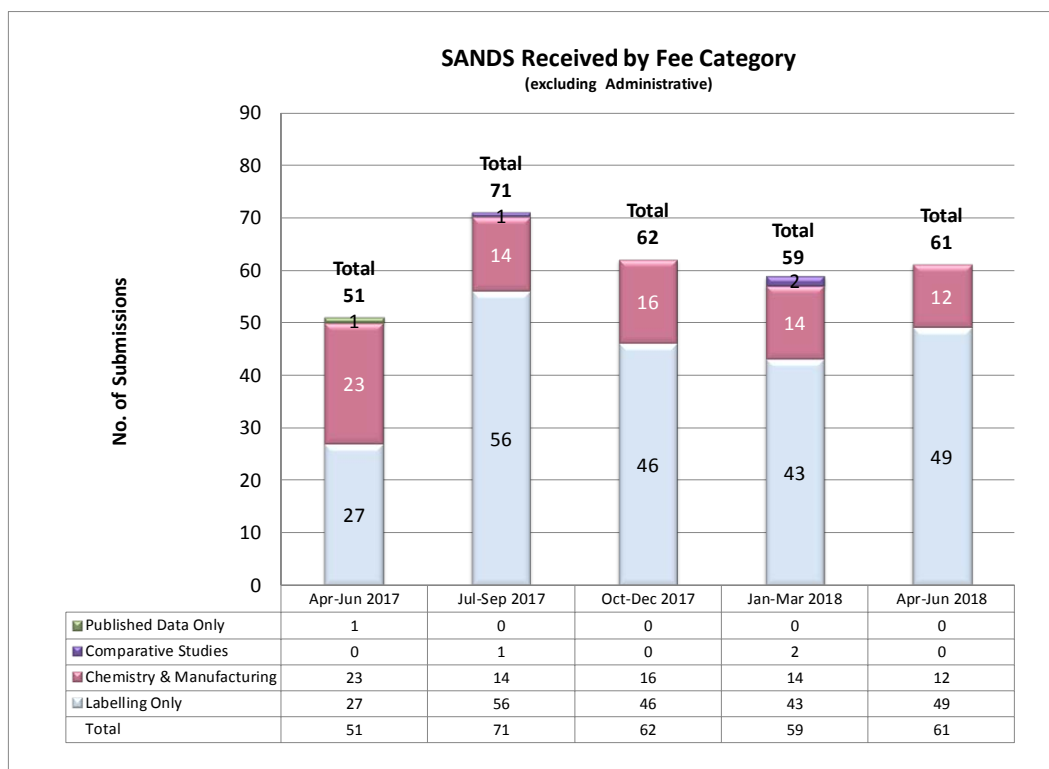
**Supplemental Abbreviated New Drug Submissions  
(SANDS)**

## SUBMISSIONS RECEIVED

### Abbreviated New Drug Submissions (ANDS) Received by Fee Category

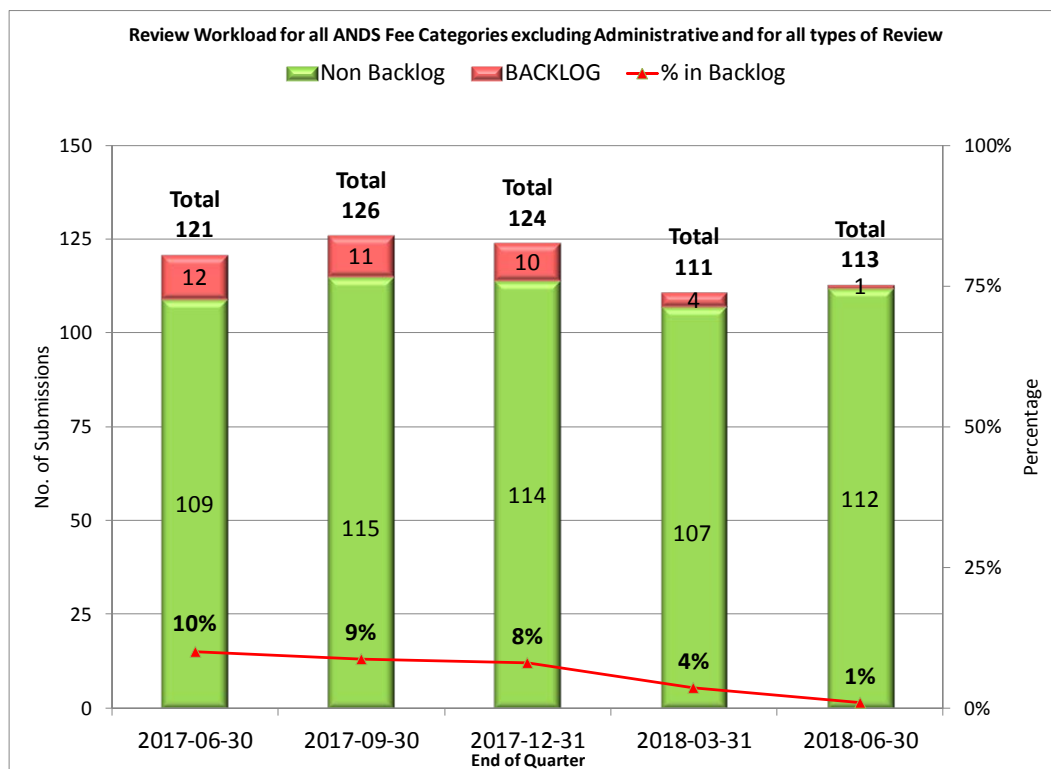


### Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category

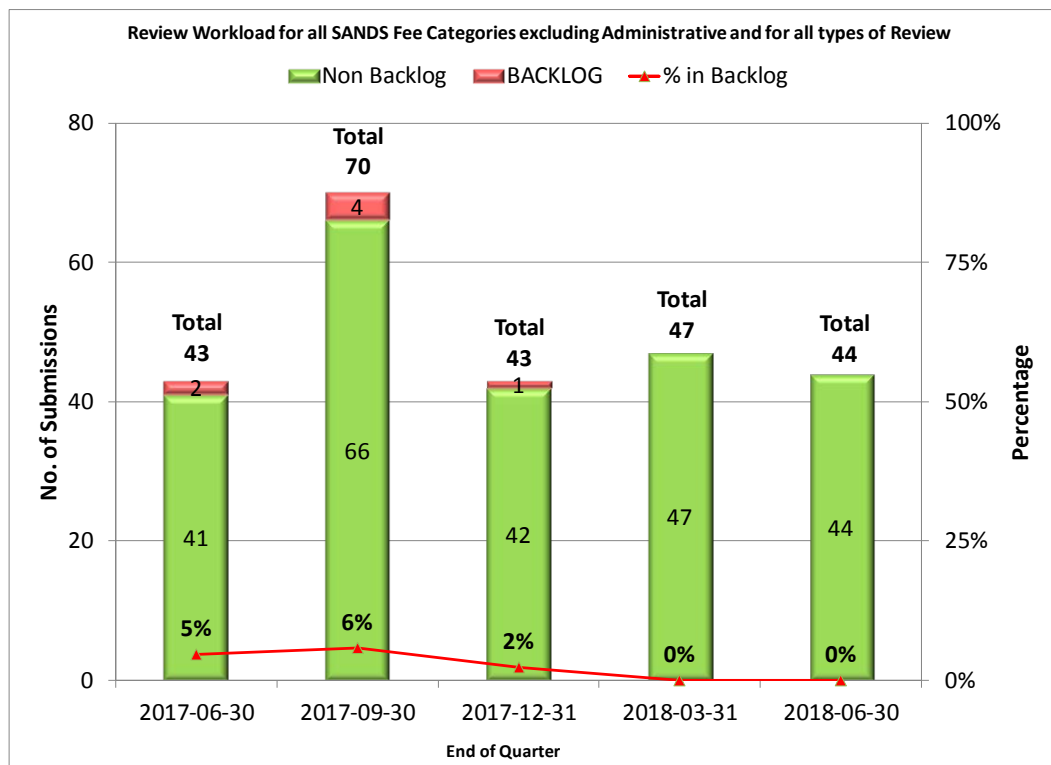


## WORKLOAD

### Abbreviated New Drug Submission (ANDS) Review Workload / Backlog



### Supplemental Abbreviated New Drug Submission (SANDS) Review Workload / Backlog





**WORKLOAD****Abbreviated New Drug Submission (ANDS) Review Workload by Fee Category**

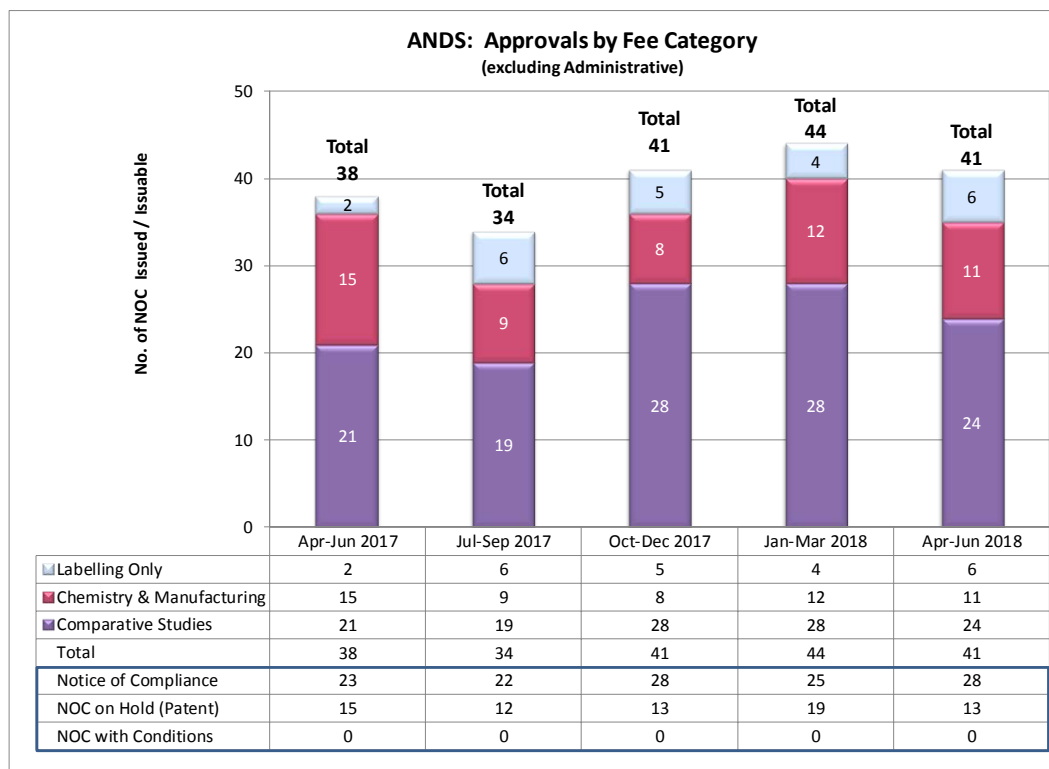
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Chemistry &amp; Manufacturing</b>	<b>46</b>	<b>46</b>	<b>49</b>	<b>43</b>	<b>45</b>
<i>Backlog</i>	5	5	4	2	1
<b>Comparative Studies</b>	<b>73</b>	<b>79</b>	<b>73</b>	<b>65</b>	<b>68</b>
<i>Backlog</i>	7	6	6	2	0
<b>Labelling Only</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>121</b>	<b>126</b>	<b>124</b>	<b>111</b>	<b>113</b>
<b>Non Backlog</b>	<b>109</b>	<b>115</b>	<b>114</b>	<b>107</b>	<b>112</b>
<b>BACKLOG</b>	<b>12</b>	<b>11</b>	<b>10</b>	<b>4</b>	<b>1</b>
<b>% in Backlog</b>	<b>10%</b>	<b>9%</b>	<b>8%</b>	<b>4%</b>	<b>1%</b>

**Supplemental Abbreviated New Drug Submission (SANDS) Review Workload by Fee Category**

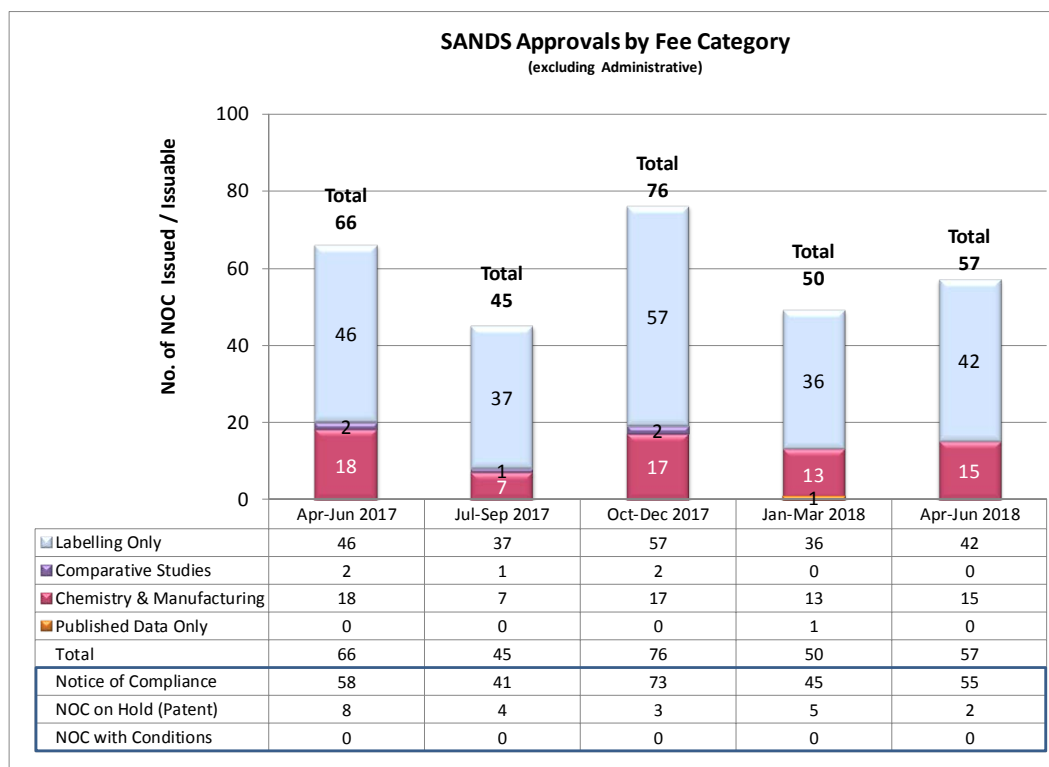
TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Chemistry &amp; Manufacturing</b>	<b>26</b>	<b>38</b>	<b>27</b>	<b>26</b>	<b>24</b>
<i>Backlog</i>	1	2	1	0	0
<b>Clinical or Non-Clin Only</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>2</b>	<b>2</b>
<i>Backlog</i>	0	1	0	0	0
<b>Published Data</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Only</b>	<b>14</b>	<b>28</b>	<b>15</b>	<b>19</b>	<b>18</b>
<i>Backlog</i>	1	1	0	0	0
<b>Total</b>	<b>43</b>	<b>70</b>	<b>43</b>	<b>47</b>	<b>44</b>
<b>Non Backlog</b>	<b>41</b>	<b>66</b>	<b>42</b>	<b>47</b>	<b>44</b>
<b>BACKLOG</b>	<b>2</b>	<b>4</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>5%</b>	<b>6%</b>	<b>2%</b>	<b>0%</b>	<b>0%</b>

## APPROVALS

### Abbreviated New Drug Submission (ANDS) Approvals by Fee Category & NOC Type



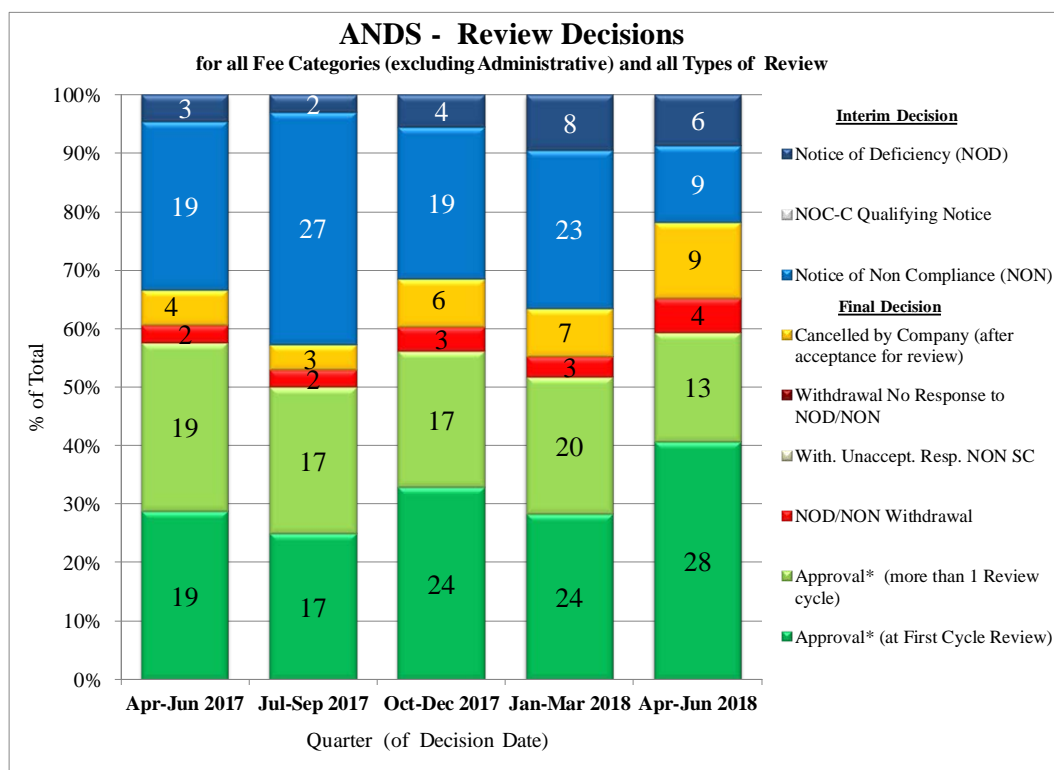
### Supplemental Abbreviated New Drug Submission (SANDS) Approvals by Fee Category and by NOC Type



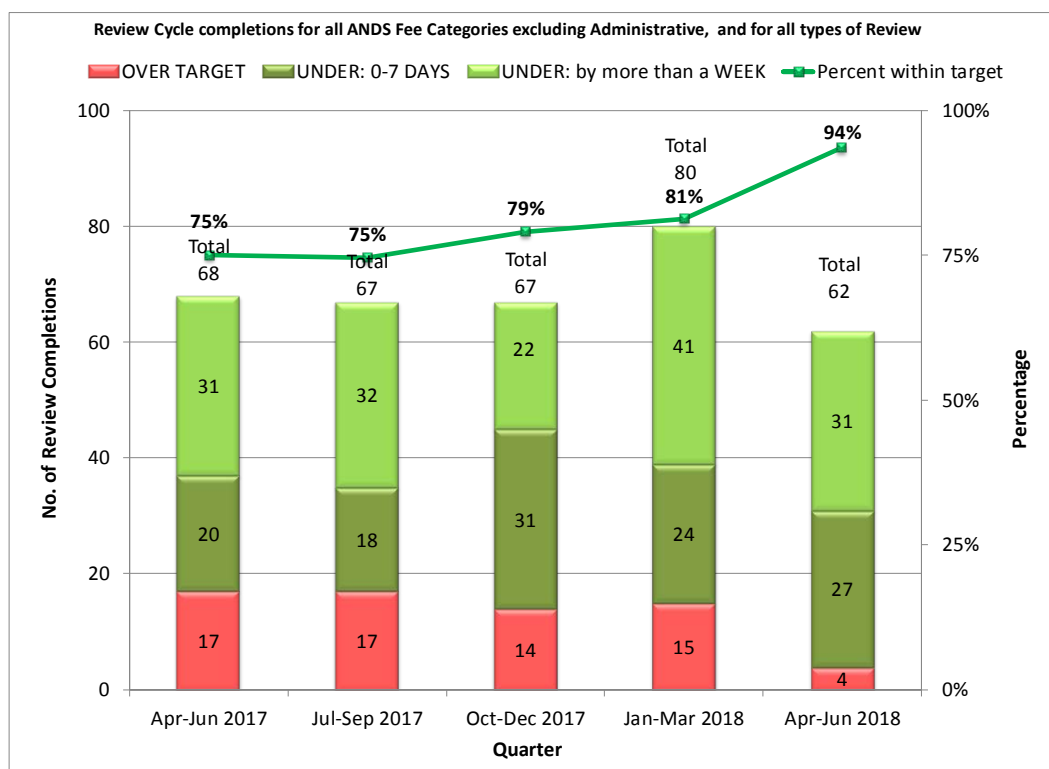
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## REVIEW CYCLE DECISIONS

### Abbreviated New Drug Submission (ANDS) Review Decisions

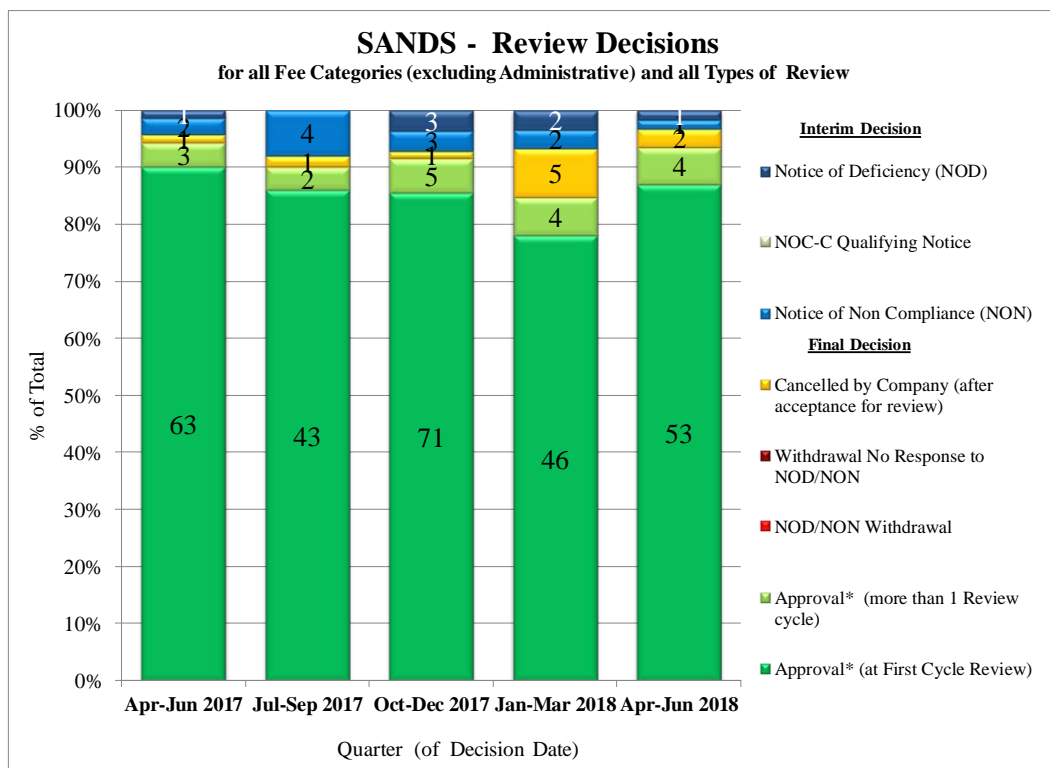


### ANDS - Review Cycle Completions Showing Percentage Within Target

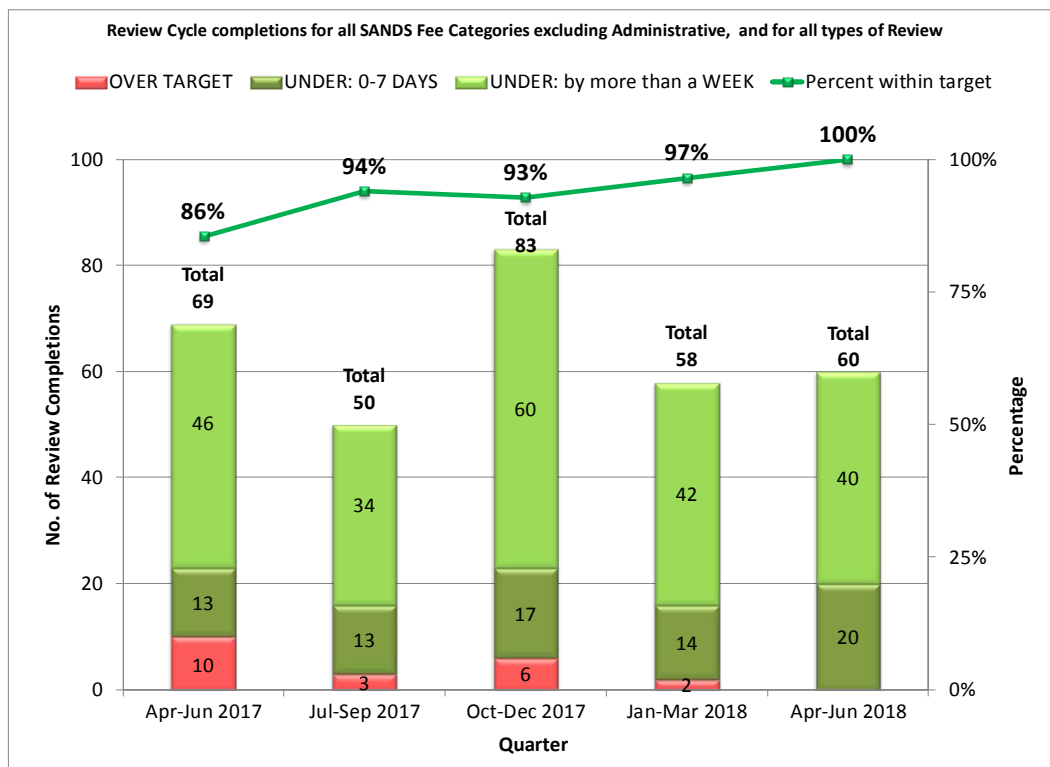


## REVIEW CYCLE DECISIONS

### Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

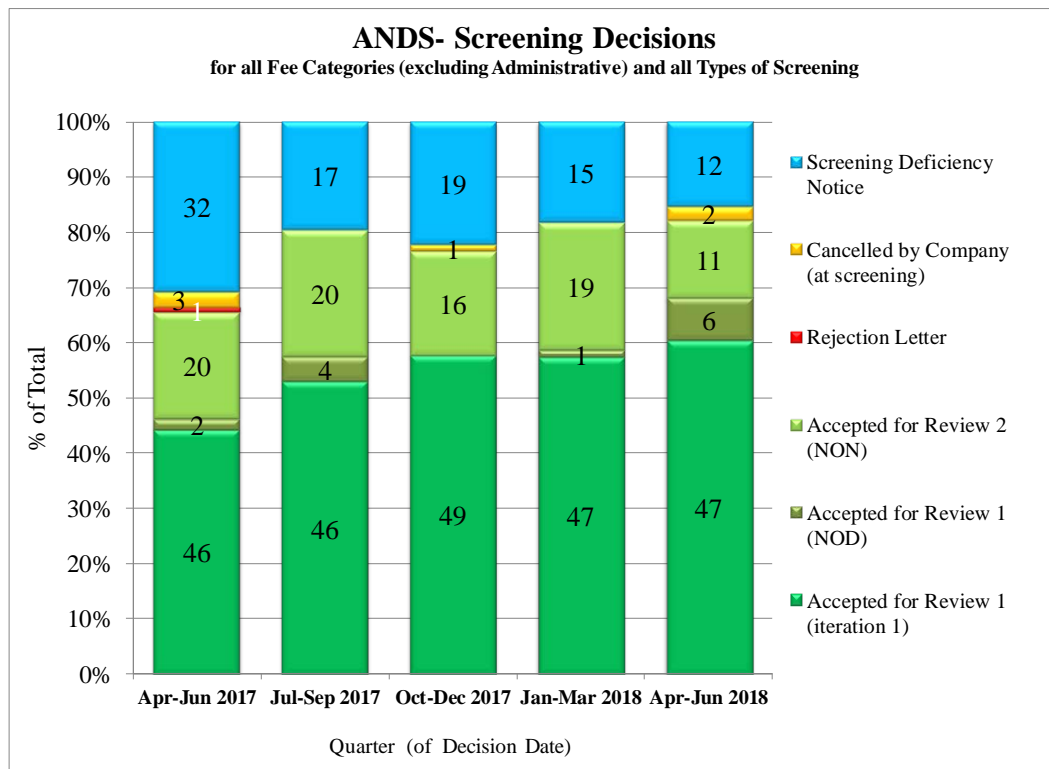


### SANDS - Review Cycle Completions Showing Percentage Within Target

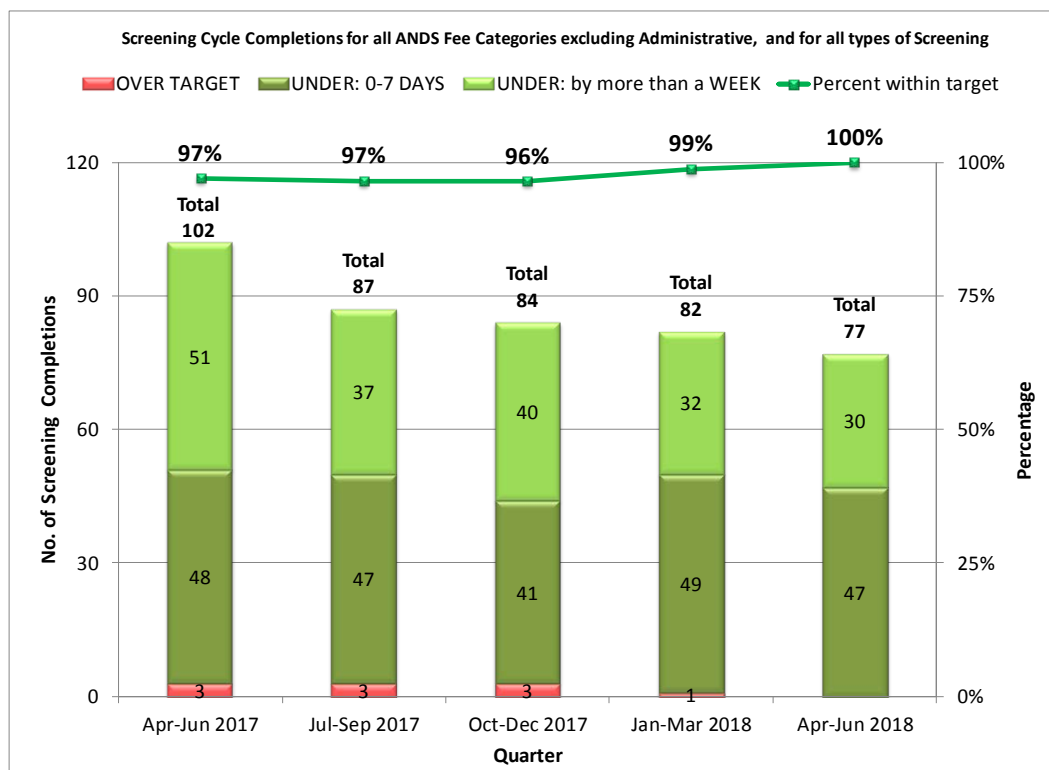


## SCREENING CYCLE DECISIONS

### Abbreviated New Drug Submission (ANDS) Screening Decisions

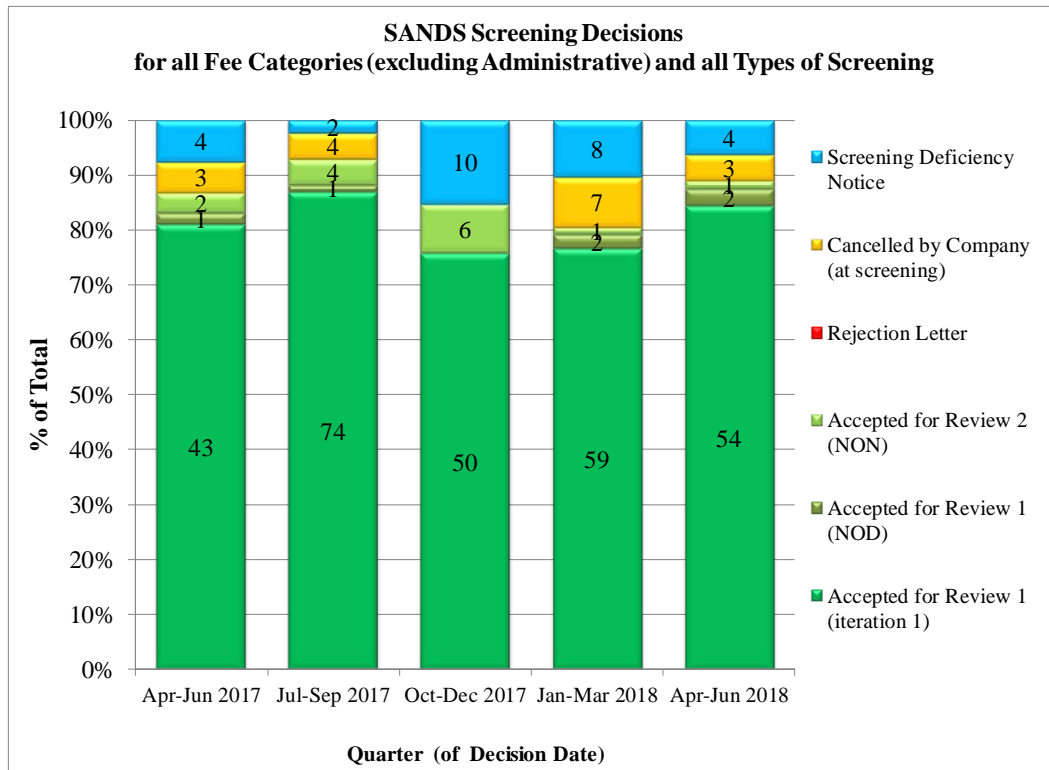


### ANDS - Screening Cycle Completions Showing Percentage Within Target

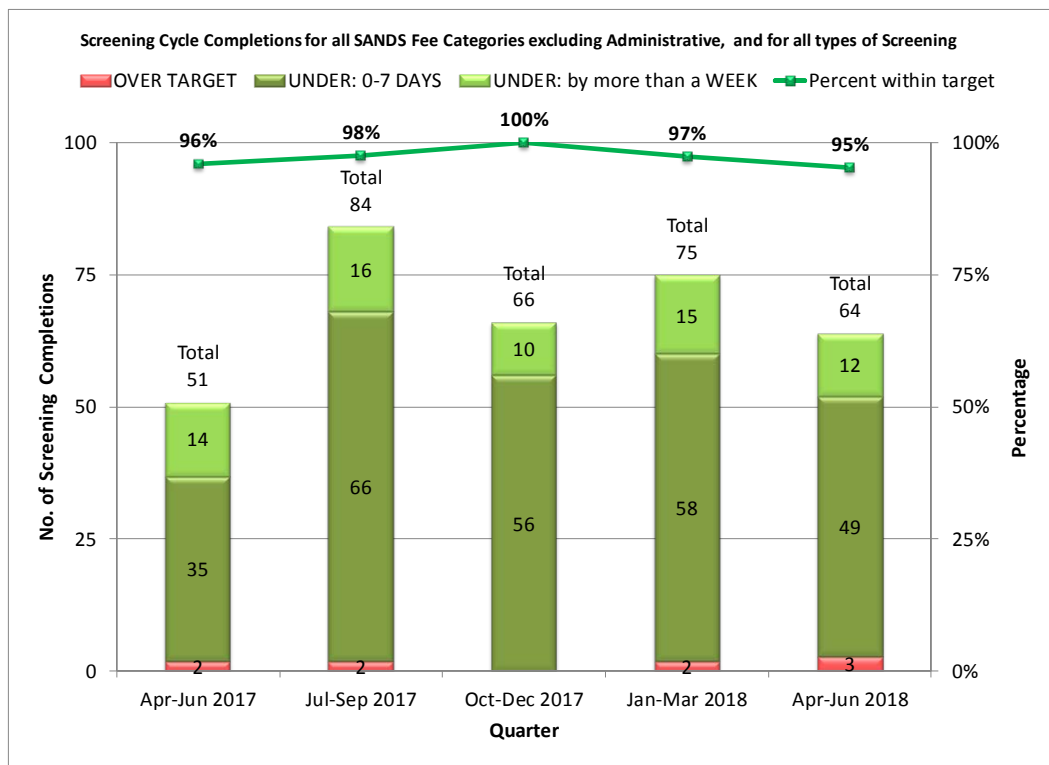


## SCREENING CYCLE DECISIONS

### Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions

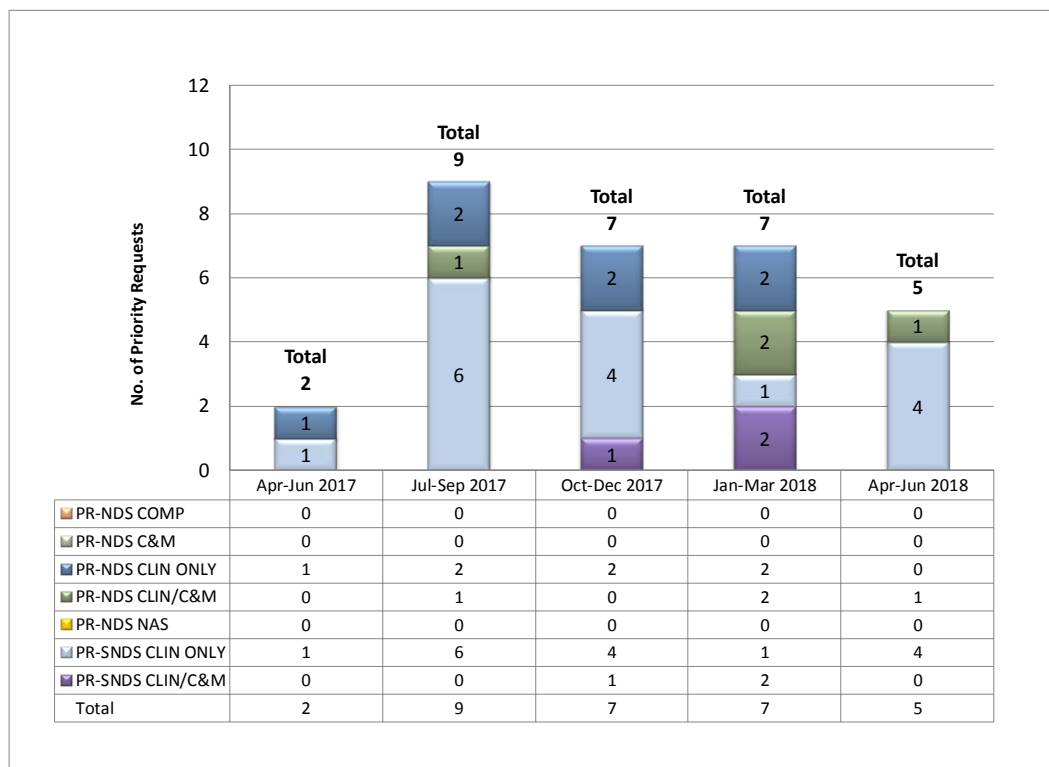


### SANDS - Screening Cycle Completions Showing Percentage Within Target



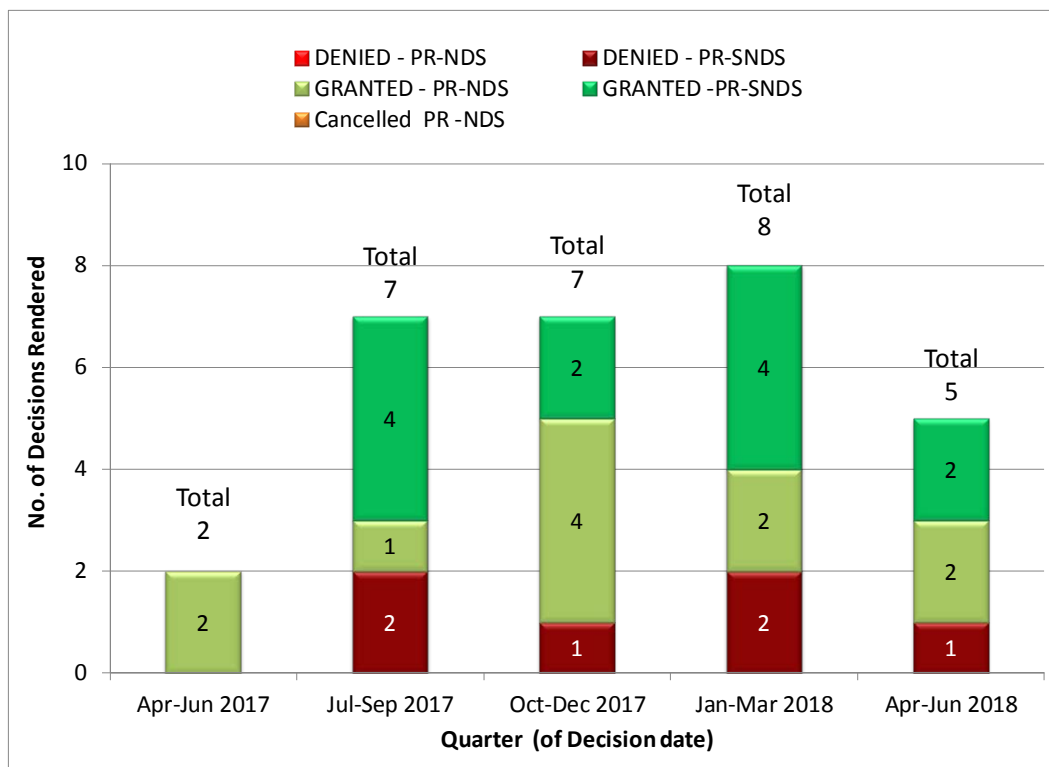
## Priority Review Status Requests (for NDS & SNDS)

### Priority Review Status Requests Received

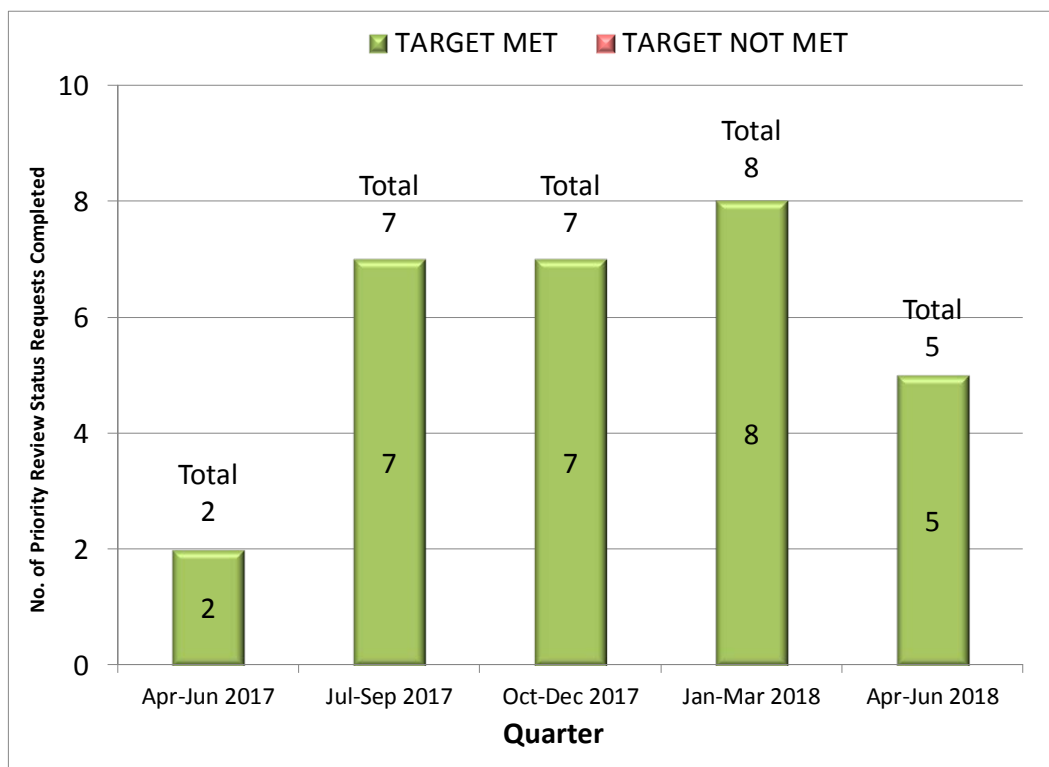




### Priority Review Status Requests: Decisions Rendered



### Priority Review Status Requests: Performance

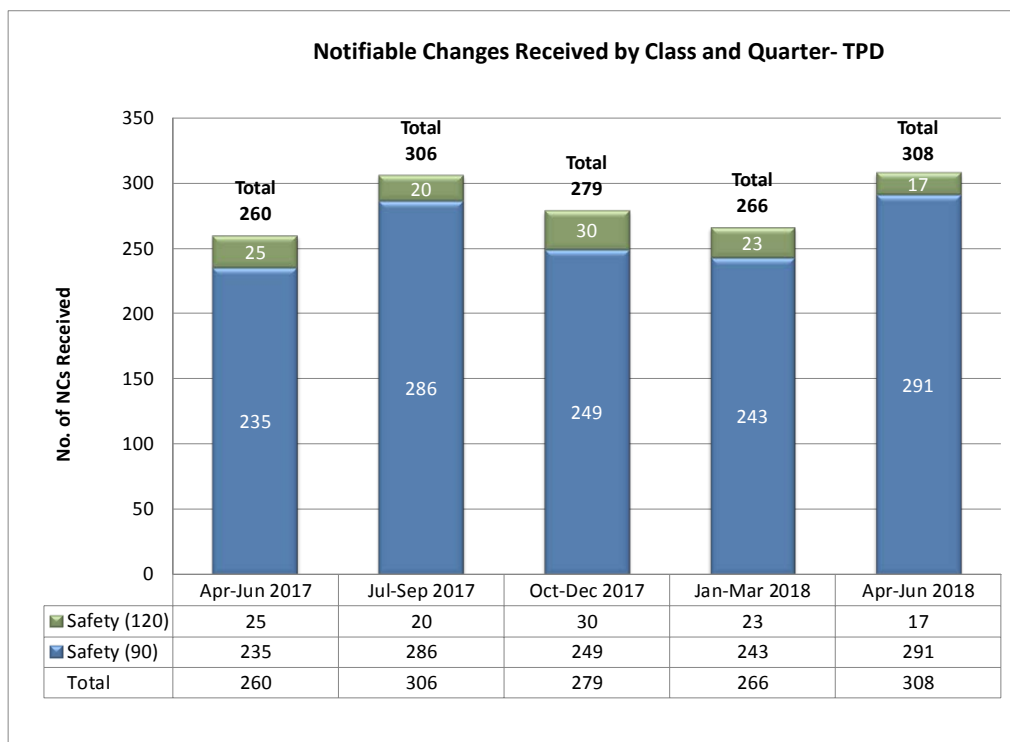


## **NOTIFIABLE CHANGES ( NC )**

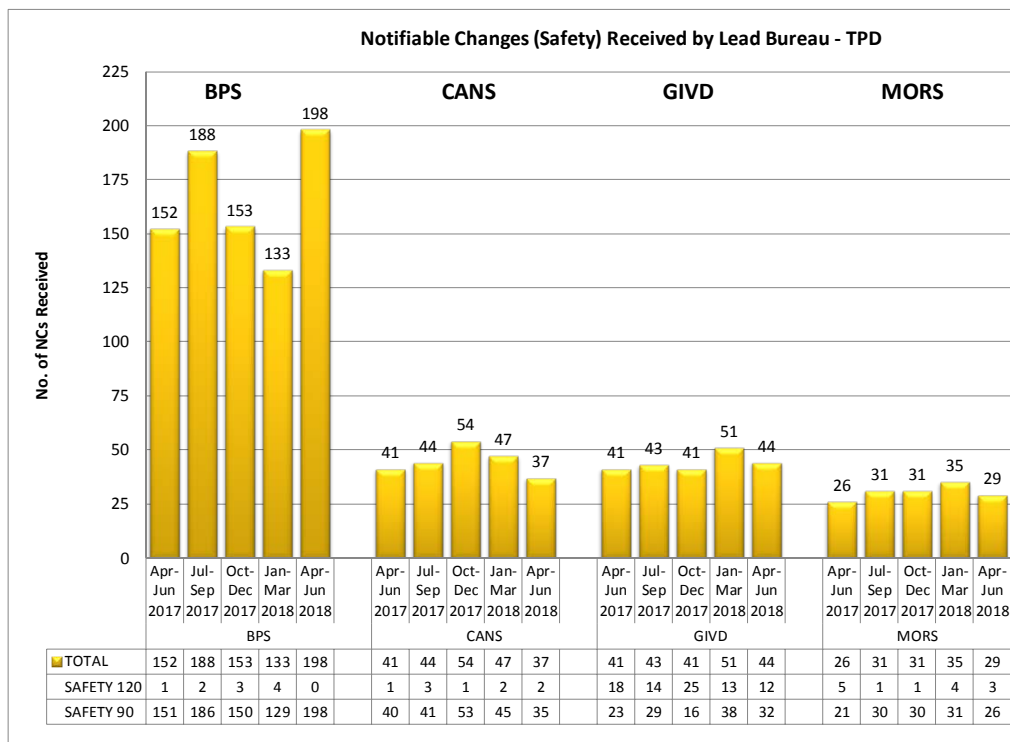
## NOTIFIABLE CHANGES<sup>11</sup>

### SUBMISSIONS RECEIVED

#### Number Received - Notifiable Changes (NC) - by Class



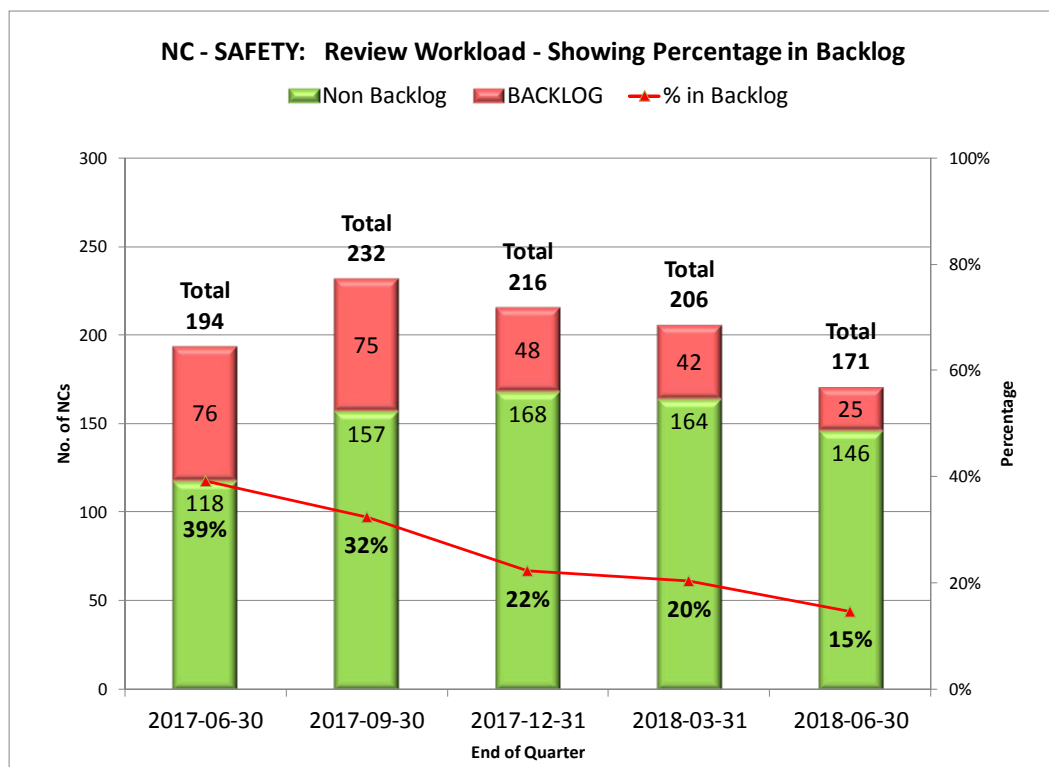
#### Number Received - Notifiable Changes (Safety) – by Lead Bureau



<sup>11</sup> In February 2013 the [Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products](#) process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals and Canadians.

## WORKLOAD

### Notifiable Change (NC) SAFETY: Review Workload / Backlog

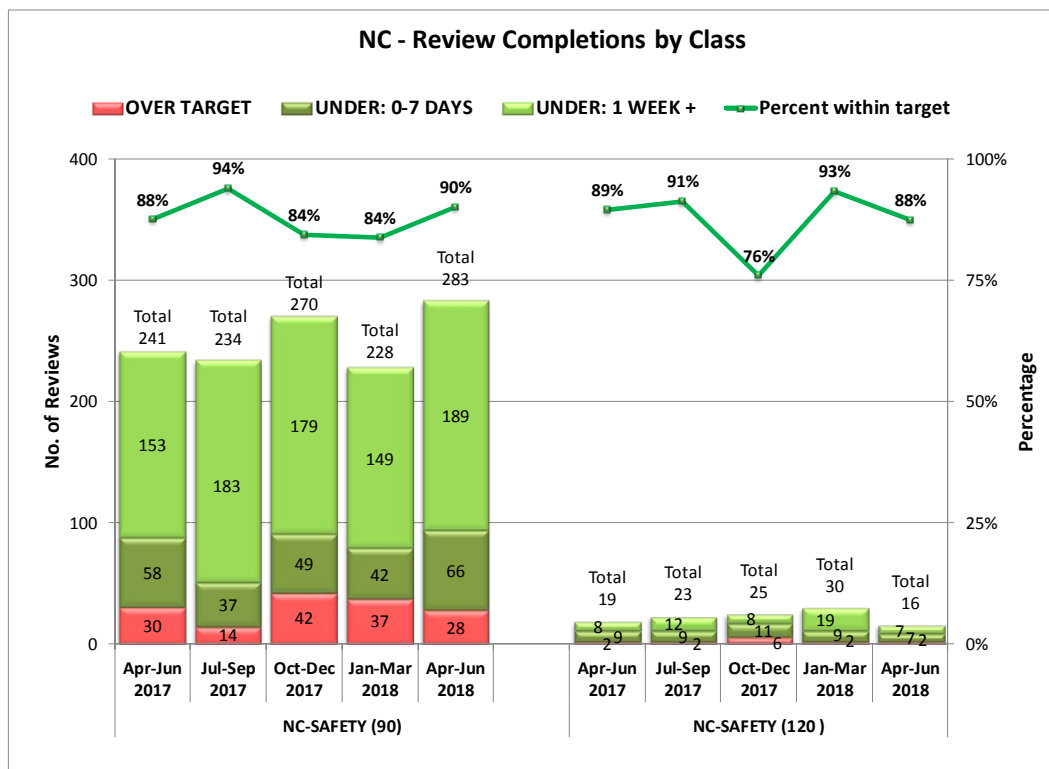


### Notifiable Change (NC) SAFETY: Review Workload by Class

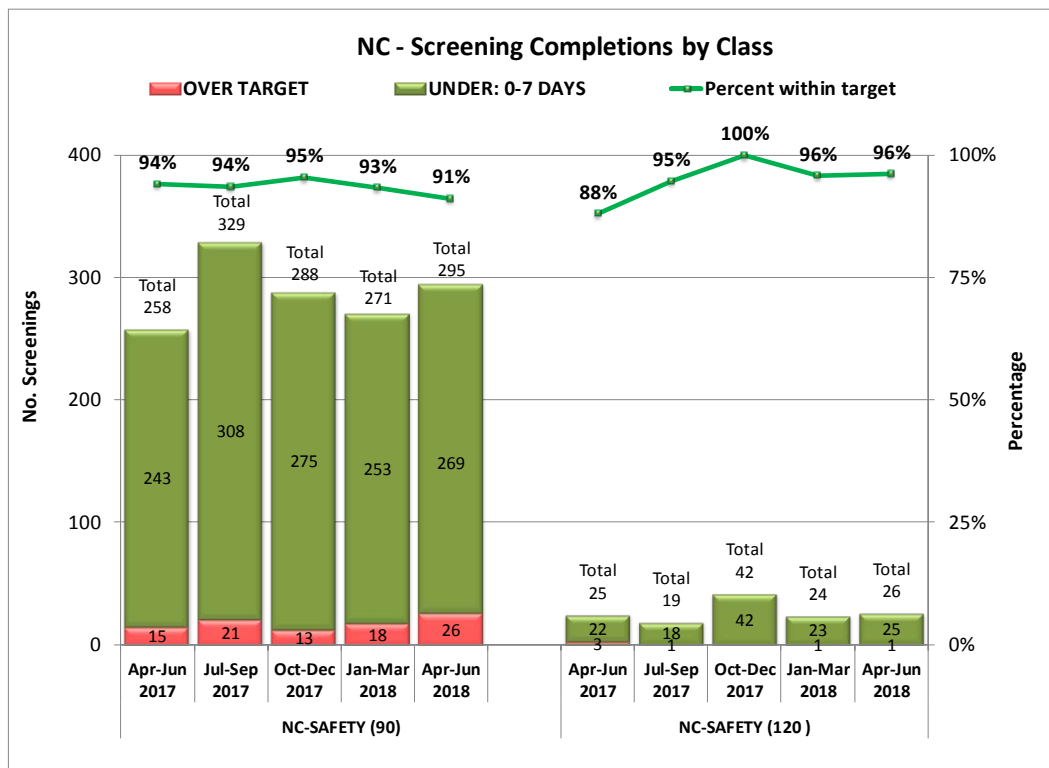
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
SAFETY - 90 day	161	206	181	184	145
Backlog	69	70	43	39	23
SAFETY - 120 day	33	26	35	22	26
Backlog	7	5	5	3	2
Total	194	232	216	206	171
Non Backlog	118	157	168	164	146
BACKLOG	76	75	48	42	25
% in Backlog	39%	32%	22%	20%	15%

## PERFORMANCE

### REVIEW Completions by Class - Notifiable Changes (NC)



### SCREENING Completions by Class - Notifiable Changes (NC)



**Decision Documents by Class - Notifiable Change (NC)**

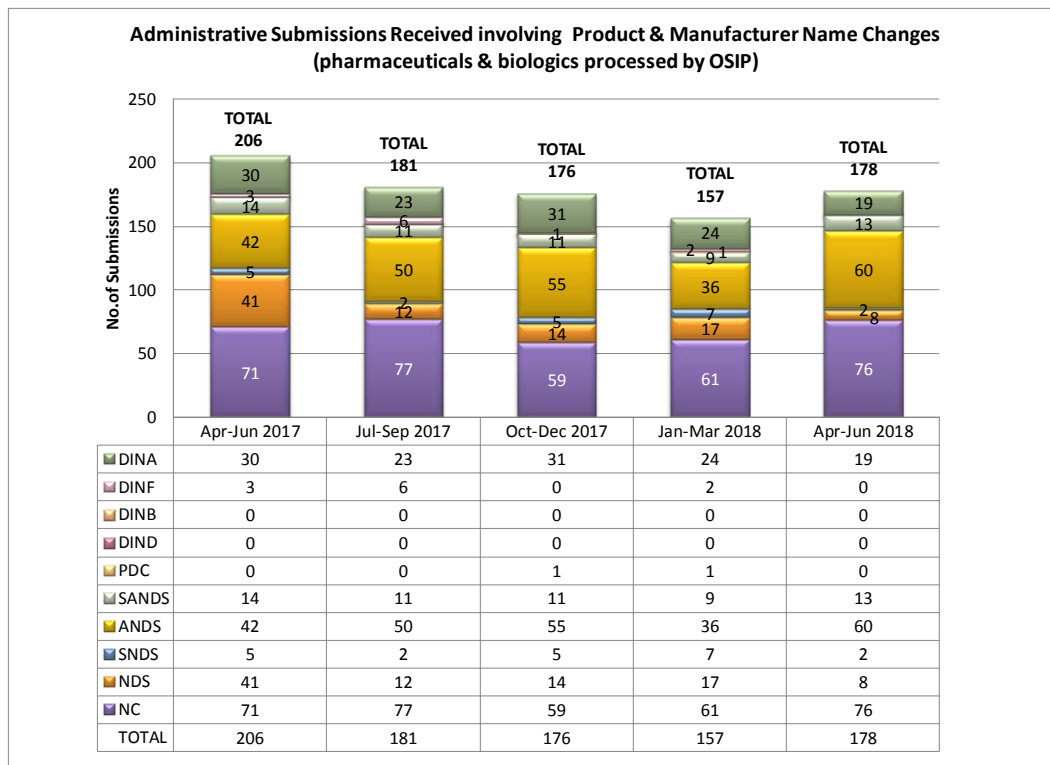
<b>NC - SAFETY (90)</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
NO OBJECTION LETTER	241	255	262	232	273
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	2	0	1	0
SCREENING DEFICIENCY NOTICE	41	44	40	36	40
CANCELLED BY COMPANY	17	20	18	11	25
NC - HOLD (PATENT)	16	11	3	16	6
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

<b>NC - SAFETY (120)</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
NO OBJECTION LETTER	14	22	24	30	15
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	4	8	6	6
CANCELLED BY COMPANY	5	1	1	1	2
REJECTION LETTER (SCR)	0	0	0	0	0

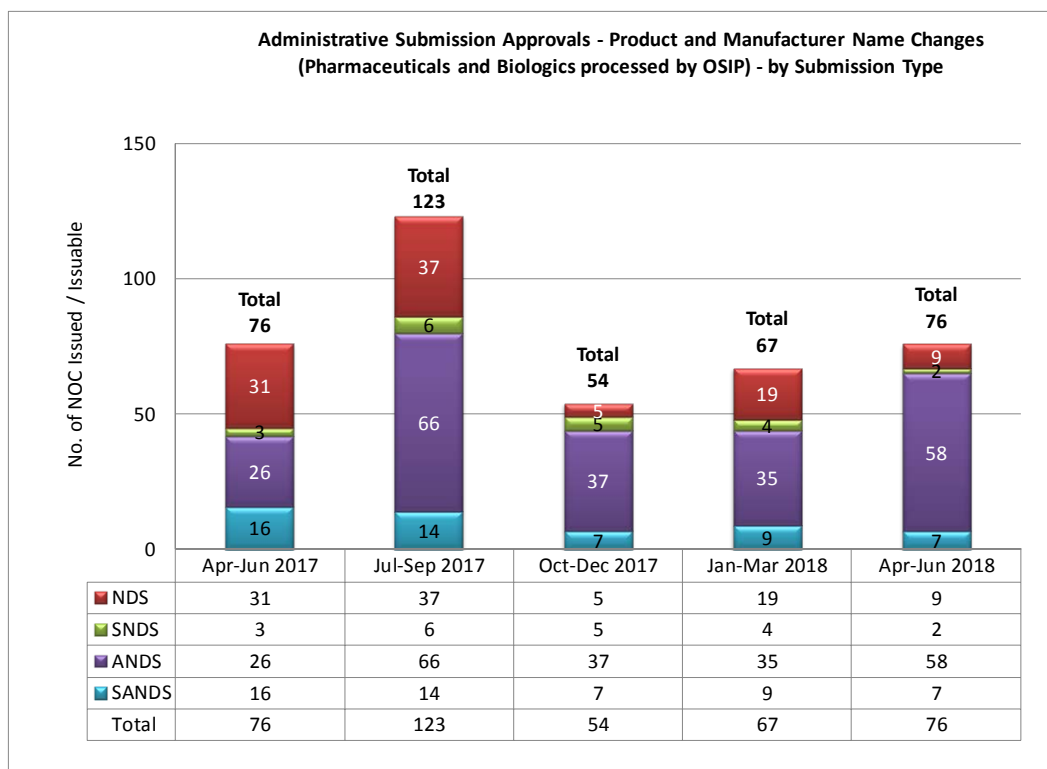
## Administrative Submissions

(Product & Manufacturer Name Changes<sup>12</sup>)

### Administrative Submissions Received by Submission Type (OSIP)



### Administrative Submission Approvals (OSIP) for NDS, SNDS, ANDS and SANDS



<sup>12</sup> For additional information, please consult the ["Changes in Manufacturer and/or Product Name Policy" \(2015\)](#)

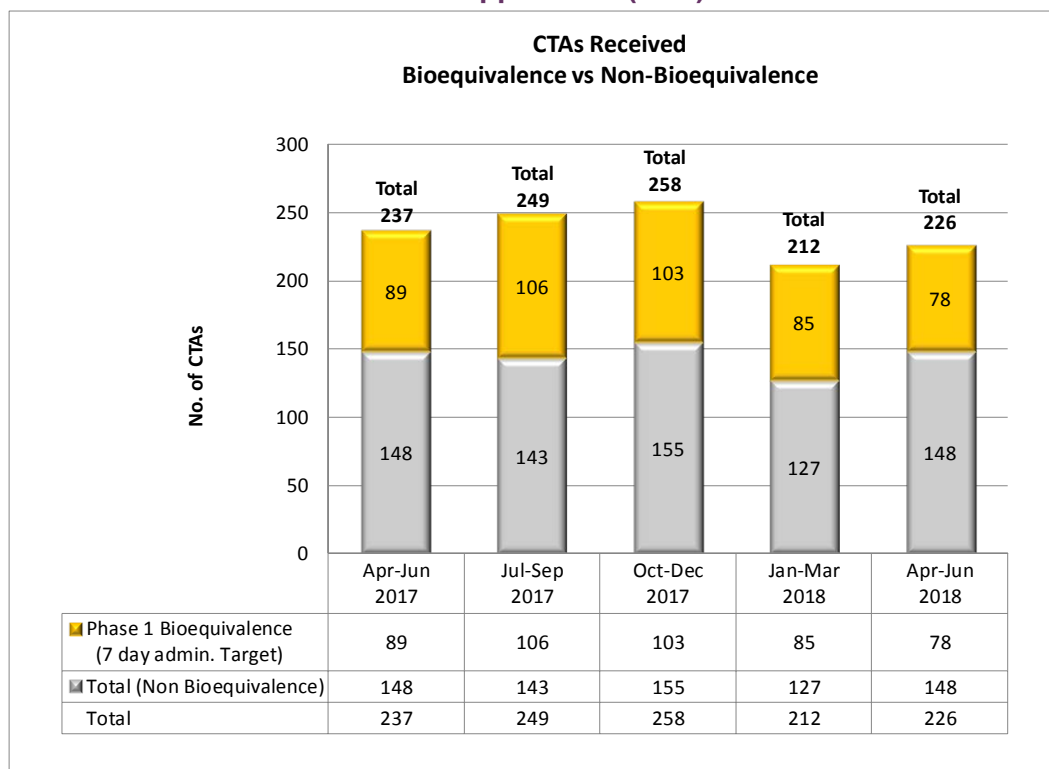
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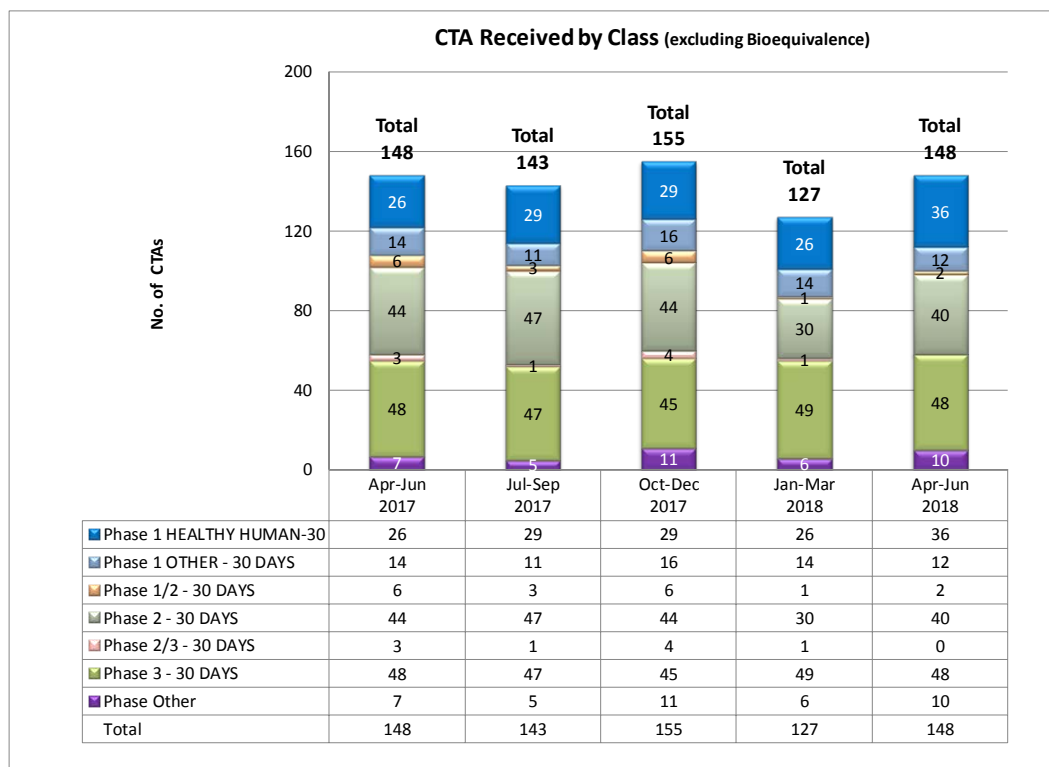
# **Clinical Trial Applications and Amendments (CTA & CTA-A)**

## Clinical Trial Applications ( CTA )

### Number Received - Clinical Trial Application (CTA)



### Number Received - Clinical Trial Application (CTA) - Excluding Bioequivalence (Generic)



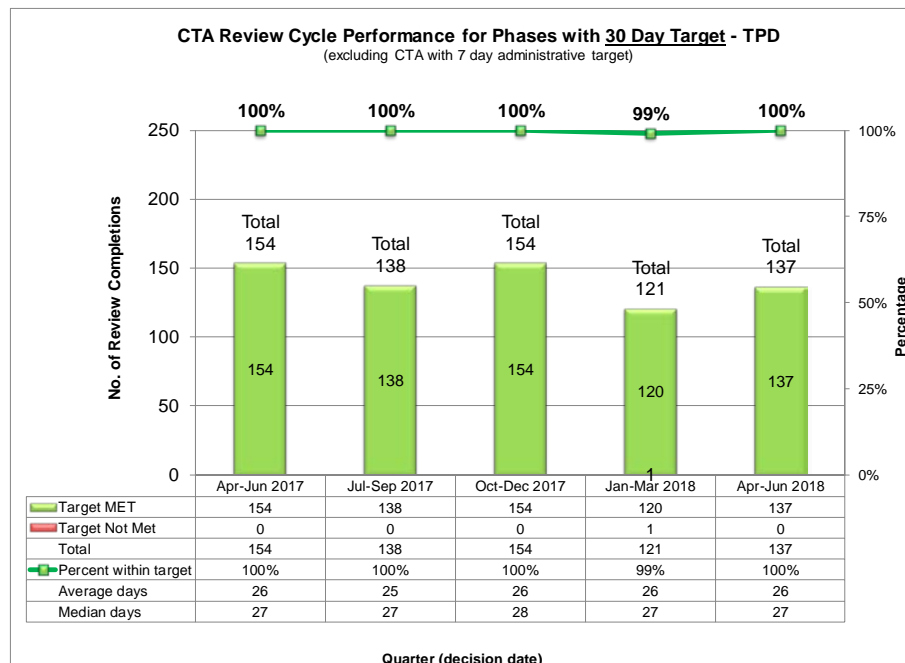
## DECISION DOCUMENTS

### Decision Documents - Clinical Trial Application (CTA)

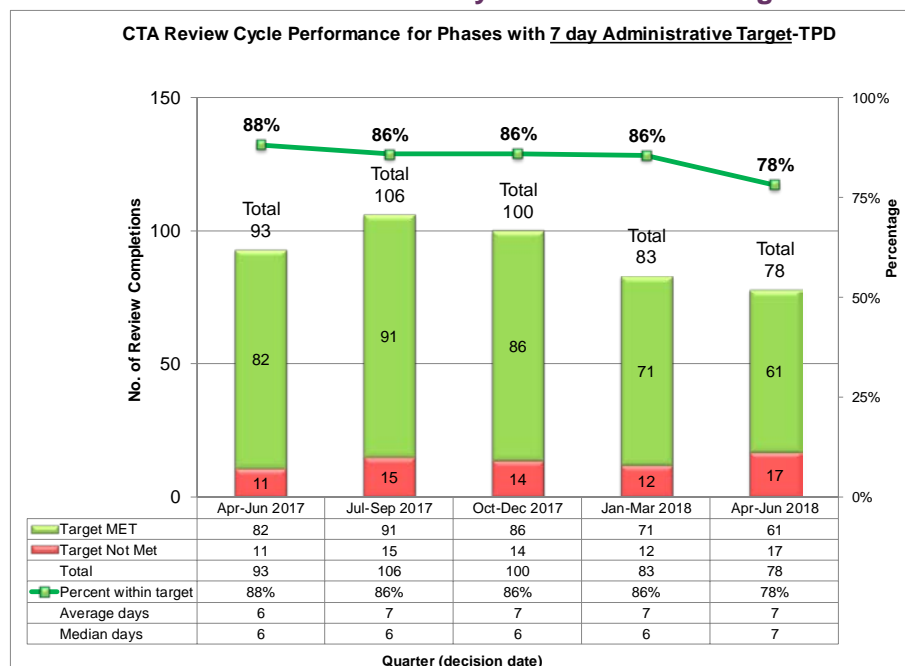
CTA					
DOCUMENT TYPE	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NO OBJECTION LETTER	234	238	237	189	208
CANCELLED BY COMPANY	15	9	20	20	12

## PERFORMANCE

### Performance - Clinical Trials Applications (CTA) Reviews: 30 Day Target

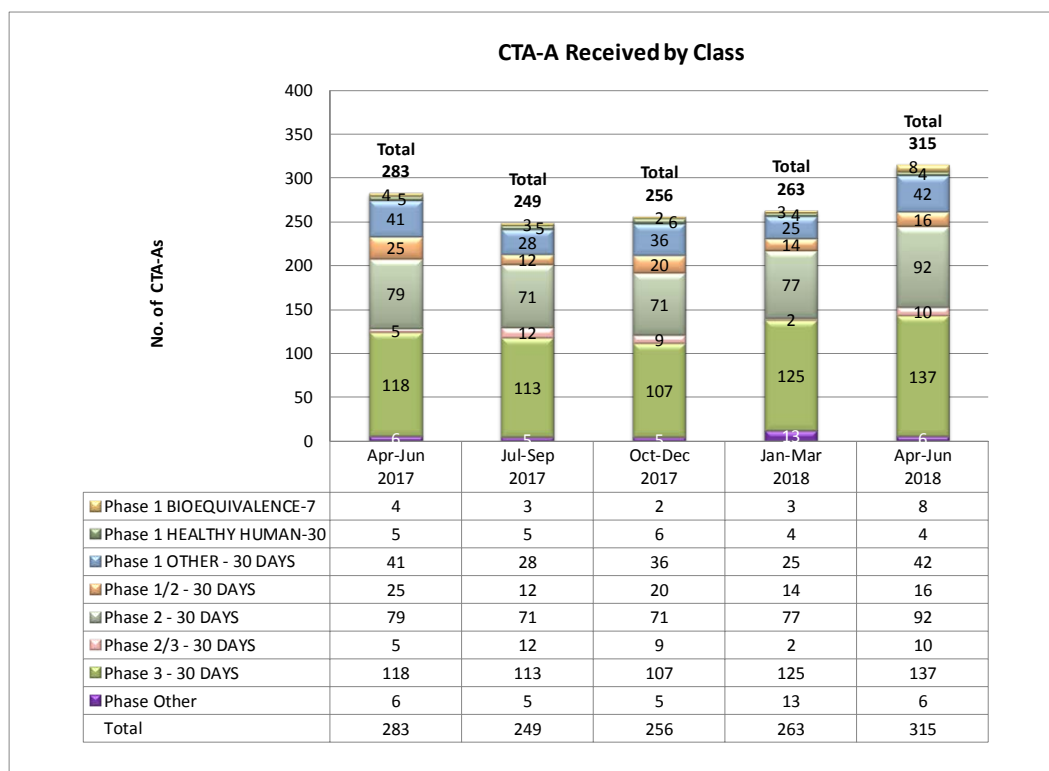


### Performance – CTA Review: 7 Day Administrative Target



## Clinical Trial Application – Amendments (CTA-A)

### Number Received - Clinical Trial Application-Amendments (CTA-A)



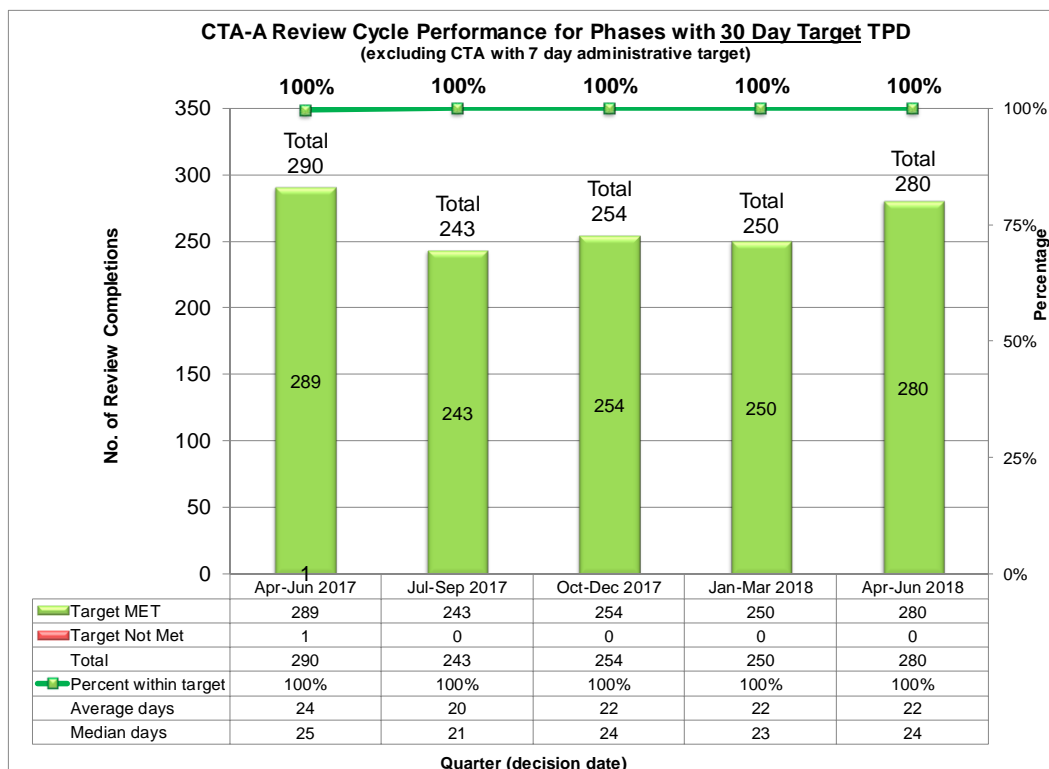
## DECISION DOCUMENTS

### Decision Documents - Clinical Trial Application-Amendments (CTA-A)

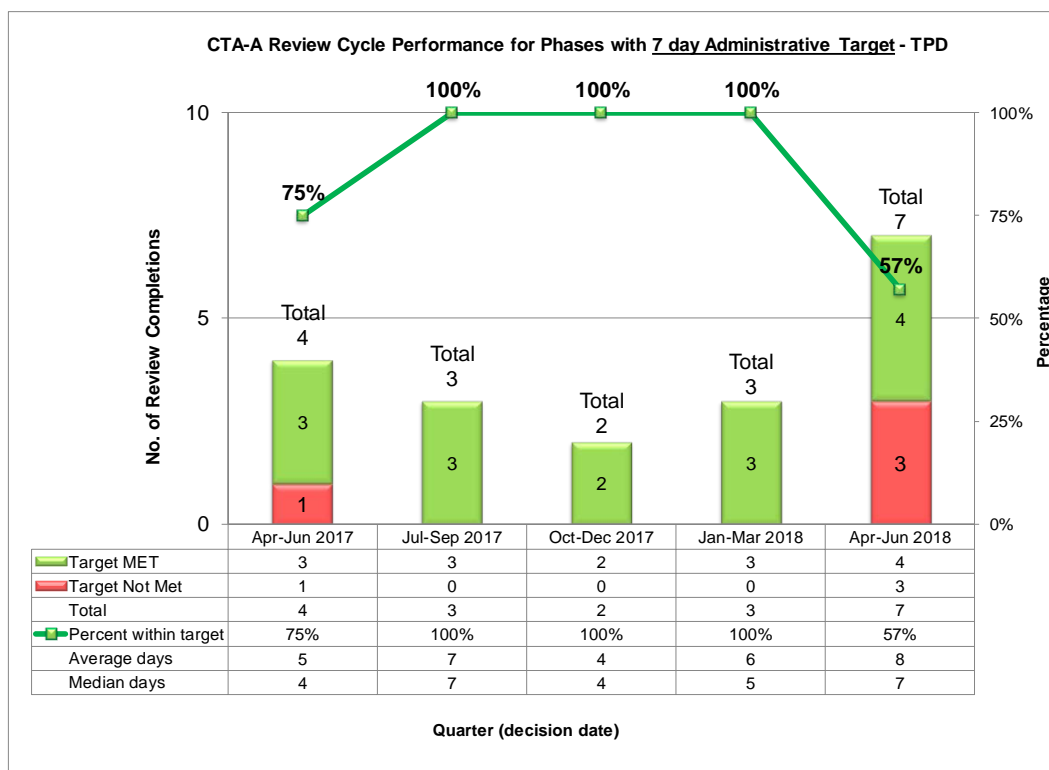
CTA-A (excluding administrative)					
DOCUMENT TYPE	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NO OBJECTION LETTER	290	245	252	250	280
CANCELLED BY COMPANY	3	1	5	3	8
NOT SATISFACTORY NOTICE	1	0	0	0	0

## PERFORMANCE

### Performance - Clinical Trial Application Amendments (CTA-A) Reviews: 30 Day Target



### Performance - CTA-A: Reviews: 7 Day Administrative Target



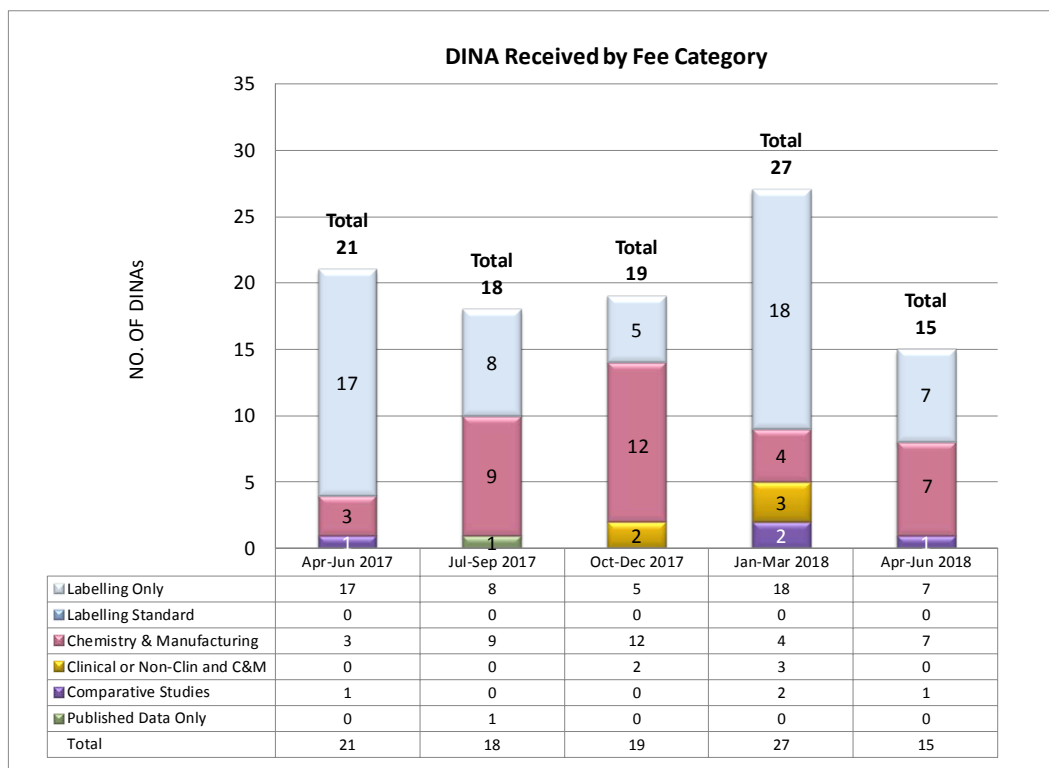
# **DINA**

## **Application for a Drug Identification Number**

The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

## DINA: Application for a Drug Identification Number<sup>13</sup>

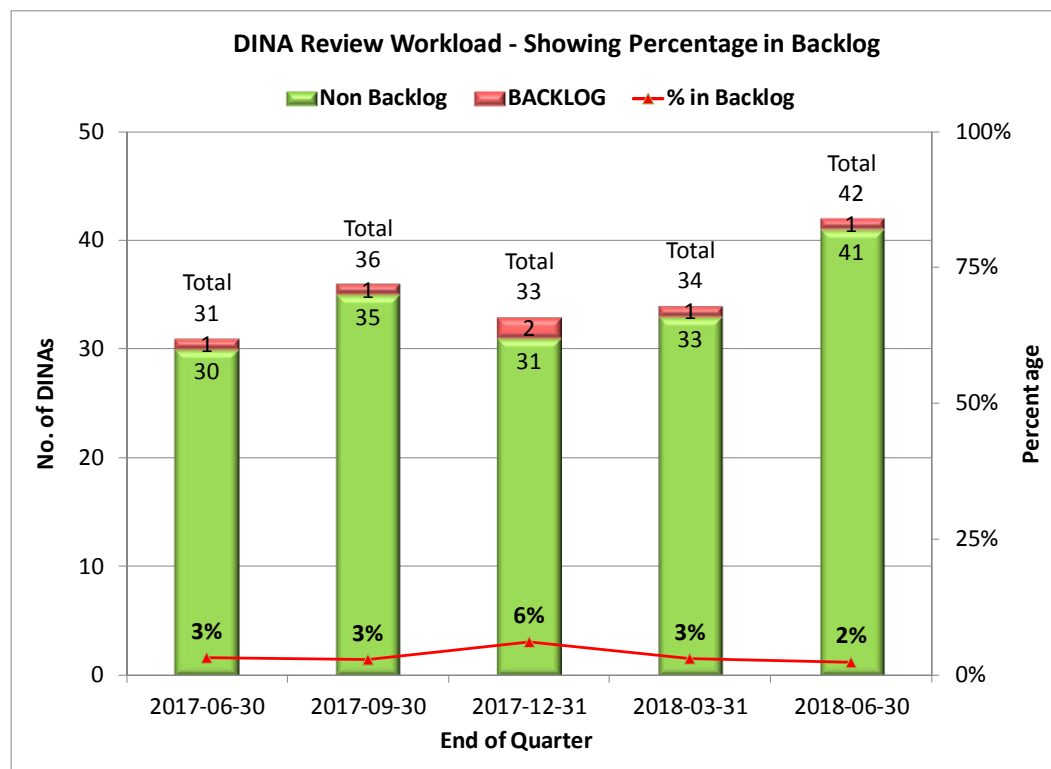
### Number Received – DINA



<sup>13</sup> The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

## REVIEW WORKLOAD

### Review Workload / Backlog - Showing Percentage in Backlog – DINA



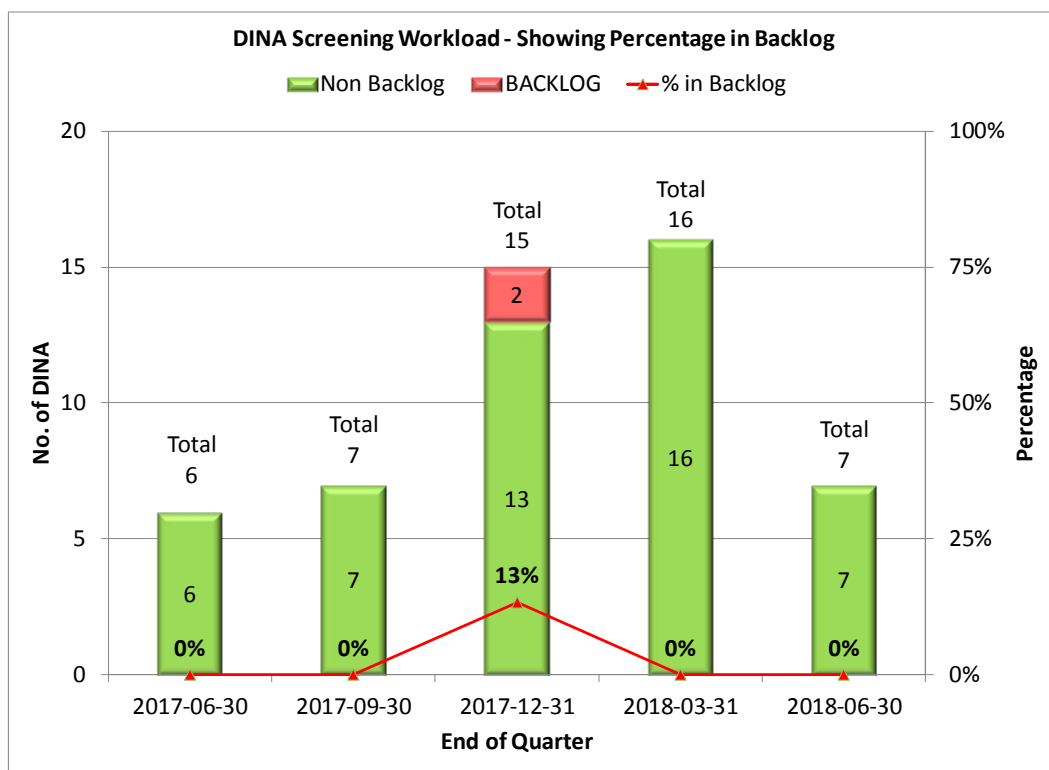
### Review Workload by Fee Category – DINA

TPD DINA ALL REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Labelling Only</b>	<b>18</b>	<b>20</b>	<b>14</b>	<b>13</b>	<b>19</b>
Backlog	1	0	1	1	1
<b>Chemistry &amp; Manufacturing</b>	<b>12</b>	<b>14</b>	<b>17</b>	<b>19</b>	<b>15</b>
Backlog	0	1	1	0	0
<b>Published Data</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>
Backlog	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>
Backlog	0	0	0	0	0
<b>Comparative Studies</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>4</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>31</b>	<b>36</b>	<b>33</b>	<b>34</b>	<b>42</b>
<b>Non Backlog</b>	<b>30</b>	<b>35</b>	<b>31</b>	<b>33</b>	<b>41</b>
<b>BACKLOG</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>1</b>
<b>% in Backlog</b>	<b>3%</b>	<b>3%</b>	<b>6%</b>	<b>3%</b>	<b>2%</b>



## SCREENING WORKLOAD

### Screening Workload / Backlog - Showing Percentage in Backlog – DINA



### Screening Workload by Fee Category – DINA

TPD DINA All SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
<b>Labelling Only</b>	4	3	3	8	3
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Standard</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	0	0	2	2	0
<i>Backlog</i>	0	0	1	0	0
<b>Chemistry &amp; Manufacturing</b>	1	3	10	4	4
<i>Backlog</i>	0	0	1	0	0
<b>Published Data</b>	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	1	0	0	2	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	6	7	15	16	7
<b>Non Backlog</b>	6	7	13	16	7
<b>BACKLOG</b>	0	0	2	0	0
<b>% in Backlog</b>	0%	0%	13%	0%	0%

## DECISION DOCUMENTS

### Decision Documents – DINA by Fee Category

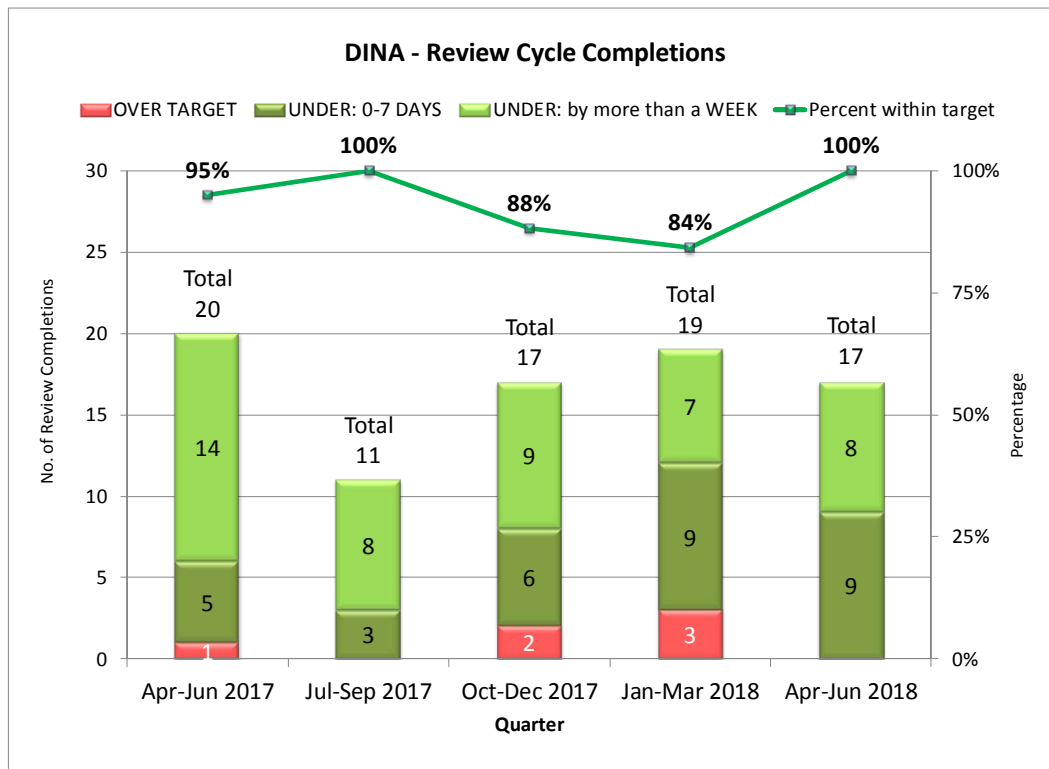
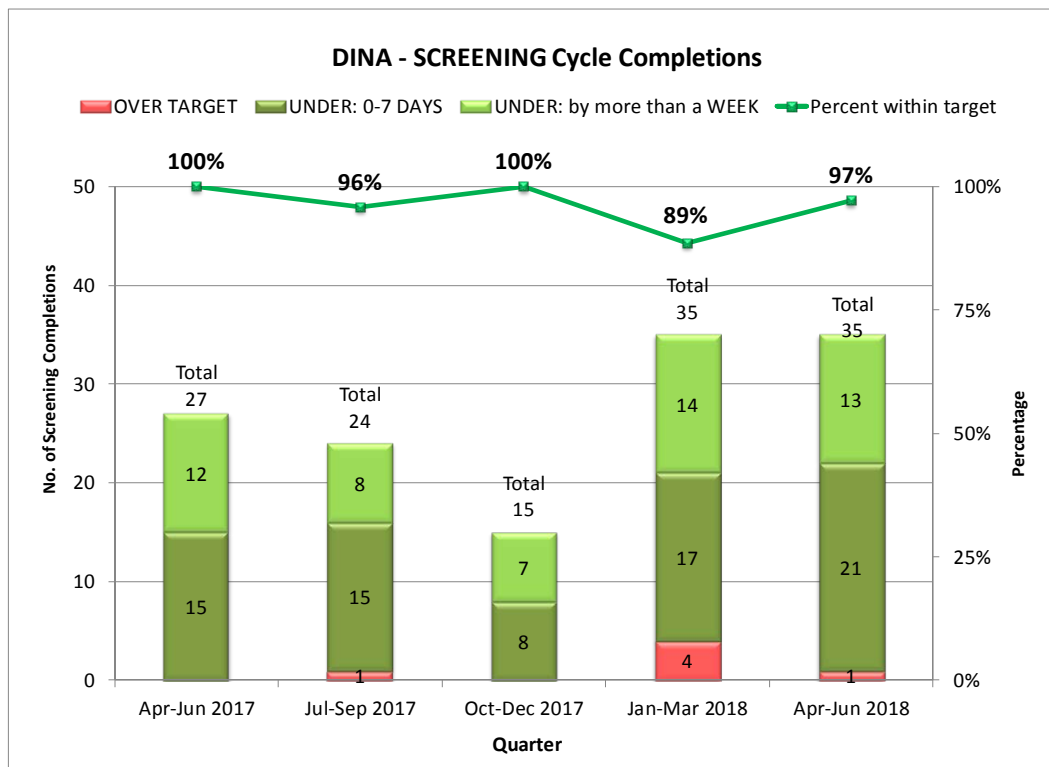
<b>DINA - Labelling Only</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
NOTIFICATION FORM/DIN ISSUED	3	1	5	3	1
NO OBJECTION LETTER	9	4	6	6	5
CANCELLED BY COMPANY	1	0	0	2	3
DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	2
REJECTION LETTER (SCR)	0	0	1	0	0
SCREENING DEFICIENCY NOTICE	1	3	1	3	2
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

<b>DINA - CHEMISTRY AND MANUFACTURING</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
NOTIFICATION FORM/DIN ISSUED	3	2	4	4	4
NO OBJECTION LETTER	0	2	0	1	3
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	1	0	0	1	0
NOTICE OF DEFICIENCY	0	0	0	2	0
NOTICE OF NON-COMPLIANCE	2	2	1	1	1
NEW DRUG LETTER REVIEW	1	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	2	0	6	3
CANCELLED BY COMPANY	0	0	0	3	1

<b>DINA - PUBLISHED DATA ONLY</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
SCREENING DEFICIENCY NOTICE	0	1	0	0	0
NO OBJECTION LETTER	0	0	0	0	1
REJECTION LETTER (SCR)	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0

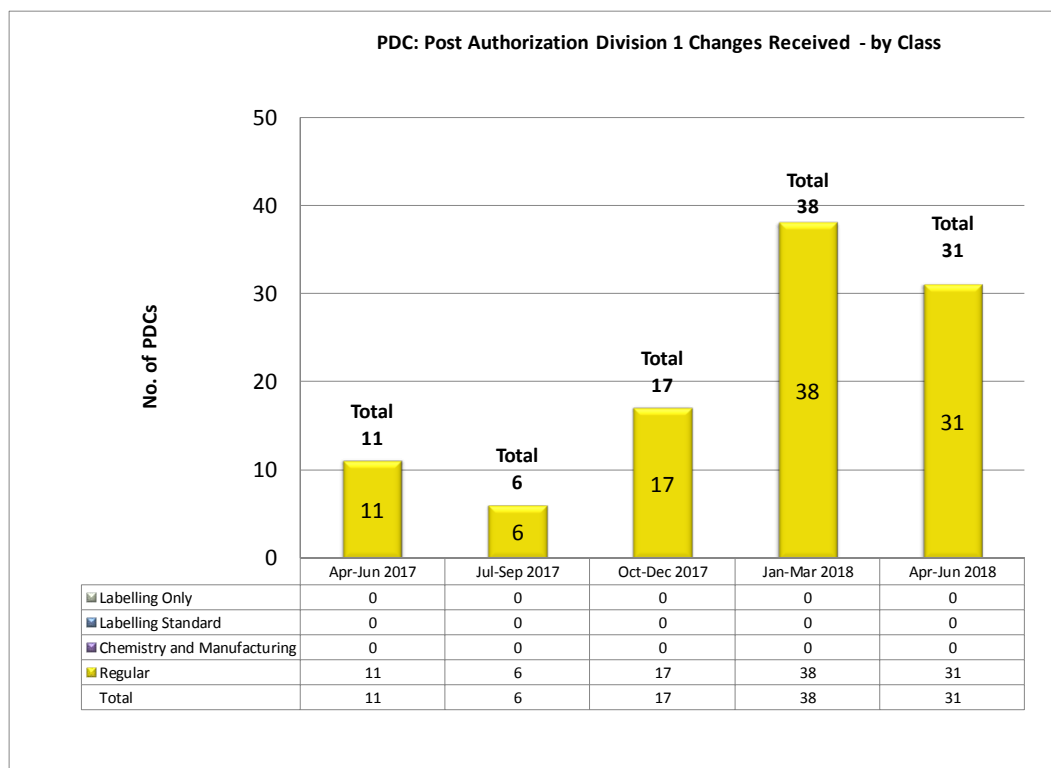
<b>DINA - COMPARATIVE STUDIES</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
NOTIFICATION FORM/DIN ISSUED	0	0	0	1	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	1	0	0
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	1	1

<b>DINA - CLINICAL OR NON CLINICAL DATA AND C&amp;M</b>					
<b>DOCUMENT TYPE</b>	<b>Apr-Jun 2017</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>
CANCELLED BY COMPANY	0	0	0	1	0
SCREENING DEFICIENCY NOTICE	0	0	0	2	2

**PERFORMANCE****Performance Review Cycle Completions Showing Percentage Within Target – DINA****Performance Screening Cycle Completions Showing Percentage Within Target – DINA**

## PDC: Post-Authorization Division 1 Changes,<sup>14</sup>

### Post-Authorization Division 1 Changes (PDC) Received



### Post-Authorization Division 1 Changes (PDC) - Decision Documents by Class

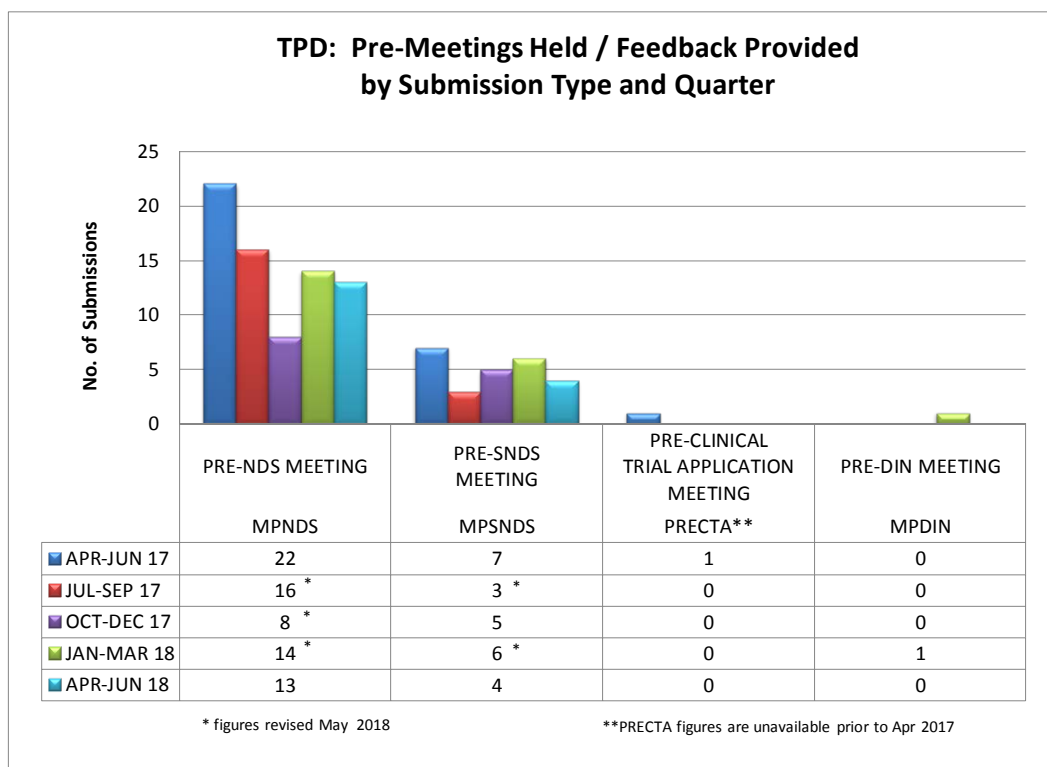
PDC					
DOCUMENT TYPE	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
<b>REGULAR</b>					
CANCELLED BY COMPANY	3	3	5	4	3
NO OBJECTION LETTER	9	2	9	15	30
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

<sup>14</sup> The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

## Appendix A: Pre-submission Meetings

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### Pre-submission Meetings Held / Feedback Provided



<sup>15</sup> Prior to filing a submission, the sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the [Management of Drug Submissions Guidance](#)