Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

July – September

2018

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 July – September 2017 to July – September 2018. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

General Information

There are several steps involved in the drug submission review[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:

Office of Submissions and Intellectual Property
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 Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[7]	Submissions in support of a manufacturer or product name change.
Disinfectants[8]	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information, 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)

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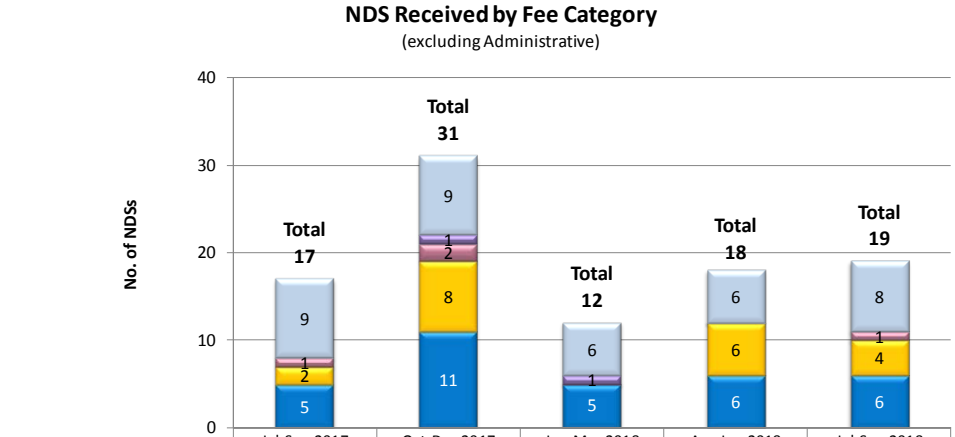
Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

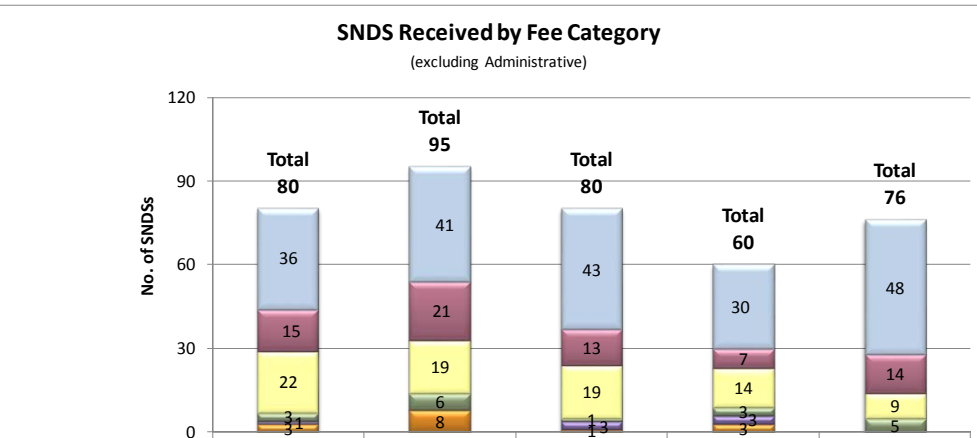
[9]

New Drug Submissions (NDS) Received by Fee Category



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	9	9	6	6	8
Comparative Studies	0	1	1	0	0
Chemistry & Manufacturing	1	2	0	0	1
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	2	8	0	6	4
New Active Substance	5	11	5	6	6
Total	17	31	12	18	19
Priority Class	1	4	2	3	1
NOC-C Class	0	1	1	2	1
Emergency Use (NDS)	0	0	0	0	0

Supplemental New Drug Submissions (SNDS) Received by Fee Category

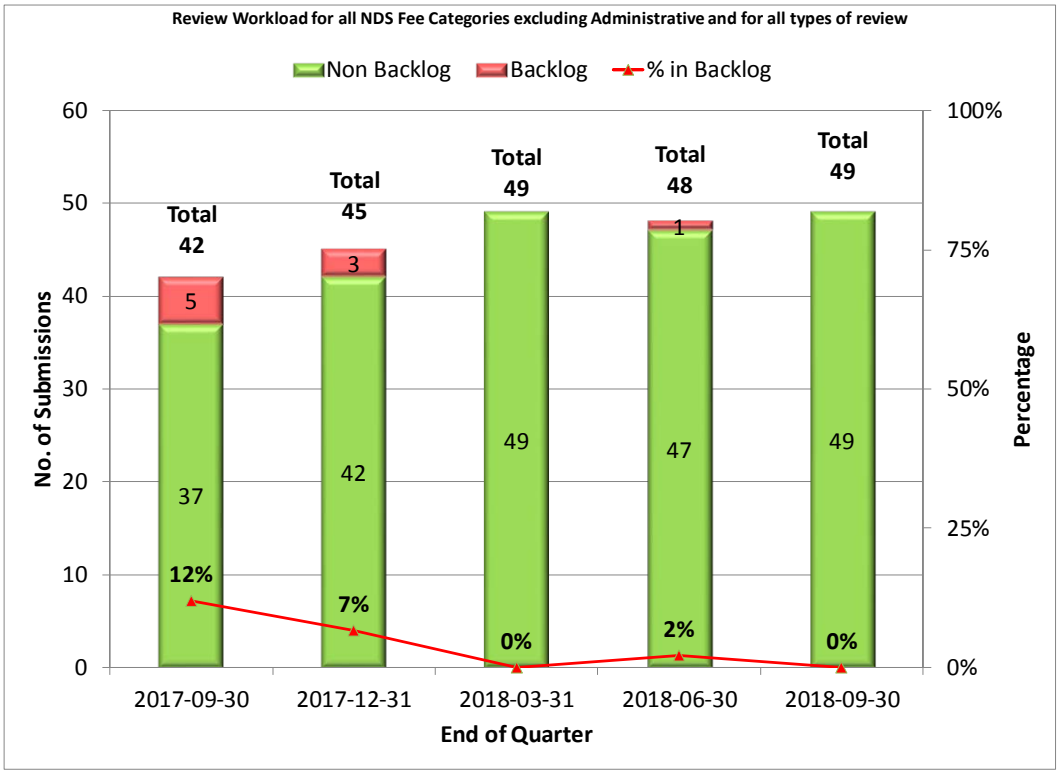


	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	36	41	43	30	48
Chemistry & Manufacturing	15	21	13	7	14
Clinical or Non-Clin Only	22	19	19	14	9
Published Data Only	3	6	1	3	5
Comparative Studies	1	0	3	3	0
Clinical or Non-Clin and C&M	3	8	1	3	0
Total	80	95	80	60	76
Priority Class	1	5	2	3	2
NOC-C Class	0	0	2	0	0
SNDS Confirmatory	1	1	0	0	0

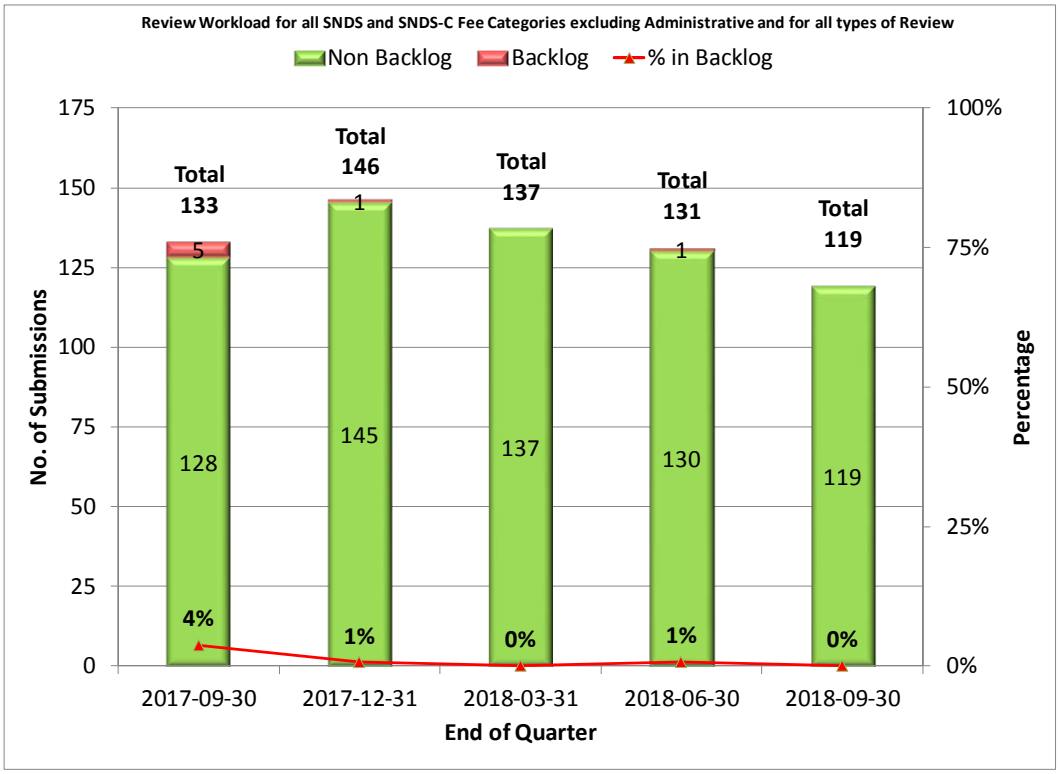
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

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

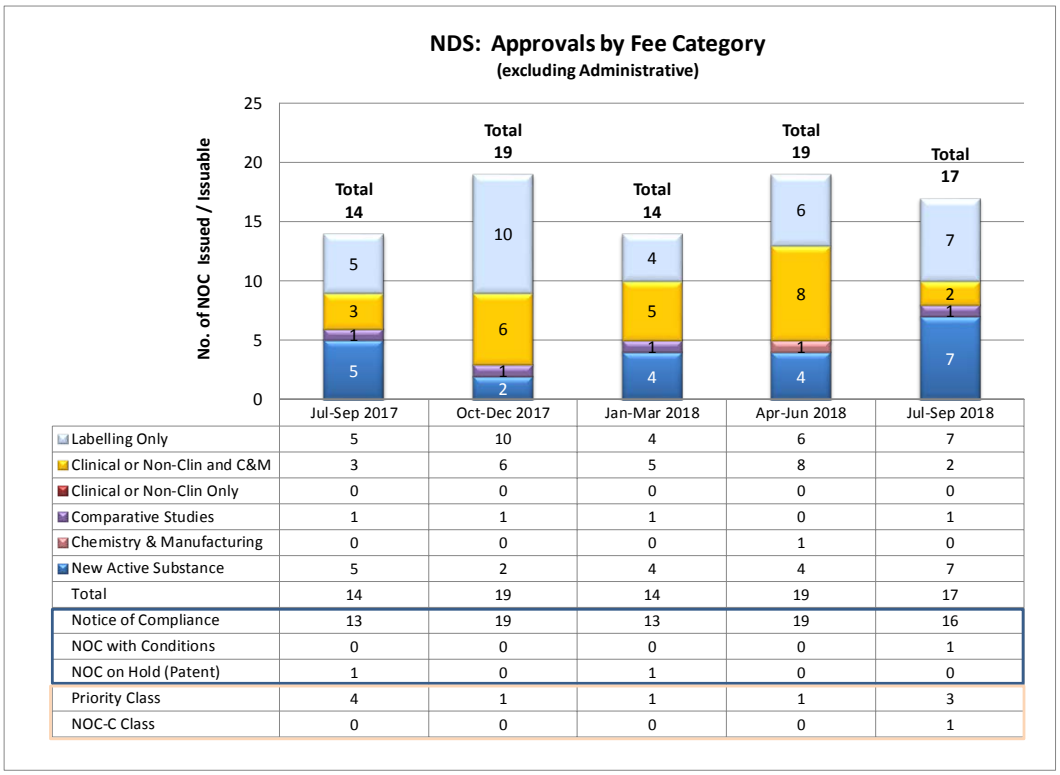
TPD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Labelling Only	**2**	**3**	**4**	**4**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**3**	**1**	**1**	**1**	**1**
Backlog	*1*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**1**	**1**	**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	**24**	**20**	**18**	**16**	**16**
Backlog	*3*	*2*	*0*	*0*	*0*
New Active Substance	**13**	**20**	**25**	**27**	**27**
Backlog	*1*	*1*	*0*	*1*	*0*
Total	**42**	**45**	**49**	**48**	**49**
Non Backlog	**37**	**42**	**49**	**47**	**49**
Backlog	**5**	**3**	**0**	**1**	**0**
% in Backlog	**12%**	**7%**	**0%**	**2%**	**0%**
Priority (subset)	**3**	**3**	**6**	**7**	**6**
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					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Labelling Only	**23**	**28**	**19**	**15**	**23**
Backlog	*2*	*0*	*0*	*1*	*0*
Comparative Studies	**8**	**4**	**4**	**8**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**38**	**34**	**30**	**26**	**25**
Backlog	*2*	*1*	*0*	*0*	*0*
Clinical or Non-Clin Only	**53**	**63**	**63**	**60**	**49**
Backlog	*1*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**6**	**9**	**11**	**13**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**5**	**8**	**10**	**9**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**133**	**146**	**137**	**131**	**119**
Non Backlog	**128**	**145**	**137**	**130**	**119**
Backlog	**5**	**1**	**0**	**1**	**0**
% in Backlog	**4%**	**1%**	**0%**	**1%**	**0%**
Priority (subset)	**2**	**5**	**7**	**7**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**6**	**5**	**3**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*

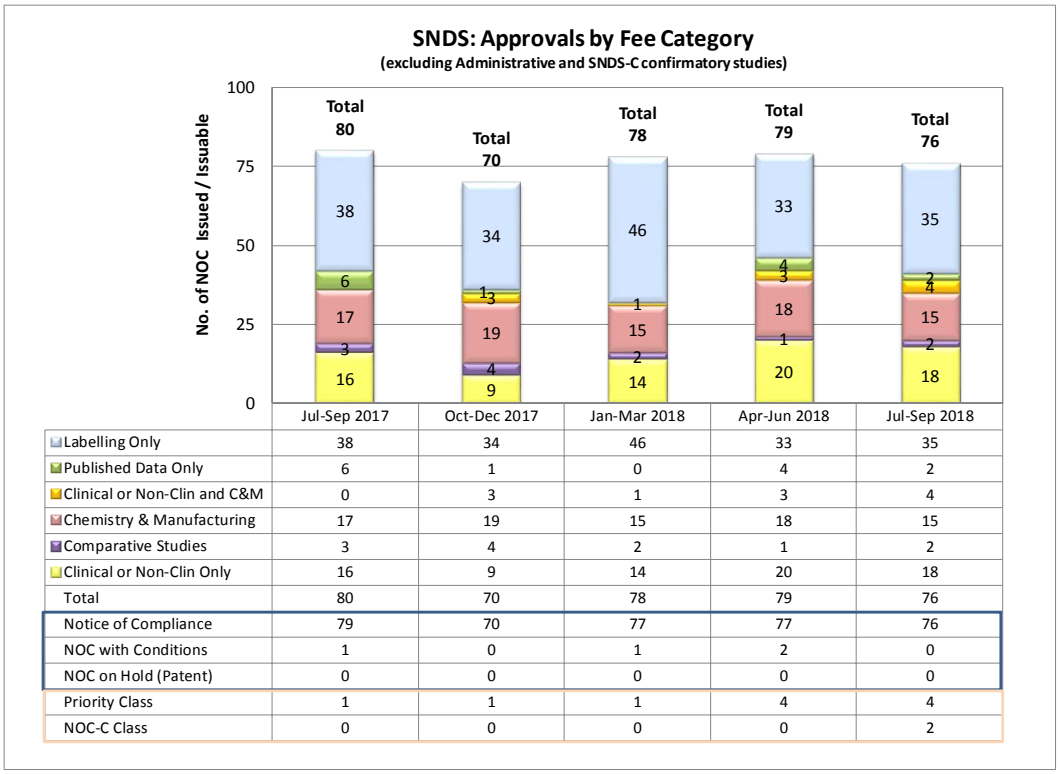
APPROVALS[10]

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	5	10	4	6	7
Clinical or Non-Clin and C&M	3	6	5	8	2
Clinical or Non-Clin Only	0	0	0	0	0
Comparative Studies	1	1	1	0	1
Chemistry & Manufacturing	0	0	0	1	0
New Active Substance	5	2	4	4	7
Total	14	19	14	19	17
Notice of Compliance	13	19	13	19	16
NOC with Conditions	0	0	0	0	1
NOC on Hold (Patent)	1	0	1	0	0
Priority Class	4	1	1	1	3
NOC-C Class	0	0	0	0	1

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	38	34	46	33	35
Published Data Only	6	1	0	4	2
Clinical or Non-Clin and C&M	0	3	1	3	4
Chemistry & Manufacturing	17	19	15	18	15
Comparative Studies	3	4	2	1	2
Clinical or Non-Clin Only	16	9	14	20	18
Total	80	70	78	79	76
Notice of Compliance	79	70	77	77	76
NOC with Conditions	1	0	1	2	0
NOC on Hold (Patent)	0	0	0	0	0
Priority Class	1	1	1	4	4
NOC-C Class	0	0	0	0	2

[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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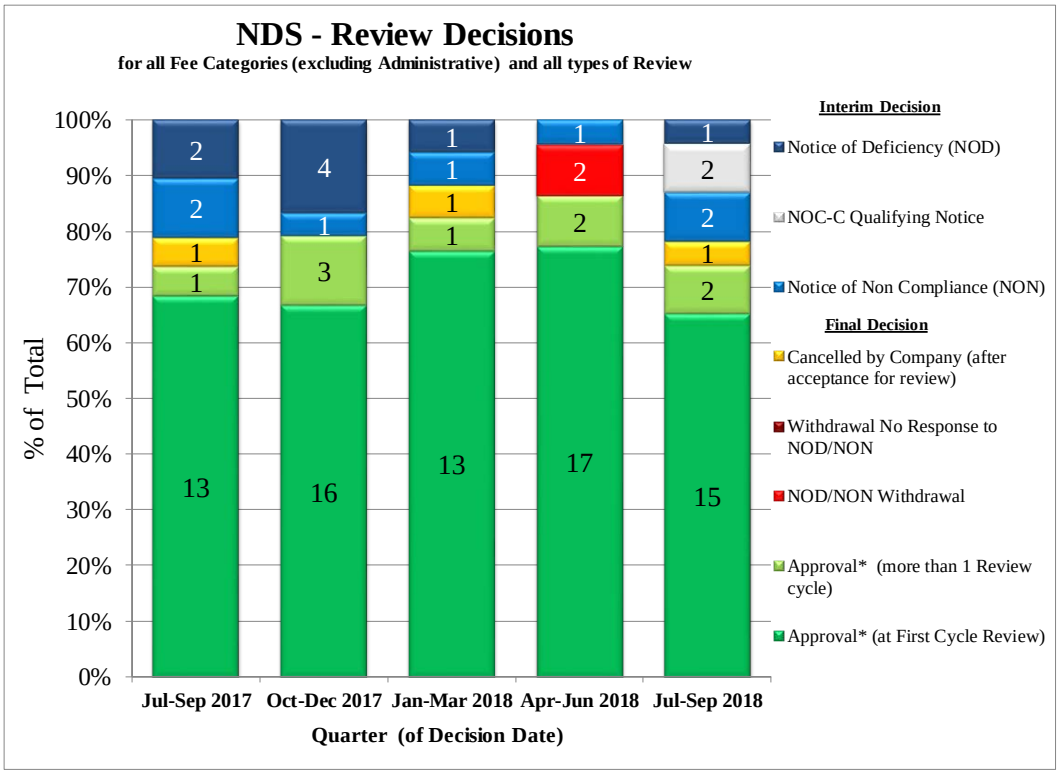
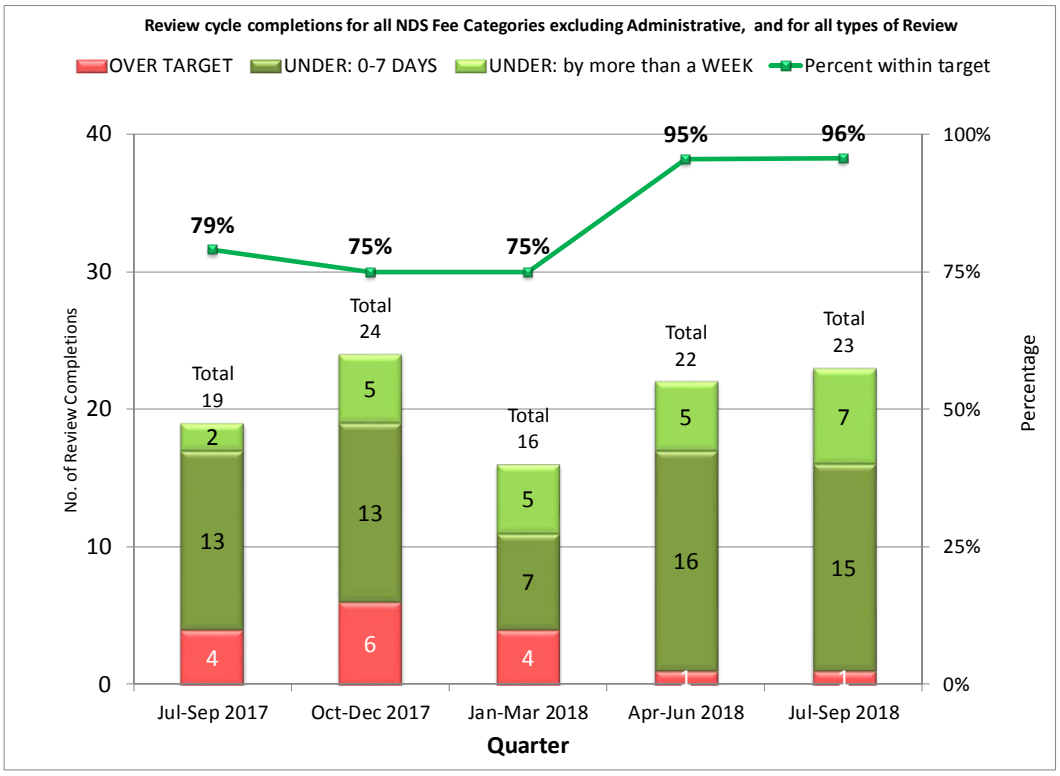
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

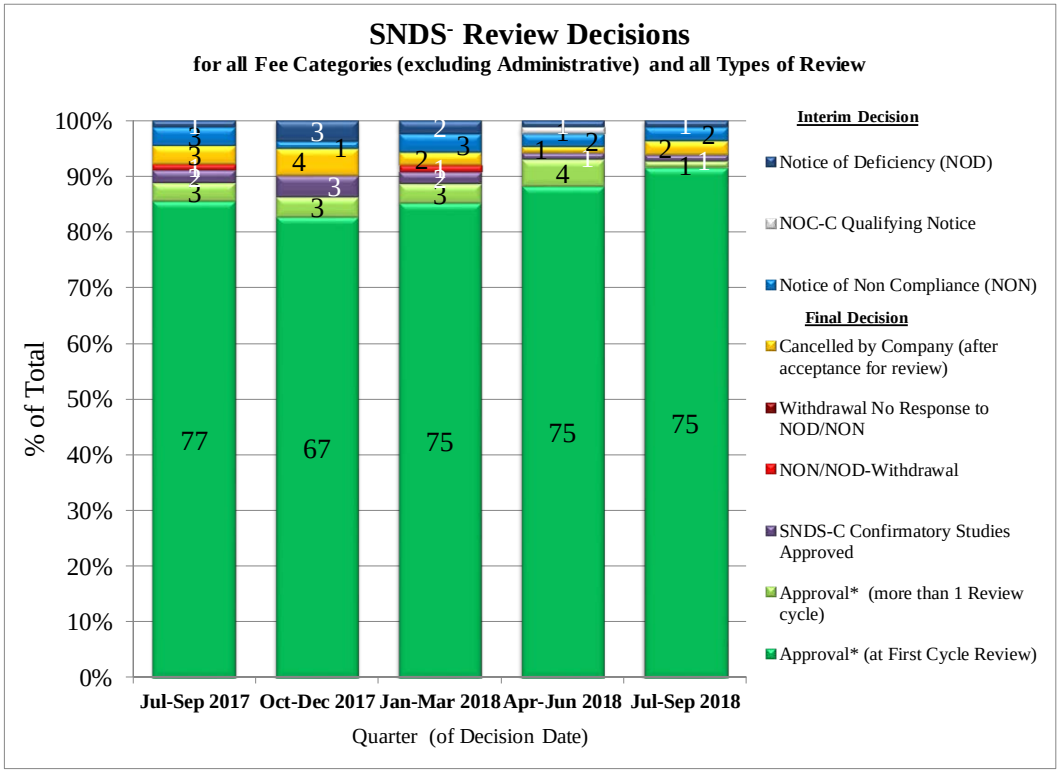


NDS - Review Cycle Completions Showing Percentage Within Target

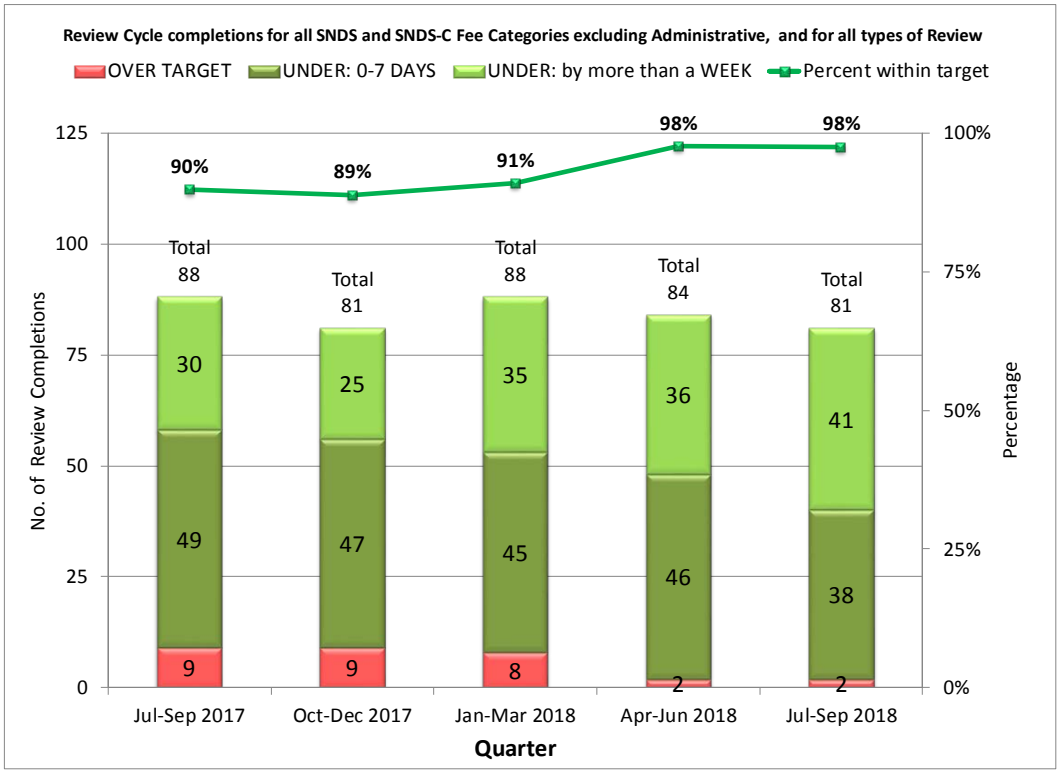


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

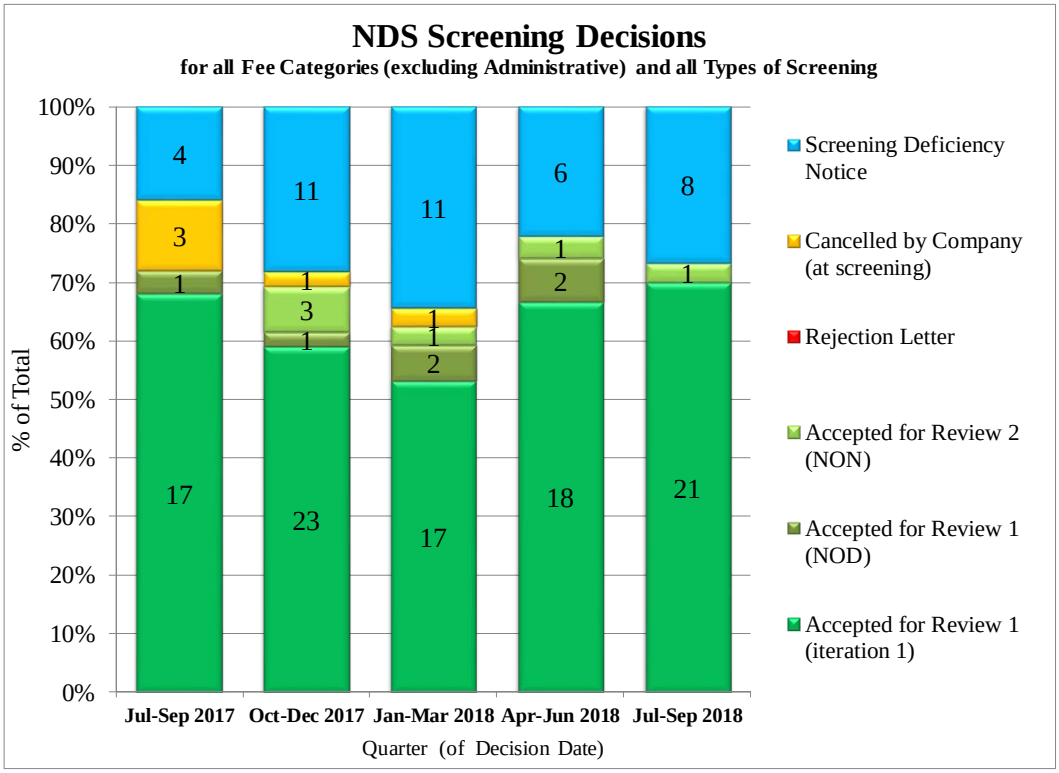


SNDS - Review Cycle Completions Showing Percentage Within Target

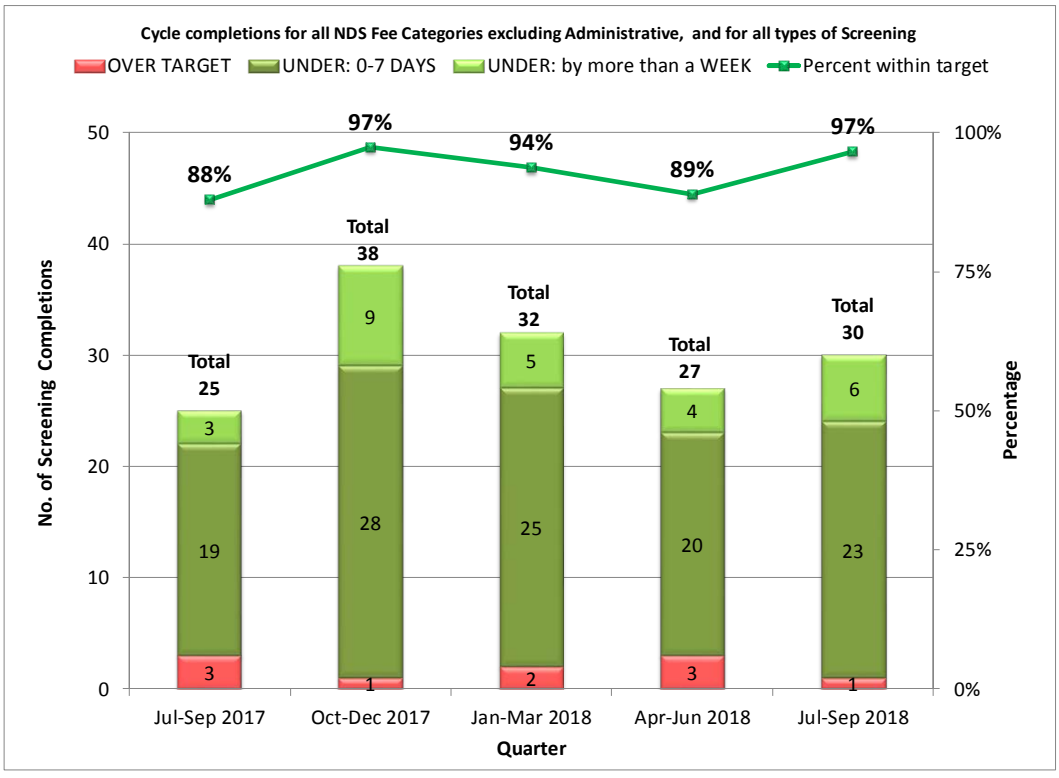


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

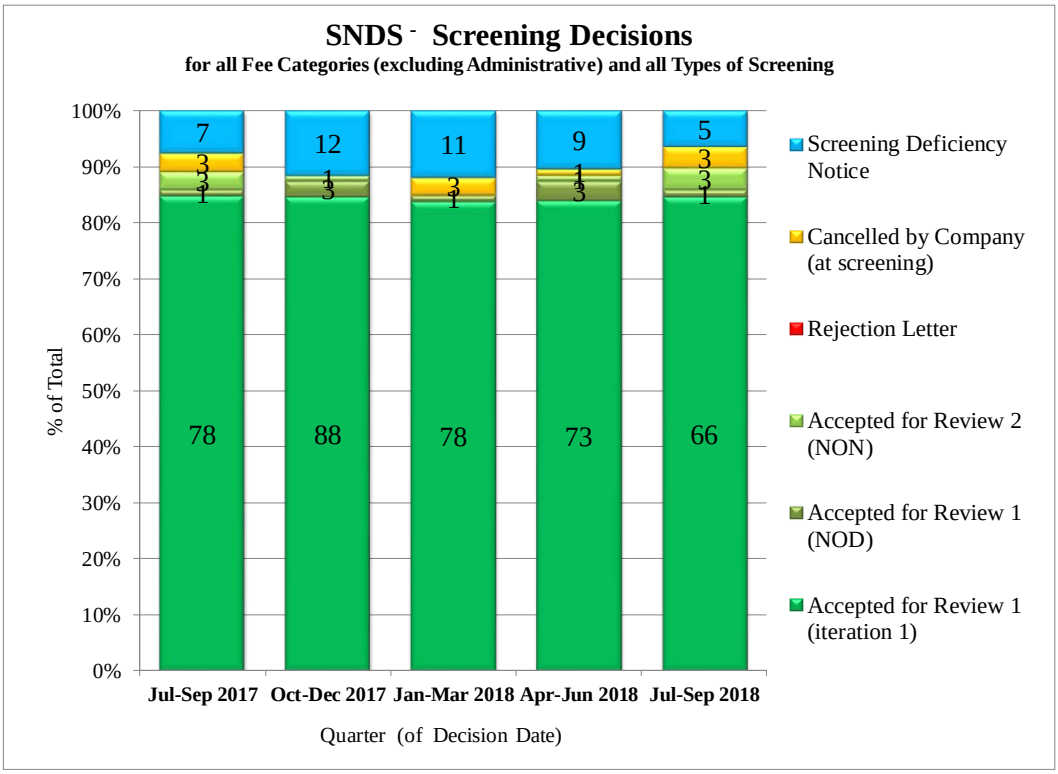


NDS - Screening Cycle Completions Showing Percentage Within Target

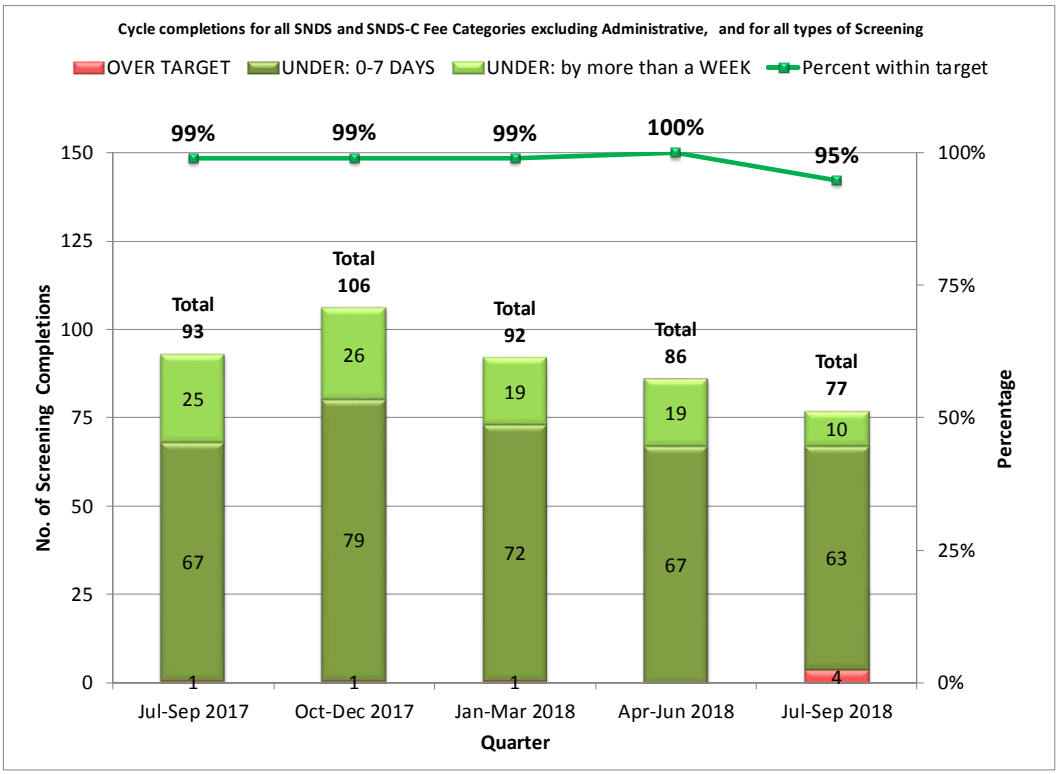


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



Abbreviated New Drug Submissions (ANDS)

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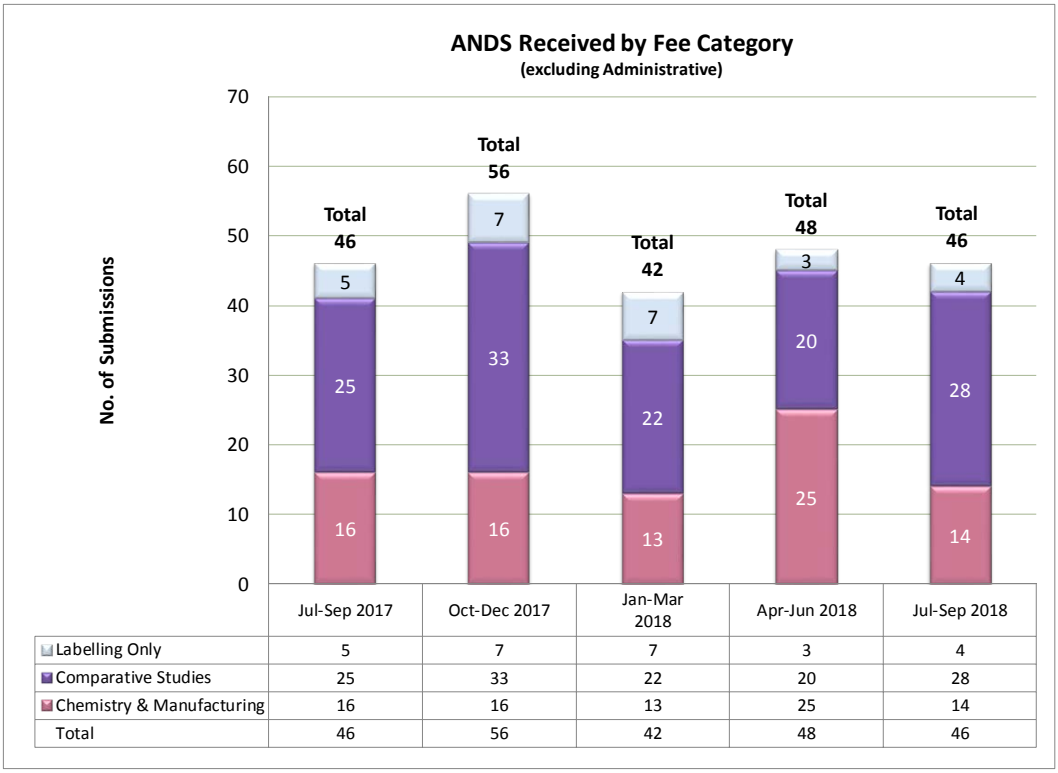
Supplemental Abbreviated New Drug Submissions

(SANDS)

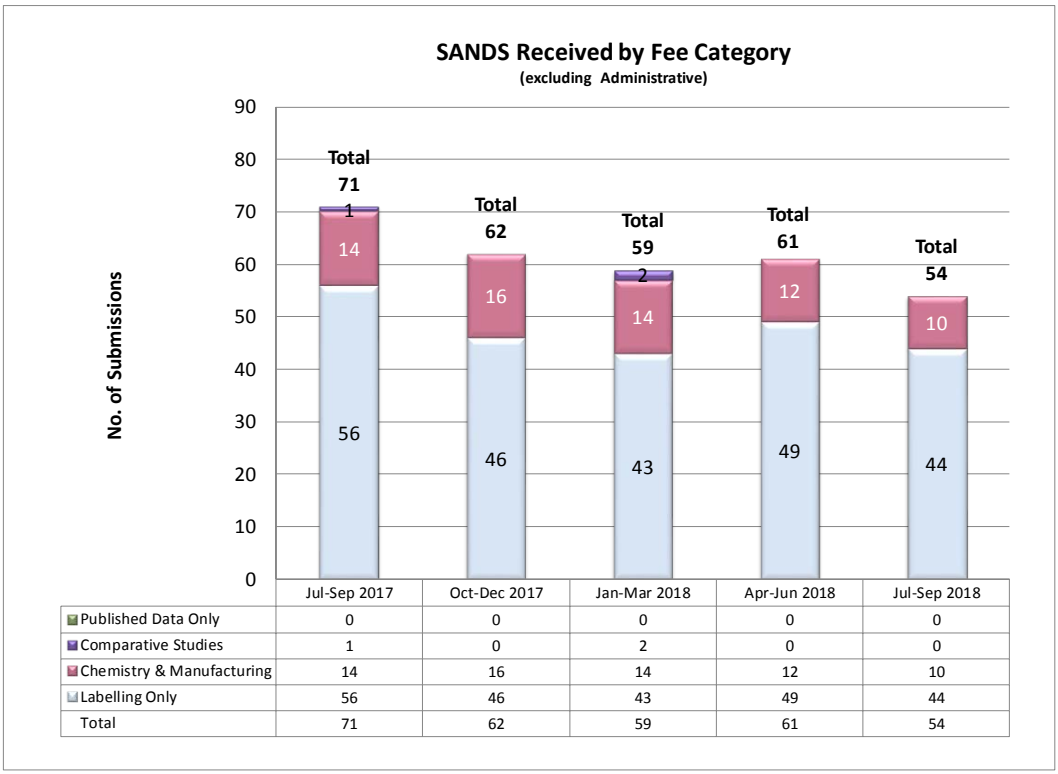
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	5	7	7	3	4
Comparative Studies	25	33	22	20	28
Chemistry & Manufacturing	16	16	13	25	14
Total	46	56	42	48	46

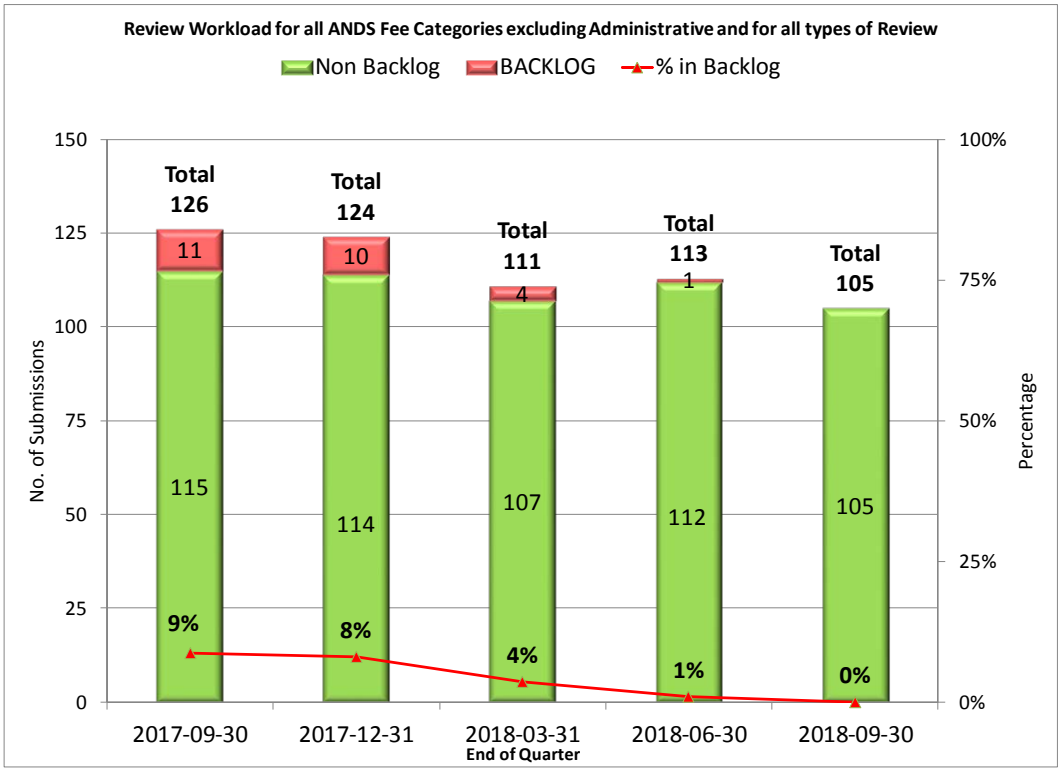
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



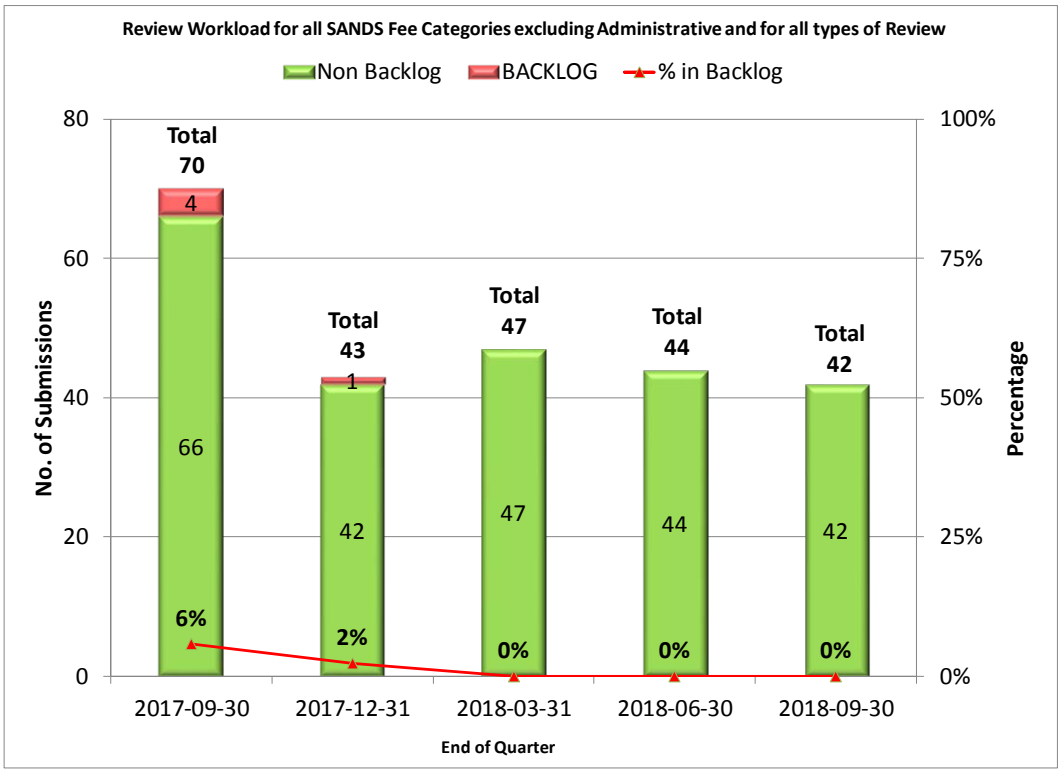
	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Published Data Only	0	0	0	0	0
Comparative Studies	1	0	2	0	0
Chemistry & Manufacturing	14	16	14	12	10
Labelling Only	56	46	43	49	44
Total	71	62	59	61	54

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

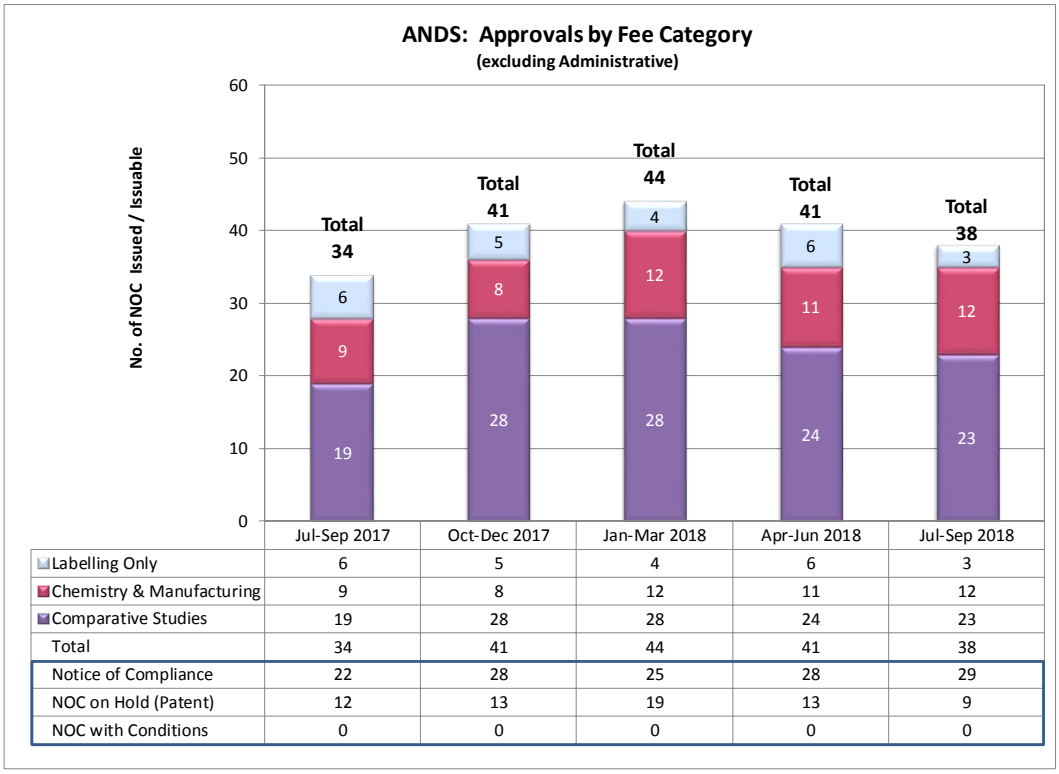
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Chemistry & Manufacturing	46	49	43	45	51
Backlog	*5*	*4*	*2*	*1*	*0*
Comparative Studies	79	73	65	68	52
Backlog	*6*	*6*	*2*	*0*	*0*
Labelling Only	1	2	3	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Total	126	124	111	113	105
Non Backlog	115	114	107	112	105
BACKLOG	11	10	4	1	0
% in Backlog	9%	8%	4%	1%	0%

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

TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Chemistry & Manufacturing	38	27	26	24	25
Backlog	*2*	*1*	*0*	*0*	*0*
Clinical or Non-Clin Only	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	3	0	2	2	1
Backlog	*1*	*0*	*0*	*0*	*0*
Published Data	1	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	28	15	19	18	16
Backlog	*1*	*0*	*0*	*0*	*0*
Total	70	43	47	44	42
Non Backlog	66	42	47	44	42
BACKLOG	4	1	0	0	0
% in Backlog	6%	2%	0%	0%	0%

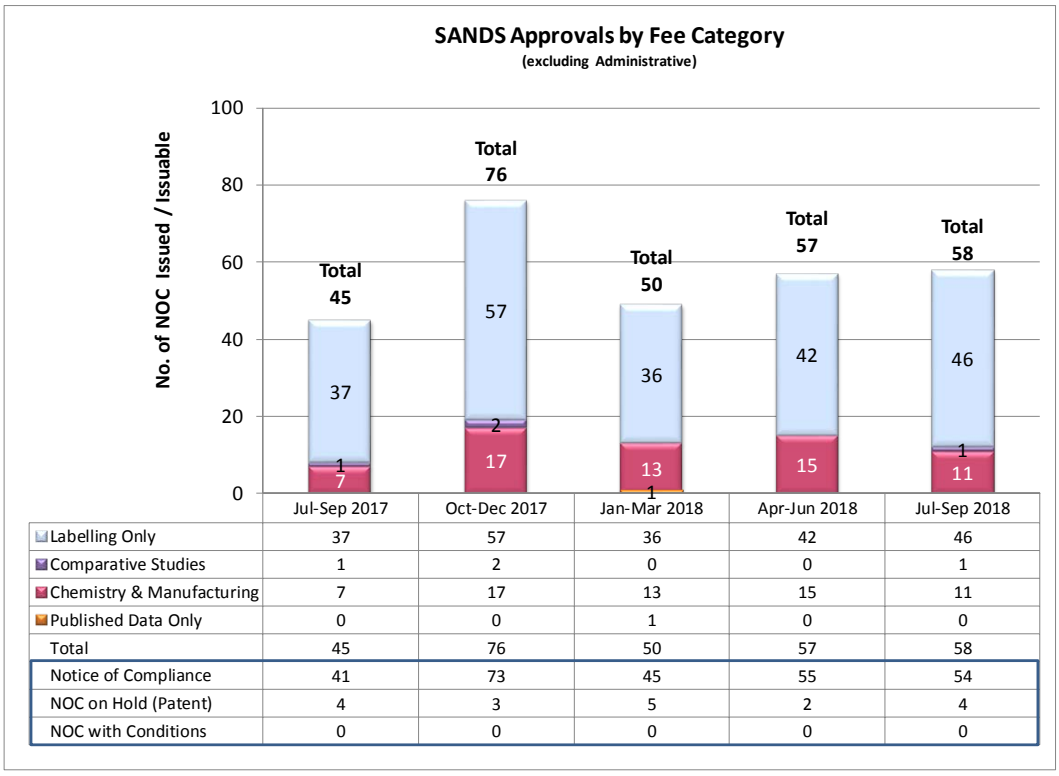
APPROVALS

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	6	5	4	6	3
Chemistry & Manufacturing	9	8	12	11	12
Comparative Studies	19	28	28	24	23
Total	34	41	44	41	38
Notice of Compliance	22	28	25	28	29
NOC on Hold (Patent)	12	13	19	13	9
NOC with Conditions	0	0	0	0	0

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	37	57	36	42	46
Comparative Studies	1	2	0	0	1
Chemistry & Manufacturing	7	17	13	15	11
Published Data Only	0	0	1	0	0
Total	45	76	50	57	58
Notice of Compliance	41	73	45	55	54
NOC on Hold (Patent)	4	3	5	2	4
NOC with Conditions	0	0	0	0	0

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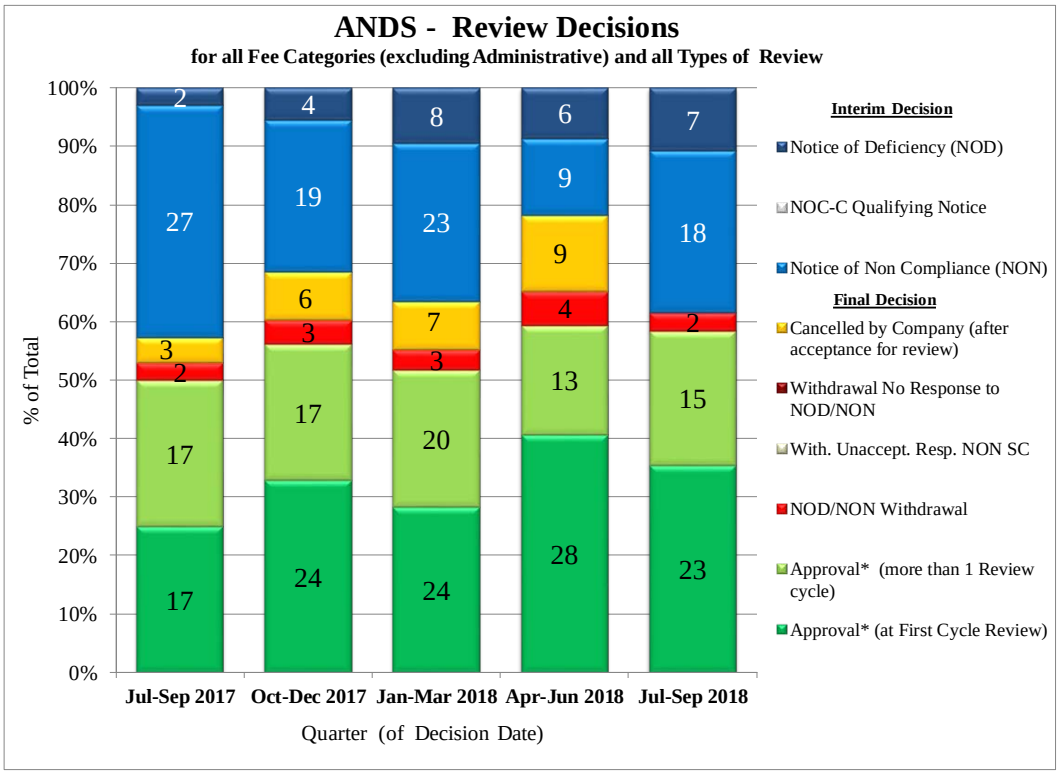
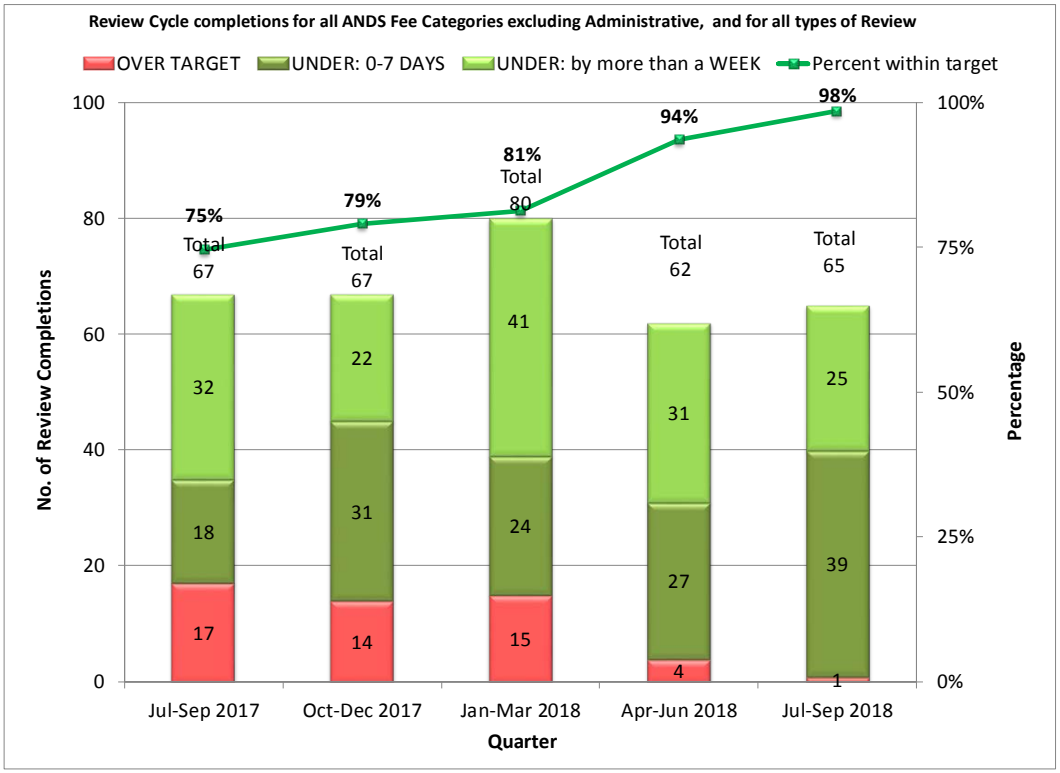
REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

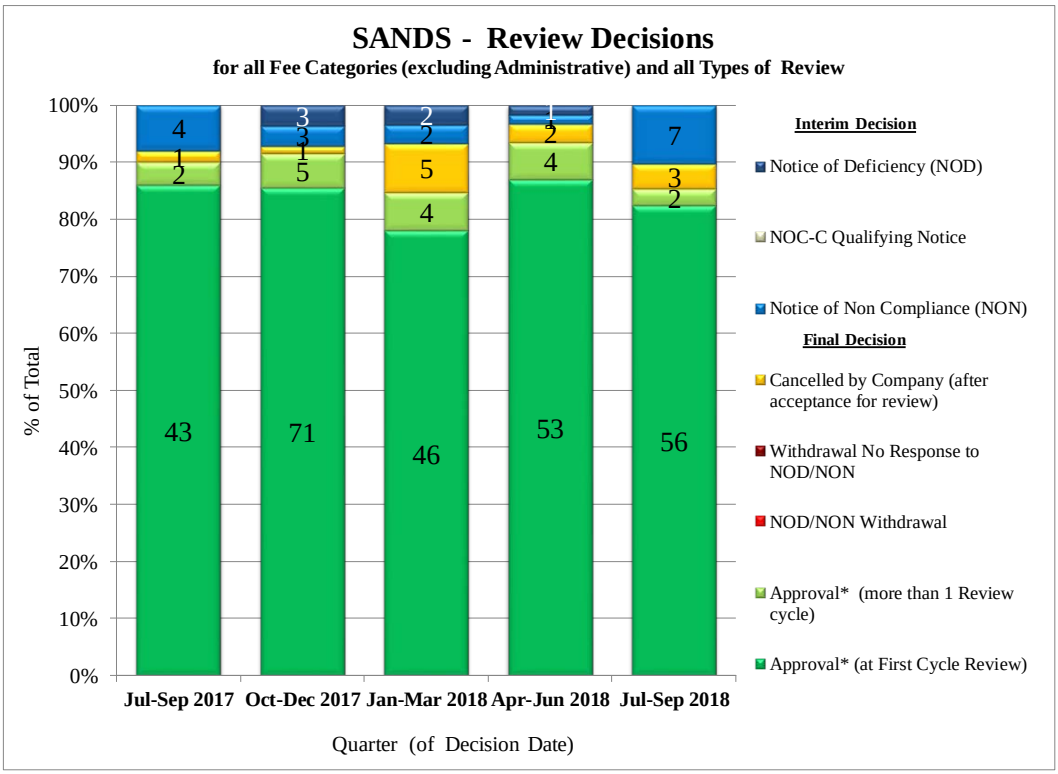


ANDS - Review Cycle Completions Showing Percentage Within Target

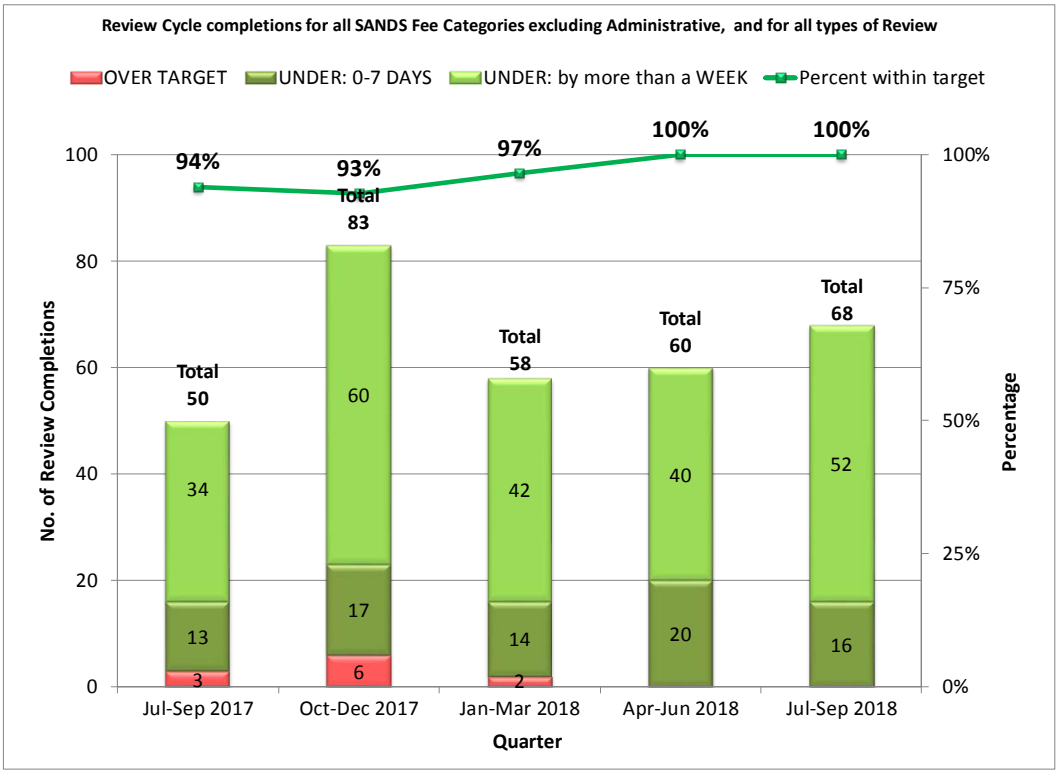


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

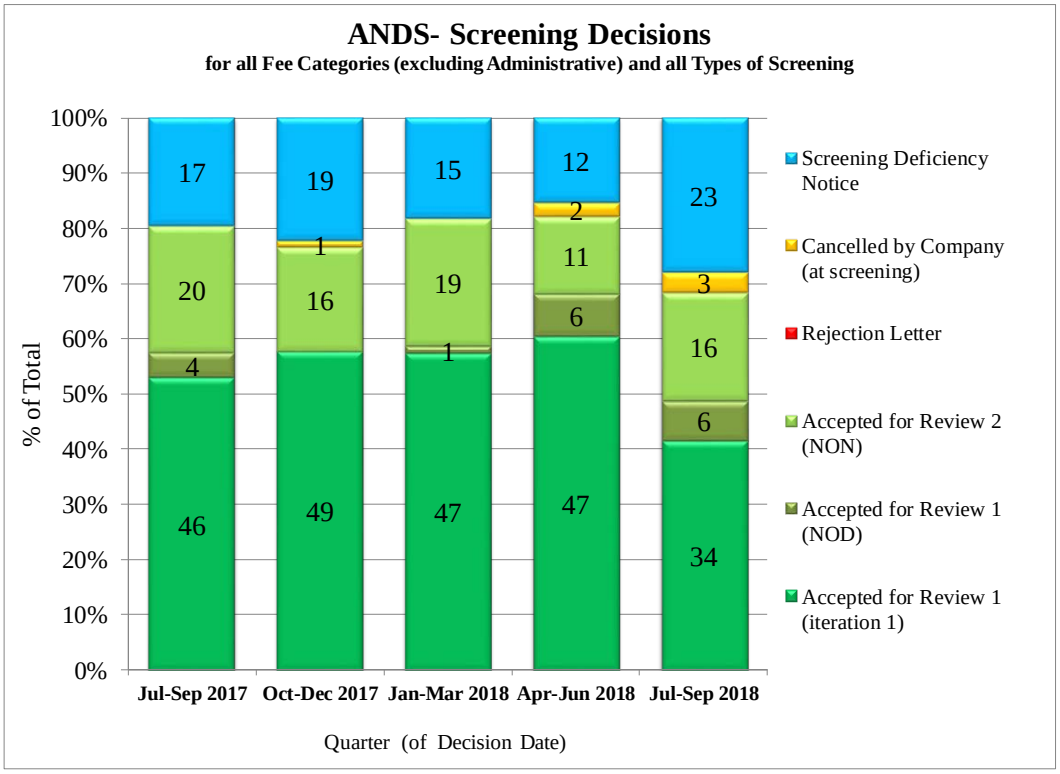


SANDS - Review Cycle Completions Showing Percentage Within Target

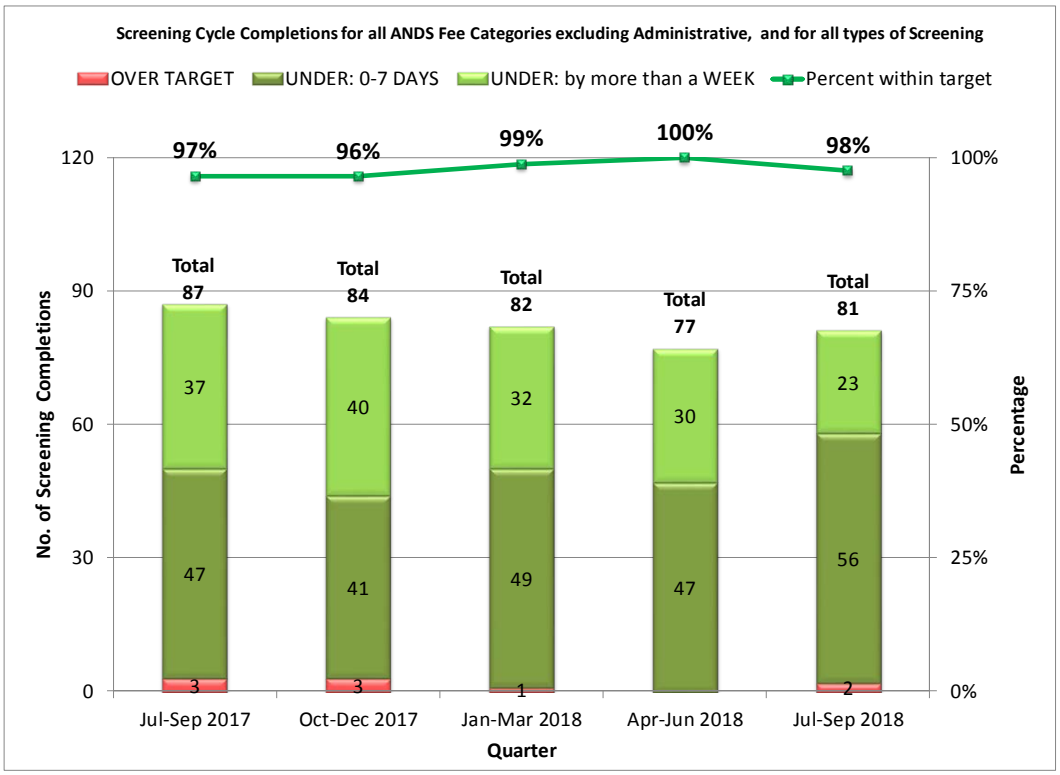


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

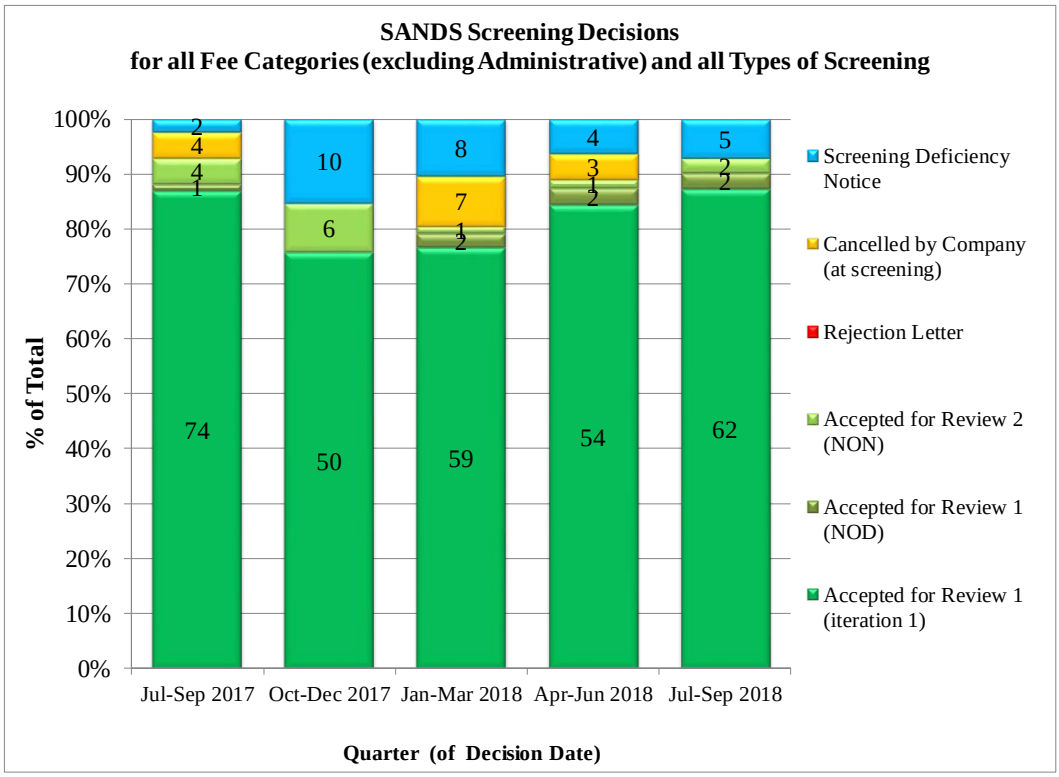


ANDS - Screening Cycle Completions Showing Percentage Within Target

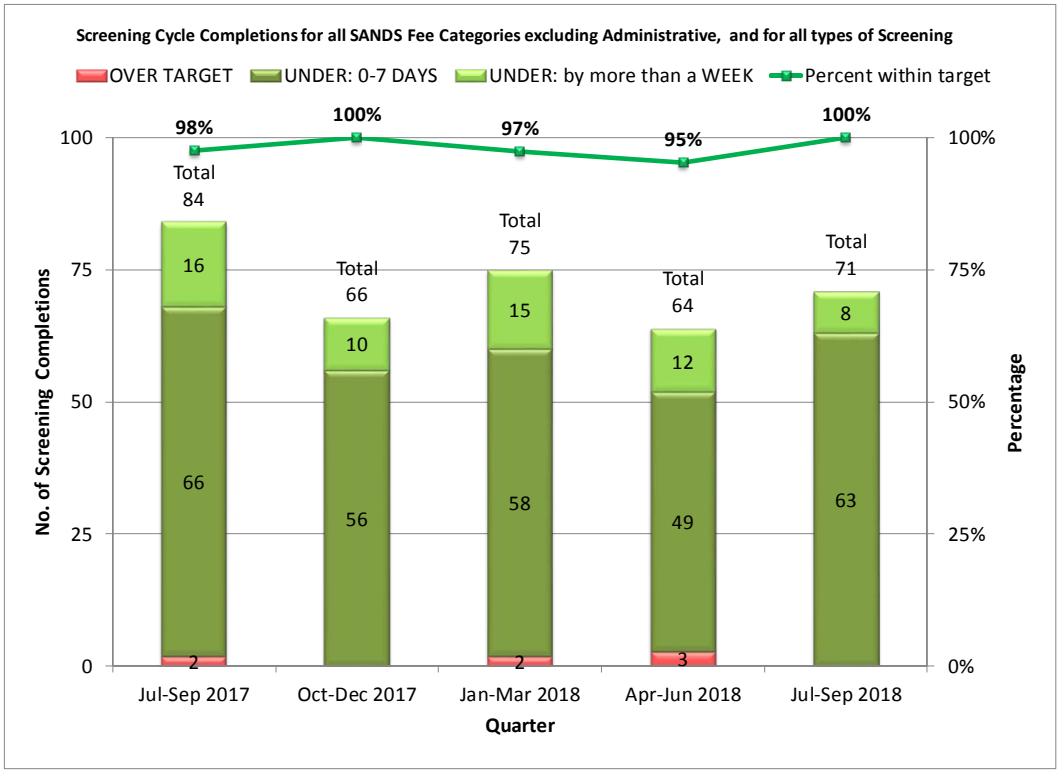


SCREENING CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions

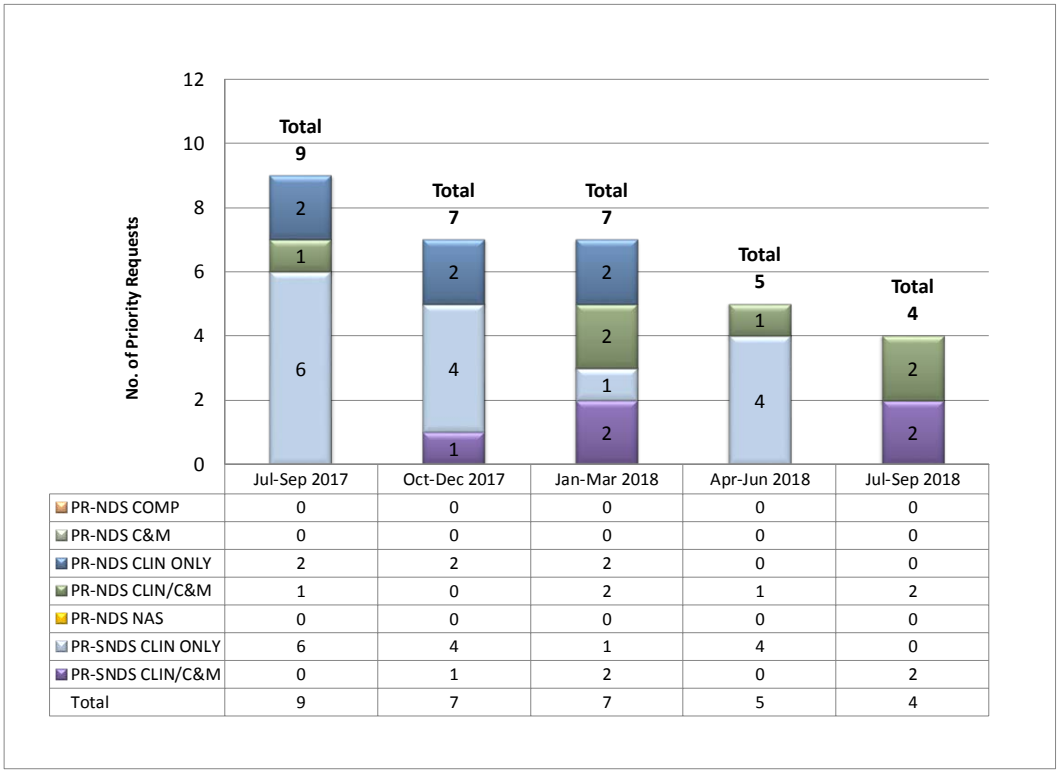


SANDS - Screening Cycle Completions Showing Percentage Within Target



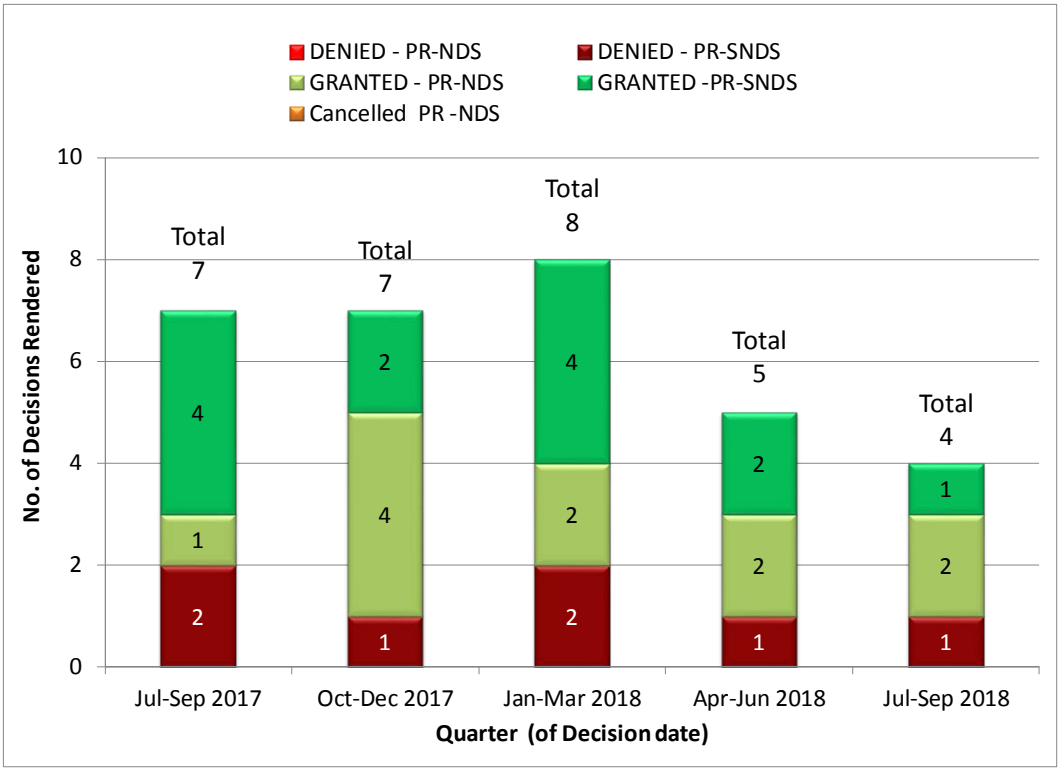
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

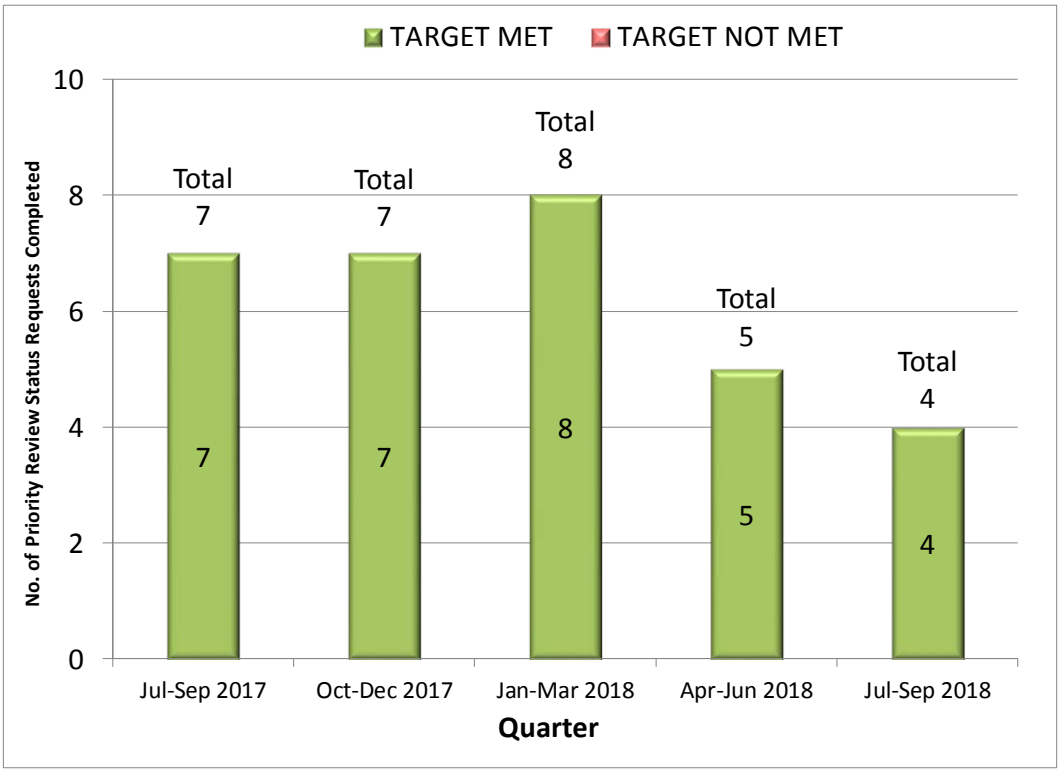


	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
PR-NDS COMP	0	0	0	0	0
PR-NDS C&M	0	0	0	0	0
PR-NDS CLIN ONLY	2	2	2	0	0
PR-NDS CLIN/C&M	1	0	2	1	2
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN ONLY	6	4	1	4	0
PR-SNDS CLIN/C&M	0	1	2	0	2
Total	9	7	7	5	4

Priority Review Status Requests: Decisions Rendered



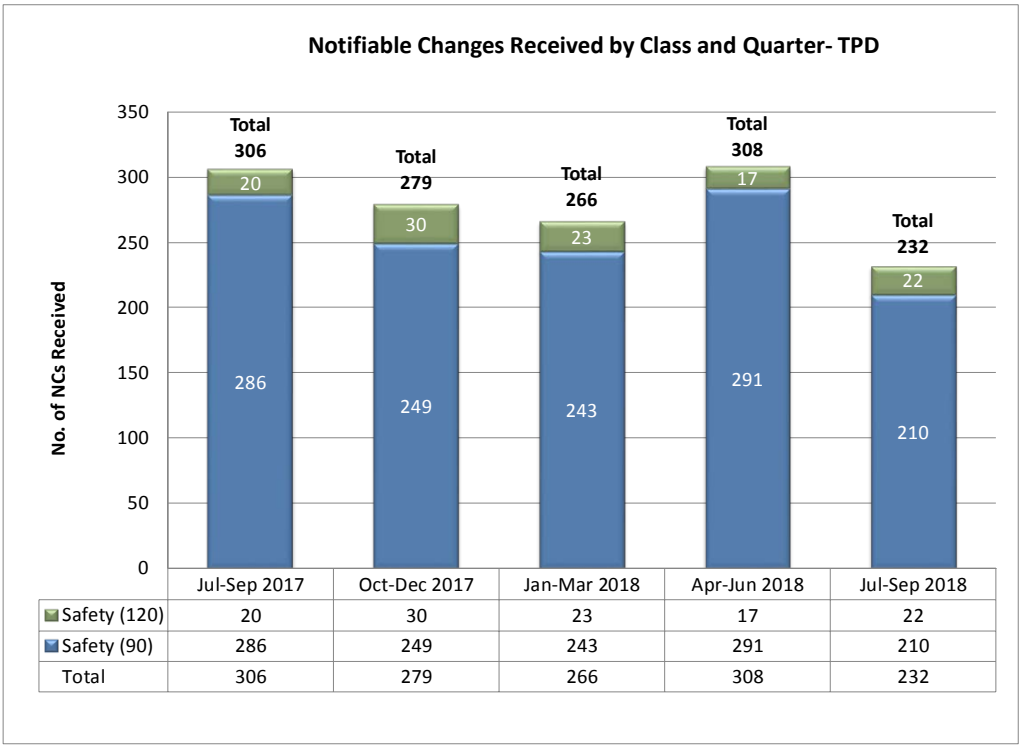
Priority Review Status Requests: Performance



NOTIFIABLE CHANGES (NC)

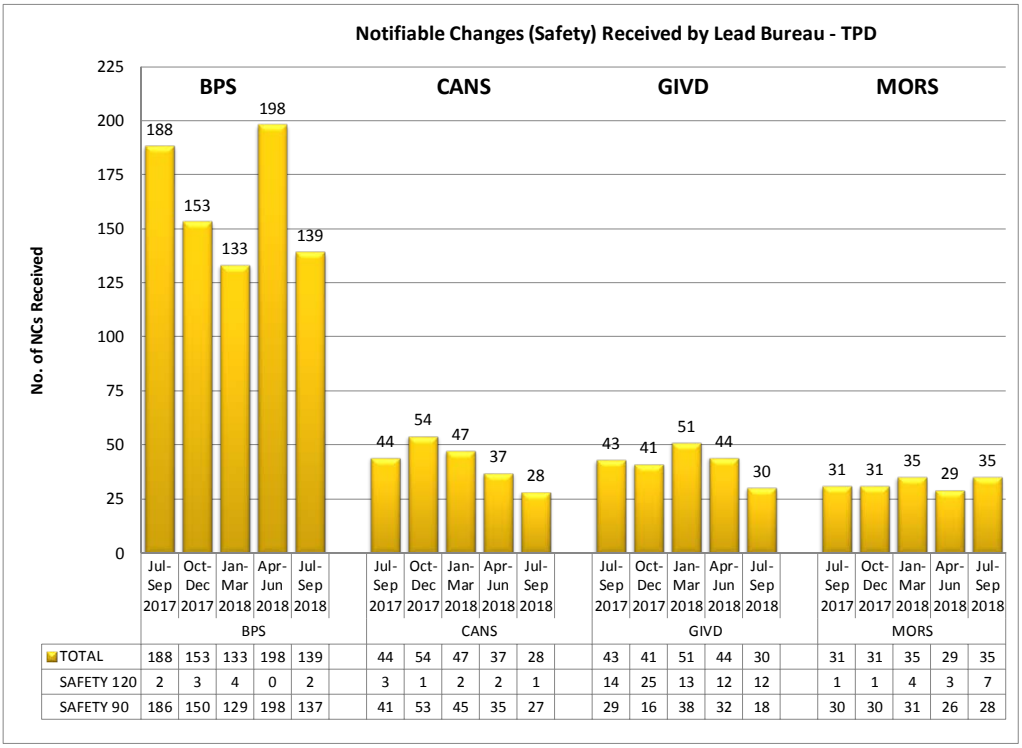
NOTIFIABLE CHANGES[11]
SUBMISSIONS RECEIVED

Number Received - Notifiable Changes (NC) - by Class



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Safety (120)	20	30	23	17	22
Safety (90)	286	249	243	291	210
Total	306	279	266	308	232

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

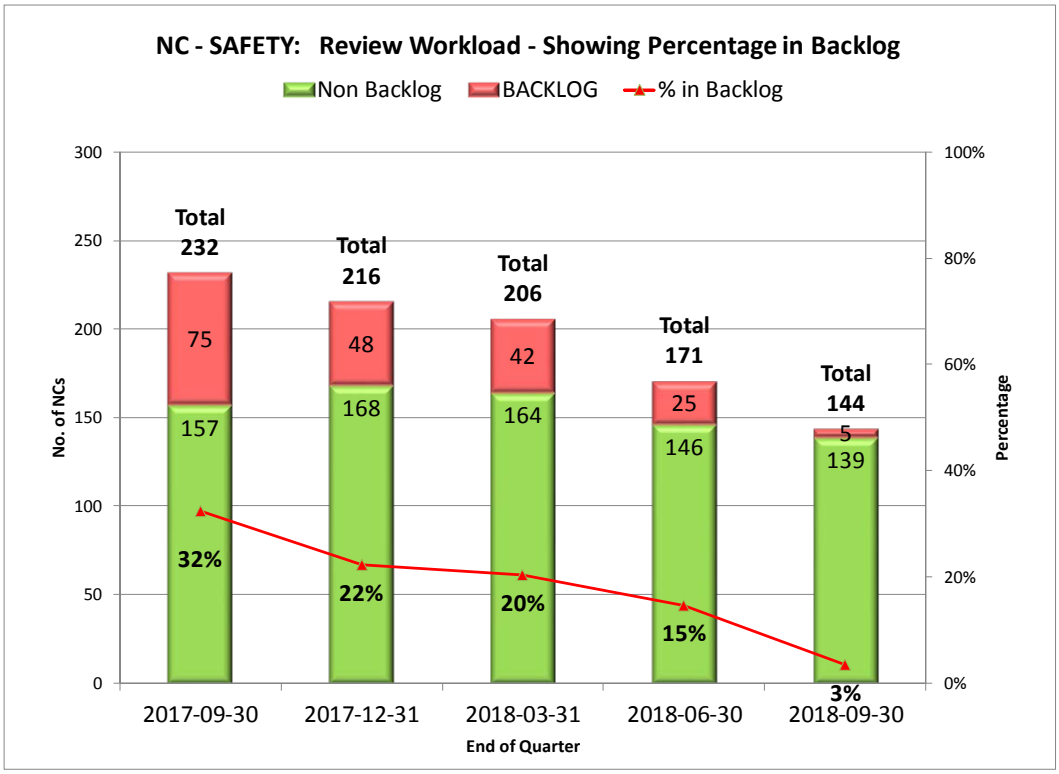


	BPS					CANS					GIVD					MORS				
	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
TOTAL	188	153	133	198	139	44	54	47	37	28	43	41	51	44	30	31	31	35	29	35
SAFETY 120	2	3	4	0	2	3	1	2	2	1	14	25	13	12	12	1	1	4	3	7
SAFETY 90	186	150	129	198	137	41	53	45	35	27	29	16	38	32	18	30	30	31	26	28

[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

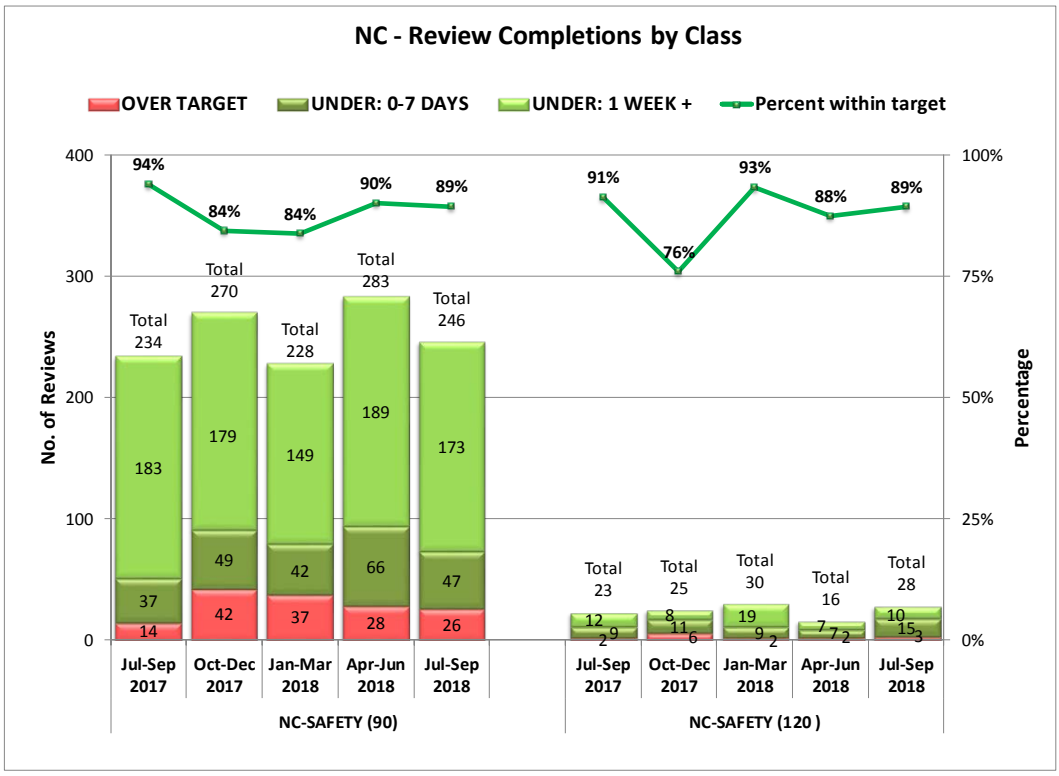


Notifiable Change (NC) SAFETY: Review Workload by Class

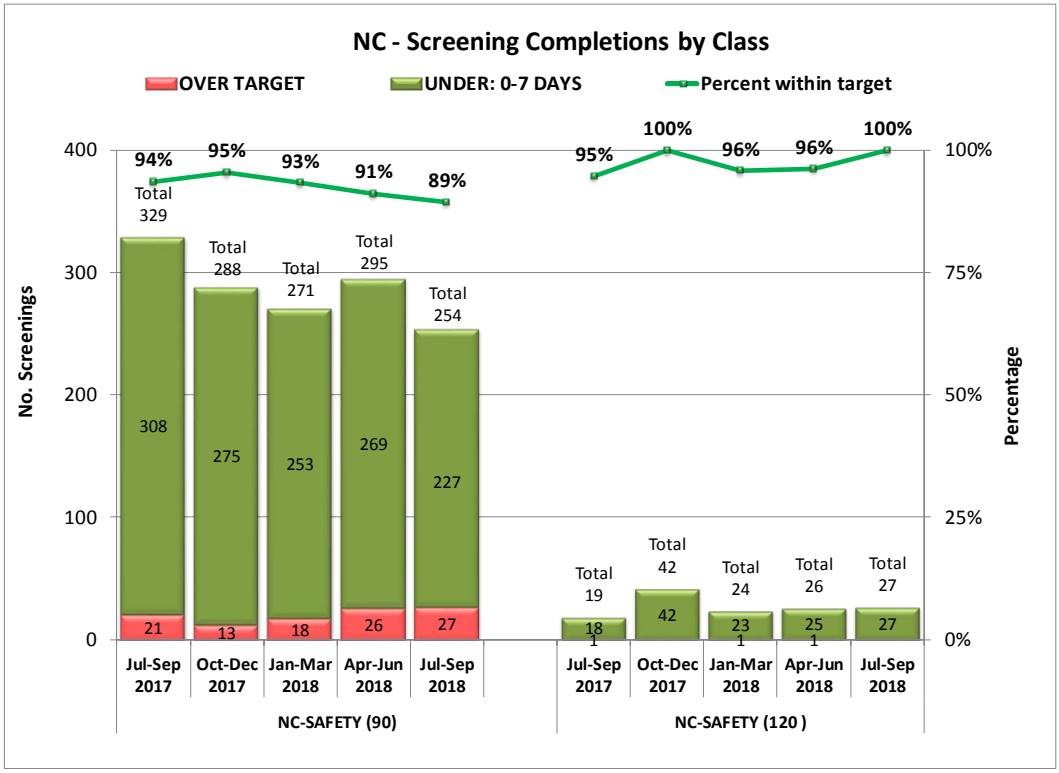
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
SAFETY - 90 day	206	181	184	145	119
Backlog	*70*	*43*	*39*	*23*	*5*
SAFETY - 120 day	26	35	22	26	25
Backlog	*5*	*5*	*3*	*2*	*0*
Total	232	216	206	171	144
Non Backlog	157	168	164	146	139
BACKLOG	75	48	42	25	5
% in Backlog	32%	22%	20%	15%	3%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



Decision Documents by Class - Notifiable Change (NC)

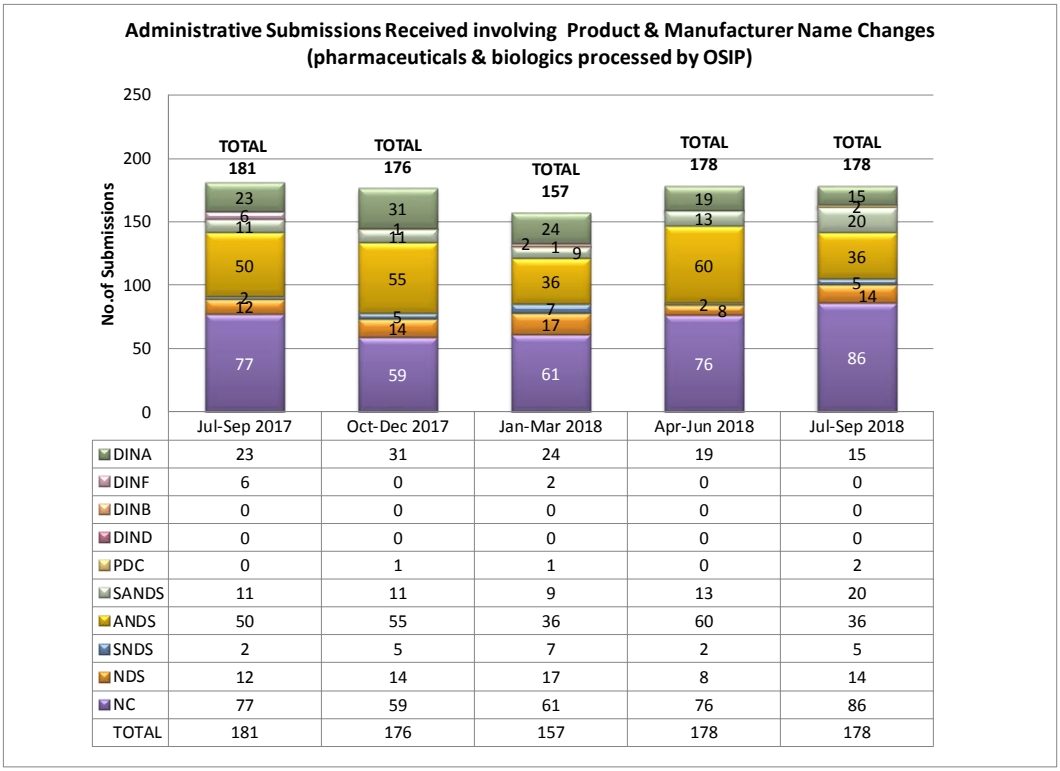
NC - SAFETY (90)					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NO OBJECTION LETTER	255	262	232	273	235
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	2	0	1	0	2
SCREENING DEFICIENCY NOTICE	44	40	36	40	25
CANCELLED BY COMPANY	20	18	11	25	10
NC - HOLD (PATENT)	11	3	16	6	13
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

NC - SAFETY (120)					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NO OBJECTION LETTER	22	24	30	15	28
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	4	8	6	6	1
CANCELLED BY COMPANY	1	1	1	2	0
REJECTION LETTER (SCR)	0	0	0	0	0

Administrative Submissions

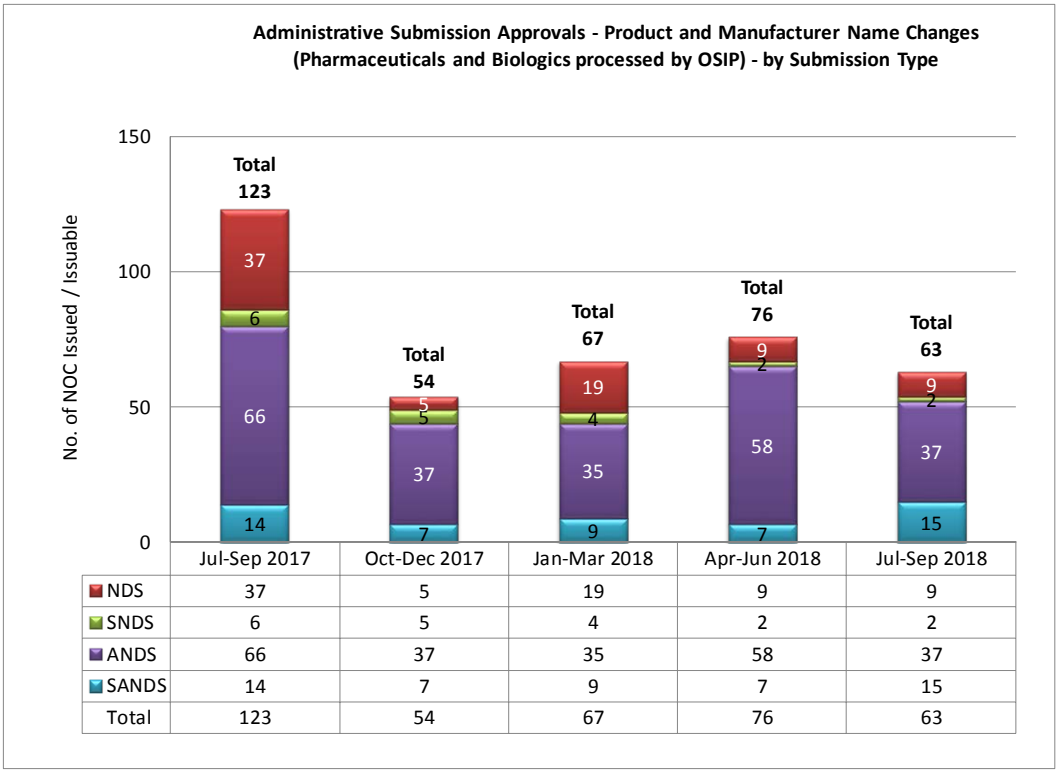
(Product & Manufacturer Name Changes[12])

Administrative Submissions Received by Submission Type (OSIP)



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
DINA	23	31	24	19	15
DINF	6	0	2	0	0
DINB	0	0	0	0	0
DIND	0	0	0	0	0
PDC	0	1	1	0	2
SANDS	11	11	9	13	20
ANDS	50	55	36	60	36
SNDS	2	5	7	2	5
NDS	12	14	17	8	14
NC	77	59	61	76	86
TOTAL	181	176	157	178	178

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
NDS	37	5	19	9	9
SNDS	6	5	4	2	2
ANDS	66	37	35	58	37
SANDS	14	7	9	7	15
Total	123	54	67	76	63

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

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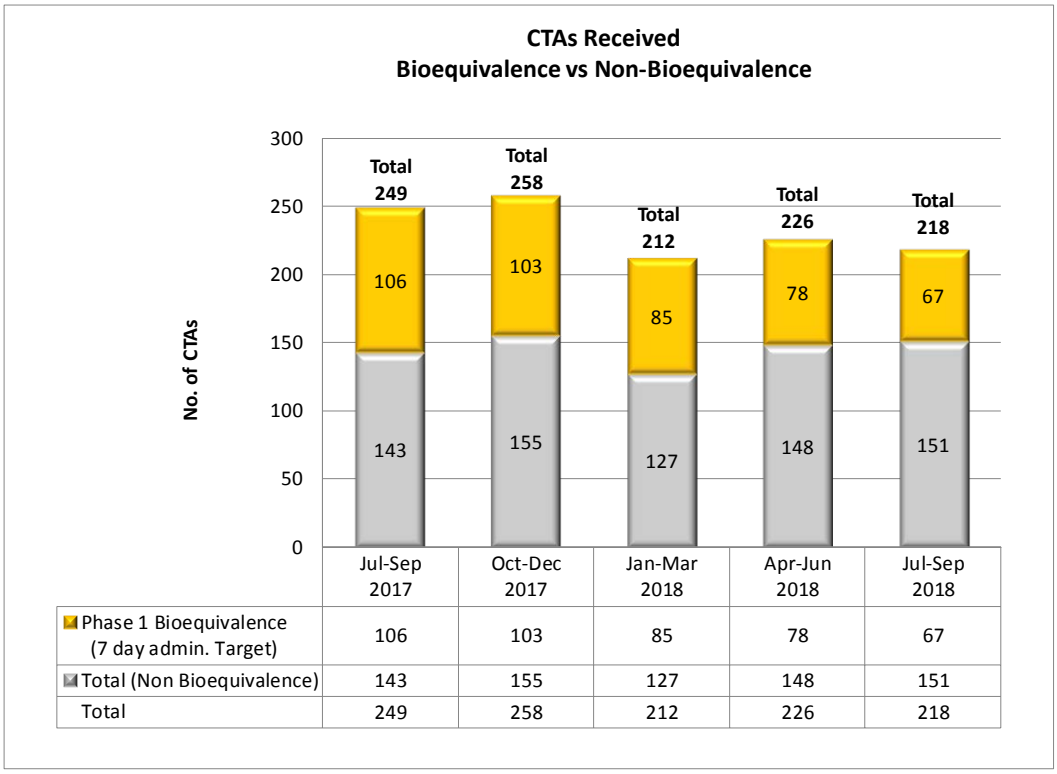
Clinical Trial Applications and Amendments

(CTA & CTA-A)

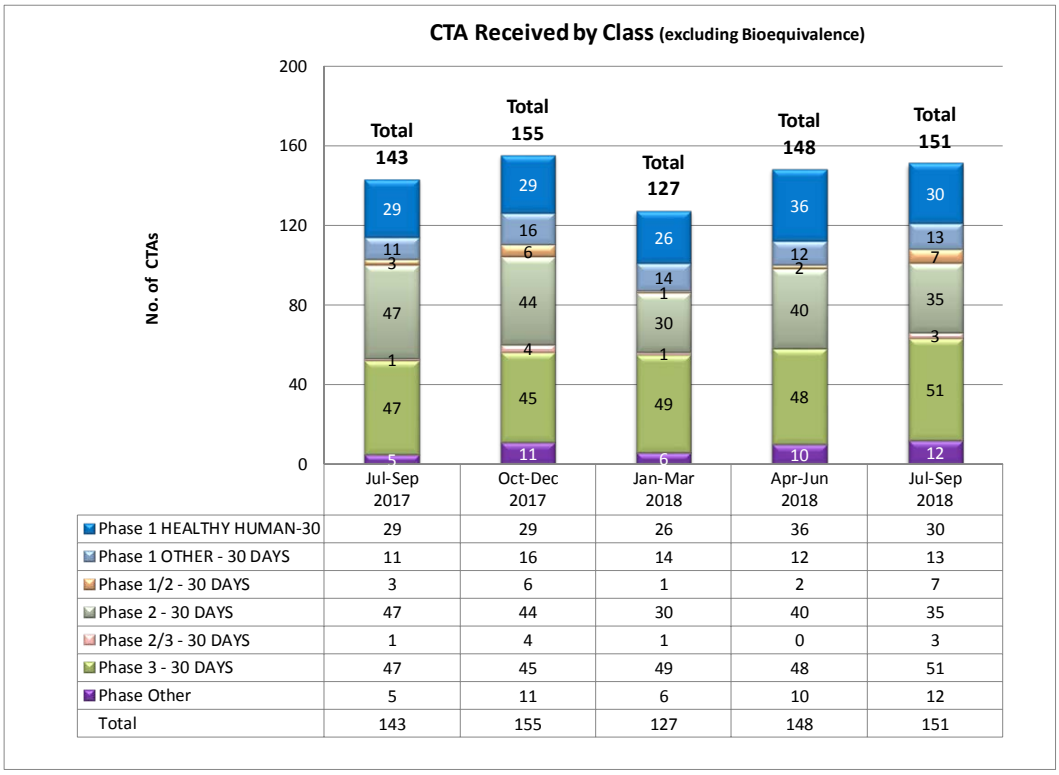
Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Phase 1 Bioequivalence (7 day admin. Target)	106	103	85	78	67
Total (Non Bioequivalence)	143	155	127	148	151
Total	249	258	212	226	218

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Phase 1 HEALTHY HUMAN-30	29	29	26	36	30
Phase 1 OTHER - 30 DAYS	11	16	14	12	13
Phase 1/2 - 30 DAYS	3	6	1	2	7
Phase 2 - 30 DAYS	47	44	30	40	35
Phase 2/3 - 30 DAYS	1	4	1	0	3
Phase 3 - 30 DAYS	47	45	49	48	51
Phase Other	5	11	6	10	12
Total	143	155	127	148	151

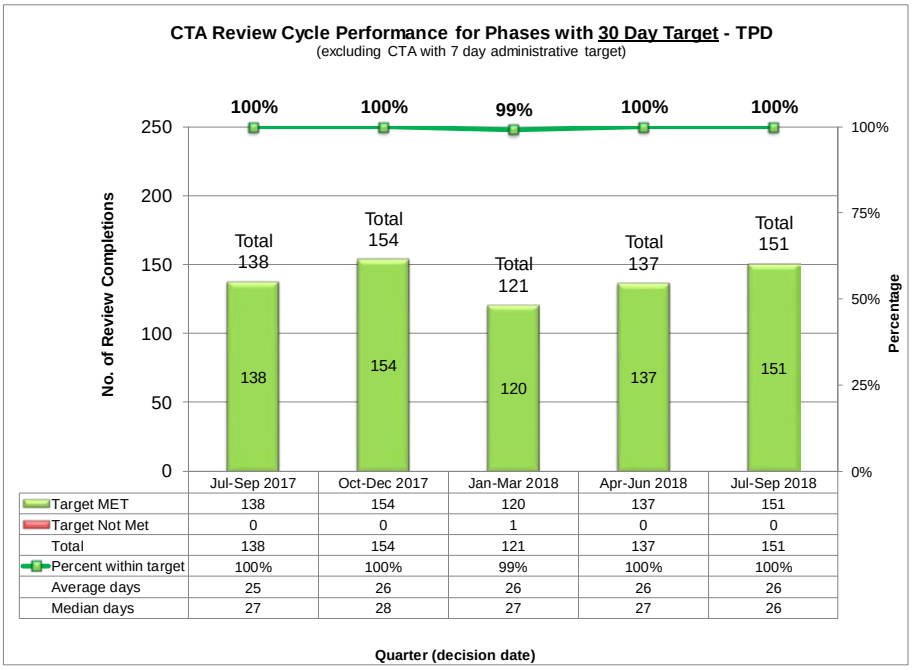
DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NO OBJECTION LETTER	238	237	189	208	211
CANCELLED BY COMPANY	9	20	20	12	9

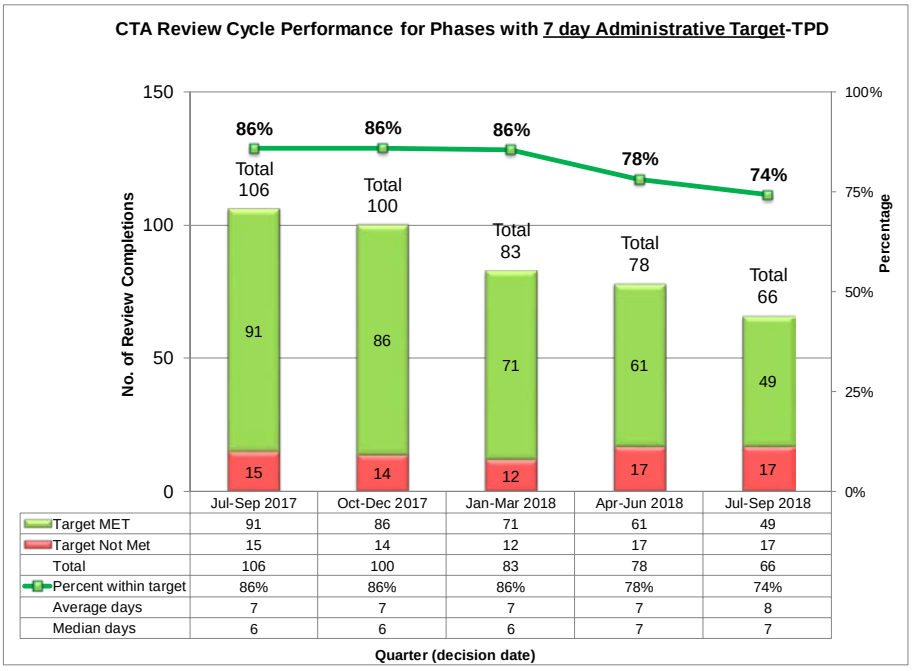
PERFORMANCE

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Target MET	138	154	120	137	151
Target Not Met	0	0	1	0	0
Total	138	154	121	137	151
Percent within target	100%	100%	99%	100%	100%
Average days	25	26	26	26	26
Median days	27	28	27	27	26

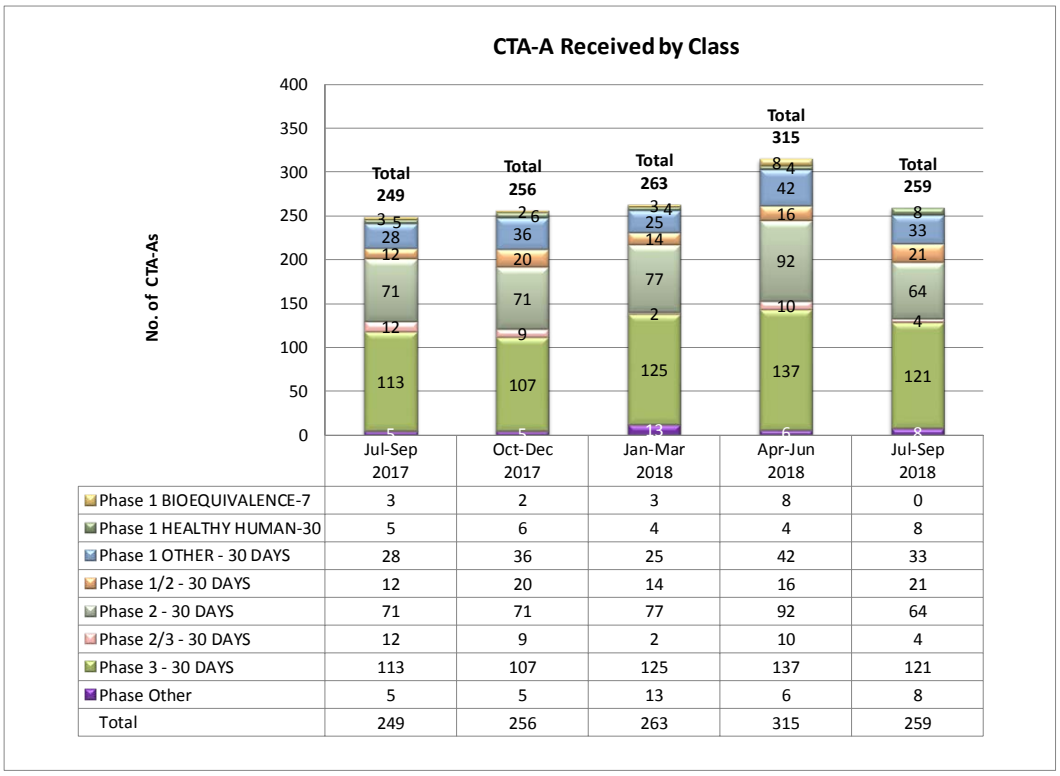
Performance – CTA Review: 7 Day Administrative Target



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Target MET	91	86	71	61	49
Target Not Met	15	14	12	17	17
Total	106	100	83	78	66
Percent within target	86%	86%	86%	78%	74%
Average days	7	7	7	7	8
Median days	6	6	6	7	7

Clinical Trial Application – Amendments (CTA–A)

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Phase 1 BIOEQUIVALENCE-7	3	2	3	8	0
Phase 1 HEALTHY HUMAN-30	5	6	4	4	8
Phase 1 OTHER - 30 DAYS	28	36	25	42	33
Phase 1/2 - 30 DAYS	12	20	14	16	21
Phase 2 - 30 DAYS	71	71	77	92	64
Phase 2/3 - 30 DAYS	12	9	2	10	4
Phase 3 - 30 DAYS	113	107	125	137	121
Phase Other	5	5	13	6	8
Total	249	256	263	315	259

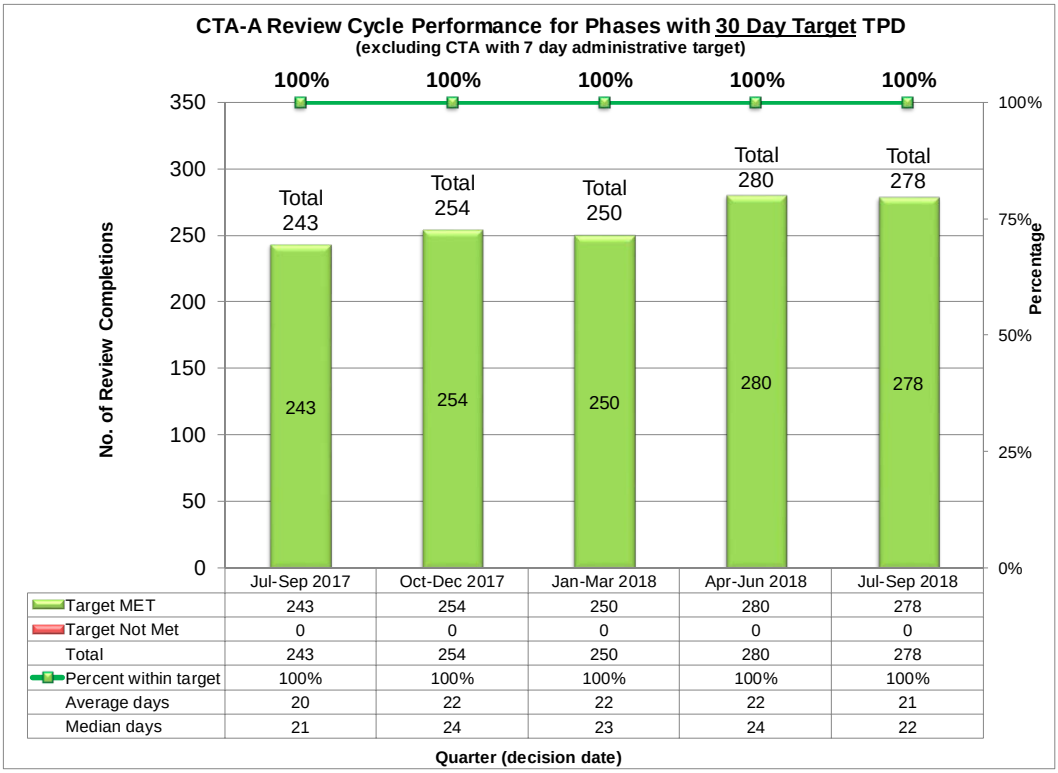
DECISION DOCUMENTS

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

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NO OBJECTION LETTER	245	252	250	280	275
CANCELLED BY COMPANY	1	5	3	8	4
NOT SATISFACTORY NOTICE	0	0	0	0	0

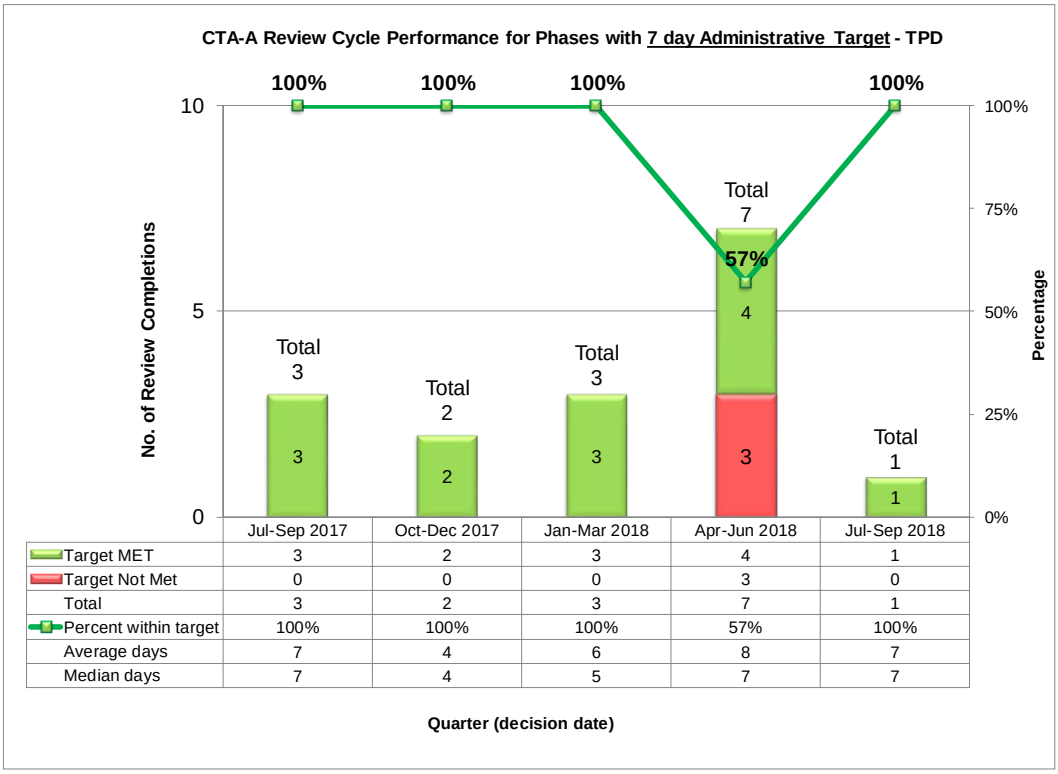
PERFORMANCE

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Target MET	243	254	250	280	278
Target Not Met	0	0	0	0	0
Total	243	254	250	280	278
Percent within target	100%	100%	100%	100%	100%
Average days	20	22	22	22	21
Median days	21	24	23	24	22

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



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Target MET	3	2	3	4	1
Target Not Met	0	0	0	3	0
Total	3	2	3	7	1
Percent within target	100%	100%	100%	57%	100%
Average days	7	4	6	8	7
Median days	7	4	5	7	7

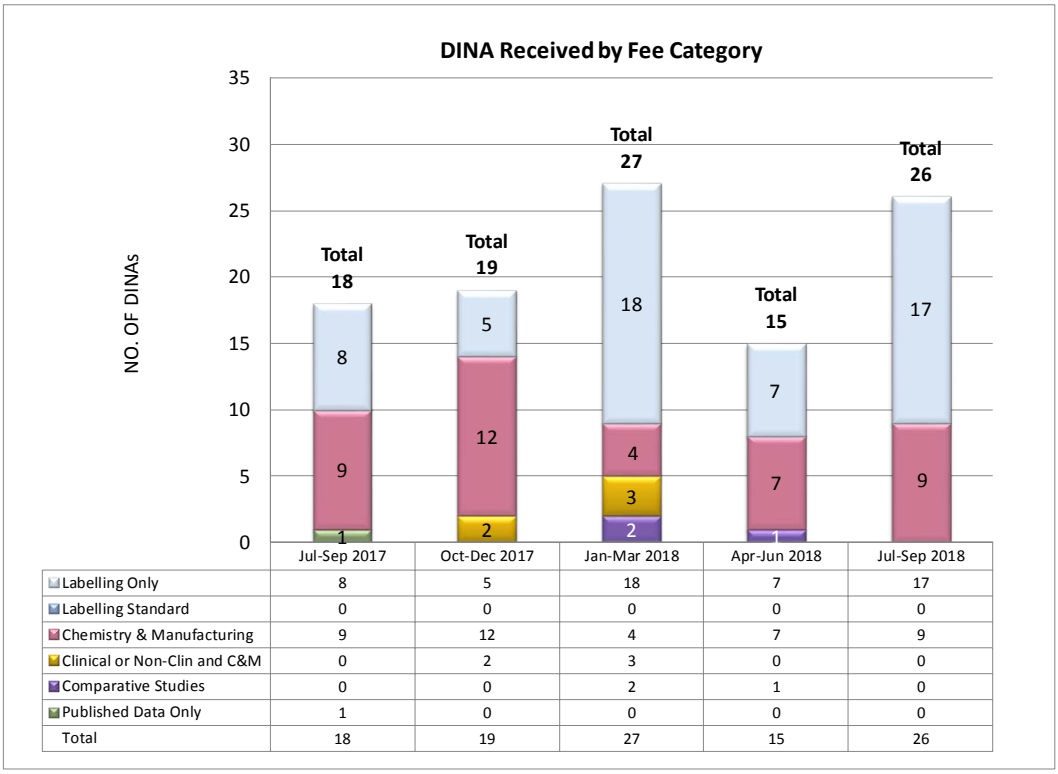
DINA

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

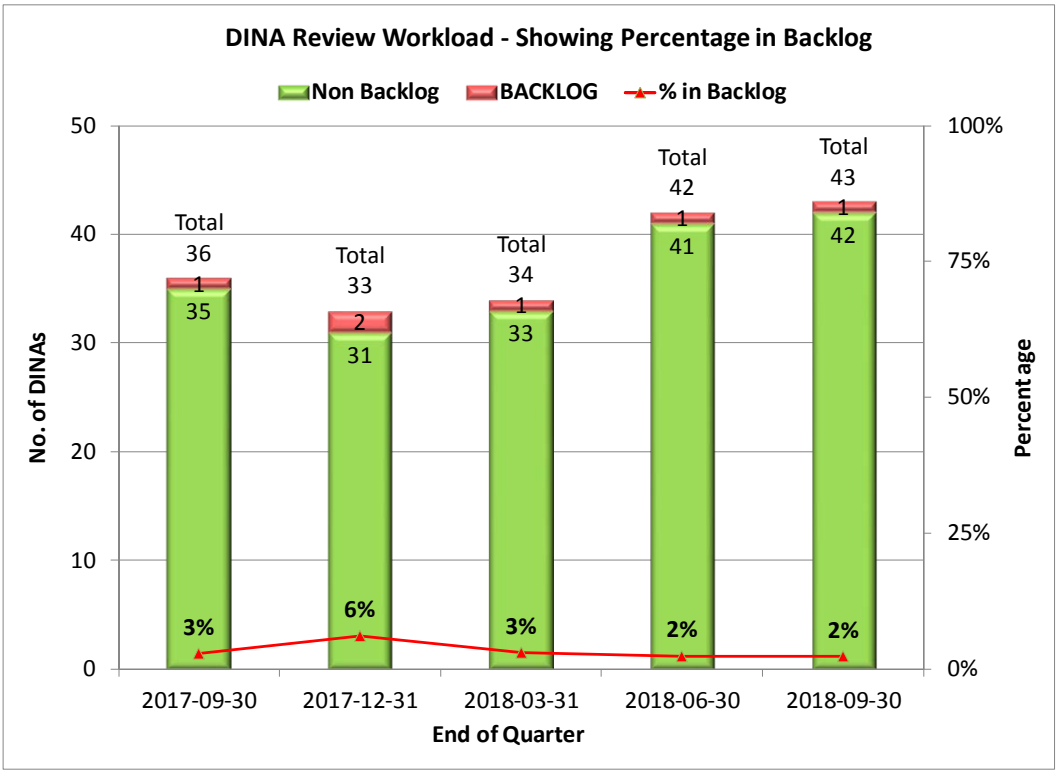


	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	8	5	18	7	17
Labelling Standard	0	0	0	0	0
Chemistry & Manufacturing	9	12	4	7	9
Clinical or Non-Clin and C&M	0	2	3	0	0
Comparative Studies	0	0	2	1	0
Published Data Only	1	0	0	0	0
Total	18	19	27	15	26

[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

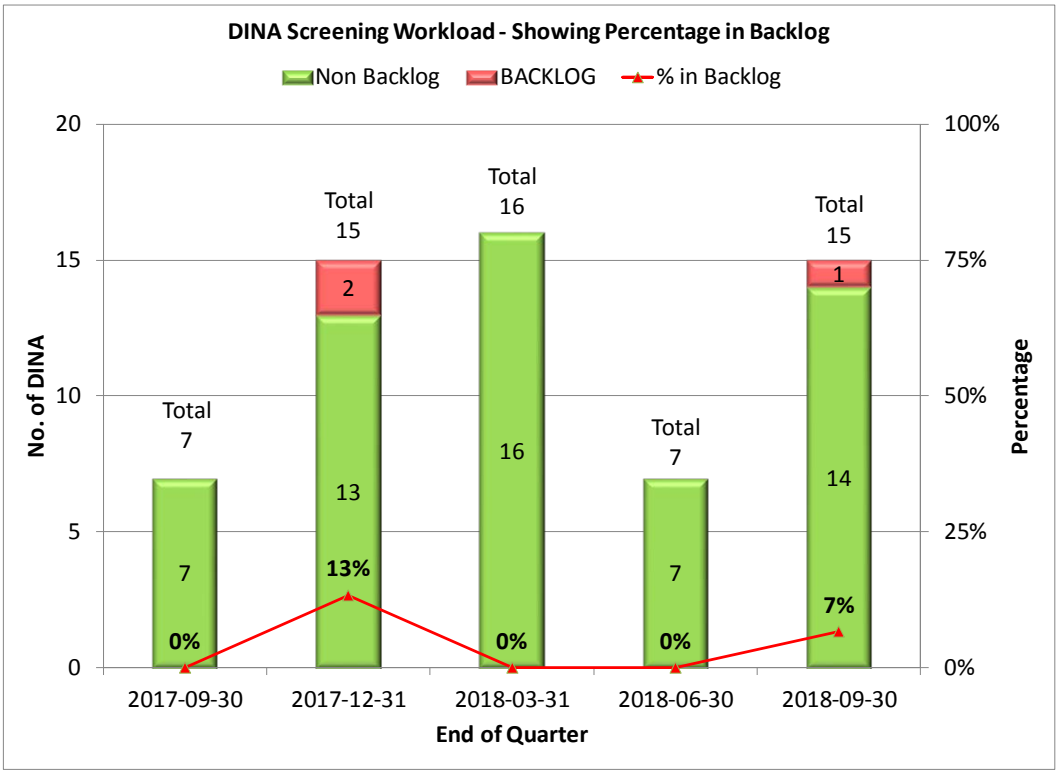


Review Workload by Fee Category – DINA

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Labelling Only	**20**	**14**	**13**	**19**	**17**
Backlog	*0*	*1*	*1*	*1*	*1*
Chemistry & Manufacturing	**14**	**17**	**19**	**15**	**20**
Backlog	*1*	*1*	*0*	*0*	*0*
Published Data	**0**	**1**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**4**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**2**	**1**	**1**	**4**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**36**	**33**	**34**	**42**	**43**
Non Backlog	**35**	**31**	**33**	**41**	**42**
BACKLOG	**1**	**2**	**1**	**1**	**1**
% in Backlog	**3%**	**6%**	**3%**	**2%**	**2%**

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					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Labelling Only	**3**	**3**	**8**	**3**	**8**
Backlog	*0*	*0*	*0*	*0*	*1*
Labelling Standard	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**2**	**2**	**0**	**0**
Backlog	*0*	*1*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**10**	**4**	**4**	**7**
Backlog	*0*	*1*	*0*	*0*	*0*
Published Data	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**0**	**2**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**7**	**15**	**16**	**7**	**15**
Non Backlog	**7**	**13**	**16**	**7**	**14**
BACKLOG	**0**	**2**	**0**	**0**	**1**
% in Backlog	**0%**	**13%**	**0%**	**0%**	**7%**

DECISION DOCUMENTS

Decision Documents – DINA by Fee Category

DINA - Labelling Only					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NOTIFICATION FORM/DIN ISSUED	1	5	3	1	3
NO OBJECTION LETTER	4	6	6	5	7
CANCELLED BY COMPANY	0	0	2	3	1
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	0	2	0
REJECTION LETTER (SCR)	0	1	0	0	0
SCREENING DEFICIENCY NOTICE	3	1	3	2	2
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

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

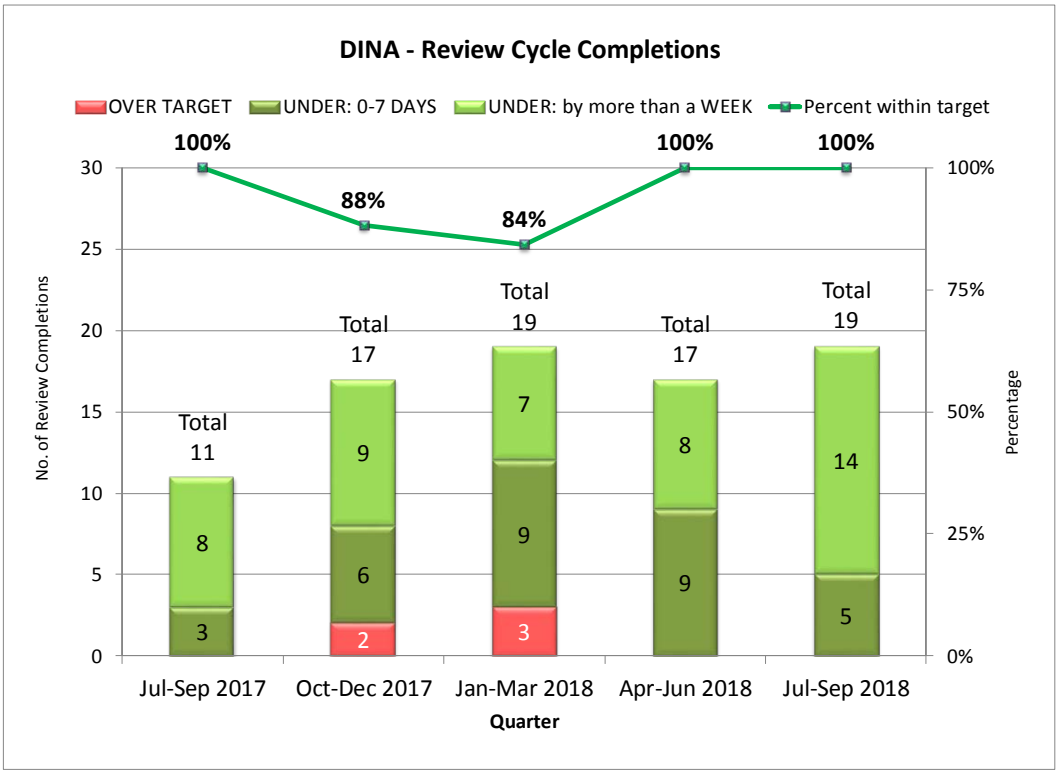
DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
NO OBJECTION LETTER	0	0	0	1	0
REJECTION LETTER (SCR)	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CANCELLED 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	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
NOTIFICATION FORM/DIN ISSUED	0	0	1	0	1
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	1	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	1
SCREENING DEFICIENCY NOTICE	0	0	1	1	0

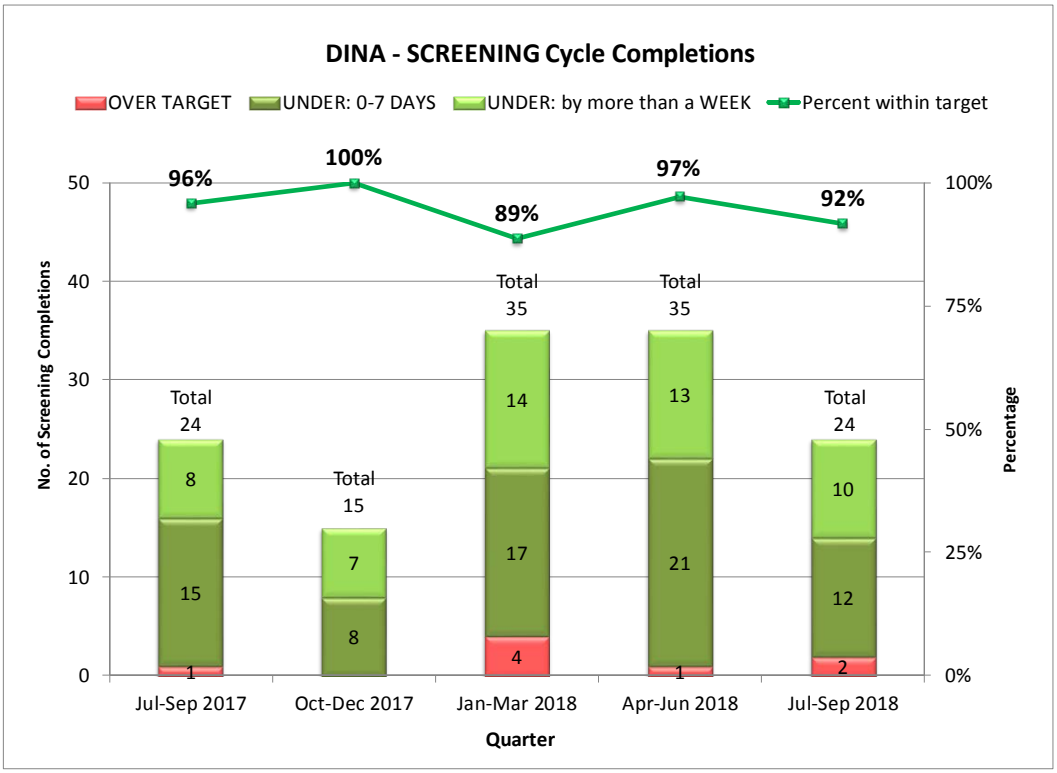
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
CANCELLED BY COMPANY	0	0	1	0	0
SCREENING DEFICIENCY NOTICE	0	0	2	2	0

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target – DINA

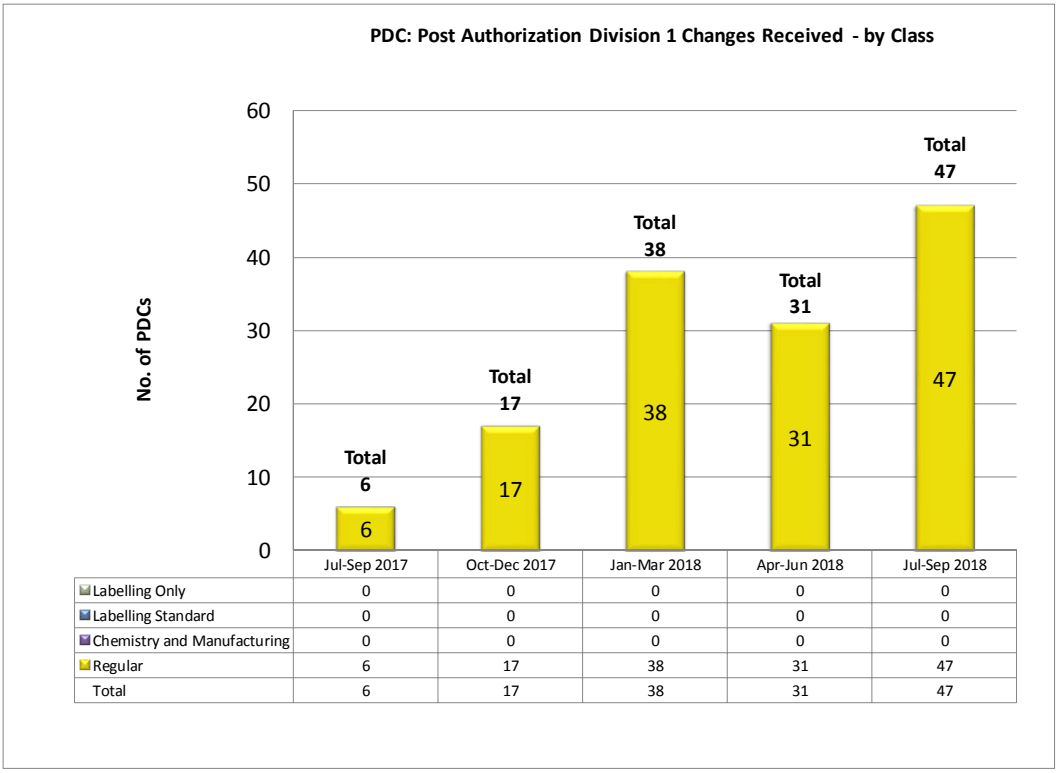


Performance Screening Cycle Completions Showing Percentage Within Target – DINA



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

Post-Authorization Division 1 Changes (PDC) Received



	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Labelling Only	0	0	0	0	0
Labelling Standard	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	0
Regular	6	17	38	31	47
Total	6	17	38	31	47

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

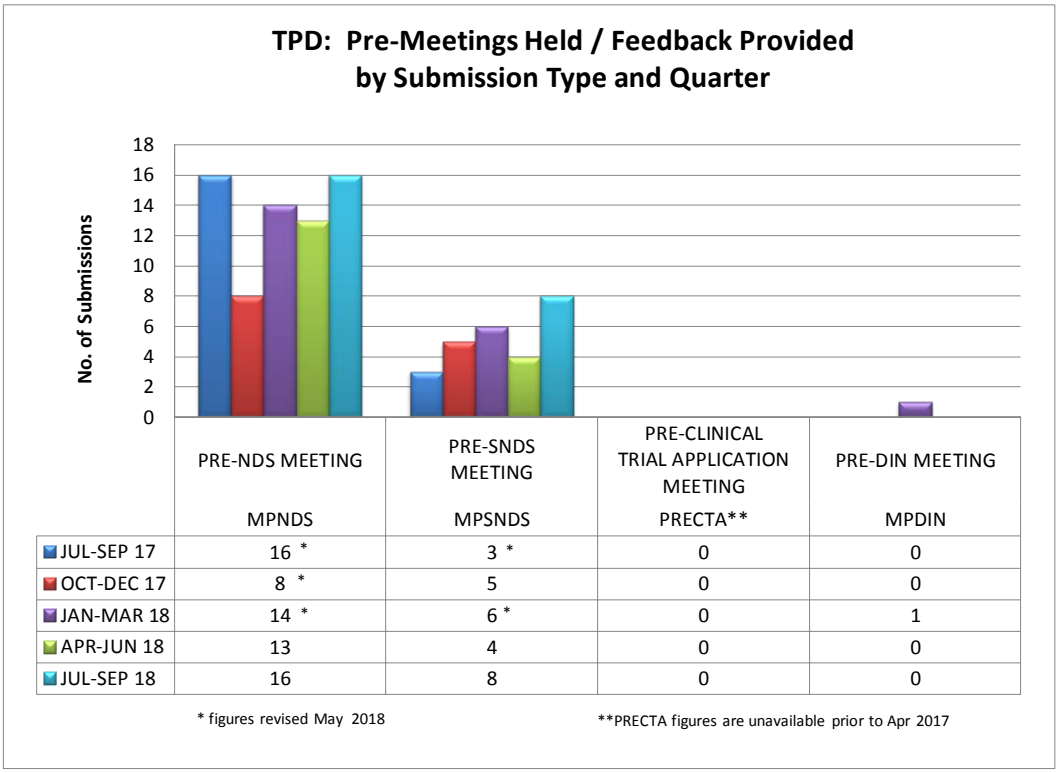
PDC					
DOCUMENT TYPE	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**
REGULAR					
CANCELLED BY COMPANY	3	5	4	3	7
NO OBJECTION LETTER	2	9	15	30	38
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

[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
JUL-SEP 17	16 *	3 *	0	0
OCT-DEC 17	8 *	5	0	0
JAN-MAR 18	14 *	6 *	0	1
APR-JUN 18	13	4	0	0
JUL-SEP 18	16	8	0	0

* figures revised May 2018

**PRECTA figures are unavailable prior to Apr 2017

[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