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# Biologics and Genetic Therapies Directorate

Drug Submission Performance Quarterly  
Report

July - September

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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# Table of Contents

<b>TABLE OF CONTENTS .....</b>	<b>3</b>
<b>OVERVIEW .....</b>	<b>6</b>
<b>ACRONYMS .....</b>	<b>8</b>
Submission Types .....	8
Documents .....	8
<b>FEE CATEGORIES .....</b>	<b>9</b>
<b>NDS &amp; SNDS.....</b>	<b>10</b>
<b>SUBMISSIONS RECEIVED , .....</b>	<b>11</b>
New Drug Submissions (NDS) Received by Fee Category .....	11
Supplemental New Drug Submissions (SNDS) Received by Fee Category .....	11
<b>WORKLOAD .....</b>	<b>12</b>
New Drug Submission (NDS) Review Workload / Backlog .....	12
Supplemental New Drug Submission (SNDS) Review Workload / Backlog .....	12
New Drug Submission (NDS) Review Workload by Fee Category .....	13
Supplemental New Drug Submission (SNDS) Review Workload by Fee Category .....	13
<b>APPROVALS.....</b>	<b>14</b>
New Drug Submission (NDS) Approvals by Fee Category and by NOC Type .....	14
Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type .....	14
<b>Biosimilars: NDS &amp; SNDS Market Authorizations.....</b>	<b>15</b>
Biosimilars: Number of NDS & SNDS that were issued an NOC by Quarter .....	15
Biosimilars: List of NDS & SNDS issued an NOC – FY 2018-19 by Quarter .....	15
<b>REVIEW CYCLE DECISIONS.....</b>	<b>16</b>
New Drug Submission (NDS) Review Decisions.....	16
NDS - Review Cycle Completions Showing Percentage Within Target .....	16
Supplemental New Drug Submission (SNDS) Review Decisions.....	17
SNDS - Review Cycle Completions Showing Percentage Within Target .....	17
<b>SCREENING CYCLE DECISIONS .....</b>	<b>18</b>
New Drug Submission (NDS) Screening Decisions.....	18
NDS - Screening Cycle Completions Showing Percentage Within Target .....	18

Supplemental New Drug Submission (SNDS) Screening Decisions .....	19
SNDS - Screening Cycle Completions Showing Percentage Within Target .....	19
<b>PRIORITY REVIEW STATUS REQUESTS (FOR NDS &amp; SNDS) .....</b>	<b>20</b>
Priority Review Status Requests Received .....	20
Priority Review Status Requests: Decisions Rendered .....	21
Priority Review Status Request: Performance .....	21
<b>NOTIFIABLE CHANGES ( NC ) .....</b>	<b>22</b>
Submissions Received - Notifiable Change (NC).....	23
Decision Documents by Class - Notifiable Change (NC).....	23
<b>WORKLOAD .....</b>	<b>24</b>
Notifiable Change (NC) SAFETY - Review Workload / Backlog .....	24
Notifiable Change (NC) QUALITY - Review Workload / Backlog.....	24
Notifiable Change (NC) SAFETY - Review Workload by Class .....	25
Notifiable Change (NC) QUALITY - Review Workload by Class .....	25
<b>PERFORMANCE.....</b>	<b>26</b>
REVIEW Completions by Class - Notifiable Change (NC) .....	26
SCREENING Completions by Class - Notifiable Changes (NC).....	26
<b>ADMINISTRATIVE SUBMISSIONS.....</b>	<b>27</b>
<b>ADMINISTRATIVE SUBMISSIONS (with BGTD Review) .....</b>	<b>28</b>
Administrative Submissions Received (with BGTD Review) .....	28
Administrative Submission Approvals (with BGTD Review).....	28
<b>ADMINISTRATIVE SUBMISSIONS (Processed by OSIP) .....</b>	<b>29</b>
Administrative Submissions Received by Submission Type (OSIP).....	29
Administrative Submission Approvals (OSIP) - for NDS, SNDS, ANDS and SANDS.....	29
<b>CLINICAL TRIAL APPLICATIONS ( CTA ).....</b>	<b>32</b>
Number Received - Clinical Trial Application (CTA).....	32
Decision Documents - Clinical Trial Application (CTA) .....	32
Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target.....	32
<b>CLINICAL TRIAL APPLICATION- AMENDMENTS ( CTA-A ) .....</b>	<b>33</b>
Number Received - Clinical Trial Application Amendments (CTA-A) .....	33
Decision Documents - Clinical Trial Application Amendments (CTA-A).....	33
Performance – CTA-A Reviews - 30 Day Target.....	33

<b>DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER – BIOLOGICAL PRODUCT .....</b>	<b>35</b>
Number Received - DINB .....	35
<b>REVIEW WORKLOAD.....</b>	<b>36</b>
Review Workload / Backlog - Showing Percentage in Backlog - DINB.....	36
Review Workload by Class - DINB .....	36
<b>SCREENING WORKLOAD.....</b>	<b>37</b>
Screening Workload / Backlog - Showing Percentage in Backlog - DINB .....	37
Screening Workload by Class - DINB .....	37
<b>DECISION DOCUMENTS .....</b>	<b>38</b>
Decision Documents – DINB by Class.....	38
<b>PERFORMANCE .....</b>	<b>39</b>
Performance Review Cycle Completions Showing Percentage Within Target - DINB .....	39
Performance Screening Cycle Completions Showing Percentage Within Target - DINB .....	39
<b>POST –AUTHORIZATION DIVISION 1 CHANGES - BIOLOGICS (PDC-B) .....</b>	<b>40</b>
Post –Authorization Division 1 Changes - Biologics (PDC-B) Received .....	40
<b>YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) .....</b>	<b>41</b>
Yearly Biologic Product Report s (YBPR) Received .....	41
<b>APPENDIX A: PRE-SUBMISSION MEETINGS.....</b>	<b>42</b>
Pre-submission Meetings Held / Feedback Provided .....	42

# OVERVIEW

The Biologics and Genetic Therapies Directorate (BGTD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from July – September 2017 to July – September 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 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

CTA	- Clinical Trial Application
CTA-A	- Clinical Trial Application-Amendment
DINB	- Application for a Drug Identification Number - Biological Product
MP-NDS	Pre- New Drug Submission Meeting
MP-SNDS	Pre- Supplemental New Drug Submission Meeting
NDS	- New Drug Submission
NC	- Notifiable Change (Level II) – 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
SNDS	- Supplemental New Drug Submission
SNDS-C	- Supplemental New Drug Submission – CONFIRMATORY
YBPR	- Yearly Biologic Product Report

## 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 (Rx to OTC)
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 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.

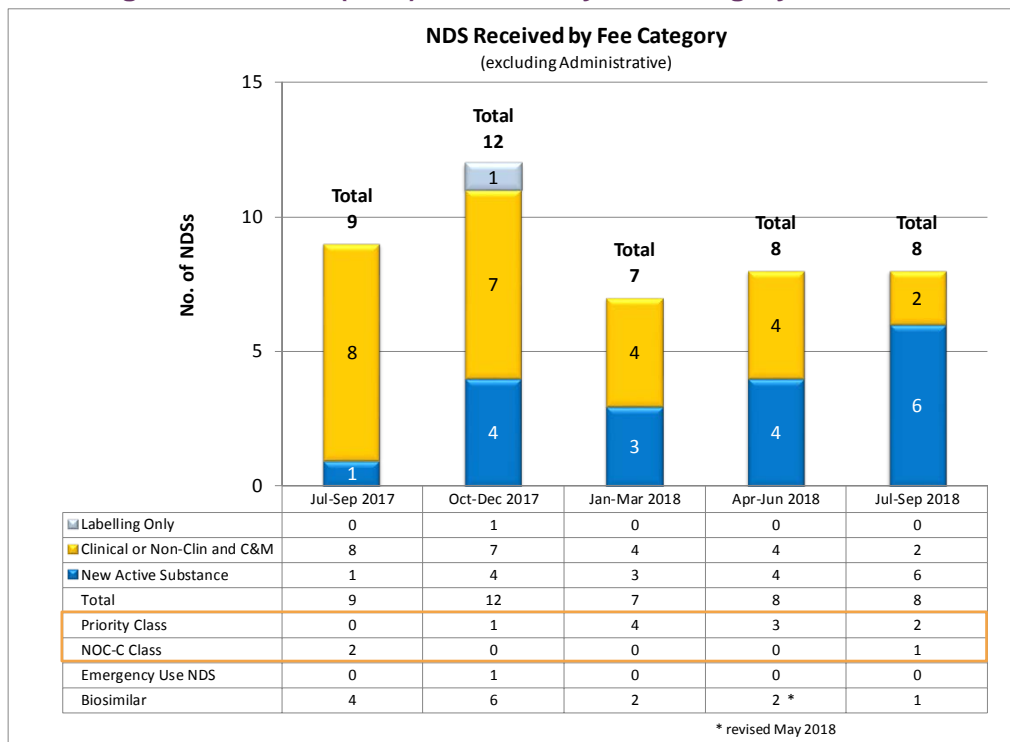
**New Drug Submissions  
(NDS)**

**&**

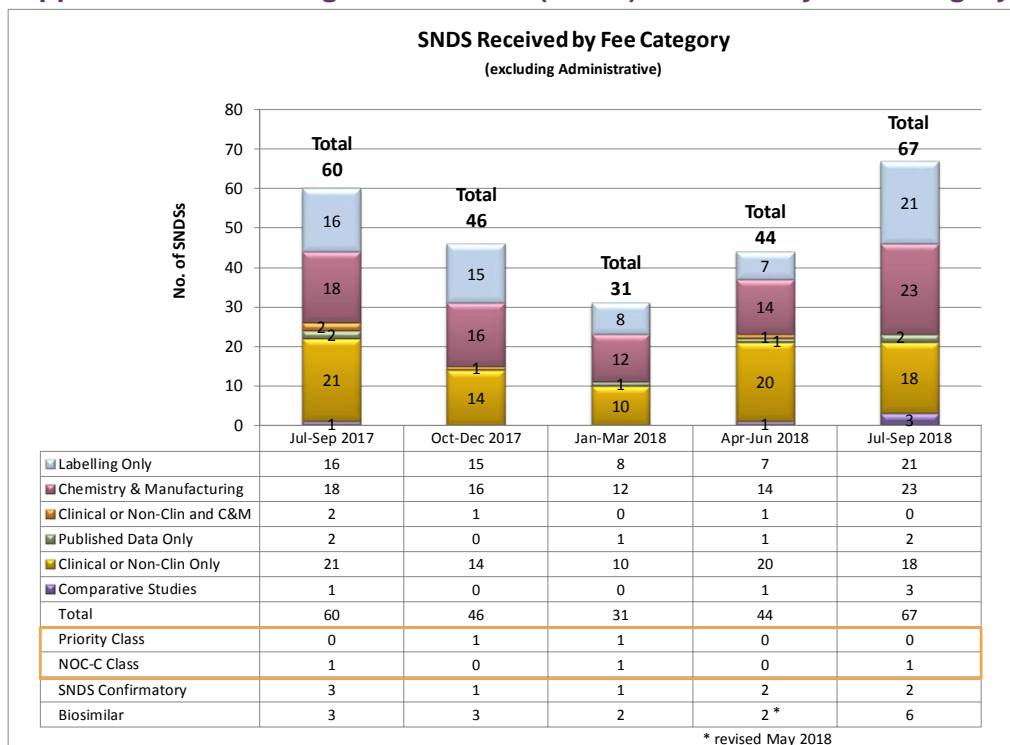
**Supplemental New Drug Submissions  
(SNDS)**

## SUBMISSIONS RECEIVED<sup>9, 10</sup>

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



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

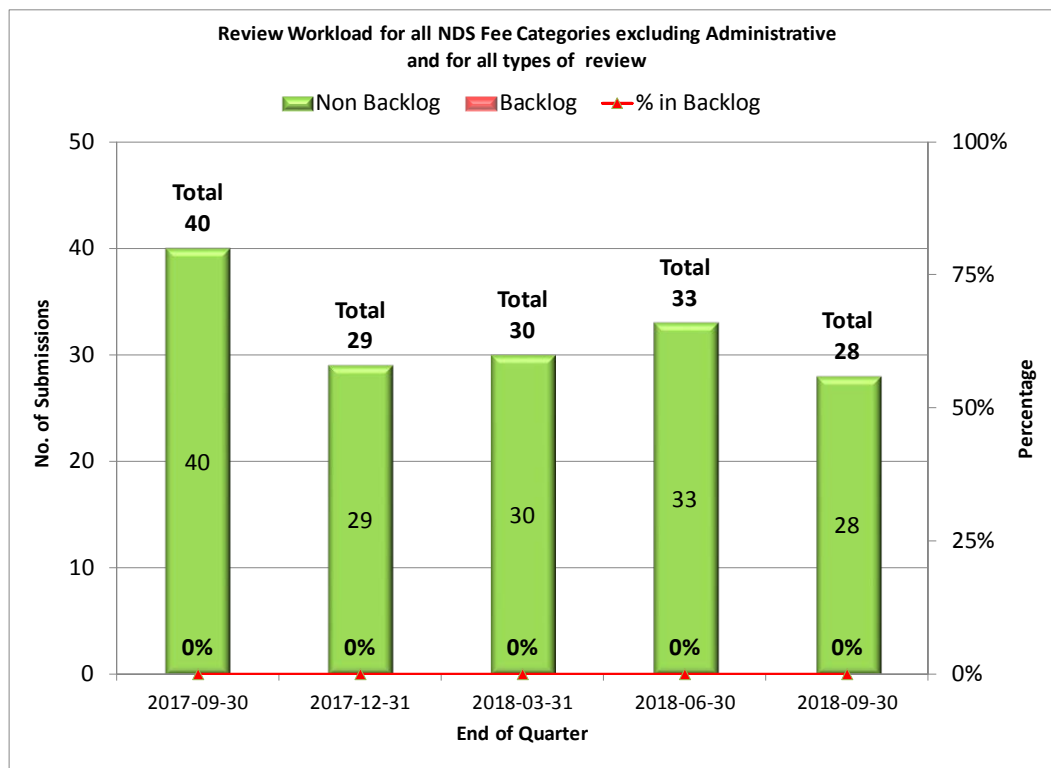


<sup>9</sup> **Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

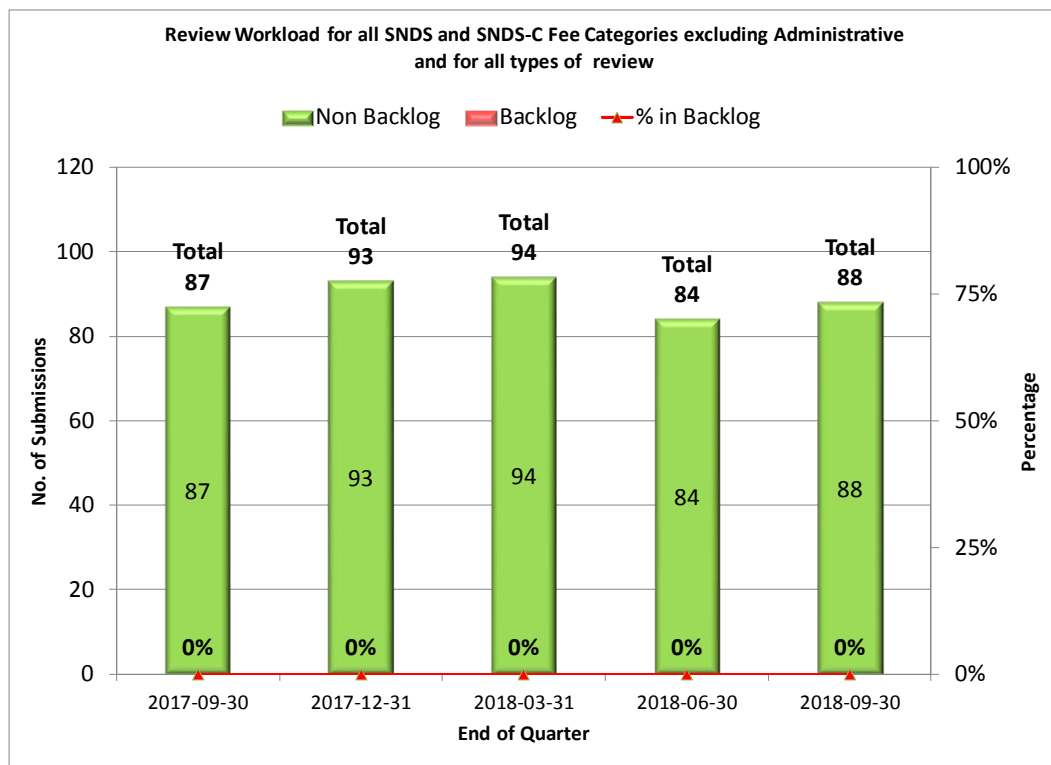
<sup>10</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice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

## 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

BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
<b>Clinical or Non-Clin and C&amp;M</b>	<b>22</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>14</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>New Active Substance</b>	<b>18</b>	<b>8</b>	<b>9</b>	<b>12</b>	<b>14</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>40</b>	<b>29</b>	<b>30</b>	<b>33</b>	<b>28</b>
<b>Non Backlog</b>	<b>40</b>	<b>29</b>	<b>30</b>	<b>33</b>	<b>28</b>
<b>Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>
<b>Priority (subset)</b>	<b>1</b>	<b>1</b>	<b>5</b>	<b>7</b>	<b>5</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

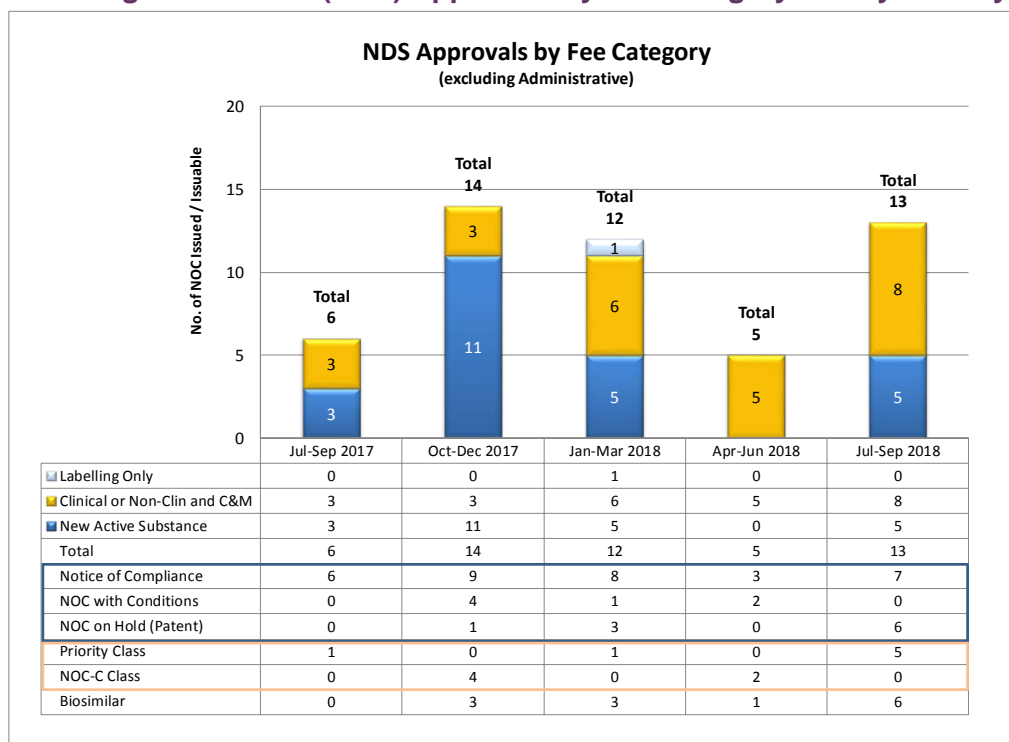
### Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

BGTD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
<b>Comparative Studies</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>3</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>17</b>	<b>23</b>	<b>26</b>	<b>26</b>	<b>22</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>51</b>	<b>51</b>	<b>54</b>	<b>48</b>	<b>48</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>7</b>	<b>6</b>	<b>4</b>	<b>4</b>	<b>2</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Published Data</b>	<b>2</b>	<b>4</b>	<b>2</b>	<b>2</b>	<b>1</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Labelling Only</b>	<b>9</b>	<b>8</b>	<b>7</b>	<b>3</b>	<b>12</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>87</b>	<b>93</b>	<b>94</b>	<b>84</b>	<b>88</b>
<b>Non Backlog</b>	<b>87</b>	<b>93</b>	<b>94</b>	<b>84</b>	<b>88</b>
<b>Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>
<b>Priority (subset)</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>0</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>6</b>	<b>6</b>	<b>5</b>	<b>2</b>	<b>6</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

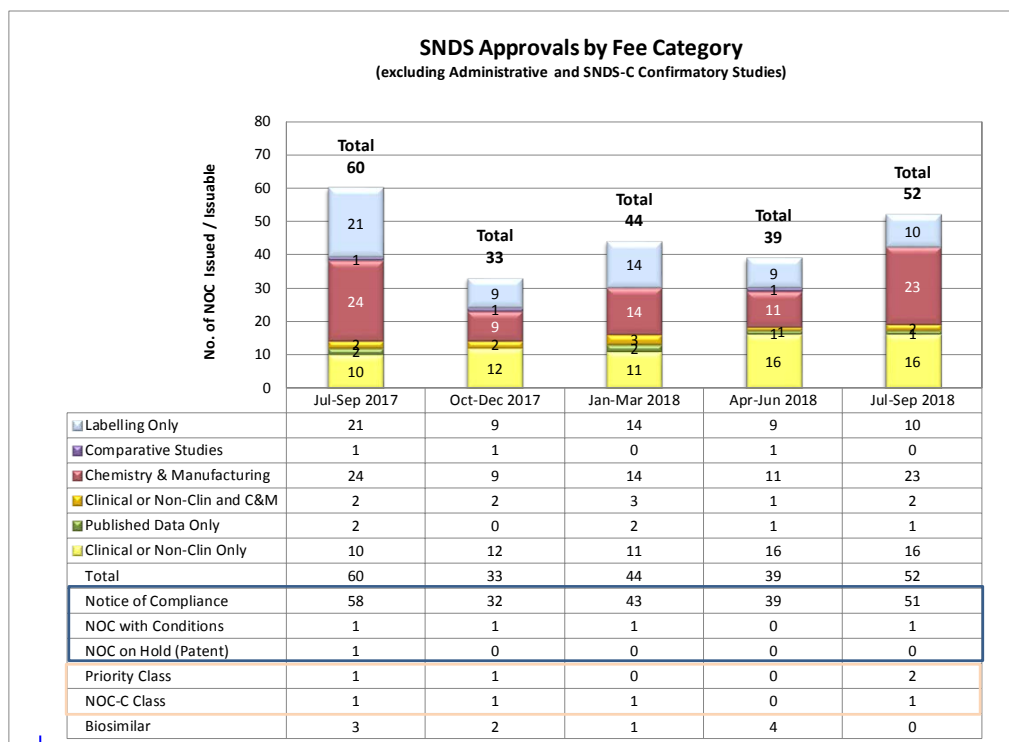
## APPROVALS

11

### New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



### Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type



<sup>11</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](#).

## Biosimilars: NDS & SNDS Market Authorizations

### Biosimilars: Number of NDS & SNDS that were issued an NOC by Quarter

Submission Type	Class	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NDS	CLIN/C&M	0	2	0	1	0
<b>NDS Total</b>		<b>0</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>0</b>
SNDS	C&M ONLY	1	0	0	1	0
	C&M/LABELLING	0	0	0	0	0
	CLIN ONLY	0	0	0	1	0
	CLIN/C&M	0	0	0	0	0
	COMP/C&M	0	0	0	0	0
	LABELLING ONLY	1	2	1	2	0
<b>SNDS Total</b>		<b>2</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>0</b>

### Biosimilars: List of NDS & SNDS issued an NOC – FY 2018-19 by Quarter

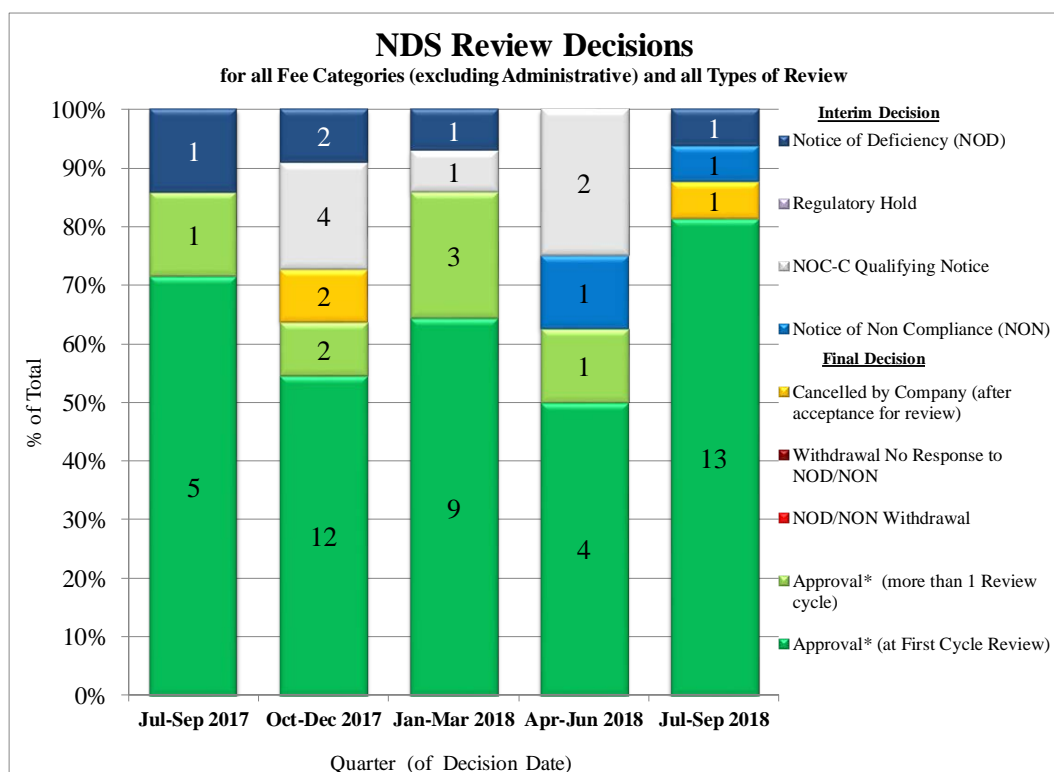
Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2018-19	Notice of Compliance (NOC) Date
NDS	LAPELGA	CLIN/C&M	APOTEX INC	PEGFILGRASTIM	Q1	2018-Apr-05
<b>New Drug Submission Total</b>					<b>1</b>	
SNDS	ADMELOG	LABELLING ONLY	SANOI-AVENTIS CANADA INC.	INSULIN LISPRO	Q1	2018-Apr-30
	BASAGLAR	C&M ONLY	ELI LILLY CANADA INC.	INSULIN GLARGINE	Q1	2018-May-10
	BRENZYS	LABELLING ONLY	SAMSUNG BIOEPIS., LTD.	ETANERCEPT	Q1	2018-Jun-18
	BRENZYS (PFP), BRENZYS (PFS)	CLIN ONLY	SAMSUNG BIOEPIS., LTD.	ETANERCEPT	Q1	2018-Jun-14
<b>Supplemental New Drug Submission Total</b>					<b>4</b>	

Please note: Approved Biosimilars that remain on Intellectual Property Hold are not included.

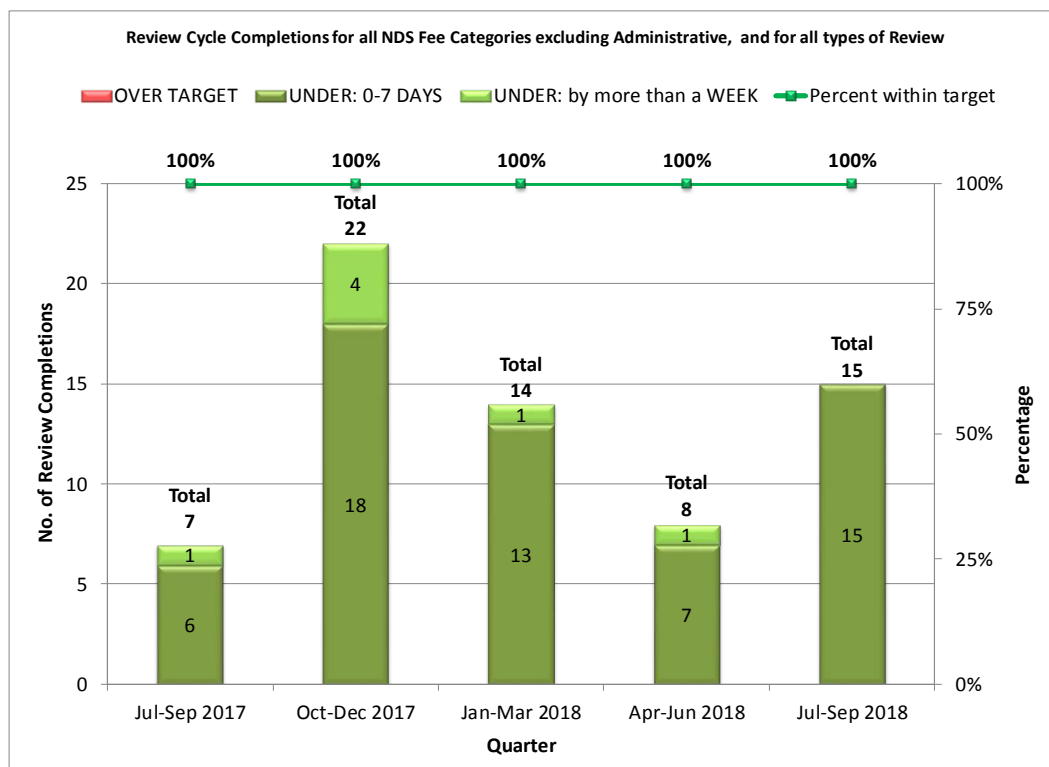
**Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required

## REVIEW CYCLE DECISIONS

### New Drug Submission (NDS) Review Decisions



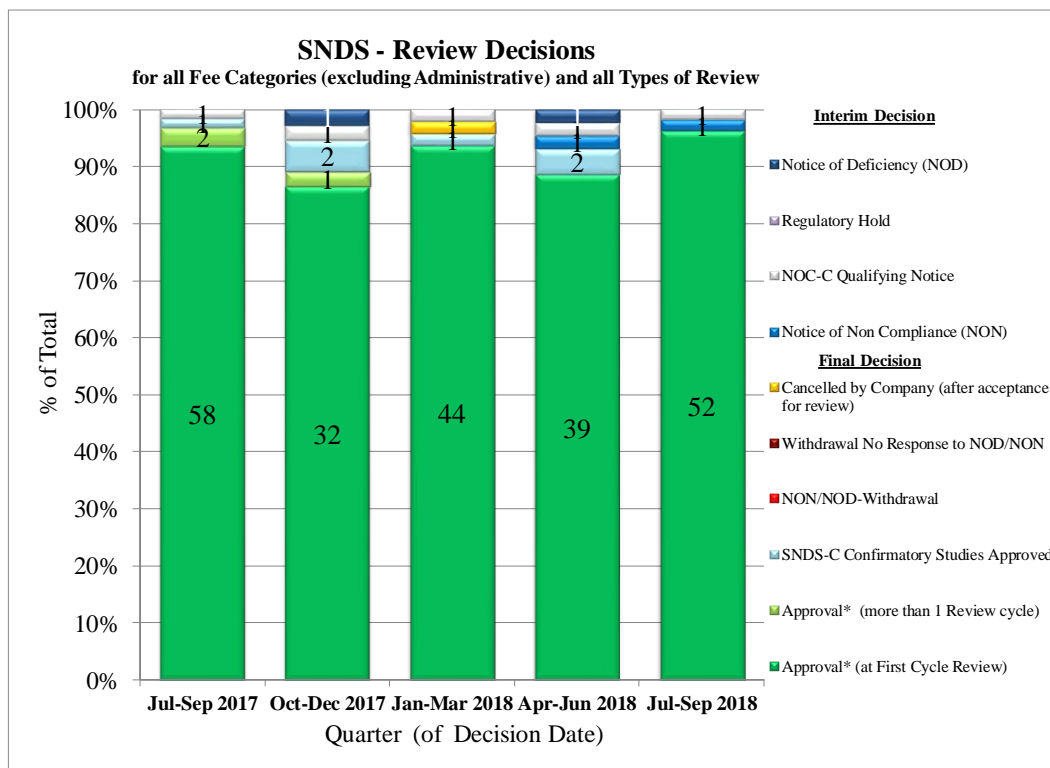
### NDS - Review Cycle Completions Showing Percentage Within Target



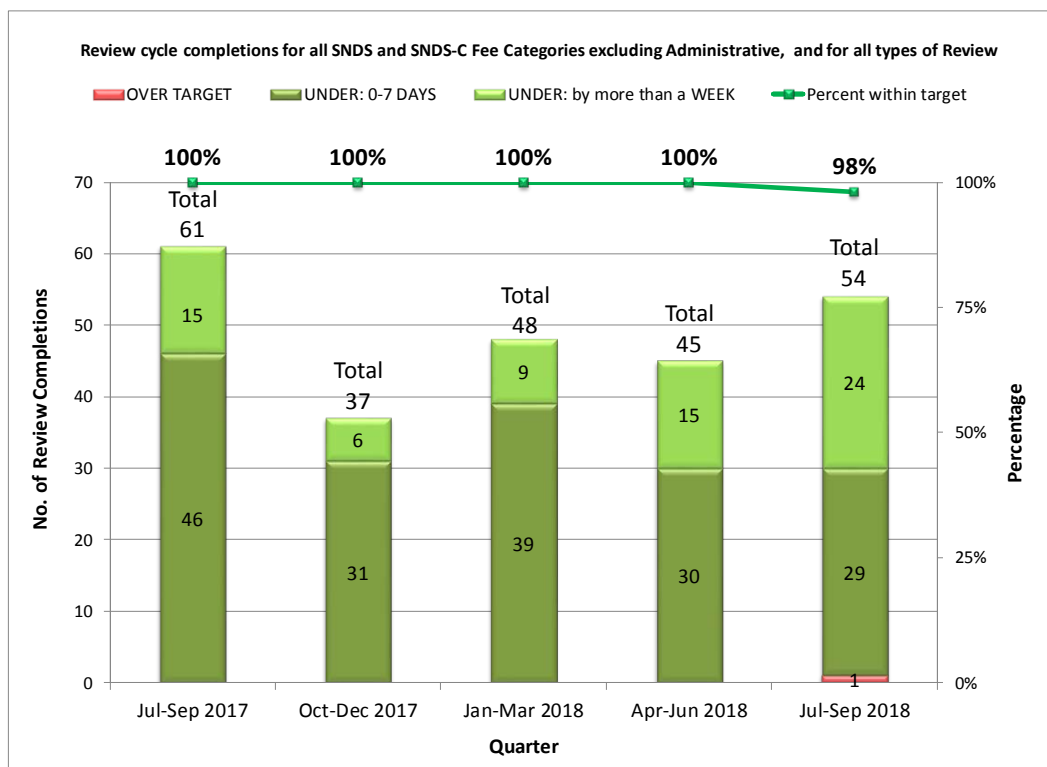


## REVIEW CYCLE DECISIONS

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

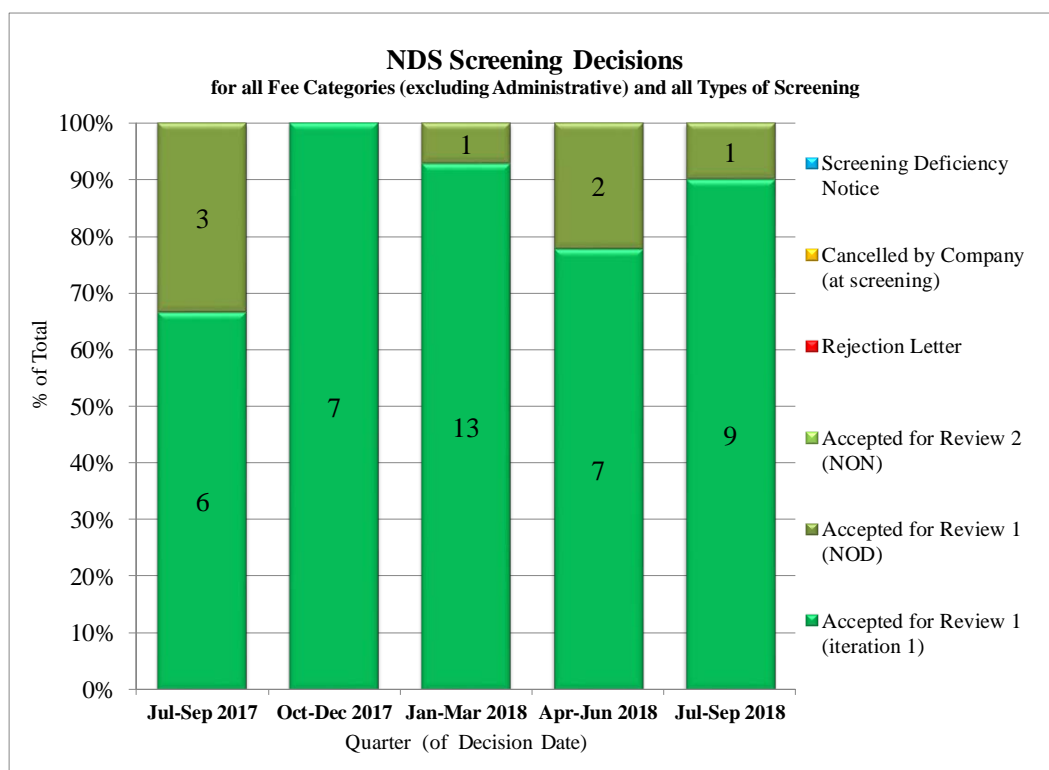


### SNDS - Review Cycle Completions Showing Percentage Within Target

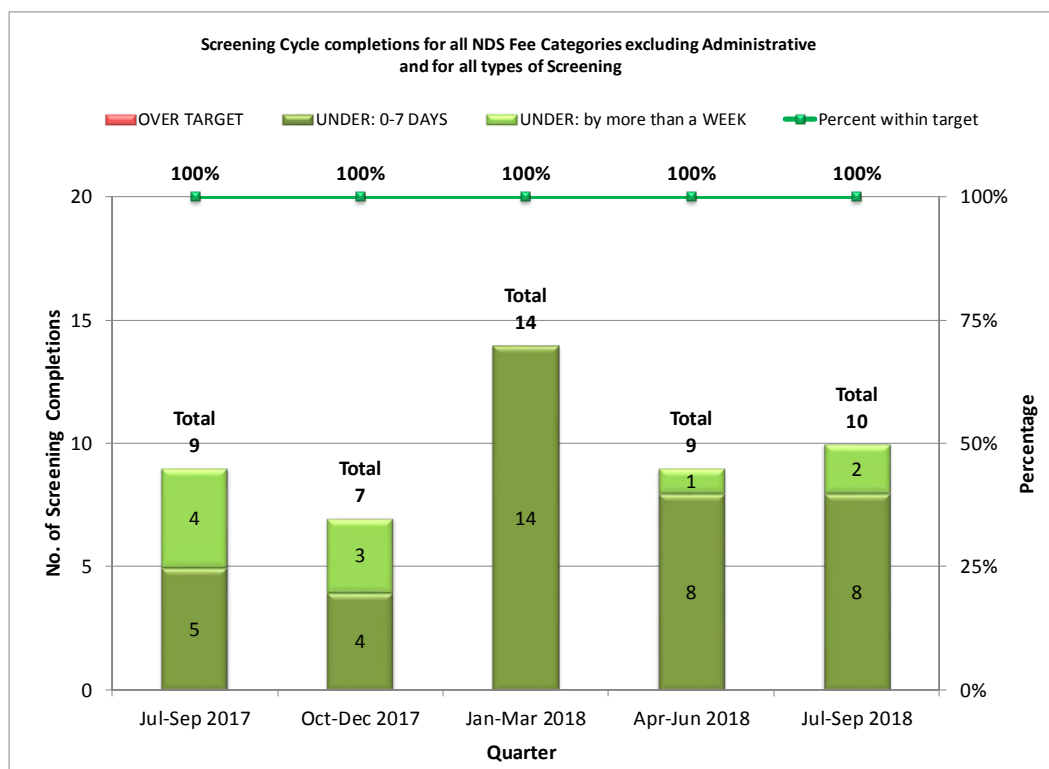


## SCREENING CYCLE DECISIONS

### New Drug Submission (NDS) Screening Decisions

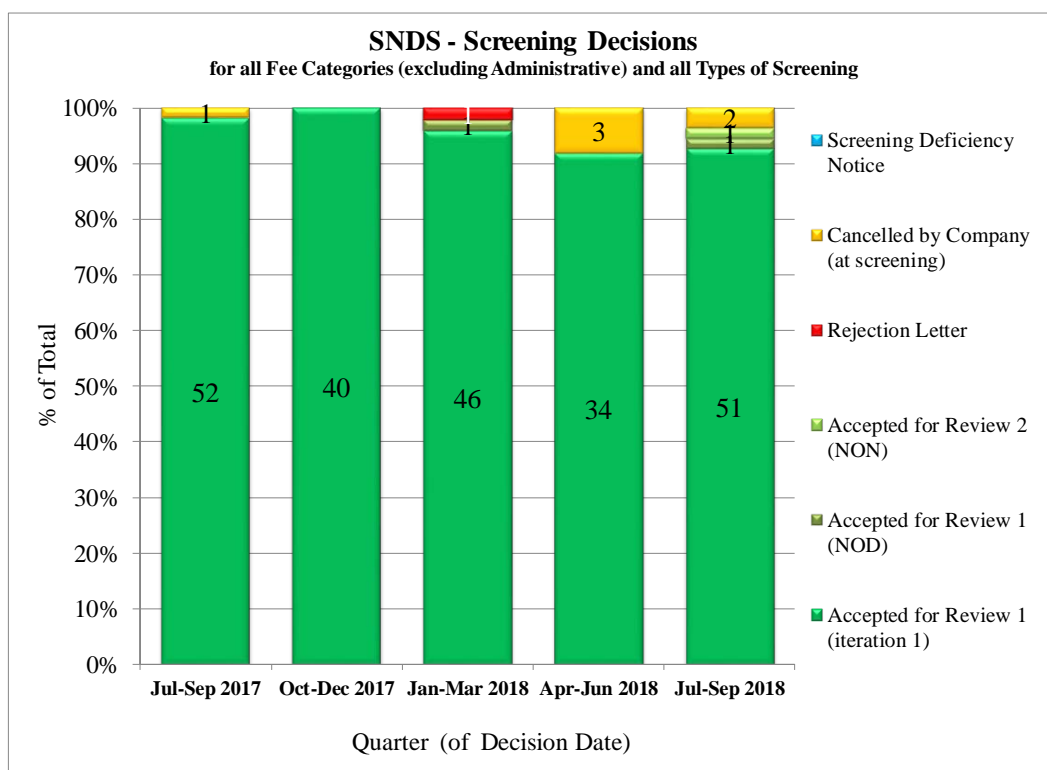


### NDS - Screening Cycle Completions Showing Percentage Within Target

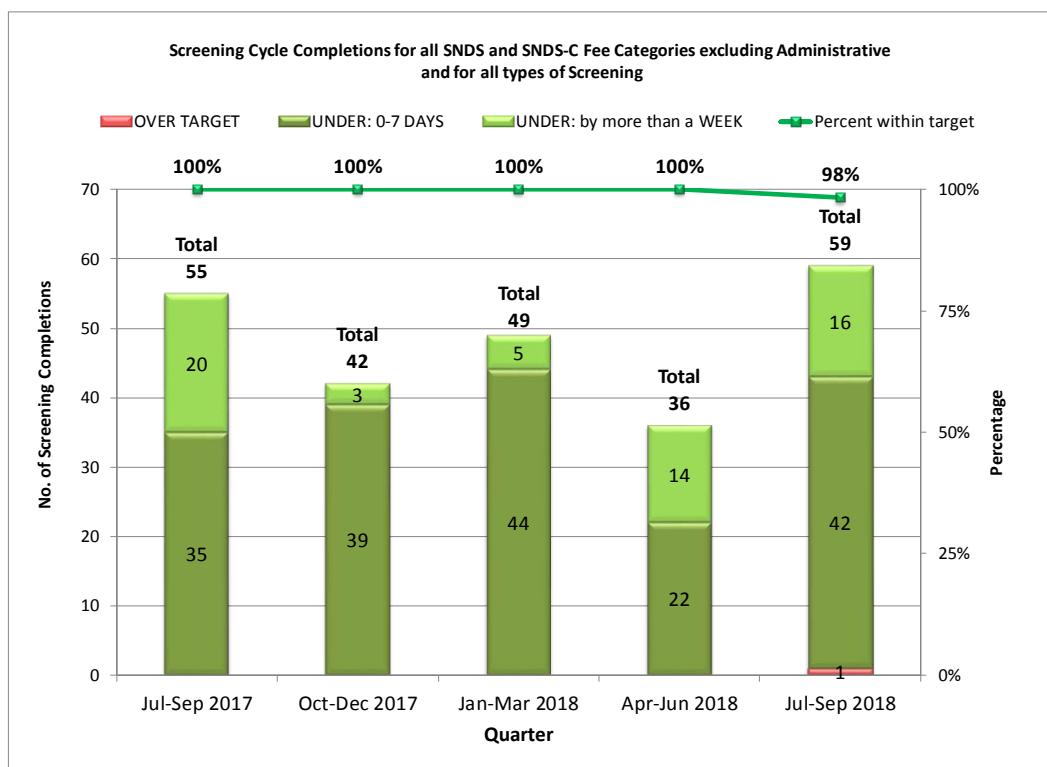


## SCREENING CYCLE DECISIONS

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

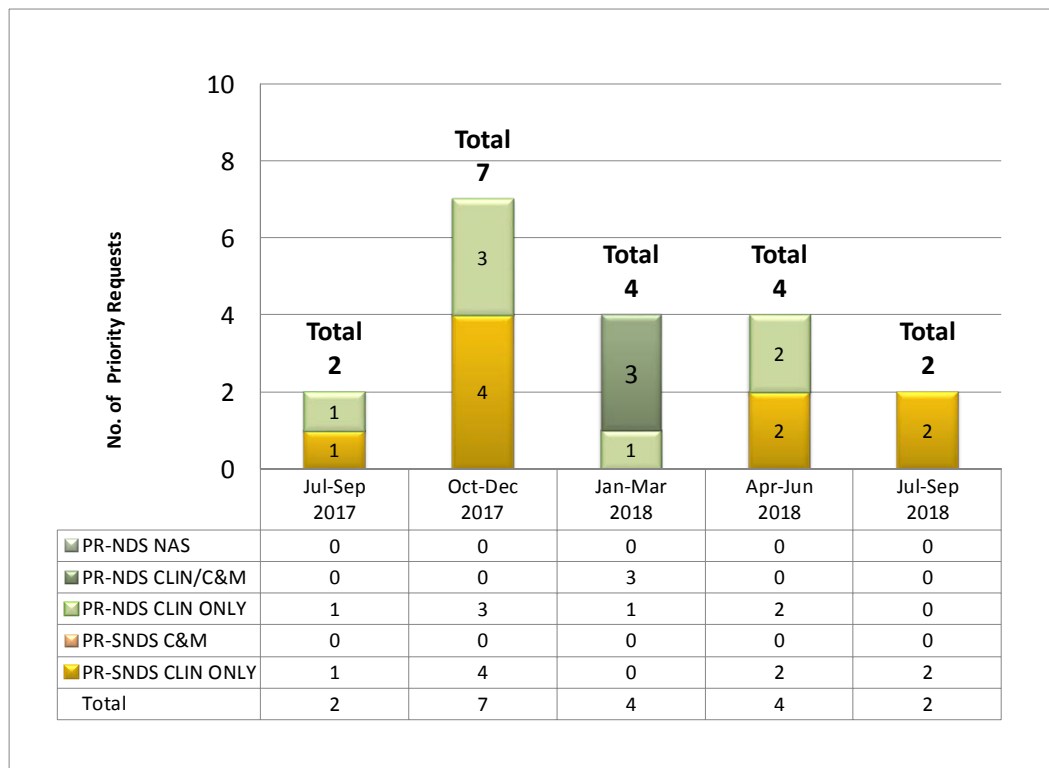


### SNDS - Screening Cycle Completions Showing Percentage Within Target

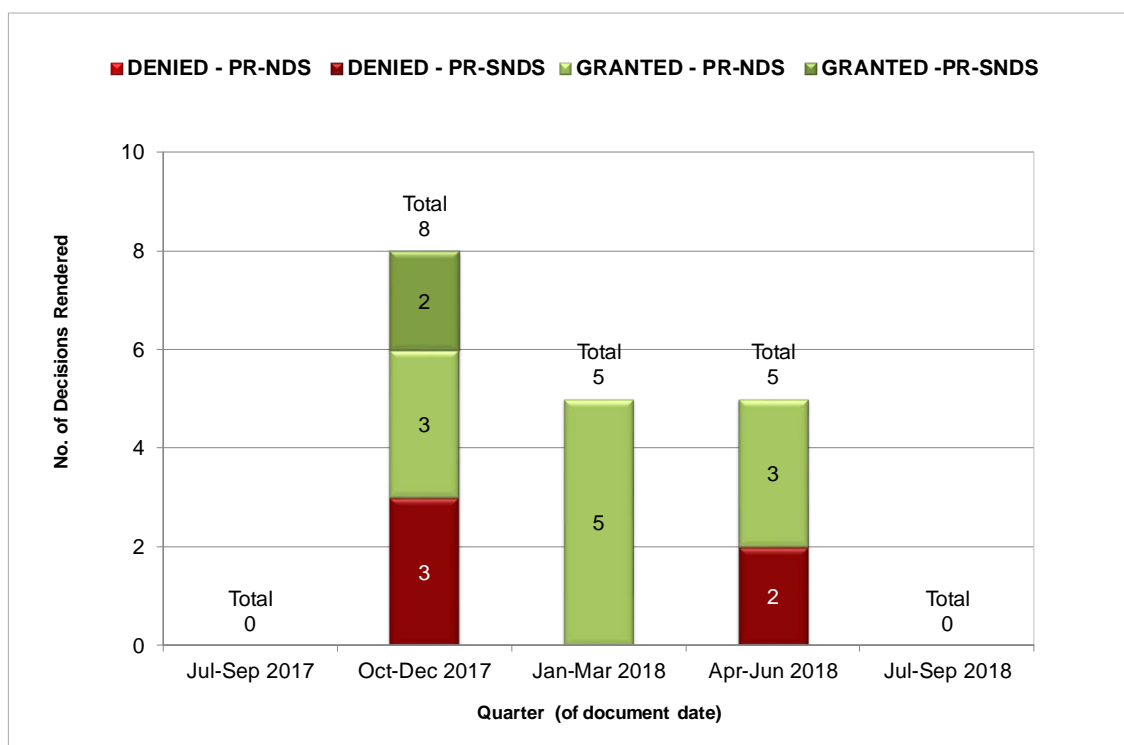


## Priority Review Status Requests (for NDS & SNDS)

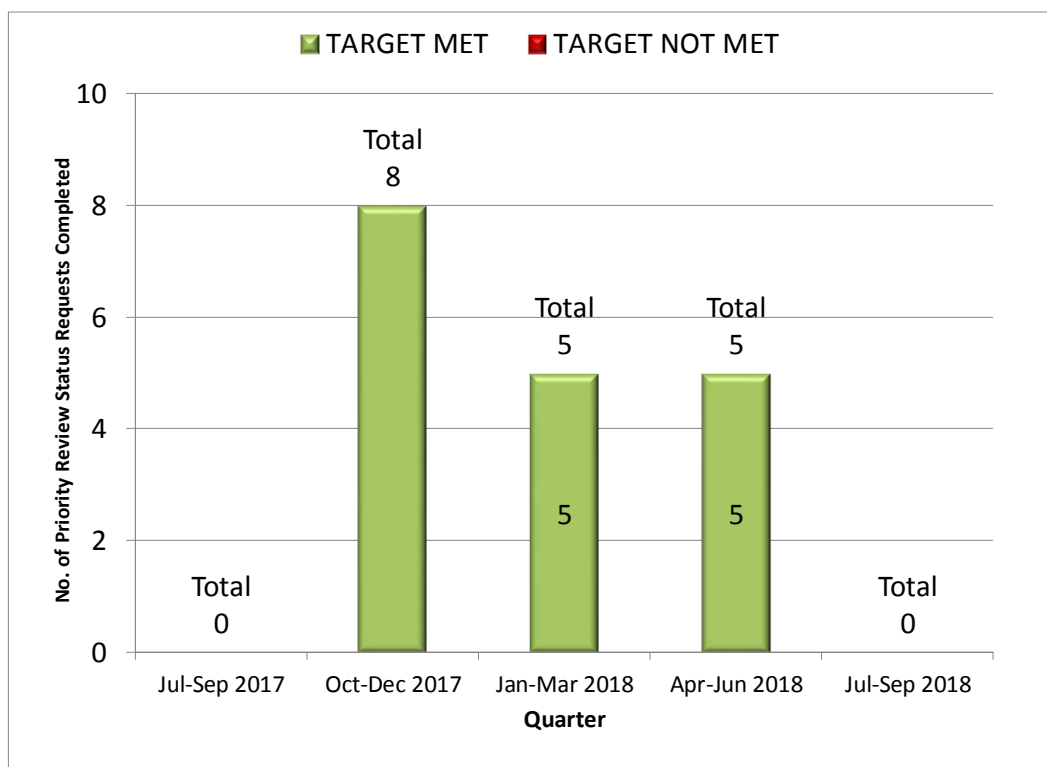
### Priority Review Status Requests Received



## Priority Review Status Requests: Decisions Rendered



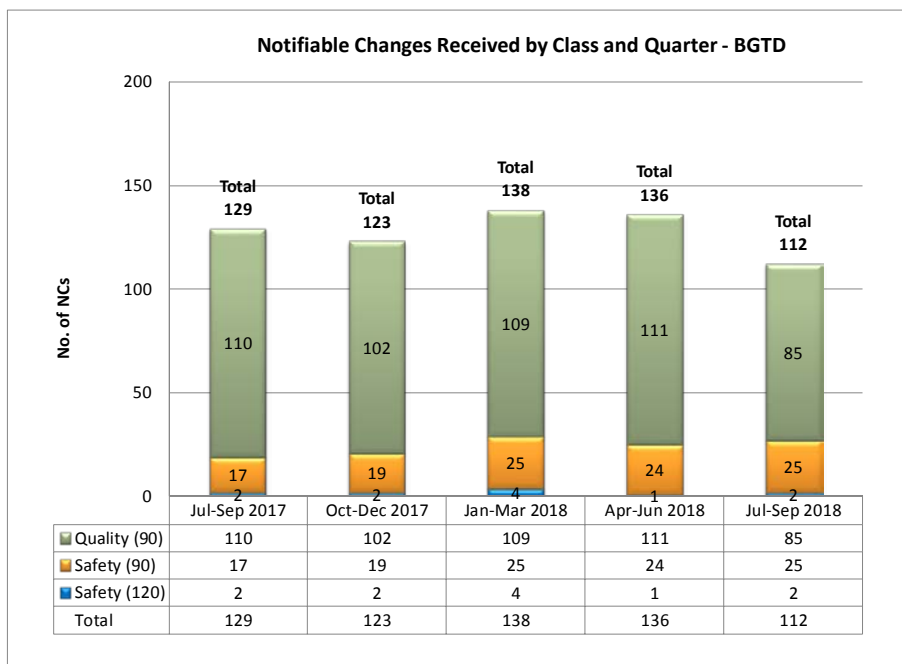
## Priority Review Status Request: Performance



## **Notifiable Changes ( NC )**

# NOTIFIABLE CHANGE

## Submissions Received - Notifiable Change (NC)



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

NC - SAFETY (90)					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	19	17	22	25	26
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	1	2	1	2	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

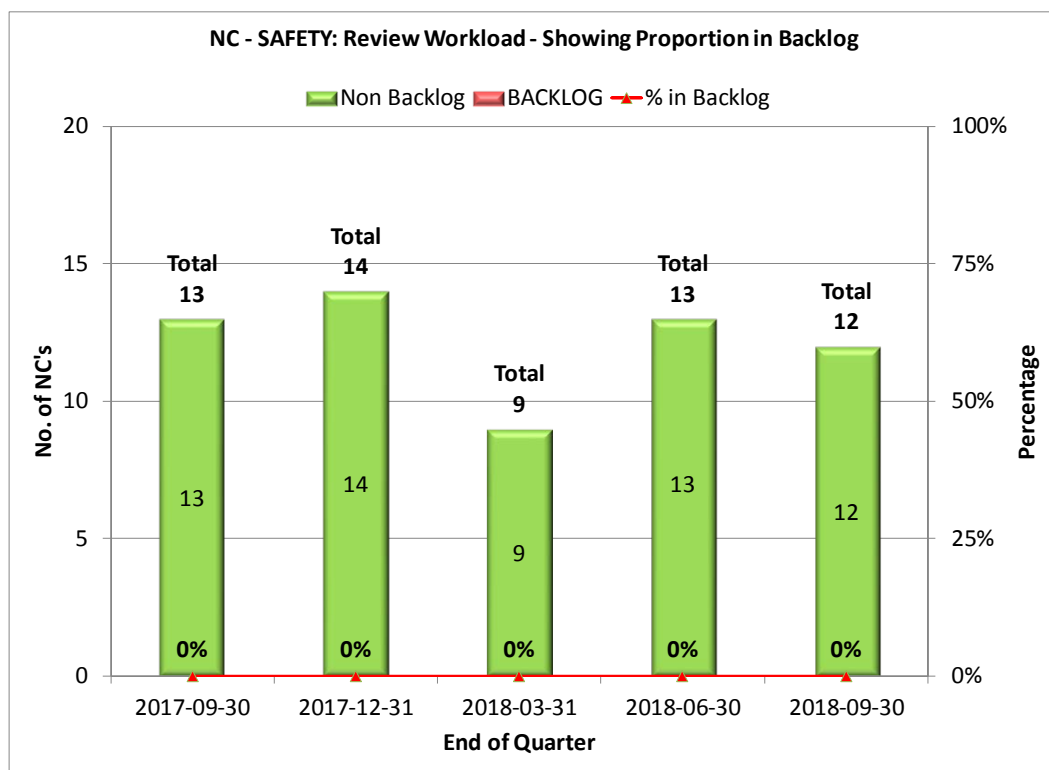
NC - QUALITY (90)					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	103	108	85	117	86
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	1	11	2	4
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
CANCELLED BY COMPANY	2	2	0	4	4

NC - SAFETY (120)					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	0	2	2	1	1
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	1	0	1	1

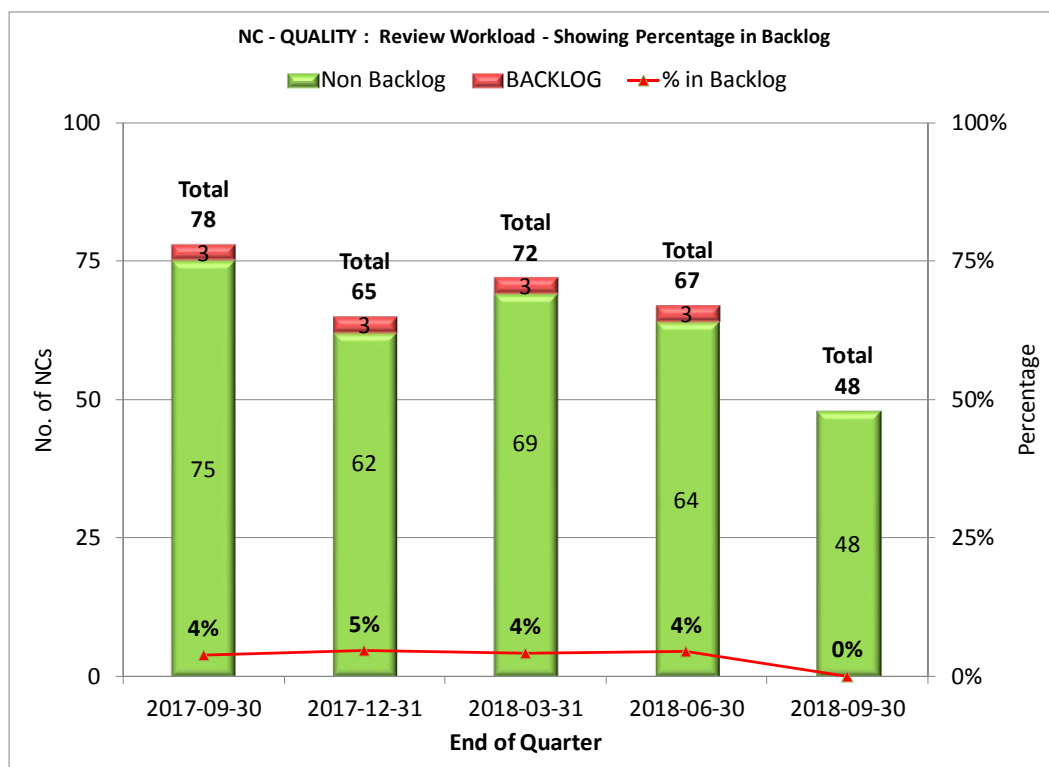
NC - ADMINISTRATIVE					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	0	3	4	2	0
CANCELLED BY COMPANY	0	0	0	0	0

## WORKLOAD

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



### Notifiable Change (NC) QUALITY - Review Workload / Backlog





## WORKLOAD

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

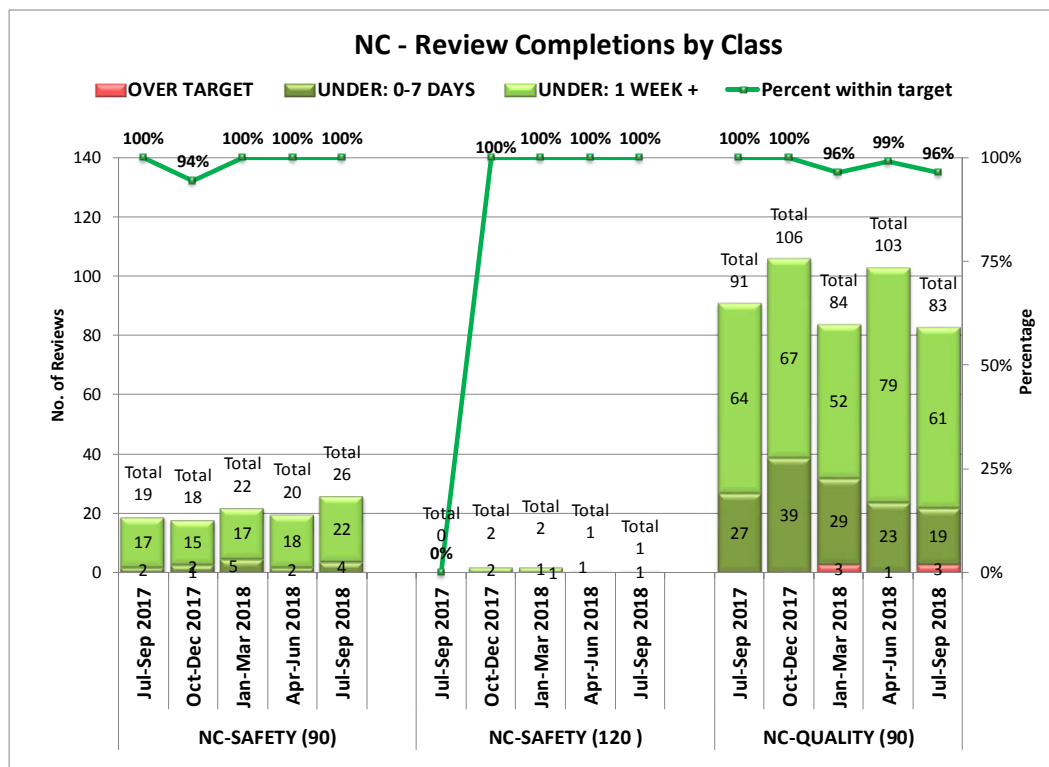
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
SAFETY - 90 day	11	13	8	11	10
Backlog	0	0	0	0	0
SAFETY - 120 day	2	1	1	2	2
Backlog	0	0	0	0	0
<b>Total</b>	<b>13</b>	<b>14</b>	<b>9</b>	<b>13</b>	<b>12</b>
<b>Non Backlog</b>	<b>13</b>	<b>14</b>	<b>9</b>	<b>13</b>	<b>12</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### Notifiable Change (NC) QUALITY - Review Workload by Class

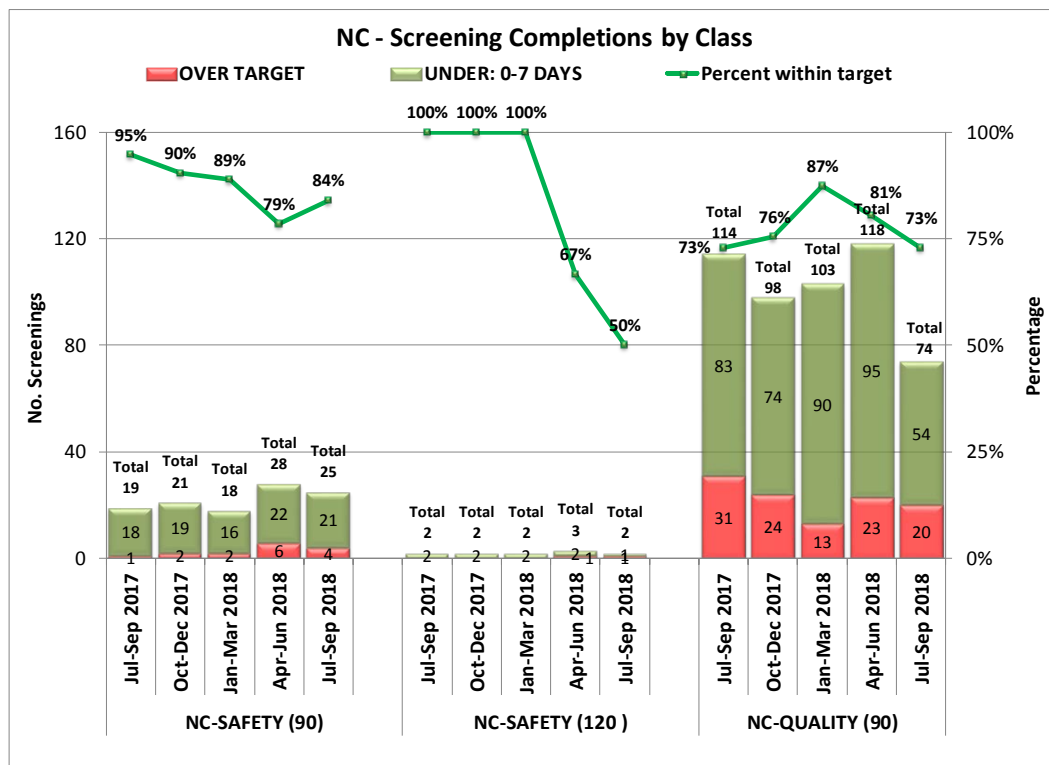
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
QUALITY - 90 day	78	65	72	67	48
Backlog	3	3	3	3	0
<b>Total</b>	<b>78</b>	<b>65</b>	<b>72</b>	<b>67</b>	<b>48</b>
<b>Non Backlog</b>	<b>75</b>	<b>62</b>	<b>69</b>	<b>64</b>	<b>48</b>
<b>BACKLOG</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>0</b>
<b>% in Backlog</b>	<b>4%</b>	<b>5%</b>	<b>4%</b>	<b>4%</b>	<b>0%</b>

## PERFORMANCE

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



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



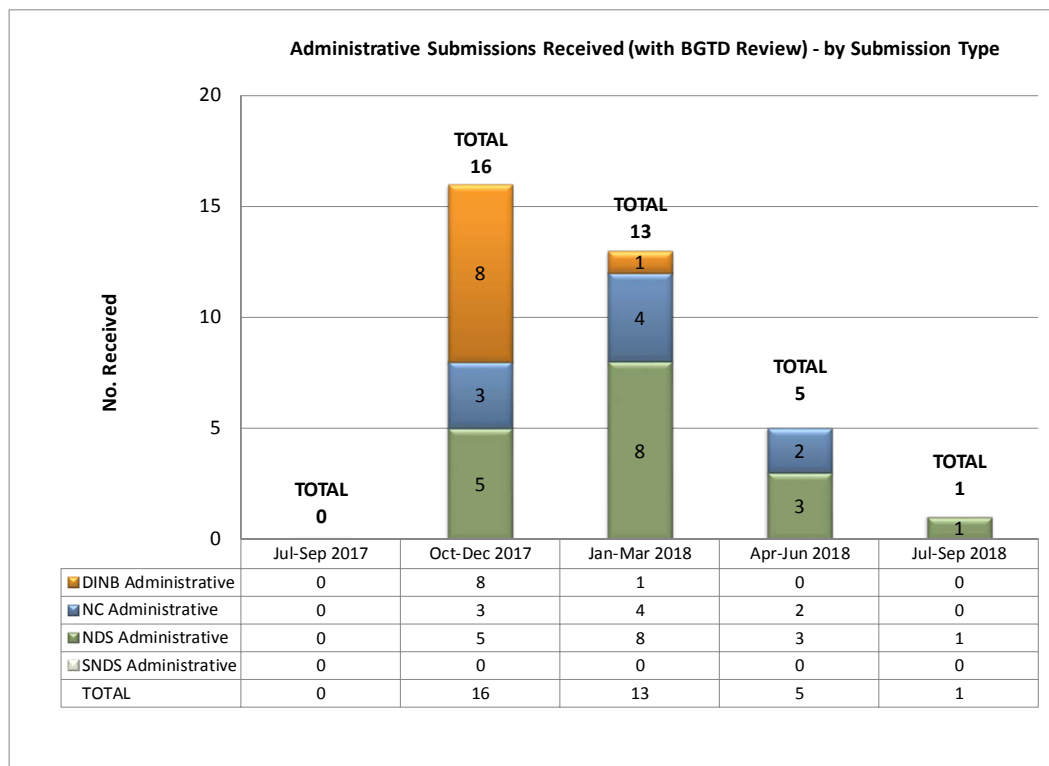
## **Administrative Submissions**

Submissions in support of a manufacturer or product name change.

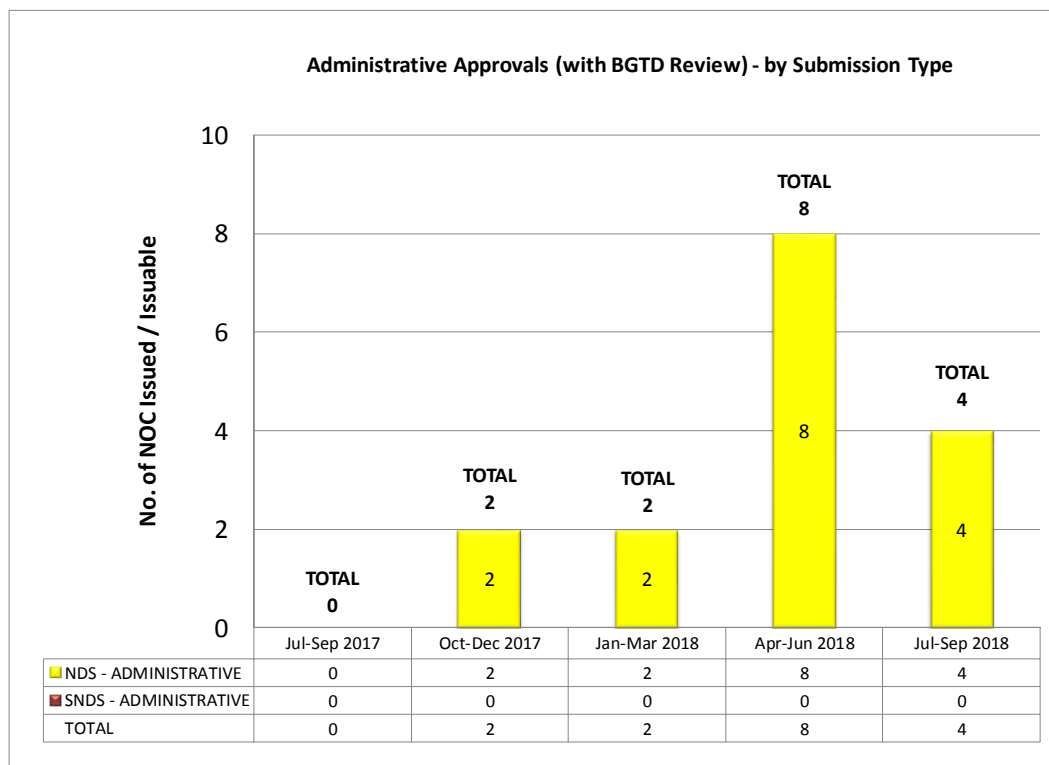
## ADMINISTRATIVE SUBMISSIONS (with BGTD Review)

(such as product name change that requires a drug name review)

### Administrative Submissions Received (with BGTD Review)



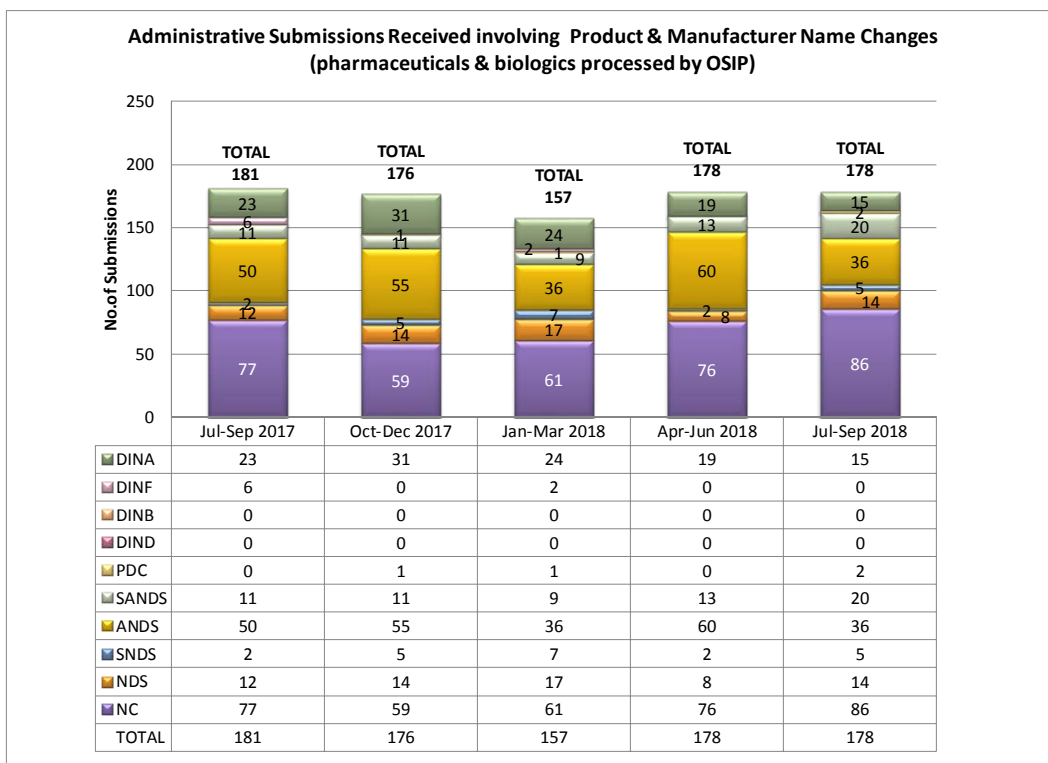
### Administrative Submission Approvals (with BGTD Review)



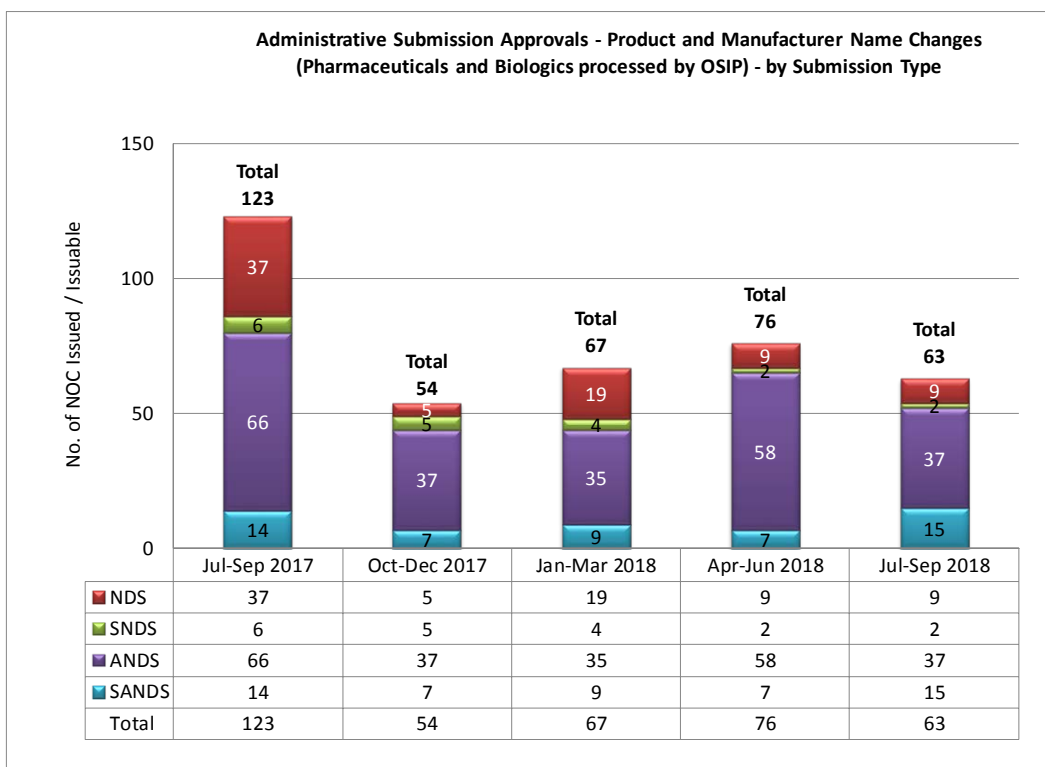
## ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

(Product & Manufacturer Name Changes) (Admin NCs are for cross-referenced changes)

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



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

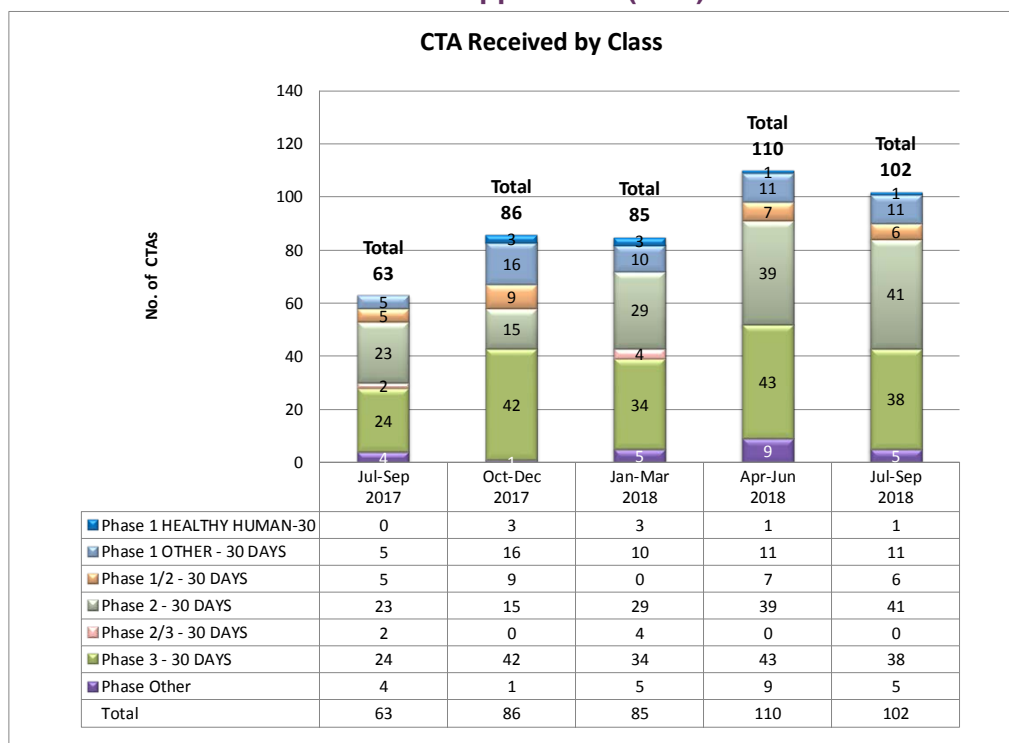


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# **Clinical Trial Applications and Amendments (CTA & CTA-A)**

## Clinical Trial Applications ( CTA )

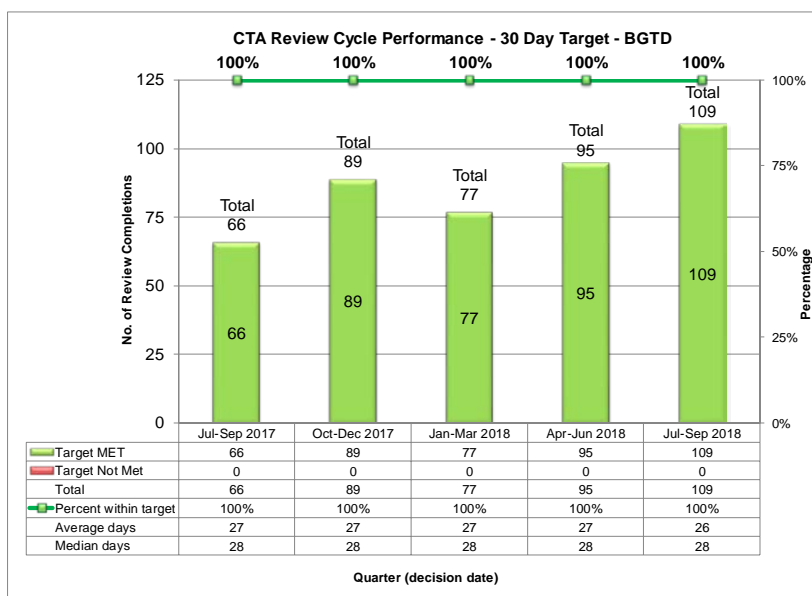
### Number Received - Clinical Trial Application (CTA)



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

CTA					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	63	85	75	92	108
CANCELLED BY COMPANY	3	6	5	3	5
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	1

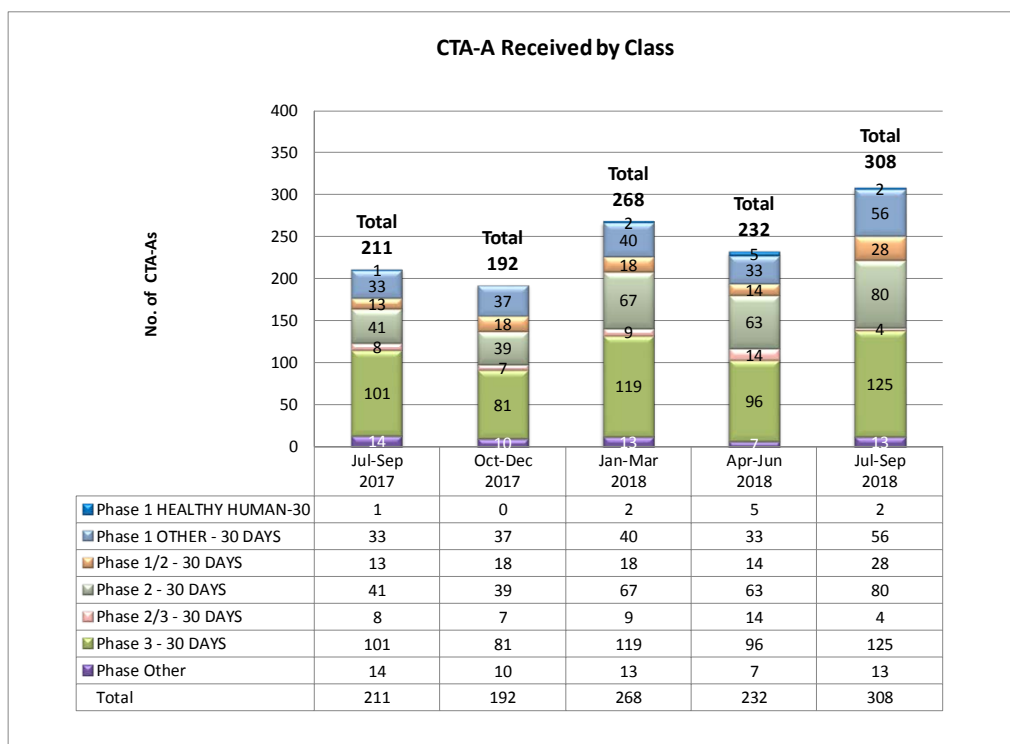
### Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target





# Clinical Trial Application- Amendments ( CTA-A )

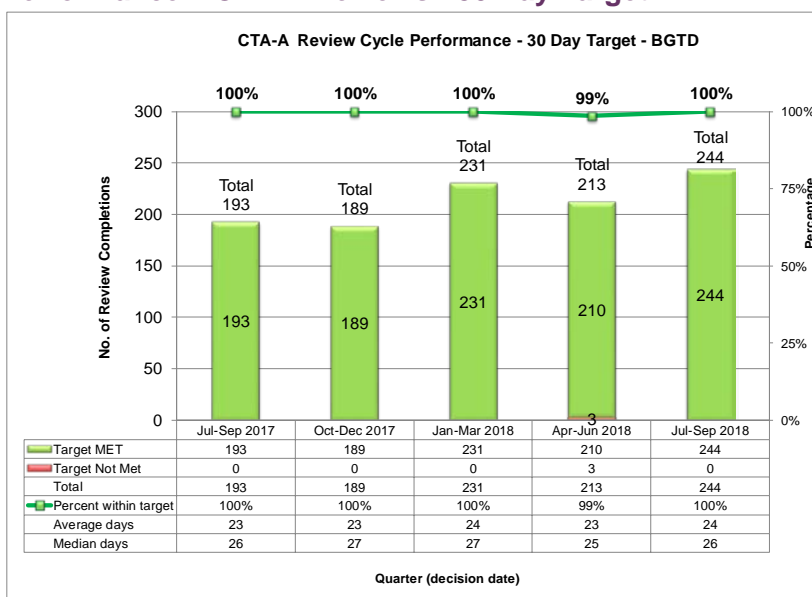
## Number Received - Clinical Trial Application Amendments (CTA-A)



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

CTA-A					
DOCUMENT TYPE	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NO OBJECTION LETTER	193	202	240	228	297
REJECTION LETTER (SCR)	4	3	4	7	4
CANCELLED BY COMPANY	14	2	5	1	4
NOT SATISFACTORY NOTICE	0	0	0	0	0

## Performance – CTA-A Reviews - 30 Day Target



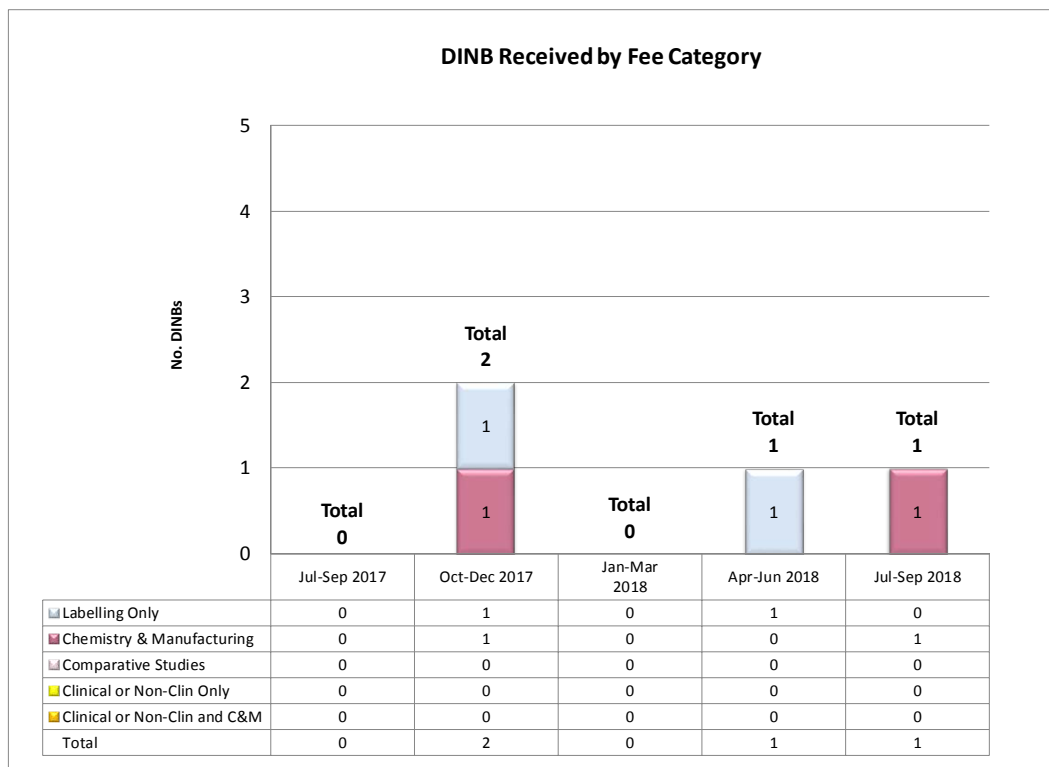
# **DINB**

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

### **Biological Product**

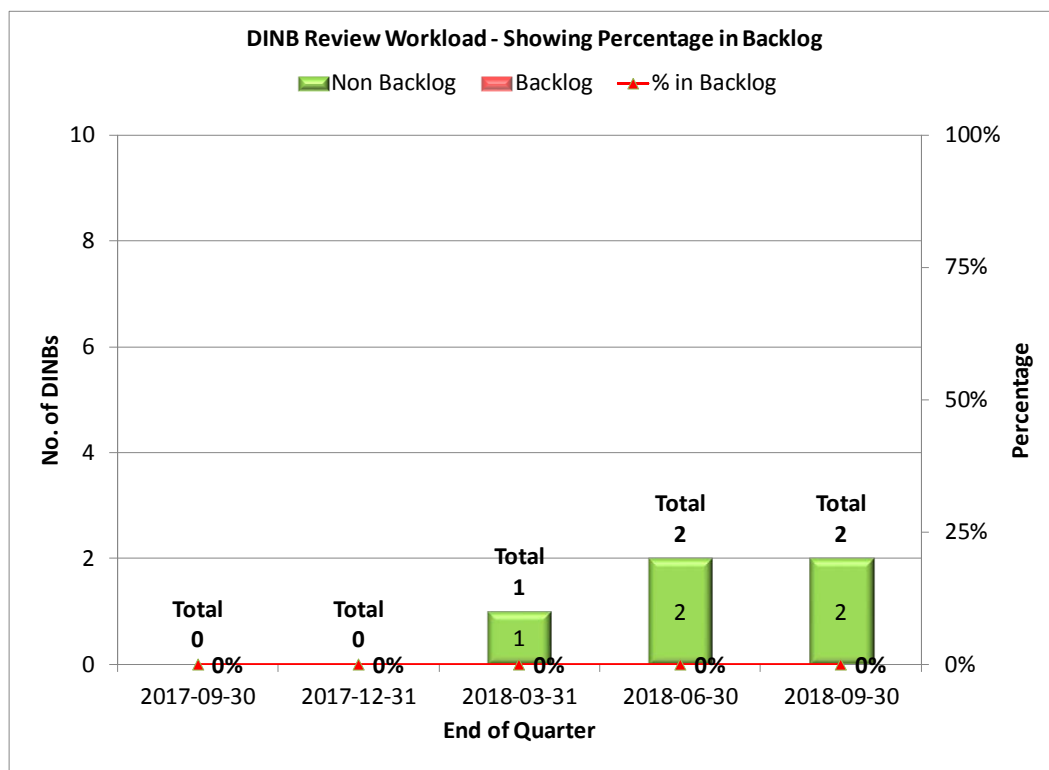
## DINB: Application for a Drug Identification Number – BIOLOGICAL PRODUCT

### Number Received - DINB



## REVIEW WORKLOAD

### Review Workload / Backlog - Showing Percentage in Backlog - DINB

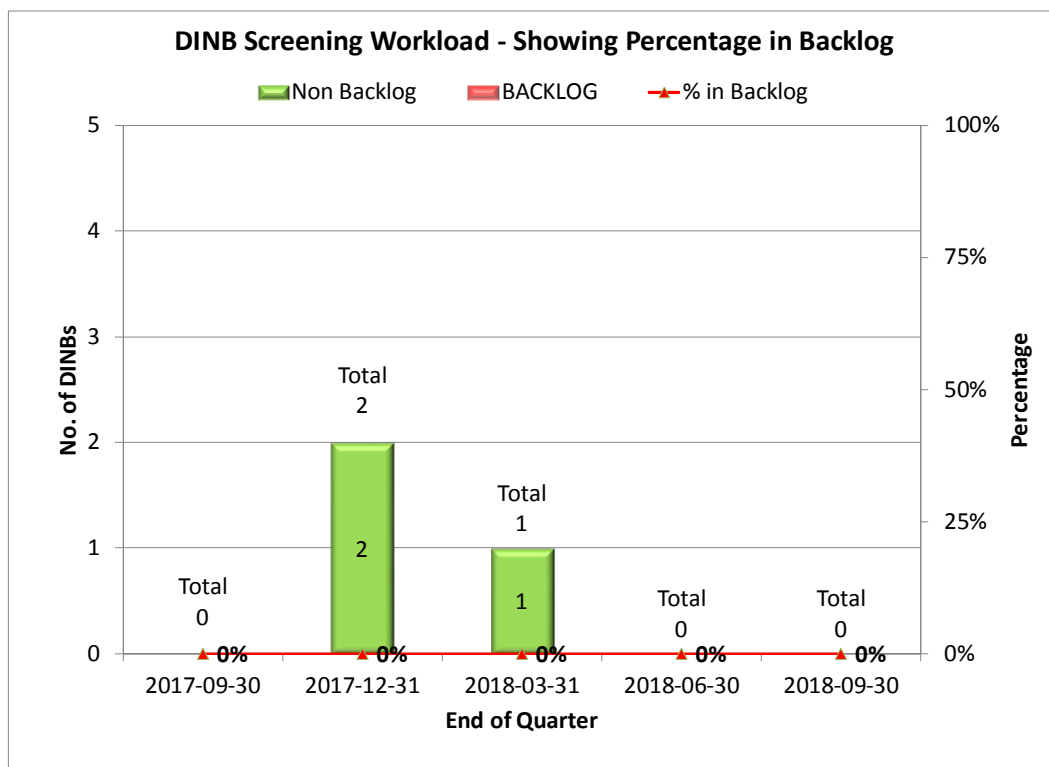


### Review Workload by Class - DINB

BGTD DINB ALL REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
<b>Labelling Only</b>	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	0	0	0	1	2
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	0	0	1	2	2
<b>Non Backlog</b>	0	0	1	2	2
<b>Backlog</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

## SCREENING WORKLOAD

### Screening Workload / Backlog - Showing Percentage in Backlog - DINB



### Screening Workload by Class - DINB

BGTD DINB ALL SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
<b>Labelling Only</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
Backlog	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>
Non Backlog	0	2	1	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## DECISION DOCUMENTS

### Decision Documents – DINB by Class

<b>DINB - Labelling Only</b>					
<b>DOCUMENT TYPE</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>	<b>Jul-Sep 2018</b>
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	2	0	0	0	0

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

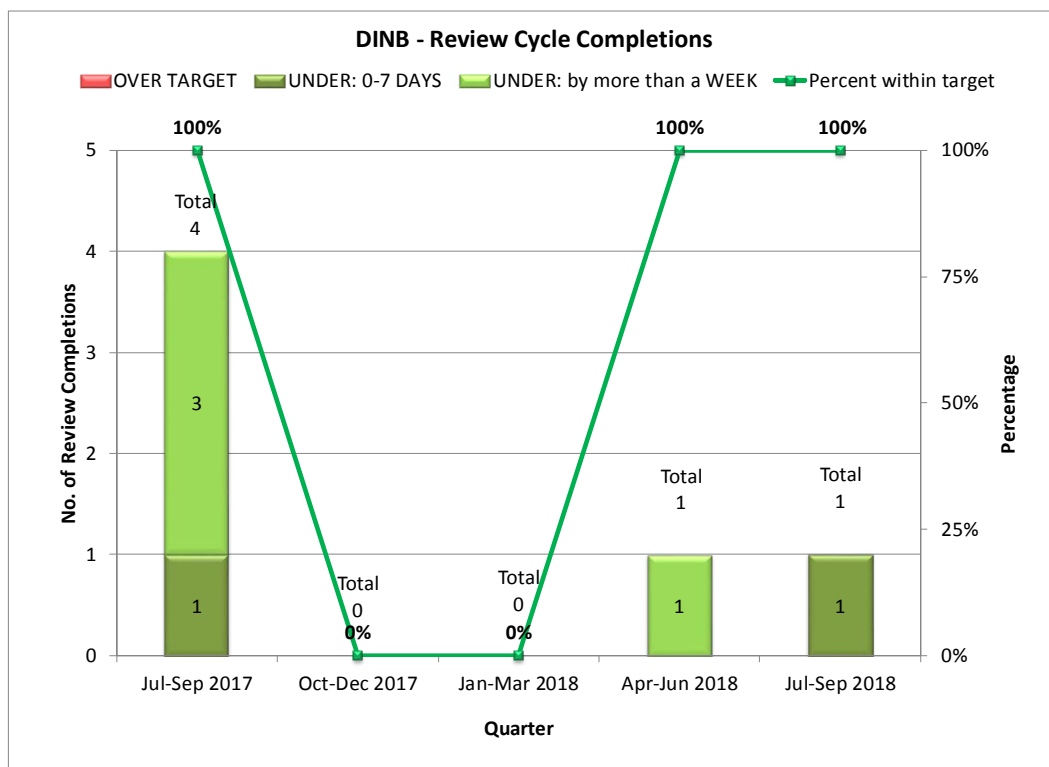
<b>DINB - CHEMISTRY &amp; MANUFACTURING</b>					
<b>DOCUMENT TYPE</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>	<b>Jul-Sep 2018</b>
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	1	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	1	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

<b>DINB - COMPARATIVE STUDIES</b>					
<b>DOCUMENT TYPE</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>	<b>Jul-Sep 2018</b>
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

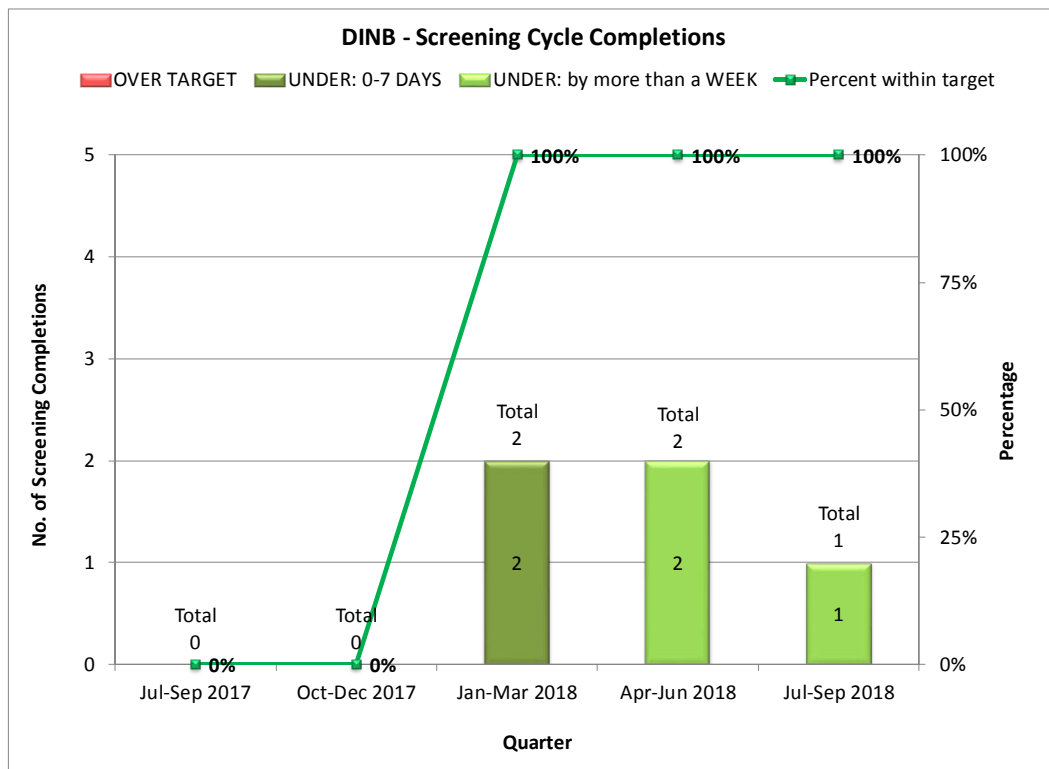
<b>DINB - Administrative</b>					
<b>DOCUMENT TYPE</b>	<b>Jul-Sep 2017</b>	<b>Oct-Dec 2017</b>	<b>Jan-Mar 2018</b>	<b>Apr-Jun 2018</b>	<b>Jul-Sep 2018</b>
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	1	0	0	0

## PERFORMANCE

### Performance Review Cycle Completions Showing Percentage Within Target - DINB

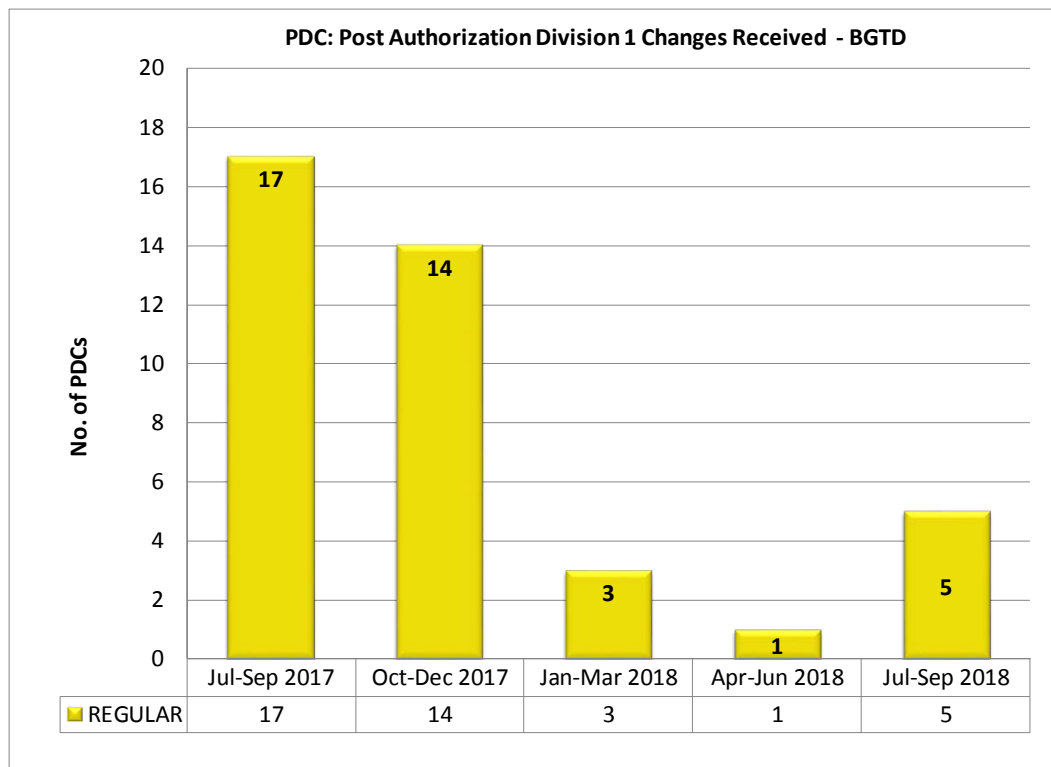


### Performance Screening Cycle Completions Showing Percentage Within Target - DINB



## Post –Authorization Division 1 Changes - Biologics (PDC-B)

### Post –Authorization Division 1 Changes - Biologics (PDC-B) Received

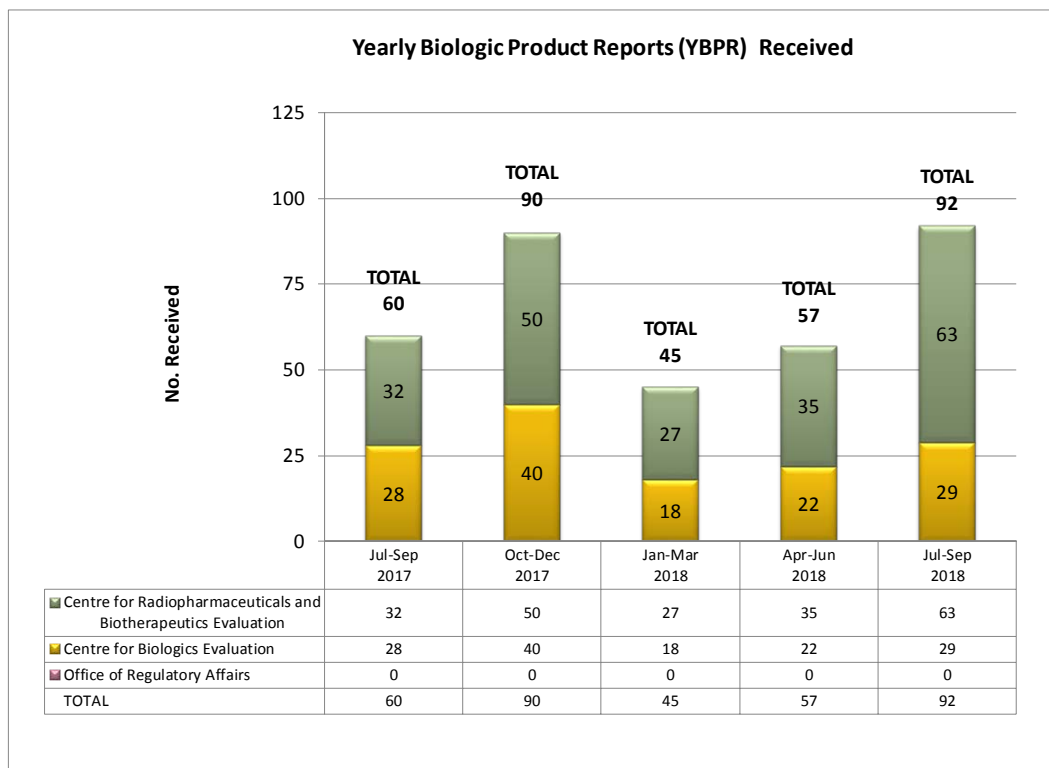




## Yearly Biologic Product Reports (YBPR)

<sup>12)</sup>

### Yearly Biologic Product Reports (YBPR) Received

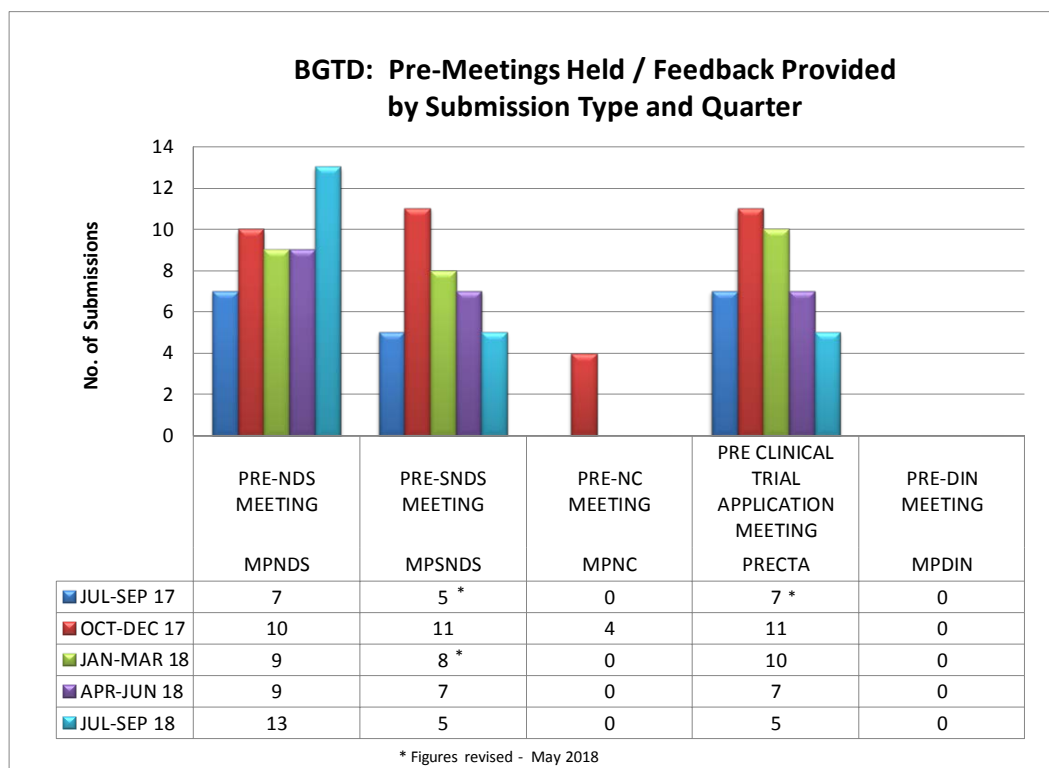


<sup>12</sup> Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

# Appendix A: Pre-submission Meetings

13

## Pre-submission Meetings Held / Feedback Provided



<sup>13</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 [Guidance for Industry: Management of Drug Submissions](#)