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# Therapeutic Products Directorate

## Drug Submission Performance Quarterly Report

October - December  
2019



**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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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 October - December 2018 to October - December 2019. 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.

<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-Cs 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 Review 1 and 90 days for Review 2. 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:

Office of Submissions and Intellectual Property,  
Resource Management and Operations Directorate  
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](mailto:hc.osip-bppi.sc@canada.ca)

<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 for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	- Application for a Drug Identification Number for a biological product
DIND	- Application for a Drug Identification Number for a disinfectant product
DINF	- Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	- Abbreviated Extraordinary Use New Drug Submission
EUNDS	- Extraordinary Use New Drug Submission
EUSANDS	- Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	- Supplement to an Extraordinary Use New Drug Submission
MPNDS	- Pre-Submission Meeting New Drug Submission
MPSNDS	- Pre-Submission Meeting Supplement to a New Drug Submission
NC	- Notifiable Change
NDS	- New Drug Submission
NDS-D	- New Drug Submission for Disinfectant products
PDC	- Post-authorization Division 1 Change for a pharmaceutical product
PDC-B	- Post-authorization Division 1 Change for a biologic drug product
PRNDS	- Request for Priority Review Status: New Drug Submission
PRSNDS	- Request for Priority Review Status: Supplemental New Drug Submission
SANDS	- Supplement to an Abbreviated New Drug Submission
SANDS-c	- Supplement to an Abbreviated New Drug Submission - Confirmatory
SNDS	- Supplement to a New Drug Submission
SNDS-c	- Supplement to a New Drug Submission - Confirmatory
SNDS-D	- Supplement to a New Drug Submission for Disinfectant products

## 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</b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants<sup>7</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](#)

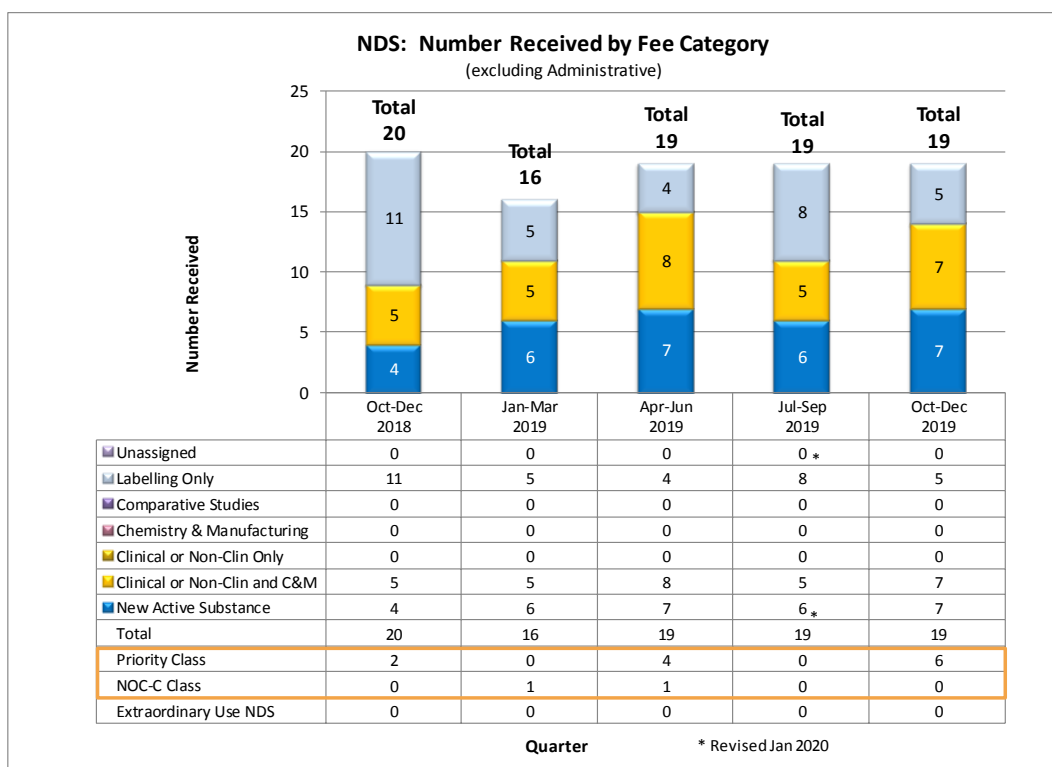
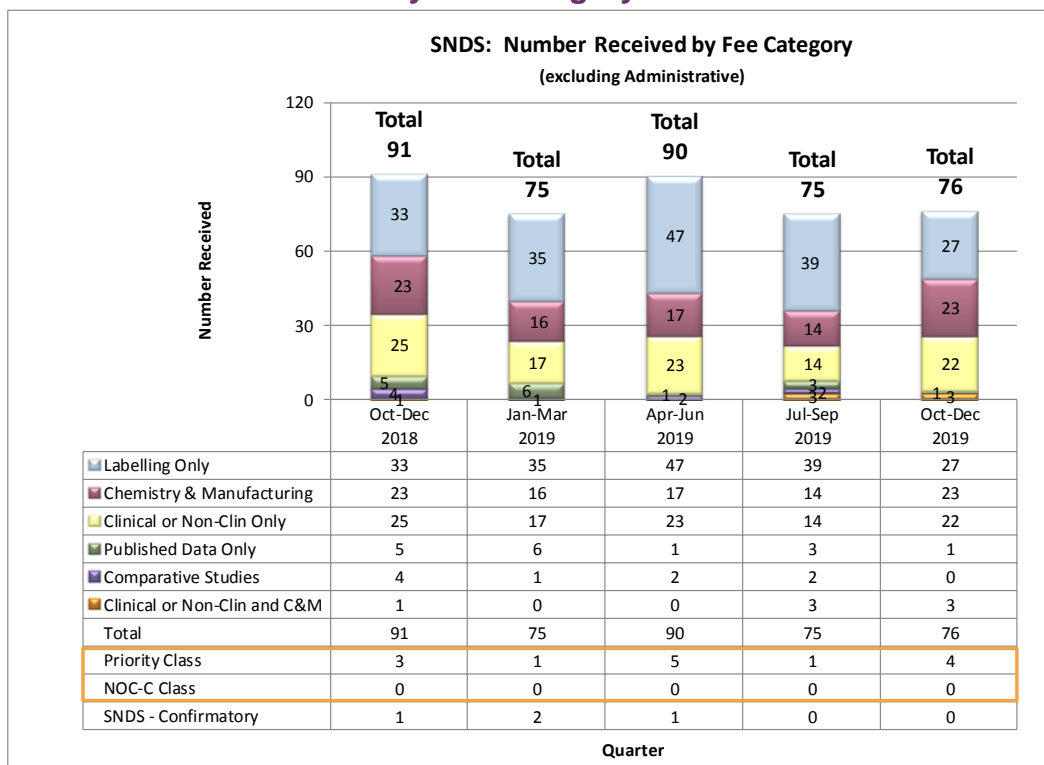
<sup>6</sup> For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#).

<sup>7</sup> The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from the Therapeutic Products Directorate (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)**

**&**

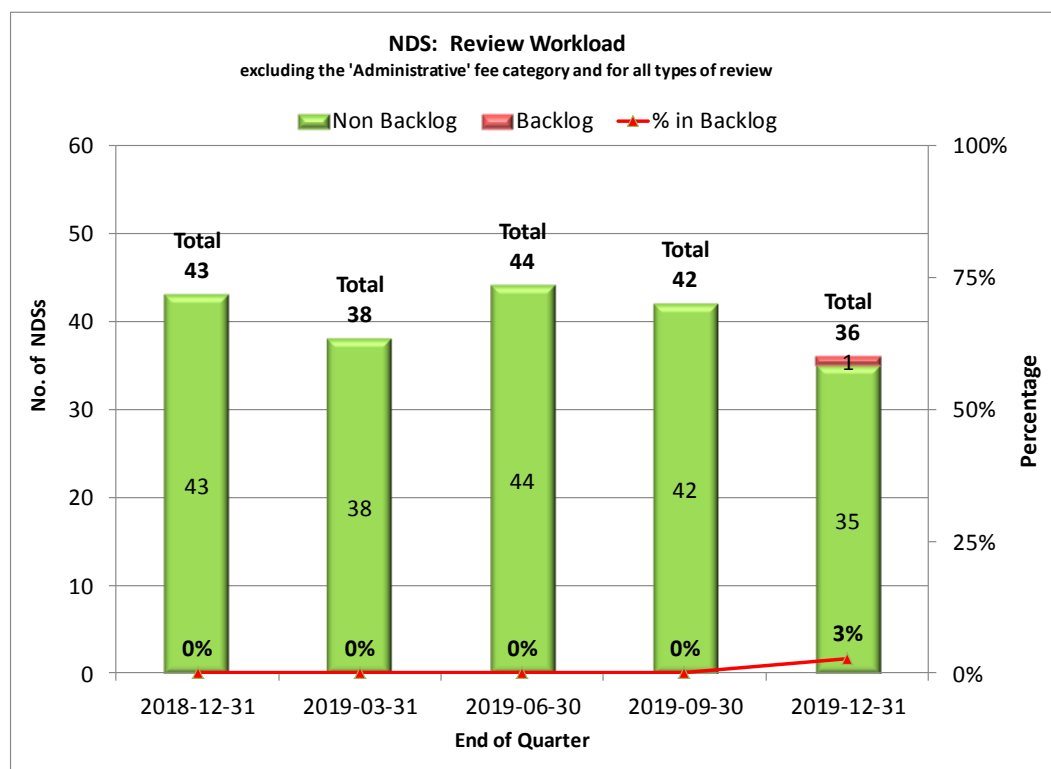
**SUPPLEMENT TO A NEW DRUG SUBMISSION  
(SNDS)**

**SUBMISSIONS RECEIVED <sup>8</sup>****NDS: Number Received by Fee Category****SNDS: Number Received by Fee Category**

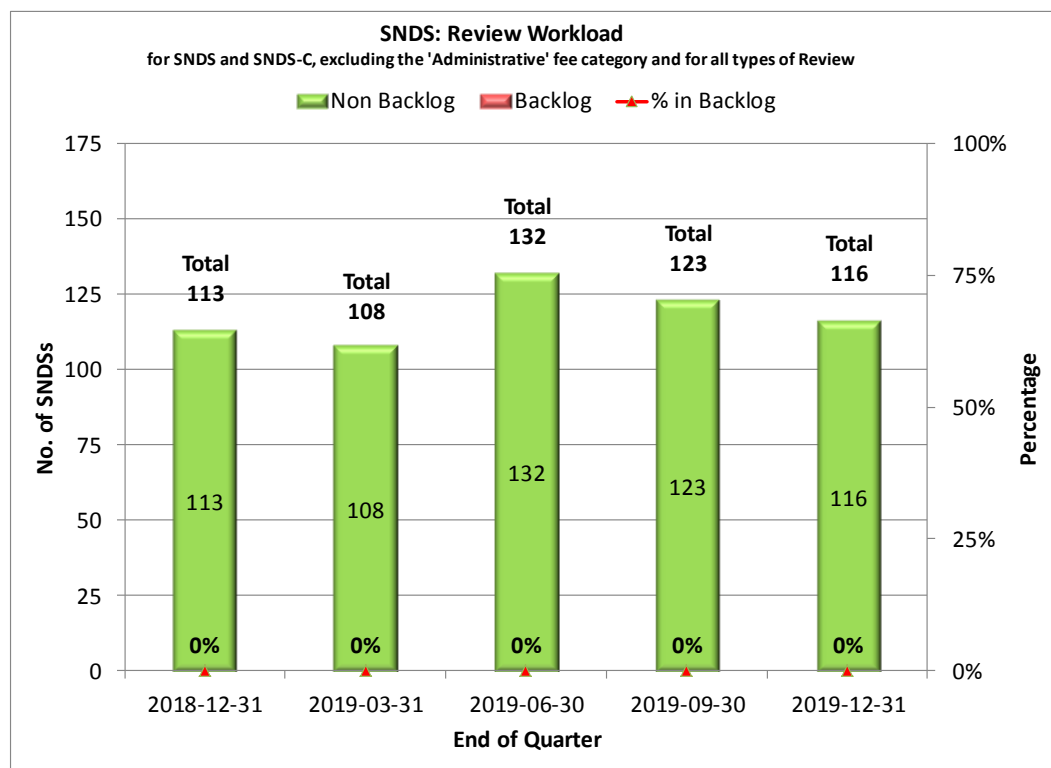
<sup>8</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

## WORKLOAD

### NDS: Review Workload



### SNDS: Review Workload

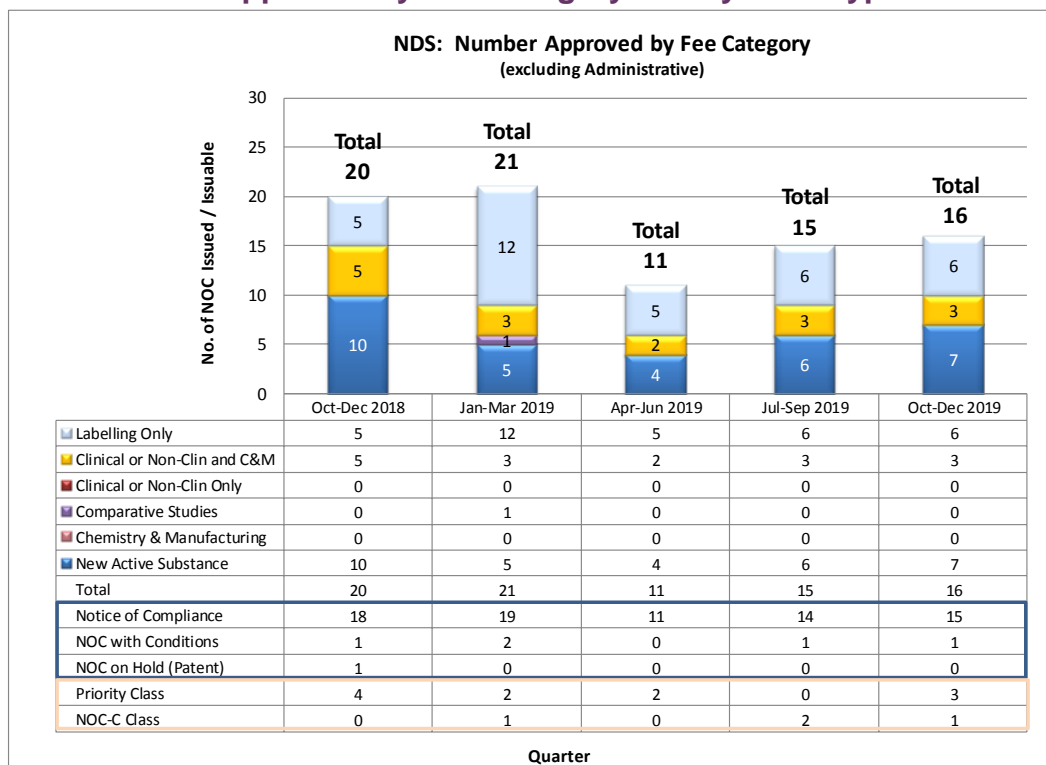
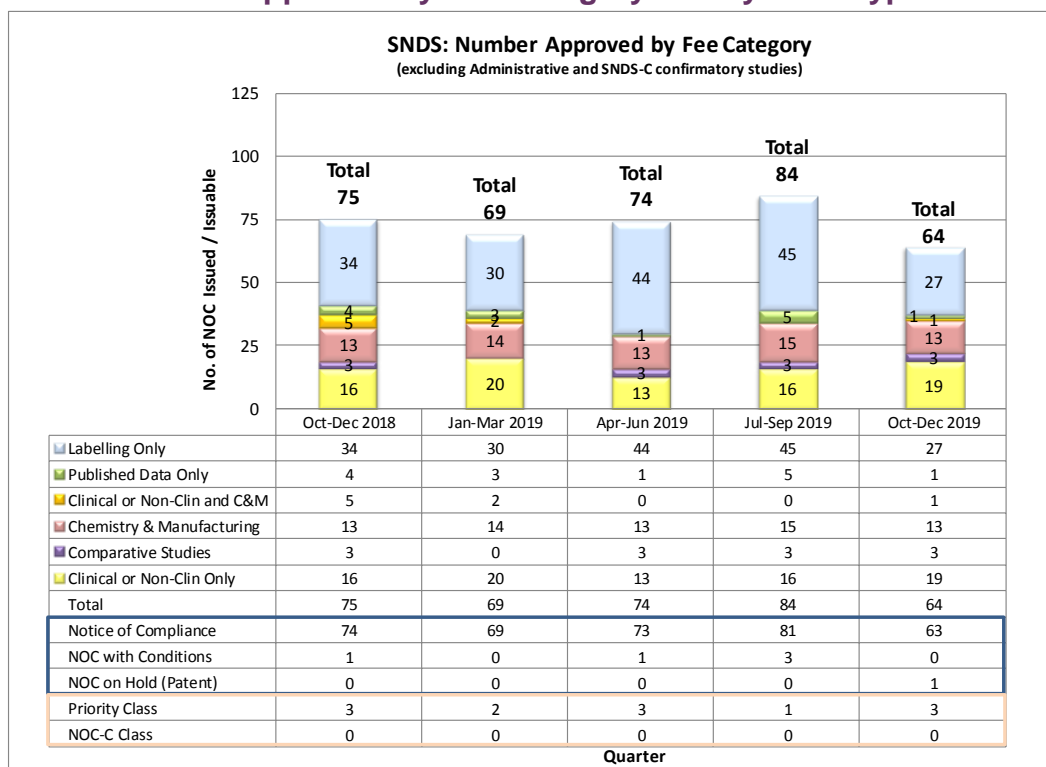


**WORKLOAD****NDS: Review Workload by Fee Category**

<b>NDS: REVIEW WORKLOAD</b> <b>BY FEE CATEGORY (excluding Administrative) and End of Quarter</b>					
<b>FEE Category</b>	<b>2018-12-31</b>	<b>2019-03-31</b>	<b>2019-06-30</b>	<b>2019-09-30</b>	<b>2019-12-31</b>
<b>Labelling Only</b>	<b>8</b>	<b>4</b>	<b>3</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>
<b>Comparative Studies</b>	<b>1</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>Chemistry &amp; Manufacturing</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 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>15</b>	<b>15</b>	<b>19</b>	<b>19</b>	<b>20</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>19</b>	<b>19</b>	<b>22</b>	<b>20</b>	<b>14</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>
<b>Total</b>	<b>43</b>	<b>38</b>	<b>44</b>	<b>42</b>	<b>36</b>
<b>Non Backlog</b>	<b>43</b>	<b>38</b>	<b>44</b>	<b>42</b>	<b>35</b>
<b>Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>3%</b>
<b>Priority (subset)</b>	<b>4</b>	<b>3</b>	<b>3</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>

**SNDS: Review Workload by Fee Category**

<b>SNDS: REVIEW WORKLOAD</b> <b>BY FEE CATEGORY (excluding Administrative) and End of Quarter</b>					
<b>FEE Category</b>	<b>2018-12-31</b>	<b>2019-03-31</b>	<b>2019-06-30</b>	<b>2019-09-30</b>	<b>2019-12-31</b>
<b>Labelling Only</b>	<b>21</b>	<b>10</b>	<b>21</b>	<b>16</b>	<b>18</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Comparative Studies</b>	<b>3</b>	<b>7</b>	<b>9</b>	<b>7</b>	<b>2</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>26</b>	<b>29</b>	<b>32</b>	<b>28</b>	<b>26</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>49</b>	<b>53</b>	<b>55</b>	<b>57</b>	<b>55</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>2</b>	<b>1</b>	<b>1</b>	<b>5</b>	<b>5</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Published Data</b>	<b>12</b>	<b>8</b>	<b>14</b>	<b>10</b>	<b>10</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>113</b>	<b>108</b>	<b>132</b>	<b>123</b>	<b>116</b>
<b>Non Backlog</b>	<b>113</b>	<b>108</b>	<b>132</b>	<b>123</b>	<b>116</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>4</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>4</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>0</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>3</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

**APPROVALS <sup>9</sup>****NDS: Number Approved by Fee Category and by NOC Type****SNDS: Number Approved by Fee Category and by NOC Type**

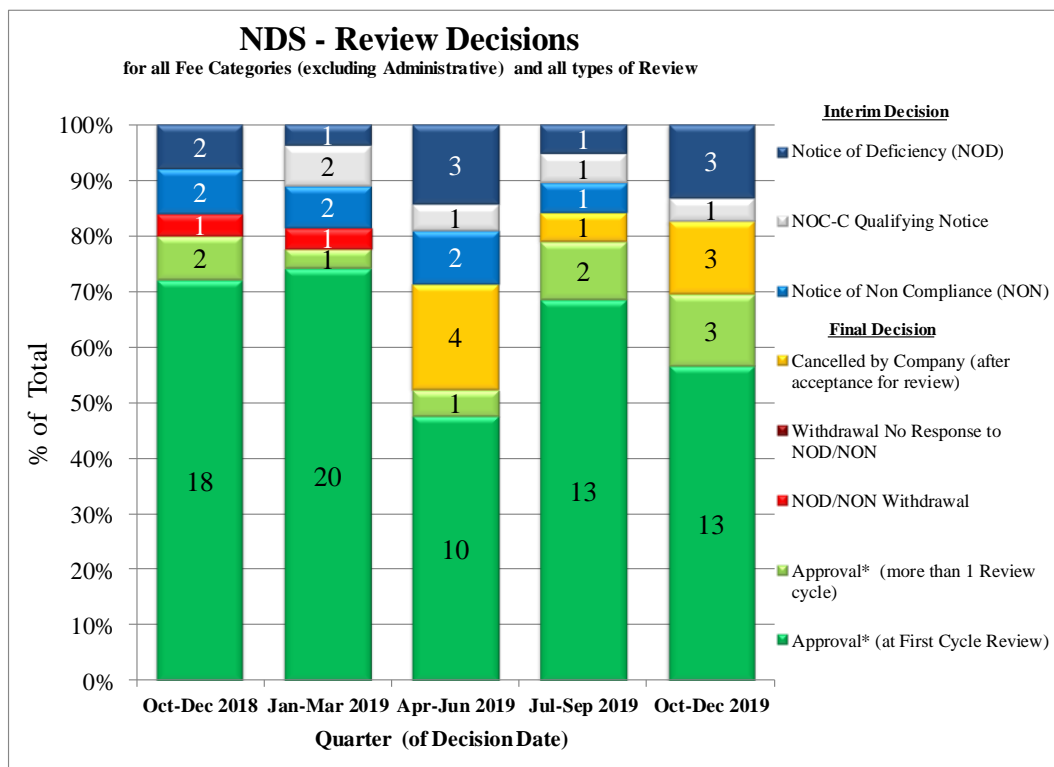
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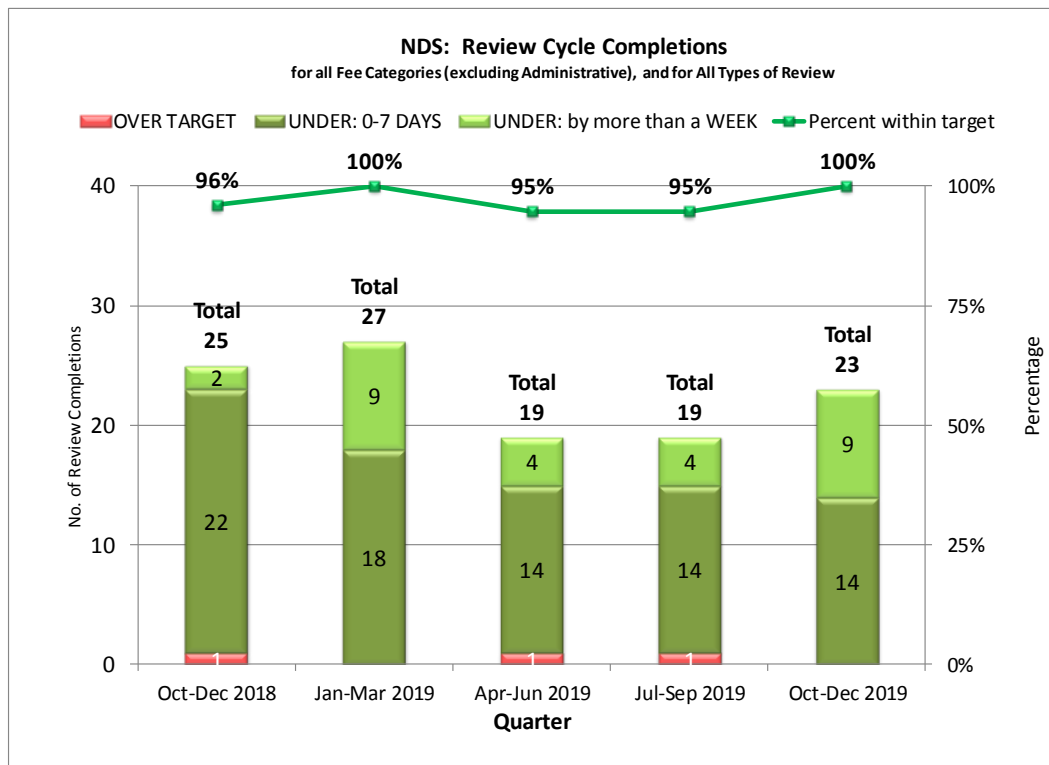
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## REVIEW PERFORMANCE

### NDS: Review Decisions by Type

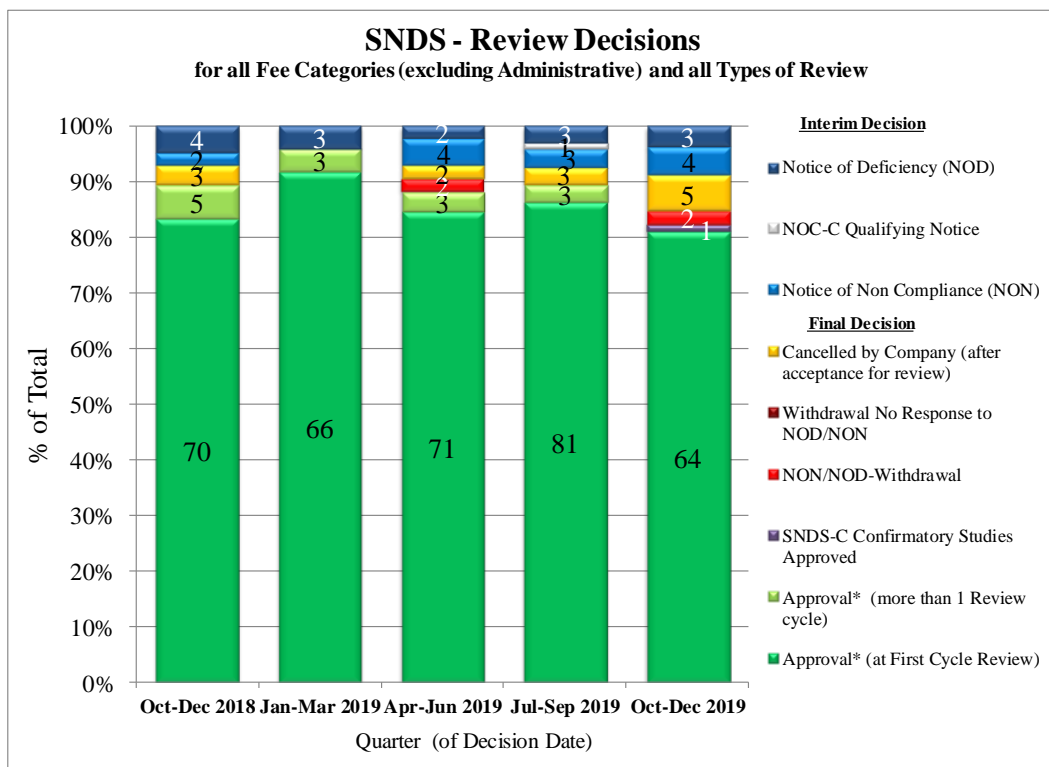


### NDS: Review Cycle Completions

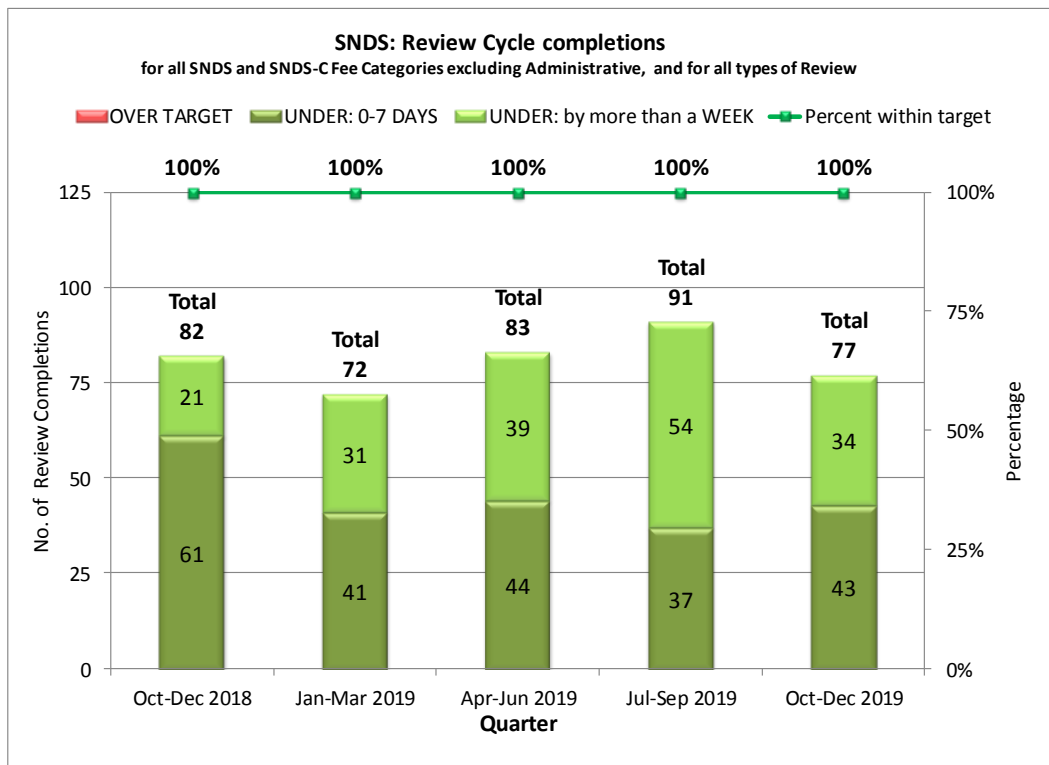


## REVIEW CYCLE DECISIONS

### SNDS: Review Decisions by Type

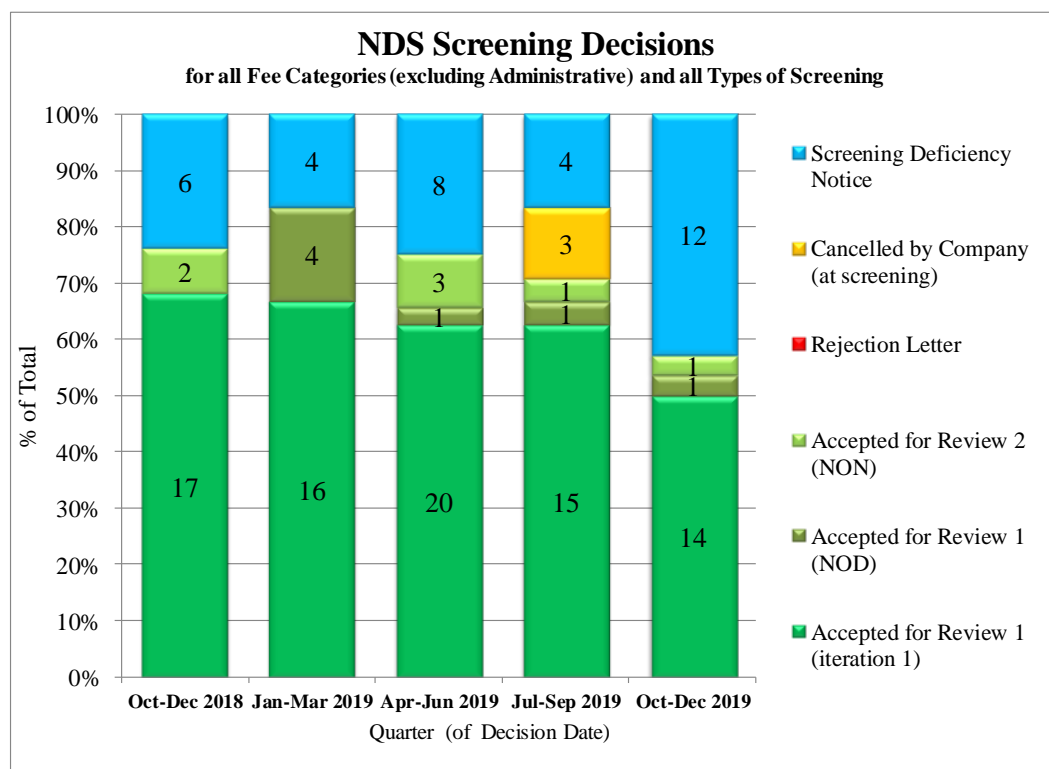


### SNDS: Review Cycle Completions

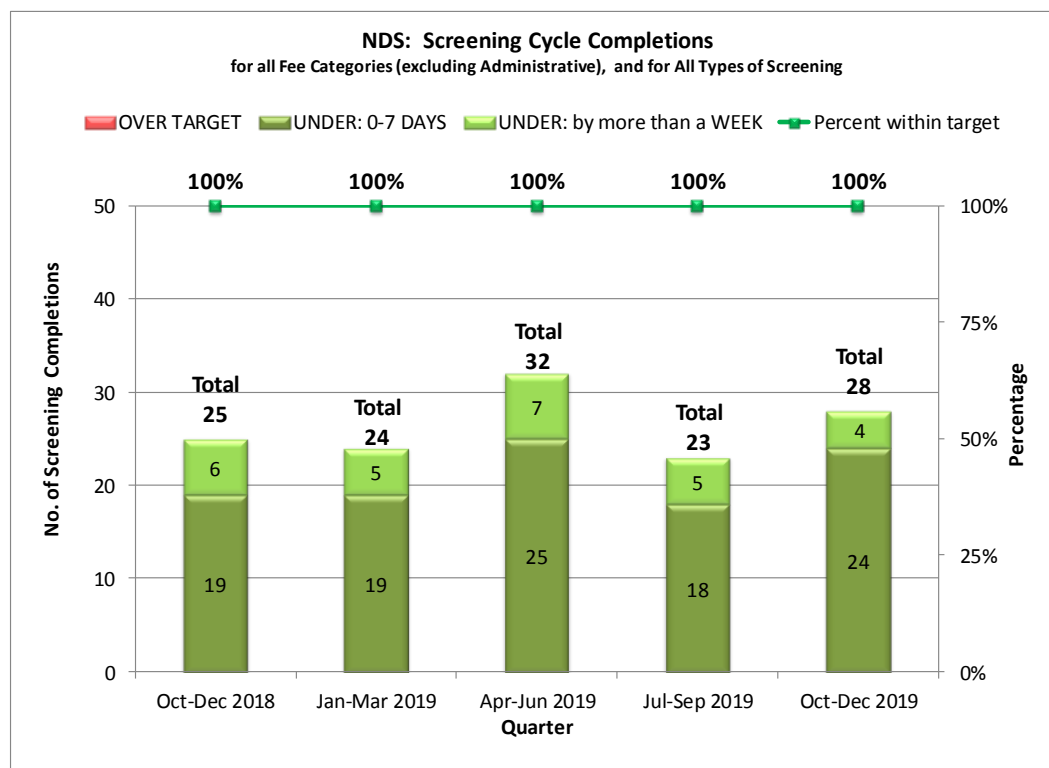


## SCREENING PERFORMANCE

### NDS: Screening Decisions by Type

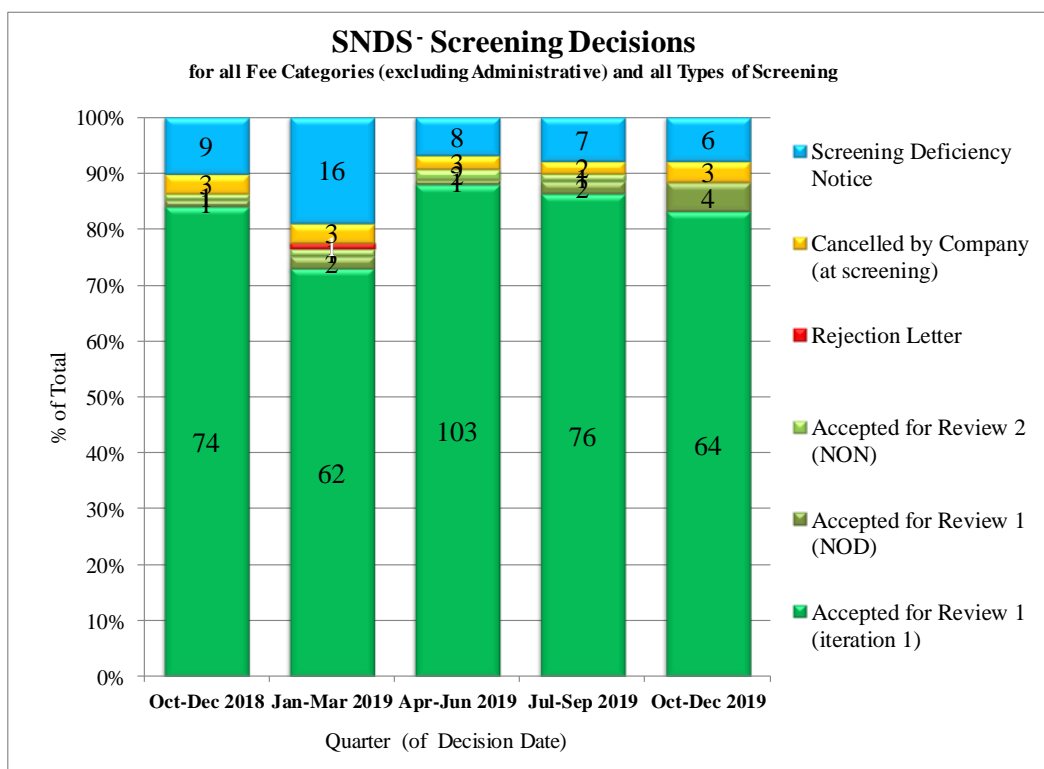


### NDS: Screening Cycle Completions

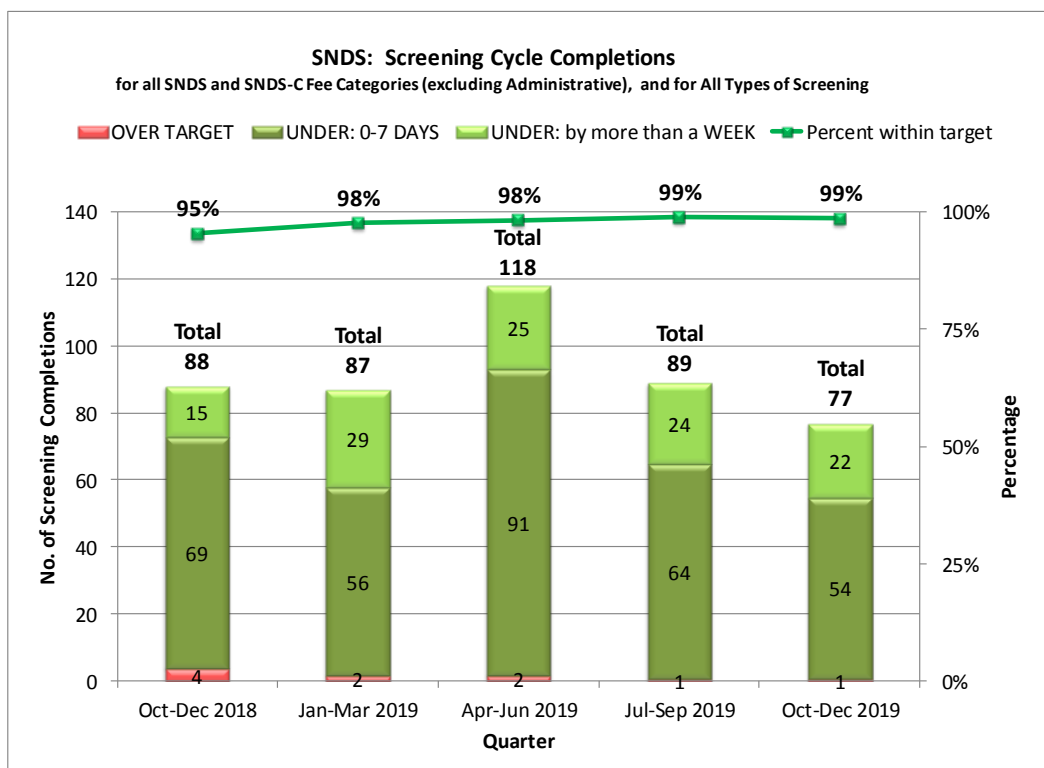


## SCREENING CYCLE DECISIONS

### SNDS: Screening Decisions by Type



### SNDS: Screening Cycle Completions



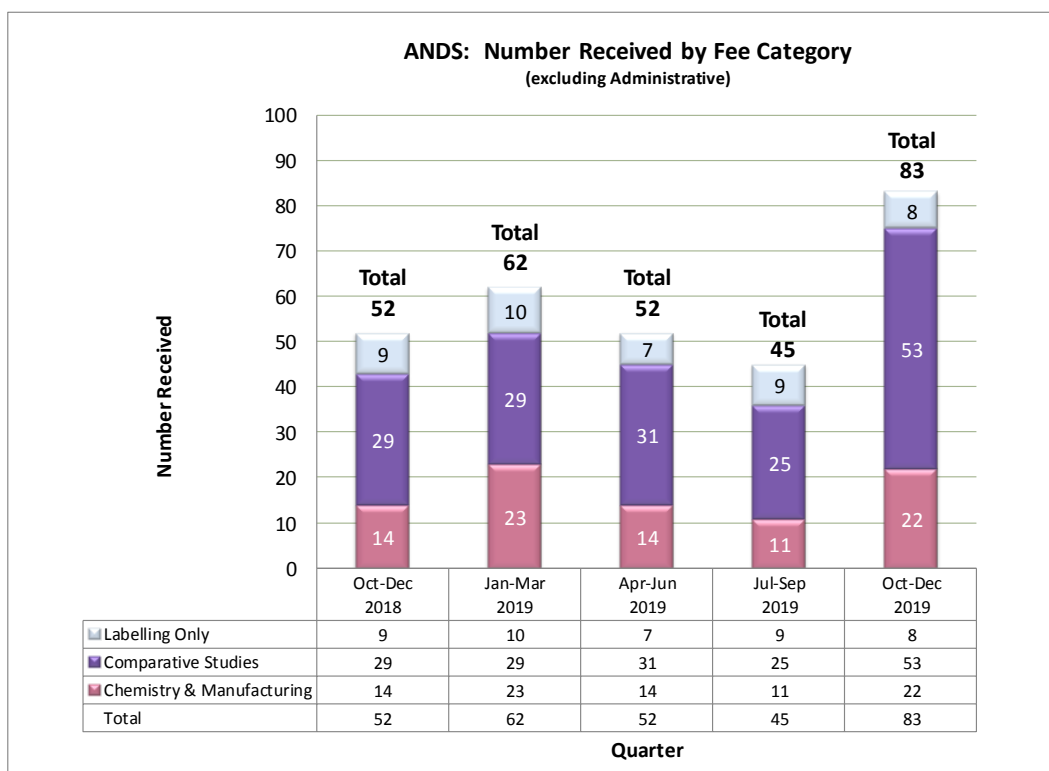
# **Abbreviated New Drug Submissions (ANDS)**

**&**

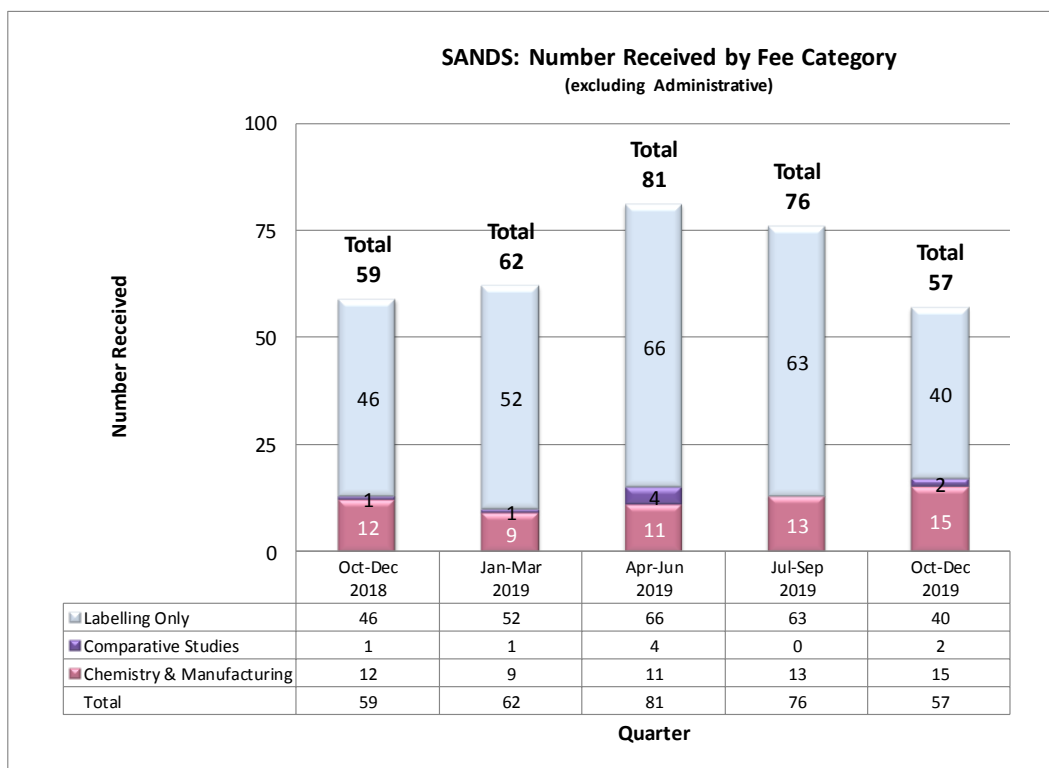
# **Supplement to an Abbreviated New Drug Submissions (SANDS)**

## SUBMISSIONS RECEIVED

### ANDS: Number Received by Fee Category

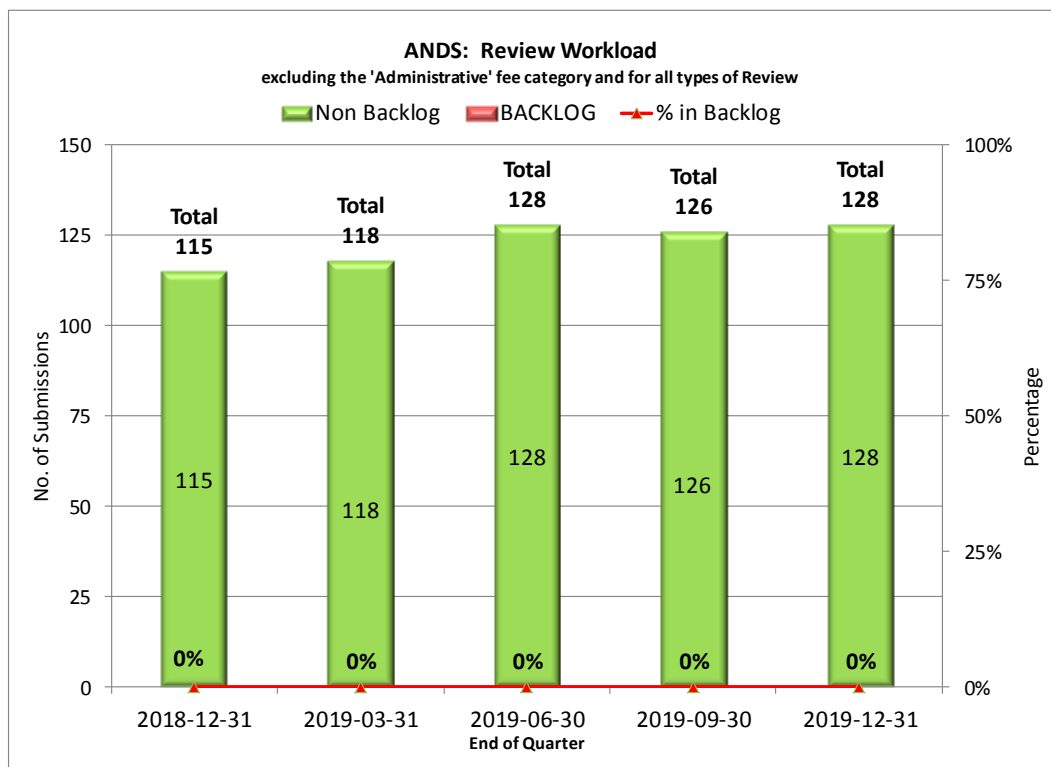


### SANDS: Number Received by Fee Category

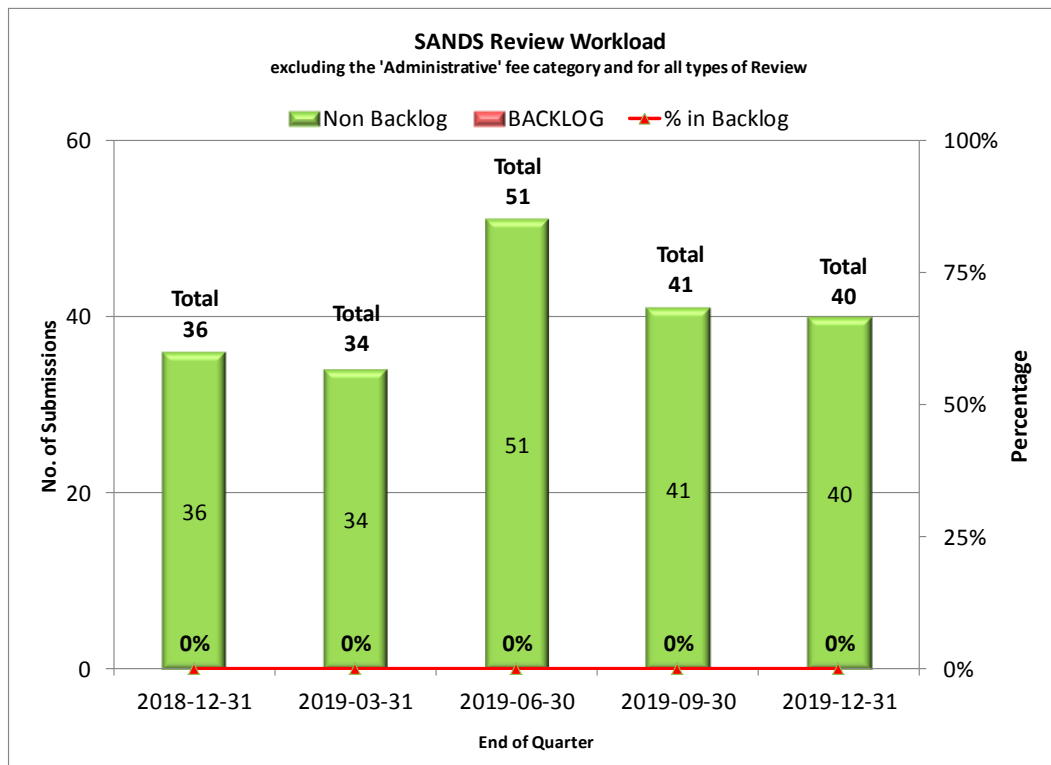


## WORKLOAD

### ANDS: Review Workload



### SANDS: Review Workload





**WORKLOAD****ANDS: Review Workload by Fee Category**

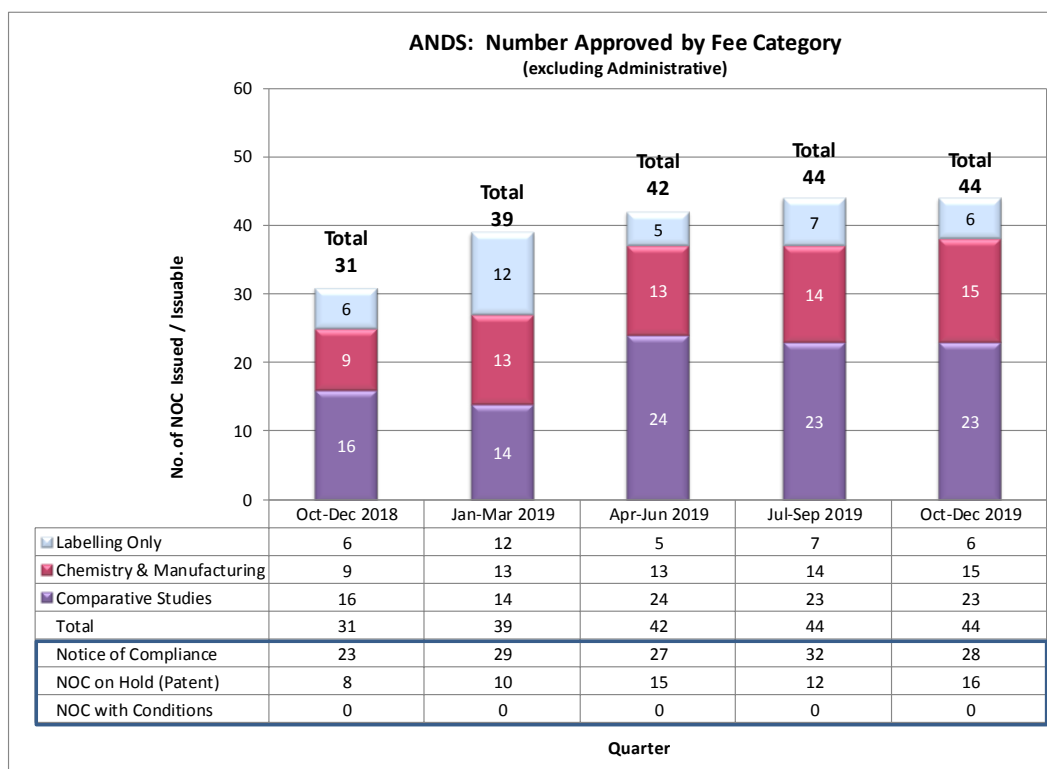
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Chemistry & Manufacturing	40	38	52	46	37
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	70	77	71	77	87
<i>Backlog</i>	0	0	0	0	0
Labelling Only	5	3	5	3	4
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>115</b>	<b>118</b>	<b>128</b>	<b>126</b>	<b>128</b>
<b>Non Backlog</b>	<b>115</b>	<b>118</b>	<b>128</b>	<b>126</b>	<b>128</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>

**SANDS: Review Workload by Fee Category**

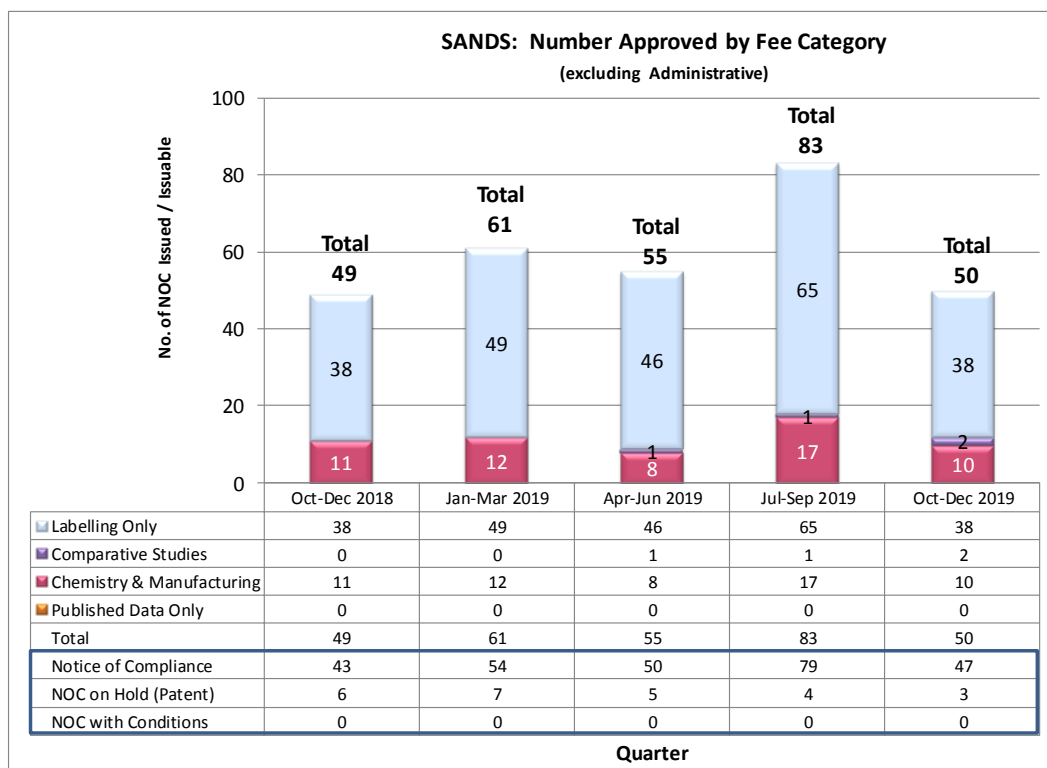
SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Chemistry & Manufacturing	21	22	22	19	17
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	0	2	3	4	5
<i>Backlog</i>	0	0	0	0	0
Labelling Only	15	10	26	18	18
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>36</b>	<b>34</b>	<b>51</b>	<b>41</b>	<b>40</b>
<b>Non Backlog</b>	<b>36</b>	<b>34</b>	<b>51</b>	<b>41</b>	<b>40</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>

## APPROVALS

### ANDS: Number Approved by Fee Category and by NOC Type



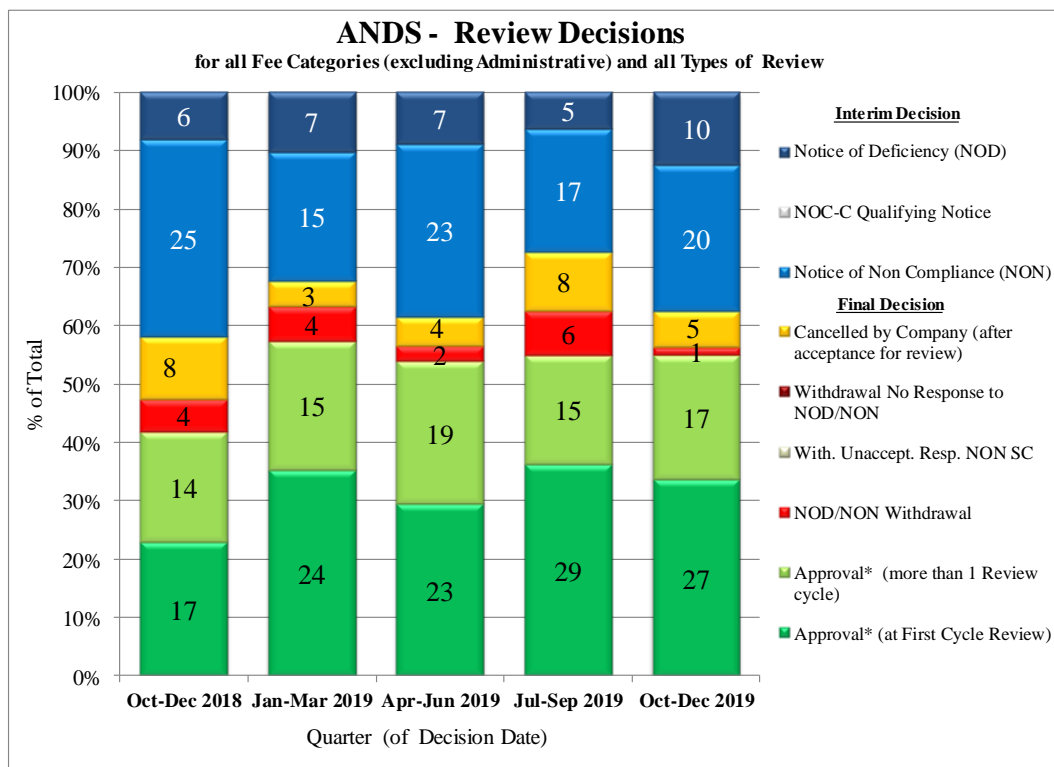
### SANDS: Number Approved by Fee Category and by NOC Type



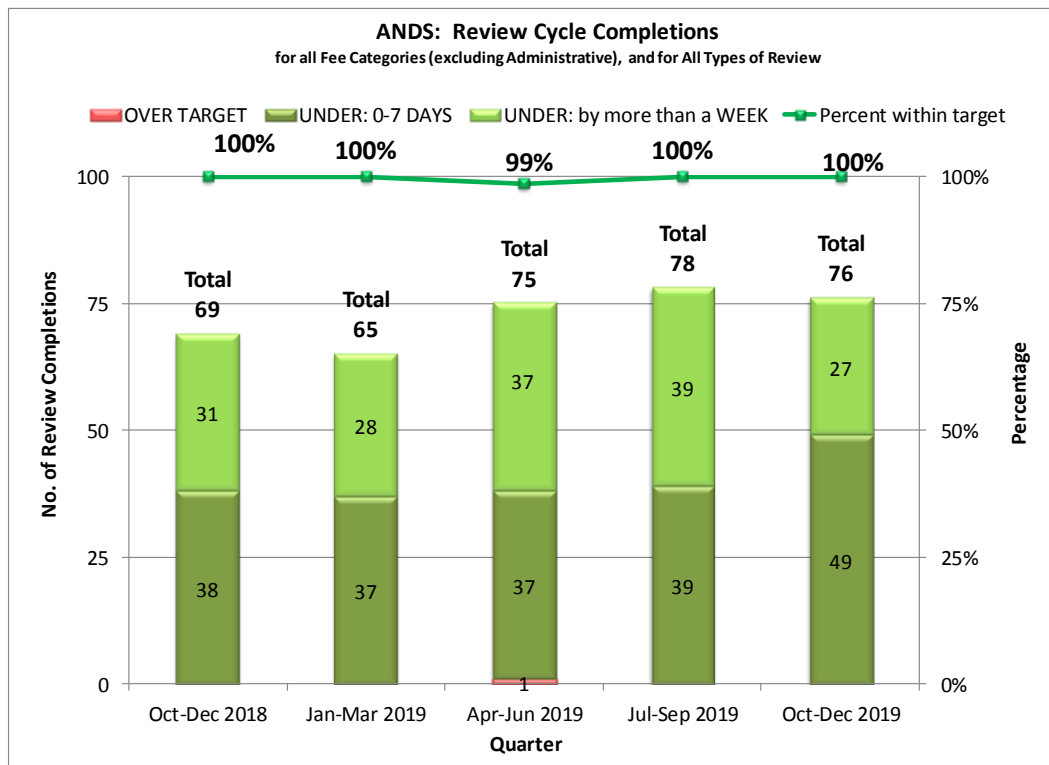
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## REVIEW PERFORMANCE

### ANDS: Review Decisions by Type

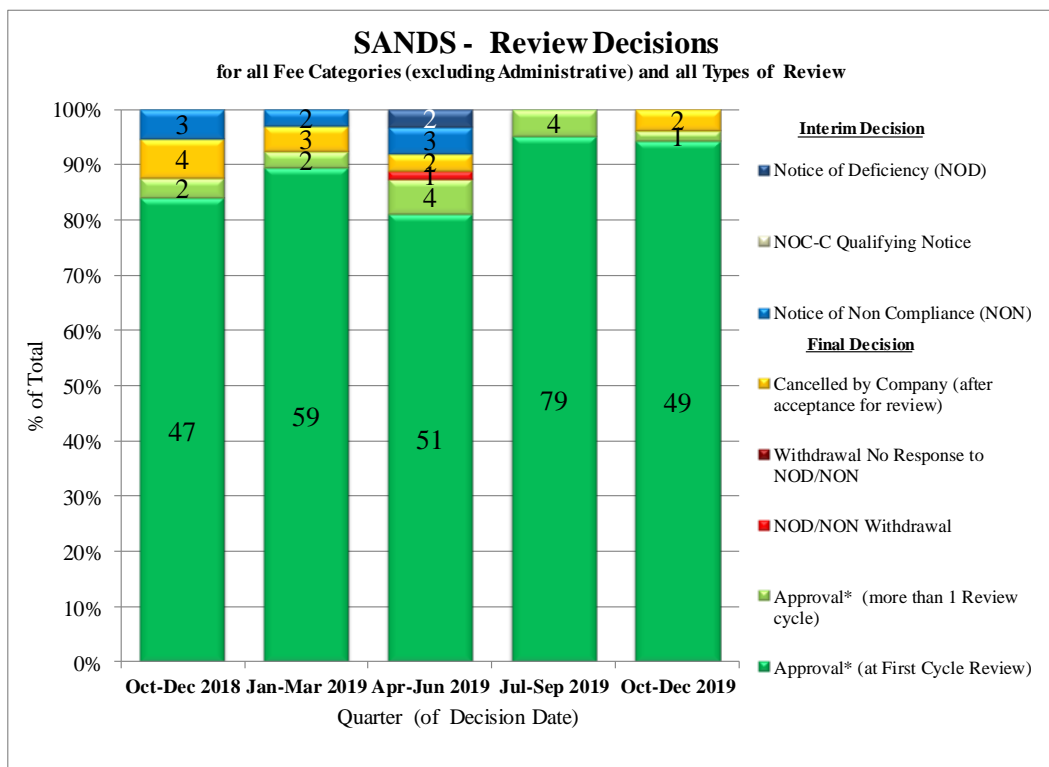


### ANDS: Review Cycle Completions

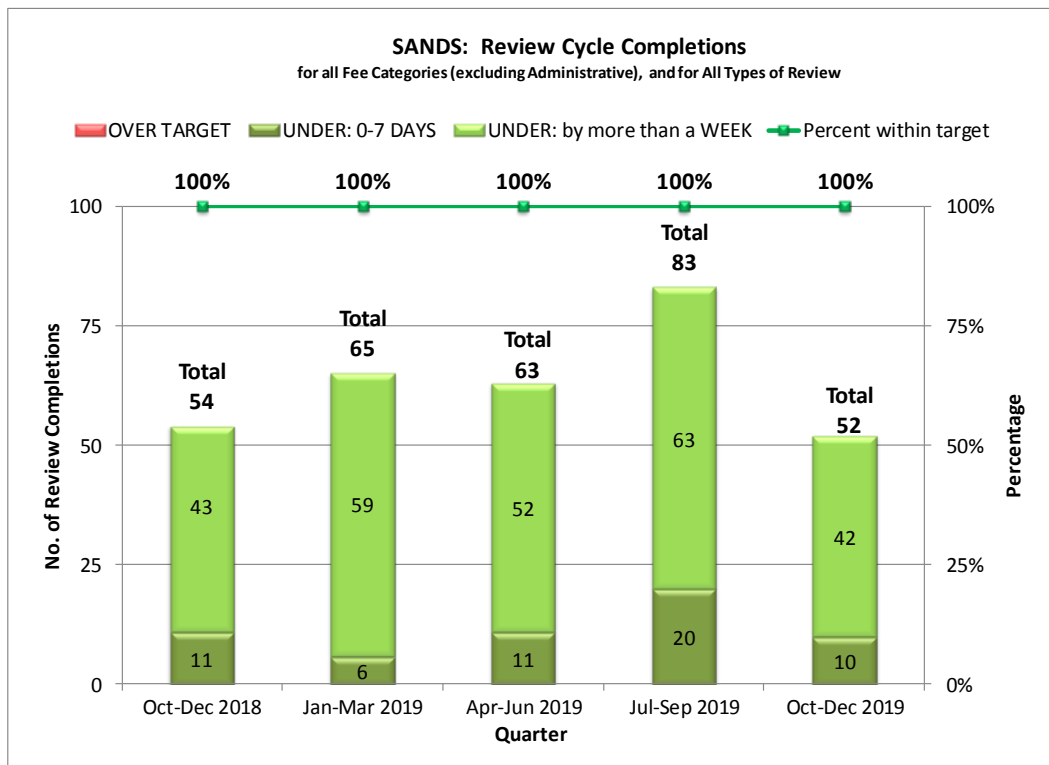


## REVIEW PERFORMANCE

### SANDS: Review Decisions by Type

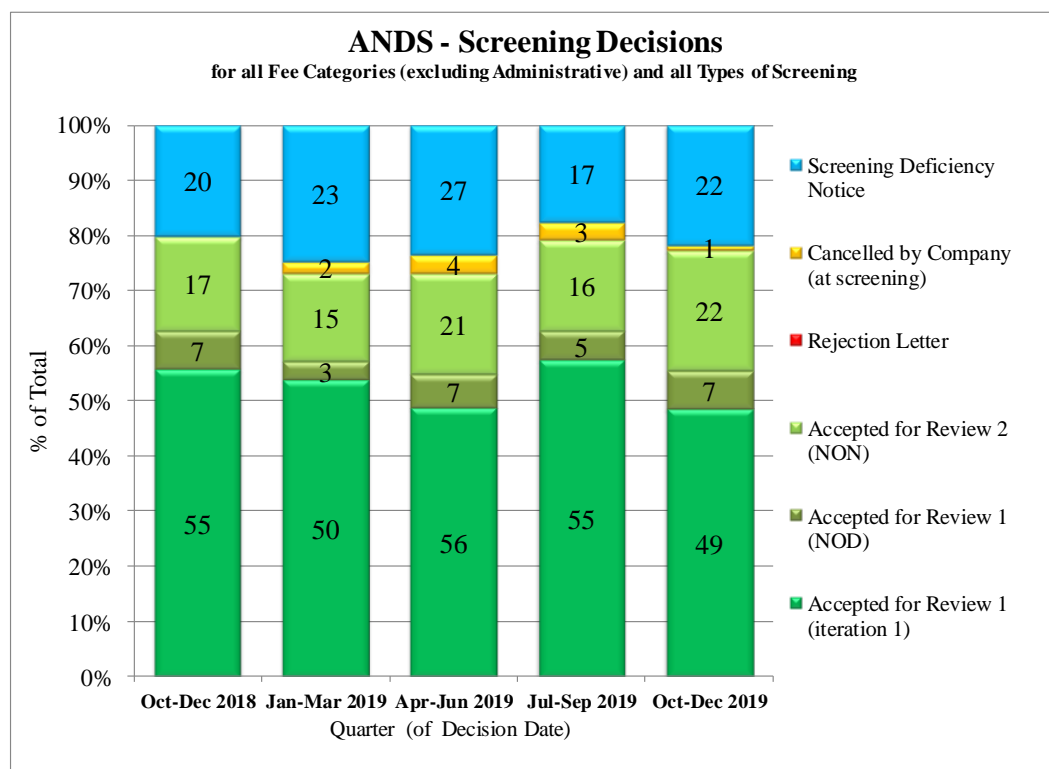


### SANDS: Review Cycle Completions

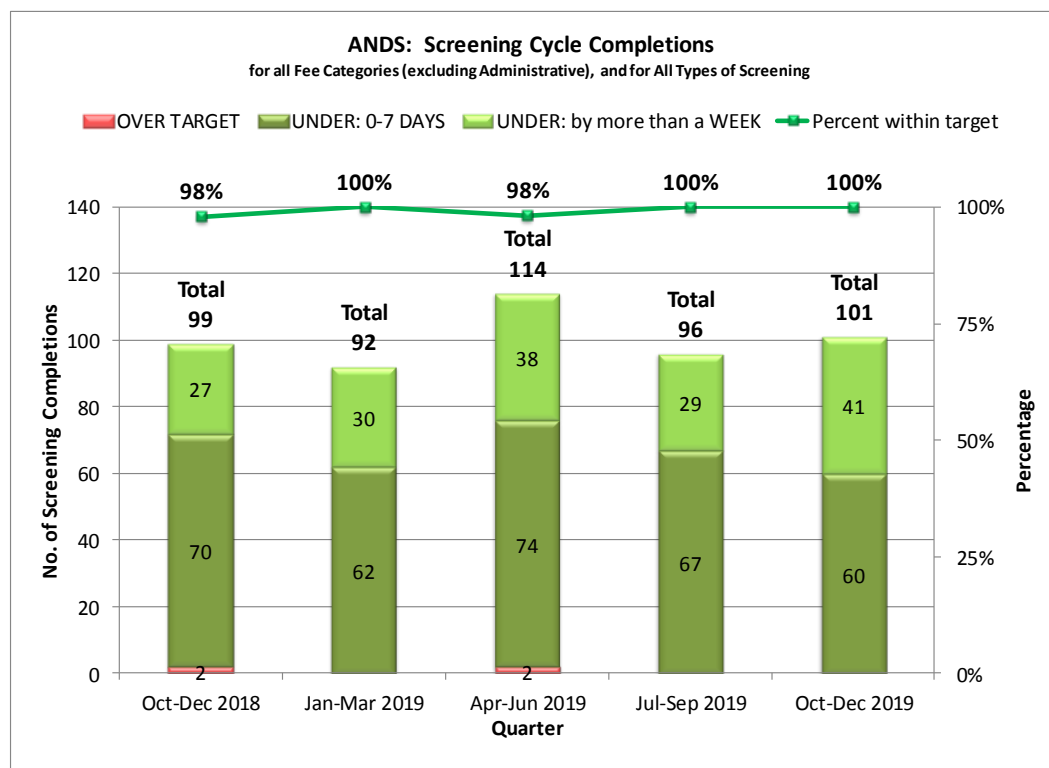


## SCREENING PERFORMANCE

### ANDS: Screening Decisions by Type

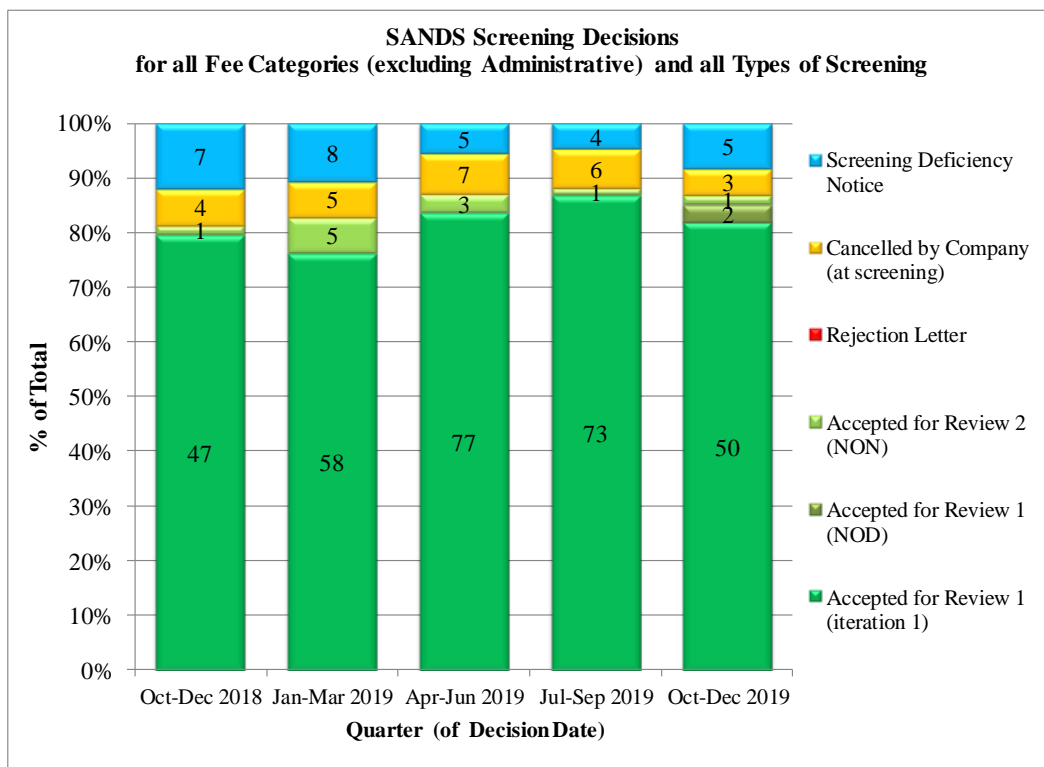


### ANDS: Screening Cycle Completions

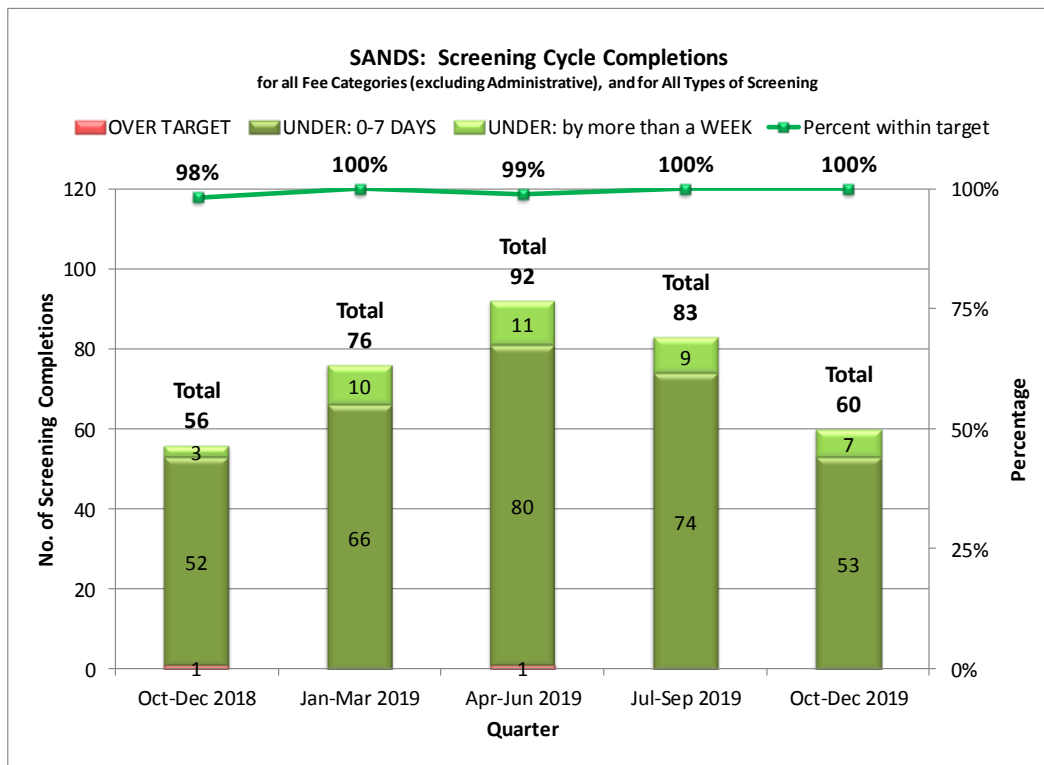


## SCREENING PERFORMANCE

### SANDS: Screening Decisions by Type

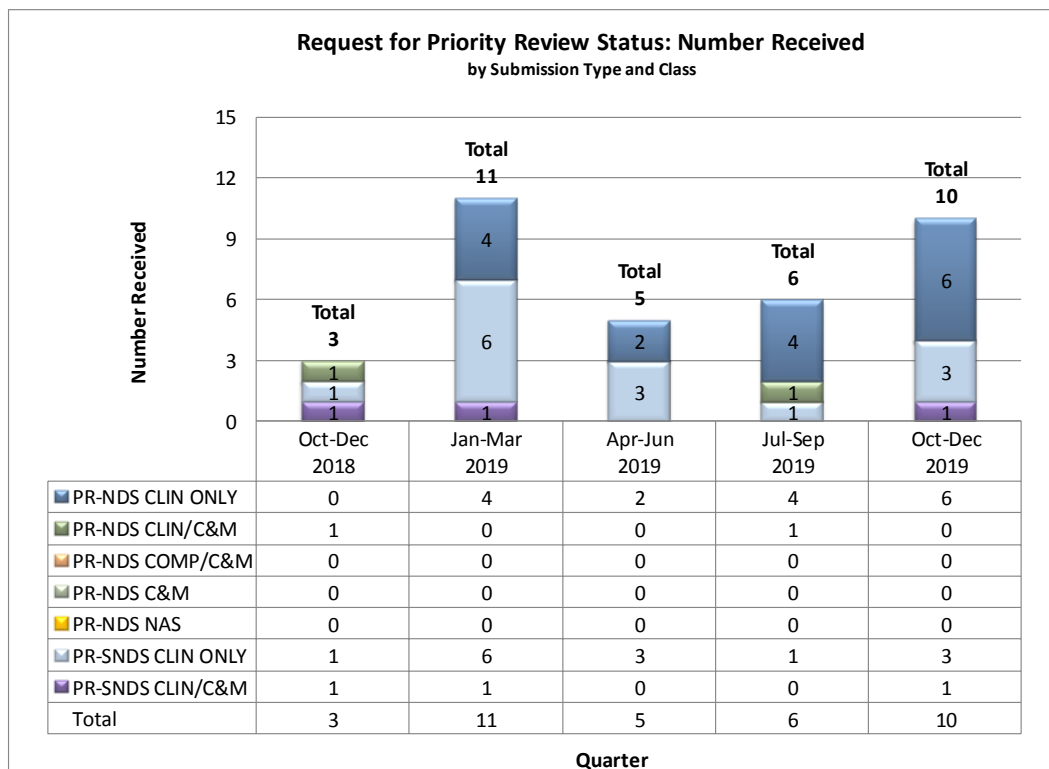


### SANDS: Screening Cycle Completions



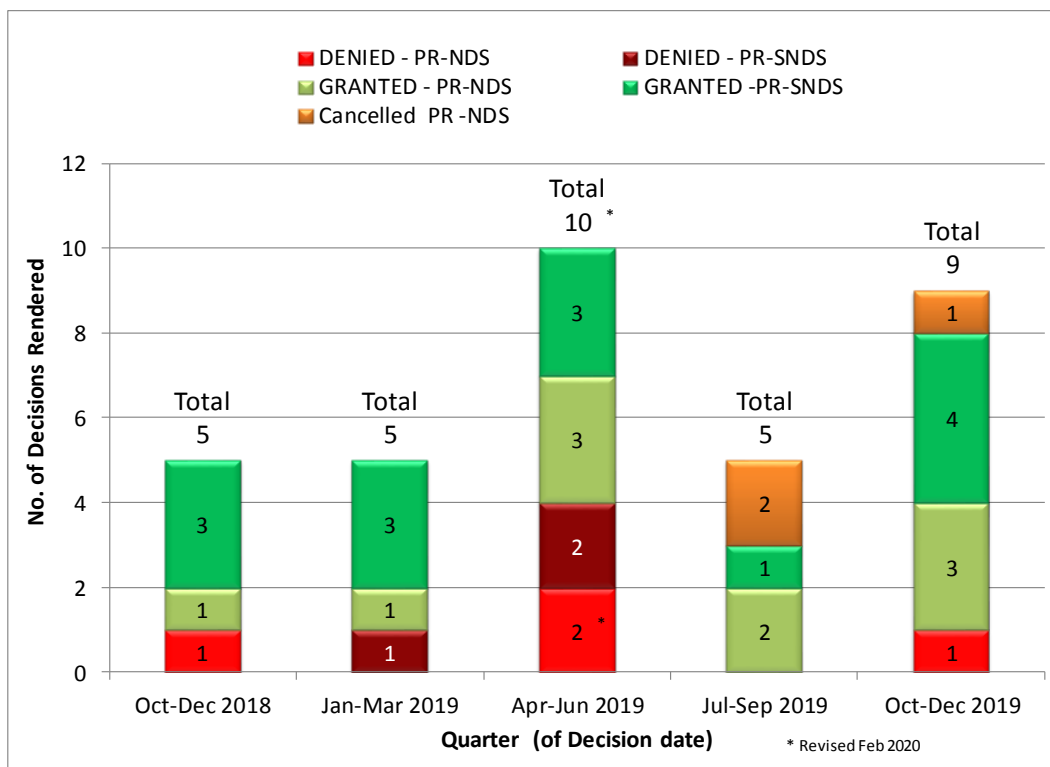
## REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

### Request for Priority Review Status: Number Received

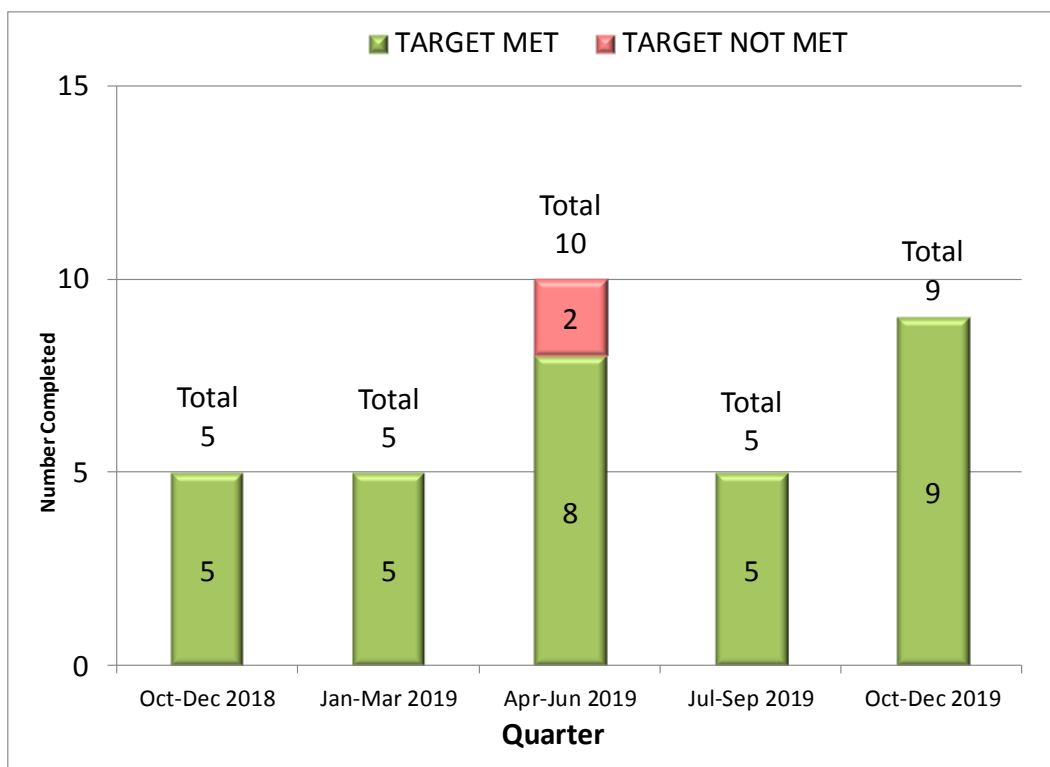




## Request for Priority Review Status: Decisions Rendered



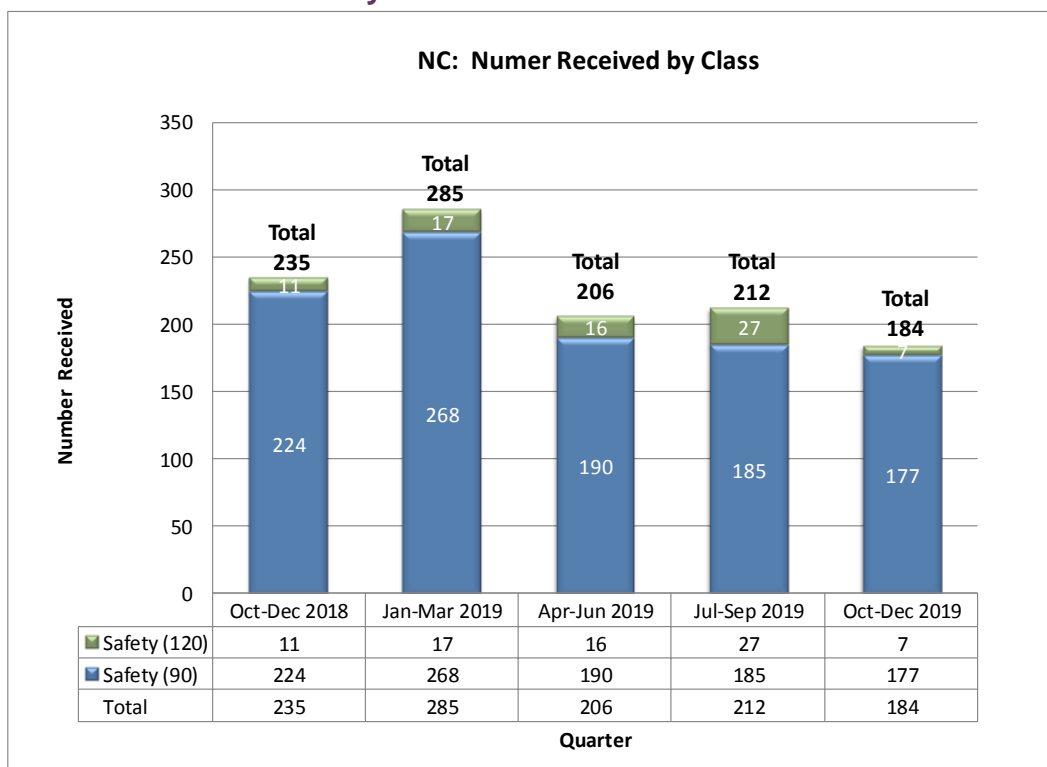
## Request for Priority Review Status: Performance



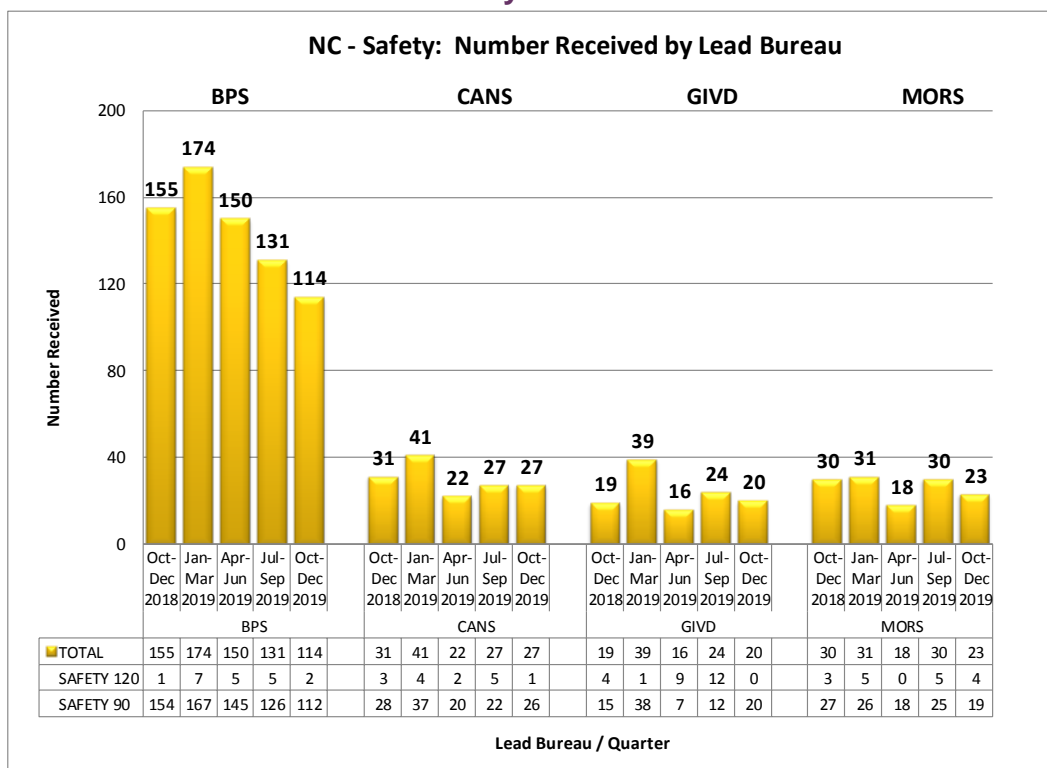
## **NC: NOTIFIABLE CHANGE**

## NOTIFIABLE CHANGE<sup>10</sup> RECEIVED

### NC: Number Received by Class



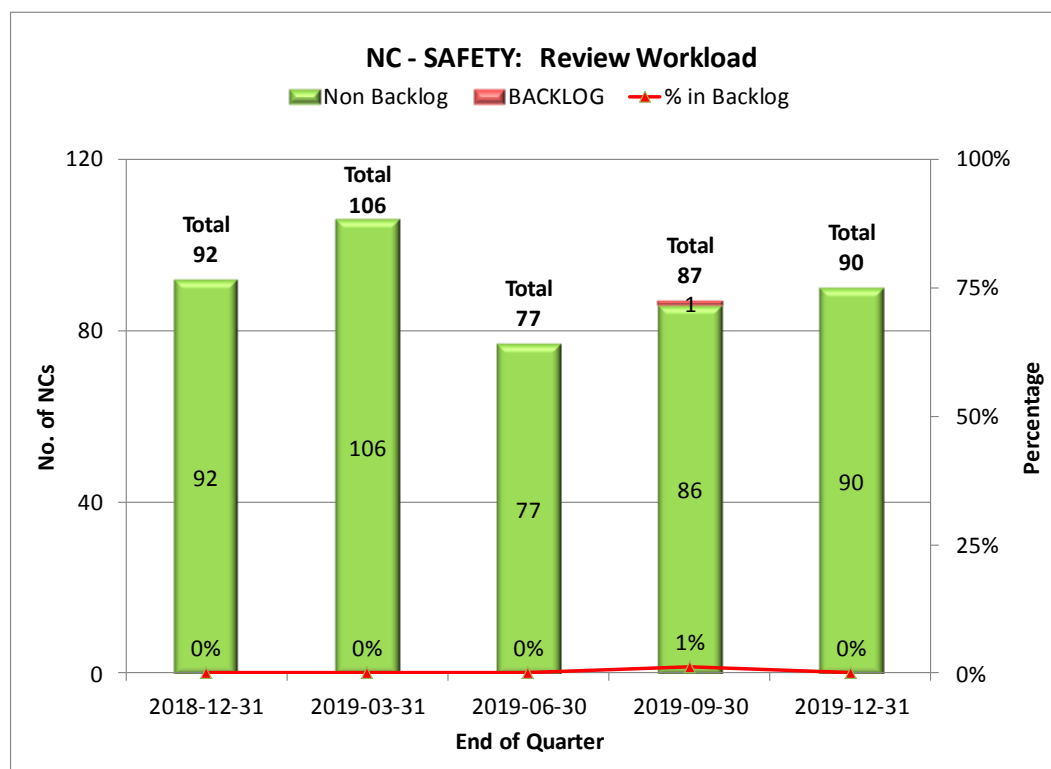
### NC-SAFETY: Number Received by Lead Bureau



<sup>10</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

### NC-SAFETY: Review Workload

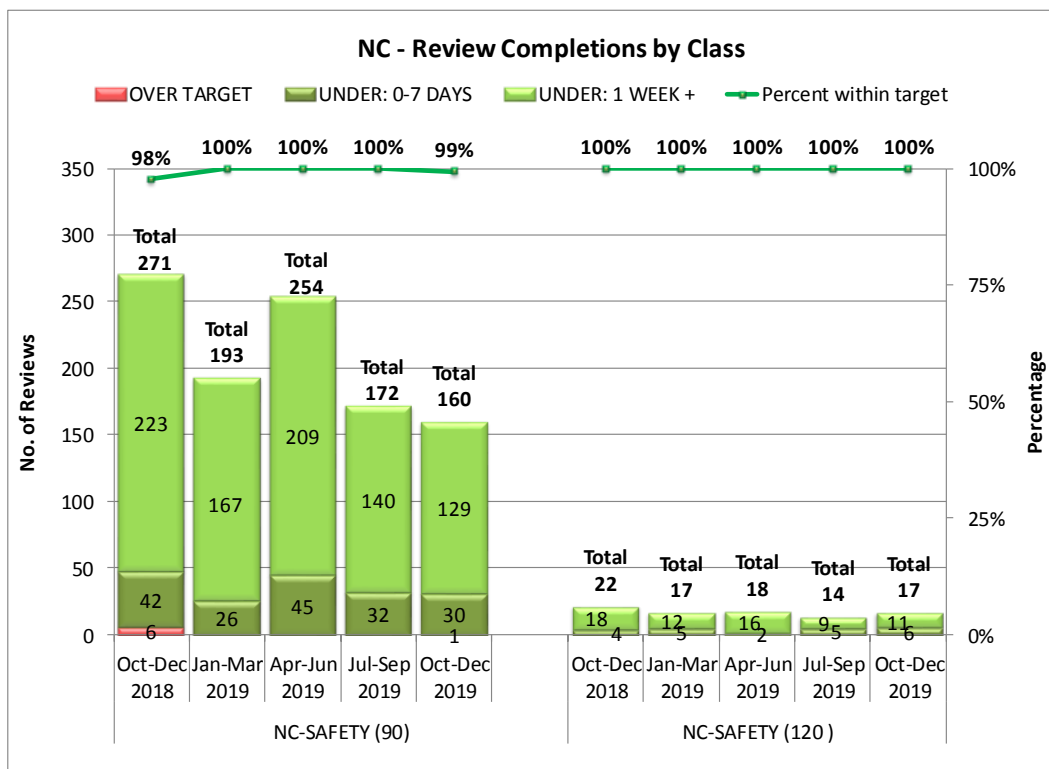


### NC-SAFETY: Review Workload by Class

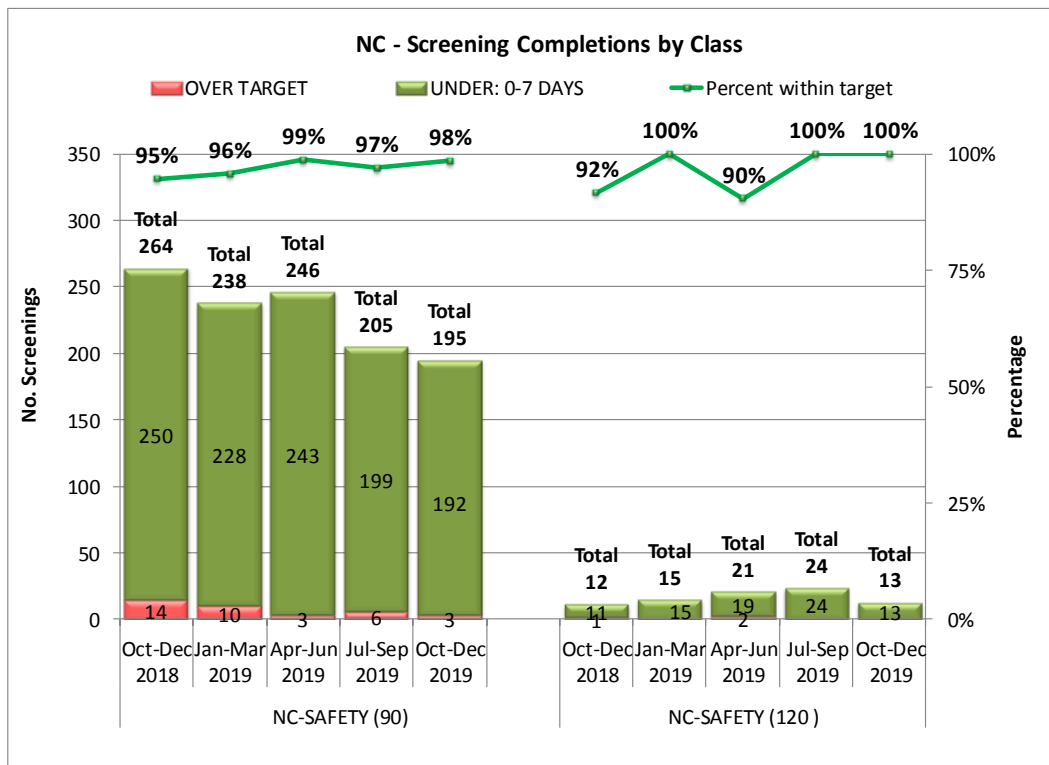
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
SAFETY - 90 day	78	95	64	64	73
Backlog	0	0	0	1	0
SAFETY - 120 day	14	11	13	23	17
Backlog	0	0	0	0	0
Total	92	106	77	87	90
Non Backlog	92	106	77	86	90
BACKLOG	0	0	0	1	0
% in Backlog	0%	0%	0%	1%	0%

## PERFORMANCE

### NC-SAFETY: Review Completions by Class



### NC-SAFETY: Screening Completions by Class



**NC–SAFETY: Number of Decisions by Class**

<b>NC - SAFETY (90)</b>					
<b>DOCUMENT TYPE</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NO OBJECTION LETTER	270	195	245	176	157
NOT SATISFACTORY NOTICE	1	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	1
SCREENING DEFICIENCY NOTICE	32	20	20	26	22
CANCELLED BY COMPANY	10	18	12	17	8
NC - HOLD (PATENT)	9	6	9	2	6

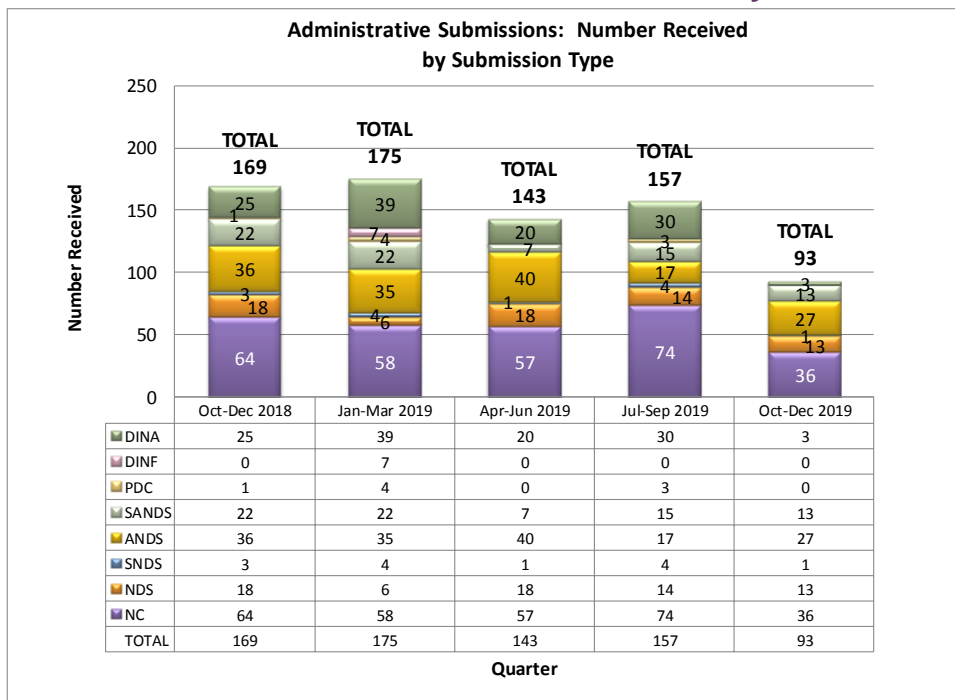
<b>NC - SAFETY (120)</b>					
<b>DOCUMENT TYPE</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NO OBJECTION LETTER	22	16	15	15	17
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	1	1	0	2
CANCELLED BY COMPANY	0	0	1	0	1
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	1	2	0	0

## ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes)<sup>11</sup>

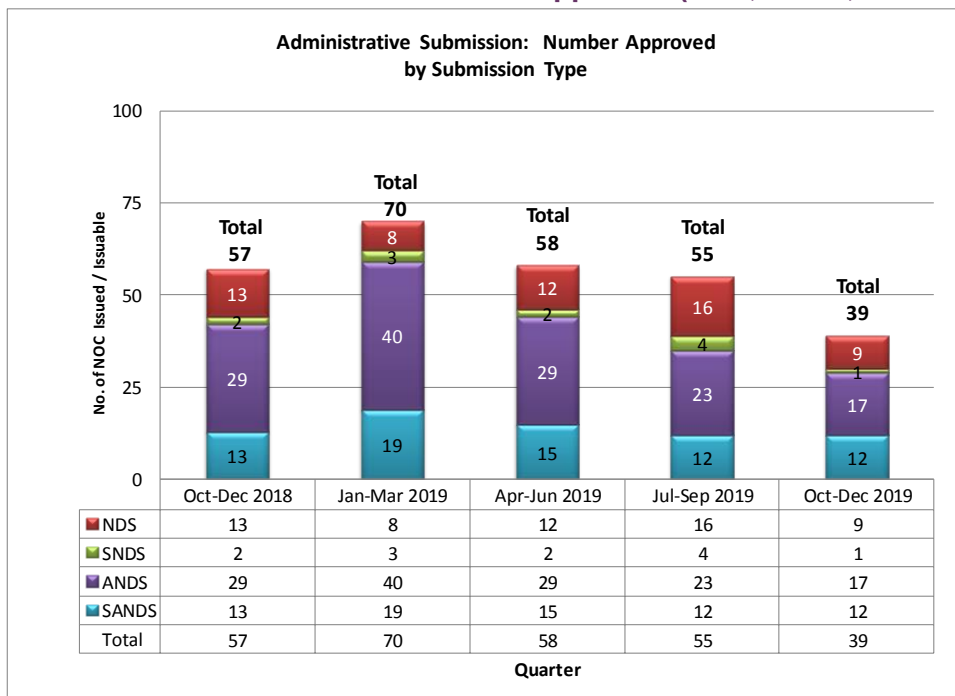
### RECEIVED

#### Administrative Submissions: Number Received by Submission Type



### APPROVALS

#### Administrative Submissions: Number Approved (NDS, SNDS, ANDS and SANDS)



<sup>11</sup> 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.

## ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes) <sup>12</sup>

### DECISIONS

#### Administrative Submissions/Applications: Number of Decisions by Submission Type

<b>NDS</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NOTICE OF COMPLIANCE	16	8	12	16	9
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	1	0	3	0	3
PROCESSING HOLD LETTER	7	2	3	6	5
<b>SNDS</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NOTICE OF COMPLIANCE	2	3	2	4	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	3	0	0	0	0
PROCESSING HOLD LETTER	1	0	0	0	0
<b>ANDS</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NOTICE OF COMPLIANCE	31	40	29	23	17
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	0	0
CANCELLATION LETTER	0	2	7	5	7
PROCESSING HOLD LETTER	6	3	10	8	5
<b>SANDS</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NOTICE OF COMPLIANCE	15	19	15	12	12
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	1	1	3	2	2
PROCESSING HOLD LETTER	5	3	3	7	4
<b>NC</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NO OBJECTION LETTER	64	48	40	81	26
NC - HOLD (PATENT)	0	0	0	0	0
CANCELLATION LETTER	3	3	5	8	7
PROCESSING HOLD LETTER	4	4	4	6	1
<b>DINA</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NOTIFICATION FORM / DIN ISSUED	13	41	11	21	4
NO OBJECTION LETTER	0	1	0	0	1
SCREENING DEFICIENCY NOTICE	7	0	0	0	0
CANCELLATION LETTER	2	5	9	11	0
PROCESSING HOLD LETTER	6	4	17	12	0
<b>PDC</b>	<b>Oct-Dec 2018</b>	<b>Jan-Mar 2019</b>	<b>Apr-Jun 2019</b>	<b>Jul-Sep 2019</b>	<b>Oct-Dec 2019</b>
NO OBJECTION LETTER	2	2	0	3	0
CANCELLATION LETTER	0	1	1	0	0
PROCESSING HOLD LETTER	0	0	0	0	0

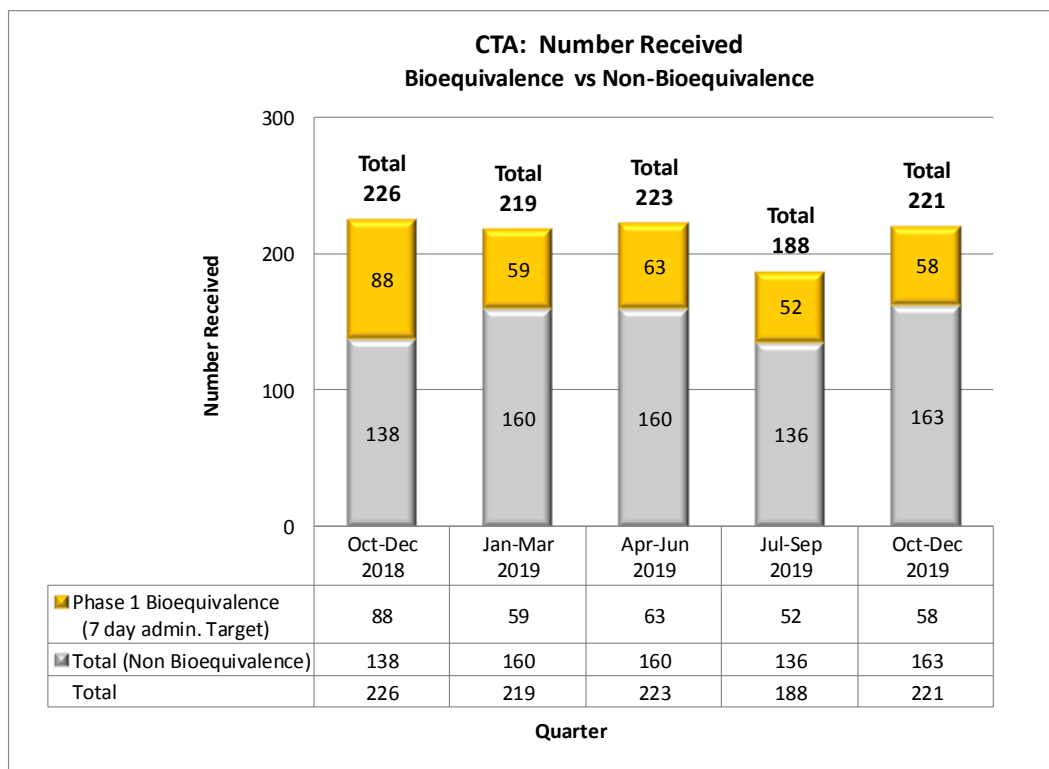
<sup>12</sup> The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.



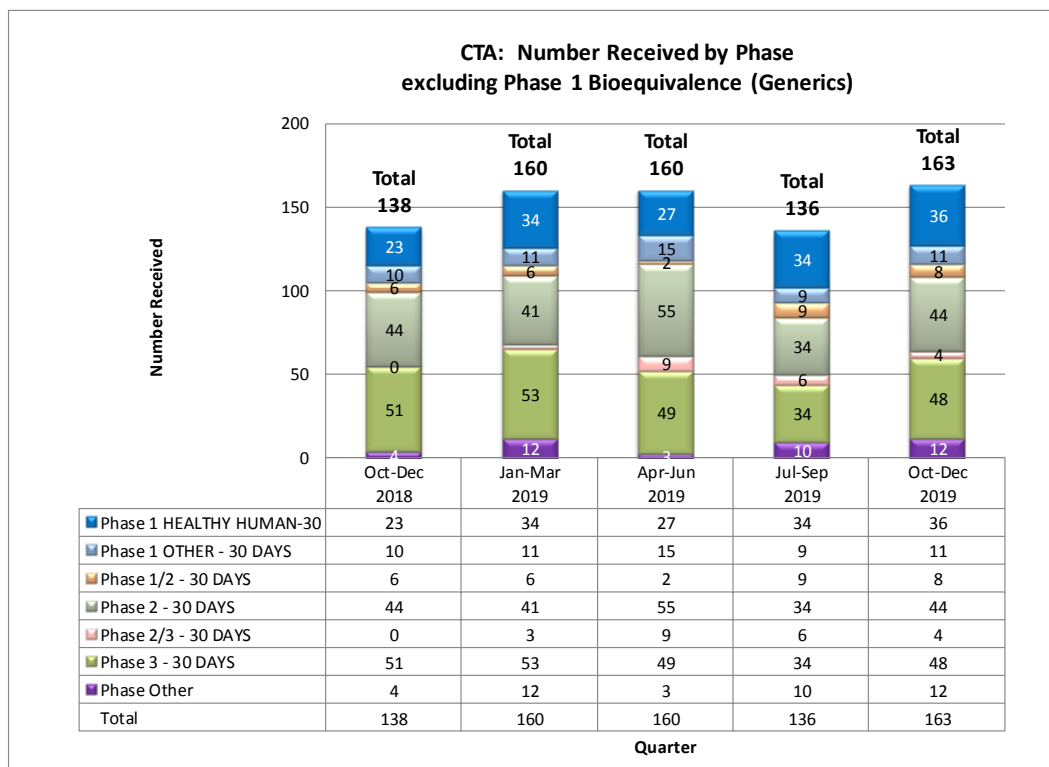
## **Clinical Trial Applications and Amendments (CTA & CTA-A)**

## CTA: CLINICAL TRIAL APPLICATIONS

### CTA: Number Received



### CTA: Number Received by Phase



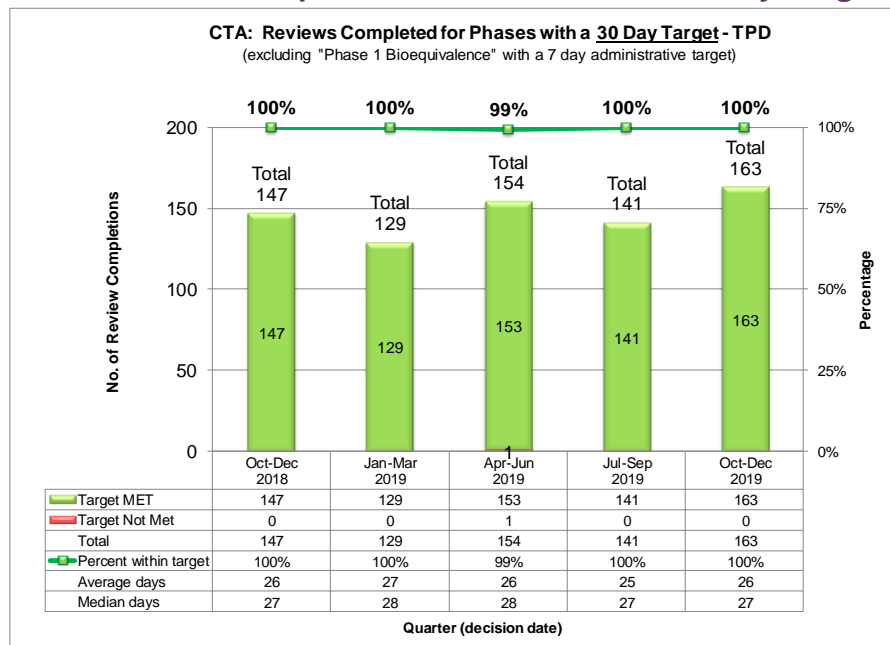
## DECISION DOCUMENTS

### CTA: Number of Decisions by Type

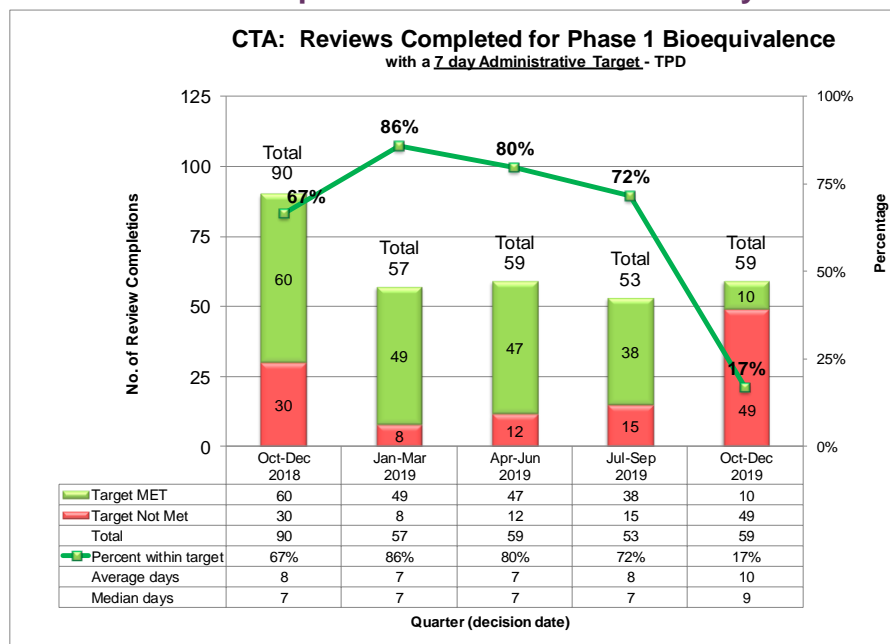
CTA					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
NO OBJECTION LETTER	226	176	202	183	203
CANCELLED BY COMPANY DURING REVIEW	12	11	12	12	19
CANCELLED BY COMPANY AT PROCESSING	2	1	3	2	2
NOT SATISFACTORY NOTICE	0	1	0	0	0

## PERFORMANCE

### CTA: Reviews Completed for Phases with a 30 Day Target

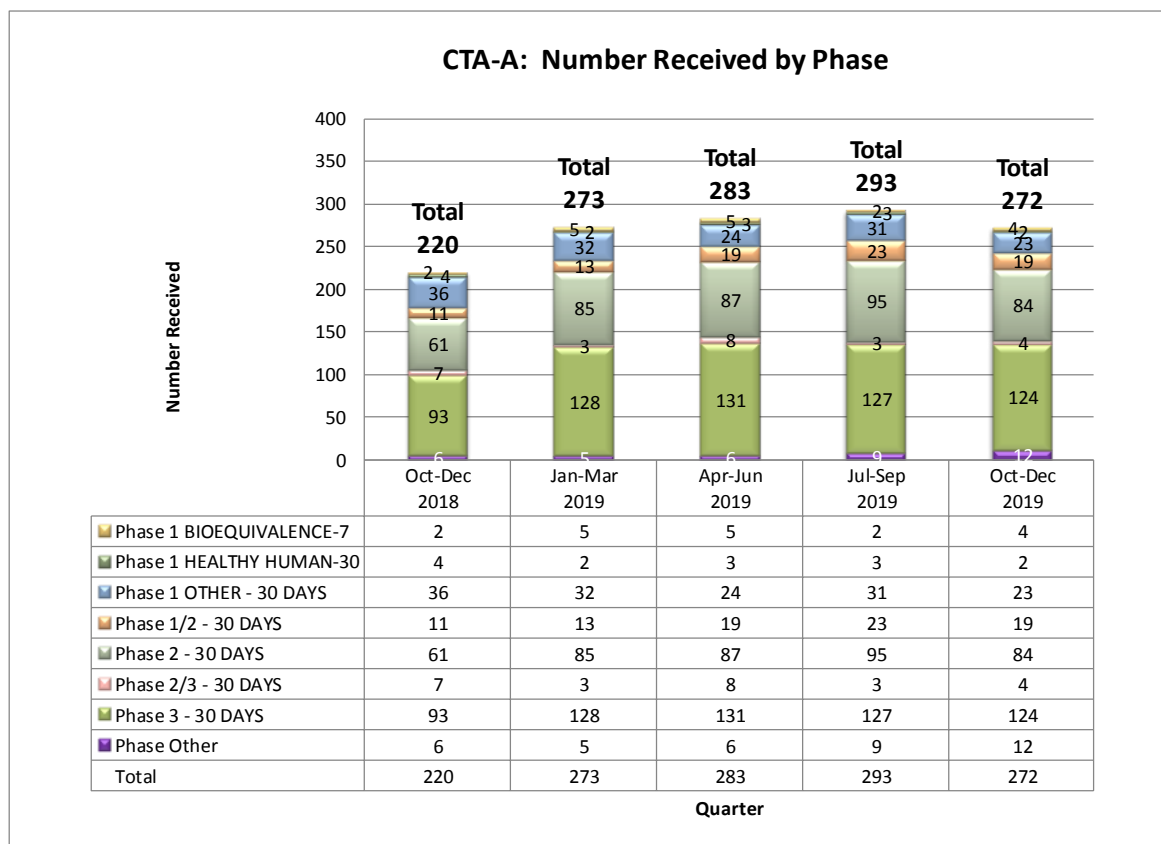


### CTA: Reviews Completed for Phases with a 7 Day Administrative Target



## CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

### CTA-A: Number Received by Phase



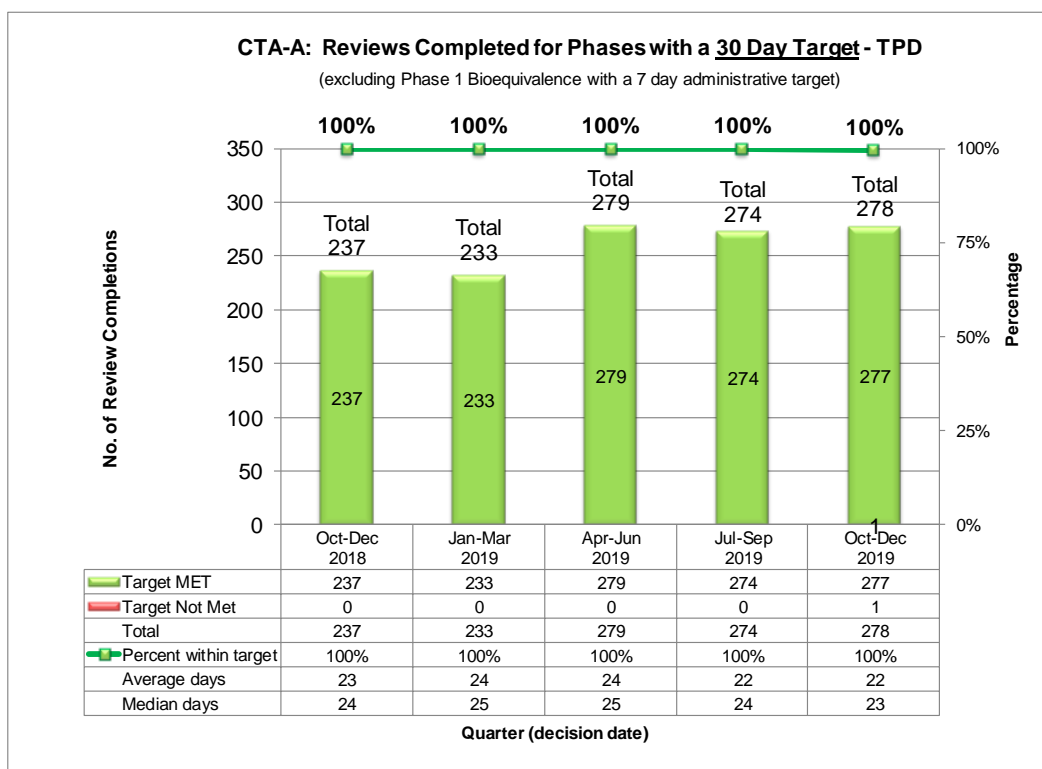
## DECISIONS

### CTA-A: Number of Decisions by Type

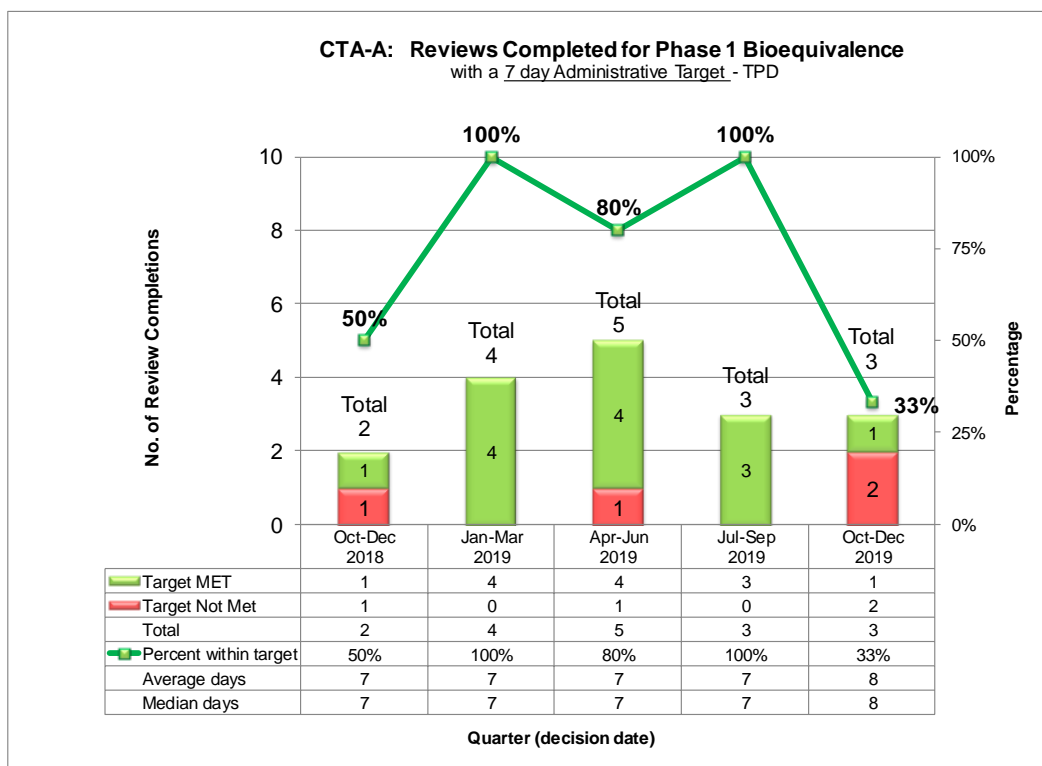
CTA-A (excluding administrative)					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
NO OBJECTION LETTER	236	236	279	270	276
CANCELLED BY COMPANY DURING REVIEW	3	1	5	8	5
CANCELLED BY COMPANY AT PROCESSING	1	1	0	12	7
REJECTION LETTER (SCR)	0	0	1	0	0

## PERFORMANCE

### CTA-A: Reviews Completed for Phases with a 30 Day Target

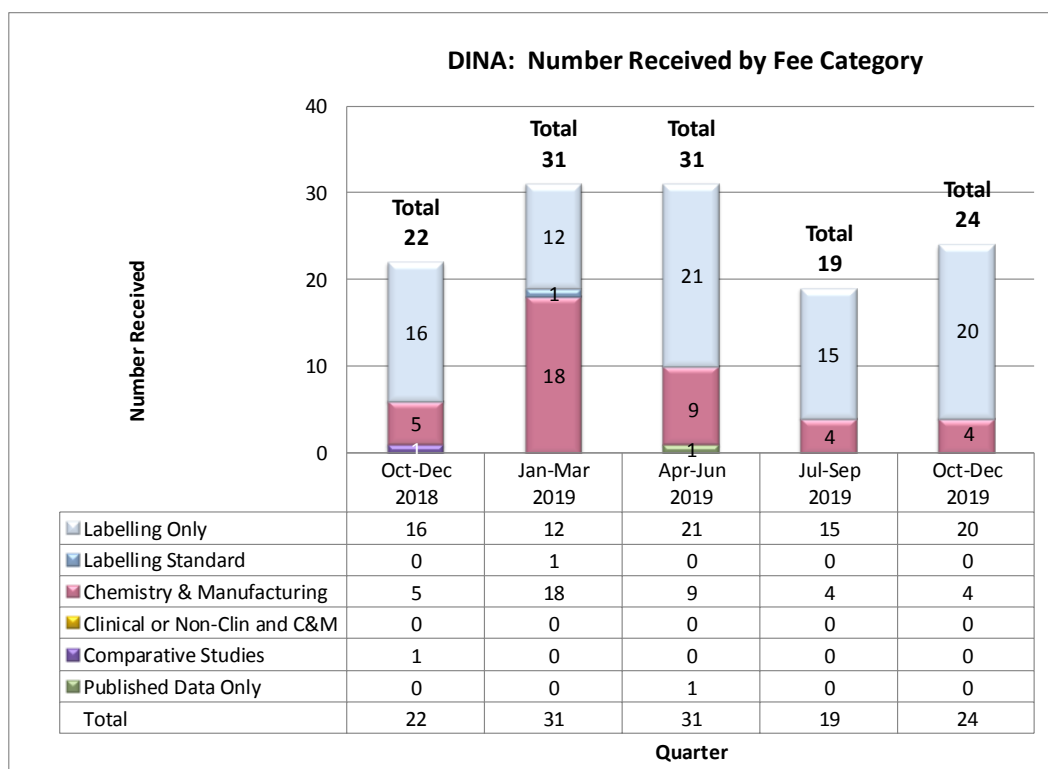


### CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target



## **DINA**

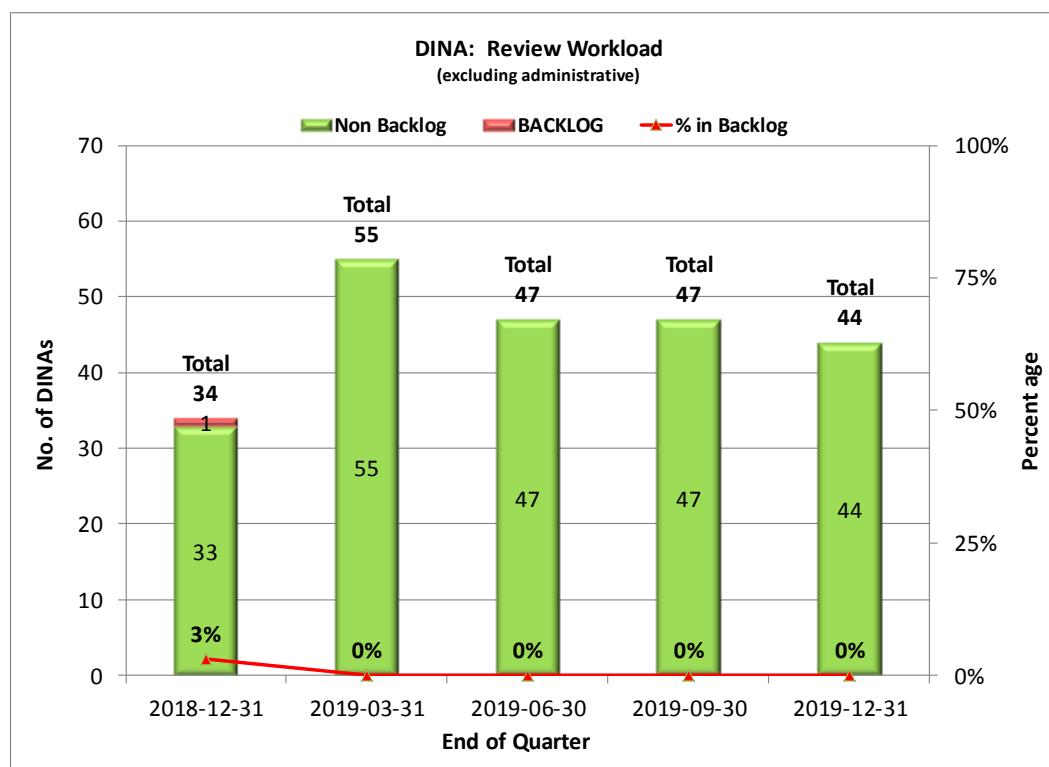
### **Application for a Drug Identification Number**

**DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER <sup>13</sup>****DINA: Number Received by Fee Category**

<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

## DINA: Review Workload



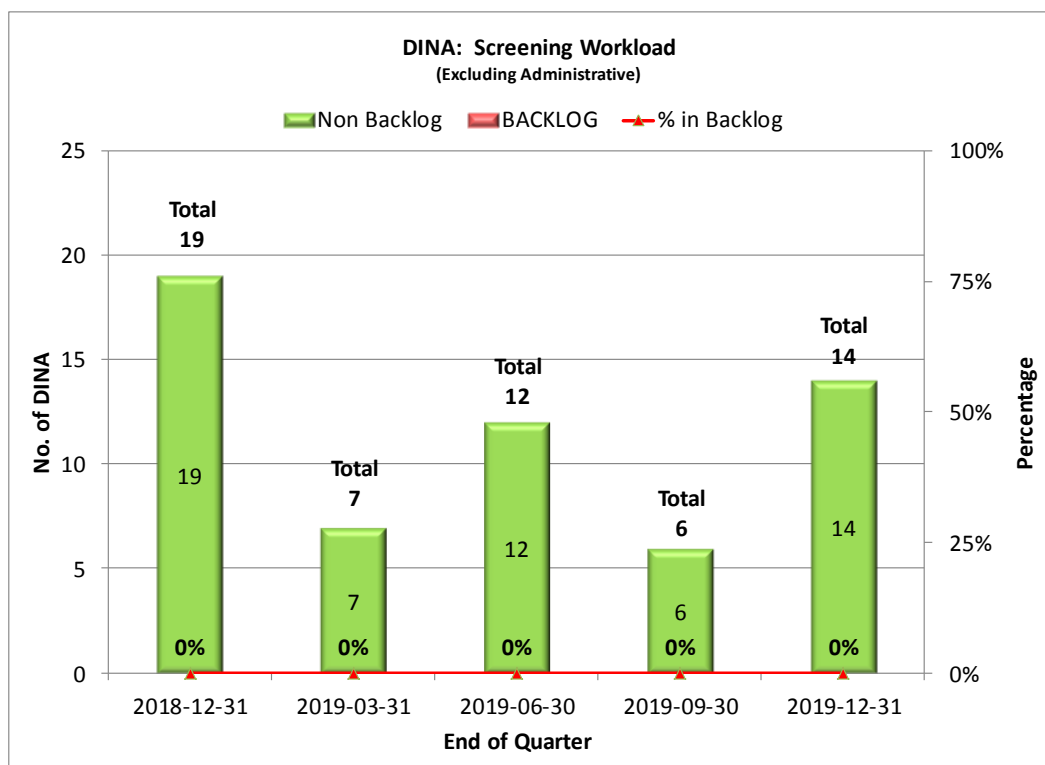
## DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
<b>Labelling Only</b>	19	27	22	30	24
<i>Backlog</i>	1	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	13	26	24	17	19
<i>Backlog</i>	0	0	0	0	0
<b>Published Data</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	1	1	1	0	1
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	34	55	47	47	44
<b>Non Backlog</b>	33	55	47	47	44
<b>BACKLOG</b>	1	0	0	0	0
<b>% in Backlog</b>	3%	0%	0%	0%	0%



## SCREENING WORKLOAD

### DINA: Screening Workload



### DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
<b>Labelling Only</b>	8	3	7	4	11
<i>Backlog</i>	0	0	0	0	0
<b>Labelling Standard</b>	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Clinical or Non-Clin and C&amp;M</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	9	3	5	2	3
<i>Backlog</i>	0	0	0	0	0
<b>Published Data</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Comparative Studies</b>	2	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	19	7	12	6	14
<b>Non Backlog</b>	19	7	12	6	14
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

## DECISIONS

## DINA: Number of Decisions by Fee Category

DINA - LABELLING ONLY					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
NOTIFICATION FORM/DIN ISSUED	4	1	1	0	1
NO OBJECTION LETTER	8	9	18	10	19
CANCELLED BY COMPANY	3	0	0	1	1
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	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	1	1	1

DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
NOTIFICATION FORM/DIN ISSUED	2	5	4	2	2
NO OBJECTION LETTER	3	3	5	8	3
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	2	0	0	0	0
NOTICE OF DEFICIENCY	2	0	0	0	0
NOTICE OF NON-COMPLIANCE	2	1	0	4	2
NEW DRUG LETTER REVIEW	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	1	2	4	0
CANCELLED BY COMPANY	2	3	1	1	0

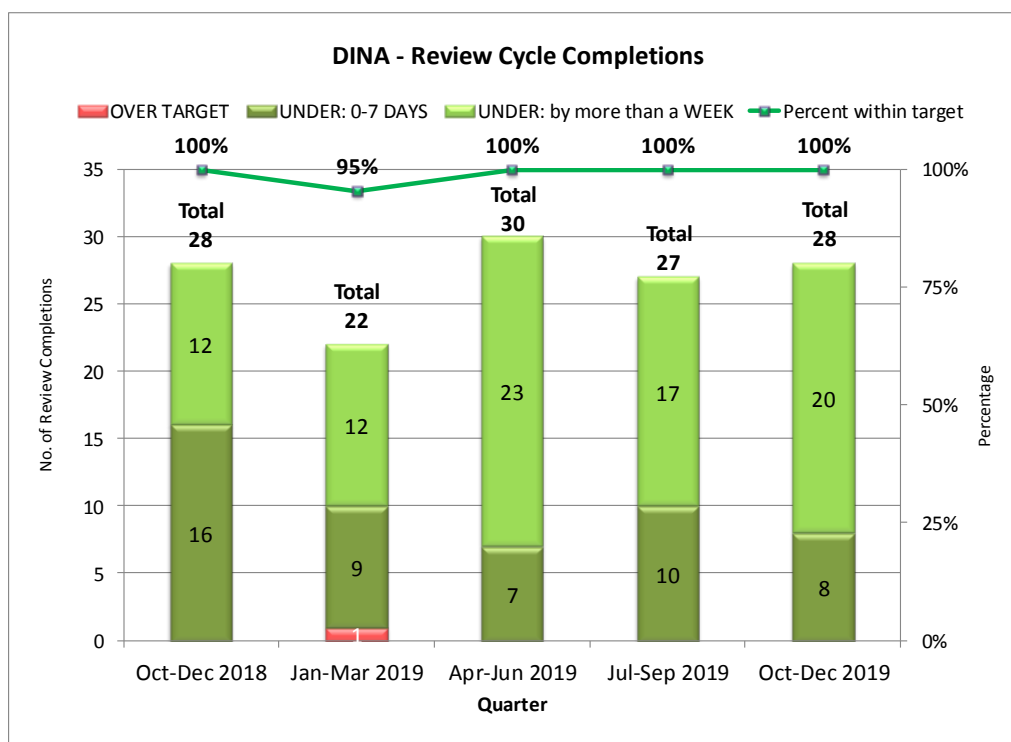
DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	1	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
NOTIFICATION FORM/DIN ISSUED	0	1	1	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	1	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	0	0	0
CANCELLED BY COMPANY	0	1	0	0	0

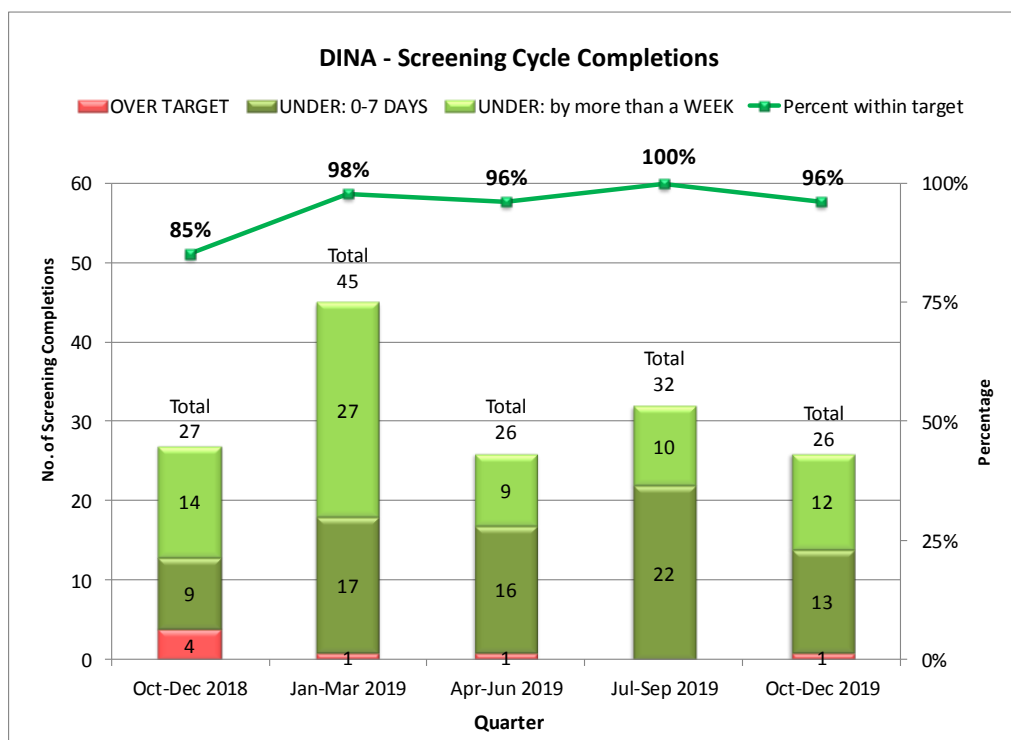
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
CANCELLED BY COMPANY	1	0	0	0	0
NOTICE OF NON-COMPLIANCE	1	1	0	0	0
NOTIFICATION FORM/DIN ISSUED	1	0	0	1	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

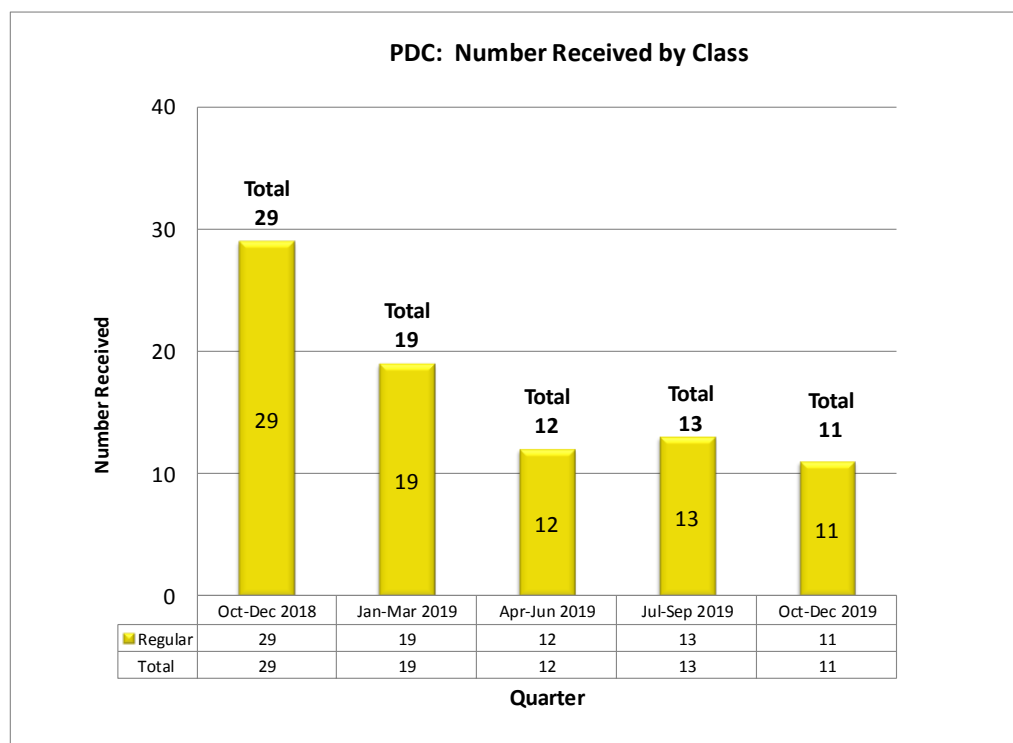
## PERFORMANCE

### DINA: Review Cycle Completions



### DINA: Screening Cycle Completions



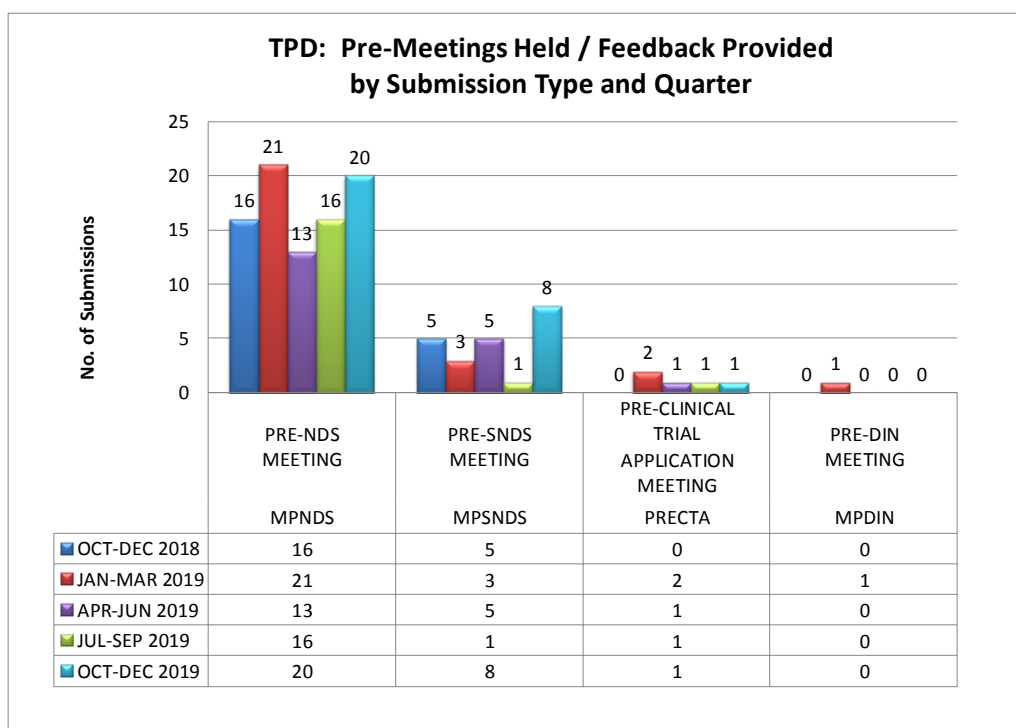
**PDC: POST-AUTHORIZATION DIVISION 1 CHANGE <sup>14</sup>****PDC: Number Received****PDC: Number of Decisions by Type**

PDC					
DOCUMENT TYPE	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
<b>REGULAR</b>					
CANCELLED BY COMPANY	4	6	6	4	7
NO OBJECTION LETTER	35	28	18	9	0
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 <sup>15</sup>

### 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](#).