Santé Canada Health Canada

# Biologics and Genetic Therapies Directorate

## Drug Submission Performance Quarterly Report

October – December

2018

Canada

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.

Également disponible en français sous le titre :
Direction des produits biologiques et des thérapies génétiques – Rapport trimestriel du rendement des présentations de drogue – octobre – décembre 2018

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# 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 October – December 2017 to July October – December 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[1] 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**[2] 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.

[1] For further clarification refer to the Guidance for Industry: Management of Drug Submissions

[2] 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**[3] 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[4] 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"[5] submissions.

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

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Finance Building, A.L. # 0202A1
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

[3] 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.

[4] 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).

[5] 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 |
|---|---|
| **New Active Substance (NAS)** | 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. |
| **Clinical or Non-Clinical Data and Chemistry and Manufacturing data** | Submissions based on clinical or non-clinical data **and** chemistry and manufacturing data for a drug that does not include a NAS. |
| **Clinical or Non-Clinical Data Only** | Submissions based only on clinical or non-clinical data for a drug that does not include a NAS. |
| **Comparative Studies** | 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. |
| **Chemistry and Manufacturing Data Only** | Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS. |
| **Published Data Only** | Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS. |
| **Switch from Prescription to Nonprescription Status** | Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug. |
| **Labelling Only**[6] | Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data. |
| **Administrative Submission**[7] | Submissions in support of a manufacturer or product name change. |
| **Disinfectants**[8] | Submissions and applications that include data in support of a disinfectant. |
| **Drug Identification Number (DIN) - Labelling Standards** | 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

[6] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling
[7] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)
[8] 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.

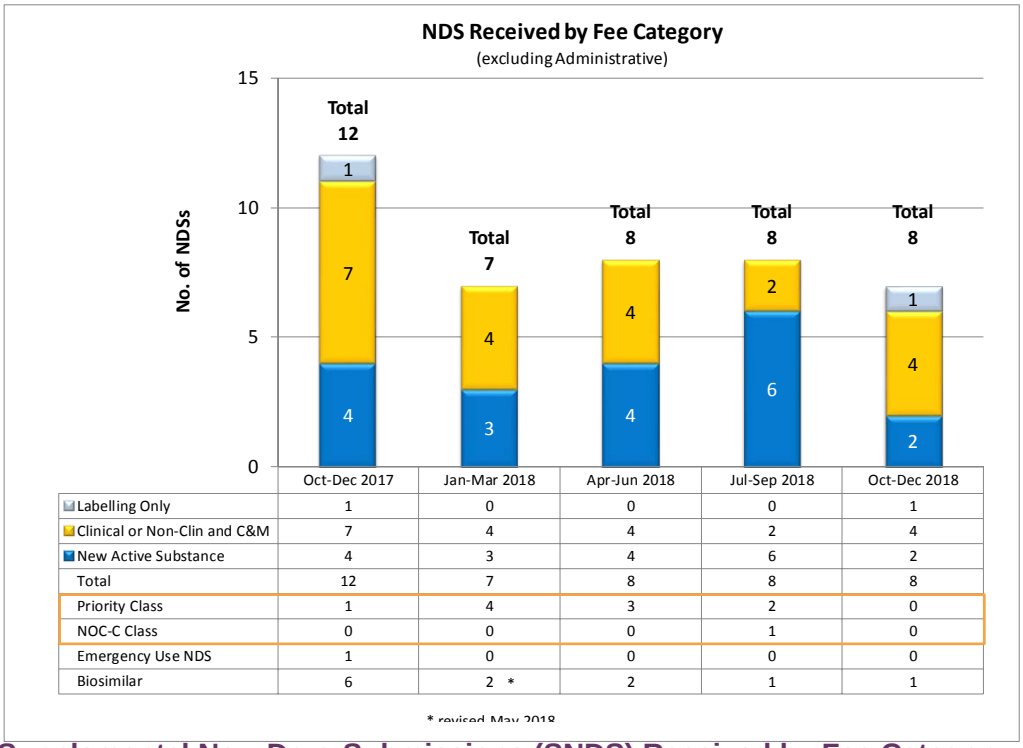
# New Drug Submissions (NDS)

# &

# Supplemental New Drug Submissions (SNDS)

# SUBMISSIONS RECEIVED[9],[10]

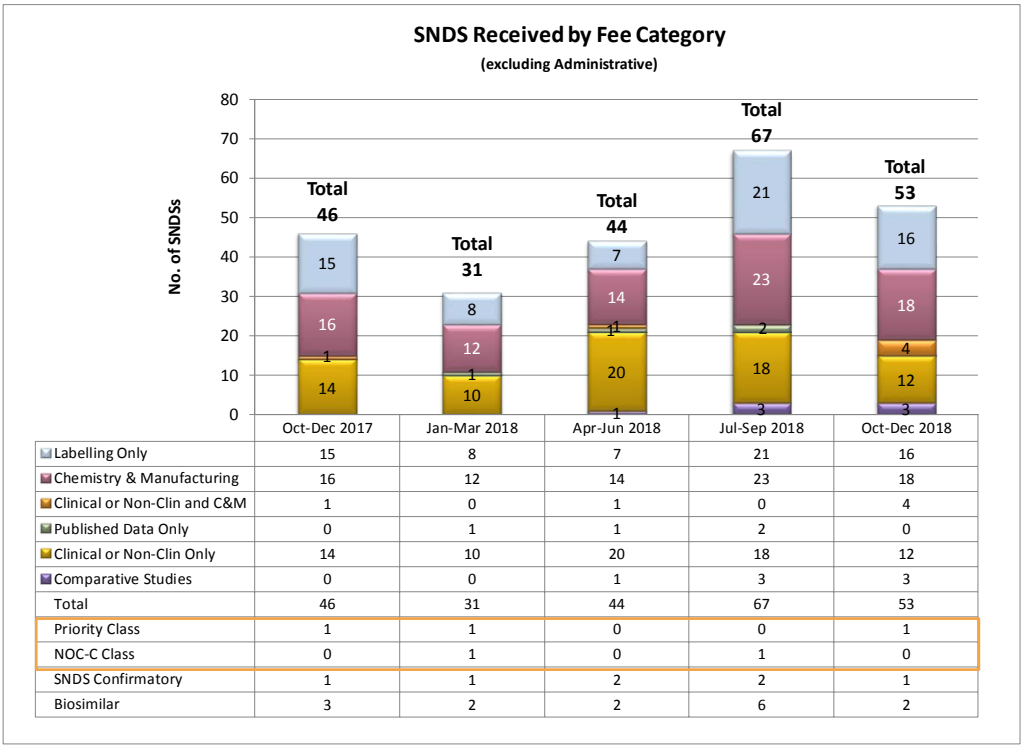
## New Drug Submissions (NDS) Received by Fee Category




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Labelling Only | 1 | 0 | 0 | 0 | 1 |
| Clinical or Non-Clin and C&M | 7 | 4 | 4 | 2 | 4 |
| New Active Substance | 4 | 3 | 4 | 6 | 2 |
| Total | 12 | 7 | 8 | 8 | 8 |
| Priority Class | 1 | 4 | 3 | 2 | 0 |
| NOC-C Class | 0 | 0 | 0 | 1 | 0 |
| Emergency Use NDS | 1 | 0 | 0 | 0 | 0 |
| Biosimilar | 6 | 2 * | 2 | 1 | 1 |

* revised May 2018

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



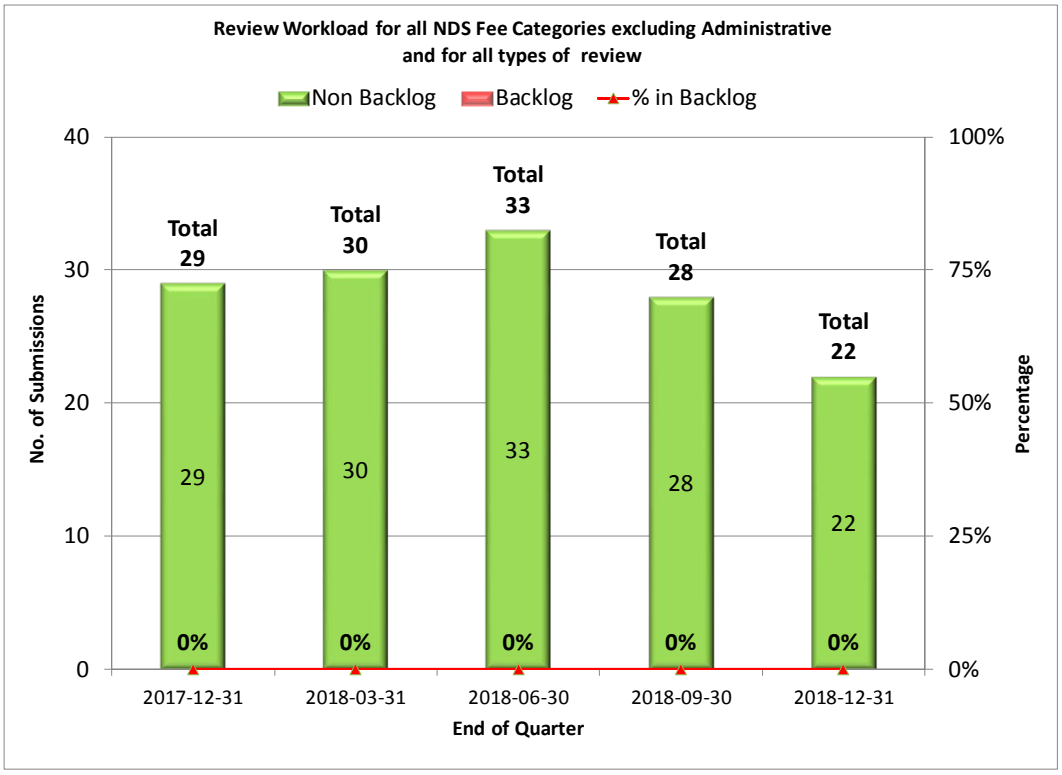

| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Labelling Only | 15 | 8 | 7 | 21 | 16 |
| Chemistry & Manufacturing | 16 | 12 | 14 | 23 | 18 |
| Clinical or Non-Clin and C&M | 1 | 0 | 1 | 0 | 4 |
| Published Data Only | 0 | 1 | 1 | 2 | 0 |
| Clinical or Non-Clin Only | 14 | 10 | 20 | 18 | 12 |
| Comparative Studies | 0 | 0 | 1 | 3 | 3 |
| Total | 46 | 31 | 44 | 67 | 53 |
| Priority Class | 1 | 1 | 0 | 0 | 1 |
| NOC-C Class | 0 | 1 | 0 | 1 | 0 |
| SNDS Confirmatory | 1 | 1 | 2 | 2 | 1 |
| Biosimilar | 3 | 2 | 2 | 6 | 2 |

[9] **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.

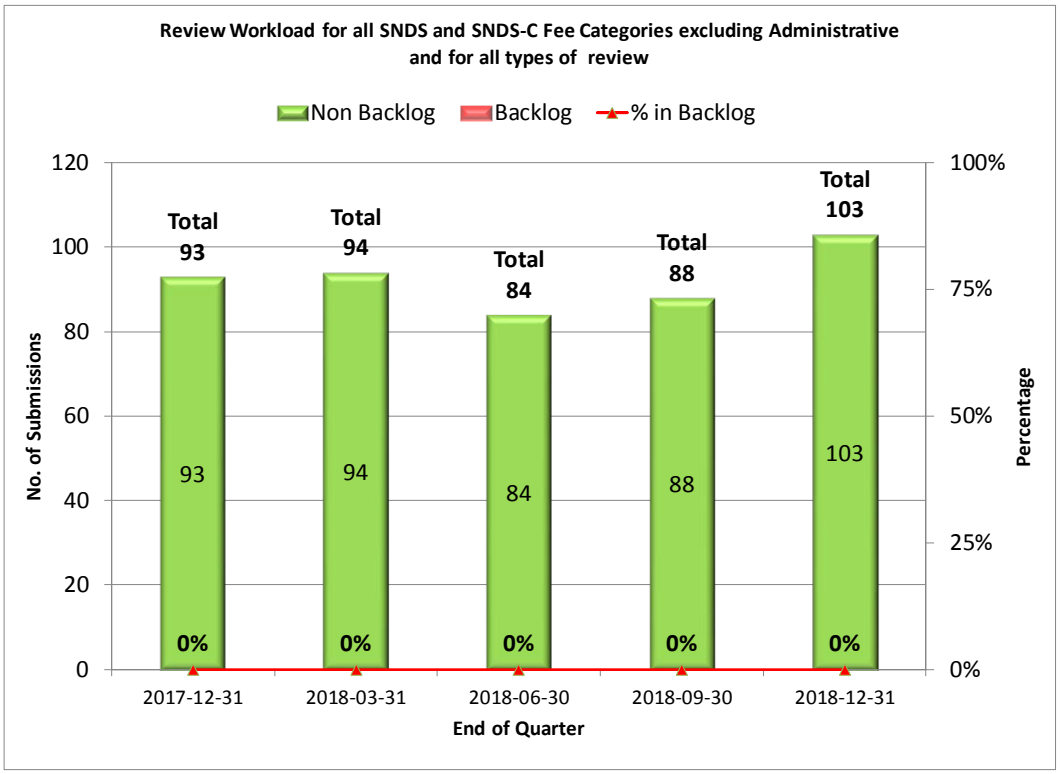
[10] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance 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 | | | | | |
|---|---|---|---|---|---|
| | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| **Clinical or Non-Clin and C&M** | **21** | **21** | **21** | **14** | **9** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **New Active Substance** | **8** | **9** | **12** | **14** | **12** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **29** | **30** | **33** | **28** | **22** |
| **Non Backlog** | **29** | **30** | **33** | **28** | **22** |
| **Backlog** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |
| **Priority (subset)** | **1** | **5** | **7** | **5** | **3** |
| Backlog | *0* | *0* | *0* | *0* | *0* |

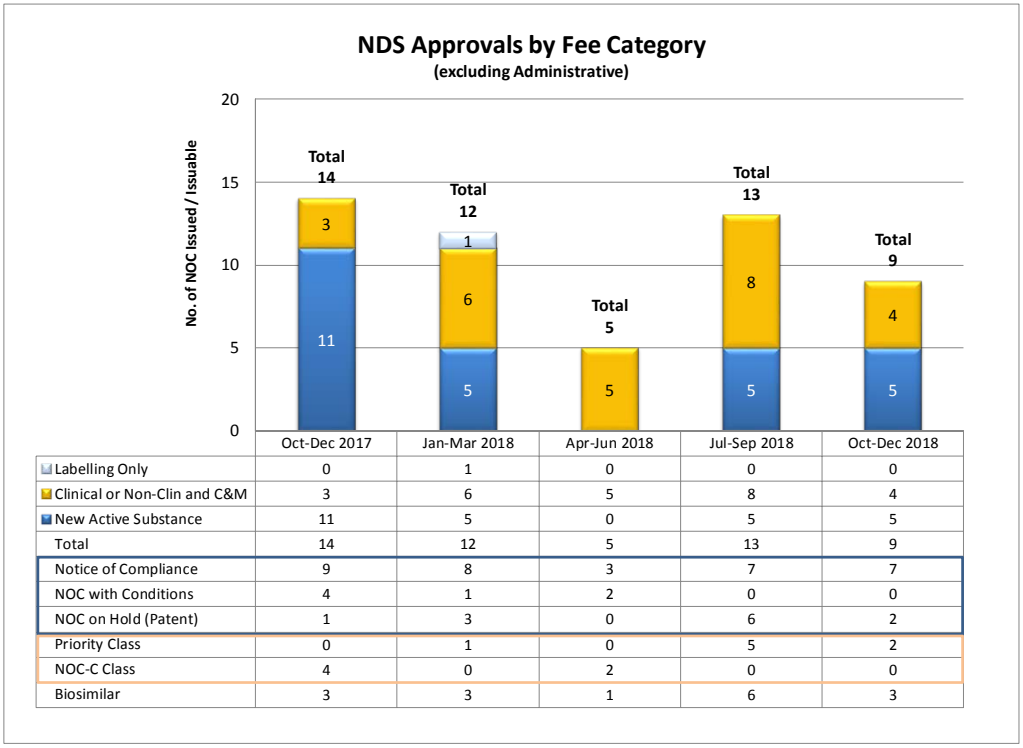
## Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

| BGTD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER | | | | | |
|---|---|---|---|---|---|
| | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| **Comparative Studies** | **1** | **1** | **1** | **3** | **6** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Chemistry & Manufacturing** | **23** | **26** | **26** | **22** | **29** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Clinical or Non-Clin Only** | **51** | **54** | **48** | **48** | **48** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Clinical or Non-Clin and C&M** | **6** | **4** | **4** | **2** | **4** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Published Data** | **4** | **2** | **2** | **1** | **3** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Only** | **8** | **7** | **3** | **12** | **13** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **93** | **94** | **84** | **88** | **103** |
| **Non Backlog** | **93** | **94** | **84** | **88** | **103** |
| **Backlog** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |
| **Priority (subset)** | **0** | **2** | **2** | **0** | **1** |
| Backlog | *0* | *0* | *0* | *0* | *0* |
| **SNDS-C (Confirmatory)** | **6** | **5** | **2** | **6** | **6** |
| Backlog | *0* | *0* | *0* | *0* | *0* |

# APPROVALS

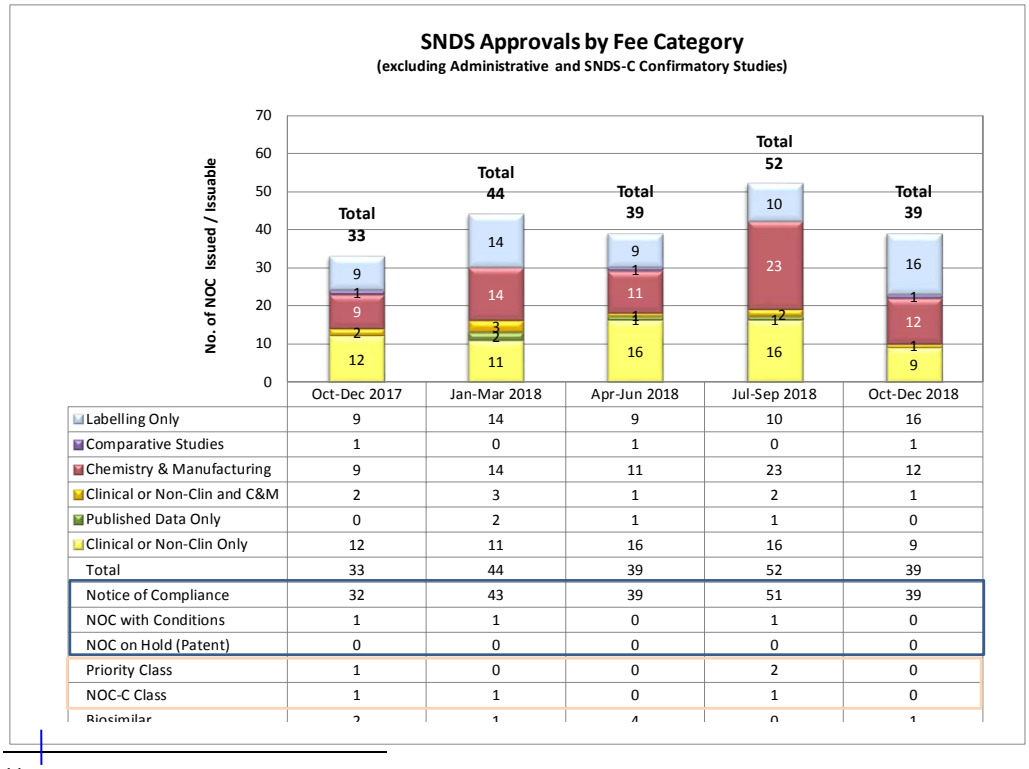
[11], [12]

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




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Labelling Only | 0 | 1 | 0 | 0 | 0 |
| Clinical or Non-Clin and C&M | 3 | 6 | 5 | 8 | 4 |
| New Active Substance | 11 | 5 | 0 | 5 | 5 |
| Total | 14 | 12 | 5 | 13 | 9 |
| Notice of Compliance | 9 | 8 | 3 | 7 | 7 |
| NOC with Conditions | 4 | 1 | 2 | 0 | 0 |
| NOC on Hold (Patent) | 1 | 3 | 0 | 6 | 2 |
| Priority Class | 0 | 1 | 0 | 5 | 2 |
| NOC-C Class | 4 | 0 | 2 | 0 | 0 |
| Biosimilar | 3 | 3 | 1 | 6 | 3 |

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




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Labelling Only | 9 | 14 | 9 | 10 | 16 |
| Comparative Studies | 1 | 0 | 1 | 0 | 1 |
| Chemistry & Manufacturing | 9 | 14 | 11 | 23 | 12 |
| Clinical or Non-Clin and C&M | 2 | 3 | 1 | 2 | 1 |
| Published Data Only | 0 | 2 | 1 | 1 | 0 |
| Clinical or Non-Clin Only | 12 | 11 | 16 | 16 | 9 |
| Total | 33 | 44 | 39 | 52 | 39 |
| Notice of Compliance | 32 | 43 | 39 | 51 | 39 |
| NOC with Conditions | 1 | 1 | 0 | 1 | 0 |
| NOC on Hold (Patent) | 0 | 0 | 0 | 0 | 0 |
| Priority Class | 1 | 0 | 0 | 2 | 0 |
| NOC-C Class | 1 | 1 | 0 | 1 | 0 |
| Biosimilar | 2 | 1 | 4 | 0 | 1 |

[11] 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 .

[12] **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.

# Biosimilars: NDS & SNDS Market Authorizations

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

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

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

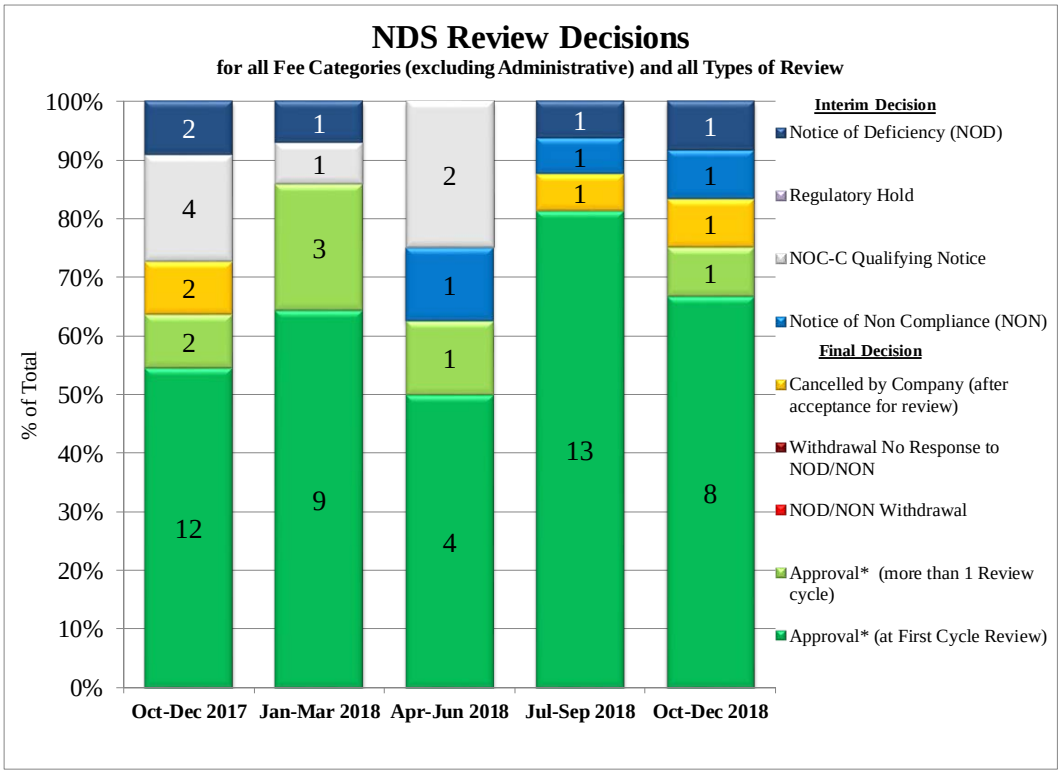
| Subm Type | Brand Name | Class | Company | Active Ingredient(s) | Quarter FY 2018-19 | Notice of Compliance (NOC) Date |
|---|---|---|---|---|---|---|
| NDS | FULPHILA | CLIN/C&M | BGP PHARMA ULC | PEGFILGRASTIM | Q3 | 2018-Dec-24 |
| | LAPELGA | CLIN/C&M | APOTEX INC | PEGFILGRASTIM | Q1 | 2018-Apr-05 |
| **New Drug Submission Total** | | | | | | **2** |
| SNDS | ADMELOG | LABELLING ONLY | SANOFI-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 CO., LTD. | ETANERCEPT | Q1 | 2018-Jun-18 |
| | BRENZYS (PFP), BRENZYS (PFS) | CLIN ONLY | SAMSUNG BIOEPIS CO., LTD. | ETANERCEPT | Q1 | 2018-Jun-14 |
| | RENFLEXIS | COMP/C&M | SAMSUNG BIOEPIS CO., LTD | INFLIXIMAB | Q3 | 2018-Nov-06 |
| **Supplemental New Drug Submission Total** | | | | | | **5** |

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

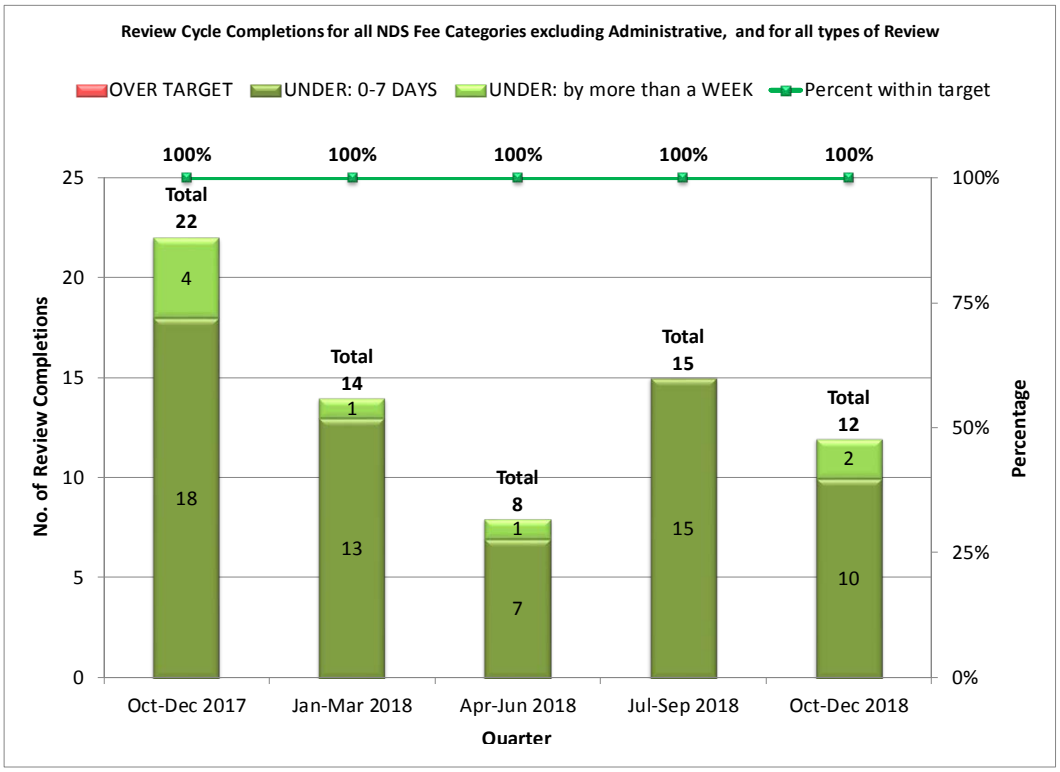
**Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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

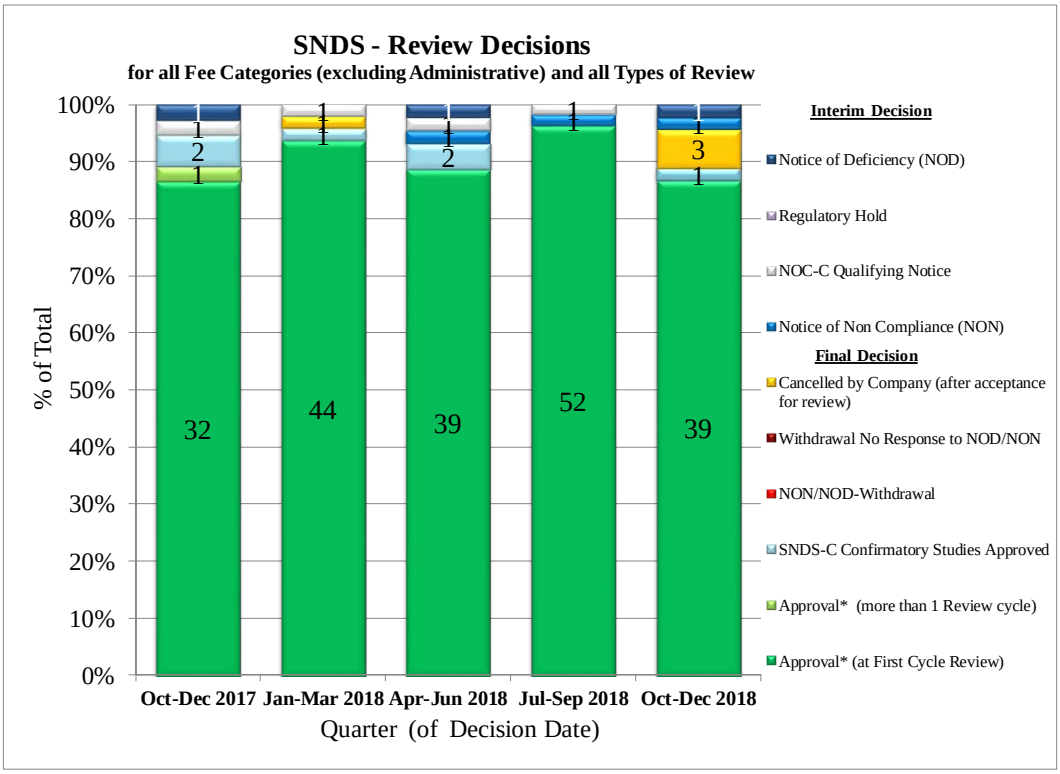



## NDS - Review Cycle Completions Showing Percentage Within Target

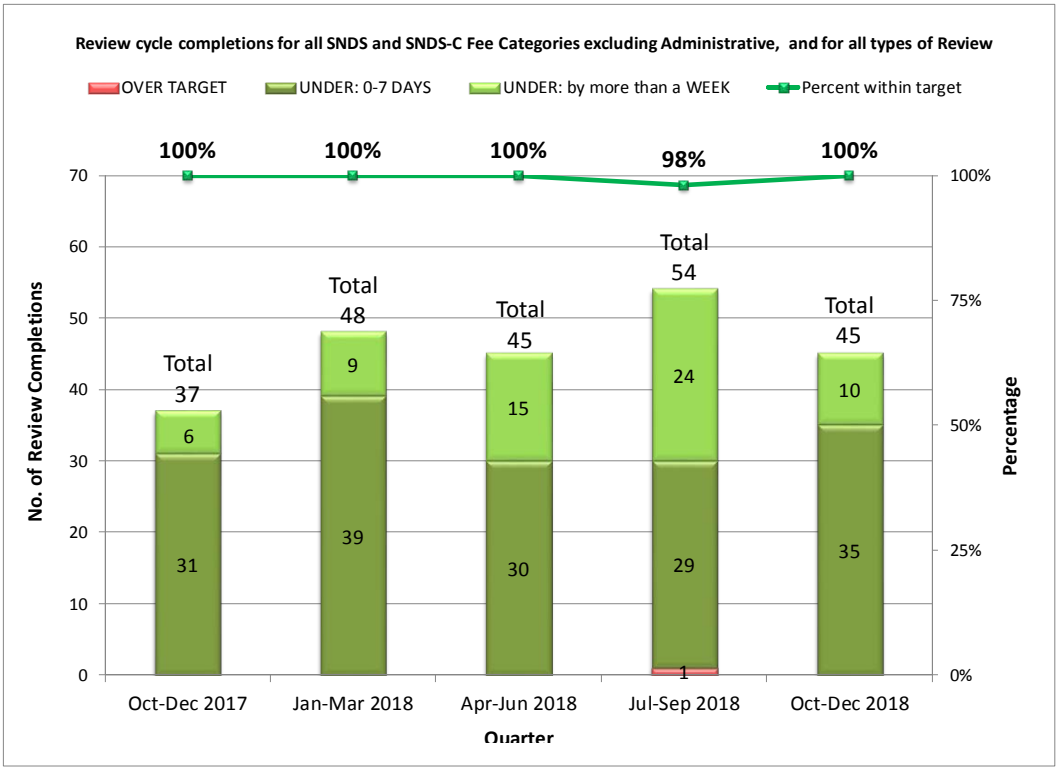


# REVIEW CYCLE DECISIONS

## Supplemental New Drug Submission (SNDS) Review Decisions

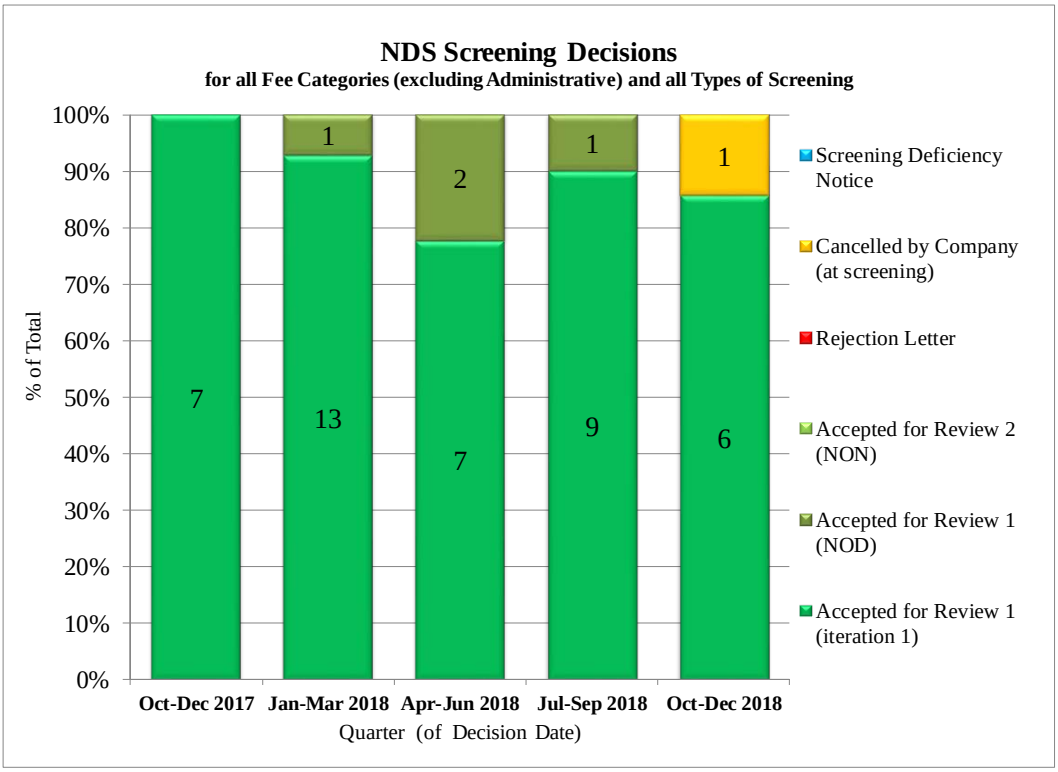



## SNDS - Review Cycle Completions Showing Percentage Within Target

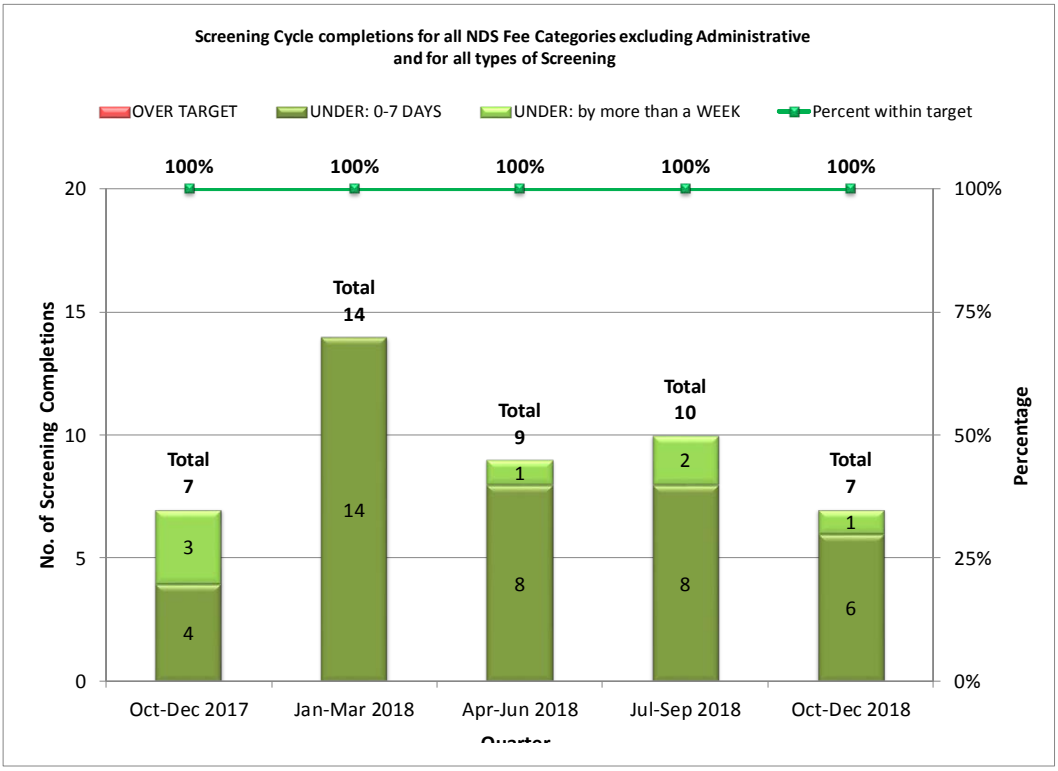


# SCREENING CYCLE DECISIONS

## New Drug Submission (NDS) Screening Decisions

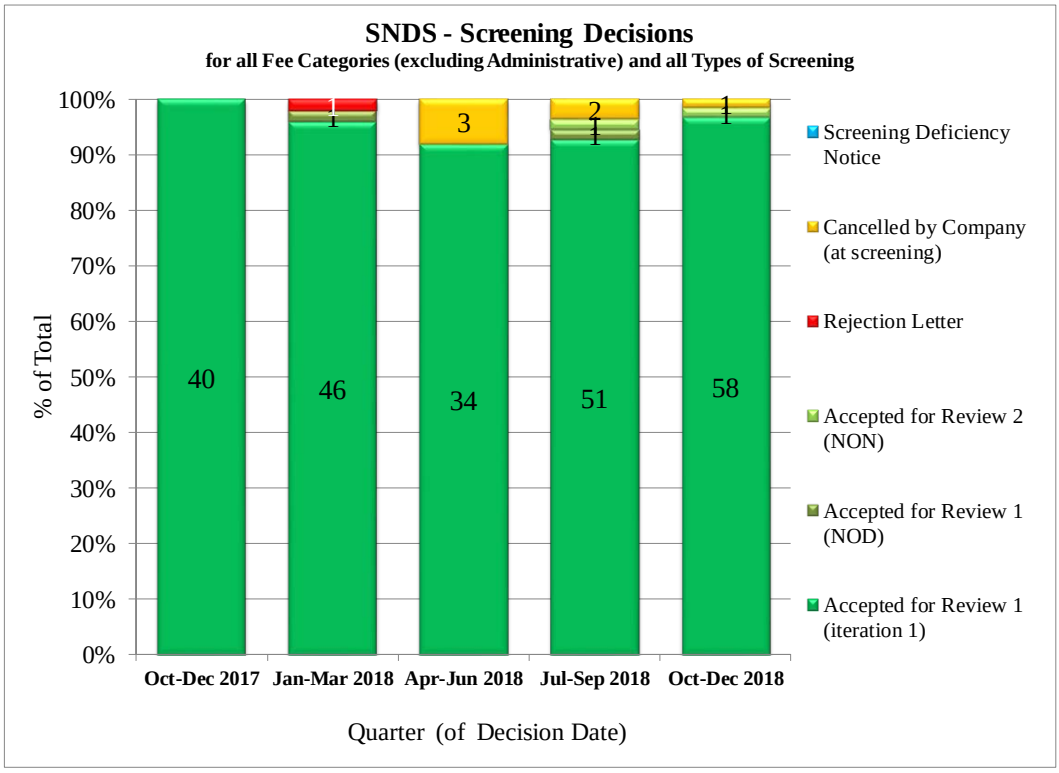



## NDS - Screening Cycle Completions Showing Percentage Within Target

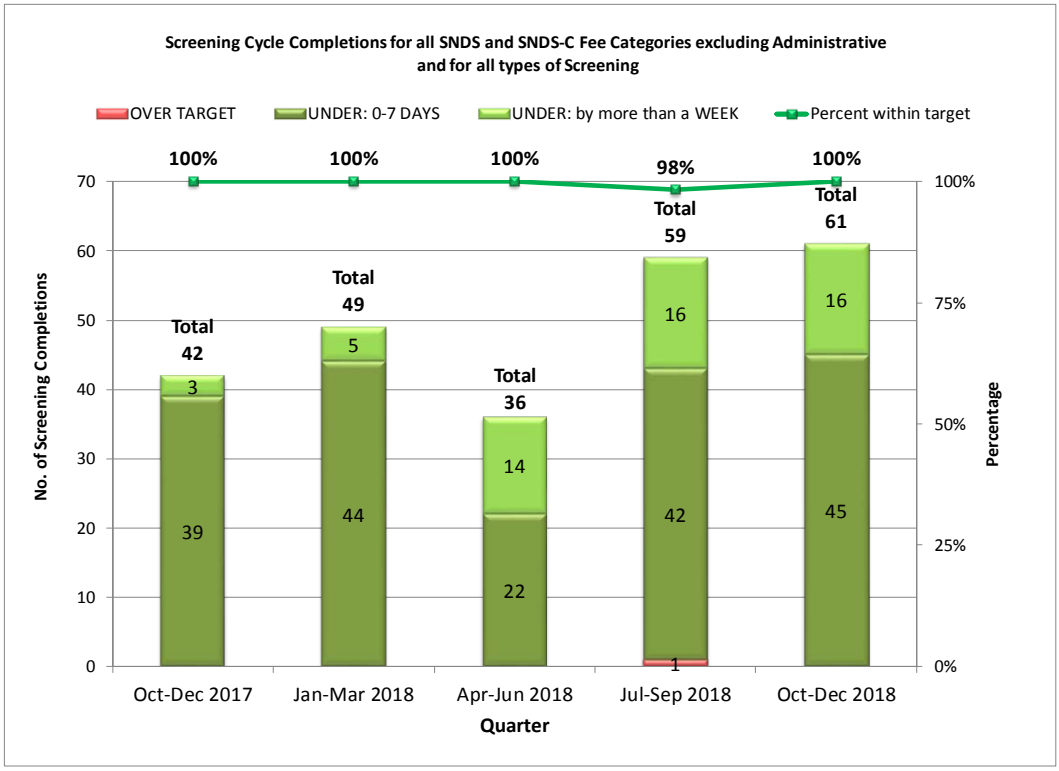


# SCREENING CYCLE DECISIONS

## Supplemental New Drug Submission (SNDS) Screening Decisions

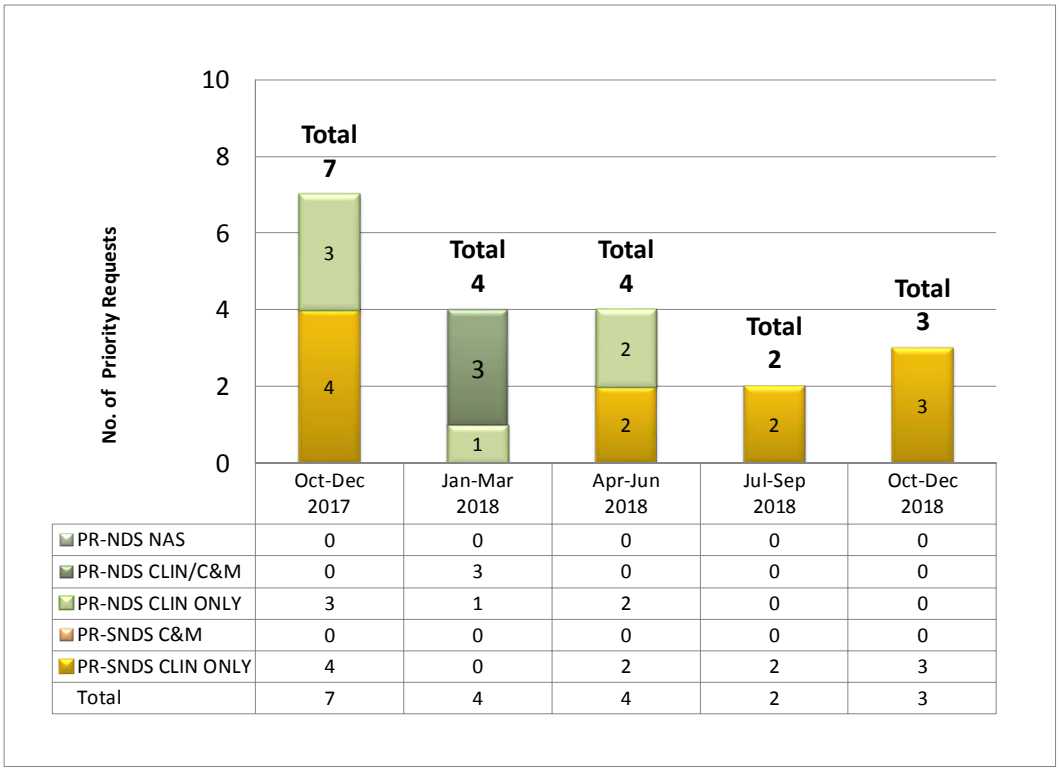



## SNDS - Screening Cycle Completions Showing Percentage Within Target



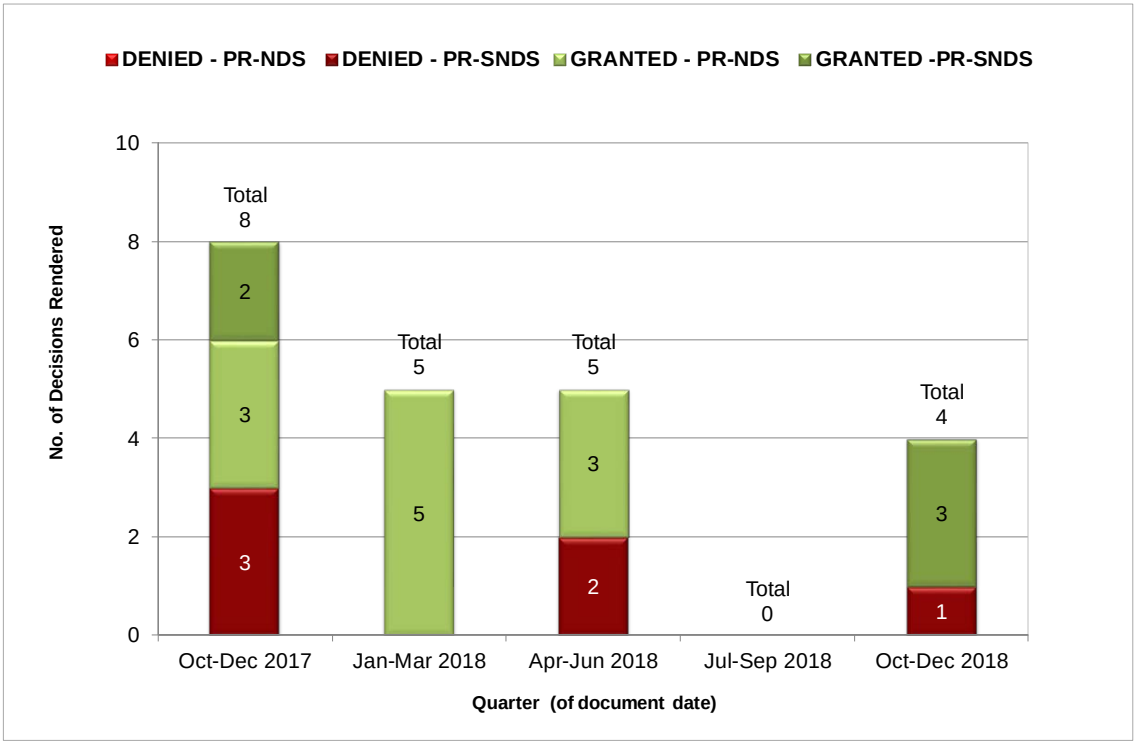
# Priority Review Status Requests (for NDS & SNDS)

## Priority Review Status Requests Received

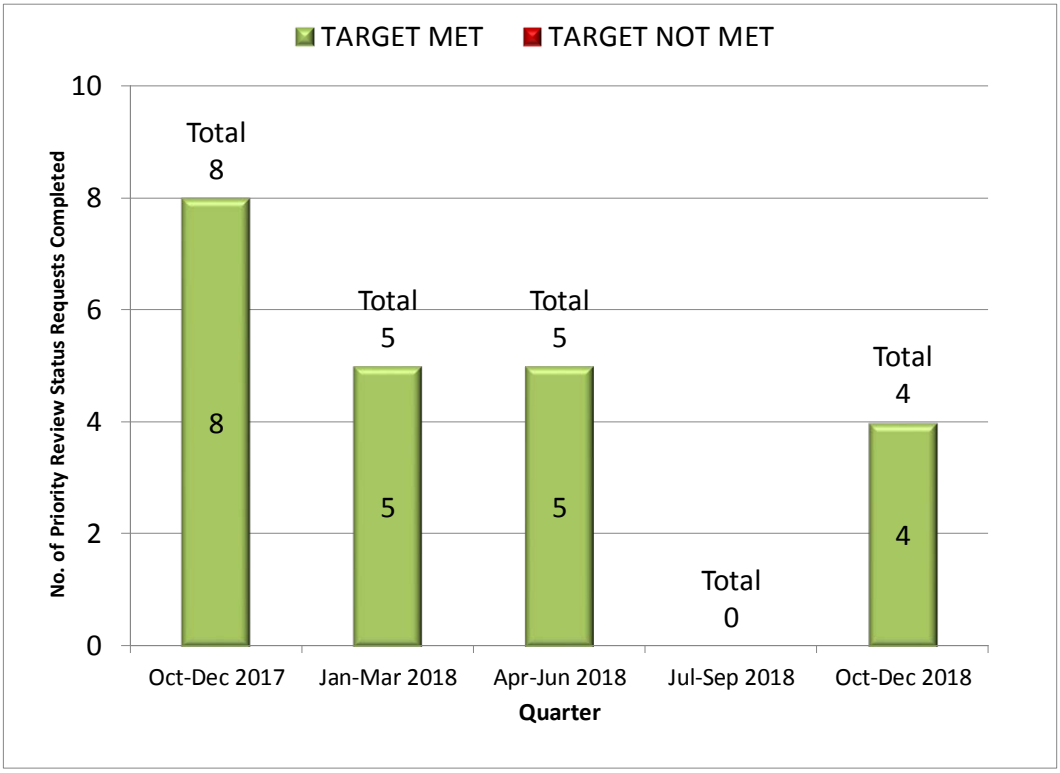



| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| PR-NDS NAS | 0 | 0 | 0 | 0 | 0 |
| PR-NDS CLIN/C&M | 0 | 3 | 0 | 0 | 0 |
| PR-NDS CLIN ONLY | 3 | 1 | 2 | 0 | 0 |
| PR-SNDS C&M | 0 | 0 | 0 | 0 | 0 |
| PR-SNDS CLIN ONLY | 4 | 0 | 2 | 2 | 3 |
| Total | 7 | 4 | 4 | 2 | 3 |

## Priority Review Status Requests: Decisions Rendered



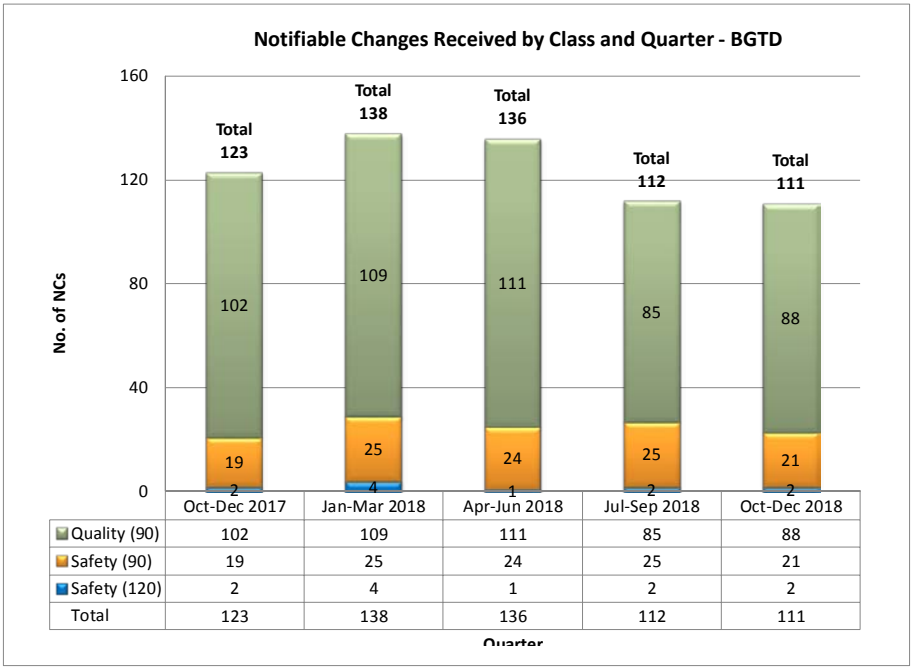

## Priority Review Status Request: Performance



# Notifiable Changes ( NC )

# NOTIFIABLE CHANGE

## Submissions Received - Notifiable Change (NC)




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Quality (90) | 102 | 109 | 111 | 85 | 88 |
| Safety (90) | 19 | 25 | 24 | 25 | 21 |
| Safety (120) | 2 | 4 | 1 | 2 | 2 |
| Total | 123 | 138 | 136 | 112 | 111 |

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

| NC - SAFETY (90) | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 17 | 22 | 25 | 26 | 11 |
| REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 2 | 1 | 2 | 0 | 2 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| NC - HOLD (PATENT) | 0 | 0 | 0 | 0 | 0 |

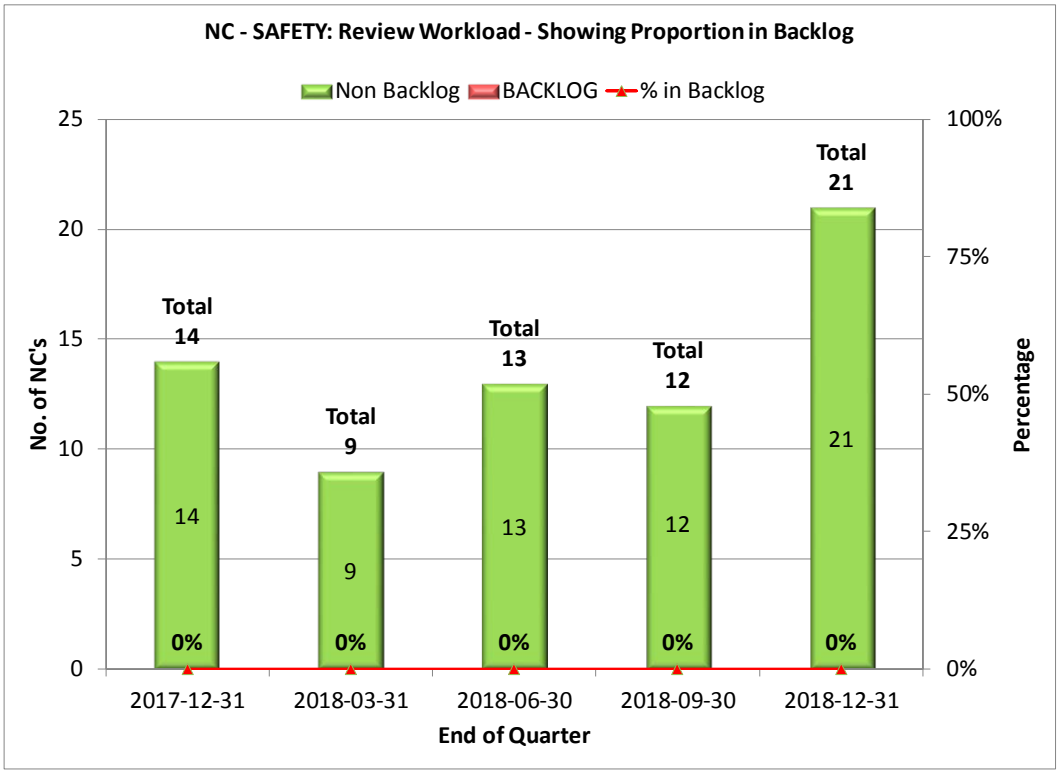
| NC - QUALITY (90) | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 108 | 85 | 117 | 86 | 79 |
| NOT SATISFACTORY NOTICE | 0 | 0 | 0 | 0 | 0 |
| REJECTION LETTER (SCR) | 1 | 11 | 2 | 4 | 1 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 2 | 0 | 4 | 4 | 6 |
| NC - HOLD (PATENT) | 0 | 0 | 0 | 0 | 2 |

| NC - SAFETY (120) | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 2 | 2 | 1 | 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 | 1 | 0 | 1 | 1 | 0 |

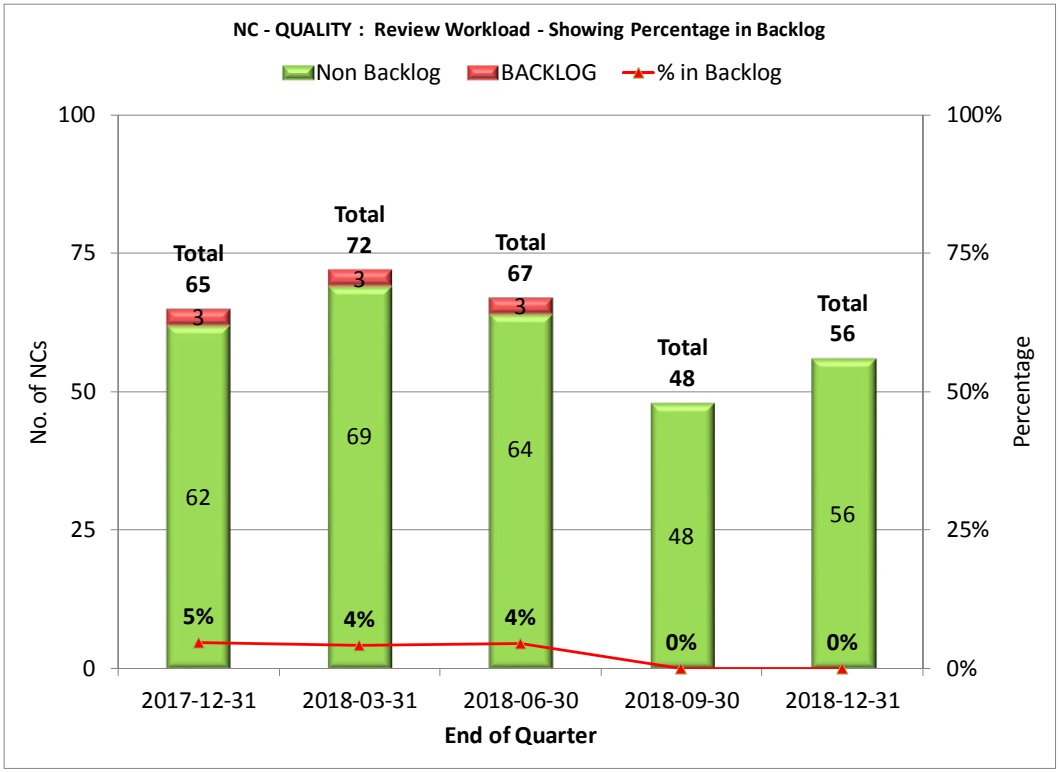
| NC - ADMINISTRATIVE | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 3 | 4 | 2 | 0 | 1 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

# WORKLOAD

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




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



# WORKLOAD

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

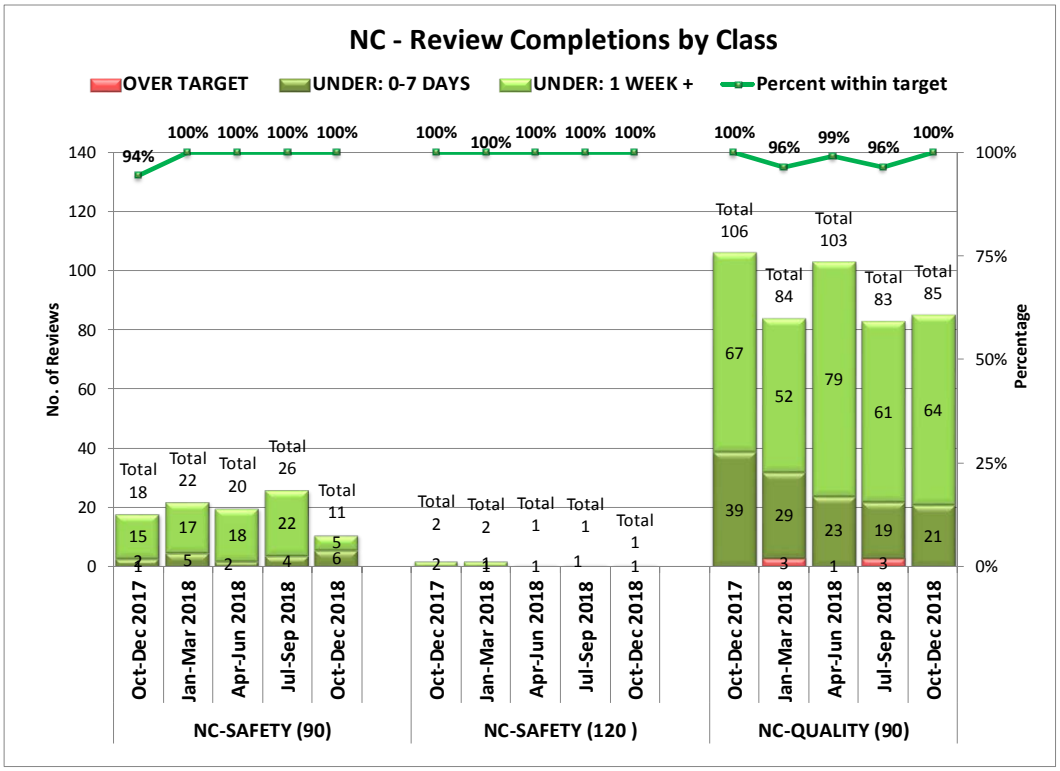
| BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER | | | | | |
|---|---|---|---|---|---|
| FEE Category | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| SAFETY - 90 day | 13 | 8 | 11 | 10 | 18 |
| Backlog | *0* | *0* | *0* | *0* | *0* |
| SAFETY - 120 day | 1 | 1 | 2 | 2 | 3 |
| Backlog | *0* | *0* | *0* | *0* | *0* |
| Total | 14 | 9 | 13 | 12 | 21 |
| Non Backlog | 14 | 9 | 13 | 12 | 21 |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

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

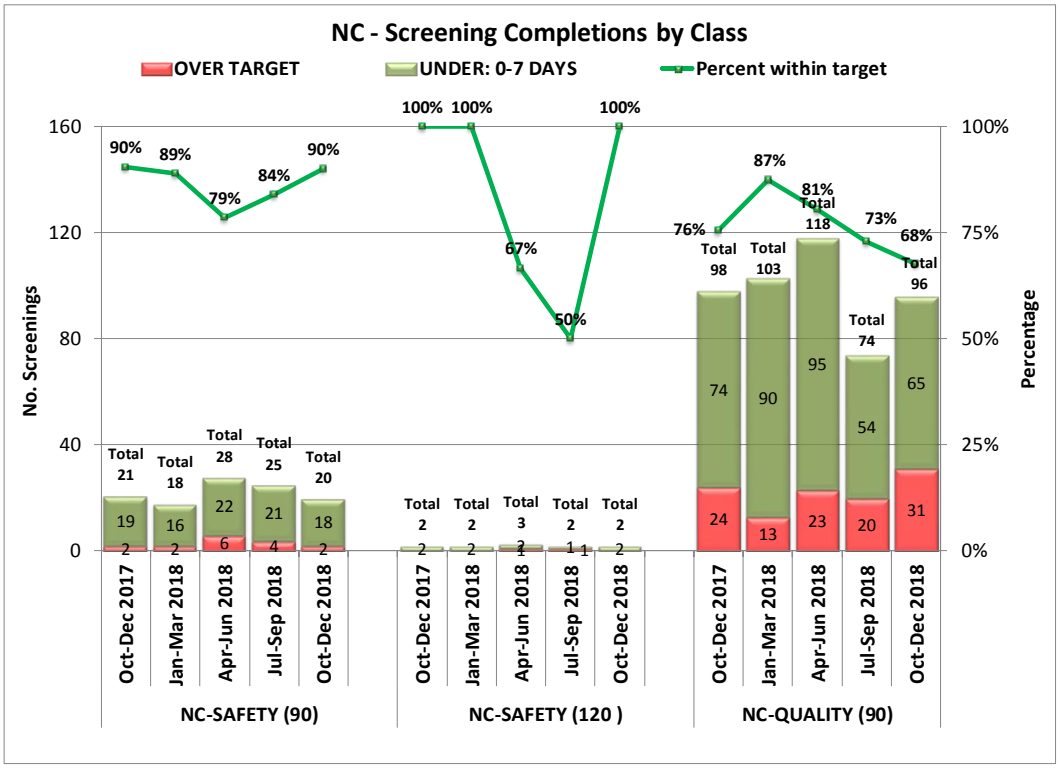
| BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER | | | | | |
|---|---|---|---|---|---|
| CLASS | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| QUALITY - 90 day | 65 | 72 | 67 | 48 | 56 |
| Backlog | *3* | *3* | *3* | *0* | *0* |
| Total | 65 | 72 | 67 | 48 | 56 |
| Non Backlog | 62 | 69 | 64 | 48 | 56 |
| BACKLOG | 3 | 3 | 3 | 0 | 0 |
| % in Backlog | 5% | 4% | 4% | 0% | 0% |

# PERFORMANCE

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




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



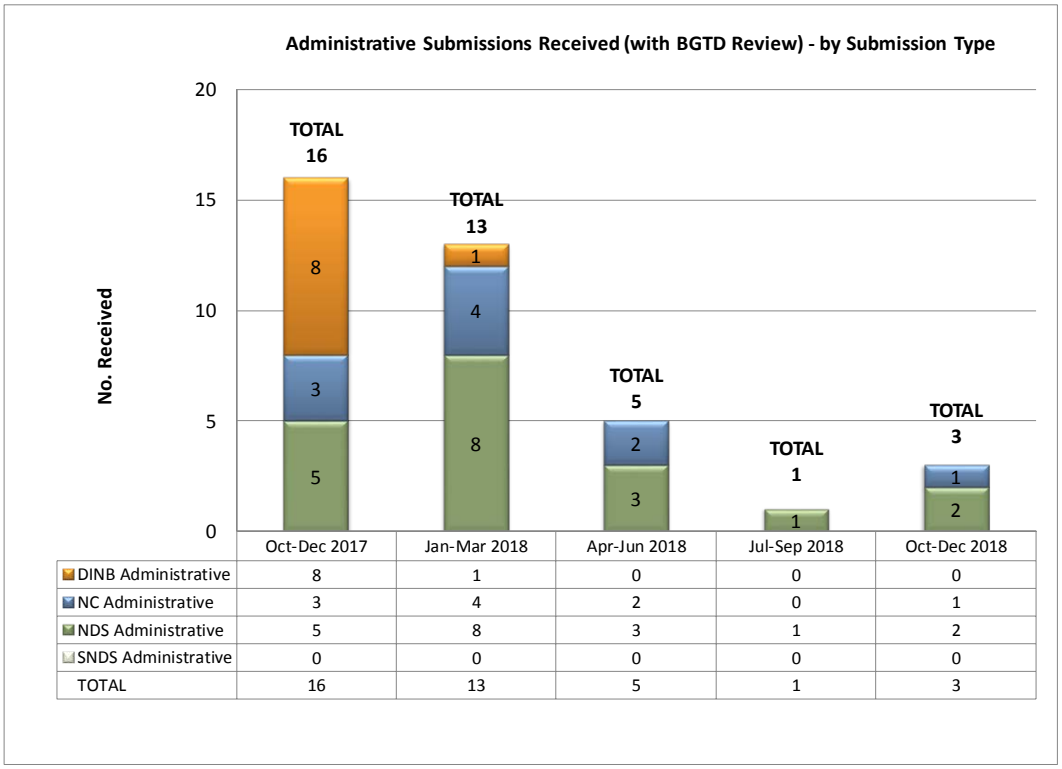
# Administrative Submissions

Submissions in support of a manufacturer or product name change.

# ADMINISTRATIVE SUBMISSIONS (BGTD)

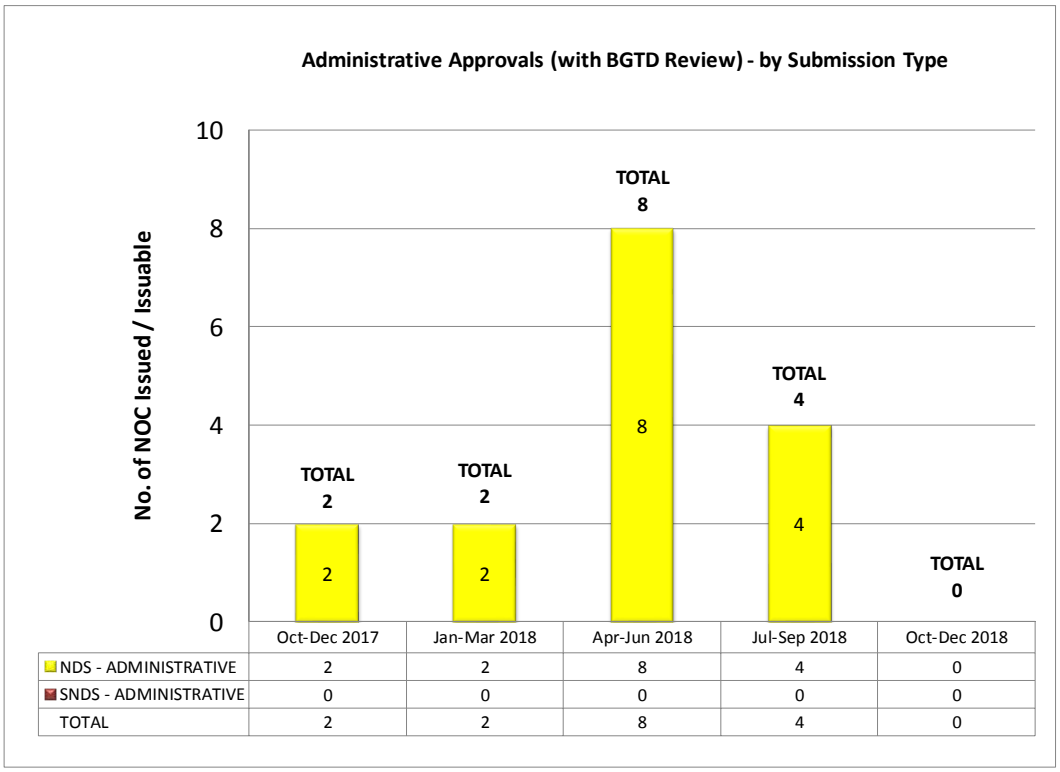
(e.g. product name changes that require a drug name review)

## Administrative Submissions Received (with BGTD Review)




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| DINB Administrative | 8 | 1 | 0 | 0 | 0 |
| NC Administrative | 3 | 4 | 2 | 0 | 1 |
| NDS Administrative | 5 | 8 | 3 | 1 | 2 |
| SNDS Administrative | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 16 | 13 | 5 | 1 | 3 |

## Administrative Submission Approvals (with BGTD Review)

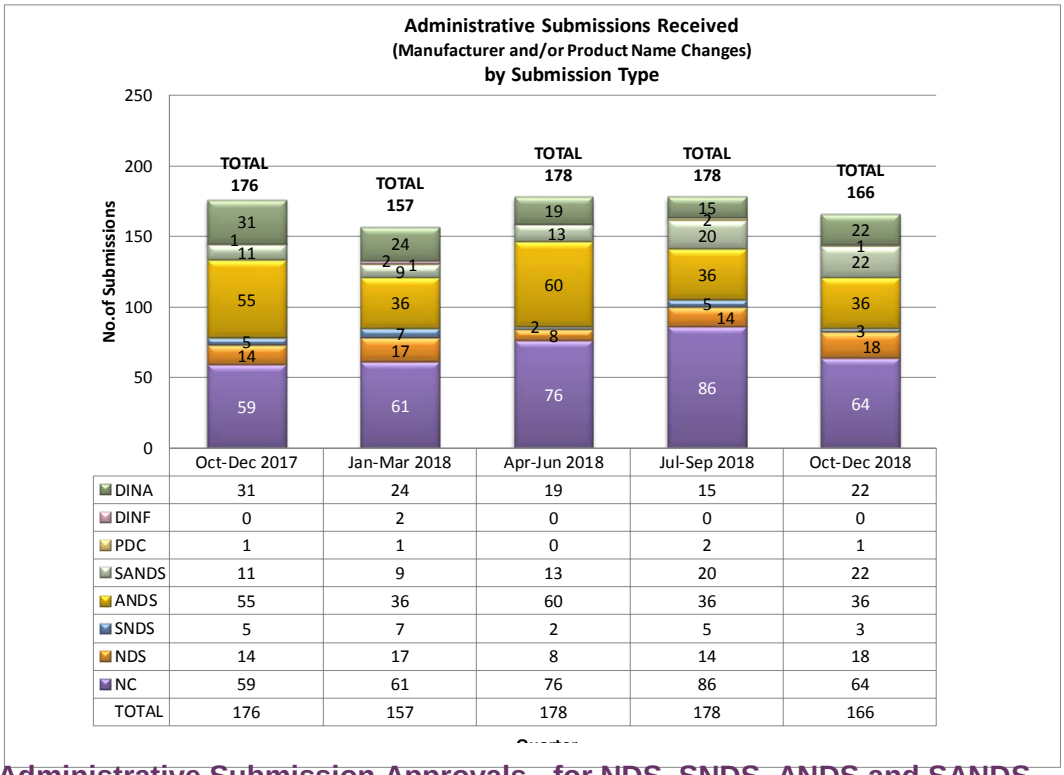



| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| NDS - ADMINISTRATIVE | 2 | 2 | 8 | 4 | 0 |
| SNDS - ADMINISTRATIVE | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 2 | 2 | 8 | 4 | 0 |

# ADMINISTRATIVE SUBMISSIONS

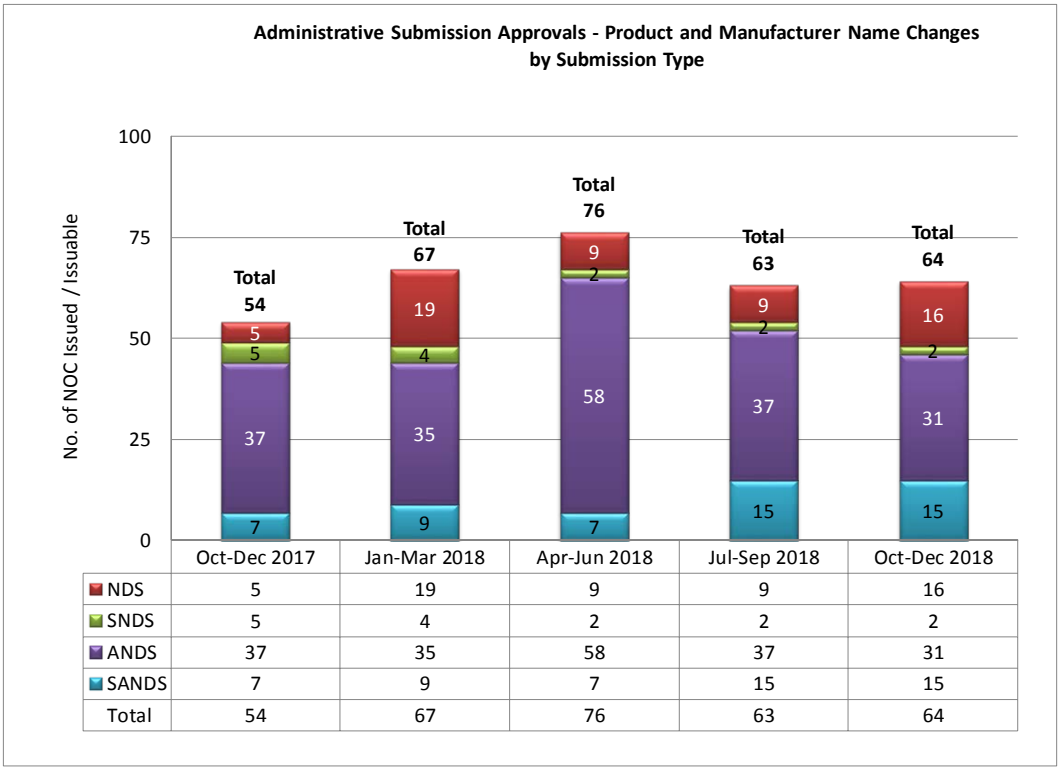
(Manufacturer and/or Product Name Changes [13] [14])

## Administrative Submissions Received by Submission Type




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| DINA | 31 | 24 | 19 | 15 | 22 |
| DINF | 0 | 2 | 0 | 0 | 0 |
| PDC | 1 | 1 | 0 | 2 | 1 |
| SANDS | 11 | 9 | 13 | 20 | 22 |
| ANDS | 55 | 36 | 60 | 36 | 36 |
| SNDS | 5 | 7 | 2 | 5 | 3 |
| NDS | 14 | 17 | 8 | 14 | 18 |
| NC | 59 | 61 | 76 | 86 | 64 |
| TOTAL | 176 | 157 | 178 | 178 | 166 |

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




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| NDS | 5 | 19 | 9 | 9 | 16 |
| SNDS | 5 | 4 | 2 | 2 | 2 |
| ANDS | 37 | 35 | 58 | 37 | 31 |
| SANDS | 7 | 9 | 7 | 15 | 15 |
| Total | 54 | 67 | 76 | 63 | 64 |

[13] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)

[14] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

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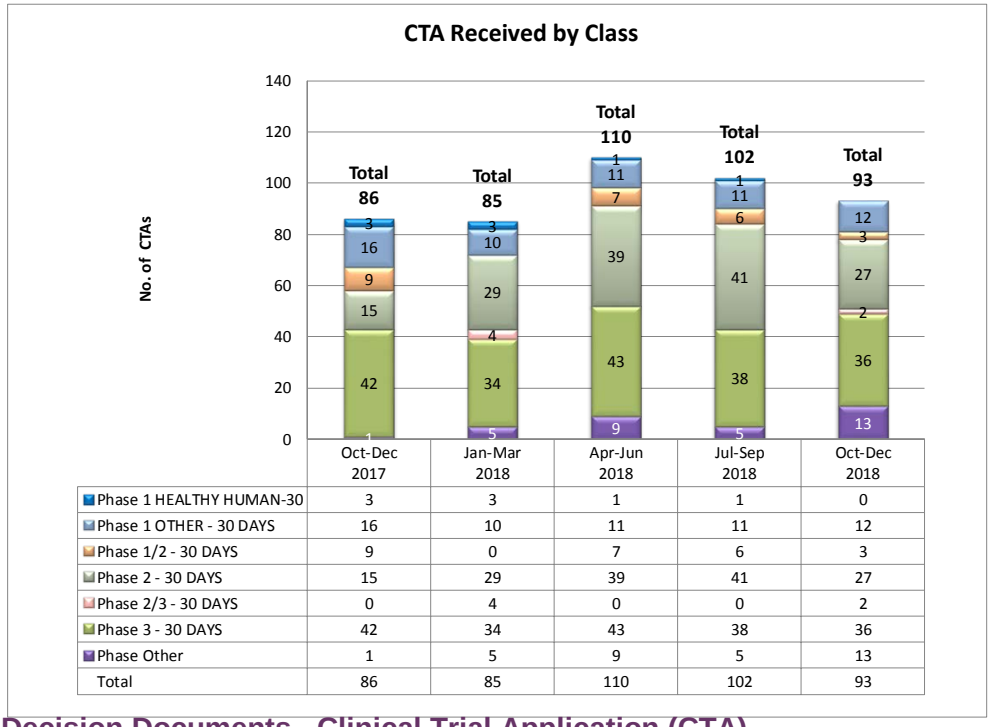
# Clinical Trial Applications and Amendments

# (CTA & CTA-A)

# Clinical Trial Applications ( CTA )

## Number Received - Clinical Trial Application (CTA)

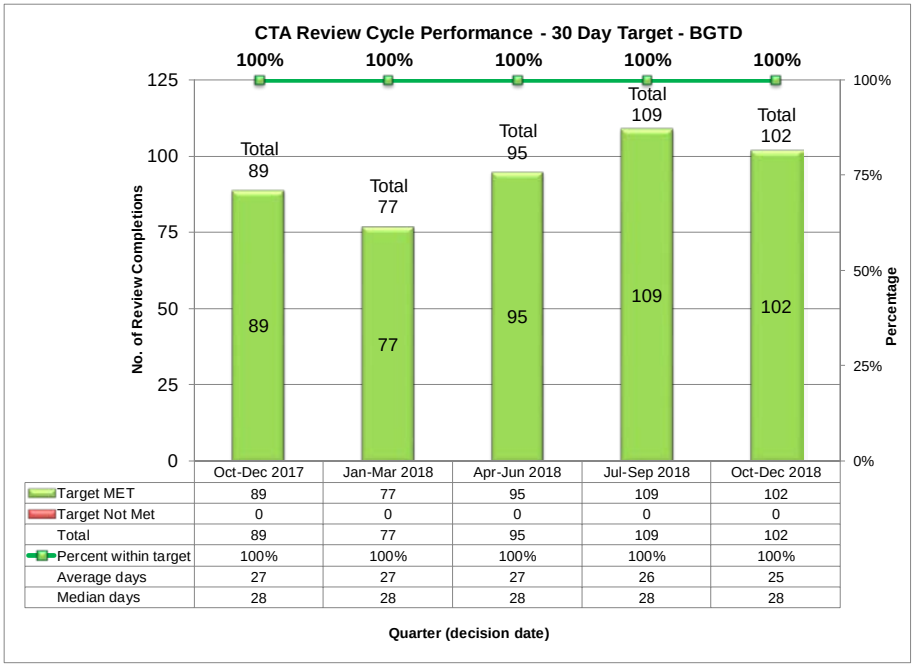



| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Phase 1 HEALTHY HUMAN-30 | 3 | 3 | 1 | 1 | 0 |
| Phase 1 OTHER - 30 DAYS | 16 | 10 | 11 | 11 | 12 |
| Phase 1/2 - 30 DAYS | 9 | 0 | 7 | 6 | 3 |
| Phase 2 - 30 DAYS | 15 | 29 | 39 | 41 | 27 |
| Phase 2/3 - 30 DAYS | 0 | 4 | 0 | 0 | 2 |
| Phase 3 - 30 DAYS | 42 | 34 | 43 | 38 | 36 |
| Phase Other | 1 | 5 | 9 | 5 | 13 |
| Total | 86 | 85 | 110 | 102 | 93 |

## Decision Documents - Clinical Trial Application (CTA)

| CTA | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 85 | 75 | 92 | 108 | 100 |
| CANCELLED BY COMPANY DURING REVIEW | 4 | 2 | 3 | 1 | 2 |
| CANCELLED BY COMPANY AT PROCESSING | 2 | 3 | 0 | 4 | 2 |
| REJECTION LETTER (SCR) | 0 | 0 | 0 | 1 | 0 |

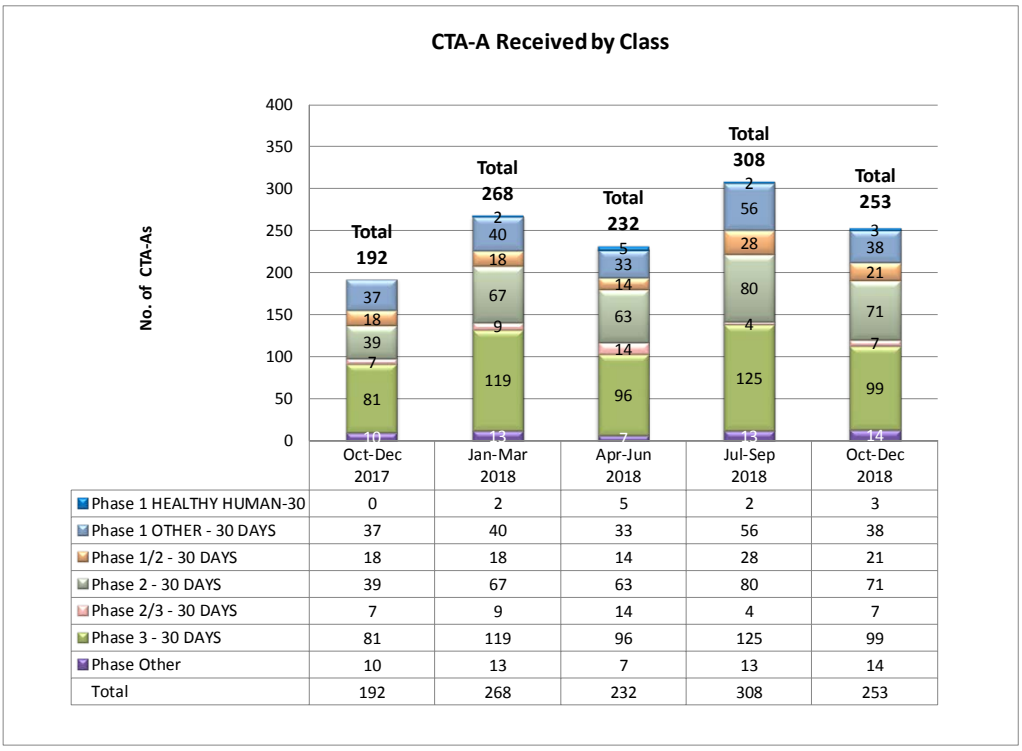
## Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Target MET | 89 | 77 | 95 | 109 | 102 |
| Target Not Met | 0 | 0 | 0 | 0 | 0 |
| Total | 89 | 77 | 95 | 109 | 102 |
| Percent within target | 100% | 100% | 100% | 100% | 100% |
| Average days | 27 | 27 | 27 | 26 | 25 |
| Median days | 28 | 28 | 28 | 28 | 28 |

# Clinical Trial Application- Amendments ( CTA-A )

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

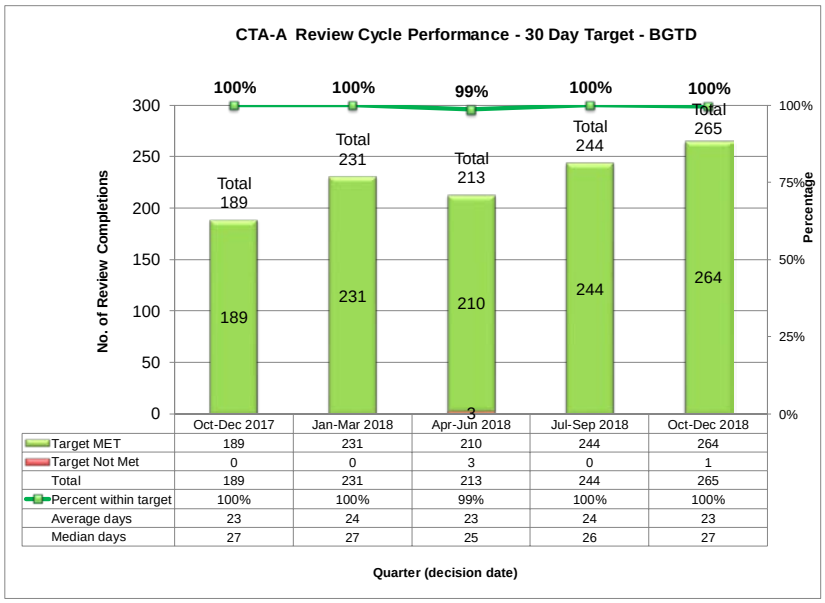



| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Phase 1 HEALTHY HUMAN-30 | 0 | 2 | 5 | 2 | 3 |
| Phase 1 OTHER - 30 DAYS | 37 | 40 | 33 | 56 | 38 |
| Phase 1/2 - 30 DAYS | 18 | 18 | 14 | 28 | 21 |
| Phase 2 - 30 DAYS | 39 | 67 | 63 | 80 | 71 |
| Phase 2/3 - 30 DAYS | 7 | 9 | 14 | 4 | 7 |
| Phase 3 - 30 DAYS | 81 | 119 | 96 | 125 | 99 |
| Phase Other | 10 | 13 | 7 | 13 | 14 |
| Total | 192 | 268 | 232 | 308 | 253 |

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

| CTA-A | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 202 | 240 | 228 | 297 | 279 |
| REJECTION LETTER (SCR) | 3 | 4 | 7 | 4 | 2 |
| CANCELLED BY COMPANY DURING REVIEW | 2 | 2 | 1 | 2 | 0 |
| CANCELLED BY COMPANY AT PROCESSING | 0 | 3 | 0 | 2 | 6 |

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




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Target MET | 189 | 231 | 210 | 244 | 264 |
| Target Not Met | 0 | 0 | 3 | 0 | 1 |
| Total | 189 | 231 | 213 | 244 | 265 |
| Percent within target | 100% | 100% | 99% | 100% | 100% |
| Average days | 23 | 24 | 23 | 24 | 23 |
| Median days | 27 | 27 | 25 | 26 | 27 |

Quarter (decision date)

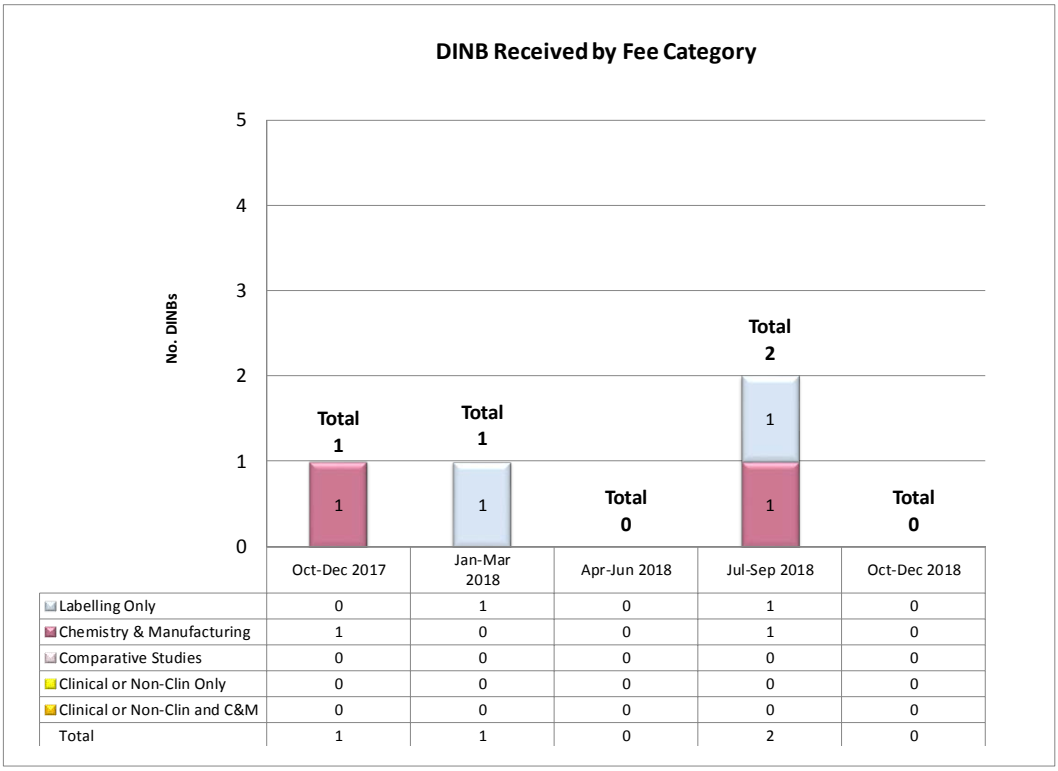
# DINB

## Application for a Drug Identification Number

## Biological Product

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

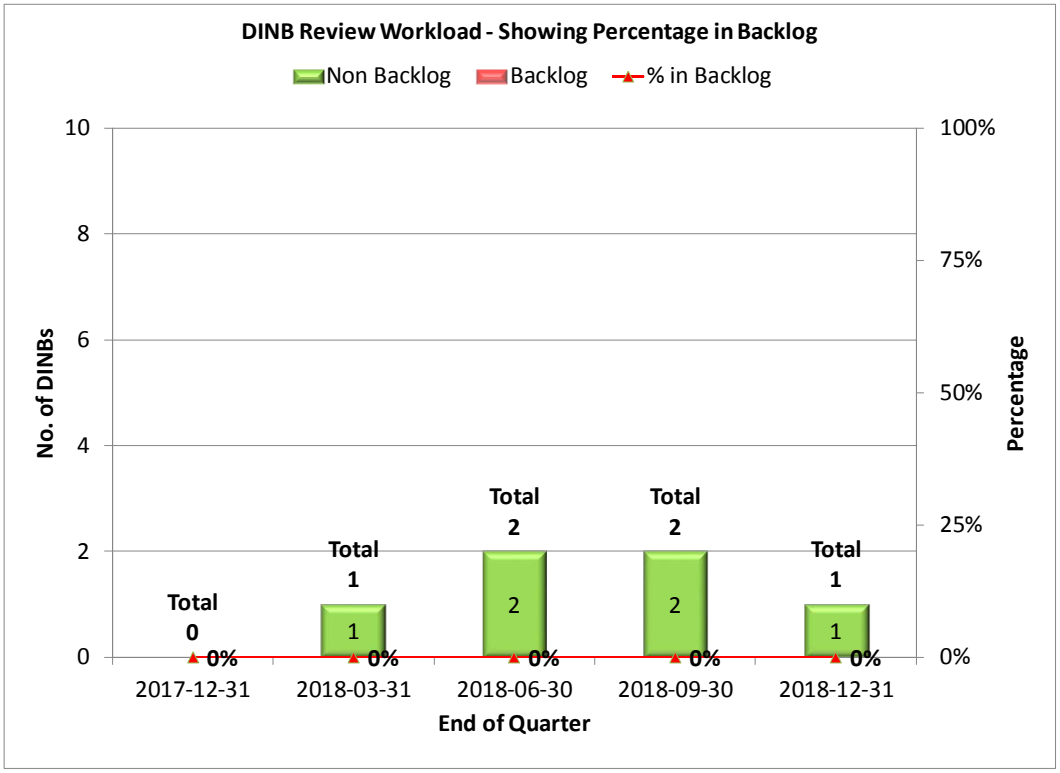
### Number Received - DINB




| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Labelling Only | 0 | 1 | 0 | 1 | 0 |
| Chemistry & Manufacturing | 1 | 0 | 0 | 1 | 0 |
| Comparative Studies | 0 | 0 | 0 | 0 | 0 |
| Clinical or Non-Clin Only | 0 | 0 | 0 | 0 | 0 |
| Clinical or Non-Clin and C&M | 0 | 0 | 0 | 0 | 0 |
| Total | 1 | 1 | 0 | 2 | 0 |

# REVIEW WORKLOAD

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

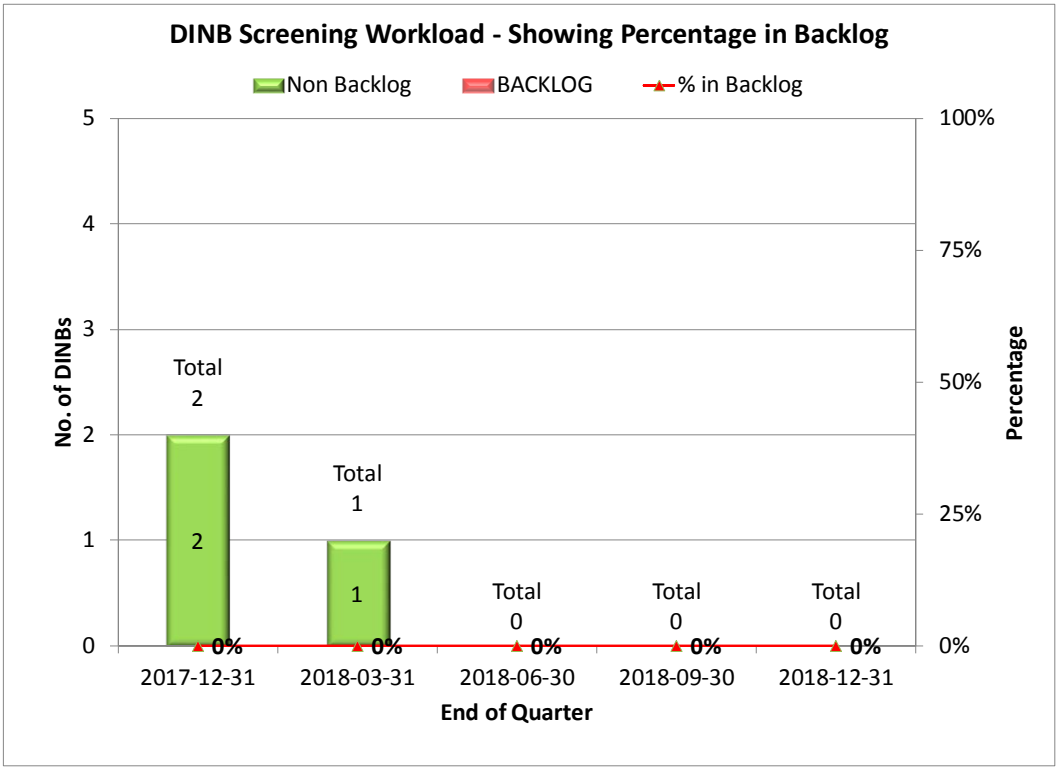



## Review Workload by Class - DINB

| BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER | | | | | |
|---|---|---|---|---|---|
| | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| **Labelling Only** | **0** | **1** | **1** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Chemistry & Manufacturing** | **0** | **0** | **1** | **2** | **1** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **0** | **1** | **2** | **2** | **1** |
| **Non Backlog** | **0** | **1** | **2** | **2** | **1** |
| **Backlog** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **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 | | | | | |
|---|---|---|---|---|---|
| | 2017-12-31 | 2018-03-31 | 2018-06-30 | 2018-09-30 | 2018-12-31 |
| **Labelling Only** | **1** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Chemistry & Manufacturing** | **1** | **1** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **2** | **1** | **0** | **0** | **0** |
| **Non Backlog** | **2** | **1** | **0** | **0** | *0* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

# DECISION DOCUMENTS

## Decision Documents – DINB by Class

| DINB - Labelling Only | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 0 | 0 | 0 | 0 | 0 |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

| DINB - CLINICAL OR NON CLINICAL DATA AND C&M | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 0 | 0 | 0 | 0 | 0 |

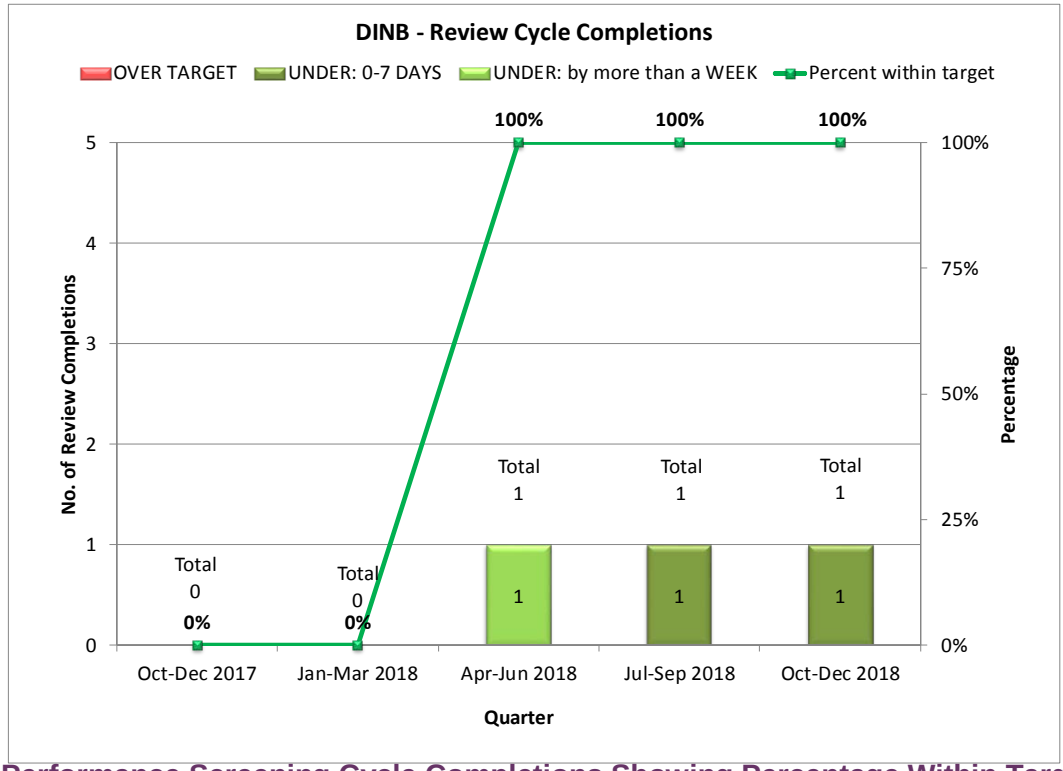
| DINB - CHEMISTRY & MANUFACTURING | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NO OBJECTION LETTER | 0 | 0 | 0 | 0 | 0 |
| SCREENING DEFICIENCY NOTICE | 0 | 1 | 0 | 0 | 0 |
| NOTICE OF DEFICIENCY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

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

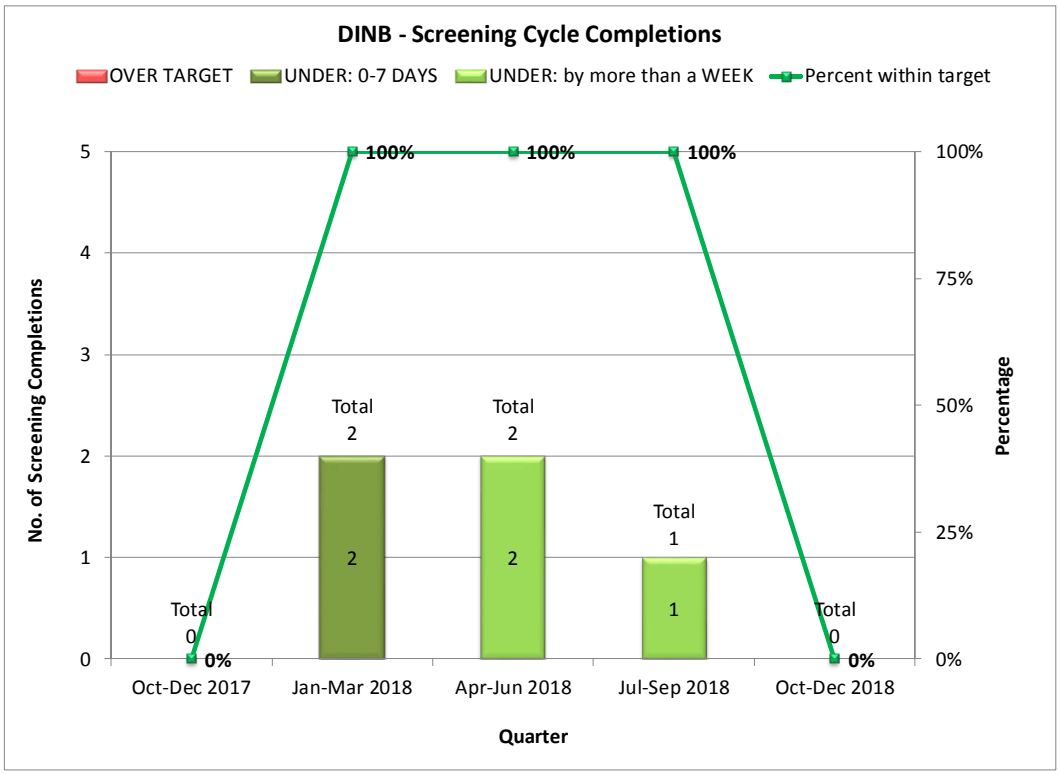
| DINB - Administrative | | | | | |
|---|---|---|---|---|---|
| **DOCUMENT TYPE** | **Oct-Dec 2017** | **Jan-Mar 2018** | **Apr-Jun 2018** | **Jul-Sep 2018** | **Oct-Dec 2018** |
| NOTIFICATION FORM/DIN ISSUED | 0 | 0 | 0 | 0 | 0 |
| CANCELLED BY COMPANY | 1 | 0 | 0 | 0 | 0 |

# PERFORMANCE

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

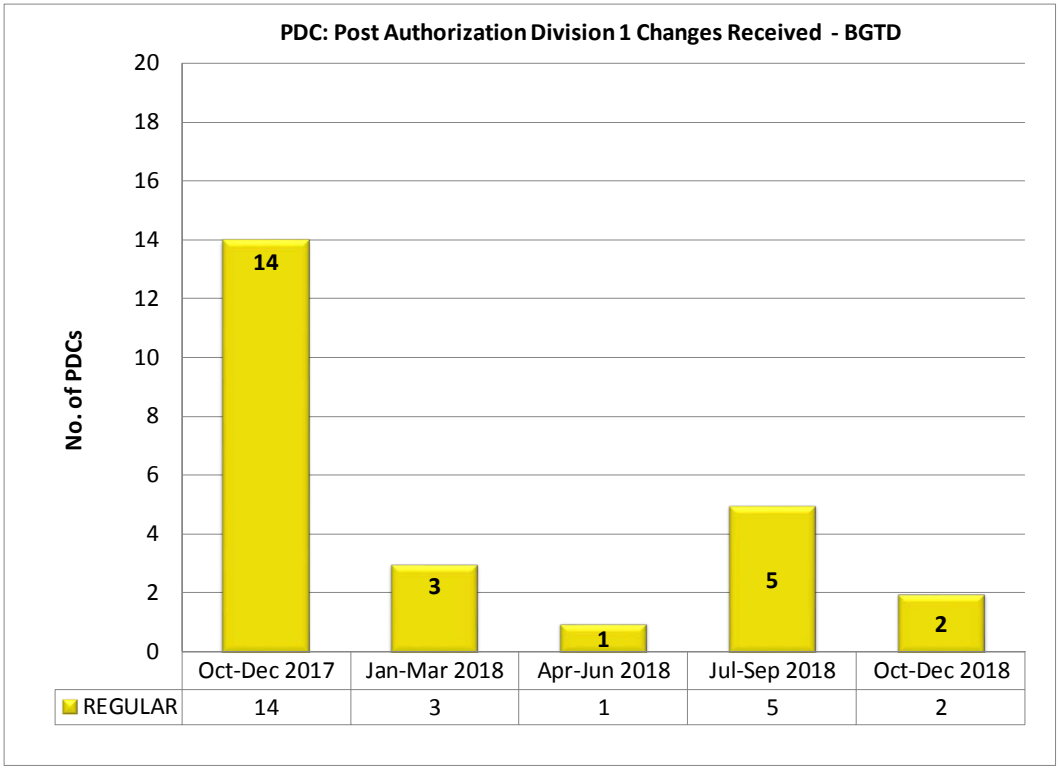



## Performance Screening Cycle Completions Showing Percentage Within Target - DINB



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

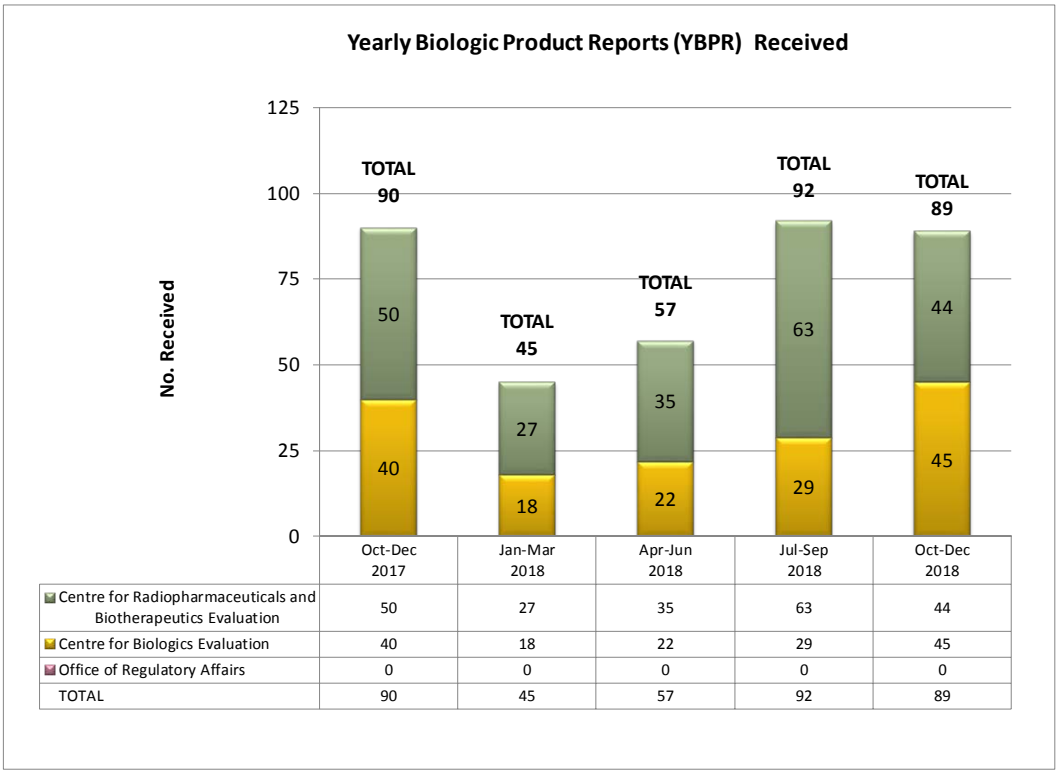
## Post –Authorization Division 1 Changes - Biologics (PDC-B) Received



# Yearly Biologic Product Reports (YBPR)

[15])

## Yearly Biologic Product Report s (YBPR) Received



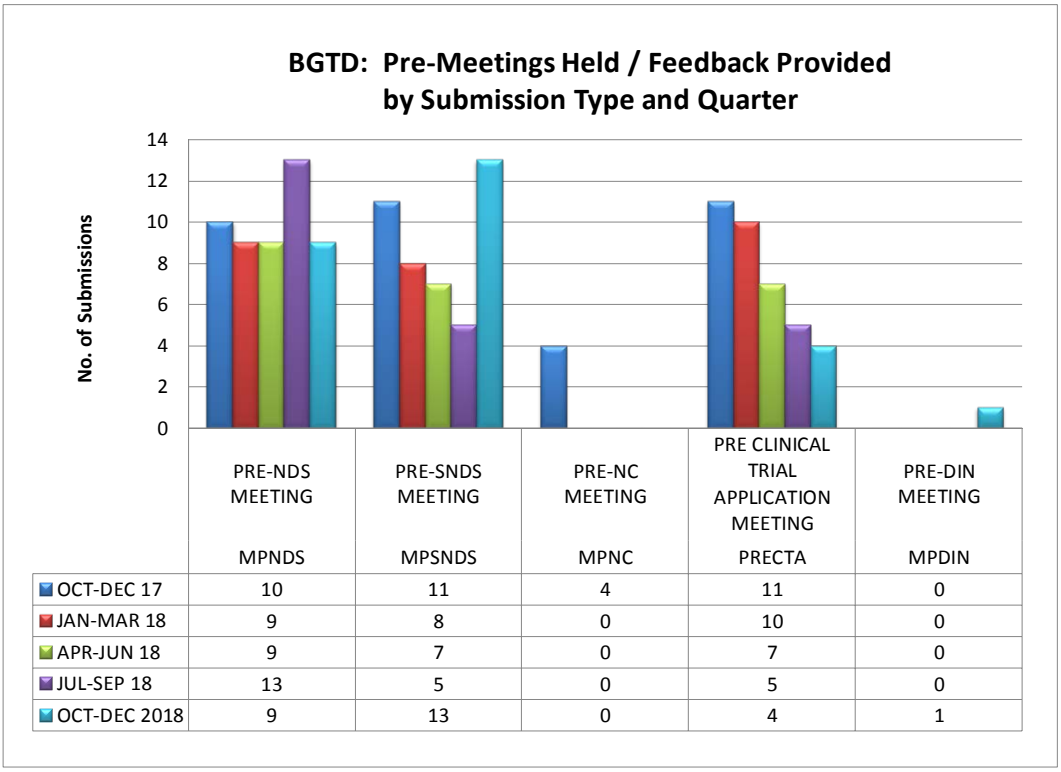

| | Oct-Dec 2017 | Jan-Mar 2018 | Apr-Jun 2018 | Jul-Sep 2018 | Oct-Dec 2018 |
|---|---|---|---|---|---|
| Centre for Radiopharmaceuticals and Biotherapeutics Evaluation | 50 | 27 | 35 | 63 | 44 |
| Centre for Biologics Evaluation | 40 | 18 | 22 | 29 | 45 |
| Office of Regulatory Affairs | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 90 | 45 | 57 | 92 | 89 |

[15] 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

16

## Pre-submission Meetings Held / Feedback Provided




| | PRE-NDS MEETING MPNDS | PRE-SNDS MEETING MPSNDS | PRE-NC MEETING MPNC | PRE CLINICAL TRIAL APPLICATION MEETING PRECTA | PRE-DIN MEETING MPDIN |
|---|---|---|---|---|---|
| OCT-DEC 17 | 10 | 11 | 4 | 11 | 0 |
| JAN-MAR 18 | 9 | 8 | 0 | 10 | 0 |
| APR-JUN 18 | 9 | 7 | 0 | 7 | 0 |
| JUL-SEP 18 | 13 | 5 | 0 | 5 | 0 |
| OCT-DEC 2018 | 9 | 13 | 0 | 4 | 1 |

[16] 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