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Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

October – December
2018



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– décembre 2018

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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 2017 to 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 review¹ 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.

Approvals² 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 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

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

Documents

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

Fee Categories

Fee Category	Fee Category Description
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 Only⁶	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission⁷	Submissions in support of a manufacturer or product name change.
Disinfectants⁸	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, please 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.

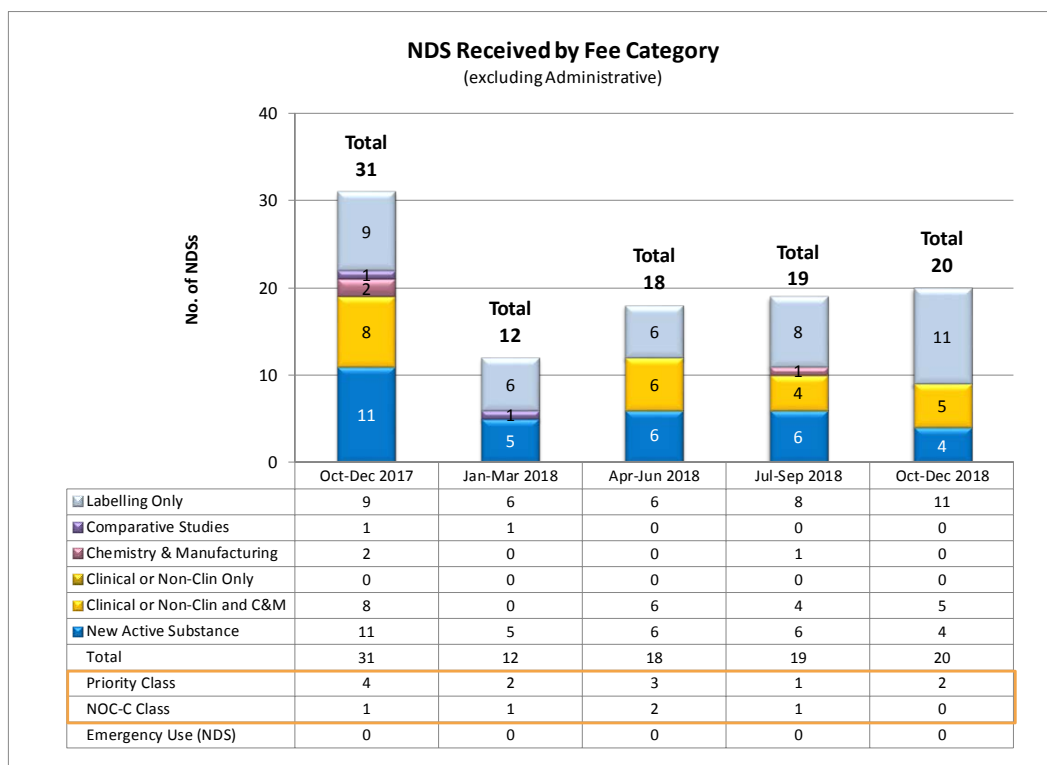
**New Drug Submission
(NDS)**

&

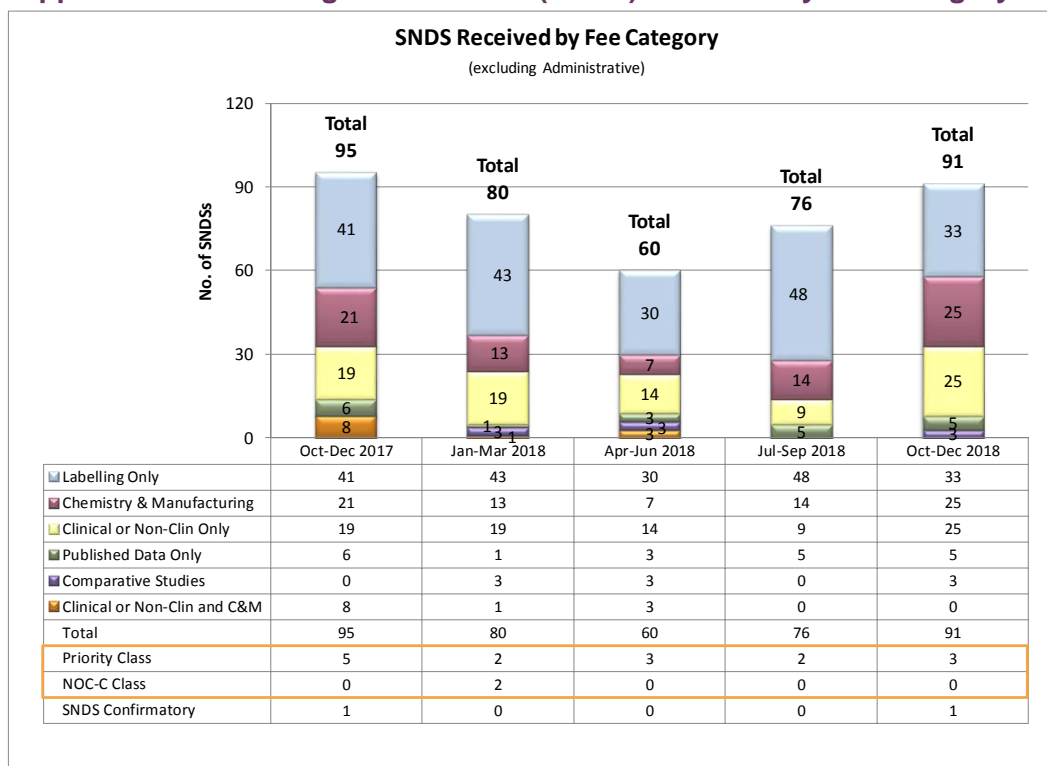
**Supplemental New Drug Submission
(SNDS)**

SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



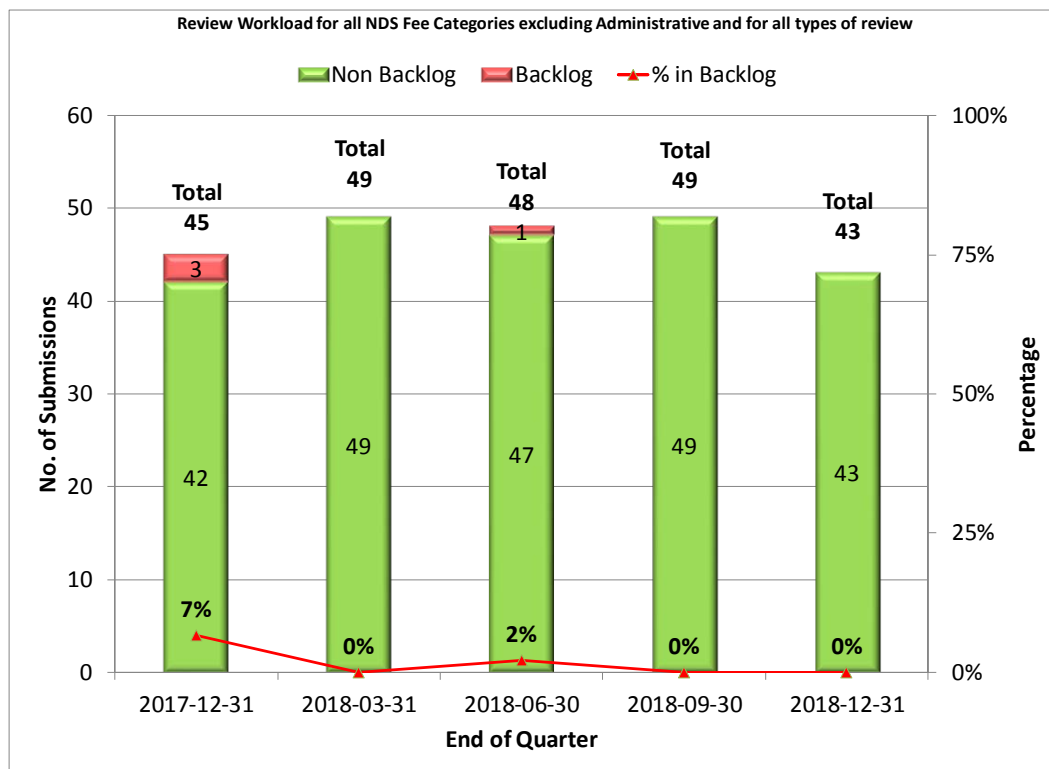
Supplemental New Drug Submissions (SNDS) Received by Fee Category



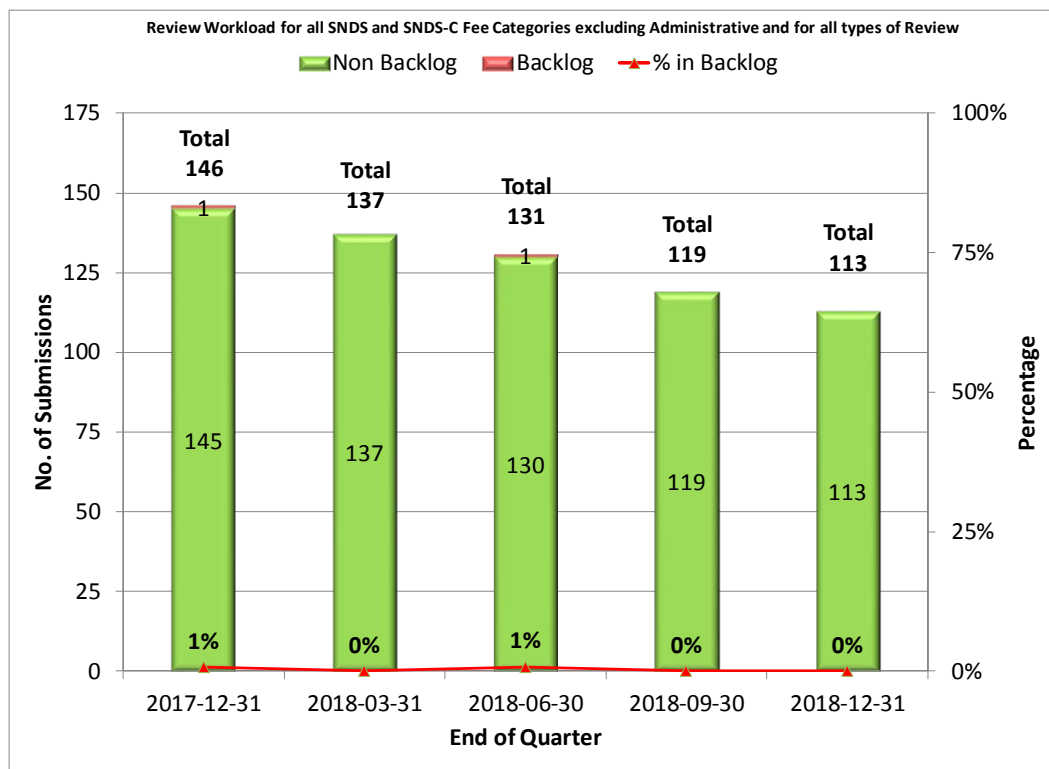
⁹ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance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

WORKLOAD

New Drug Submission (NDS) Review Workload / Backlog



Supplemental New Drug Submission (SNDS) Review Workload / Backlog

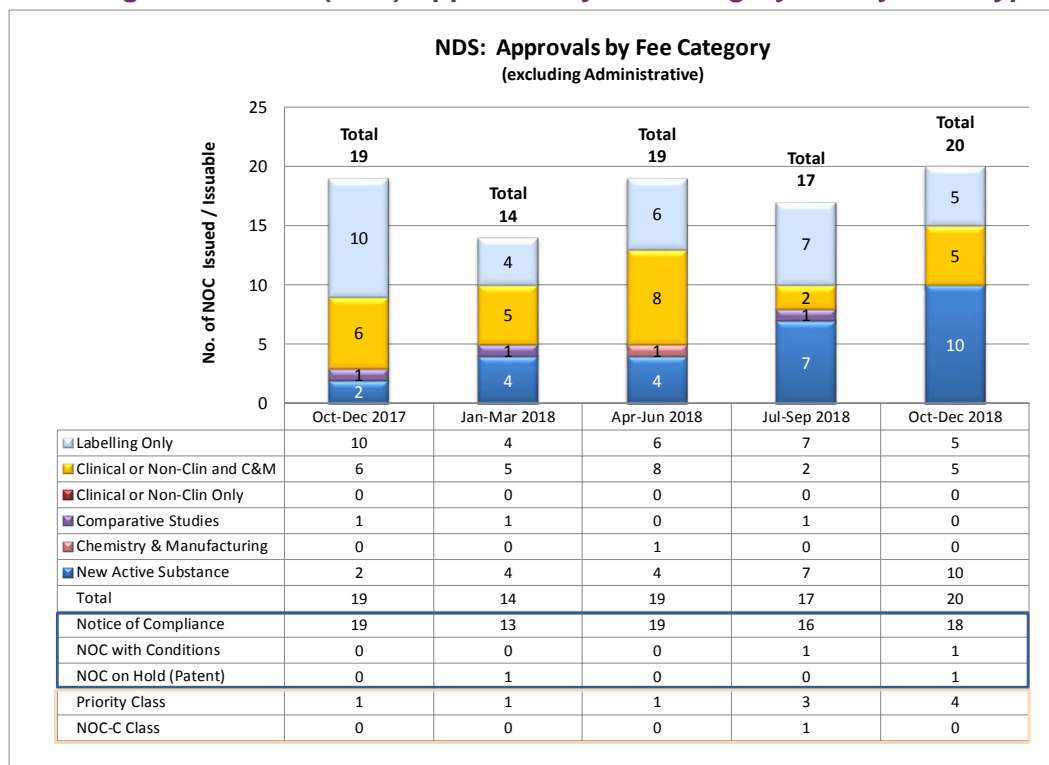
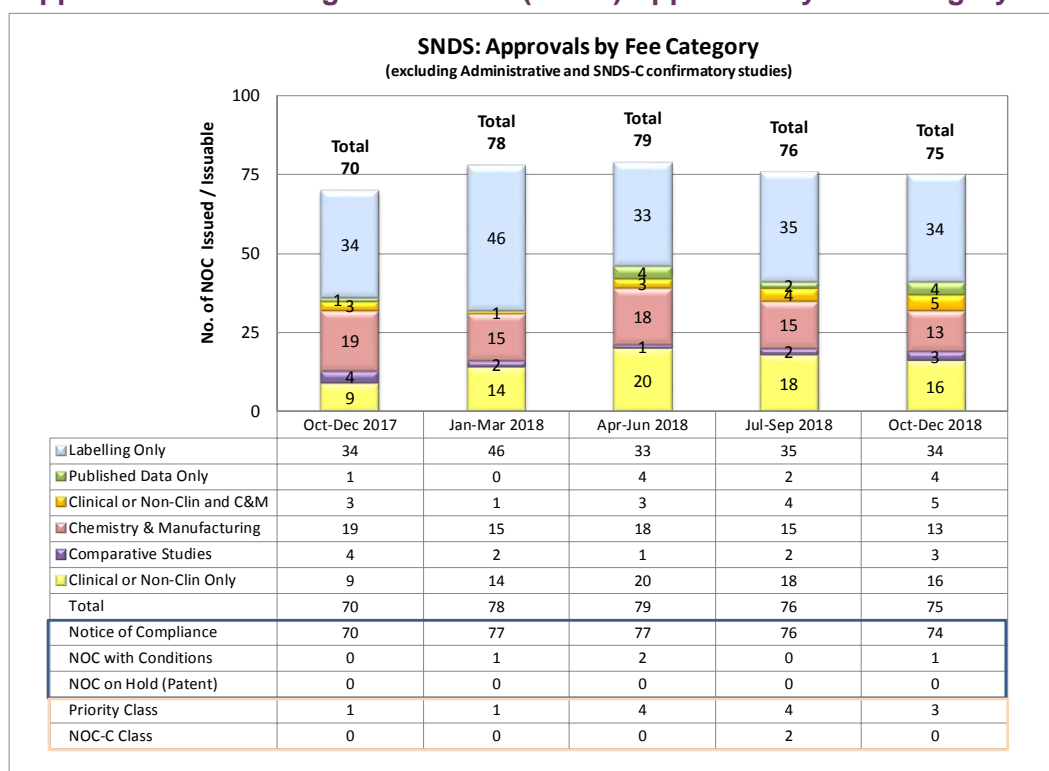


WORKLOAD**New Drug Submission (NDS) Review Workload by Fee Category**

TPD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Labelling Only	3	4	4	5	8
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Comparative Studies	1	1	1	1	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry & Manufacturing	1	1	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clin Only	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clin and C&M	20	18	16	16	15
<i>Backlog</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
New Active Substance	20	25	27	27	19
<i>Backlog</i>	<i>1</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>
Total	45	49	48	49	43
Non Backlog	42	49	47	49	43
Backlog	3	0	1	0	0
% in Backlog	7%	0%	2%	0%	0%
Priority (subset)	3	6	7	6	4
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

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

TPD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Labelling Only	28	19	15	23	21
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>
Comparative Studies	4	4	8	6	3
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry & Manufacturing	34	30	26	25	26
<i>Backlog</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clin Only	63	63	60	49	49
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clin and C&M	9	11	13	7	2
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Published Data	8	10	9	9	12
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	146	137	131	119	113
Non Backlog	145	137	130	119	113
Backlog	1	0	1	0	0
% in Backlog	1%	0%	1%	0%	0%
Priority (subset)	5	7	7	5	4
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
SNDS-C (Confirmatory)	5	3	2	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>

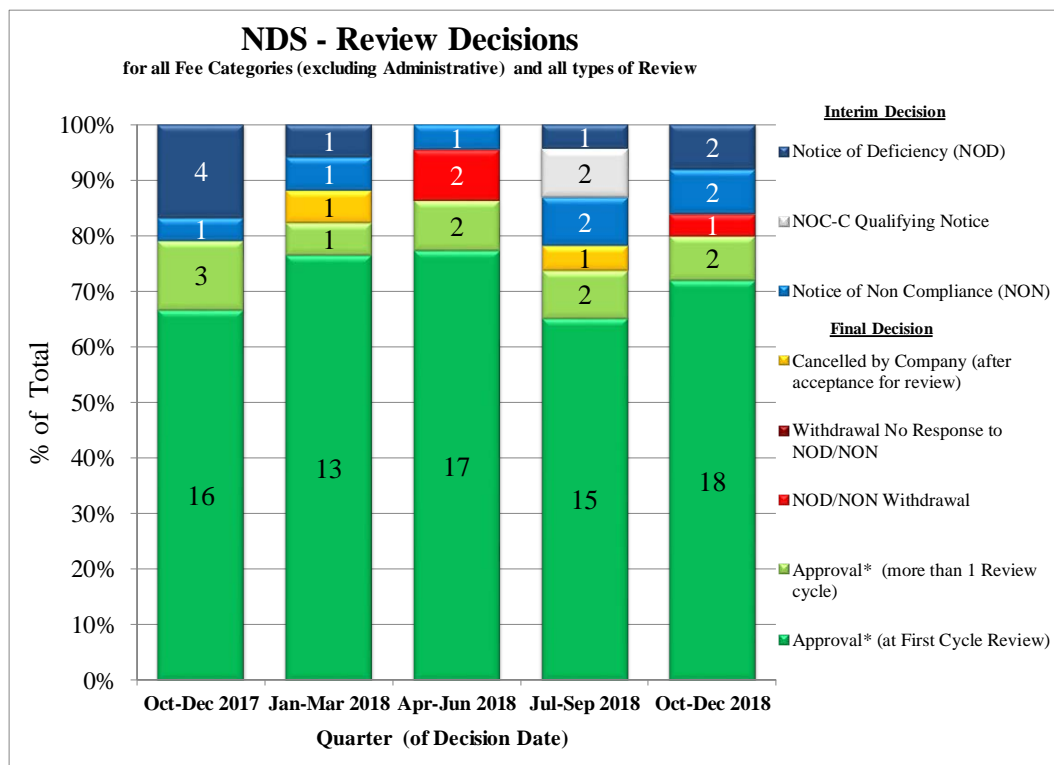
APPROVALS¹⁰**New Drug Submission (NDS) Approvals by Fee Category and by NOC Type****Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type**

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](#).

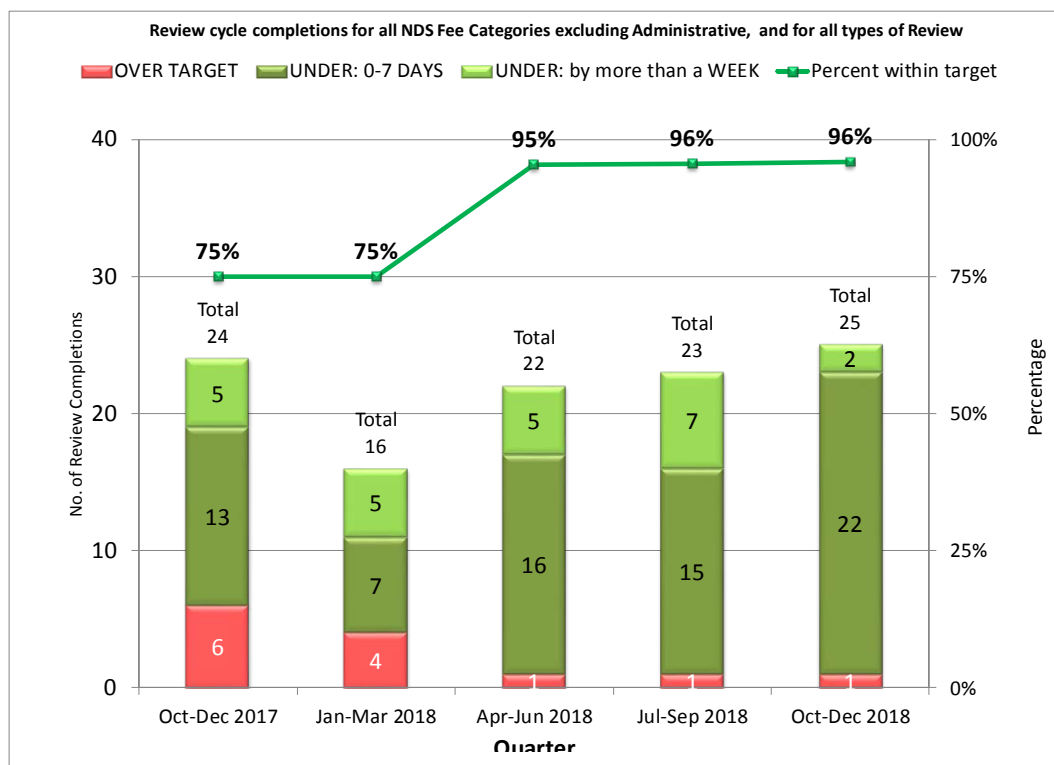
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REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

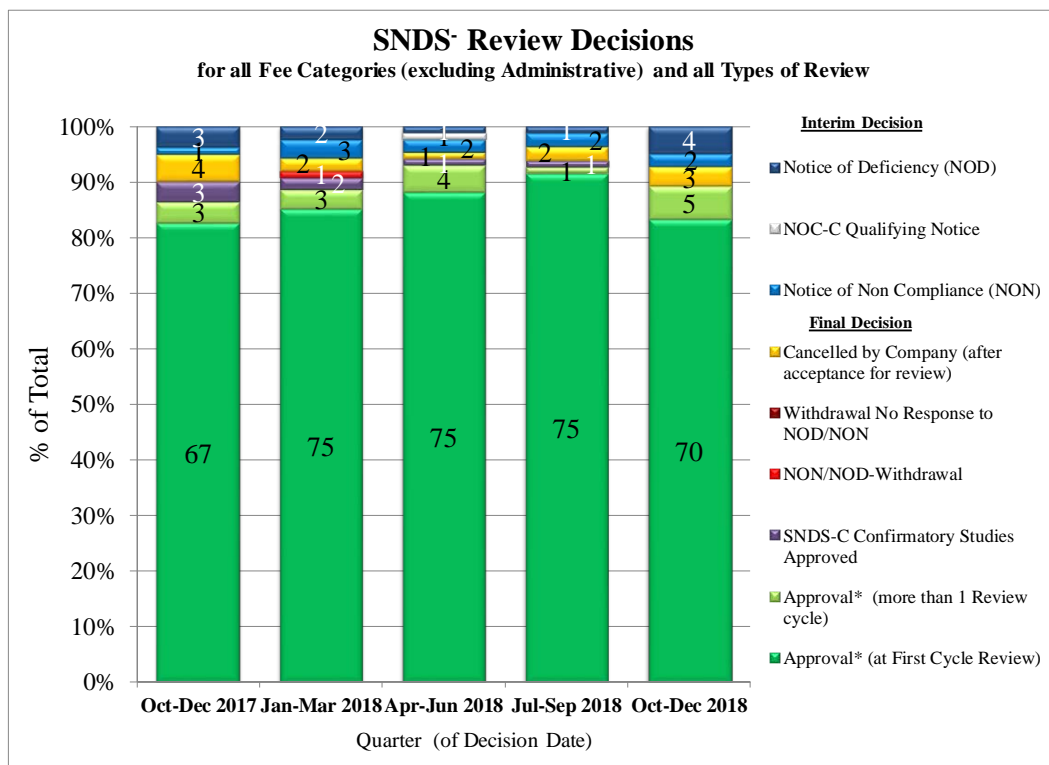


NDS - Review Cycle Completions Showing Percentage Within Target

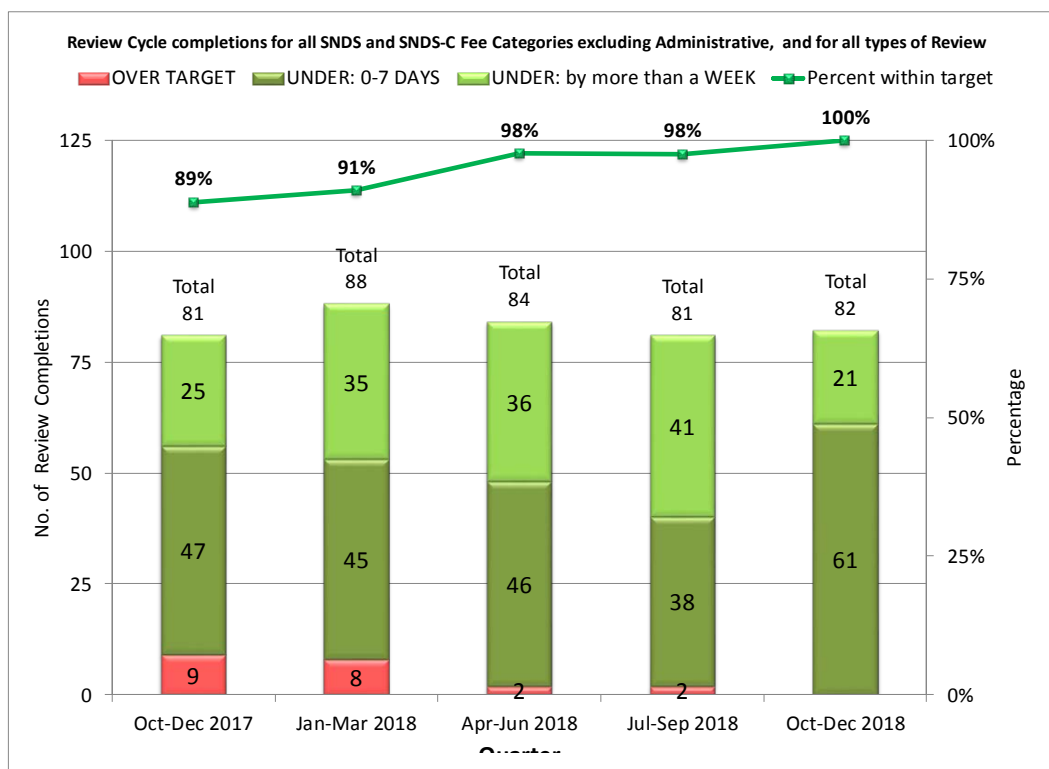


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

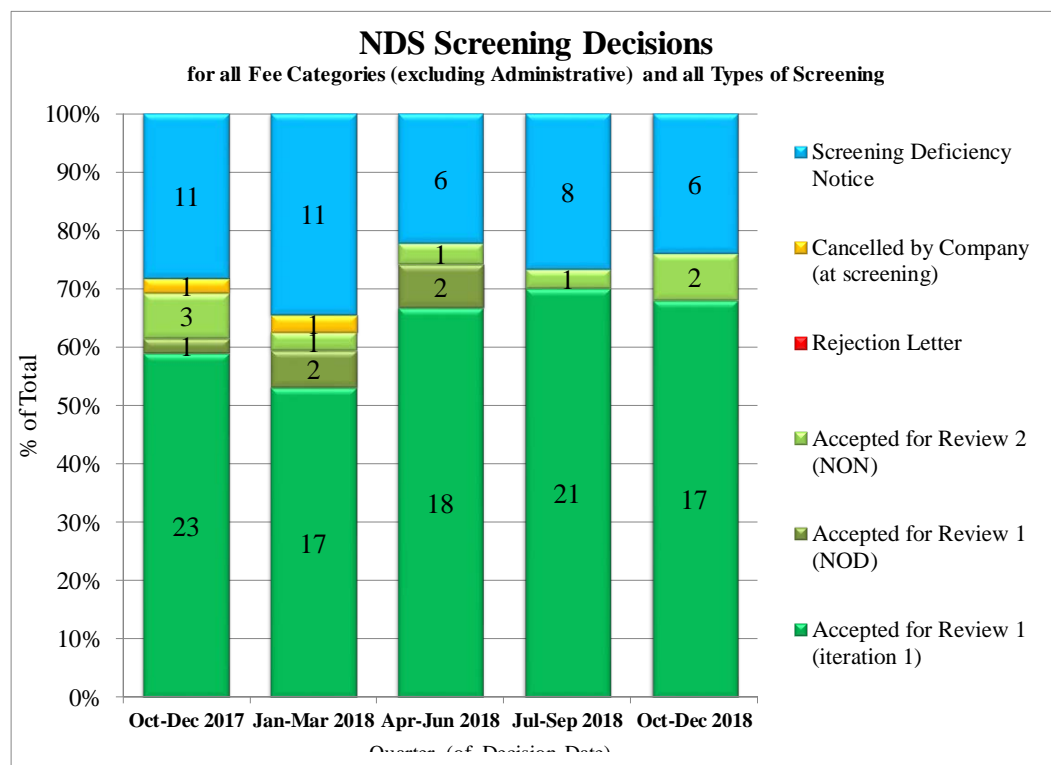


SNDS - Review Cycle Completions Showing Percentage Within Target

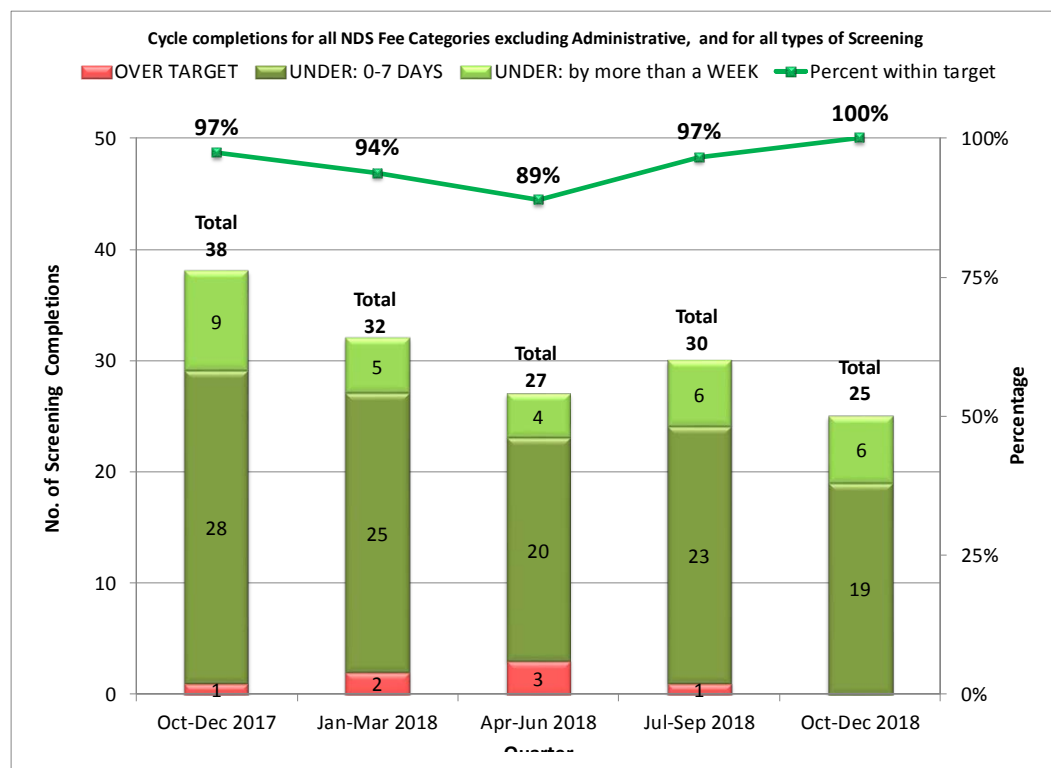


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

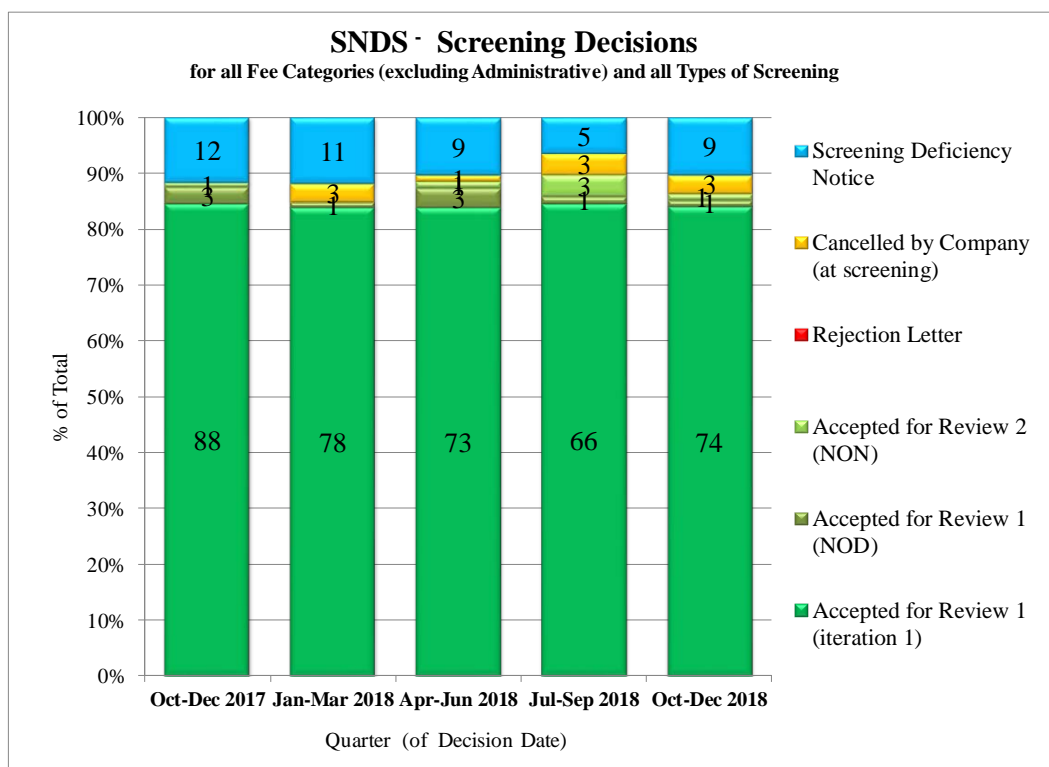


NDS - Screening Cycle Completions Showing Percentage Within Target

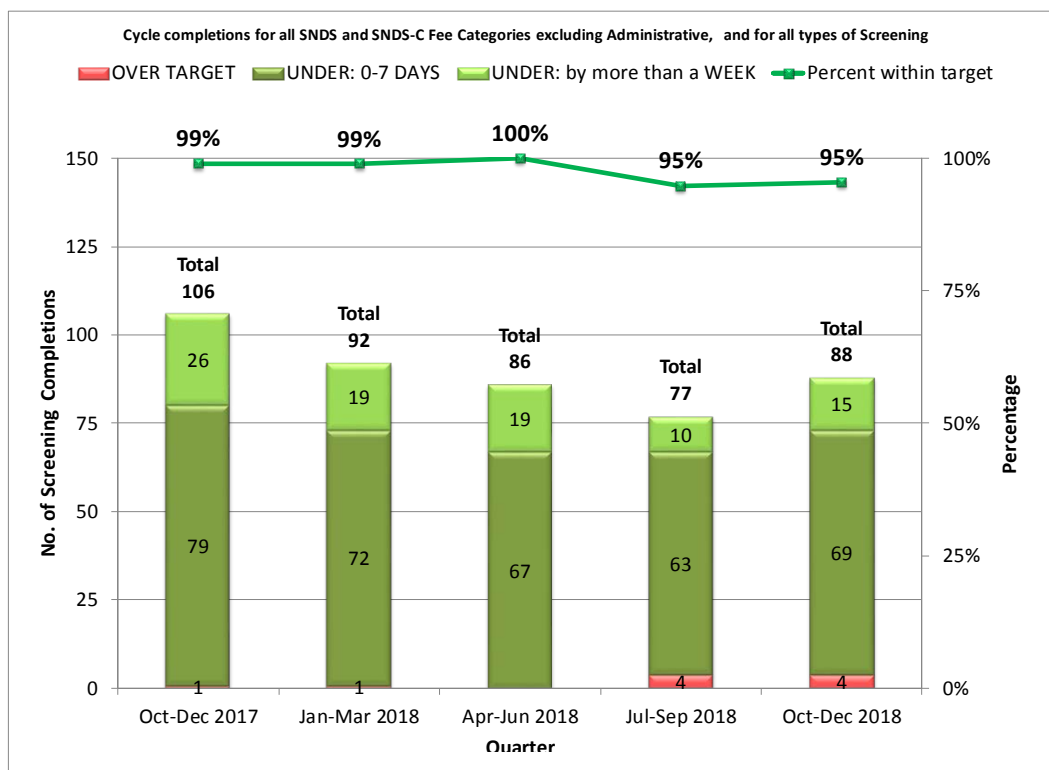


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



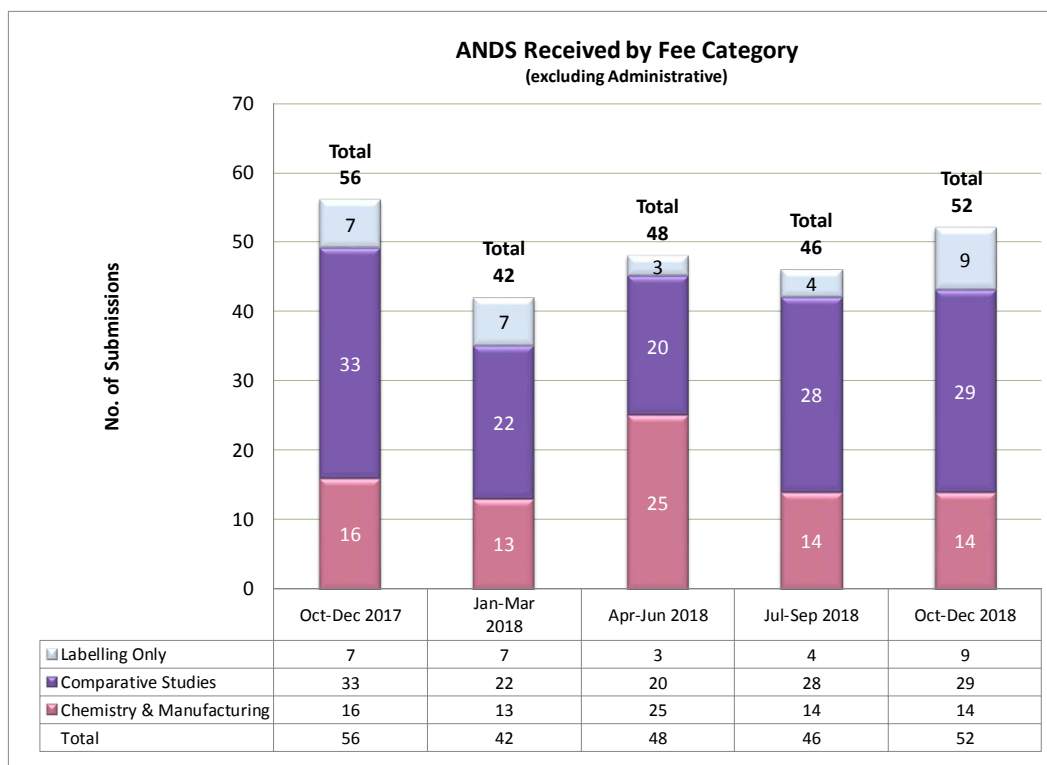
**Abbreviated New Drug Submissions
(ANDS)**

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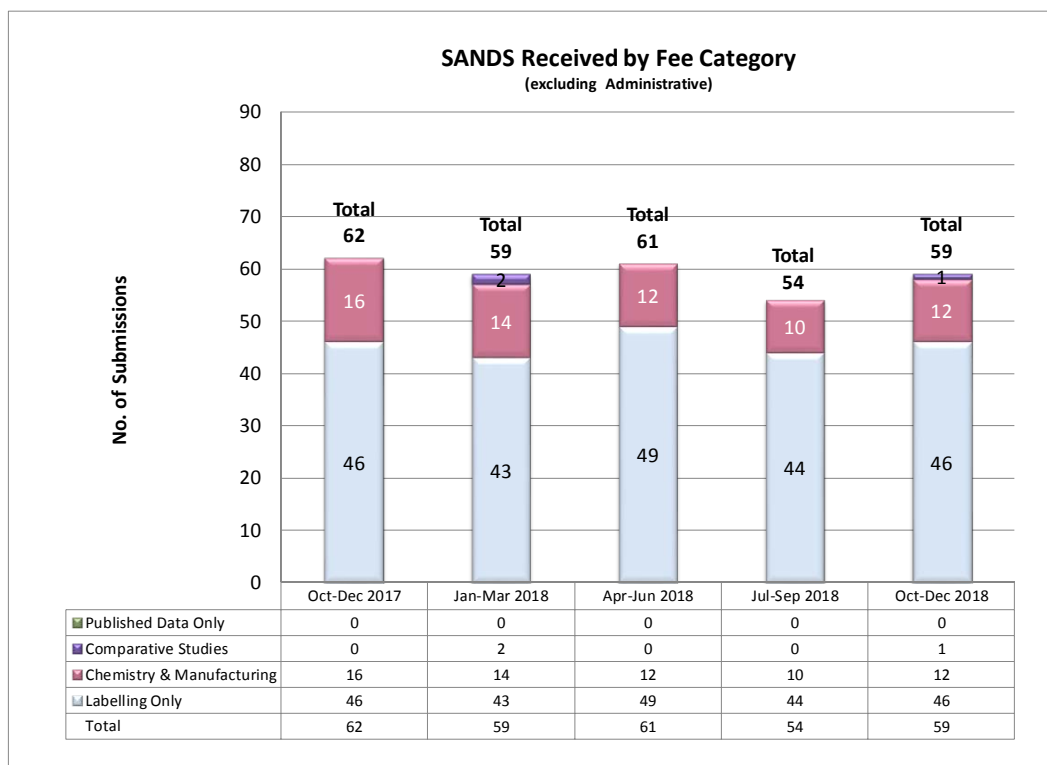
**Supplemental Abbreviated New Drug Submissions
(SANDS)**

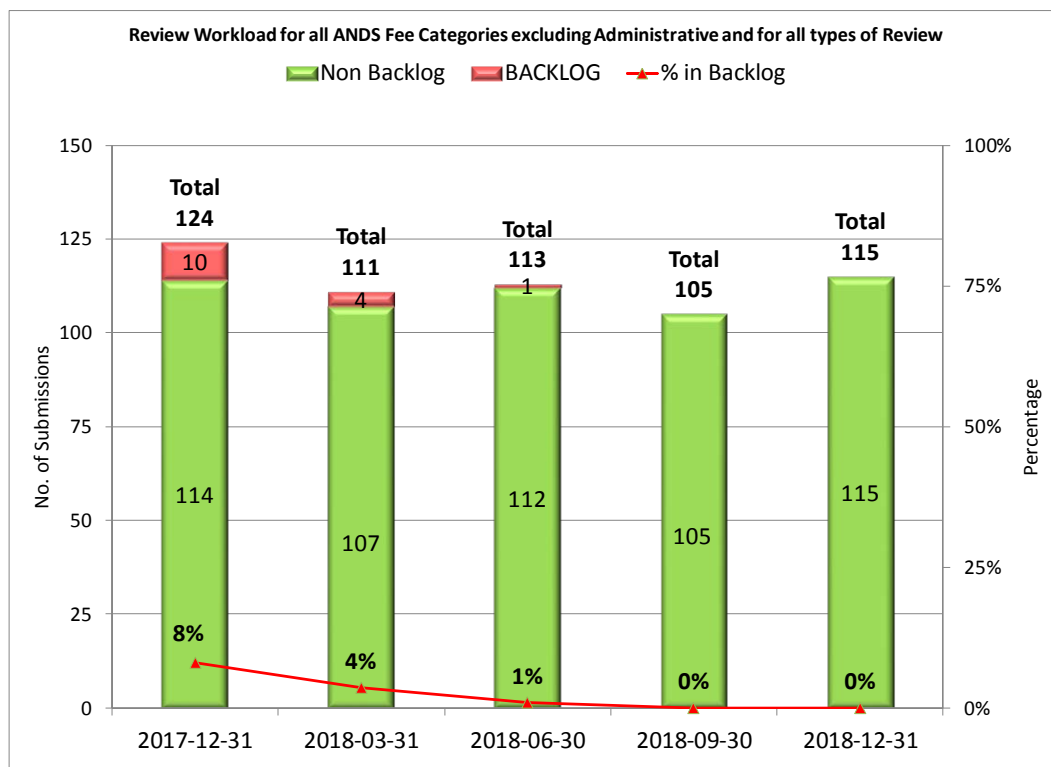
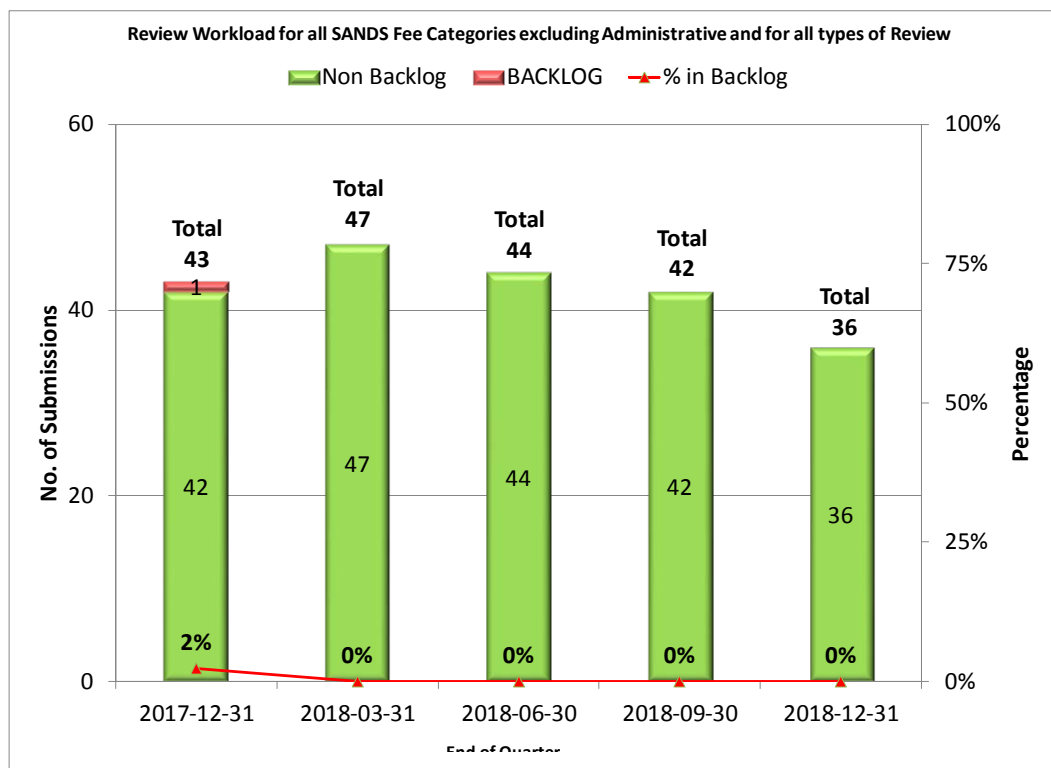
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



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



WORKLOAD**Abbreviated New Drug Submission (ANDS) Review Workload / Backlog****Supplemental Abbreviated New Drug Submission (SANDS) Review Workload / Backlog**

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

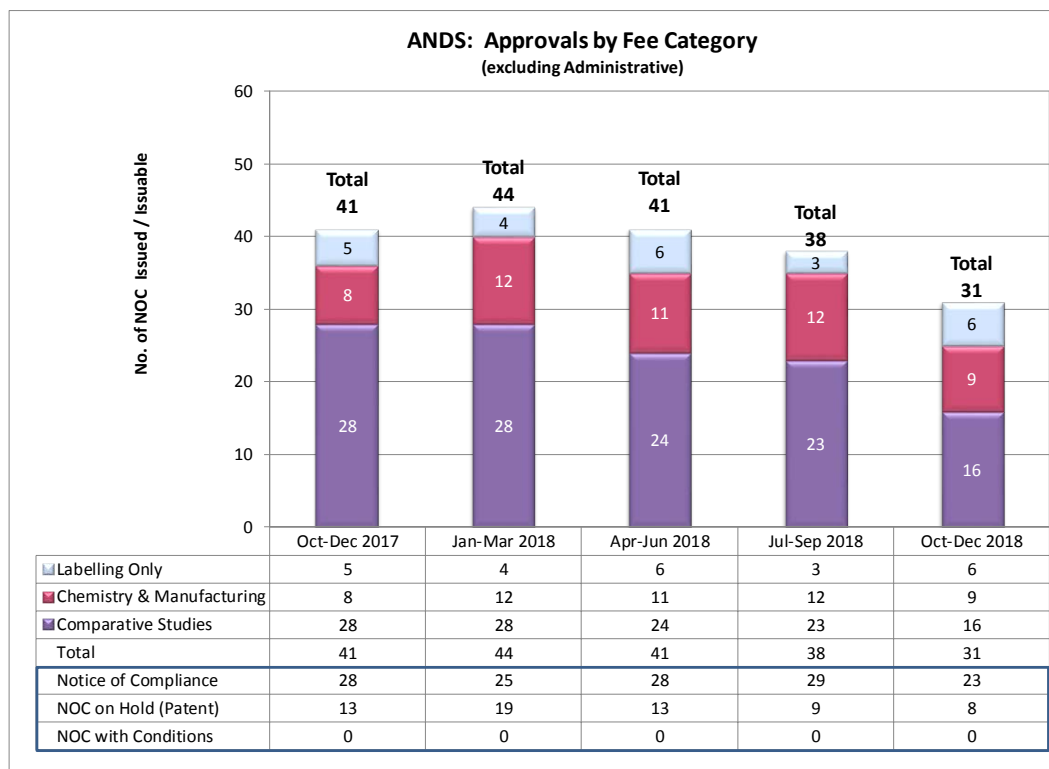
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Chemistry & Manufacturing	49	43	45	51	40
<i>Backlog</i>	4	2	1	0	0
Comparative Studies	73	65	68	52	70
<i>Backlog</i>	6	2	0	0	0
Labelling Only	2	3	0	2	5
<i>Backlog</i>	0	0	0	0	0
Total	124	111	113	105	115
Non Backlog	114	107	112	105	115
BACKLOG	10	4	1	0	0
% in Backlog	8%	4%	1%	0%	0%

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

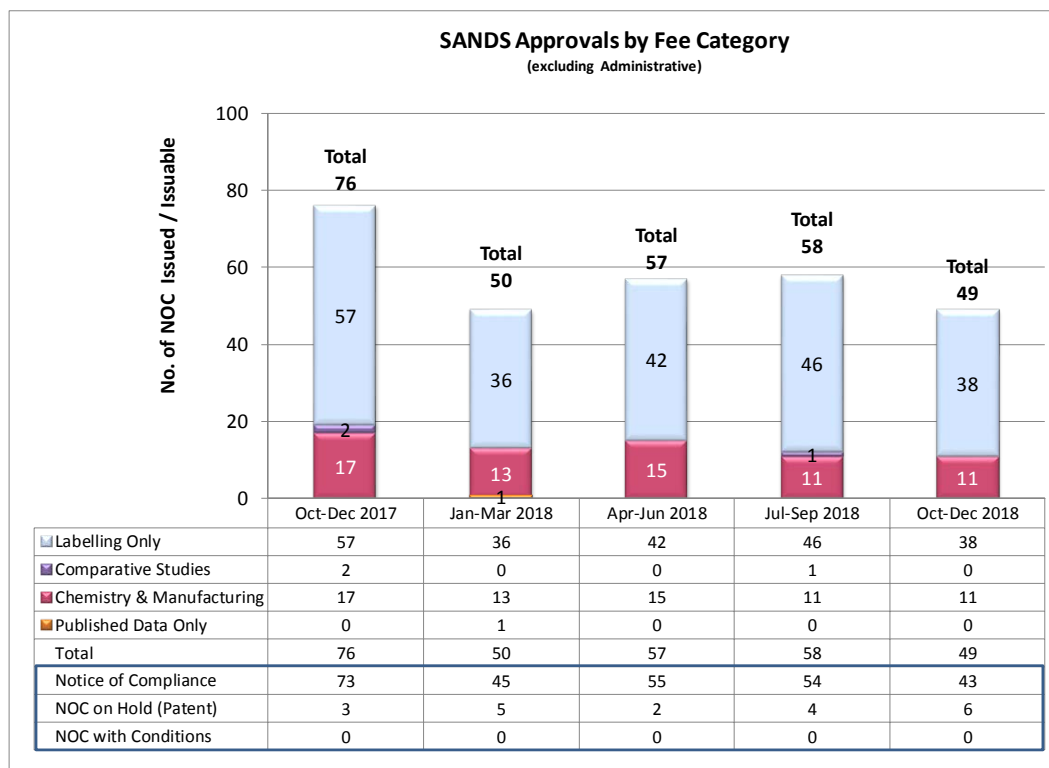
TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Chemistry & Manufacturing	27	26	24	25	21
<i>Backlog</i>	1	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	0	2	2	1	0
<i>Backlog</i>	0	0	0	0	0
Published Data	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	15	19	18	16	15
<i>Backlog</i>	0	0	0	0	0
Total	43	47	44	42	36
Non Backlog	42	47	44	42	36
BACKLOG	1	0	0	0	0
% in Backlog	2%	0%	0%	0%	0%

APPROVALS

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



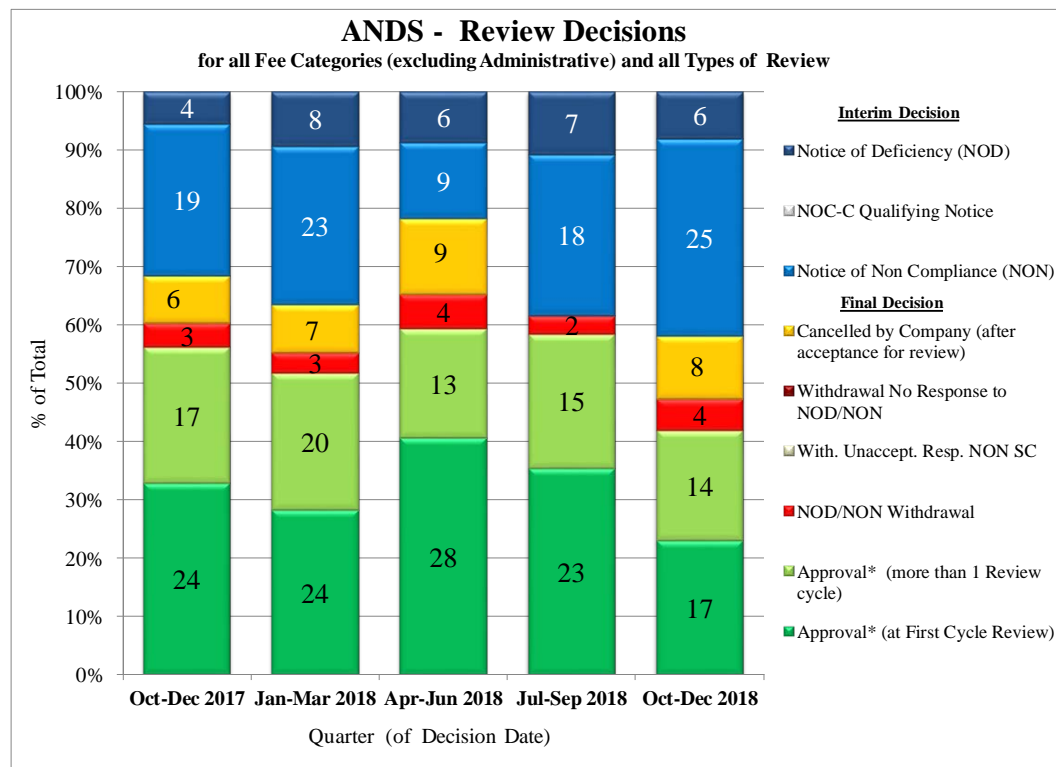
Supplemental Abbreviated New Drug Submission (SANDS) Approvals by Fee Category and by NOC Type



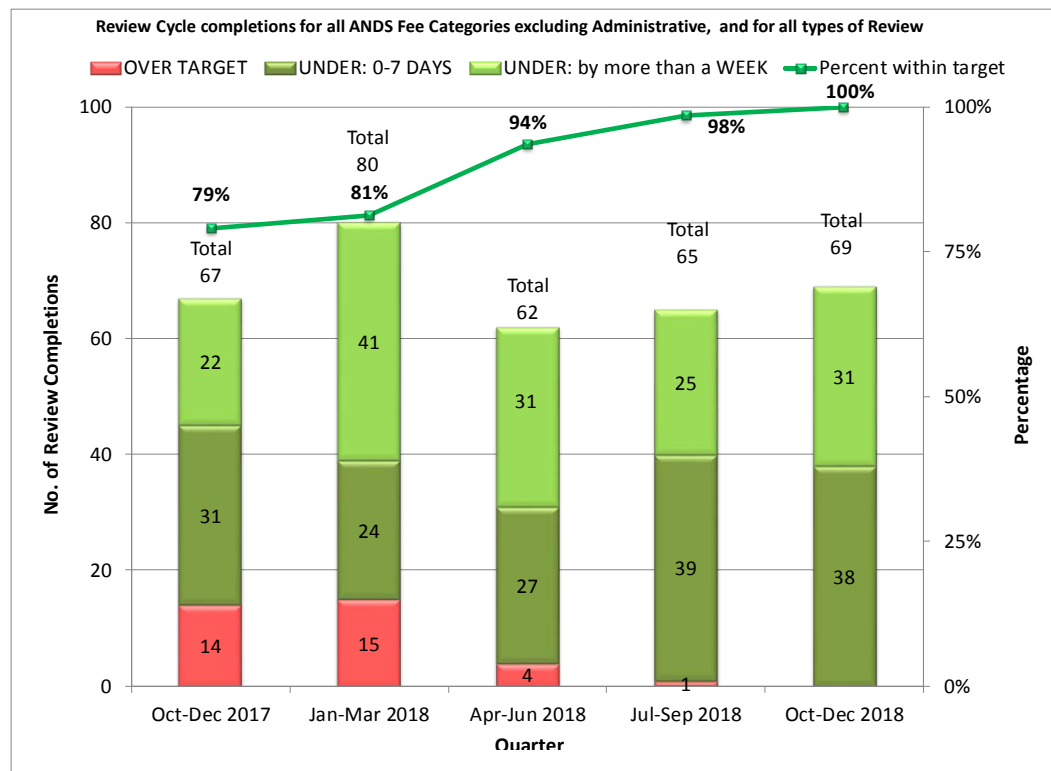
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REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

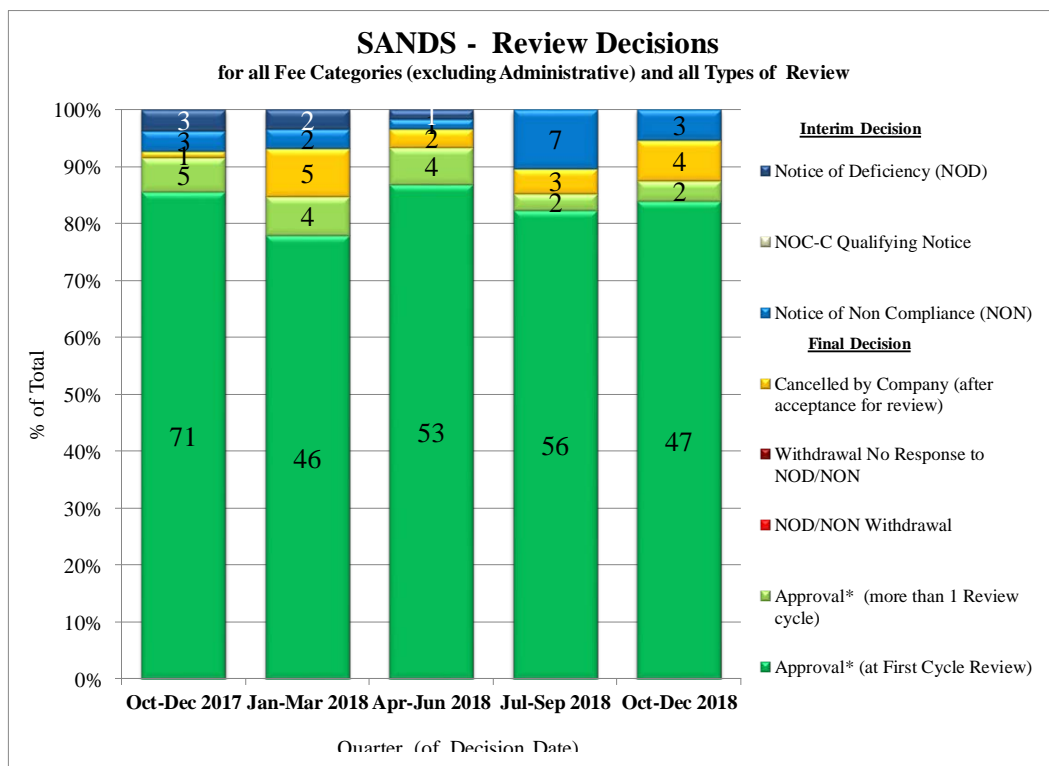


ANDS - Review Cycle Completions Showing Percentage Within Target

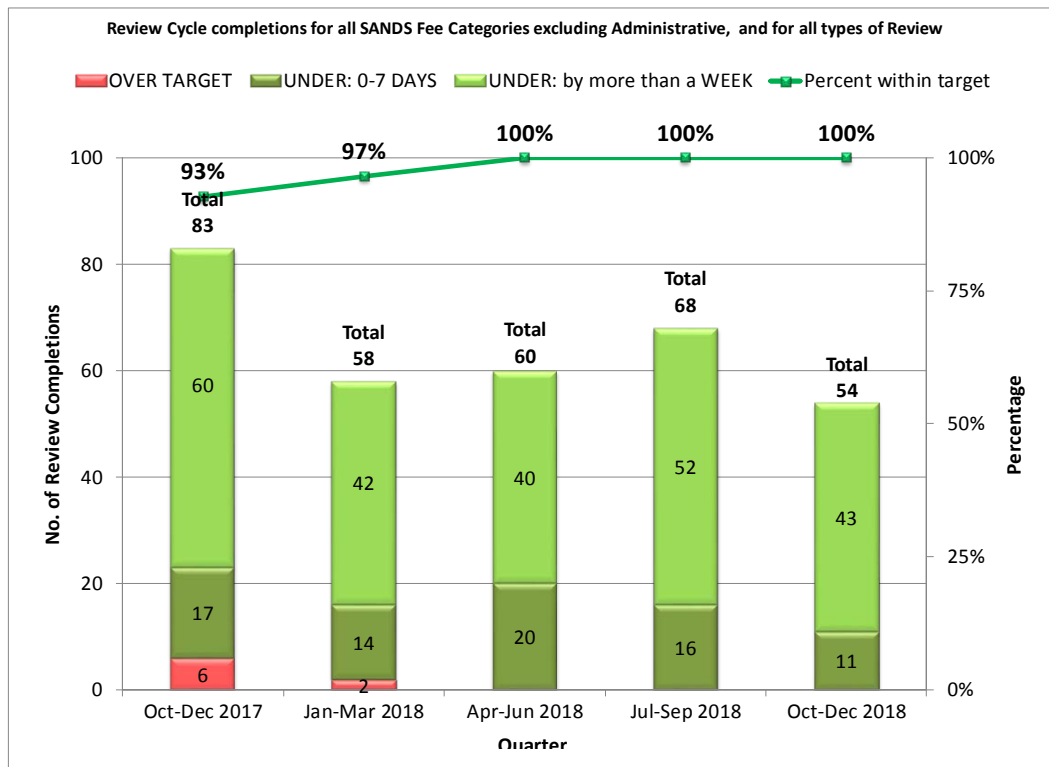


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

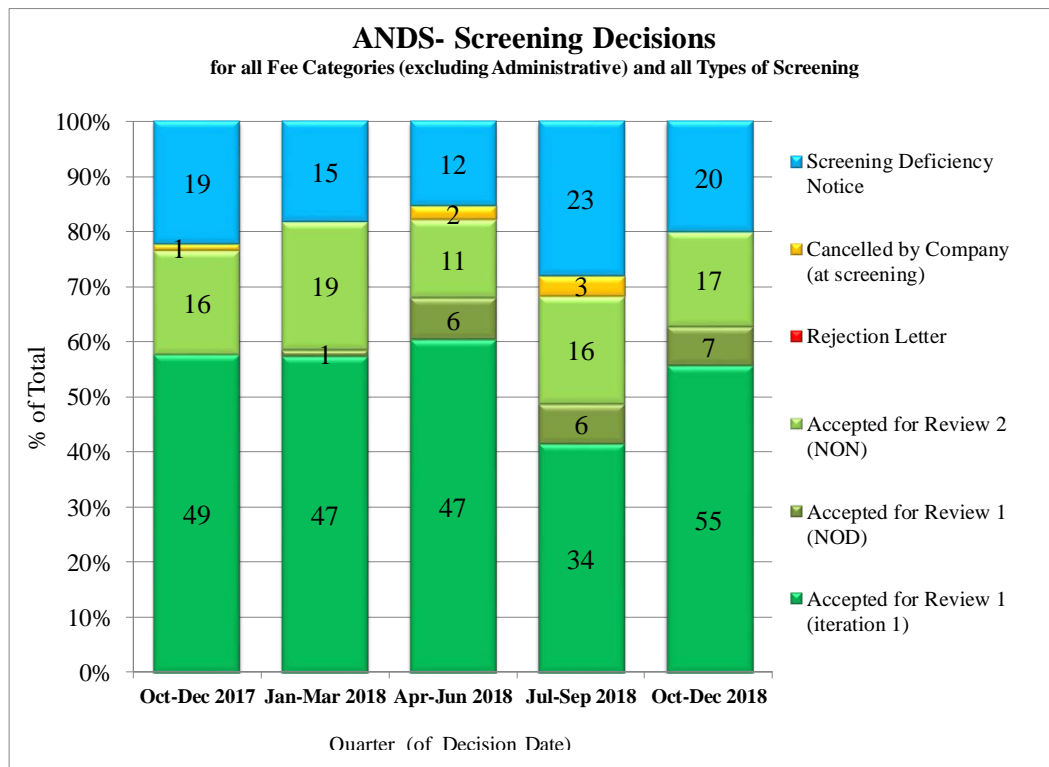


SANDS - Review Cycle Completions Showing Percentage Within Target

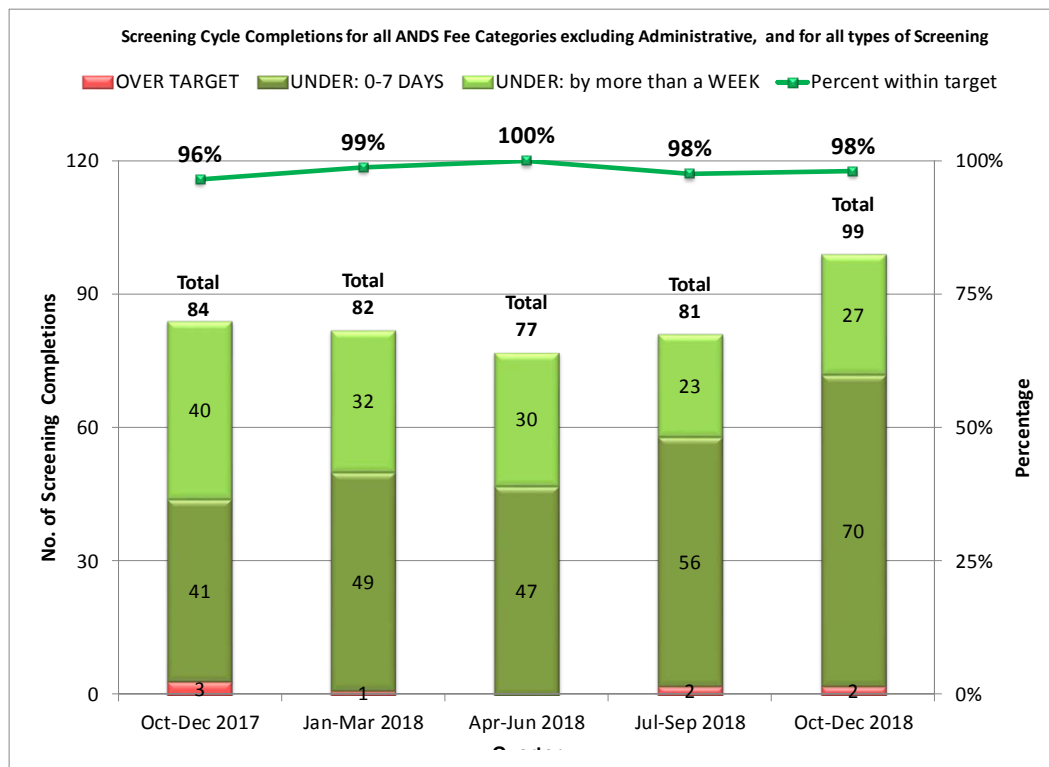


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

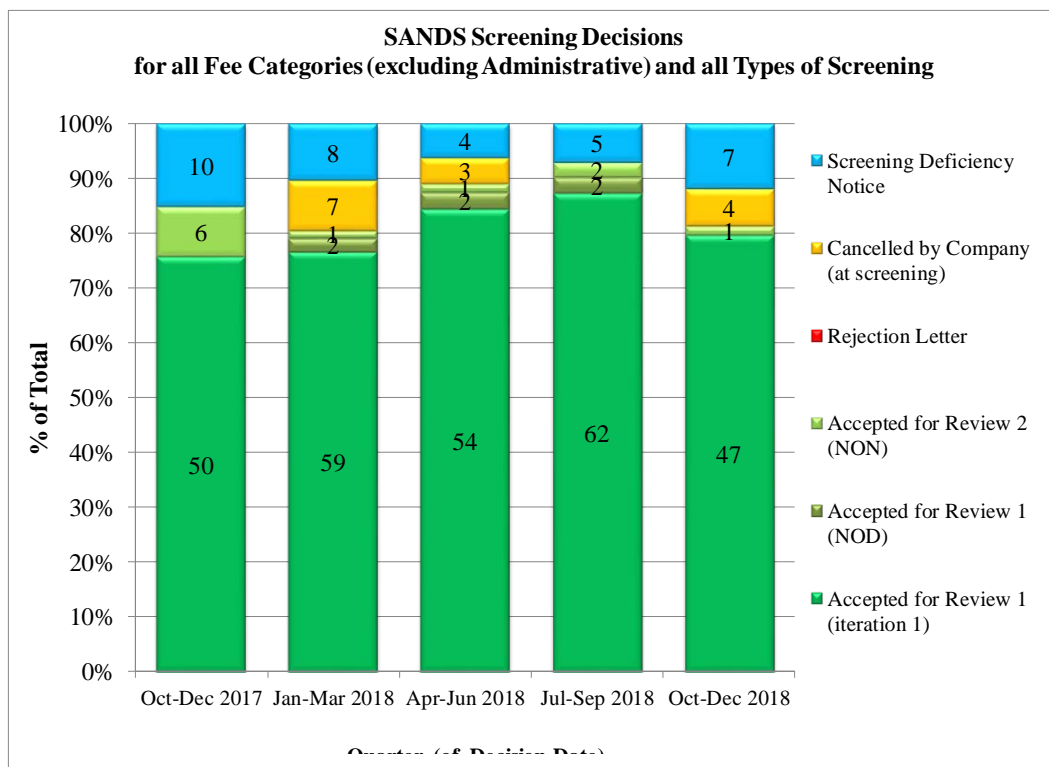


ANDS - Screening Cycle Completions Showing Percentage Within Target

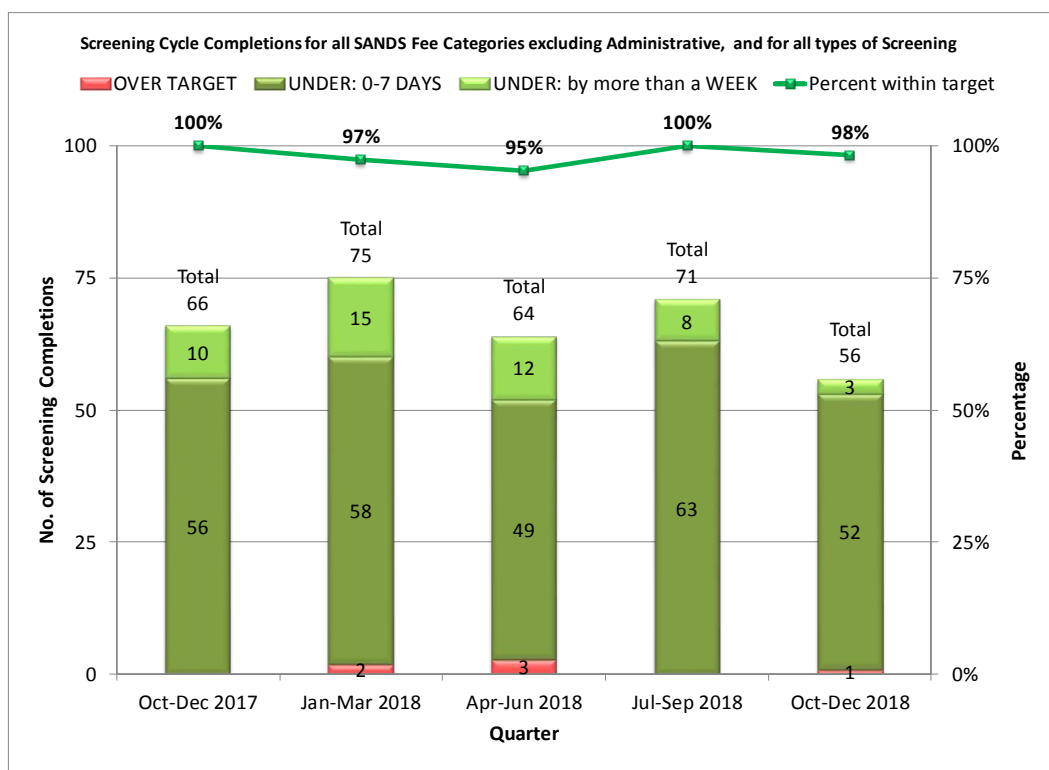


SCREENING CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions

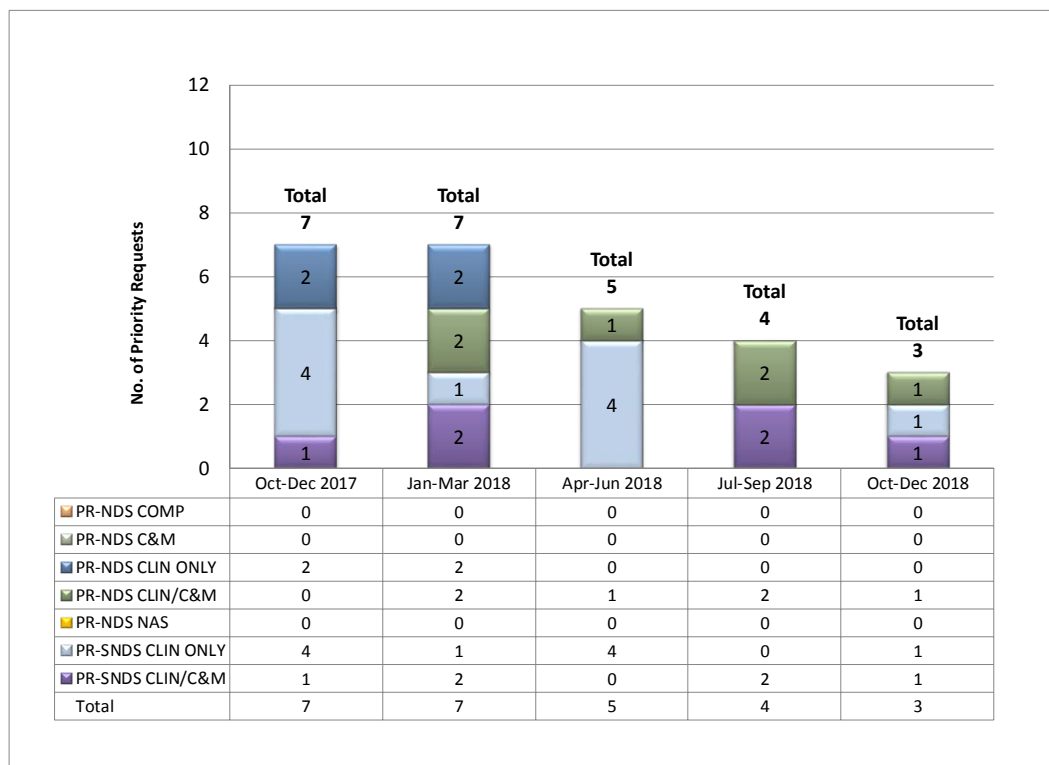


SANDS - Screening Cycle Completions Showing Percentage Within Target

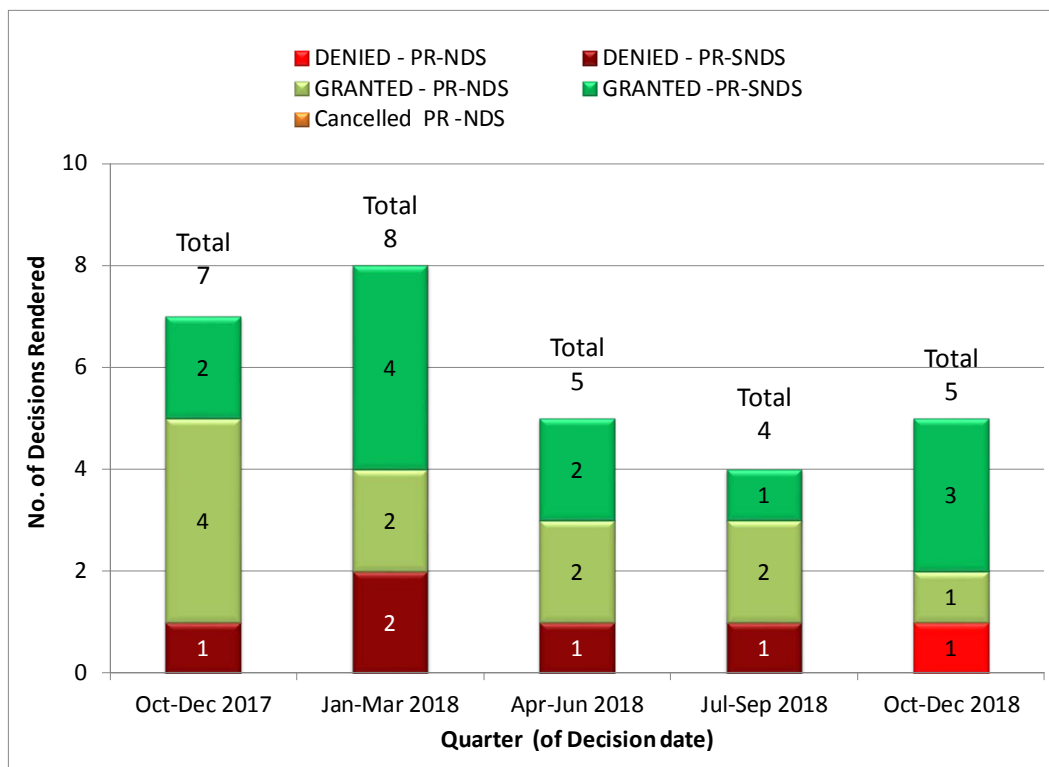


Priority Review Status Requests (for NDS & SNDS)

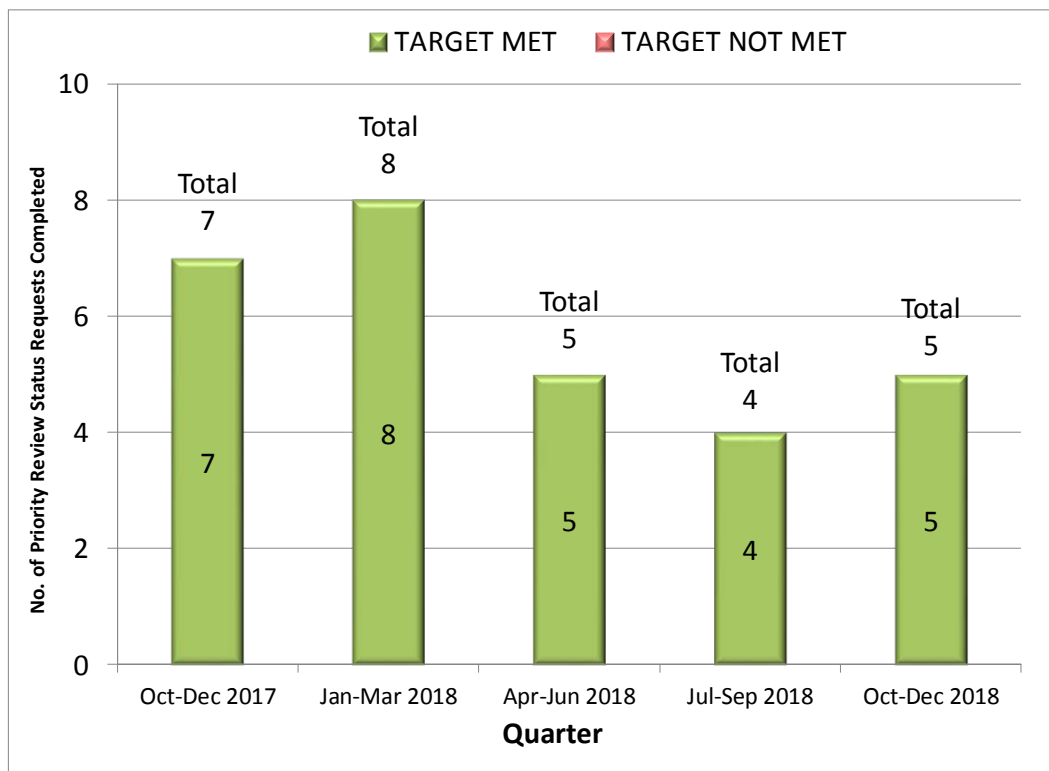
Priority Review Status Requests Received



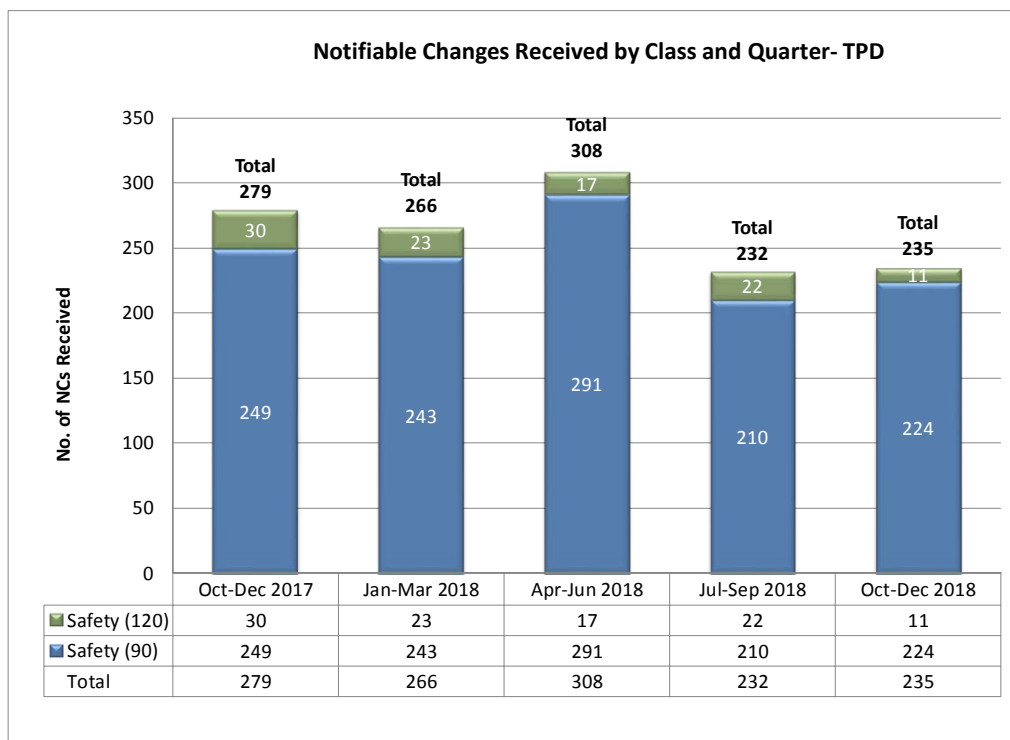
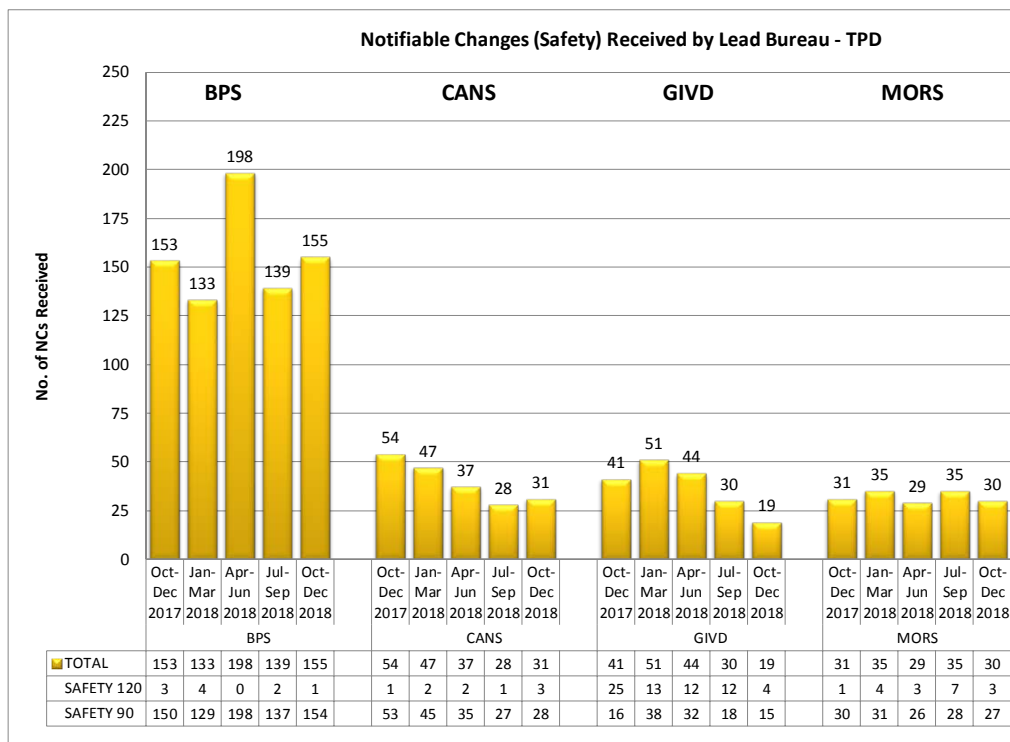
Priority Review Status Requests: Decisions Rendered



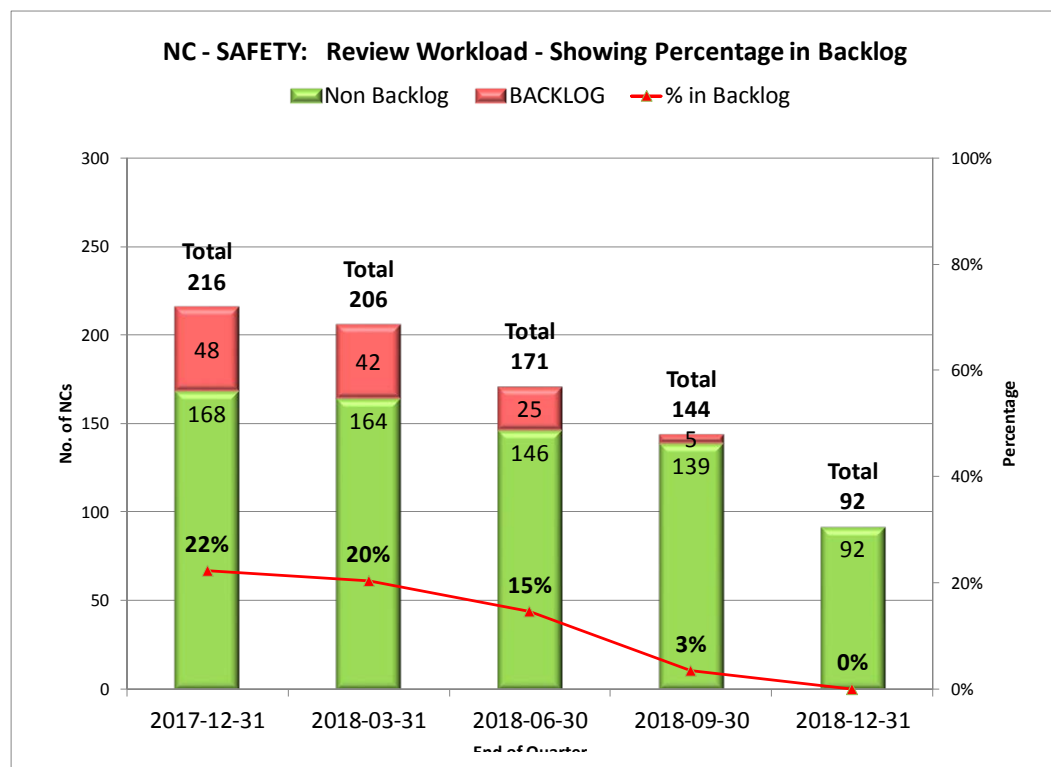
Priority Review Status Requests: Performance



NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES¹¹**SUBMISSIONS RECEIVED****Number Received - Notifiable Changes (NC) - by Class****Number Received - Notifiable Changes (Safety) – by Lead Bureau**

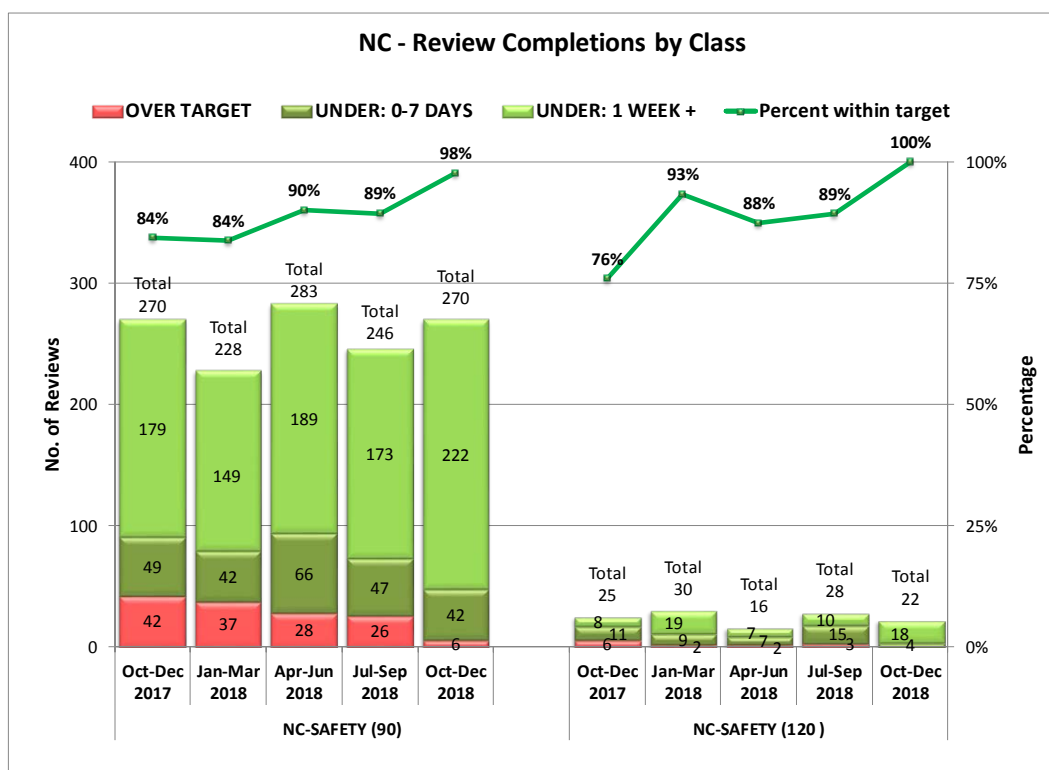
¹¹ In February 2013 the [Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products](#) process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals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

WORKLOAD**Notifiable Change (NC) SAFETY: Review Workload / Backlog****Notifiable Change (NC) SAFETY: Review Workload by Class**

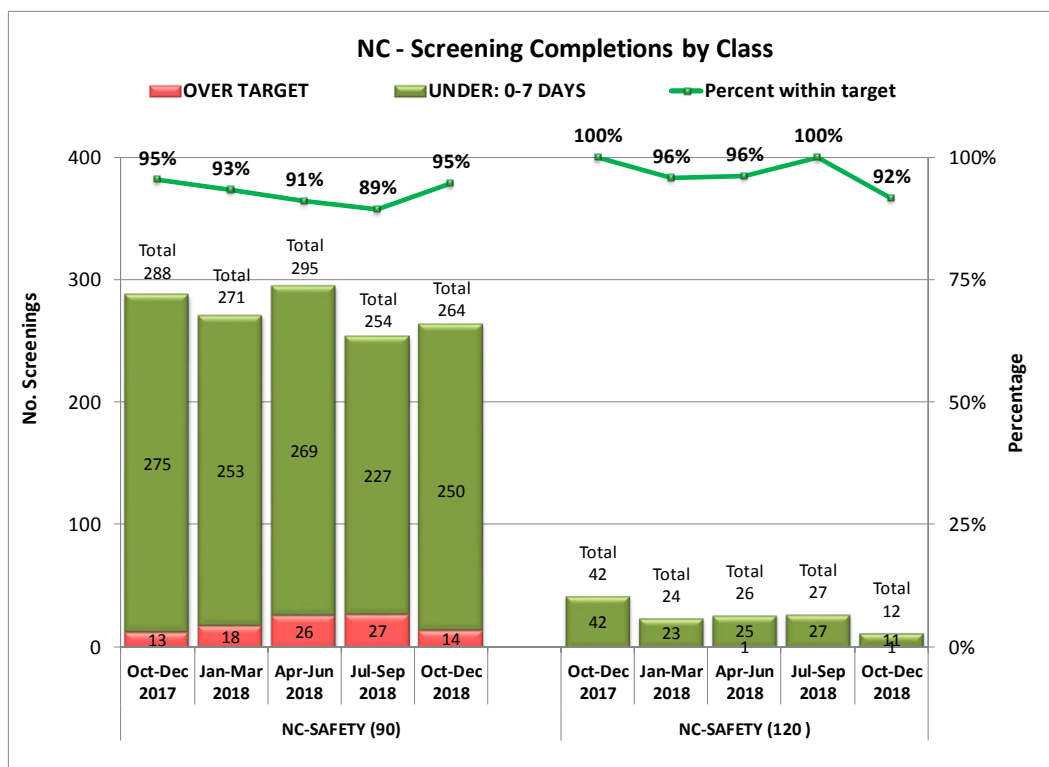
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
SAFETY - 90 day	181	184	145	119	78
Backlog	43	39	23	5	0
SAFETY - 120 day	35	22	26	25	14
Backlog	5	3	2	0	0
Total	216	206	171	144	92
Non Backlog	168	164	146	139	92
BACKLOG	48	42	25	5	0
% in Backlog	22%	20%	15%	3%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



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	262	232	273	235	269
NOT SATISFACTORY NOTICE	0	0	0	0	1
REJECTION LETTER (SCR)	0	1	0	2	0
SCREENING DEFICIENCY NOTICE	40	36	40	25	32
CANCELLED BY COMPANY	18	11	25	10	10
NC - HOLD (PATENT)	3	16	6	13	9
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

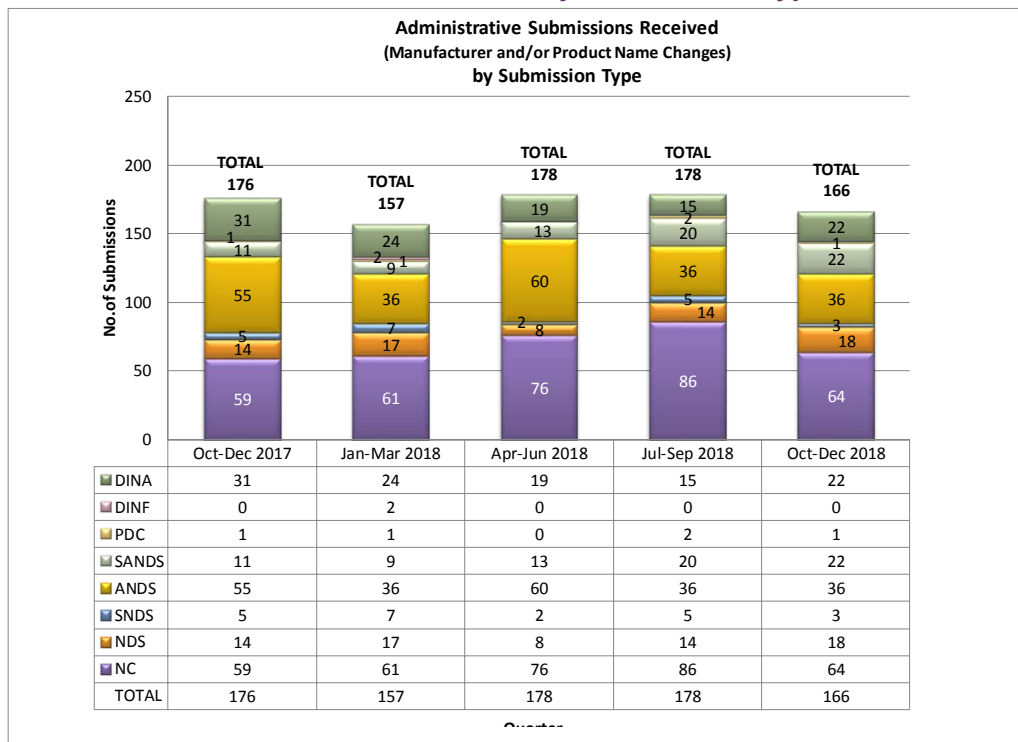
NC - SAFETY (120)					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NO OBJECTION LETTER	24	30	15	28	22
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	8	6	6	1	1
CANCELLED BY COMPANY	1	1	2	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

Administrative Submissions

(Manufacturer and/or Product Name Changes) ¹² ¹³

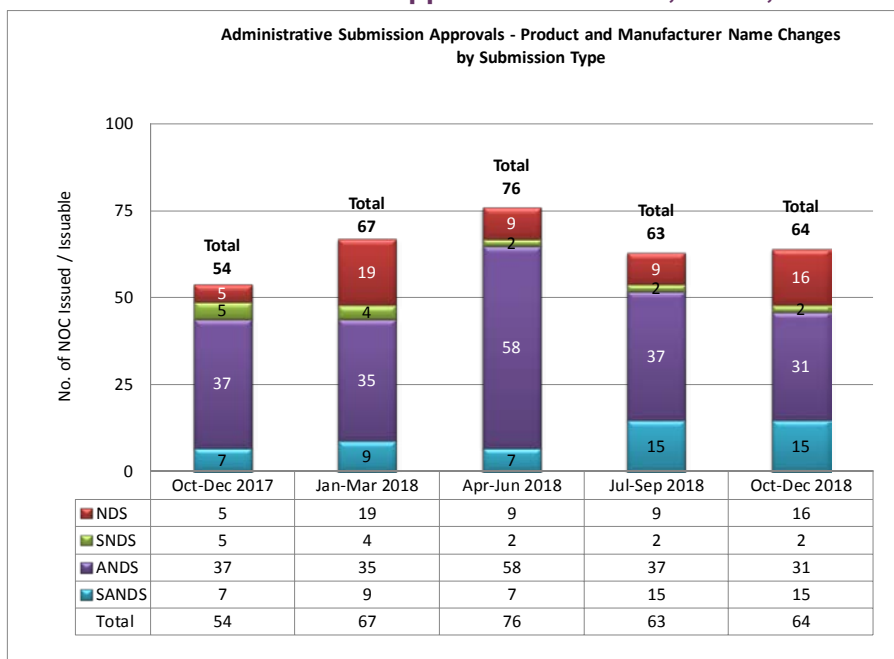
RECEIVED

Administrative Submissions Received by Submission Type



APPROVALS

Administrative Submission Approvals * for NDS, SNDS, ANDS and SANDS



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

¹³ 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^{14 15})

DECISIONS

Administrative Submissions/ Applications: DECISIONS

Administrative Submission/Applications - Decisions by Submission Type - TPD

ANDS					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER	10	23	12	6	
SCREEN. DEFICIENCY NOTICE		3		2	
CANCELLATION LETTER	4	4			1
NOC ON IP HOLD	1	1			
NOTICE OF COMPLIANCE	34	57	37	31	13

NDS					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER	5		3	7	2
SCREEN. DEFICIENCY NOTICE					
CANCELLATION LETTER		2	1	1	
NOTICE OF COMPLIANCE	19	9	9	16	3

SANDS					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER	6	7	5	5	
SCREEN. DEFICIENCY NOTICE		1	1		
CANCELLATION LETTER		1	6	1	
NOTICE OF COMPLIANCE	9	7	15	15	8

SND					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER		1	3	1	
CANCELLATION LETTER		2	2	3	
NOTICE OF COMPLIANCE	4	2	2	2	

NC					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER		4	4	4	
SCREEN. DEFICIENCY NOTICE					
CANCELLATION LETTER	7	5	10	3	
NC - HOLD (PATENT)			1		
NO OBJECTION LETTER	70	53	100	64	7

DINA					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER	4	4	13	5	1
SCREEN. DEFICIENCY NOTICE			1	7	
CANCELLATION LETTER		2	2	2	
NO OBJECTION LETTER			1		
NOTIFICATION FORM DIN SUB	19	20	10	13	5

DINF					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER	1				
CANCELLATION LETTER					
NO OBJECTION LETTER	1				
NOTIFICATION FORM DIN SUB	1				

PDC					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
PROCESSING HOLD LETTER		2			
CANCELLATION LETTER		1	1		
NO OBJECTION LETTER	1		1	2	

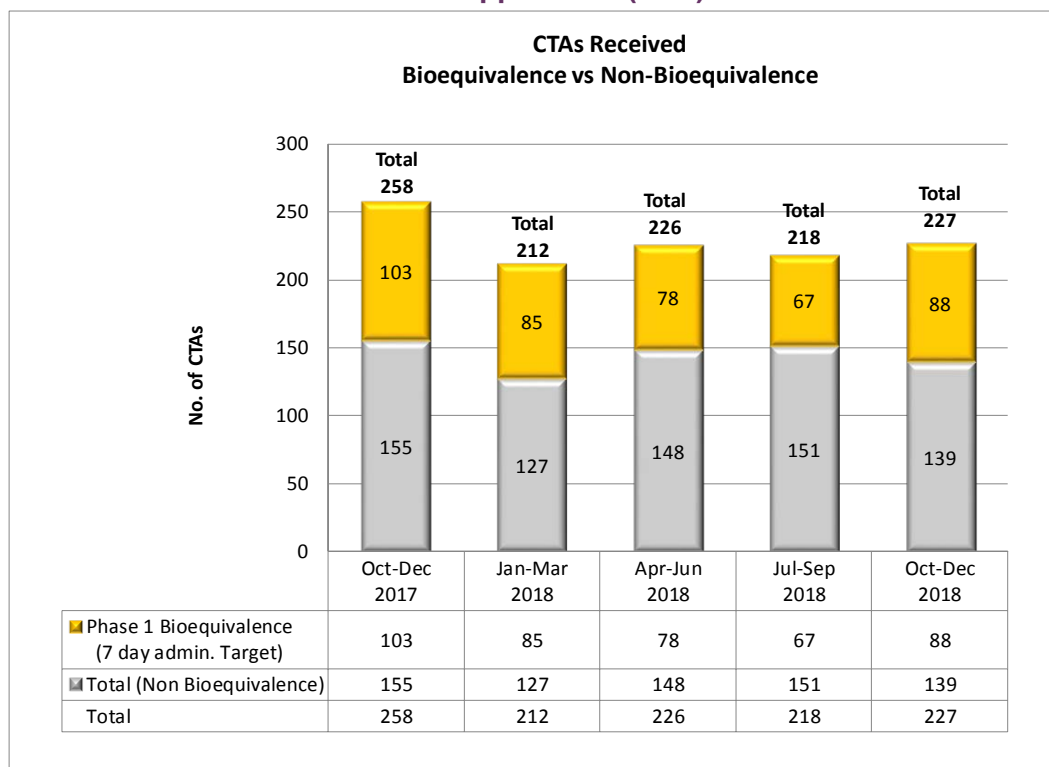
¹⁴ For additional information, please consult the "[Changes in Manufacturer and/or Product Name Policy](#)" (2015)

¹⁵ 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.

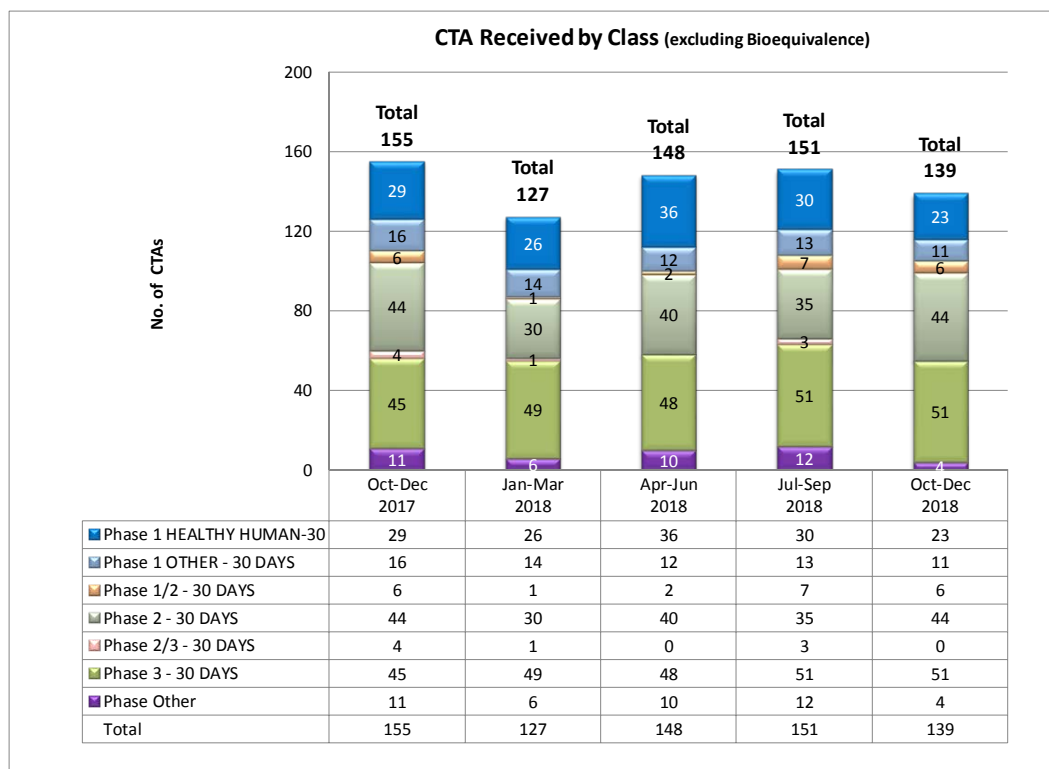
Clinical Trial Applications and Amendments (CTA & CTA-A)

Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)



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



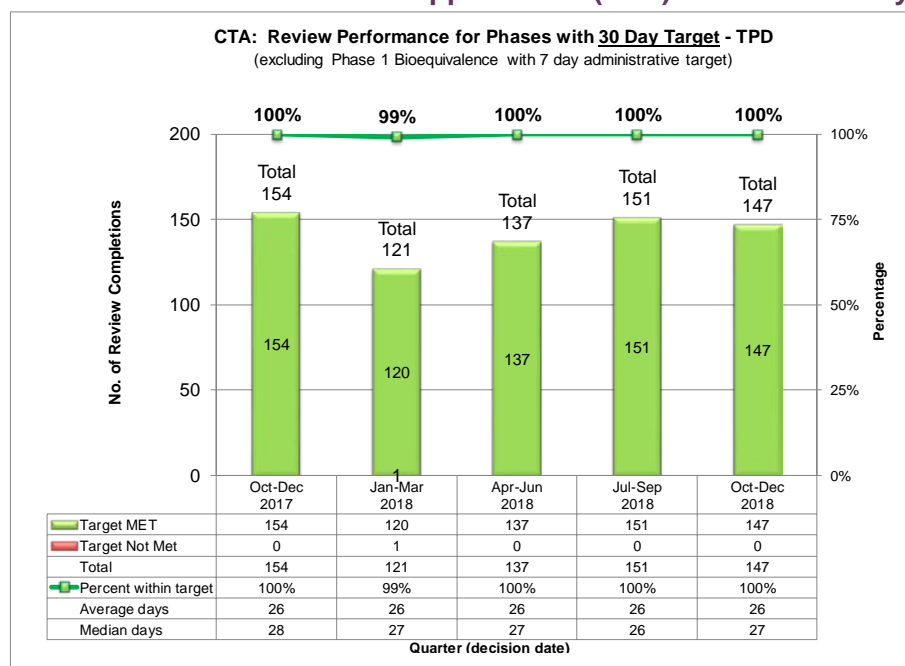
DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

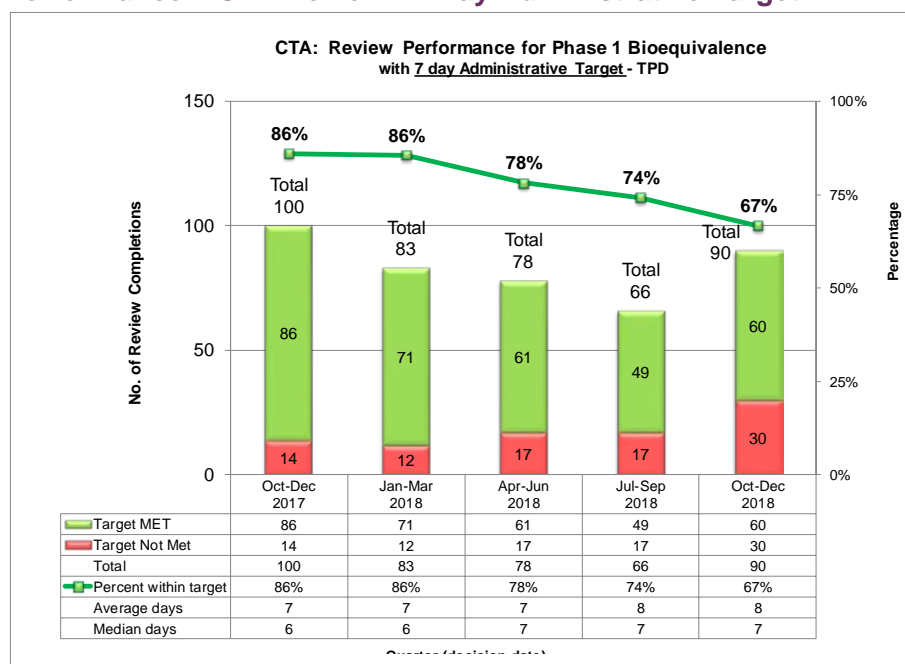
CTA					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NO OBJECTION LETTER	237	189	208	211	226
CANCELLED BY COMPANY DURING REVIEW	17	15	7	6	11
CANCELLED BY COMPANY AT PROCESSING	3	5	5	3	2

PERFORMANCE

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

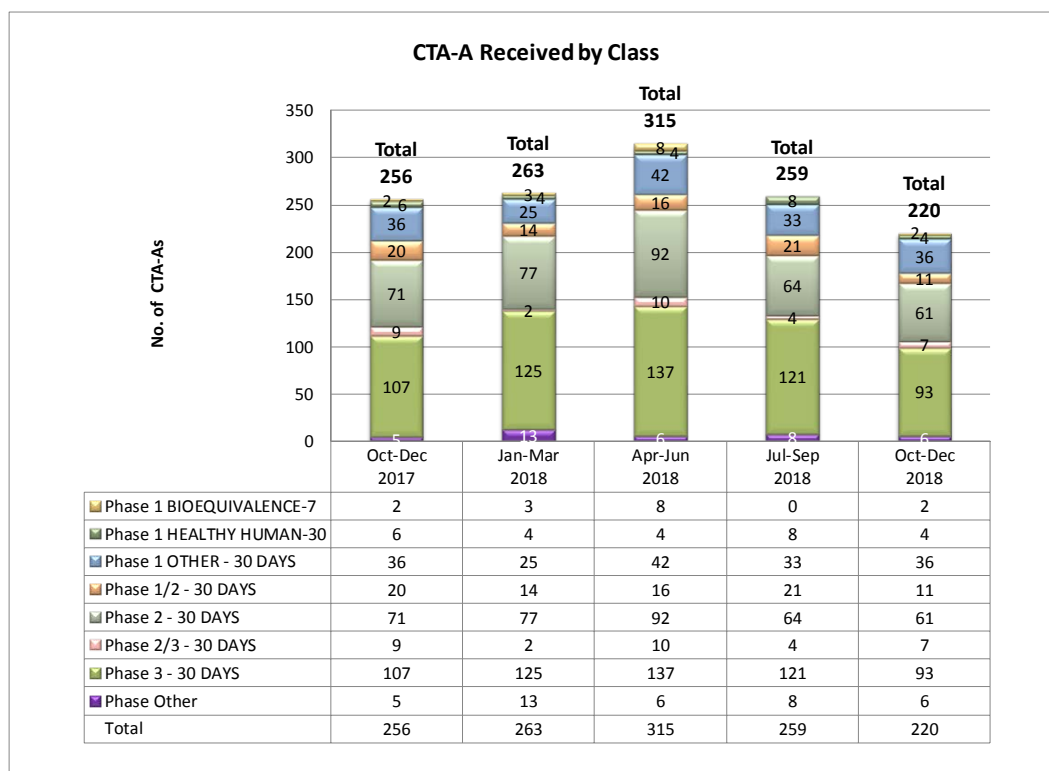


Performance – CTA Review: 7 Day Administrative Target



Clinical Trial Application – Amendments (CTA-A)

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



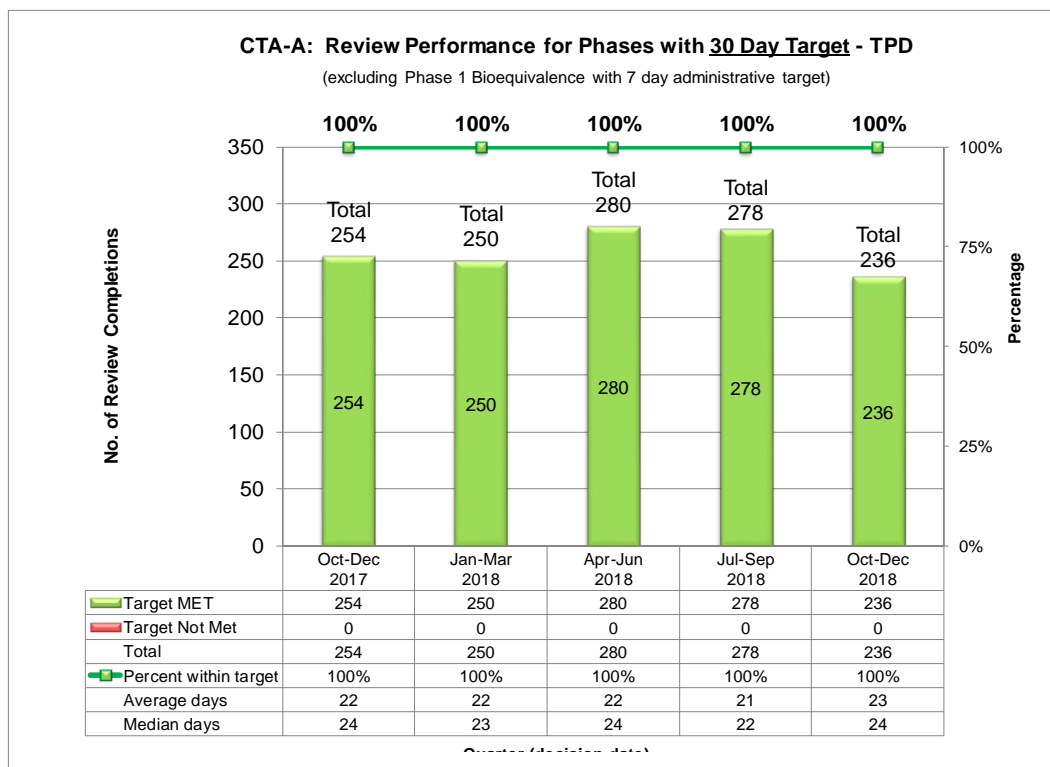
DECISION DOCUMENTS

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

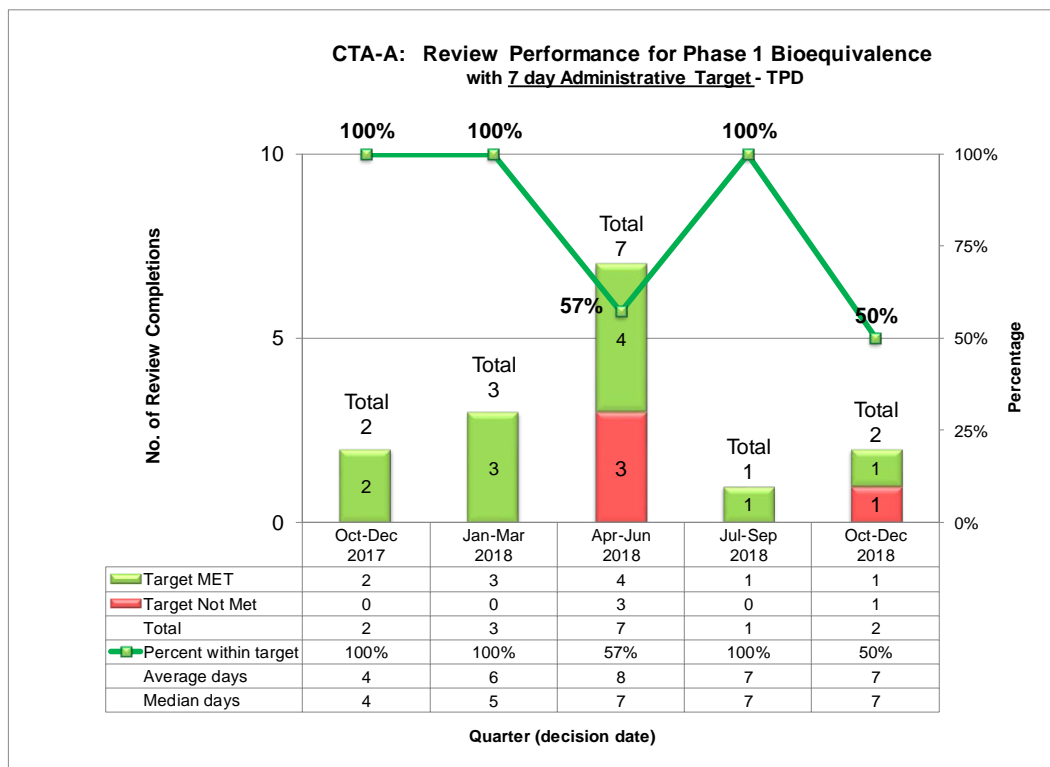
CTA-A (excluding administrative)					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NO OBJECTION LETTER	252	250	280	275	235
CANCELLED BY COMPANY DURING REVIEW	4	3	7	4	3
CANCELLED BY COMPANY AT PROCESSING	1	0	1	0	1

PERFORMANCE

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



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



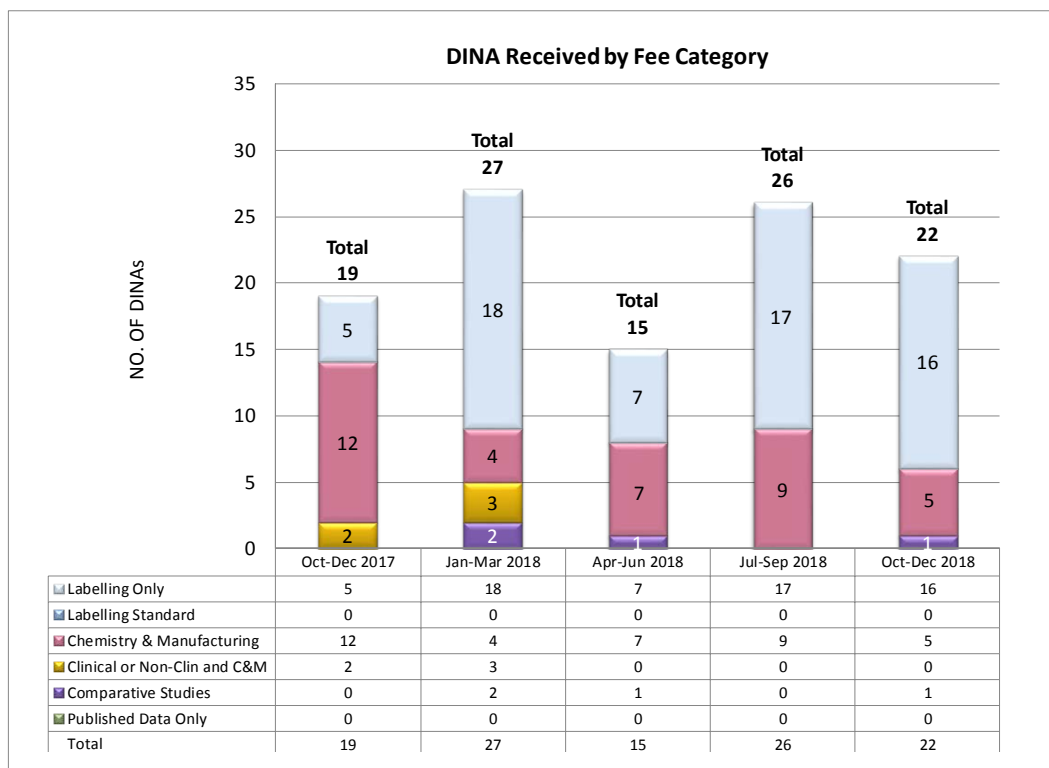
DINA

Application for a Drug Identification Number

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

DINA: Application for a Drug Identification Number¹⁶

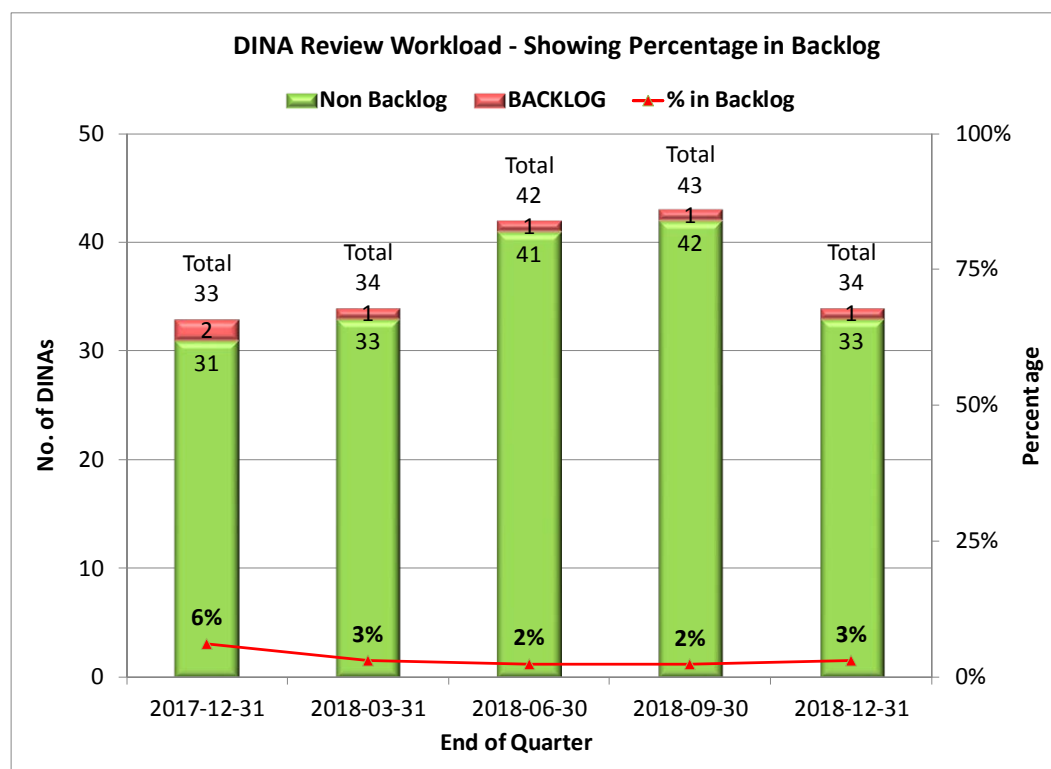
Number Received – DINA



¹⁶ The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog – DINA

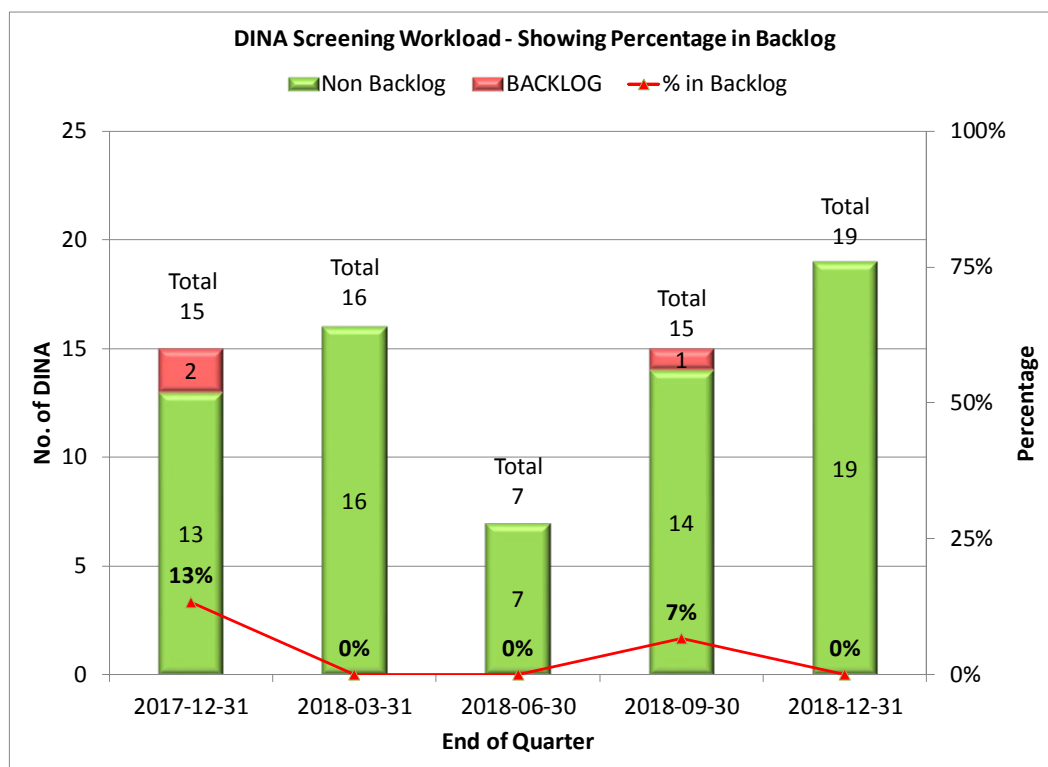


Review Workload by Fee Category – DINA

TPD DINA ALL REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Labelling Only	14	13	19	17	19
Backlog	1	1	1	1	1
Chemistry & Manufacturing	17	19	15	20	13
Backlog	1	0	0	0	0
Published Data	1	1	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	4	4	1
Backlog	0	0	0	0	0
Comparative Studies	1	1	4	2	1
Backlog	0	0	0	0	0
Total	33	34	42	43	34
Non Backlog	31	33	41	42	33
BACKLOG	2	1	1	1	1
% in Backlog	6%	3%	2%	2%	3%

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog – DINA



Screening Workload by Fee Category – DINA

TPD DINA All SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-12-31	2018-03-31	2018-06-30	2018-09-30	2018-12-31
Labelling Only	3	8	3	8	8
Backlog	0	0	0	1	0
Labelling Standard	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	2	2	0	0	0
Backlog	1	0	0	0	0
Chemistry & Manufacturing	10	4	4	7	9
Backlog	1	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies	0	2	0	0	2
Backlog	0	0	0	0	0
Total	15	16	7	15	19
Non Backlog	13	16	7	14	19
BACKLOG	2	0	0	1	0
% in Backlog	13%	0%	0%	7%	0%

DECISION DOCUMENTS

Decision Documents – DINA by Fee Category

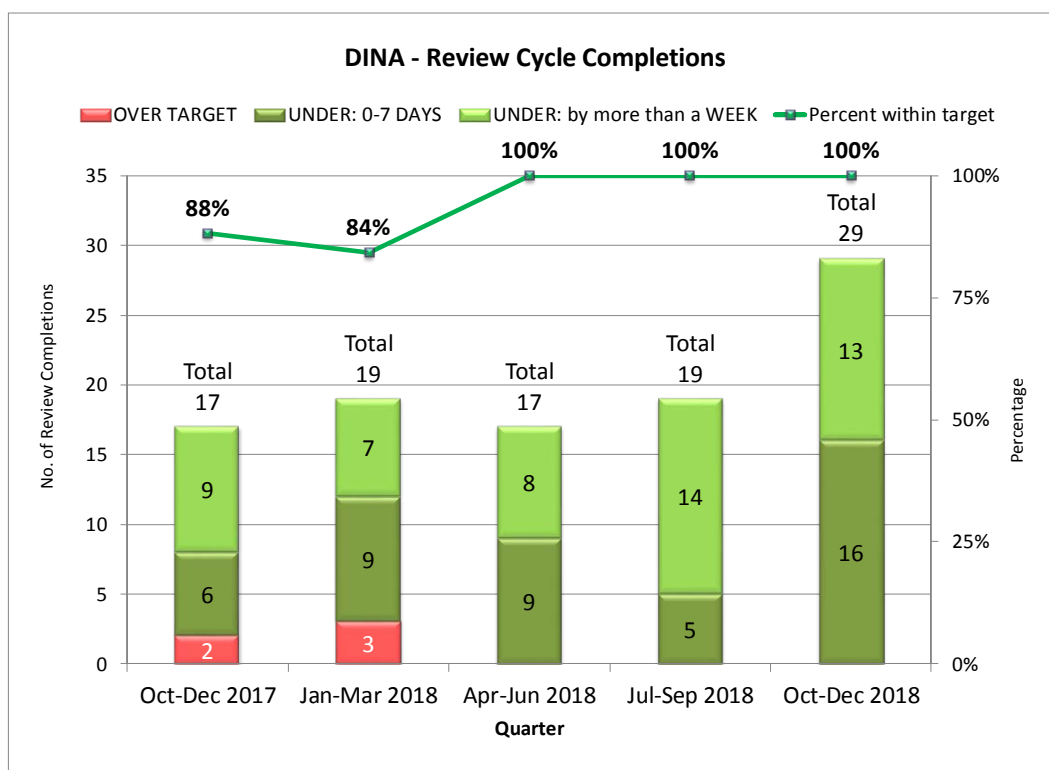
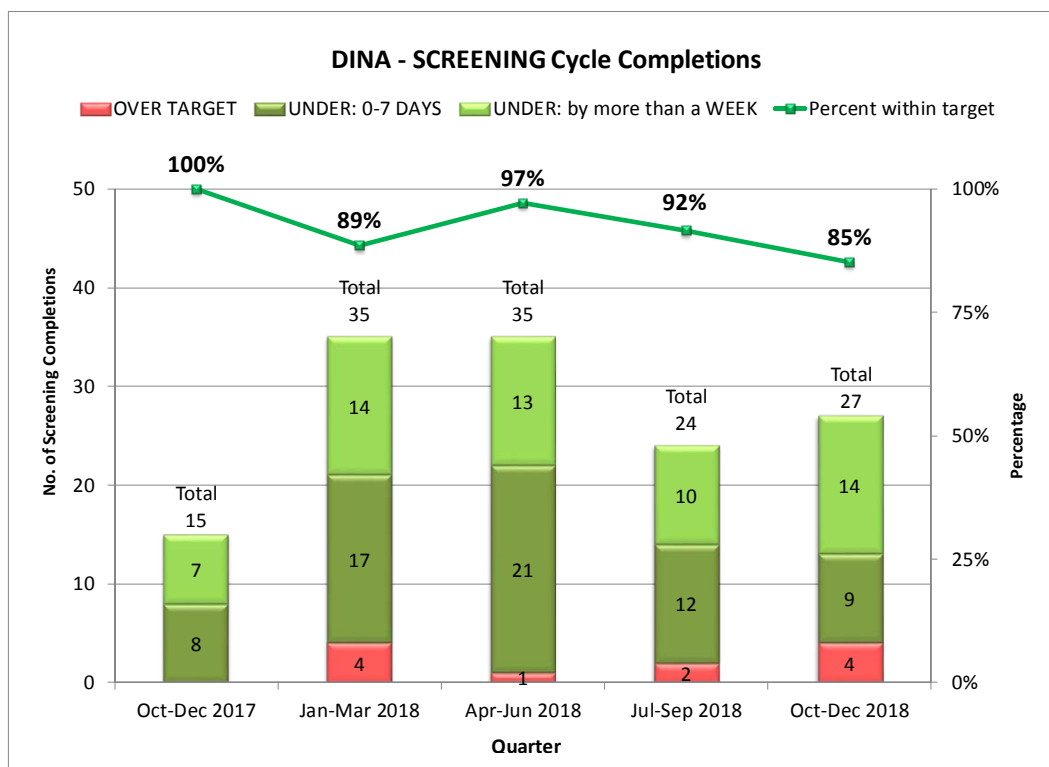
DINA - Labelling Only					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NOTIFICATION FORM/DIN ISSUED	5	3	1	3	4
NO OBJECTION LETTER	6	6	5	7	8
CANCELLED BY COMPANY	0	2	3	1	3
DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	2	0	0
REJECTION LETTER (SCR)	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	3	2	2	2
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NOTIFICATION FORM/DIN ISSUED	4	4	4	1	3
NO OBJECTION LETTER	0	1	3	2	3
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	1	0	0	2
NOTICE OF DEFICIENCY	0	2	0	1	2
NOTICE OF NON-COMPLIANCE	1	1	1	3	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	0	6	3	1	2
CANCELLED BY COMPANY	0	3	1	1	2

DINA - PUBLISHED DATA ONLY					
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
NO OBJECTION LETTER	0	0	1	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	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0

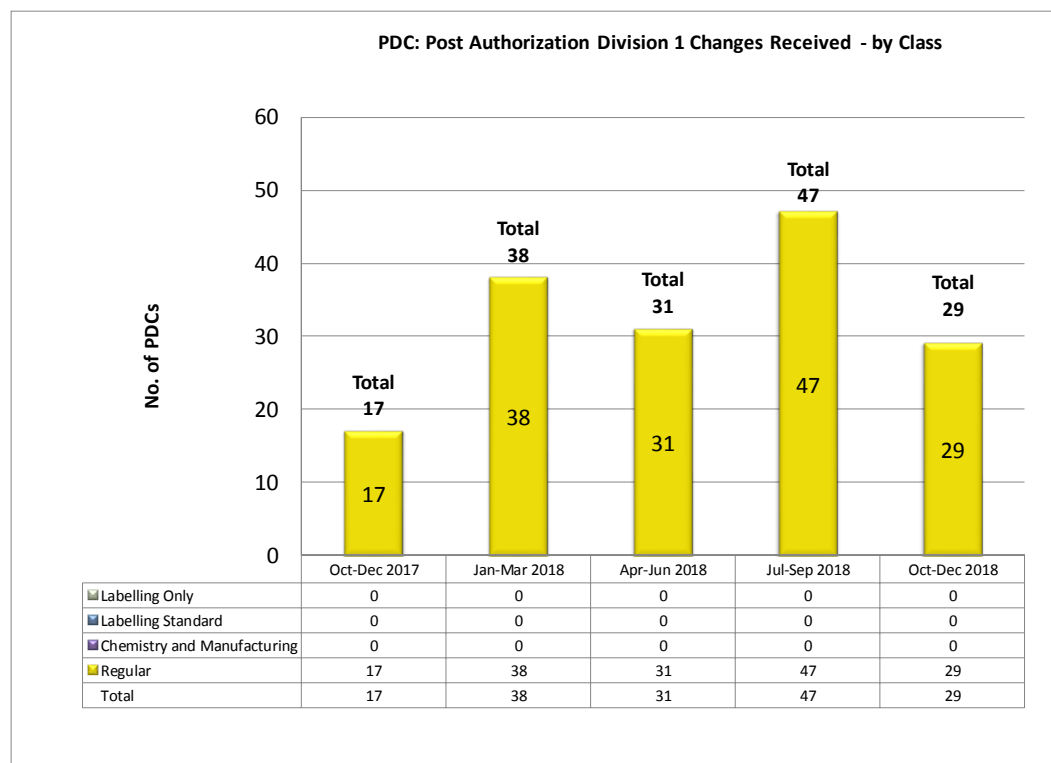
DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
NOTIFICATION FORM/DIN ISSUED	0	1	0	1	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	1	0	0	0	1
NO OBJECTION LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	1	0
SCREENING DEFICIENCY NOTICE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

DINA - 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
CANCELLED BY COMPANY	0	1	0	0	1
NOTICE OF NON-COMPLIANCE	0	0	0	0	1
NOTIFICATION FORM DIN SUB	0	0	0	0	1
SCREENING DEFICIENCY NOTICE	0	2	2	0	0

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

PDC: Post-Authorization Division 1 Changes,¹⁷

Post-Authorization Division 1 Changes (PDC) Received



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

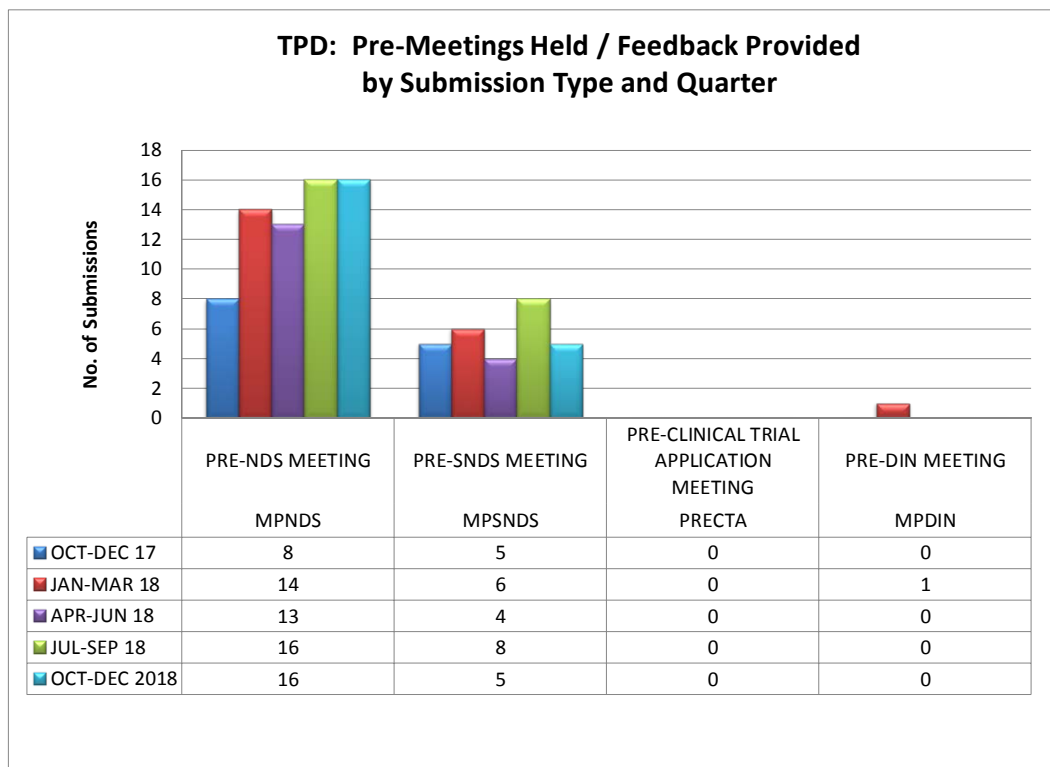
PDC					
DOCUMENT TYPE	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018
REGULAR					
CANCELLED BY COMPANY	5	4	3	7	4
NO OBJECTION LETTER	9	15	30	38	34
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

¹⁷ The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

Appendix A: Pre-submission Meetings

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Pre-submission Meetings Held / Feedback Provided



¹⁸ 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](#)