Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

January - March

2019

Canada

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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 January – March 2018 to January – March 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[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 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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[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 Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission	Submissions in support of a manufacturer or product name change.
Disinfectants[7]	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] 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)

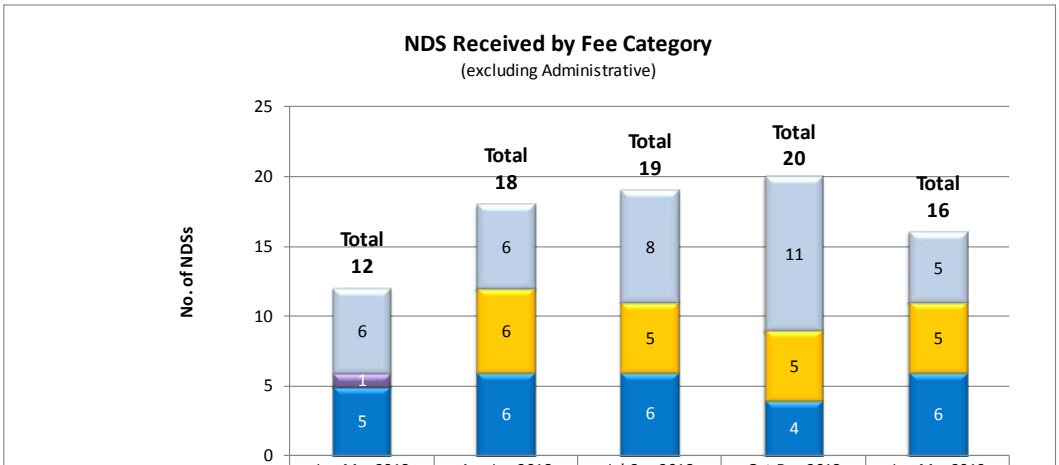
&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

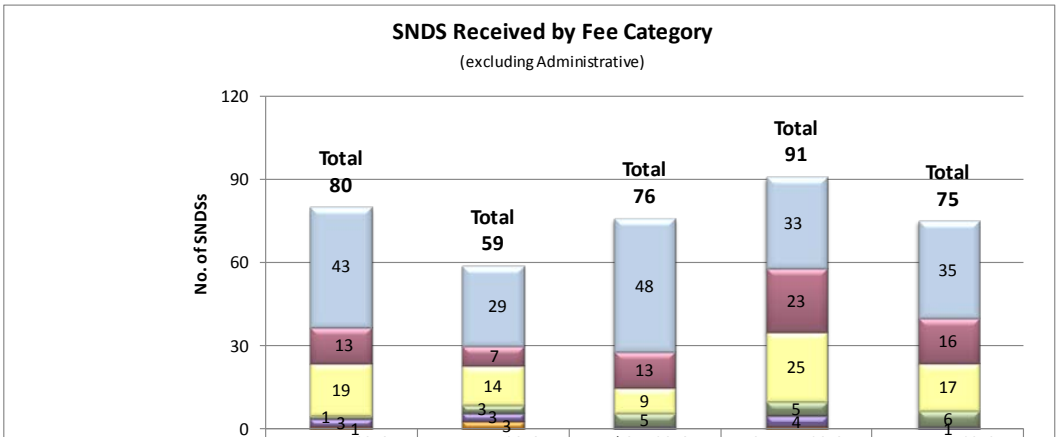
[8]

New Drug Submissions (NDS) Received by Fee Category



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	6	6	8	11	5
Comparative Studies	1	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	0	6	5	5	5
New Active Substance	5	6	6	4	6
Total	12	18	19	20	16
Priority Class	2	3	1	2	0
NOC-C Class	1	2	1	0	1
Emergency Use (NDS)	0	0	0	0	0

Supplemental New Drug Submissions (SNDS) Received by Fee Category

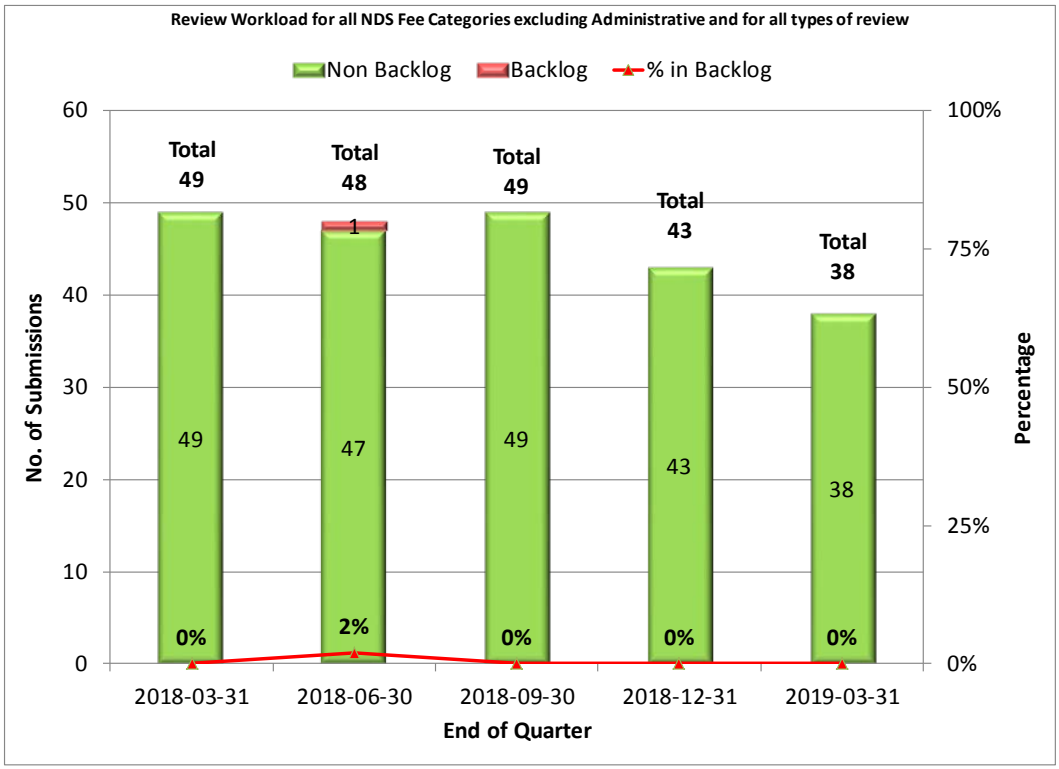


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	43	29	48	33	35
Chemistry & Manufacturing	13	7	13	23	16
Clinical or Non-Clin Only	19	14	9	25	17
Published Data Only	1	3	5	5	6
Comparative Studies	3	3	1	4	1
Clinical or Non-Clin and C&M	1	3	0	1	0
Total	80	59	76	91	75
Priority Class	2	3	2	3	1
NOC-C Class	2	0	0	0	0
SNDS Confirmatory	0	0	0	1	2

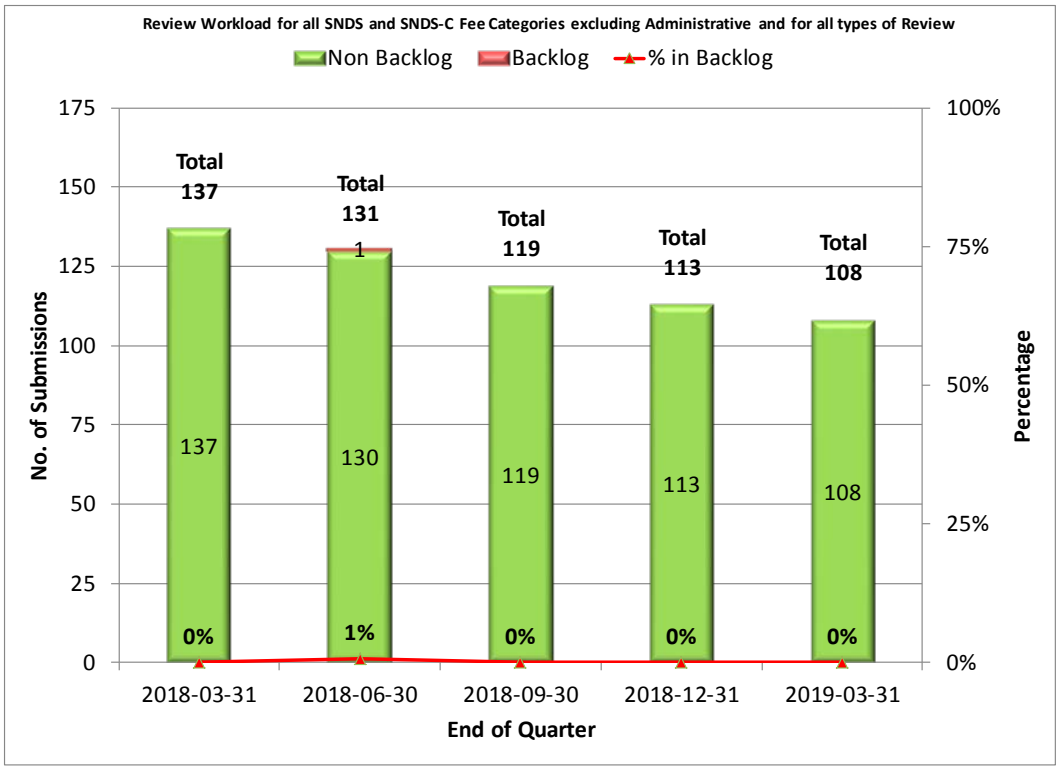
[8] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance 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

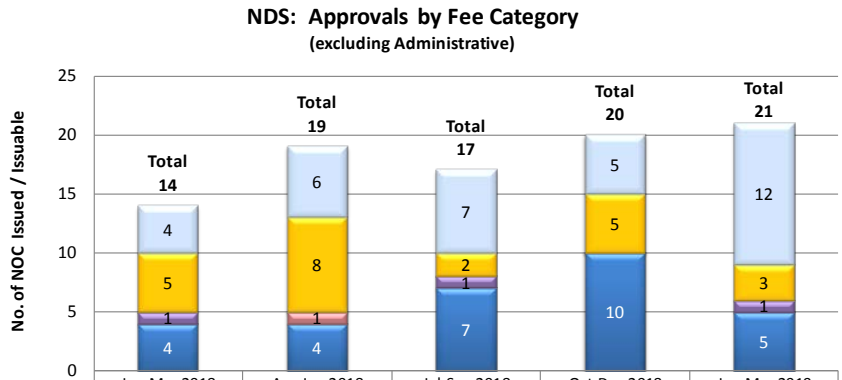
TPD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**4**	**4**	**5**	**8**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**1**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**18**	**16**	**16**	**15**	**15**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**25**	**27**	**27**	**19**	**19**
Backlog	*0*	*1*	*0*	*0*	*0*
Total	**49**	**48**	**49**	**43**	**38**
Non Backlog	**49**	**47**	**49**	**43**	**38**
Backlog	**0**	**1**	**0**	**0**	**0**
% in Backlog	**0%**	**2%**	**0%**	**0%**	**0%**
Priority (subset)	**6**	**7**	**6**	**4**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*

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

TPD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**19**	**15**	**23**	**21**	**10**
Backlog	*0*	*1*	*0*	*0*	*0*
Comparative Studies	**4**	**8**	**6**	**3**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**30**	**26**	**25**	**26**	**29**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**63**	**60**	**49**	**49**	**53**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**11**	**13**	**7**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**10**	**9**	**9**	**12**	**8**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**137**	**131**	**119**	**113**	**108**
Non Backlog	**137**	**130**	**119**	**113**	**108**
Backlog	**0**	**1**	**0**	**0**	**0**
% in Backlog	**0%**	**1%**	**0%**	**0%**	**0%**
Priority (subset)	**7**	**7**	**5**	**4**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**3**	**2**	**1**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

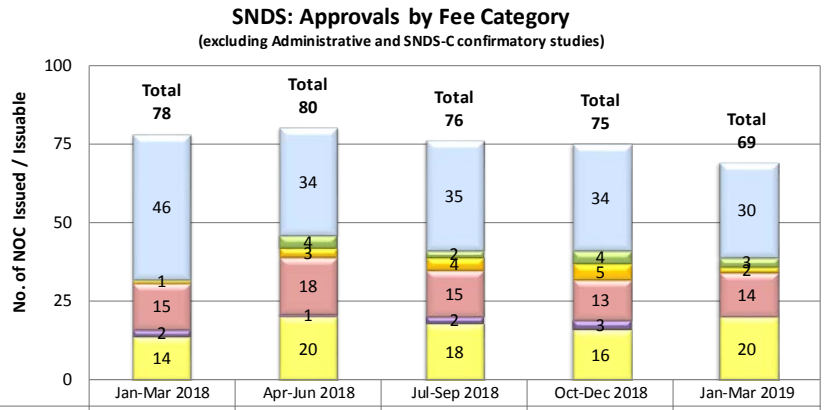
APPROVALS[9]

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	4	6	7	5	12
Clinical or Non-Clin and C&M	5	8	2	5	3
Clinical or Non-Clin Only	0	0	0	0	0
Comparative Studies	1	0	1	0	1
Chemistry & Manufacturing	0	1	0	0	0
New Active Substance	4	4	7	10	5
Total	14	19	17	20	21
Notice of Compliance	13	19	16	18	19
NOC with Conditions	0	0	1	1	2
NOC on Hold (Patent)	1	0	0	1	0
Priority Class	1	1	3	4	2
NOC-C Class	0	0	1	0	1

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	46	34	35	34	30
Published Data Only	0	4	2	4	3
Clinical or Non-Clin and C&M	1	3	4	5	2
Chemistry & Manufacturing	15	18	15	13	14
Comparative Studies	2	1	2	3	0
Clinical or Non-Clin Only	14	20	18	16	20
Total	78	80	76	75	69
Notice of Compliance	77	78	76	74	69
NOC with Conditions	1	2	0	1	0
NOC on Hold (Patent)	0	0	0	0	0
Priority Class	1	4	4	3	2
NOC-C Class	0	0	2	0	0

[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 .

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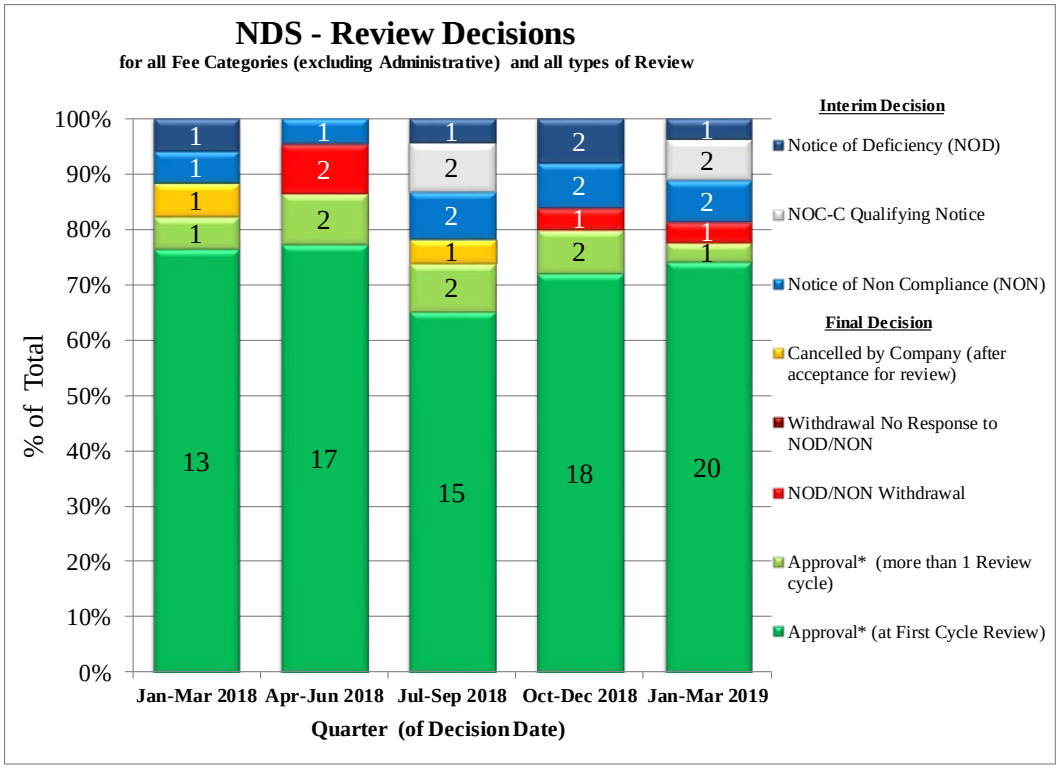
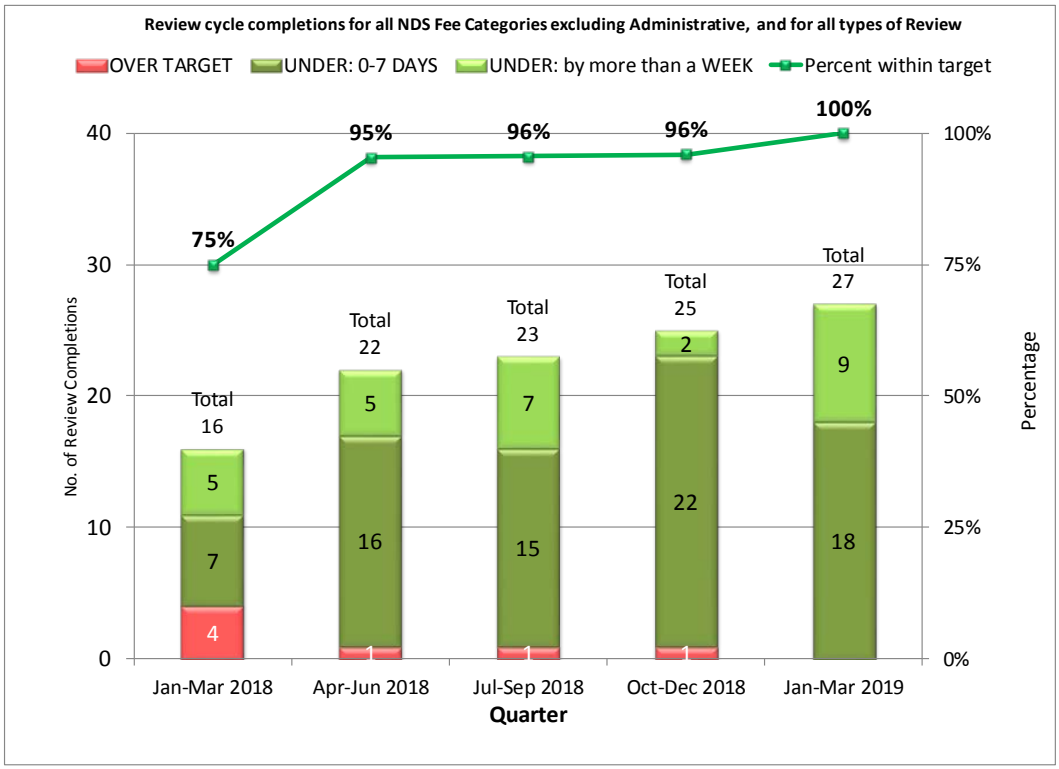
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

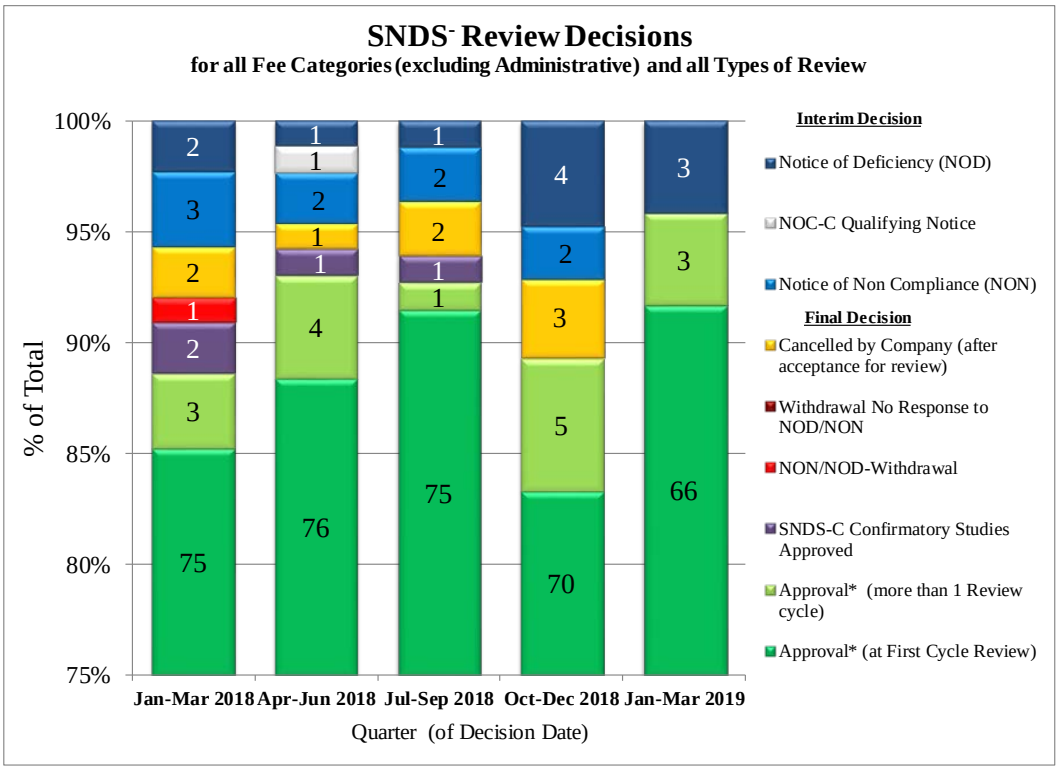


NDS - Review Cycle Completions Showing Percentage Within Target

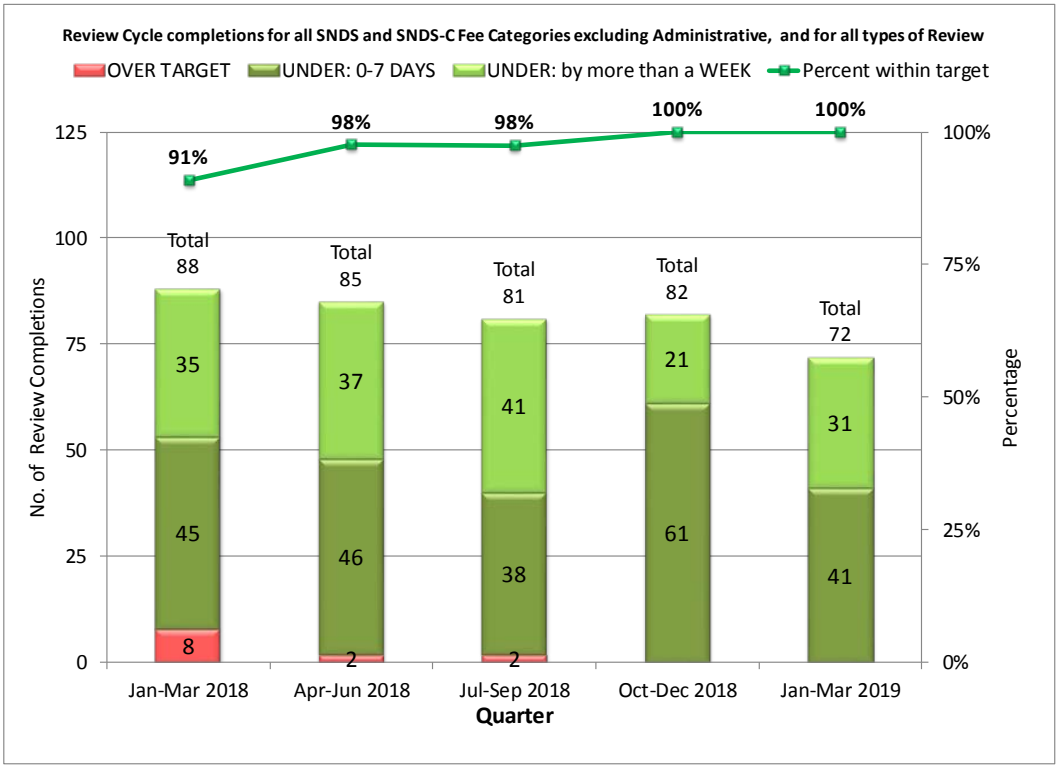


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

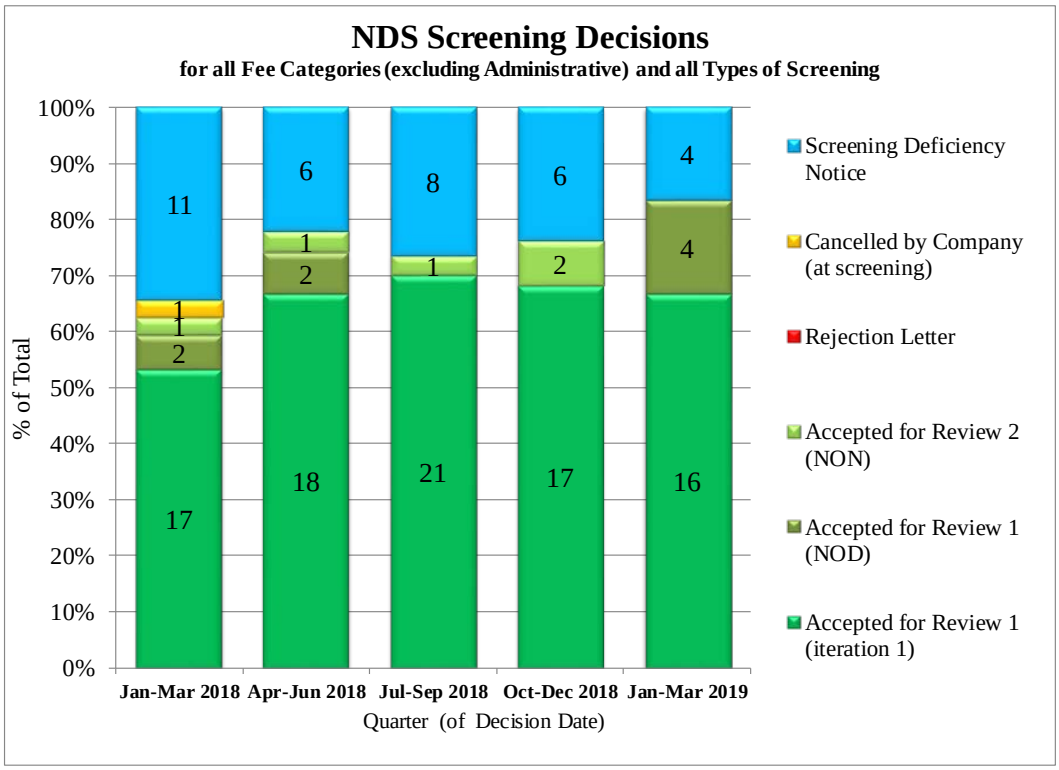


SNDS - Review Cycle Completions Showing Percentage Within Target

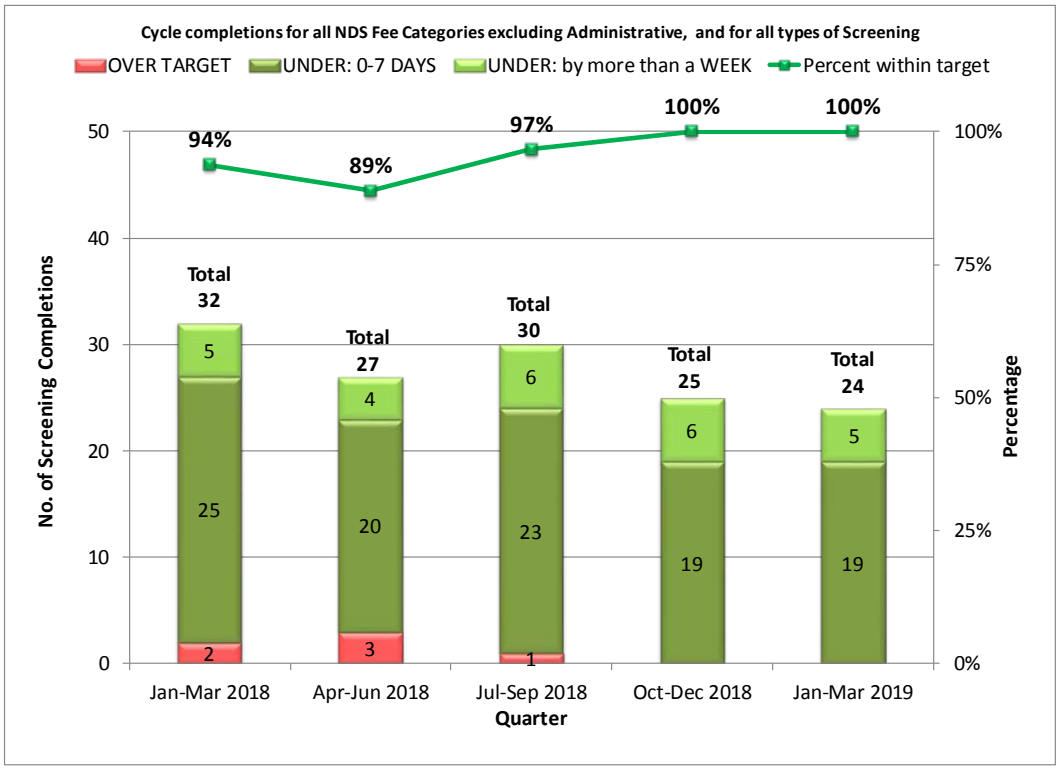


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

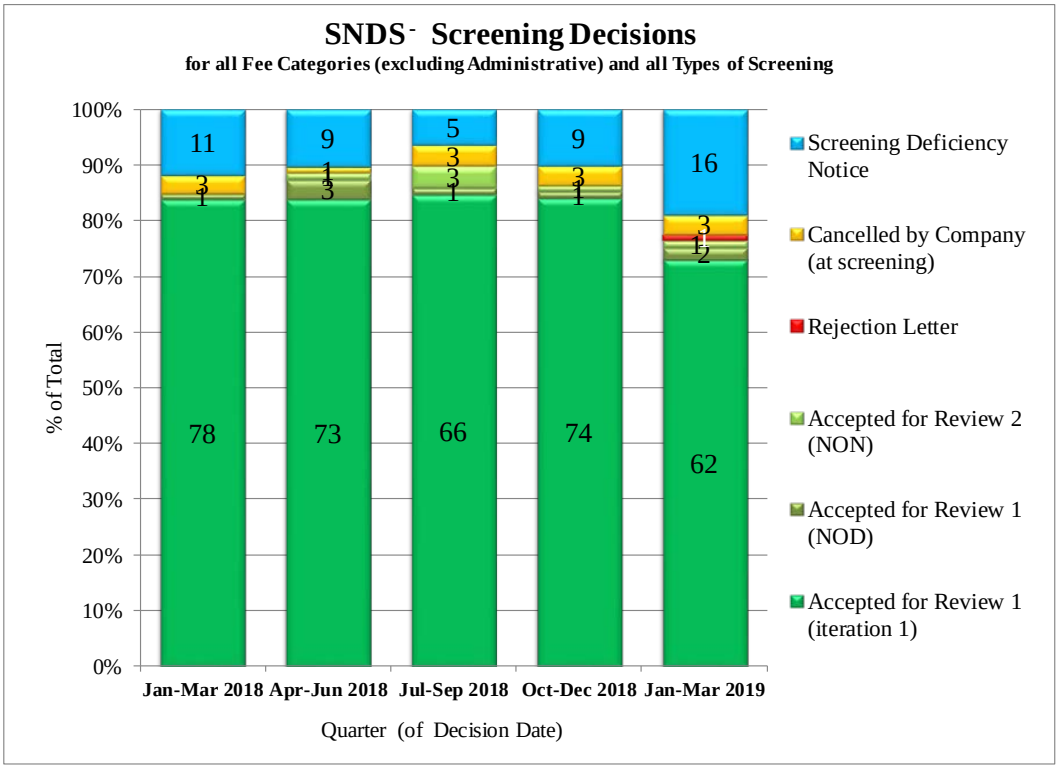


NDS - Screening Cycle Completions Showing Percentage Within Target

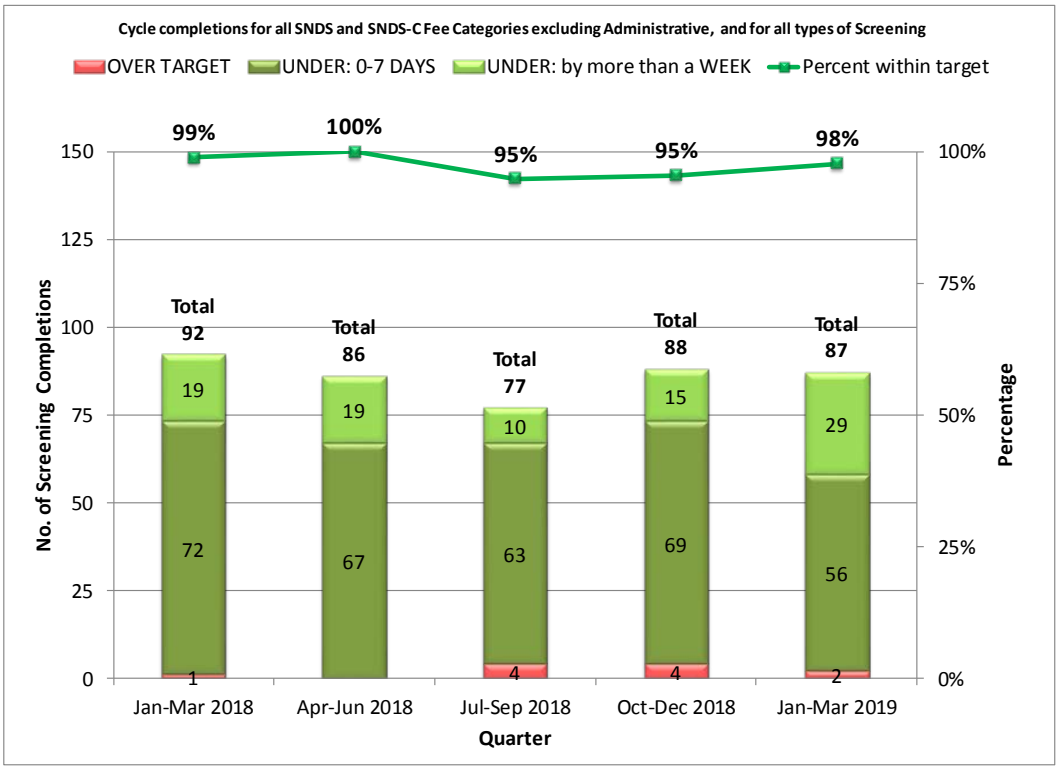


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



Abbreviated New Drug Submissions (ANDS)

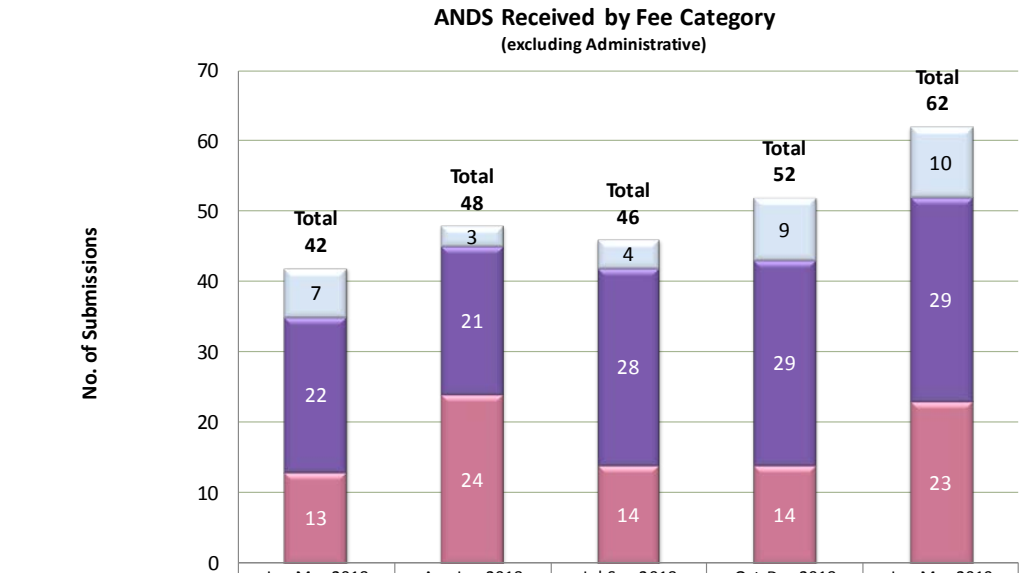
&

Supplemental Abbreviated New Drug Submissions

(SANDS)

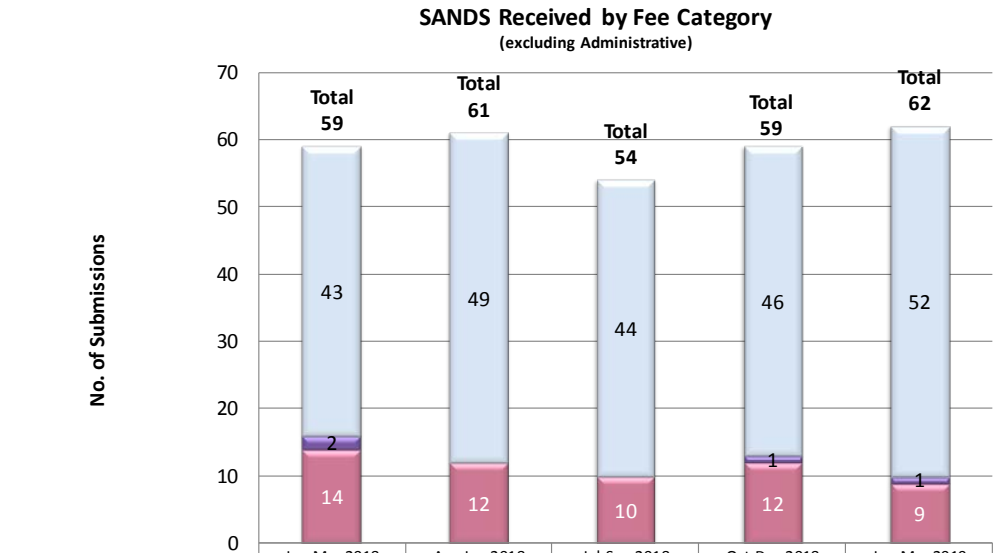
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	7	3	4	9	10
Comparative Studies	22	21	28	29	29
Chemistry & Manufacturing	13	24	14	14	23
Total	42	48	46	52	62

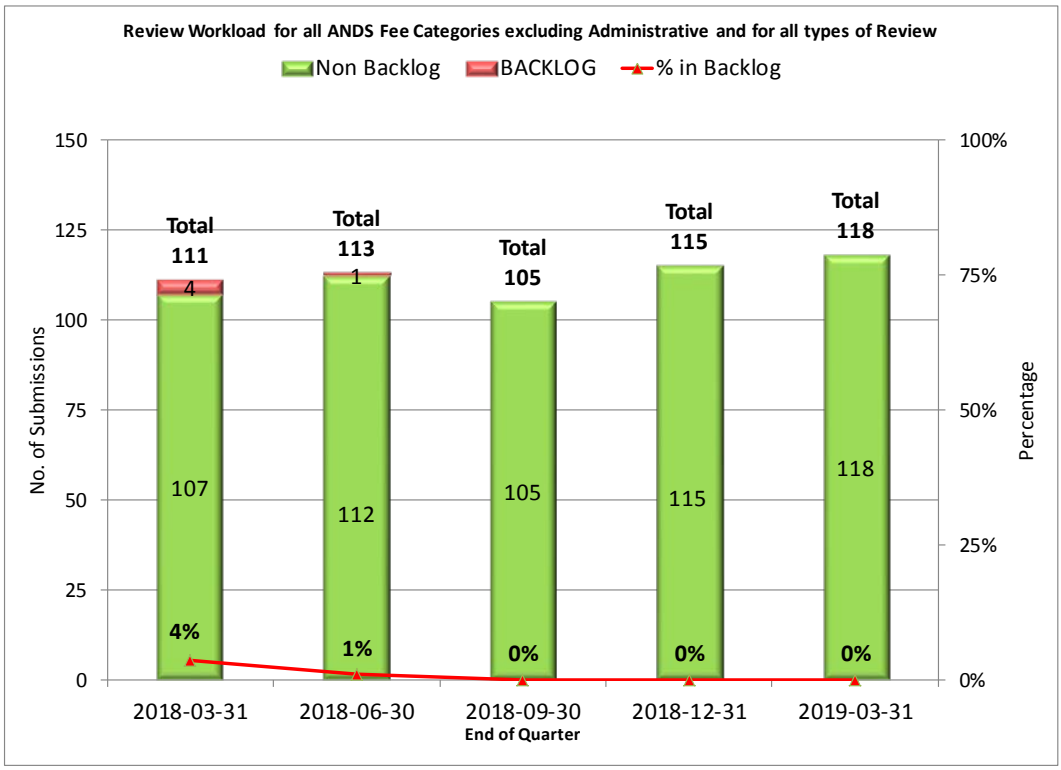
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



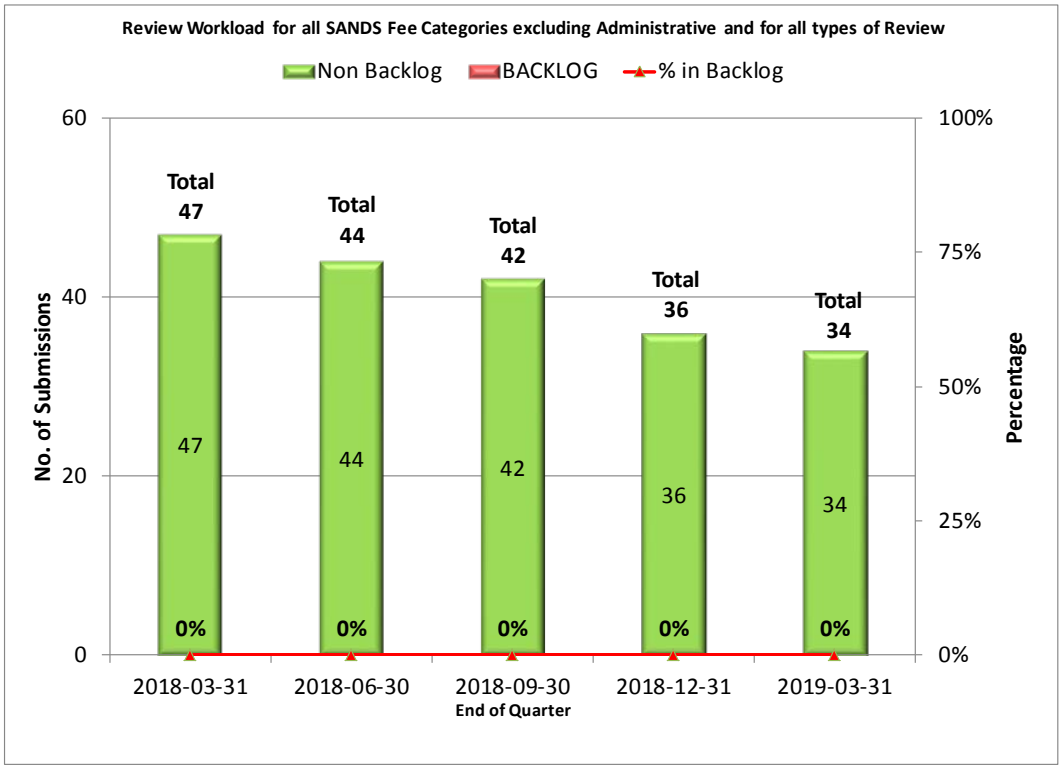
	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	43	49	44	46	52
Comparative Studies	2	0	0	1	1
Chemistry & Manufacturing	14	12	10	12	9
Total	59	61	54	59	62

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

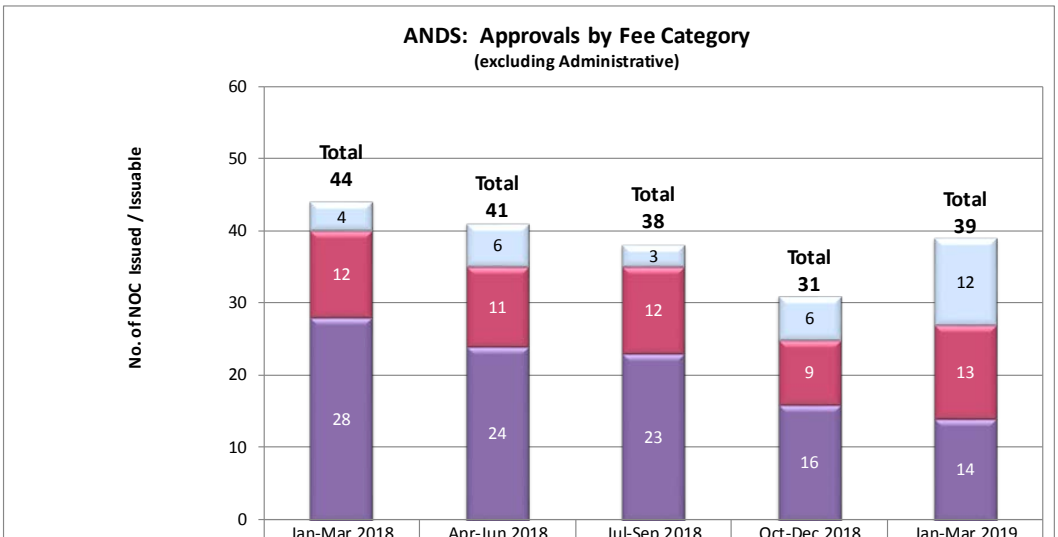
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Chemistry & Manufacturing	43	45	51	40	38
Backlog	*2*	*1*	*0*	*0*	*0*
Comparative Studies	65	68	52	70	77
Backlog	*2*	*0*	*0*	*0*	*0*
Labelling Only	3	0	2	5	3
Backlog	*0*	*0*	*0*	*0*	*0*
Total	111	113	105	115	118
Non Backlog	107	112	105	115	118
BACKLOG	4	1	0	0	0
% in Backlog	4%	1%	0%	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					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Chemistry & Manufacturing	26	24	25	21	22
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	2	1	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	19	18	16	15	10
Backlog	*0*	*0*	*0*	*0*	*0*
Total	47	44	42	36	34
Non Backlog	47	44	42	36	34
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

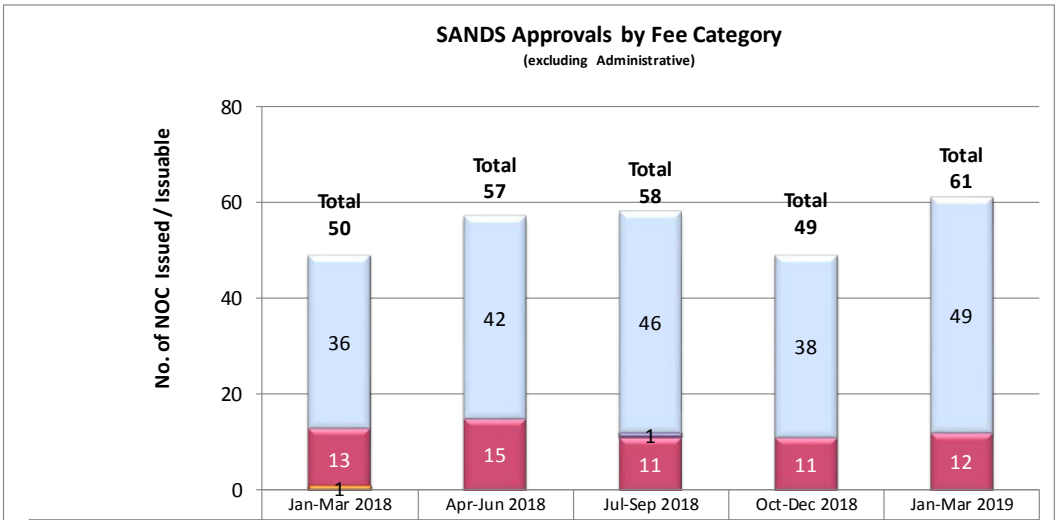
APPROVALS

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	4	6	3	6	12
Chemistry & Manufacturing	12	11	12	9	13
Comparative Studies	28	24	23	16	14
Total	44	41	38	31	39
Notice of Compliance	25	28	29	23	29
NOC on Hold (Patent)	19	13	9	8	10
NOC with Conditions	0	0	0	0	

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	36	42	46	38	49
Comparative Studies	0	0	1	0	0
Chemistry & Manufacturing	13	15	11	11	12
Published Data Only	1	0	0	0	0
Total	50	57	58	49	61
Notice of Compliance	45	55	54	43	54
NOC on Hold (Patent)	5	2	4	6	7
NOC with Conditions	0	0	0	0	0

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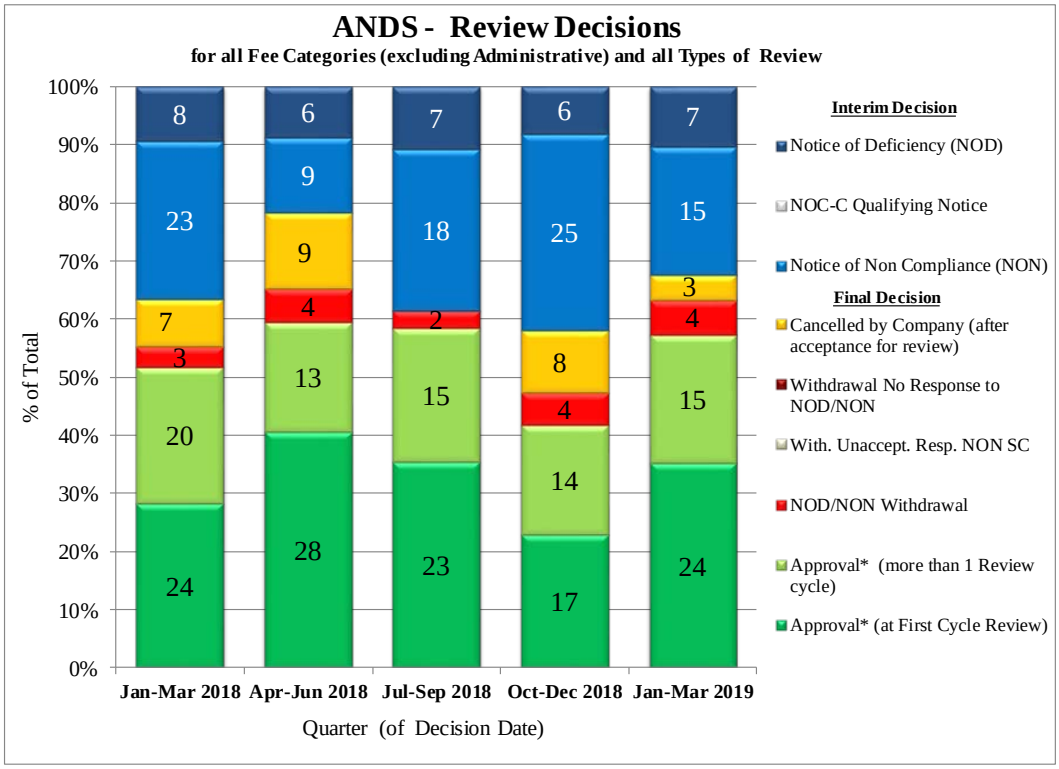
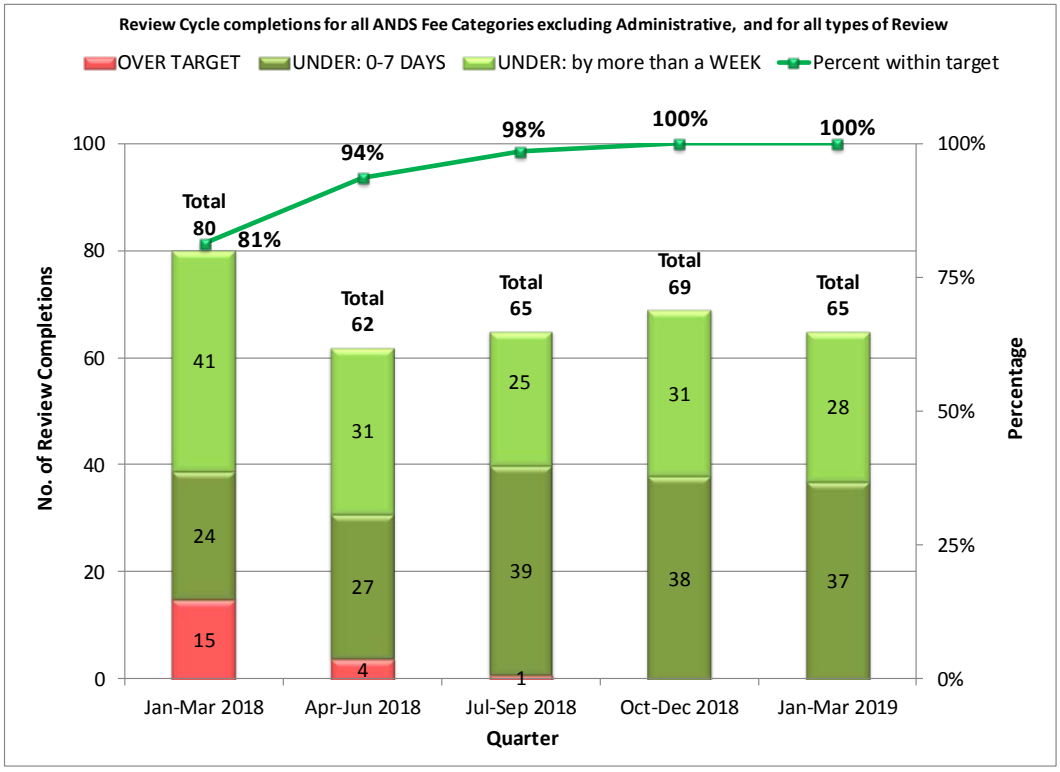
REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

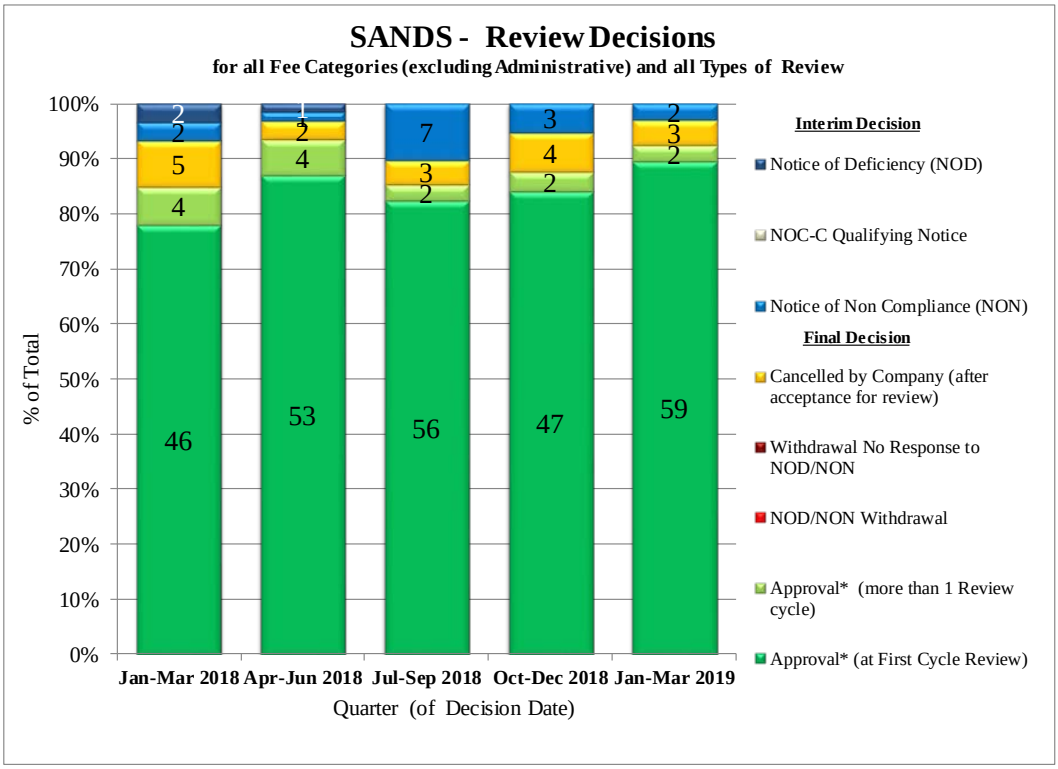


ANDS - Review Cycle Completions Showing Percentage Within Target

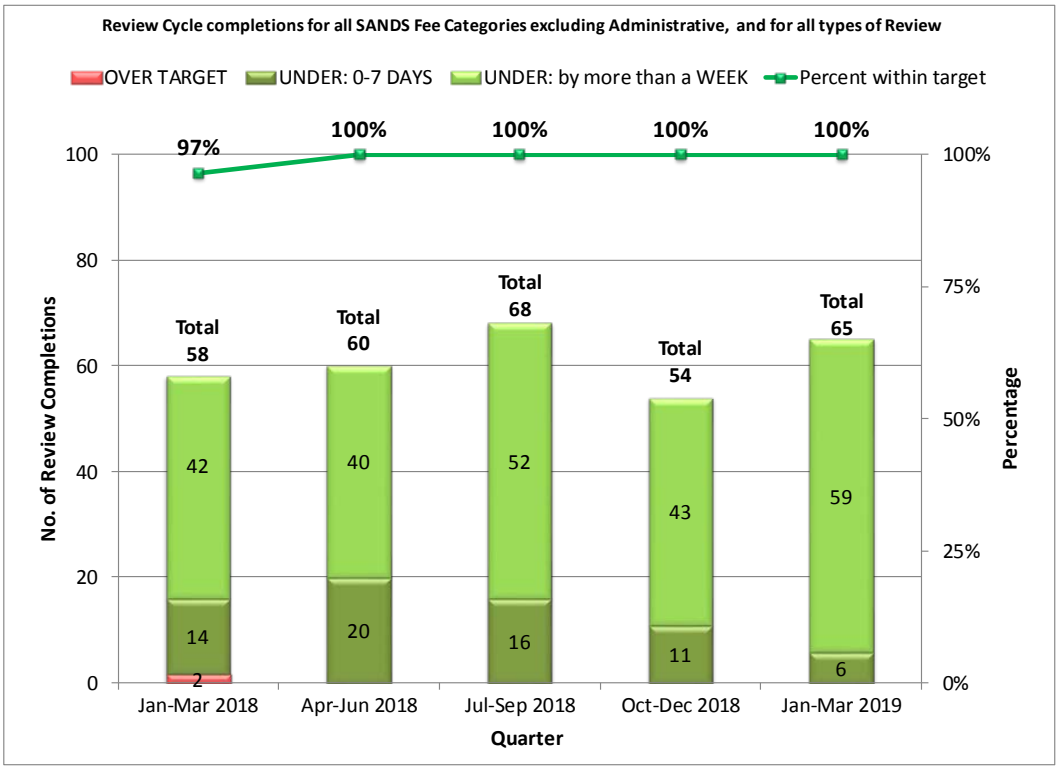


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

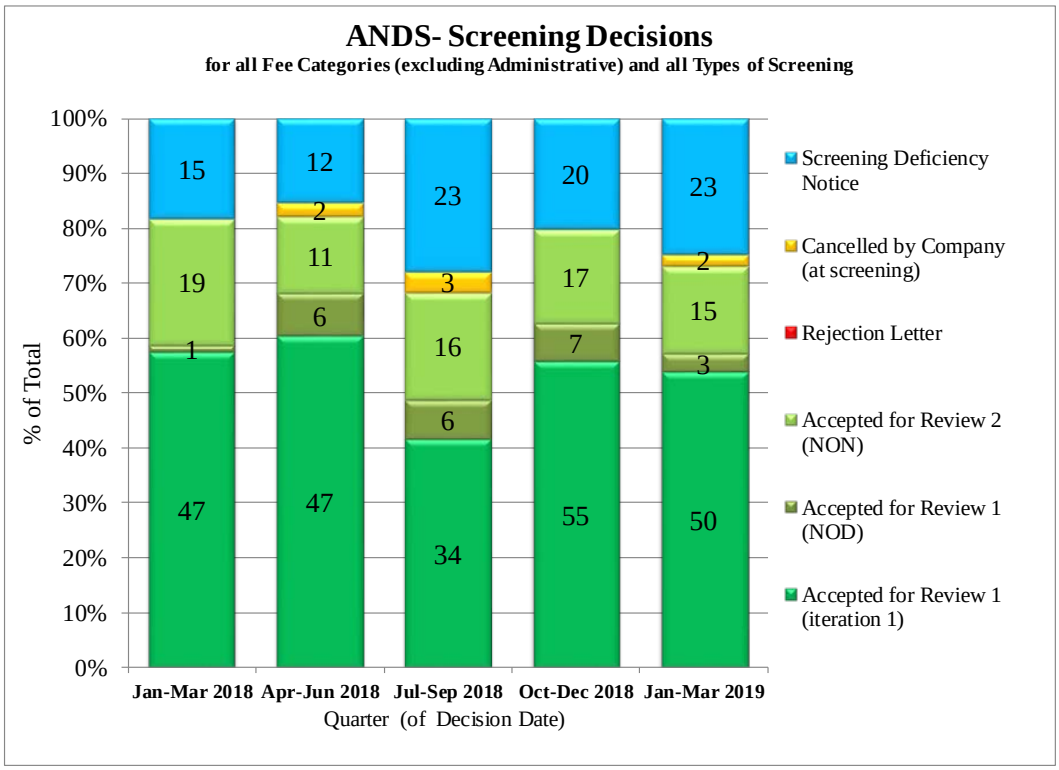


SANDS - Review Cycle Completions Showing Percentage Within Target

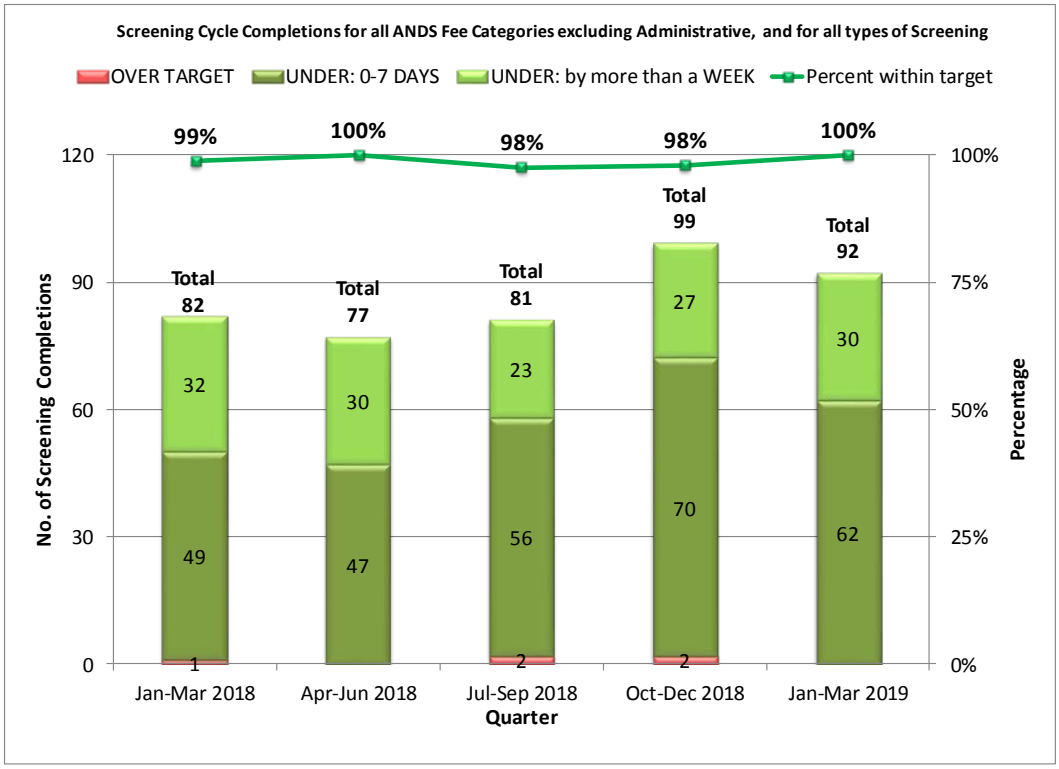


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

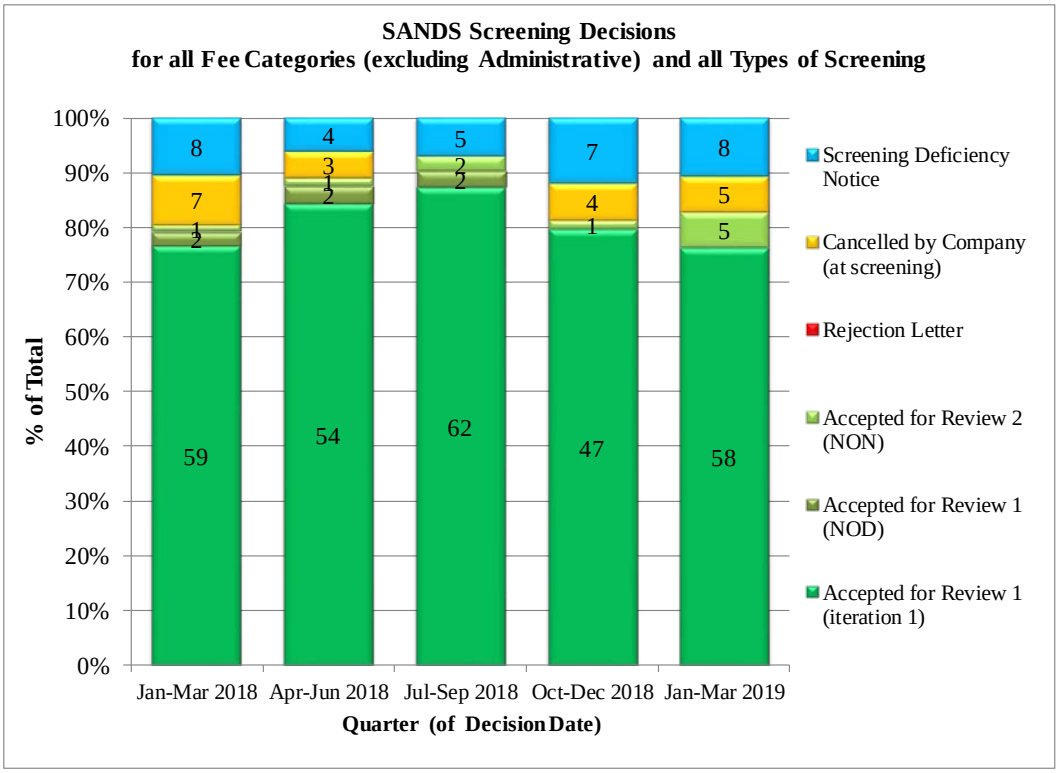


ANDS - Screening Cycle Completions Showing Percentage Within Target

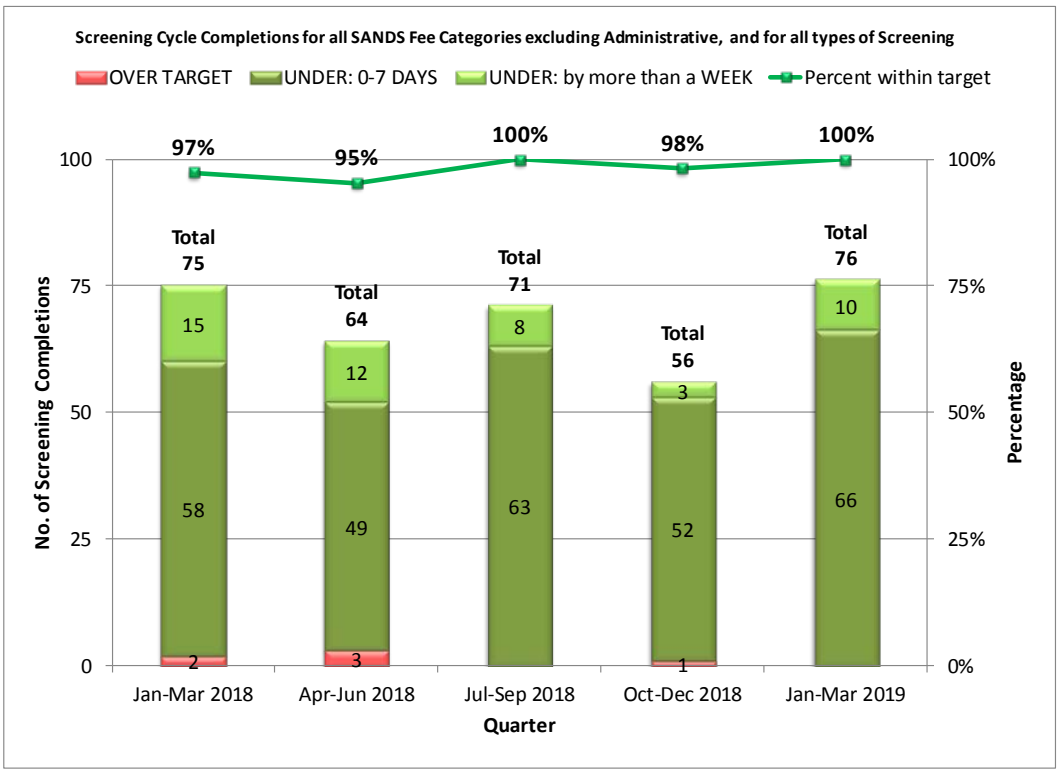


SCREENING CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions

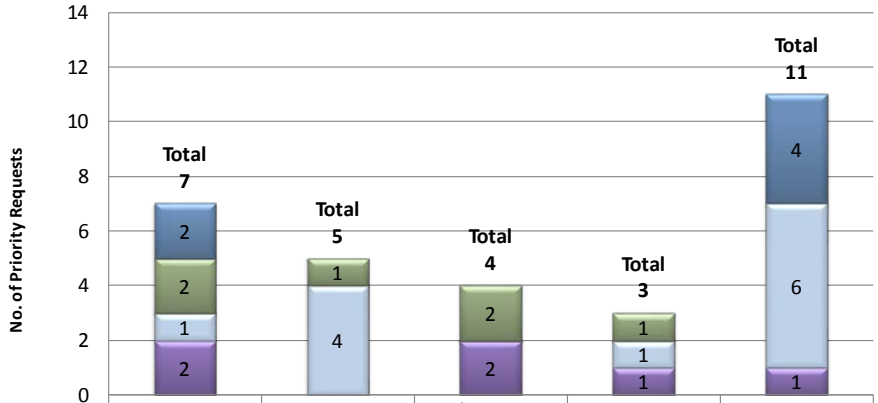


SANDS - Screening Cycle Completions Showing Percentage Within Target



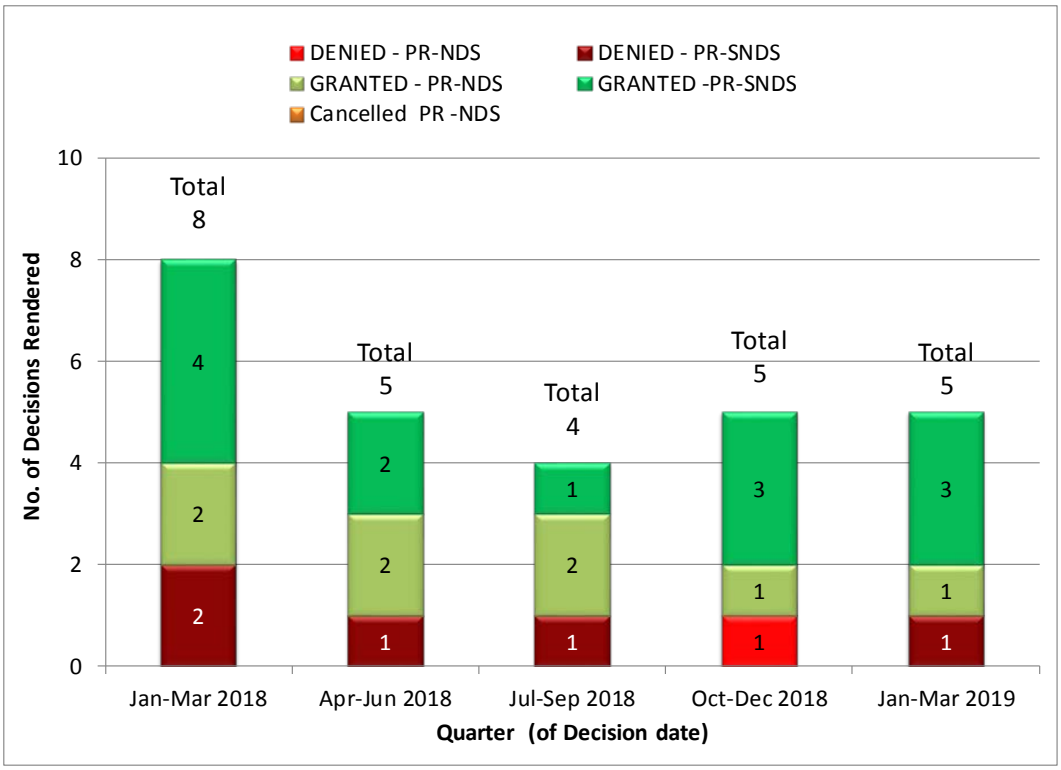
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

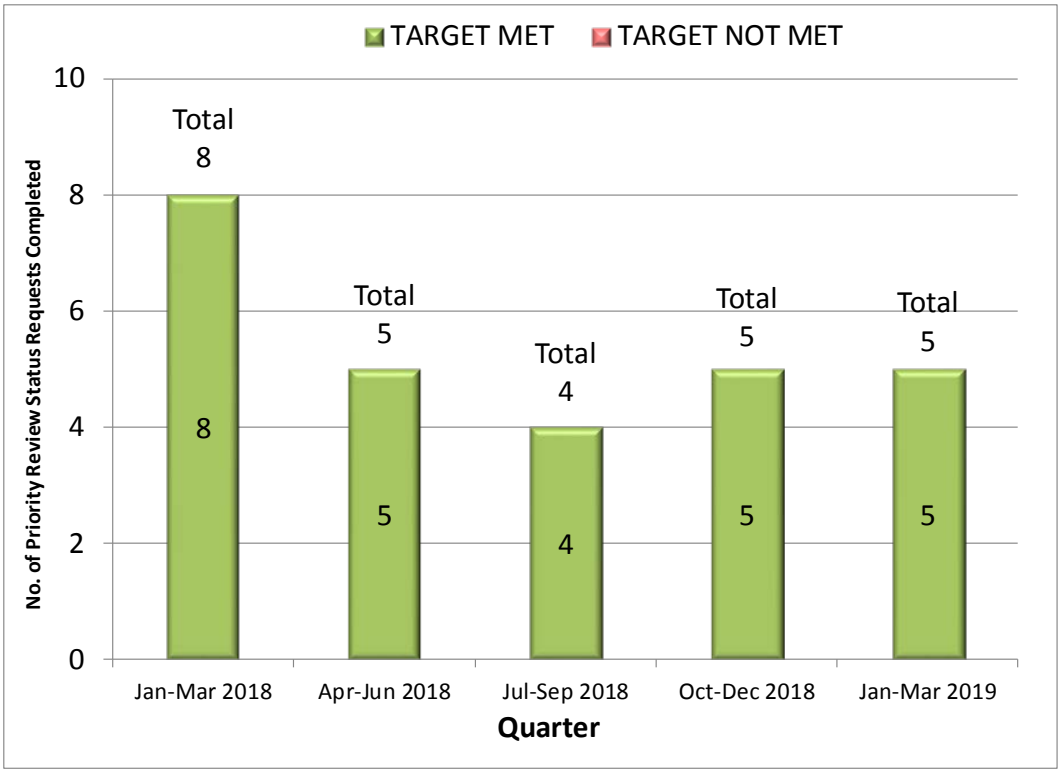


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
PR-NDS COMP/C&M	0	0	0	0	0
PR-NDS C&M	0	0	0	0	0
PR-NDS CLIN ONLY	2	0	0	0	4
PR-NDS CLIN/C&M	2	1	2	1	0
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN ONLY	1	4	0	1	6
PR-SNDS CLIN/C&M	2	0	2	1	1
Total	7	5	4	3	11

Priority Review Status Requests: Decisions Rendered



Priority Review Status Requests: Performance

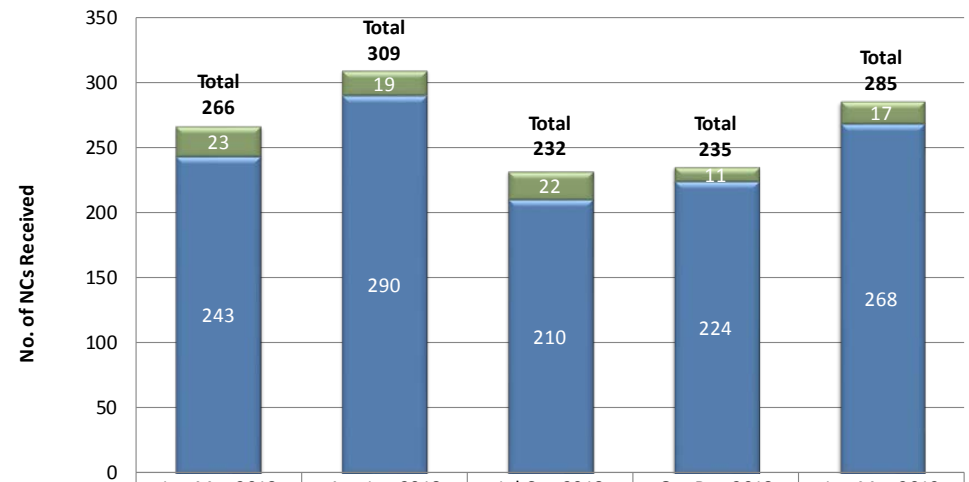


NOTIFIABLE CHANGES (NC)

NOTIFIABLE CHANGES[10]

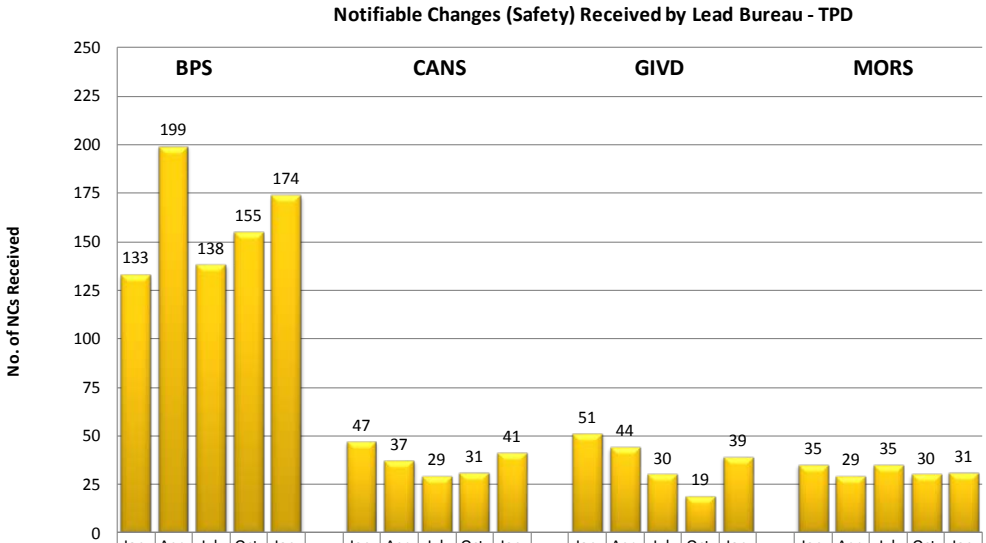
SUBMISSIONS RECEIVED

Number Received - Notifiable Changes (NC) - by Class



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Safety (120)	23	19	22	11	17
Safety (90)	243	290	210	224	268
Total	266	309	232	235	285

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

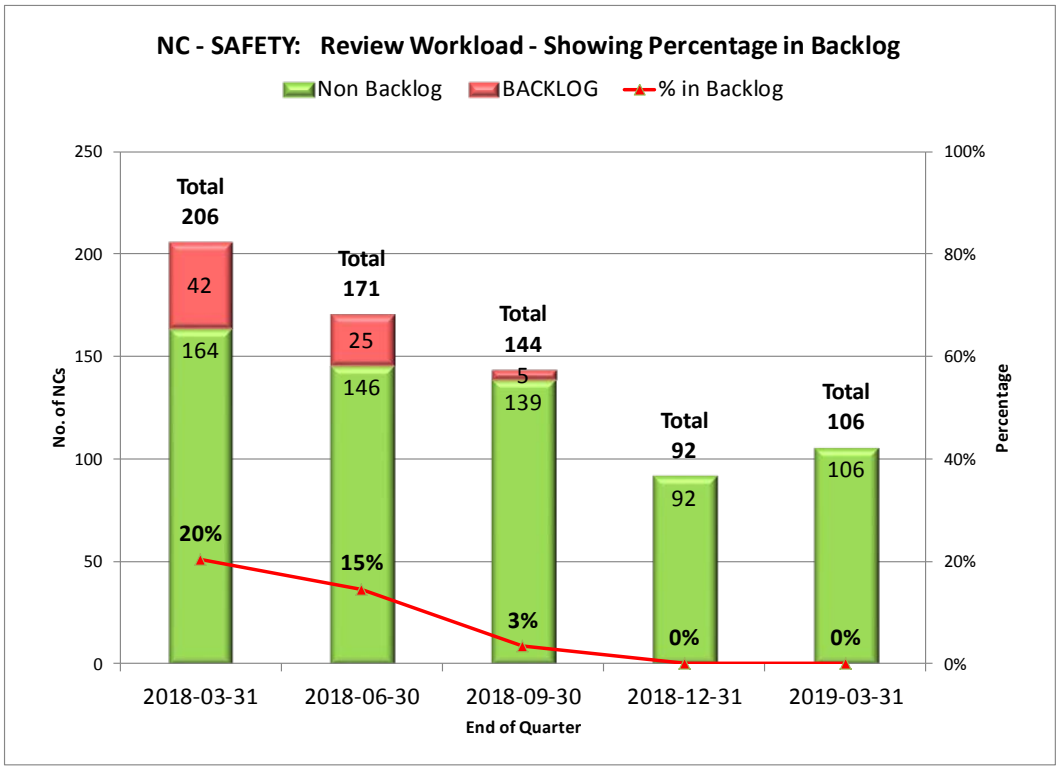


	BPS Jan-Mar 2018	BPS Apr-Jun 2018	BPS Jul-Sep 2018	BPS Oct-Dec 2018	BPS Jan-Mar 2019	CANS Jan-Mar 2018	CANS Apr-Jun 2018	CANS Jul-Sep 2018	CANS Oct-Dec 2018	CANS Jan-Mar 2019	GIVD Jan-Mar 2018	GIVD Apr-Jun 2018	GIVD Jul-Sep 2018	GIVD Oct-Dec 2018	GIVD Jan-Mar 2019	MORS Jan-Mar 2018	MORS Apr-Jun 2018	MORS Jul-Sep 2018	MORS Oct-Dec 2018	MORS Jan-Mar 2019
TOTAL	133	199	138	155	174	47	37	29	31	41	51	44	30	19	39	35	29	35	30	31
SAFETY 120	4	0	2	1	7	2	2	1	3	4	13	12	12	4	1	4	5	7	3	5
SAFETY 90	129	199	136	154	167	45	35	28	28	37	38	32	18	15	38	31	24	28	27	26

[10] 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

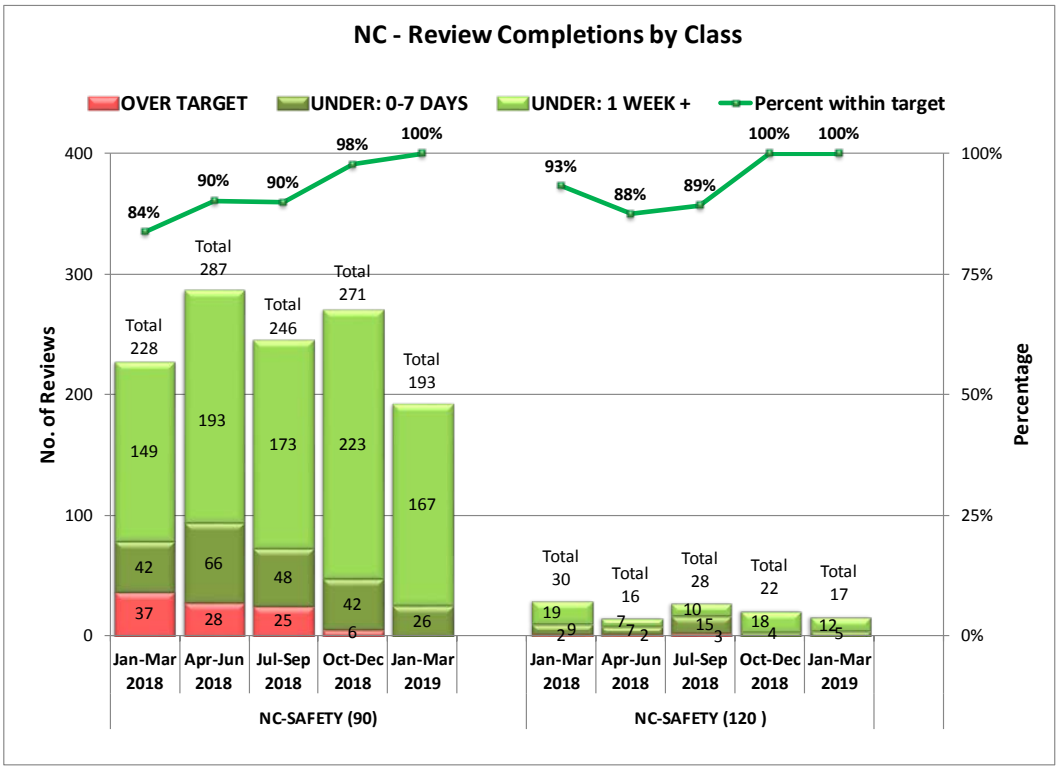


Notifiable Change (NC) SAFETY: Review Workload by Class

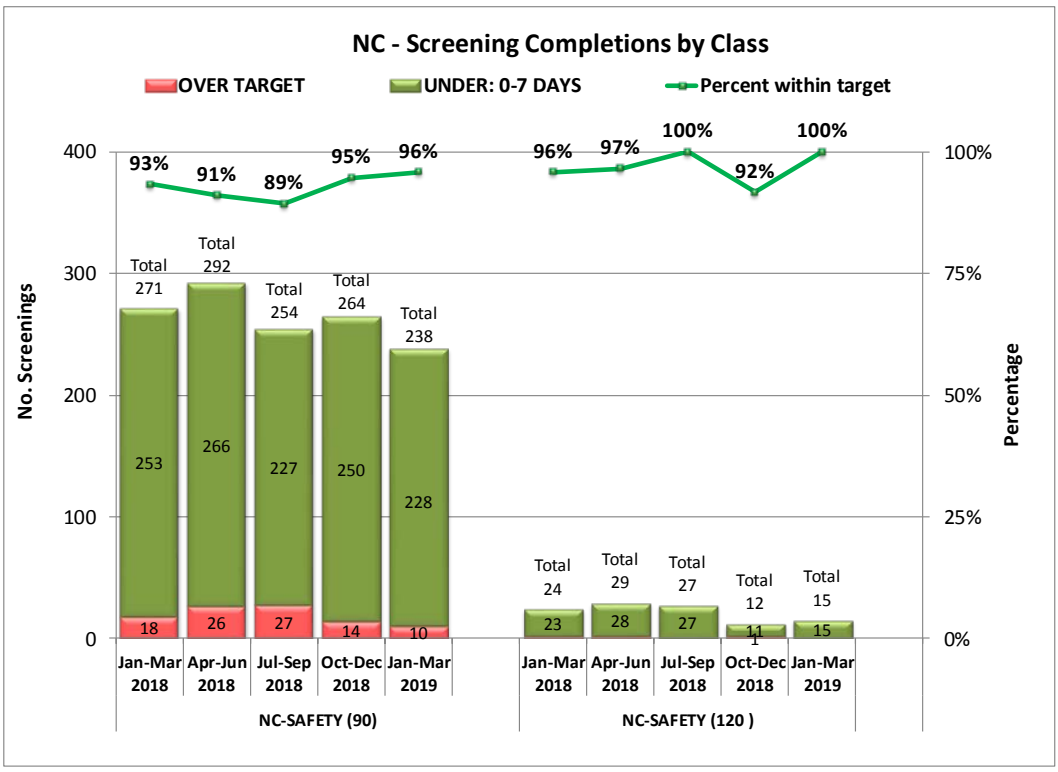
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
SAFETY - 90 day	184	145	119	78	95
Backlog	*39*	*23*	*5*	*0*	*0*
SAFETY - 120 day	22	26	25	14	11
Backlog	*3*	*2*	*0*	*0*	*0*
Total	206	171	144	92	106
Non Backlog	164	146	139	92	106
BACKLOG	42	25	5	0	0
% in Backlog	20%	15%	3%	0%	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	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	232	278	234	270	195
NOT SATISFACTORY NOTICE	0	0	0	1	0
REJECTION LETTER (SCR)	1	0	2	0	0
SCREENING DEFICIENCY NOTICE	36	38	25	32	20
CANCELLED BY COMPANY	11	25	10	10	18
NC - HOLD (PATENT)	16	6	14	9	6
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

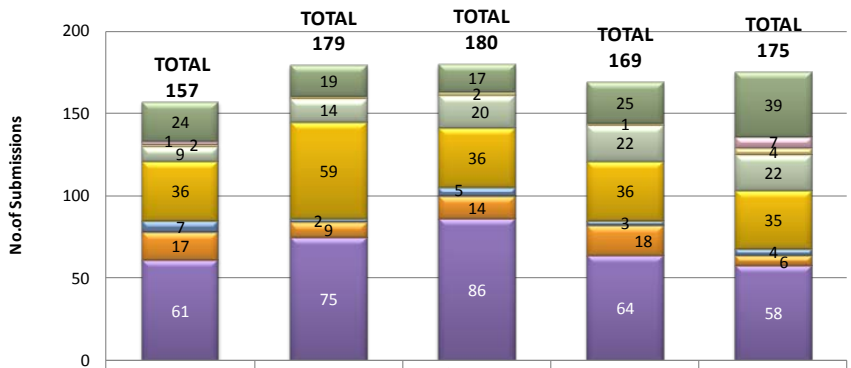
NC - SAFETY (120)					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	30	15	28	22	16
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	6	8	1	1	1
CANCELLED BY COMPANY	1	2	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	1

Administrative Submissions

(Manufacturer and/or Product Name Changes) [11]

RECEIVED

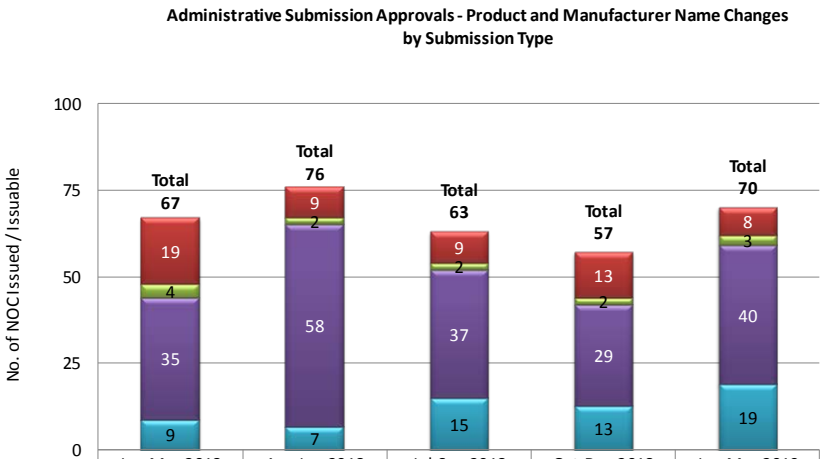
Administrative Submissions Received by Submission Type



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
DINA	24	19	17	25	39
DINF	2	0	0	0	7
PDC	1	1	2	1	4
SANDS	9	14	20	22	22
ANDS	36	59	36	36	35
SNDS	7	2	5	3	4
NDS	17	9	14	18	6
NC	61	75	86	64	58
TOTAL	157	179	180	169	175

APPROVALS

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
NDS	19	9	9	13	8
SNDS	4	2	2	2	3
ANDS	35	58	37	29	40
SANDS	9	7	15	13	19
Total	67	76	63	57	70

[11] 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 [12])

DECISIONS

Administrative Submissions/ Applications: DECISIONS

Administrative Submission/Applications - Decisions by Submission Type - TPD *Figures Corrected

NDS	Jan-Mar 2018*	Apr-Jun 2018*	Jul-Sep 2018*	Oct-Dec 2018*	Jan-Mar 2019*
NOTICE OF COMPLIANCE	19	9	9	16	8
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	0	2	1	1	0
PROCESSING HOLD LETTER	5	0	3	7	2
SNDS	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NOTICE OF COMPLIANCE	4	2	2	2	3
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	0	2	2	3	0
PROCESSING HOLD LETTER	0	1	3	1	0
ANDS	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NOTICE OF COMPLIANCE	34	57	37	31	40
NOC ON IP HOLD	1	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	3	0	2	0
CANCELLATION LETTER	4	4	0	0	2
PROCESSING HOLD LETTER	10	23	12	6	3
SANDS	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NOTICE OF COMPLIANCE	9	7	15	15	19
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	1	0	0
CANCELLATION LETTER	0	1	6	1	1
PROCESSING HOLD LETTER	6	7	5	5	3
NC	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NO OBJECTION LETTER	70	53	100	64	48
NC - HOLD (PATENT)	0	0	1	0	0
CANCELLATION LETTER	7	5	10	3	3
PROCESSING HOLD LETTER		4	4	4	4
DINA	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NOTIFICATION FORM / DIN Issued	19	20	10	13	41
NO OBJECTION LETTER	0	0	1	0	1
SCREENING DEFICIENCY NOTICE	0	0	1	7	0
CANCELLATION LETTER	0	2	2	2	5
PROCESSING HOLD LETTER	4	4	13	6	4
PDC	**Jan-Mar 2018***	**Apr-Jun 2018***	**Jul-Sep 2018***	**Oct-Dec 2018***	**Jan-Mar 2019***
NO OBJECTION LETTER	1	0	1	2	2
CANCELLATION LETTER	0	1	1	0	1
PROCESSING HOLD LETTER	0	2	0	0	0

*This table was introduced in the previous quarterly report. The correction required was that the quarterly figures in the original table needed to be transcribed to the following quarter.

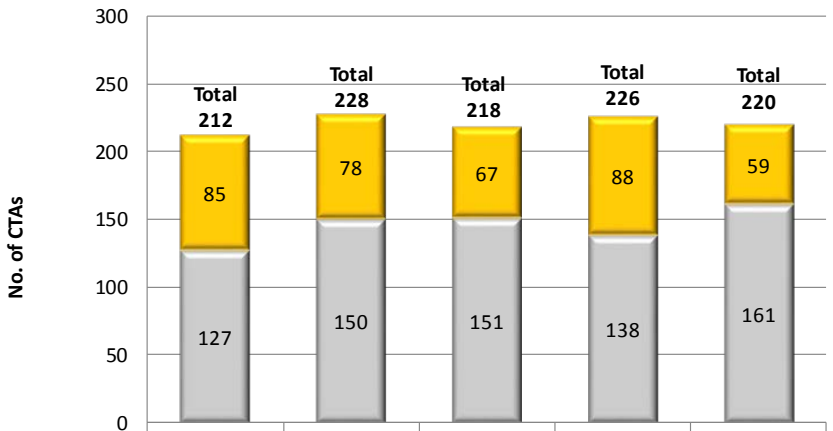
[12] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

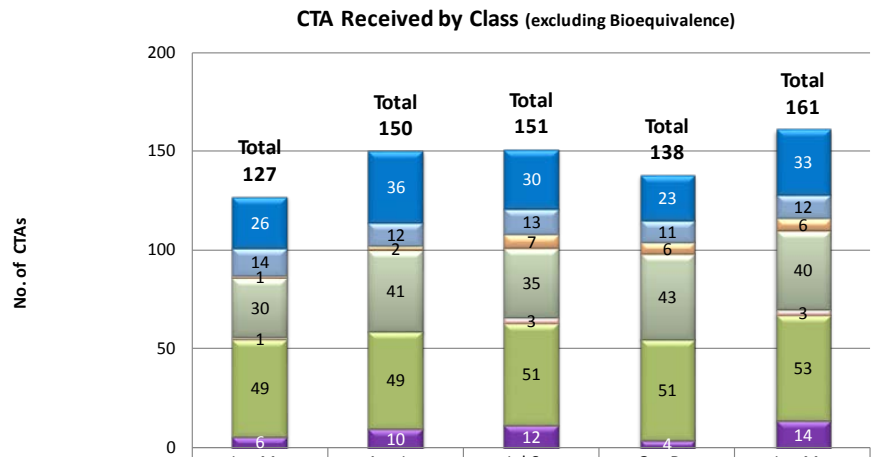
Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Phase 1 Bioequivalence (7 day admin. Target)	85	78	67	88	59
Total (Non Bioequivalence)	127	150	151	138	161
Total	212	228	218	226	220

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Phase 1 HEALTHY HUMAN-30	26	36	30	23	33
Phase 1 OTHER - 30 DAYS	14	12	13	11	12
Phase 1/2 - 30 DAYS	1	2	7	6	6
Phase 2 - 30 DAYS	30	41	35	43	40
Phase 2/3 - 30 DAYS	1	0	3	0	3
Phase 3 - 30 DAYS	49	49	51	51	53
Phase Other	6	10	12	4	14
Total	127	150	151	138	161

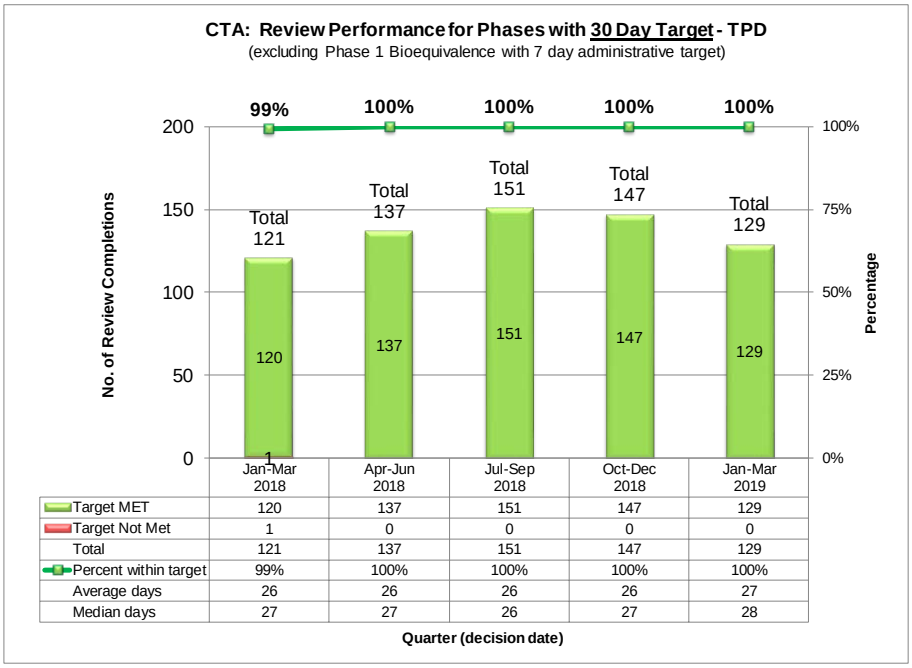
DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

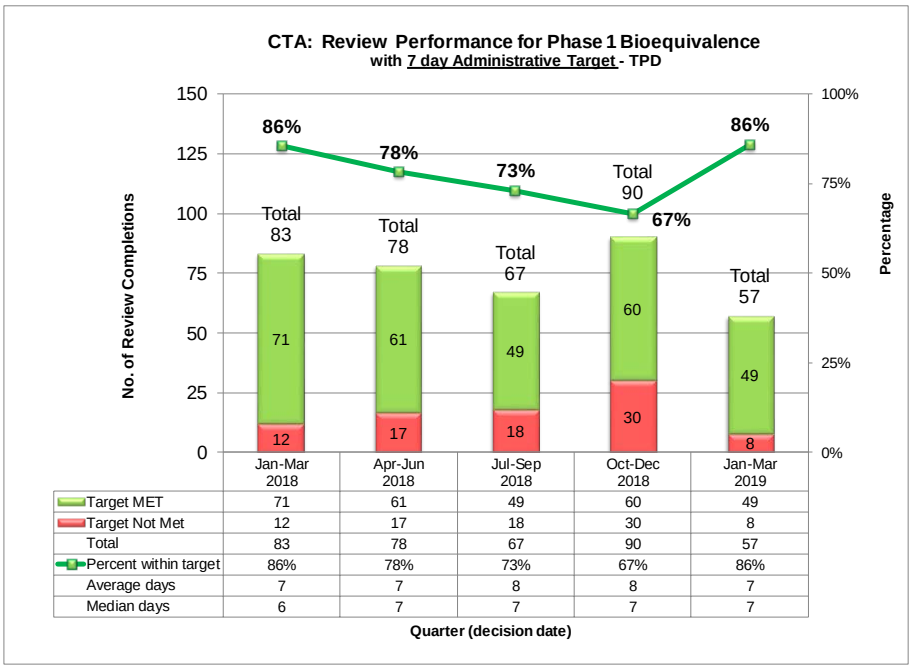
CTA					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	189	208	211	226	176
CANCELLED BY COMPANY DURING REVIEW	15	7	6	12	12
CANCELLED BY COMPANY AT PROCESSING	5	5	3	2	1
NOT SATISFACTORY NOTICE	0	0	0	0	1

PERFORMANCE

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

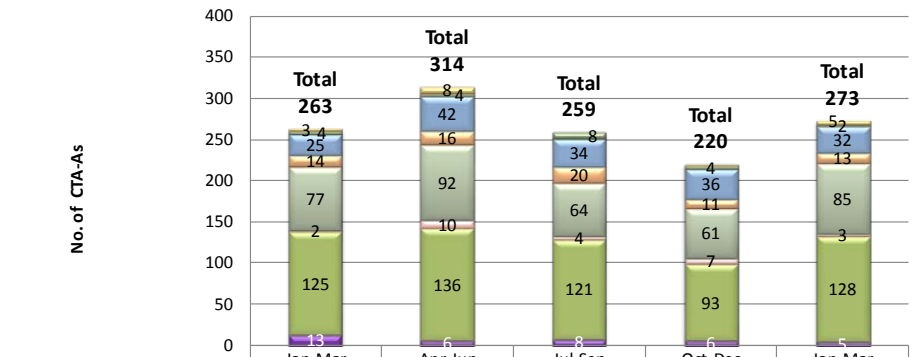


Performance – CTA Review: 7 Day Administrative Target



Clinical Trial Application – Amendments (CTA–A)

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Phase 1 BIOEQUIVALENCE-7	3	8	0	2	5
Phase 1 HEALTHY HUMAN-30	4	4	8	4	2
Phase 1 OTHER - 30 DAYS	25	42	34	36	32
Phase 1/2 - 30 DAYS	14	16	20	11	13
Phase 2 - 30 DAYS	77	92	64	61	85
Phase 2/3 - 30 DAYS	2	10	4	7	3
Phase 3 - 30 DAYS	125	136	121	93	128
Phase Other	13	6	8	6	5
Total	263	314	259	220	273

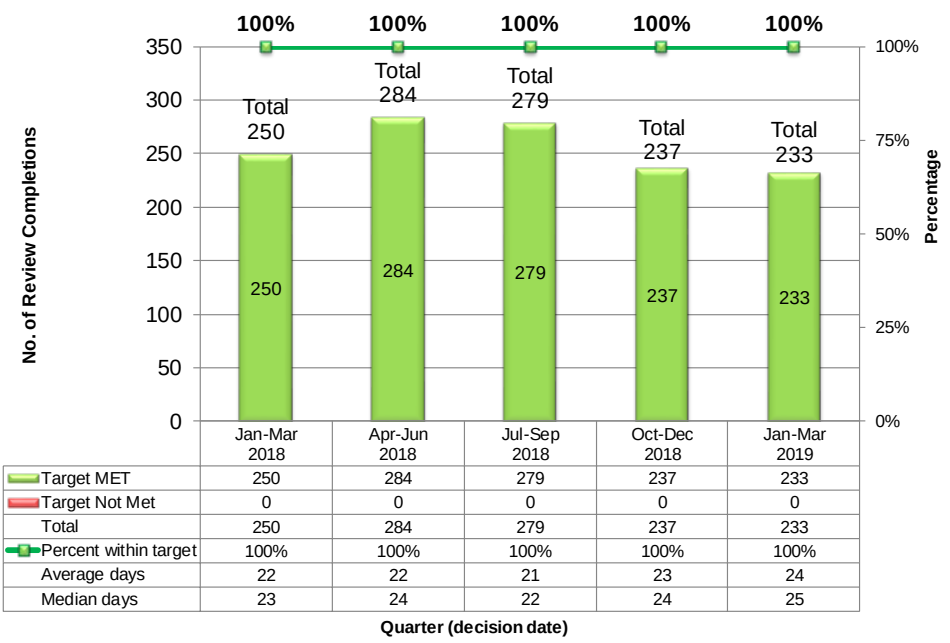
DECISION DOCUMENTS

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

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	250	284	276	236	236
CANCELLED BY COMPANY DURING REVIEW	3	7	4	3	1
CANCELLED BY COMPANY AT PROCESSING	0	1	0	1	1

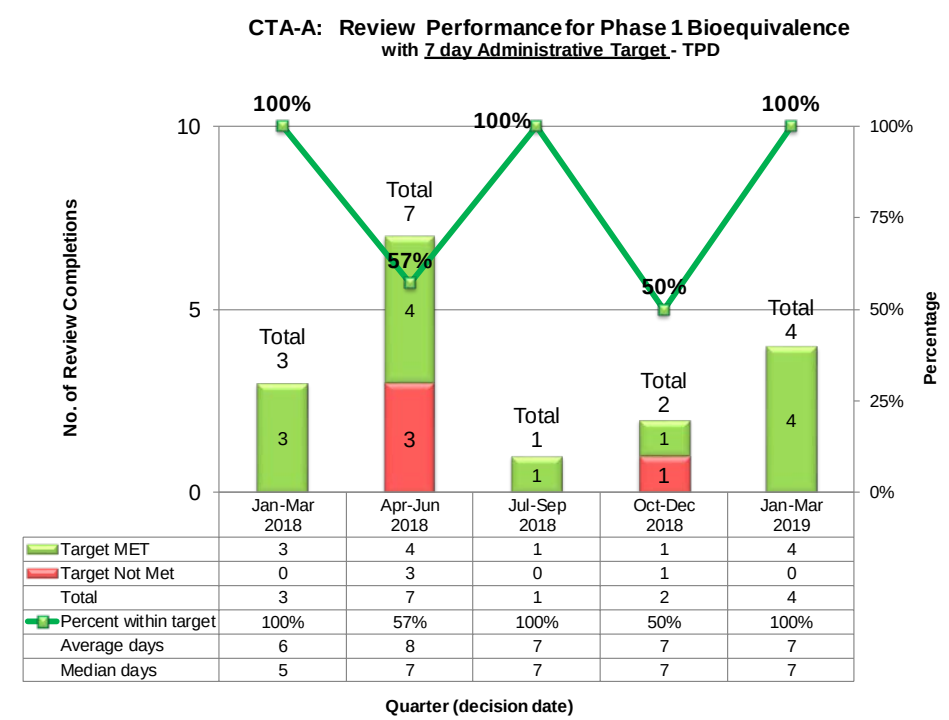
PERFORMANCE

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Target MET	250	284	279	237	233
Target Not Met	0	0	0	0	0
Total	250	284	279	237	233
Percent within target	100%	100%	100%	100%	100%
Average days	22	22	21	23	24
Median days	23	24	22	24	25

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



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Target MET	3	4	1	1	4
Target Not Met	0	3	0	1	0
Total	3	7	1	2	4
Percent within target	100%	57%	100%	50%	100%
Average days	6	8	7	7	7
Median days	5	7	7	7	7

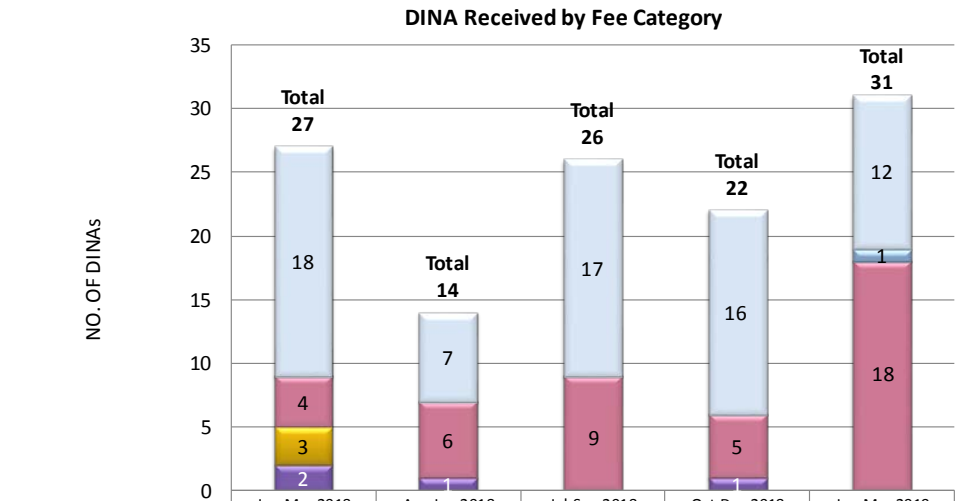
DINA

Application for a Drug Identification Number

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

DINA: Application for a Drug Identification Number[13]

Number Received – DINA

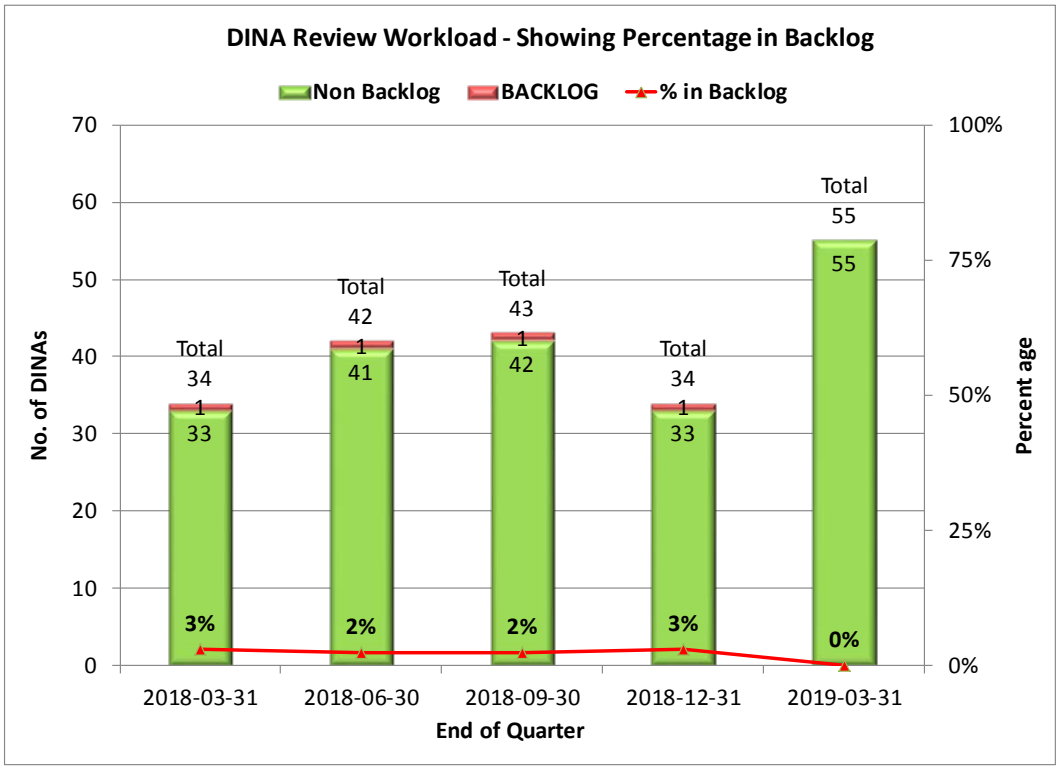


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	18	7	17	16	12
Labelling Standard	0	0	0	0	1
Chemistry & Manufacturing	4	6	9	5	18
Clinical or Non-Clin and C&M	3	0	0	0	0
Comparative Studies	2	1	0	1	0
Published Data Only	0	0	0	0	0
Total	27	14	26	22	31

[13] 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

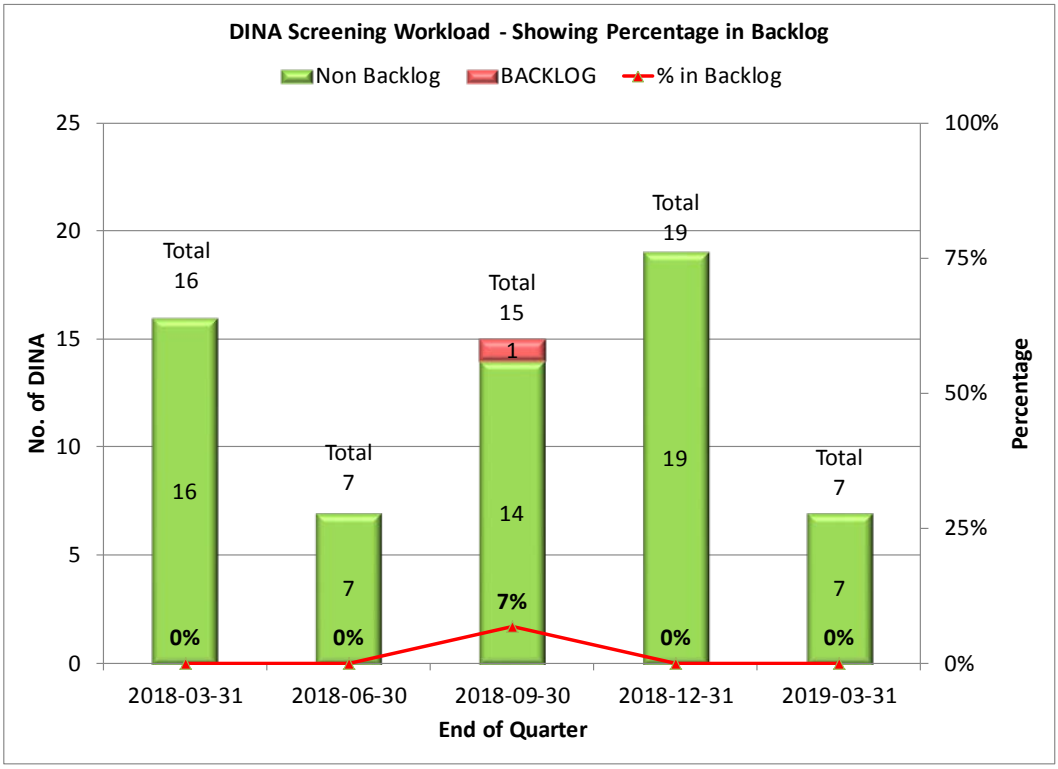


Review Workload by Fee Category – DINA

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**13**	**19**	**17**	**19**	**27**
Backlog	*1*	*1*	*1*	*1*	*0*
Chemistry & Manufacturing	**19**	**15**	**20**	**13**	**26**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**4**	**4**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**4**	**2**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**34**	**42**	**43**	**34**	**55**
Non Backlog	**33**	**41**	**42**	**33**	**55**
BACKLOG	**1**	**1**	**1**	**1**	**0**
% in Backlog	**3%**	**2%**	**2%**	**3%**	**0%**

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					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**8**	**3**	**8**	**8**	**3**
Backlog	*0*	*0*	*1*	*0*	*0*
Clinical or Non-Clin and C&M	**2**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**4**	**4**	**7**	**9**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**2**	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**16**	**7**	**15**	**19**	**7**
Non Backlog	**16**	**7**	**14**	**19**	**7**
BACKLOG	**0**	**0**	**1**	**0**	**0**
% in Backlog	**0%**	**0%**	**7%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINA by Fee Category

DINA - Labelling Only					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NOTIFICATION FORM/DIN ISSUED	3	1	3	4	1
NO OBJECTION LETTER	6	5	7	8	9
CANCELLED BY COMPANY	2	3	1	3	0
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	2	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	3	2	2	2	0
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NOTIFICATION FORM/DIN ISSUED	4	4	1	2	5
NO OBJECTION LETTER	1	3	2	3	3
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	1	0	0	2	0
NOTICE OF DEFICIENCY	2	0	1	2	0
NOTICE OF NON-COMPLIANCE	1	1	3	2	1
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	6	3	1	2	1
CANCELLED BY COMPANY	3	1	1	2	3

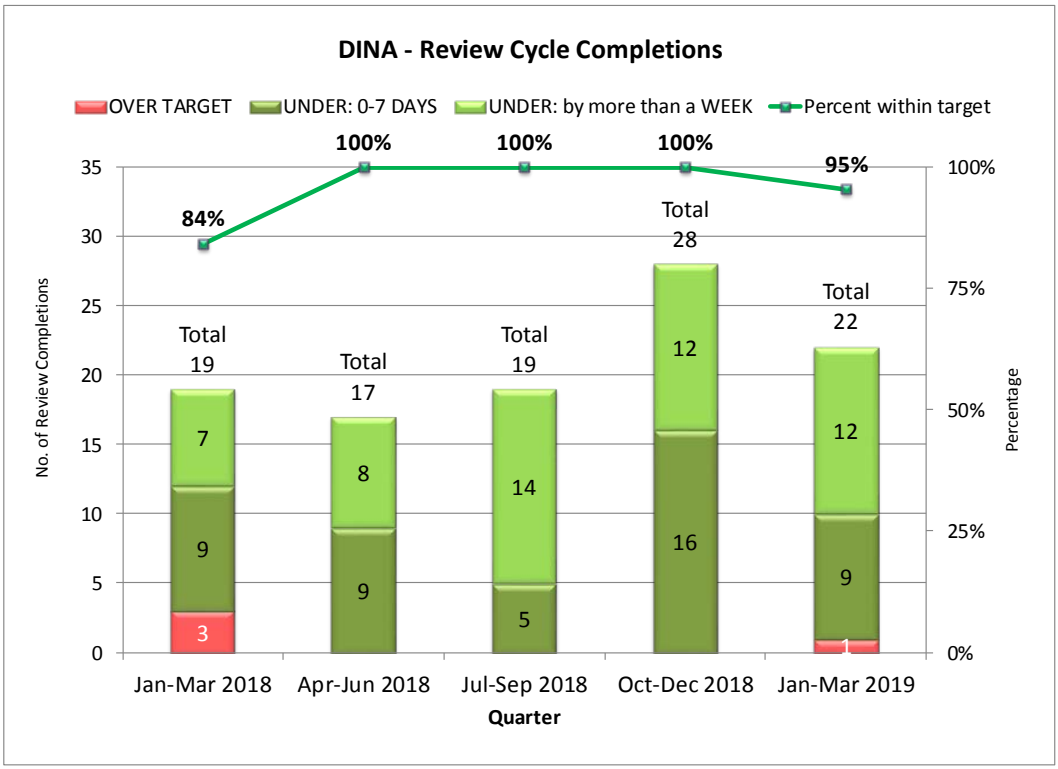
DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NO OBJECTION LETTER	0	1	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CANCELLED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

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

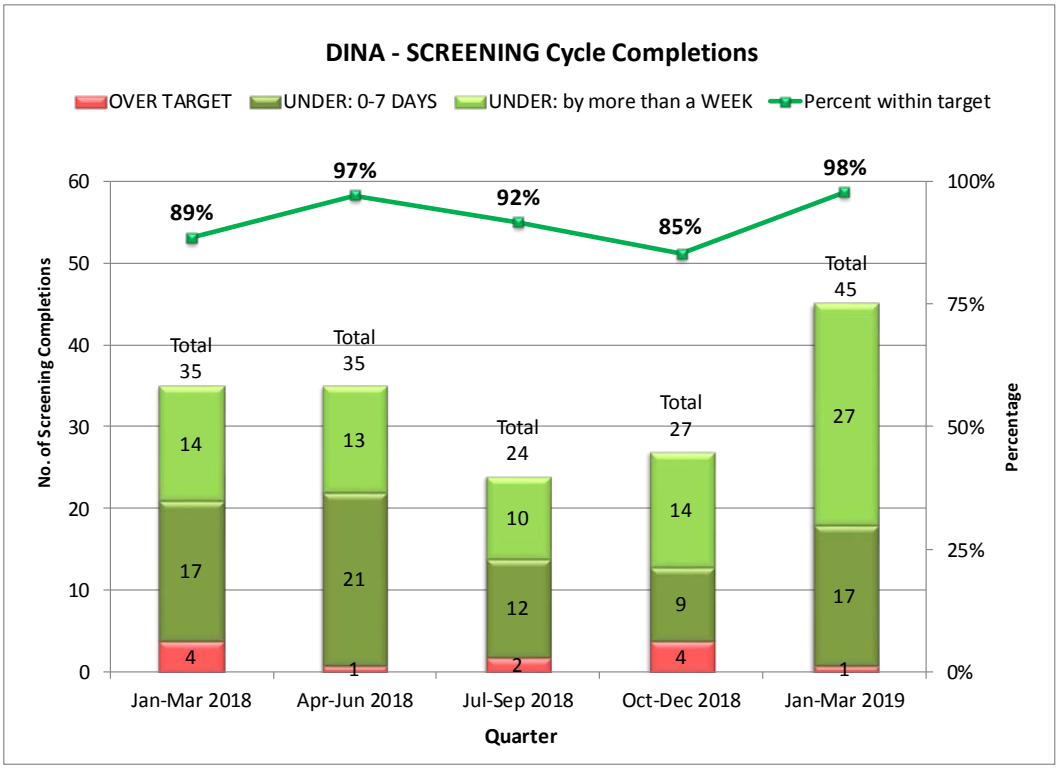
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
CANCELLED BY COMPANY	1	0	0	1	0
NOTICE OF NON-COMPLIANCE	0	0	0	1	1
NOTIFICATION FORM/DIN ISSUED	0	0	0	1	0
SCREENING DEFICIENCY NOTICE	2	2	0	0	0

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target – DINA

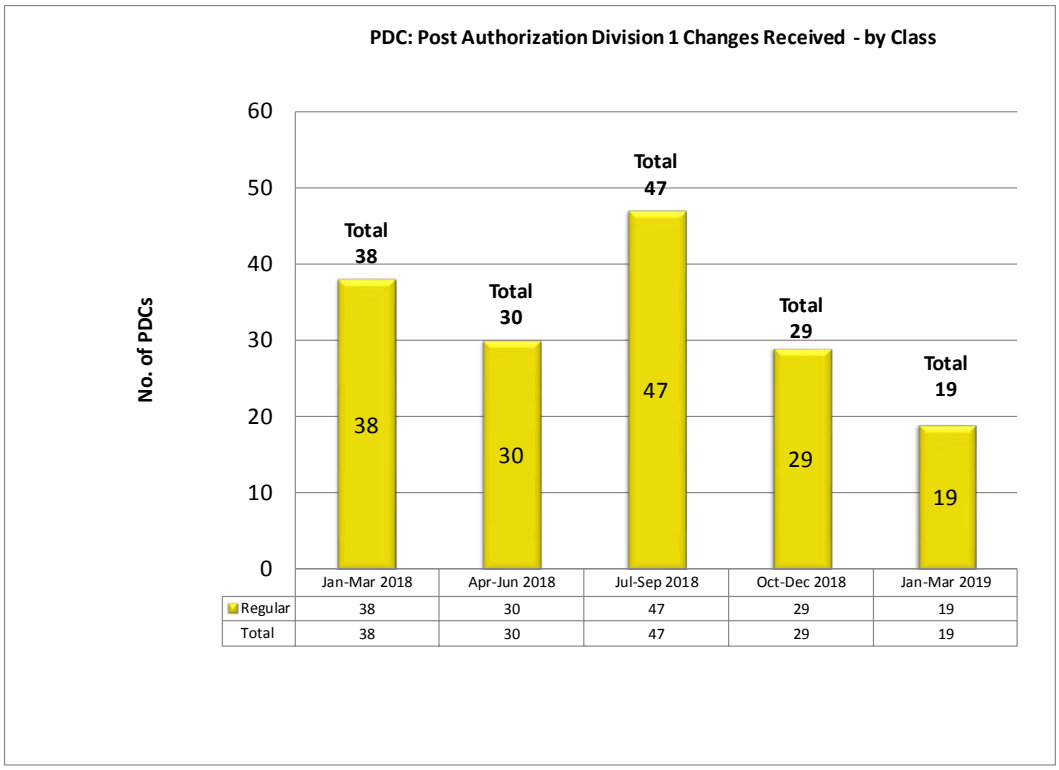


Performance Screening Cycle Completions Showing Percentage Within Target – DINA



PDC: Post-Authorization Division 1 Changes,[14]

Post-Authorization Division 1 Changes (PDC) Received



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

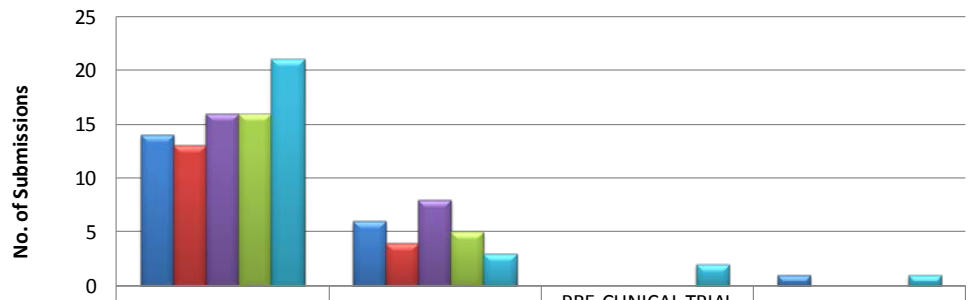
PDC					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
REGULAR					
CANCELLED BY COMPANY	4	3	7	4	6
NO OBJECTION LETTER	15	30	38	35	28
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

[14] 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

[15]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-CLINICAL TRIAL APPLICATION MEETING PRECTA	PRE-DIN MEETING MPDIN
JAN-MAR 18	14	6	0	1
APR-JUN 18	13	4	0	0
JUL-SEP 18	16	8	0	0
OCT-DEC 2018	16	5	0	0
JAN-MAR 2019	21	3	2	1

[15] 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