Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

July – September

2019

Canada

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Direction des produits thérapeutiques - Rapport trimestriel du rendement des présentations de drogue – juillet - septembre 2019

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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 2018 to July – September 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-Cs are not included in the SNDS Approval figures. For further Clarification refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

A **review cycle completion**[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 Review 1 and 90 days for Review 2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude "refiled"[5] submissions.

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

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101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

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

Documents

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

Fee Categories

Fee Category	Fee Category Description
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 the Therapeutic Products Directorate (TPD) to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

NEW DRUG SUBMISSION (NDS)

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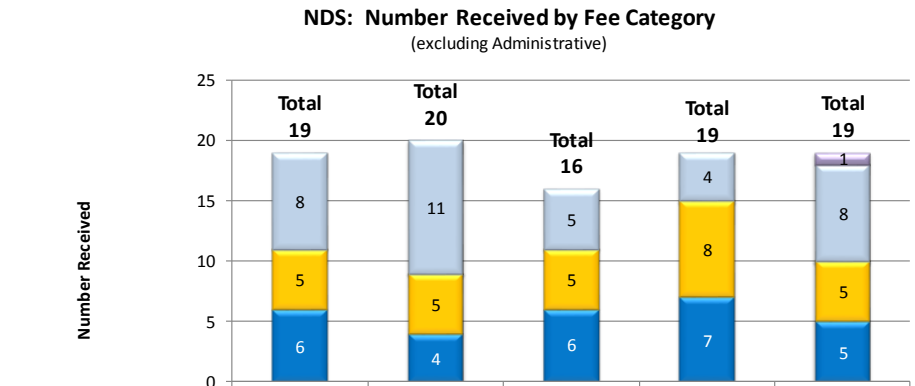
SUPPLEMENT TO A NEW DRUG SUBMISSION (SNDS)

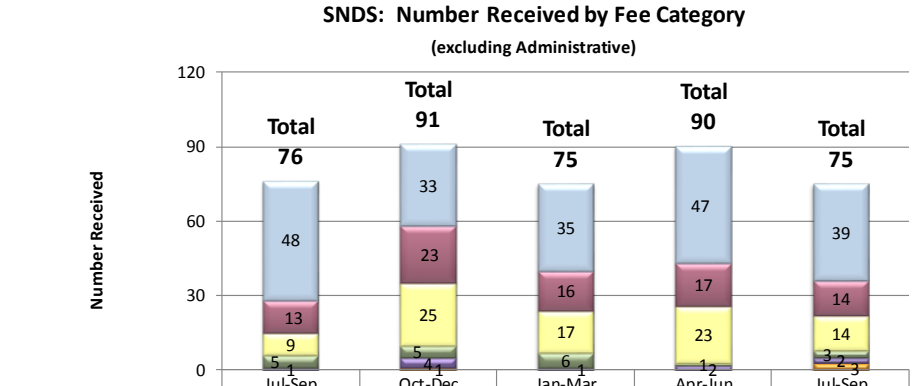
SUBMISSIONS RECEIVED [8]

NDS: Number Received by Fee Category



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Unassigned	0	0	0	0	1
Labelling Only	8	11	5	4	8
Comparative Studies	0	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	5	5	5	8	5
New Active Substance	6	4	6	7	5
Total	19	20	16	19	19
Priority Class	1	2	0	4	0
NOC-C Class	1	0	1	1	0
Extraordinary Use NDS	0	0	0	0	0

SNDS: Number Received by Fee Category

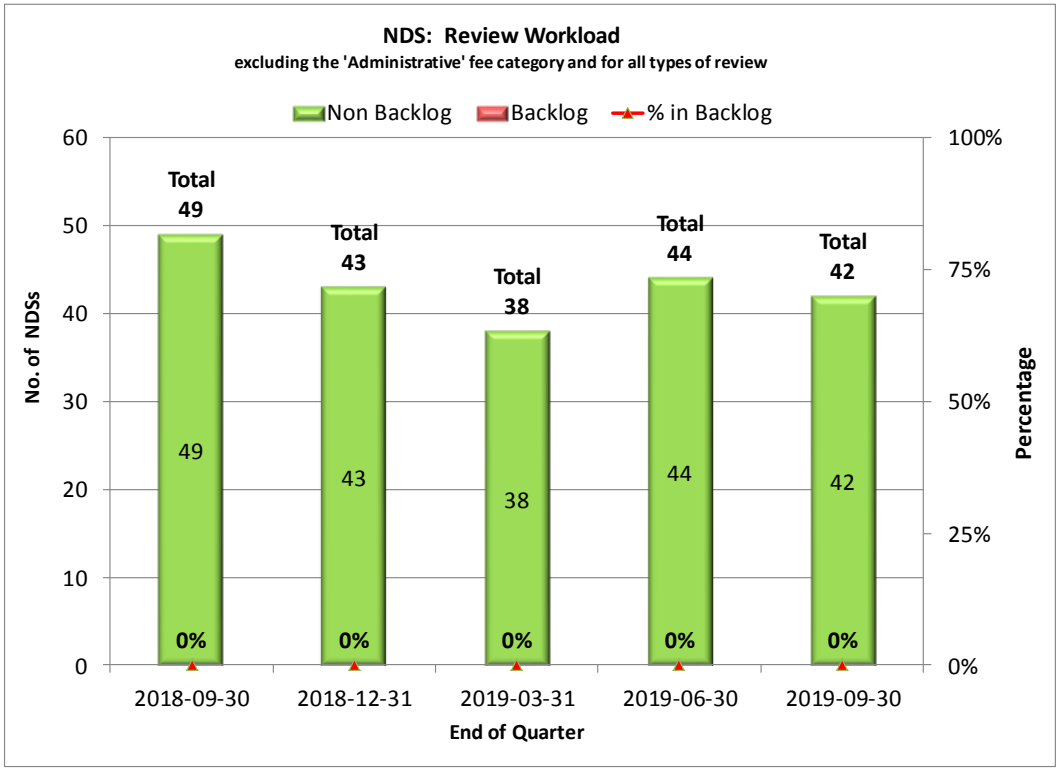


	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	48	33	35	47	39
Chemistry & Manufacturing	13	23	16	17	14
Clinical or Non-Clin Only	9	25	17	23	14
Published Data Only	5	5	6	1	3
Comparative Studies	1	4	1	2	2
Clinical or Non-Clin and C&M	0	1	0	0	3
Total	76	91	75	90	75
Priority Class	2	3	1	5	1
NOC-C Class	0	0	0	0	0
SNDS - Confirmatory	0	1	2	1	0

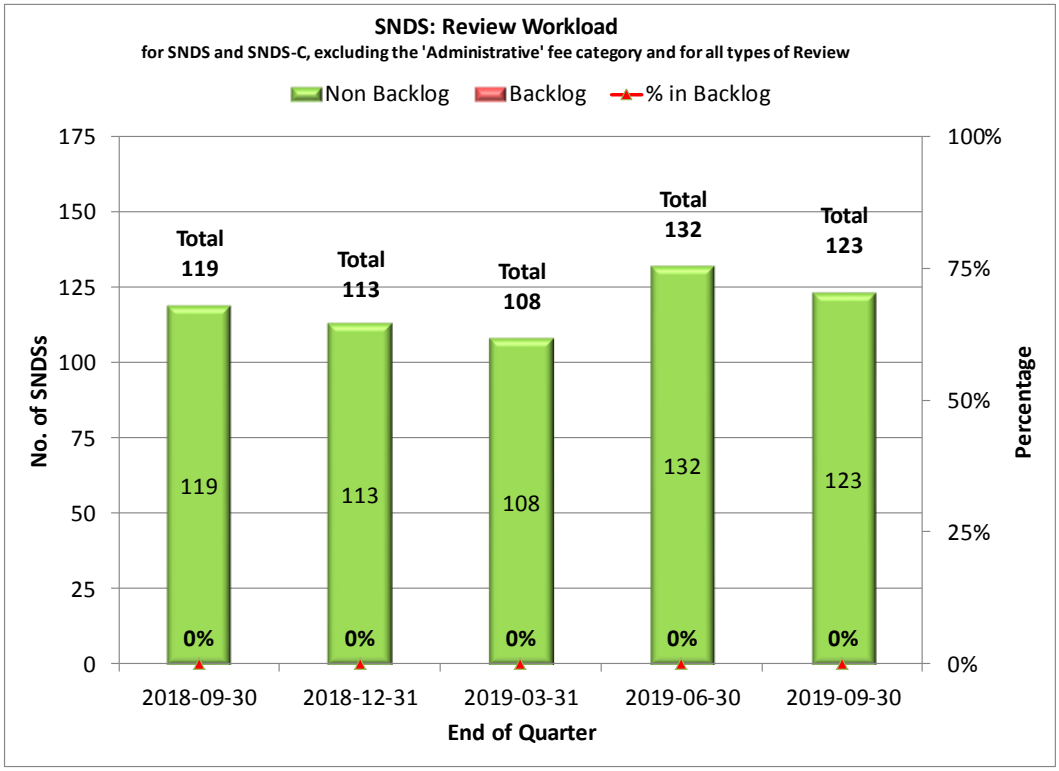
[8] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

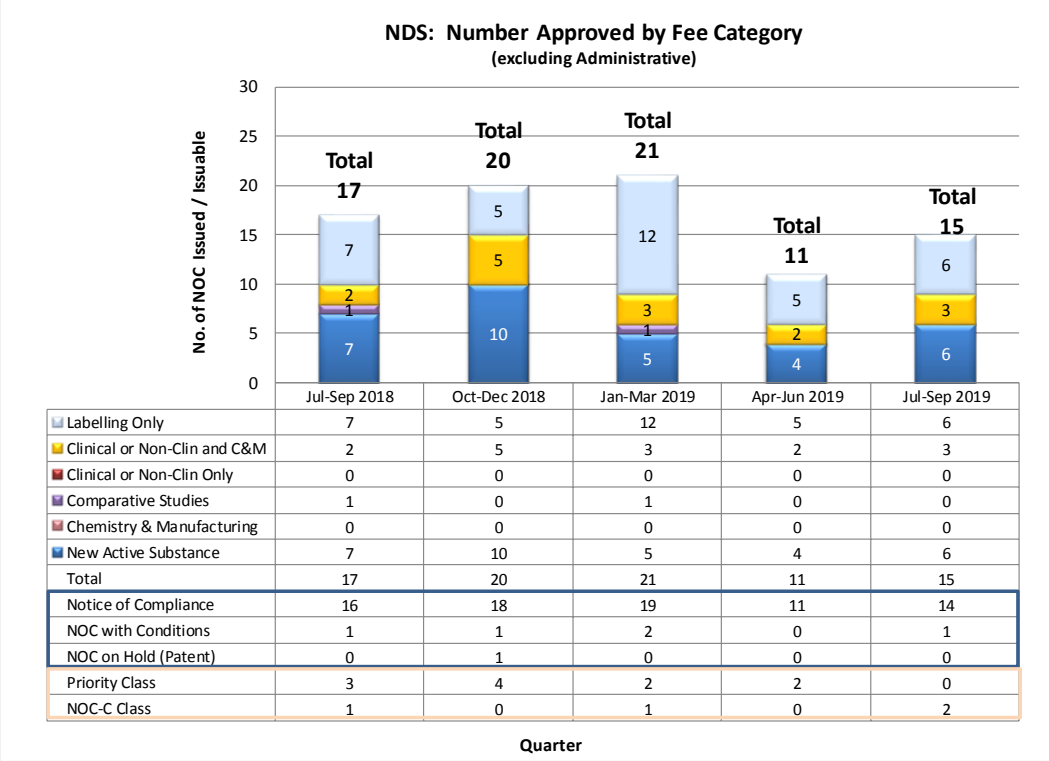
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2018-09-30**	**2018-12-31**	**2019-03-31**	**2019-06-30**	**2019-09-30**
Labelling Only	**5**	**8**	**4**	**3**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**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	**16**	**15**	**15**	**19**	**19**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**27**	**19**	**19**	**22**	**20**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**49**	**43**	**38**	**44**	**42**
Non Backlog	**49**	**43**	**38**	**44**	**42**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**6**	**4**	**3**	**3**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*

SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Labelling Only	**23**	**21**	**10**	**21**	**16**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**6**	**3**	**7**	**9**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**25**	**26**	**29**	**32**	**28**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**49**	**49**	**53**	**55**	**57**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**7**	**2**	**1**	**1**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**9**	**12**	**8**	**14**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**119**	**113**	**108**	**132**	**123**
Non Backlog	**119**	**113**	**108**	**132**	**123**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**5**	**4**	**4**	**5**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**1**	**0**	**2**	**3**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*

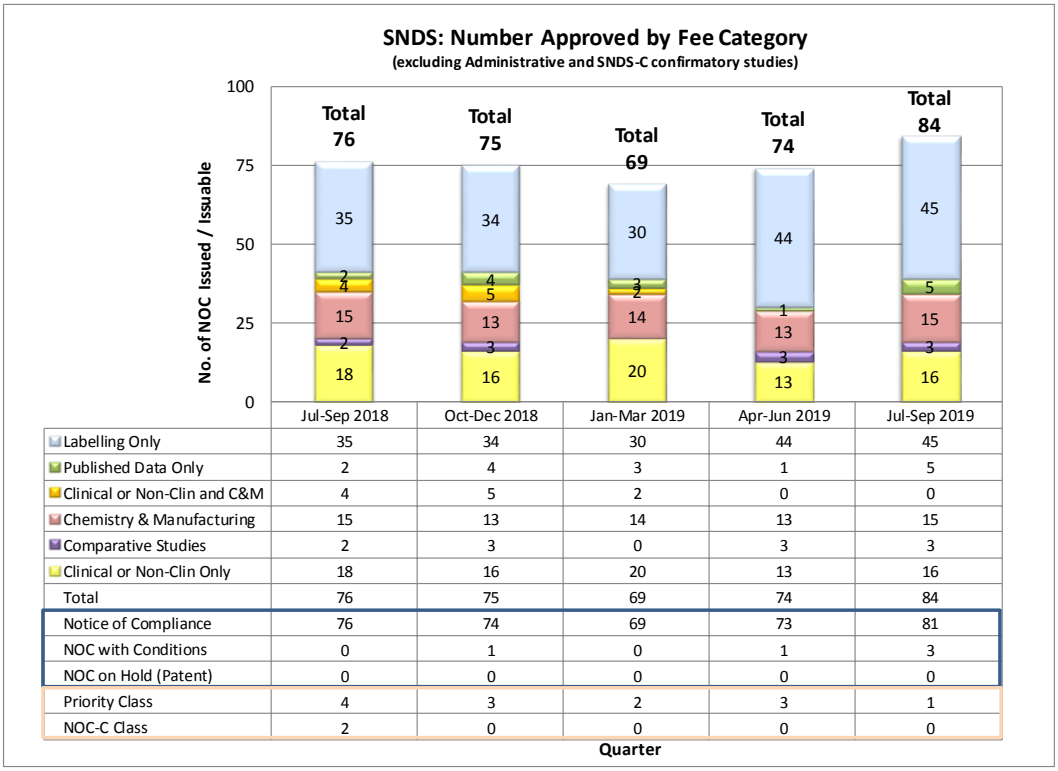
APPROVALS[8][9]

NDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	7	5	12	5	6
Clinical or Non-Clin and C&M	2	5	3	2	3
Clinical or Non-Clin Only	0	0	0	0	0
Comparative Studies	1	0	1	0	0
Chemistry & Manufacturing	0	0	0	0	0
New Active Substance	7	10	5	4	6
Total	17	20	21	11	15
Notice of Compliance	16	18	19	11	14
NOC with Conditions	1	1	2	0	1
NOC on Hold (Patent)	0	1	0	0	0
Priority Class	3	4	2	2	0
NOC-C Class	1	0	1	0	2

SNDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	35	34	30	44	45
Published Data Only	2	4	3	1	5
Clinical or Non-Clin and C&M	4	5	2	0	0
Chemistry & Manufacturing	15	13	14	13	15
Comparative Studies	2	3	0	3	3
Clinical or Non-Clin Only	18	16	20	13	16
Total	76	75	69	74	84
Notice of Compliance	76	74	69	73	81
NOC with Conditions	0	1	0	1	3
NOC on Hold (Patent)	0	0	0	0	0
Priority Class	4	3	2	3	1
NOC-C Class	2	0	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.

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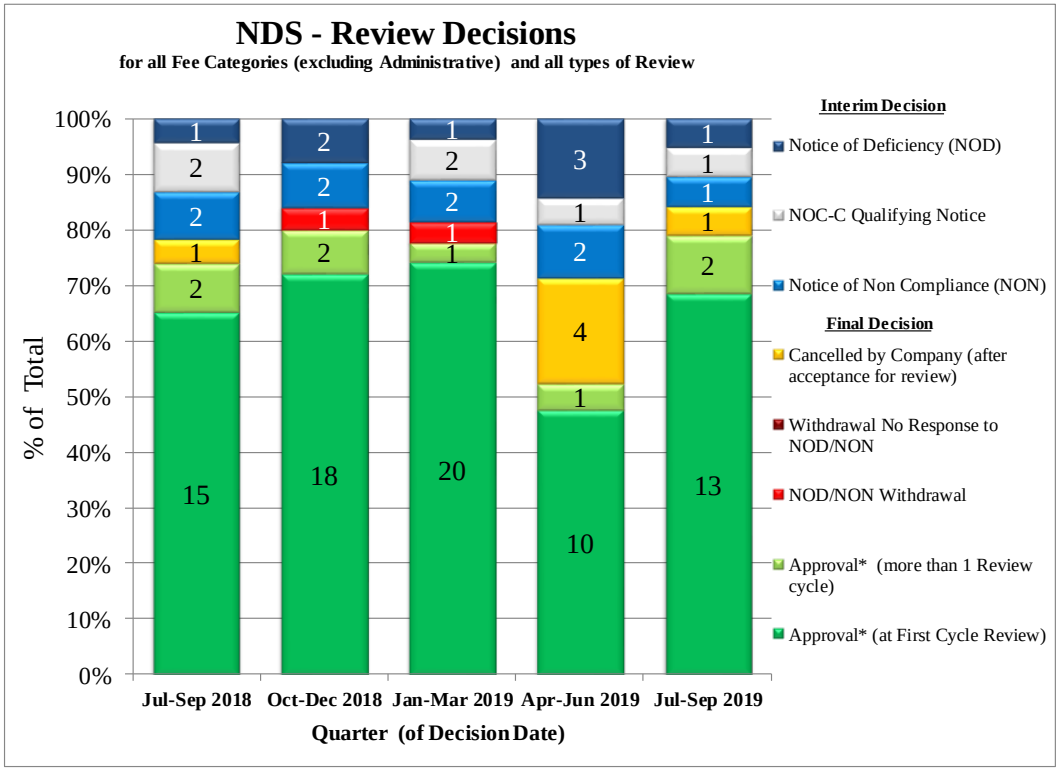
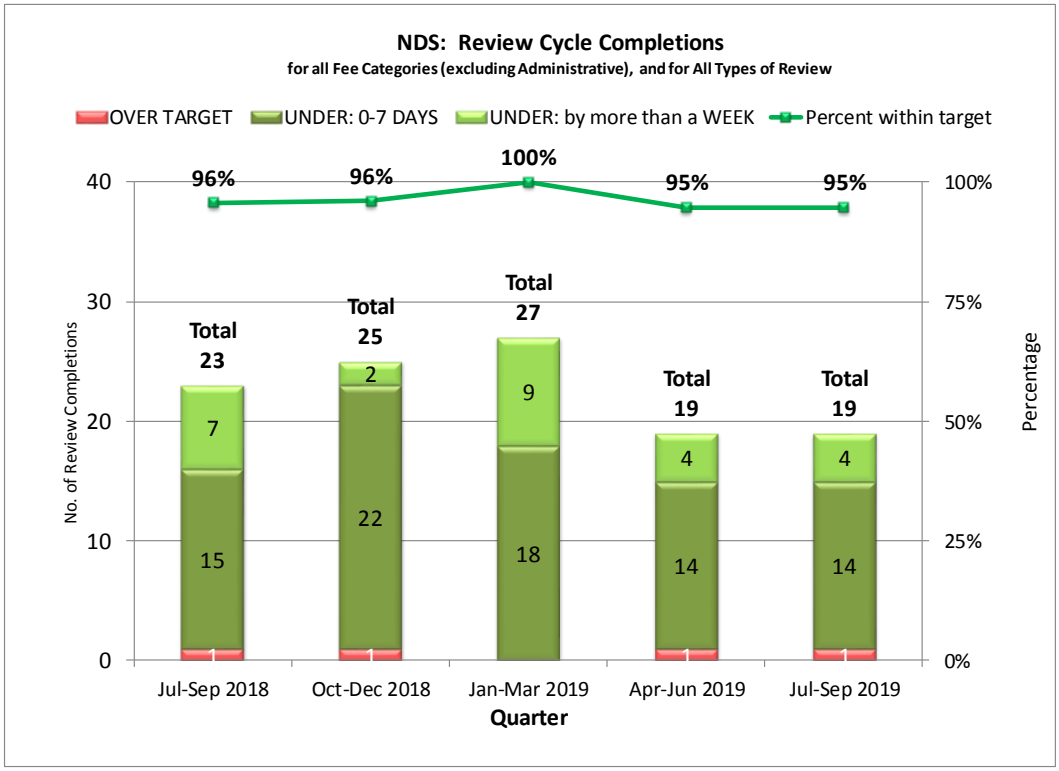
REVIEW PERFORMANCE

NDS: Review Decisions by Type

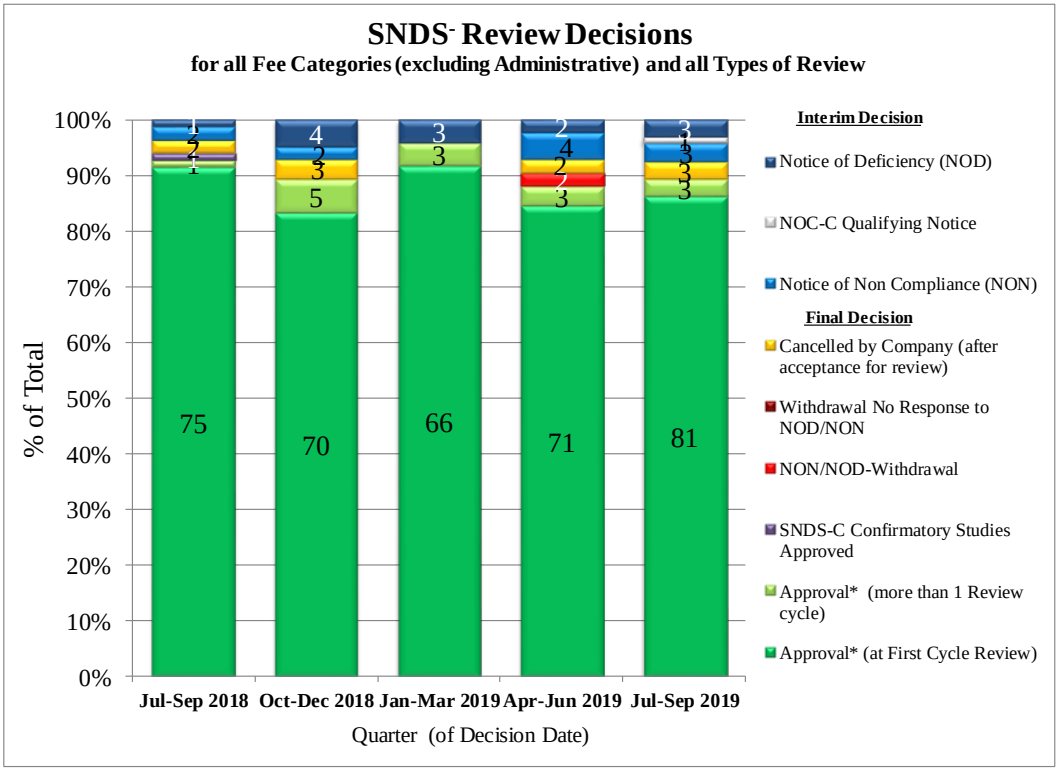


NDS: Review Cycle Completions

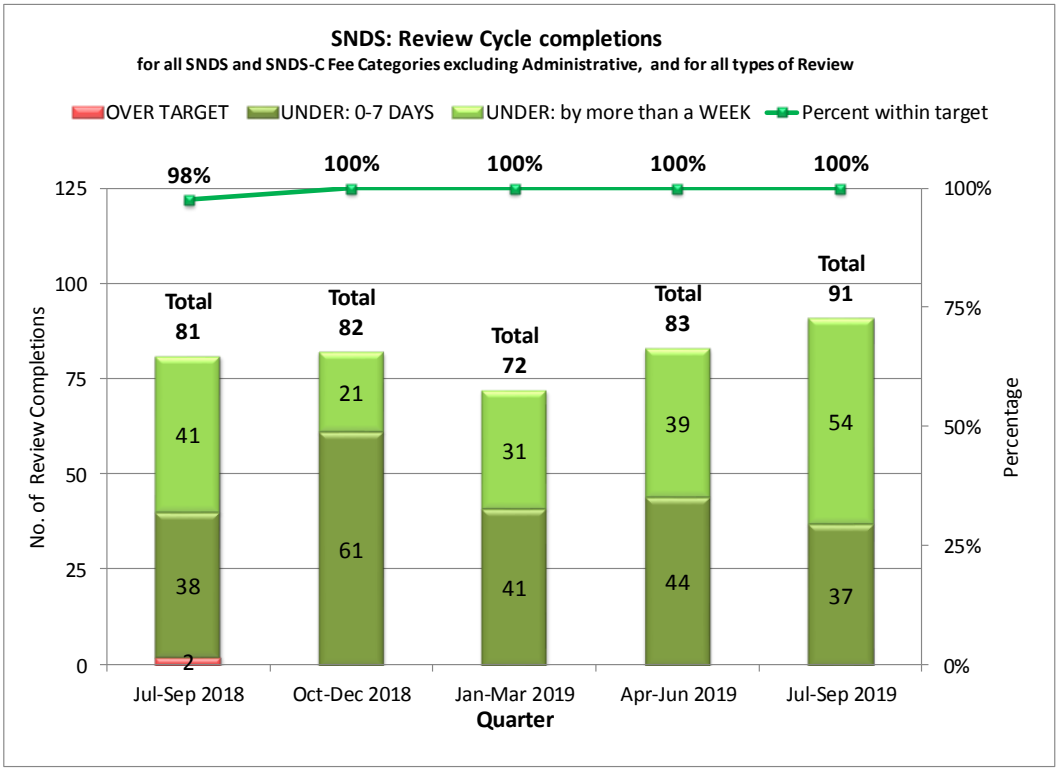


REVIEW CYCLE DECISIONS

SNDS: Review Decisions by Type

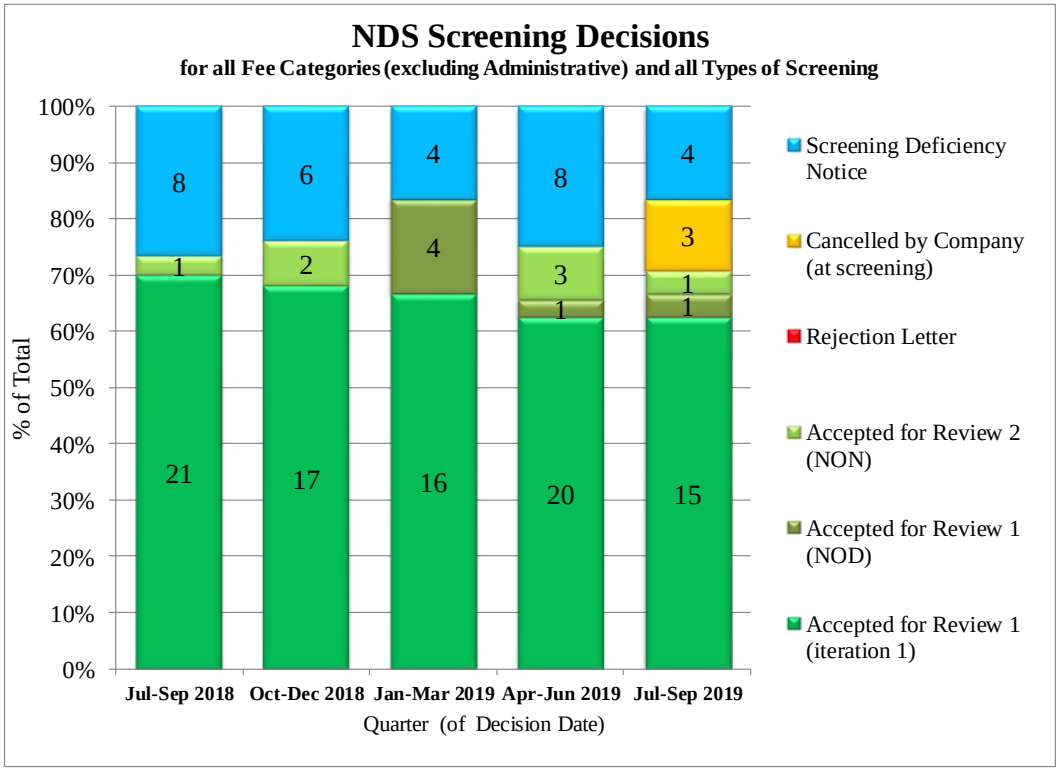


SNDS: Review Cycle Completions

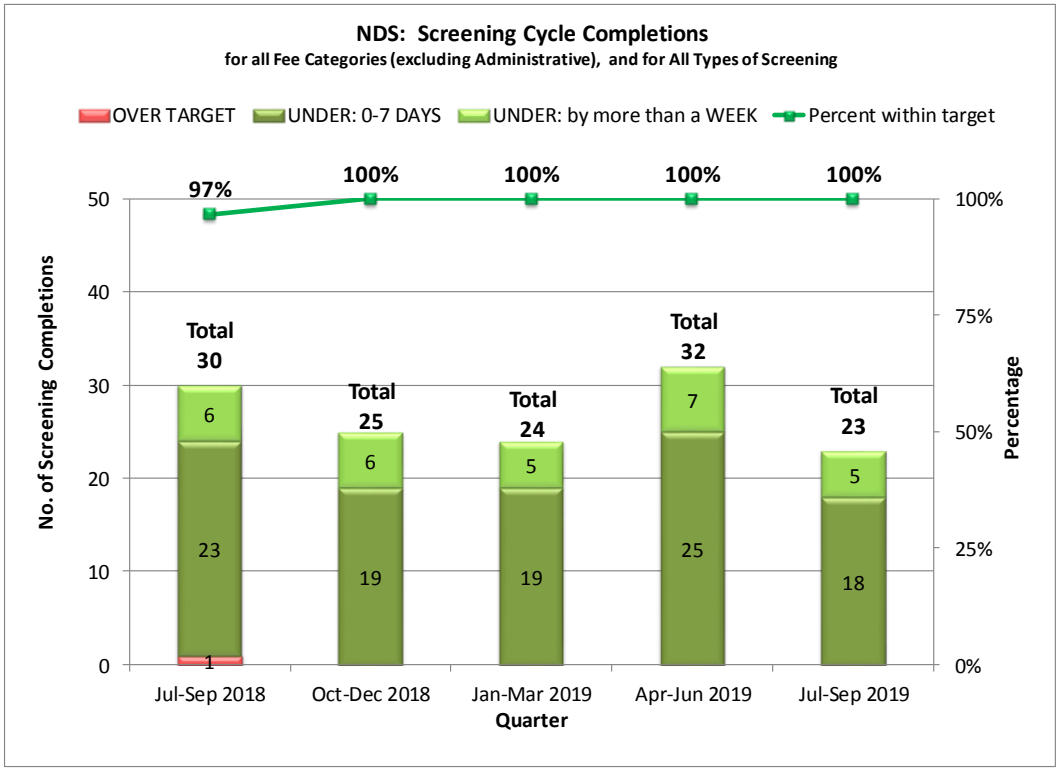


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

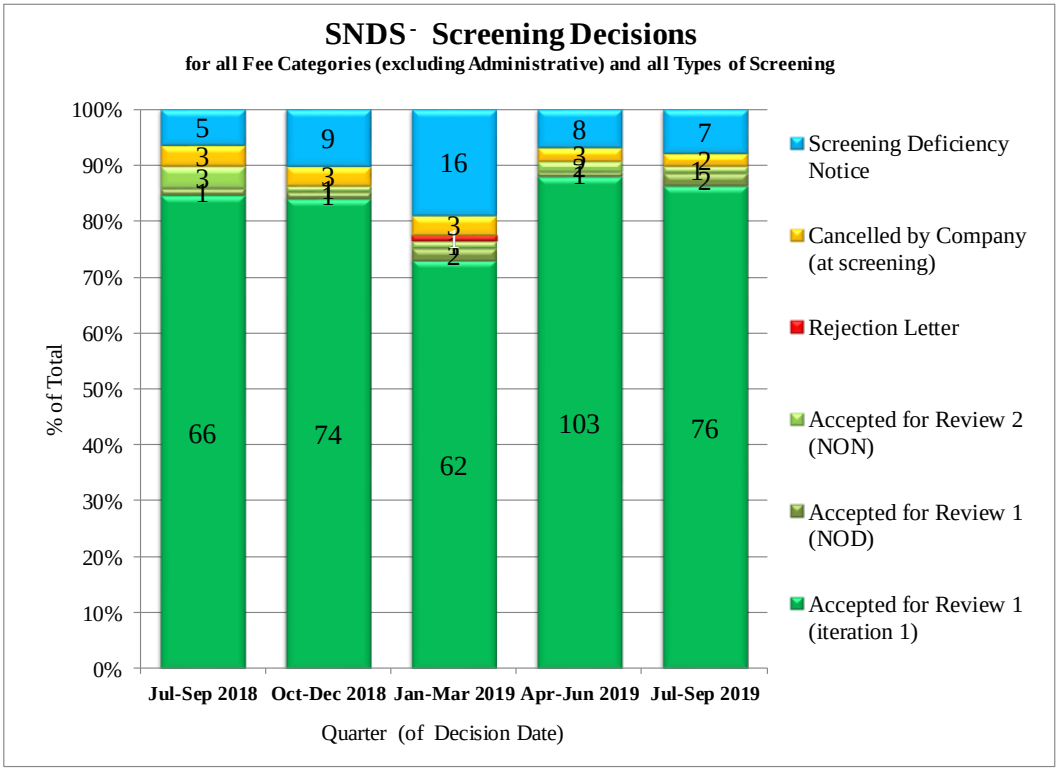


NDS: Screening Cycle Completions

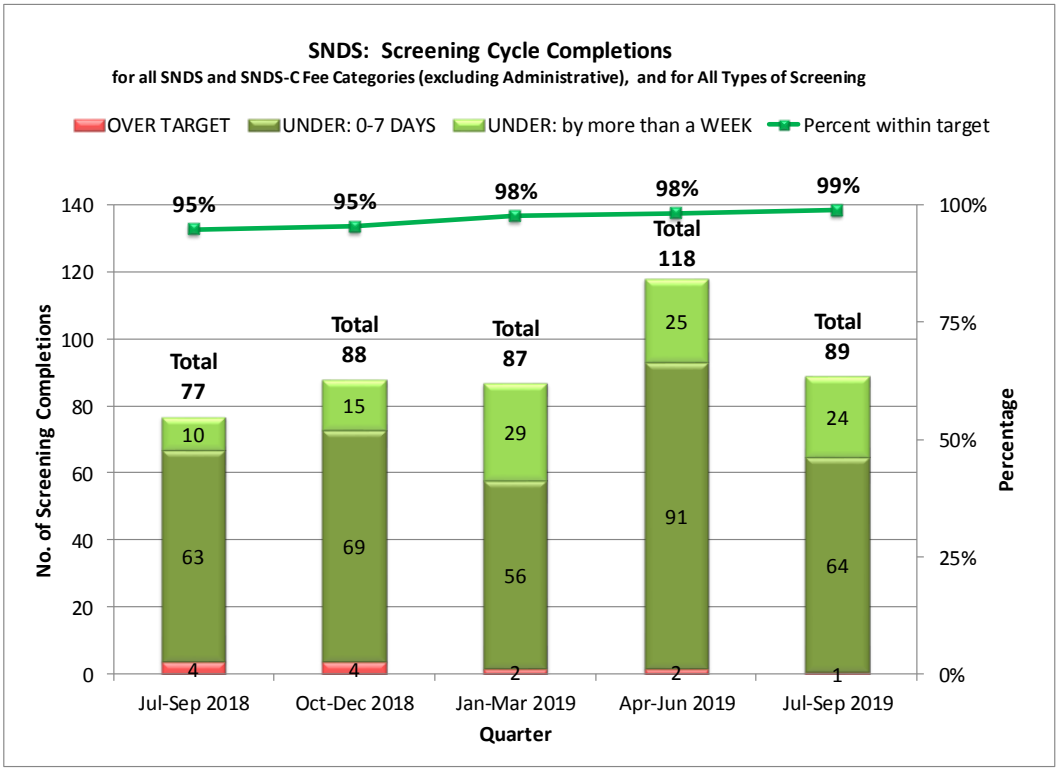


SCREENING CYCLE DECISIONS

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



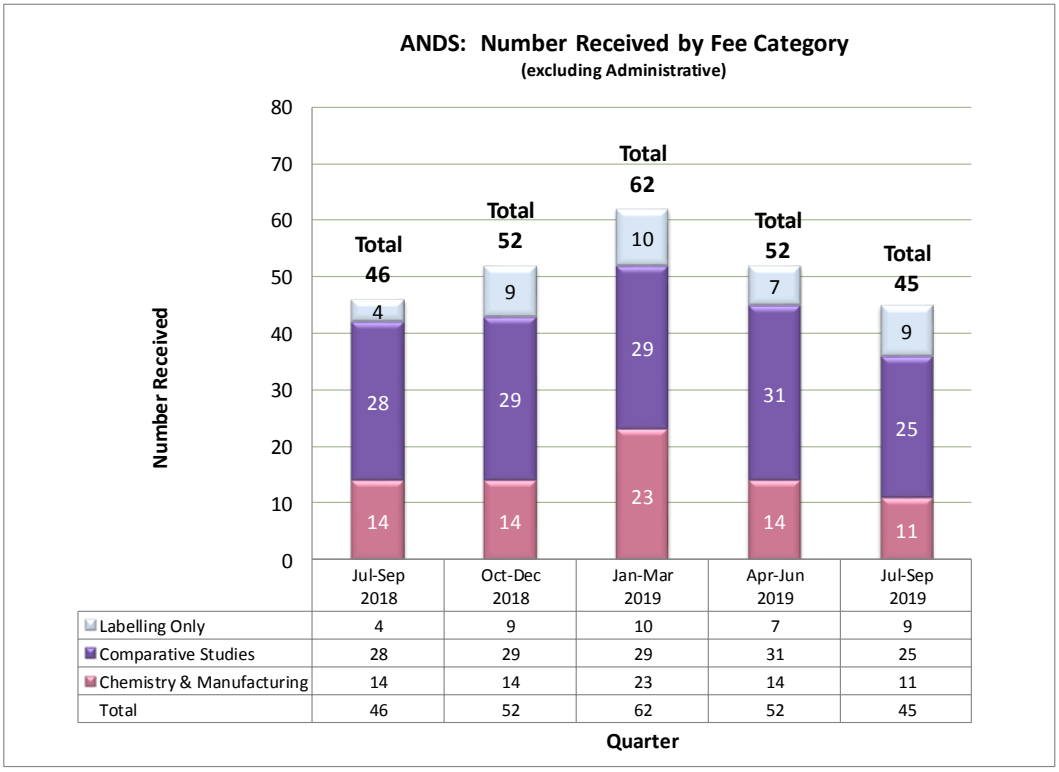
Abbreviated New Drug Submissions (ANDS)

&

Supplement to an Abbreviated New Drug Submissions (SANDS)

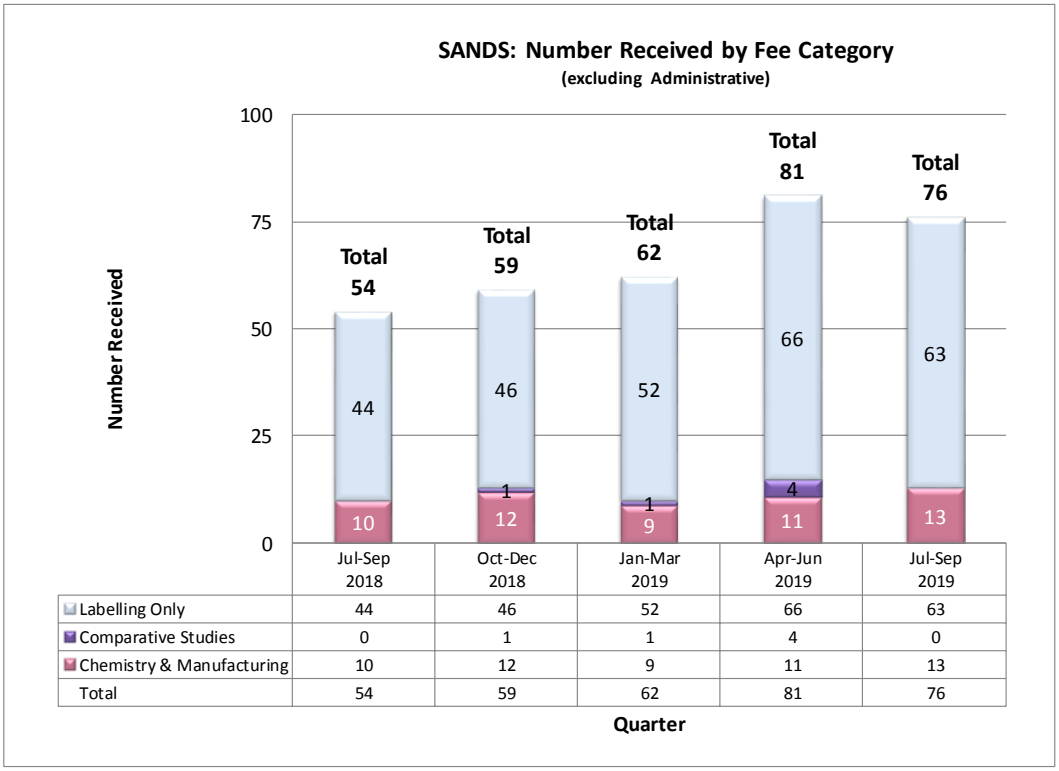
SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	4	9	10	7	9
Comparative Studies	28	29	29	31	25
Chemistry & Manufacturing	14	14	23	14	11
Total	46	52	62	52	45

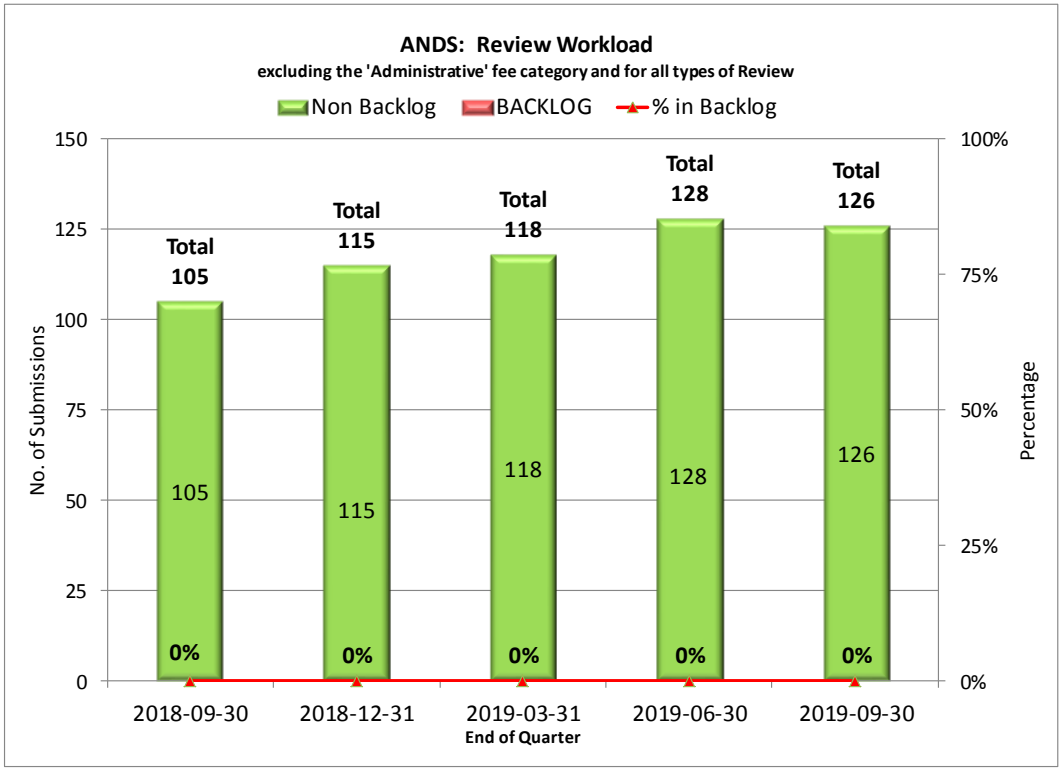
SANDS: Number Received by Fee Category



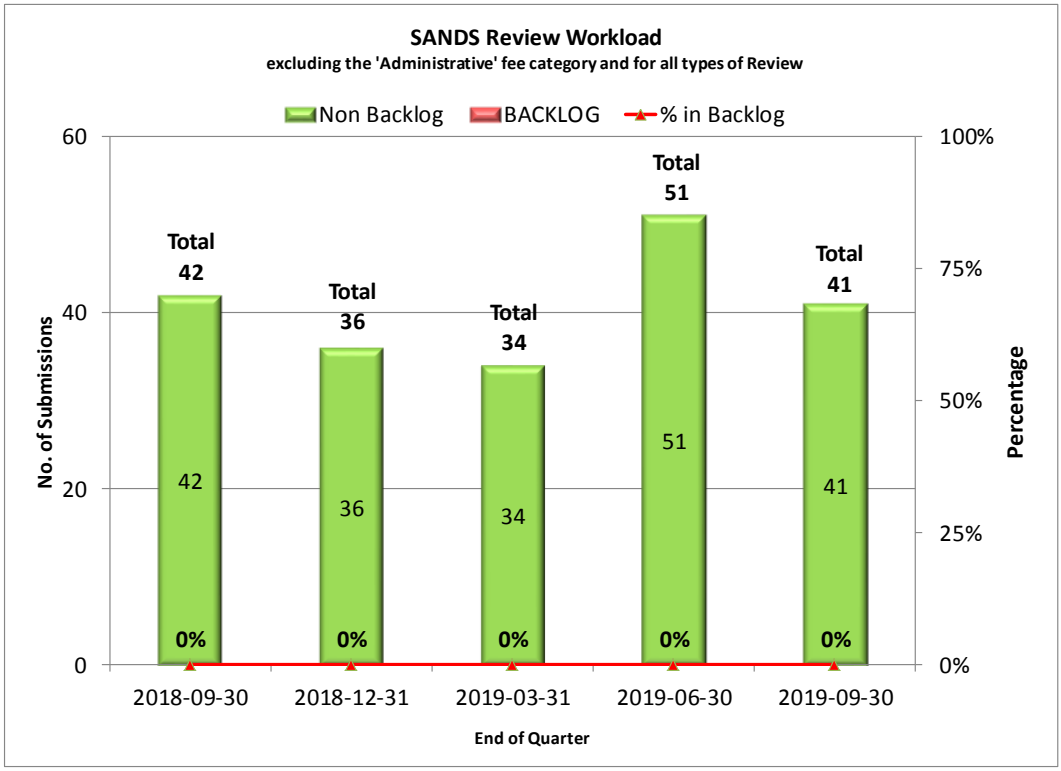
	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	44	46	52	66	63
Comparative Studies	0	1	1	4	0
Chemistry & Manufacturing	10	12	9	11	13
Total	54	59	62	81	76

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

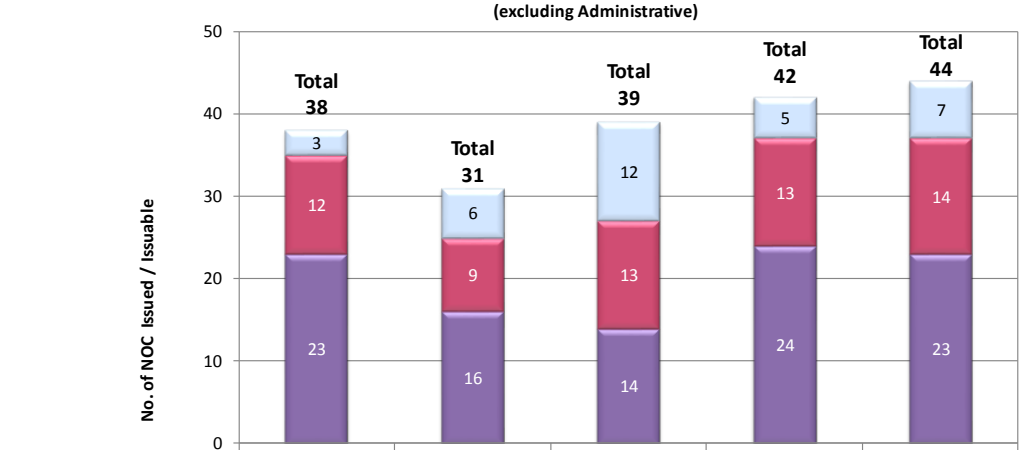
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Chemistry & Manufacturing	51	40	38	52	46
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	52	70	77	71	77
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	2	5	3	5	3
Backlog	*0*	*0*	*0*	*0*	*0*
Total	105	115	118	128	126
Non Backlog	105	115	118	128	126
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Chemistry & Manufacturing	25	21	22	22	19
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	0	2	3	4
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	16	15	10	26	18
Backlog	*0*	*0*	*0*	*0*	*0*
Total	42	36	34	51	41
Non Backlog	42	36	34	51	41
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

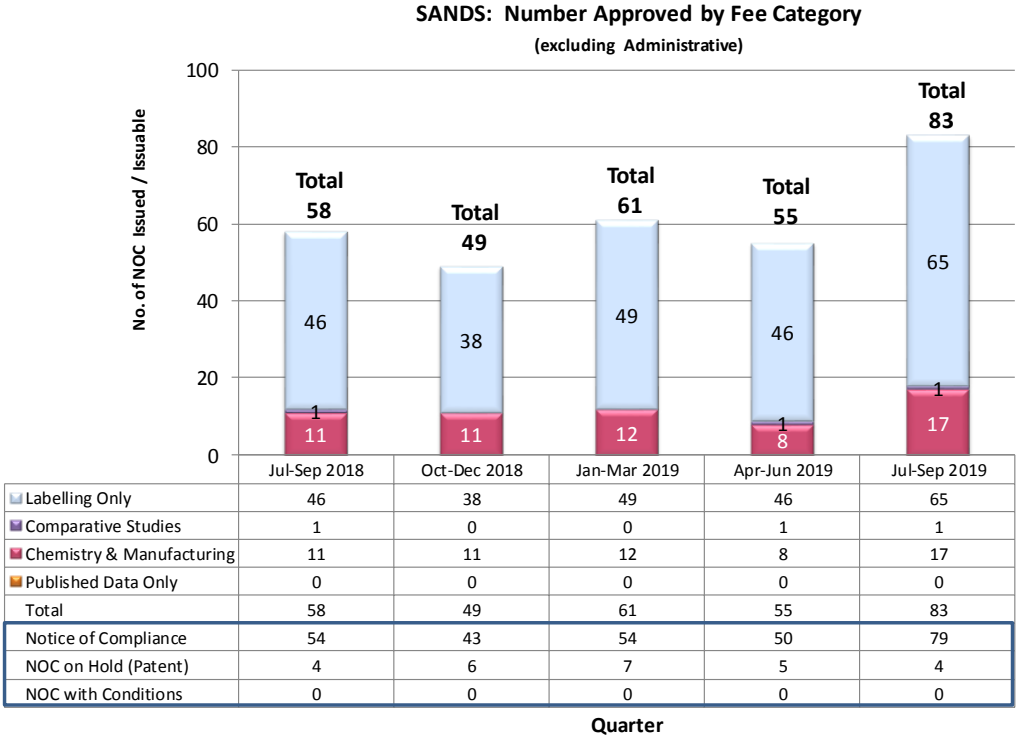
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	3	6	12	5	7
Chemistry & Manufacturing	12	9	13	13	14
Comparative Studies	23	16	14	24	23
Total	38	31	39	42	44
Notice of Compliance	29	23	29	27	32
NOC on Hold (Patent)	9	8	10	15	12
NOC with Conditions	0	0	0	0	0

SANDS: Number Approved by Fee Category and by NOC Type



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	46	38	49	46	65
Comparative Studies	1	0	0	1	1
Chemistry & Manufacturing	11	11	12	8	17
Published Data Only	0	0	0	0	0
Total	58	49	61	55	83
Notice of Compliance	54	43	54	50	79
NOC on Hold (Patent)	4	6	7	5	4
NOC with Conditions	0	0	0	0	0

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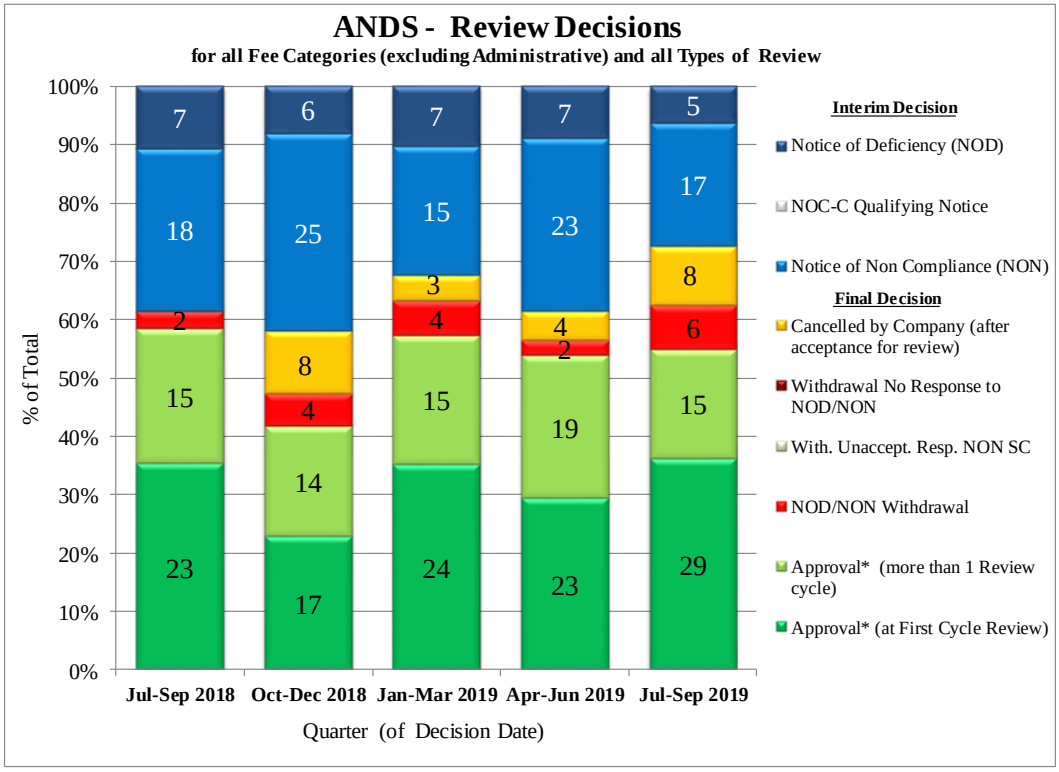
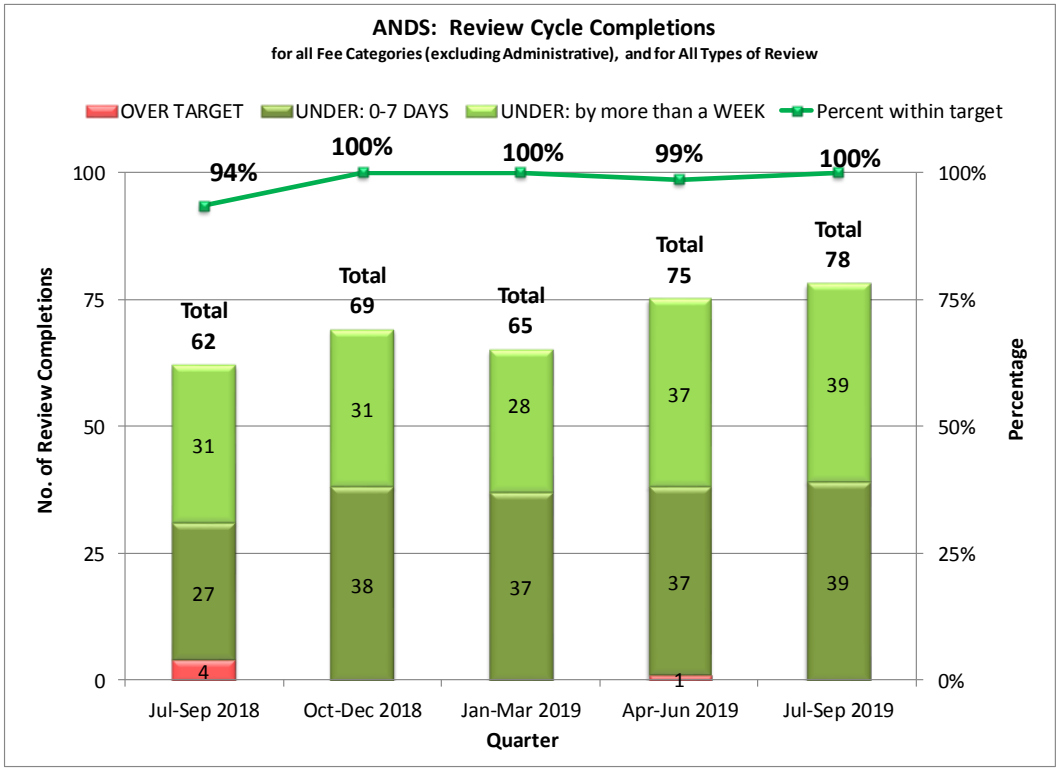
REVIEW PERFORMANCE

ANDS: Review Decisions by Type

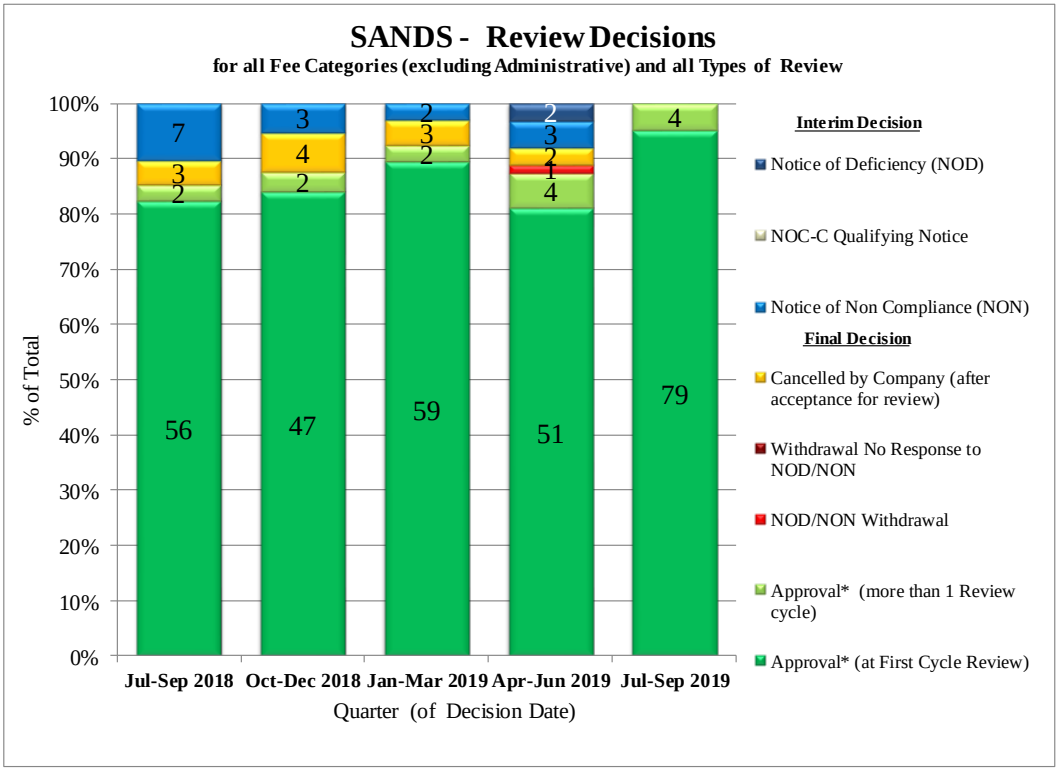


ANDS: Review Cycle Completions

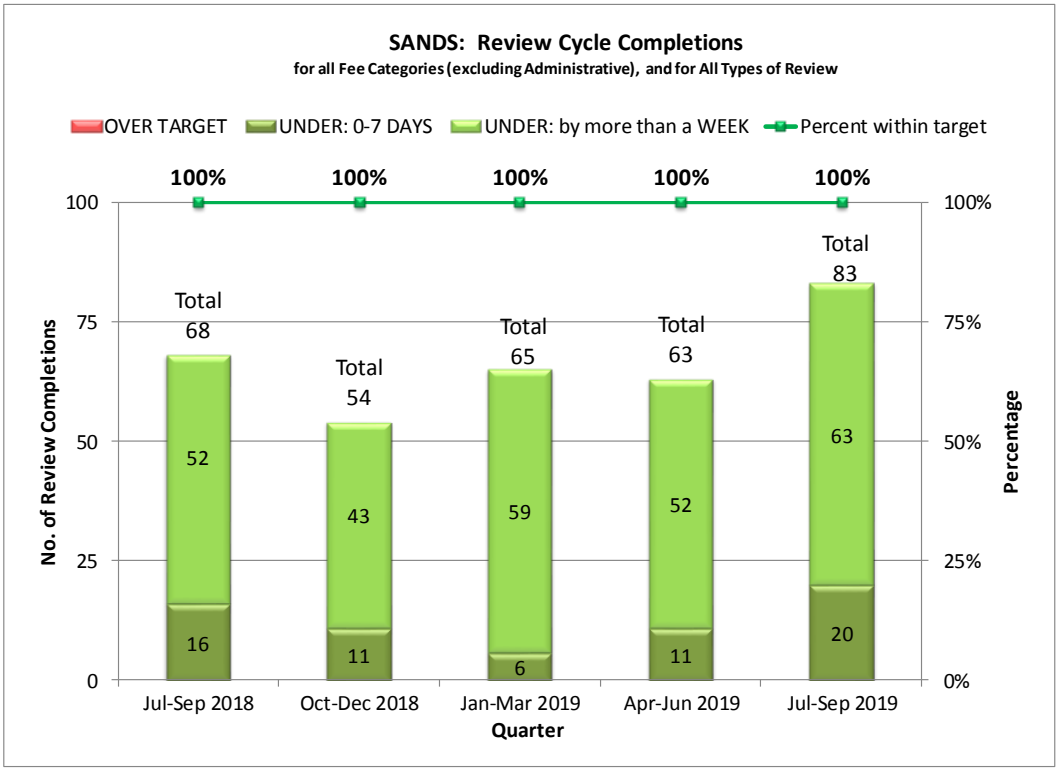


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

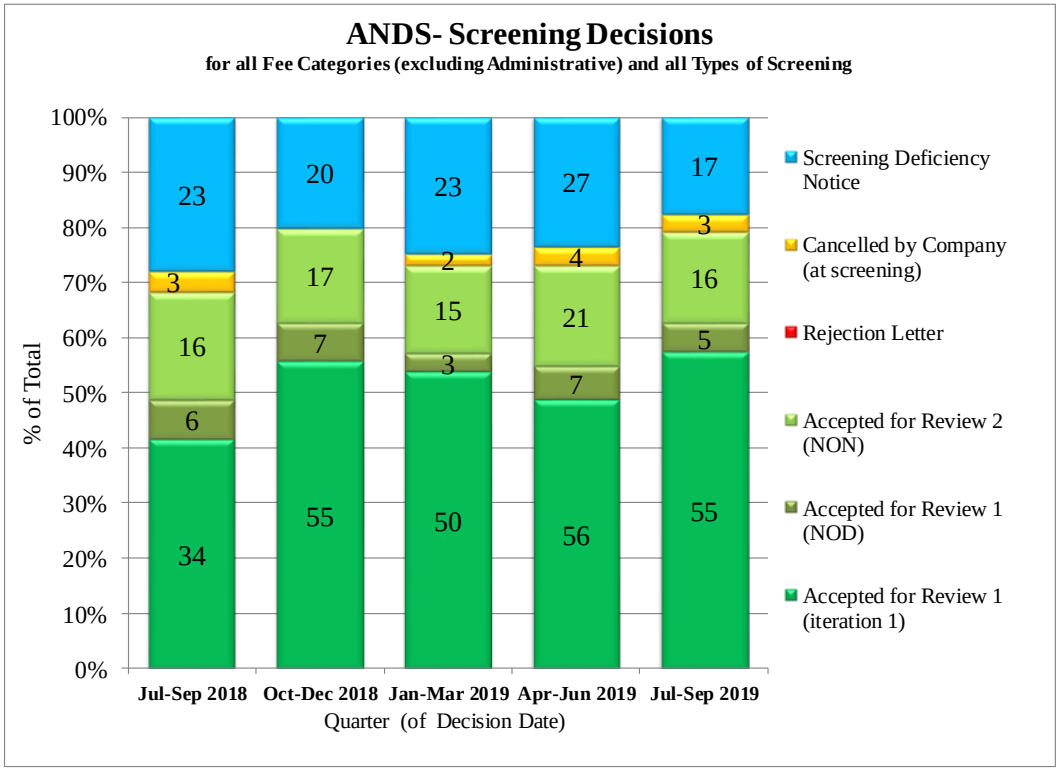


SANDS: Review Cycle Completions

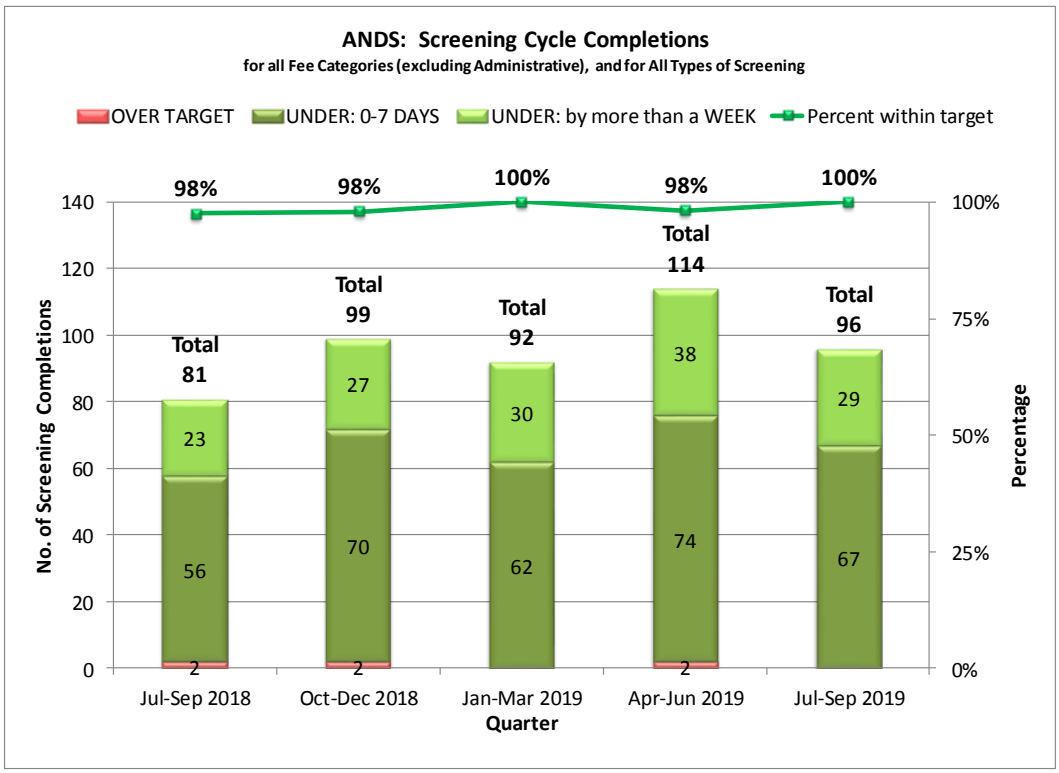


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

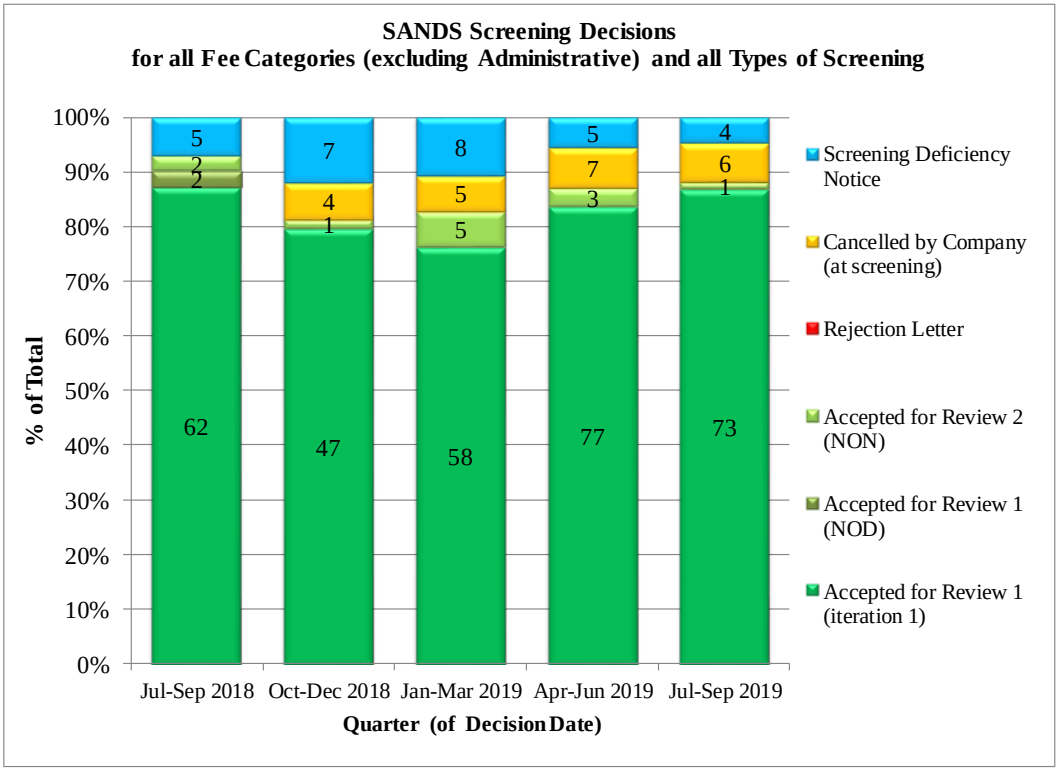


ANDS: Screening Cycle Completions

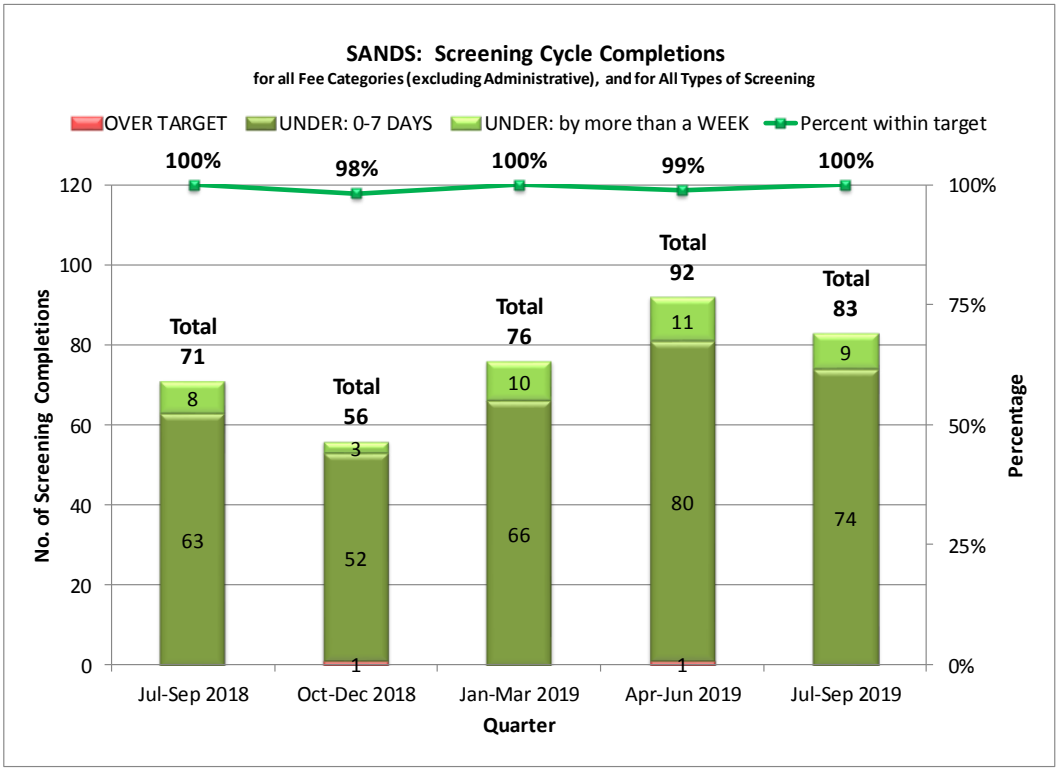


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type

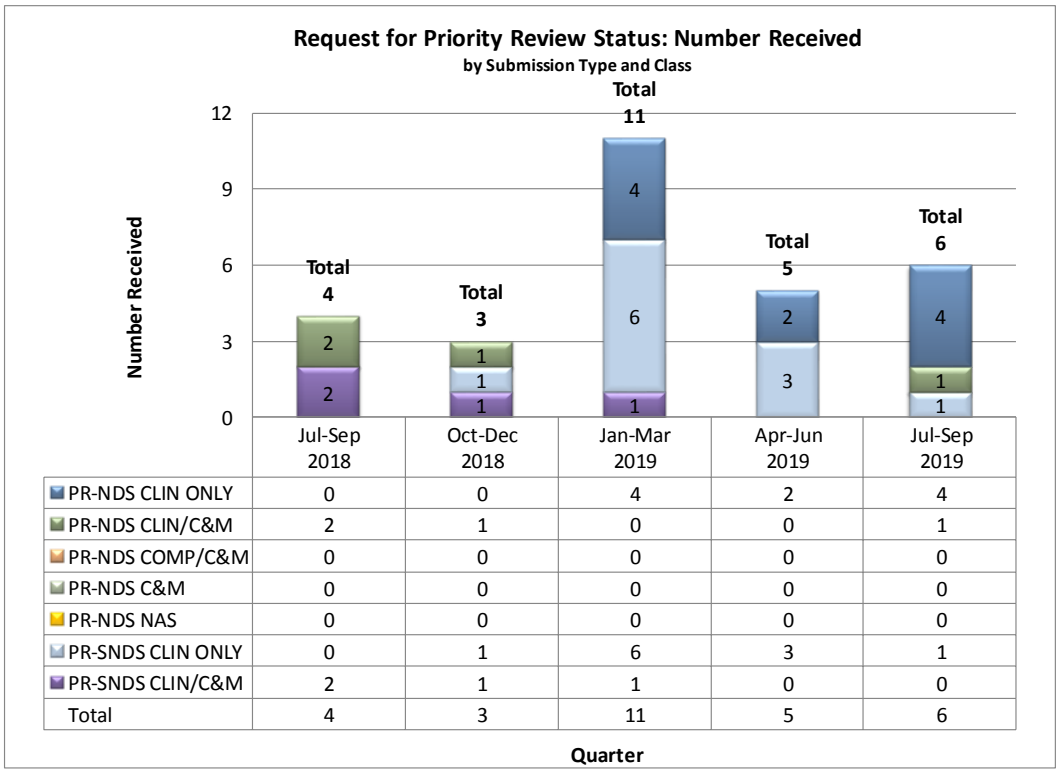


SANDS: Screening Cycle Completions



REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

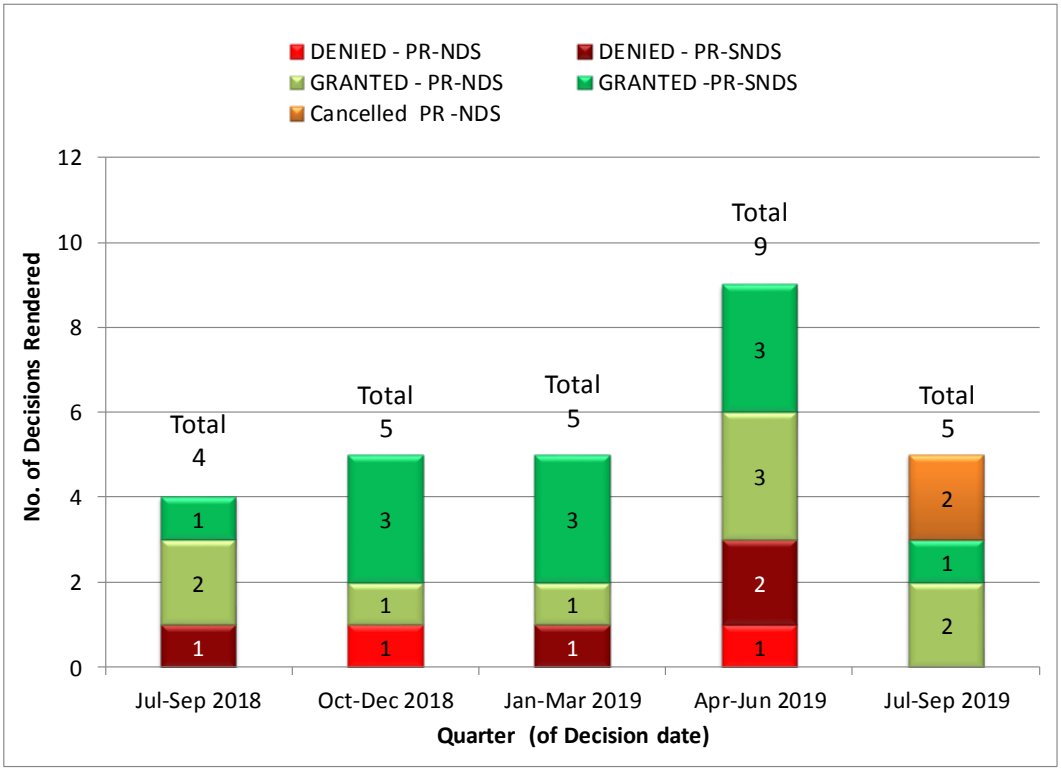
Request for Priority Review Status: Number Received



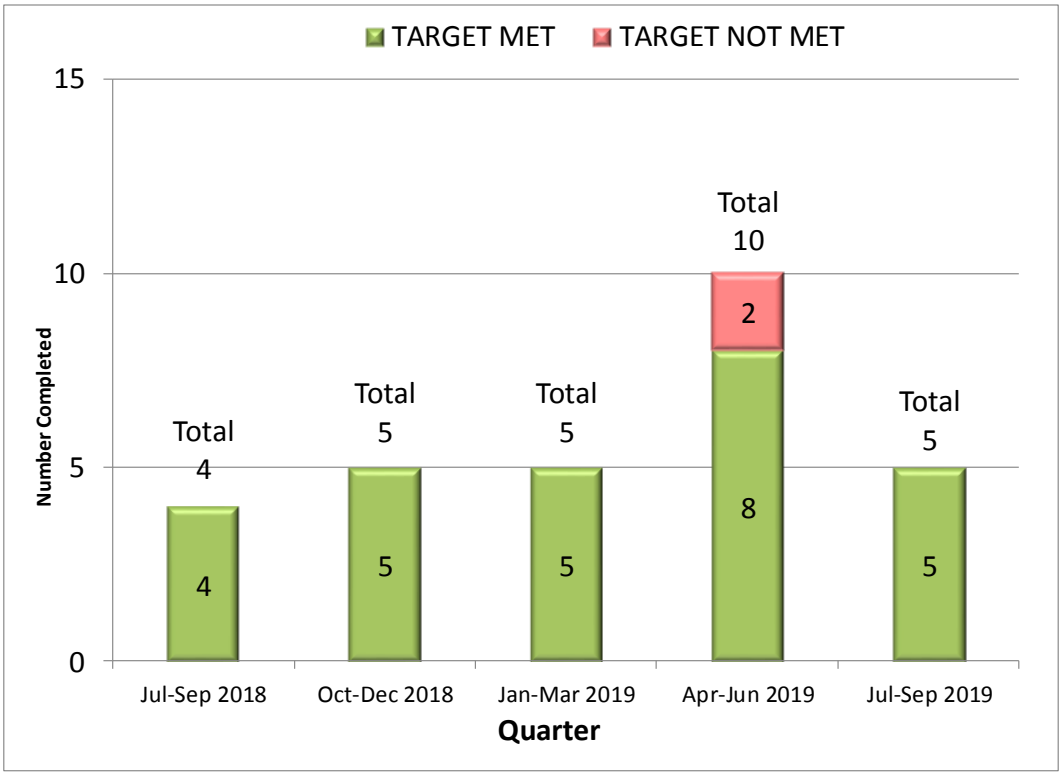
	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
PR-NDS CLIN ONLY	0	0	4	2	4
PR-NDS CLIN/C&M	2	1	0	0	1
PR-NDS COMP/C&M	0	0	0	0	0
PR-NDS C&M	0	0	0	0	0
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN ONLY	0	1	6	3	1
PR-SNDS CLIN/C&M	2	1	1	0	0
Total	4	3	11	5	6

Quarter

Request for Priority Review Status: Decisions Rendered



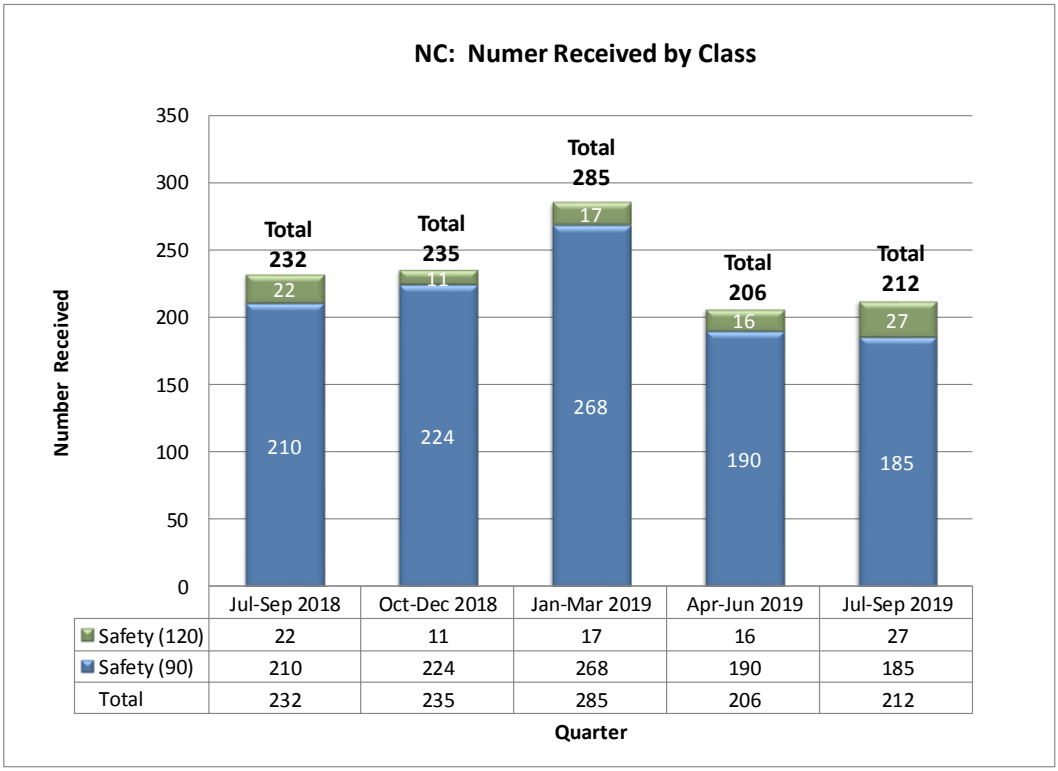
Request for Priority Review Status: Performance



NC: NOTIFIABLE CHANGE

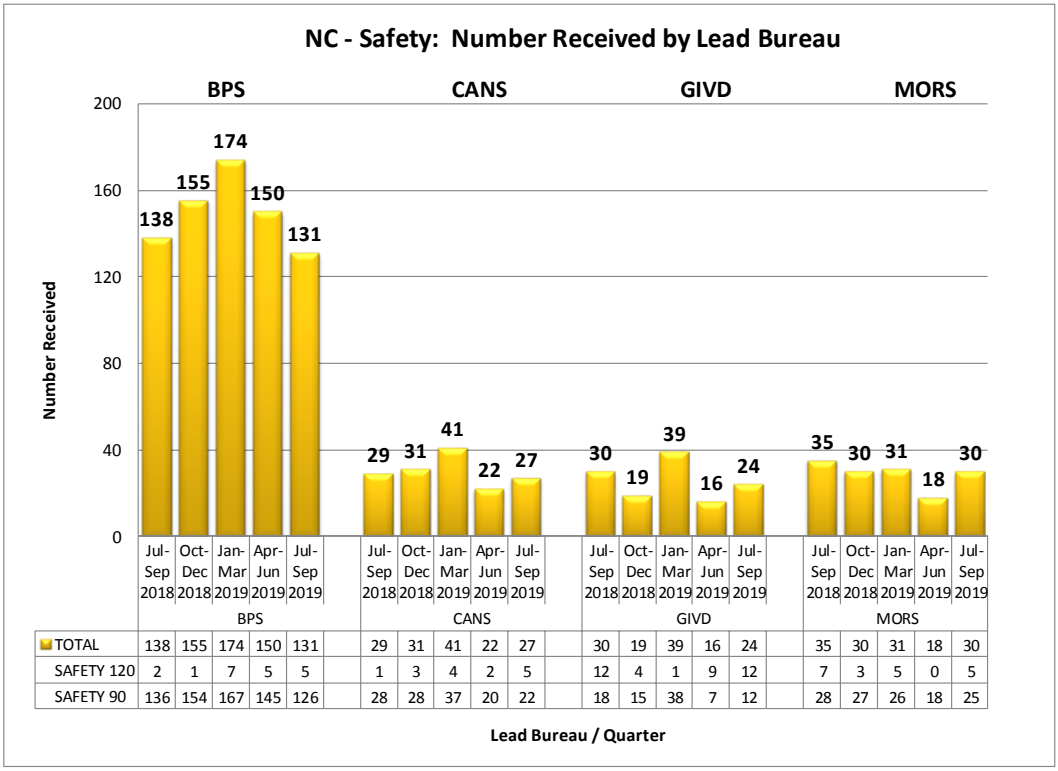
NOTIFIABLE CHANGE[10]
RECEIVED

NC: Number Received by Class



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Safety (120)	22	11	17	16	27
Safety (90)	210	224	268	190	185
Total	232	235	285	206	212

NC-SAFETY: Number Received by Lead Bureau

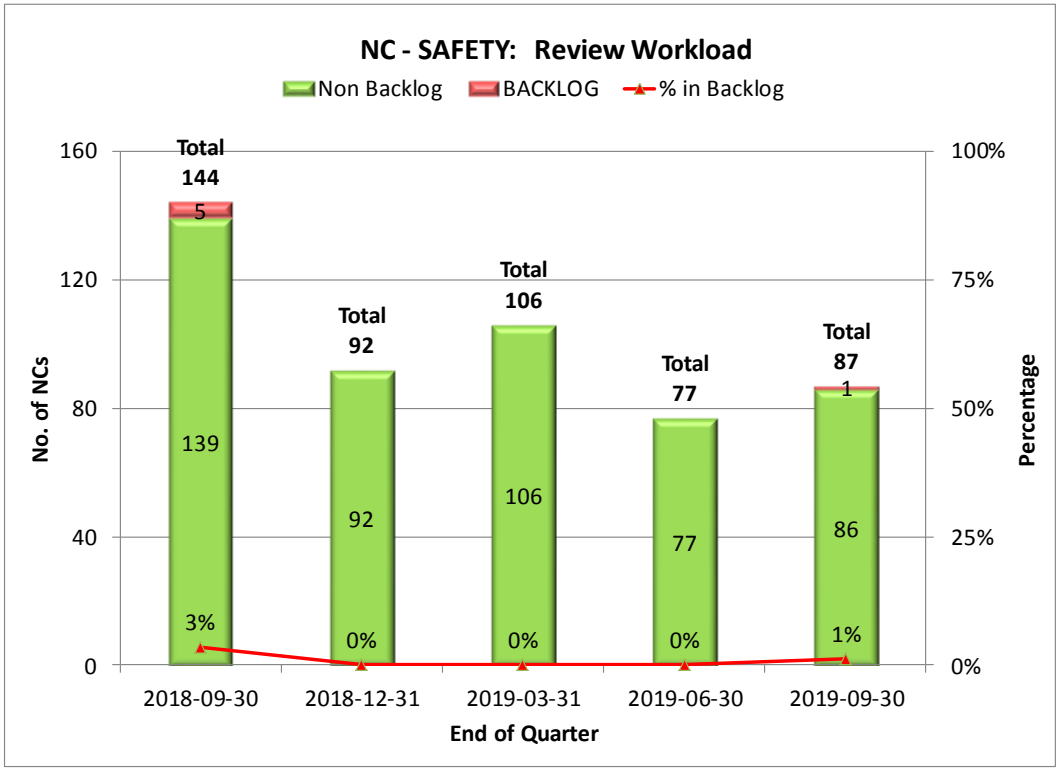


	BPS					CANS					GIVD					MORS				
	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
TOTAL	138	155	174	150	131	29	31	41	22	27	30	19	39	16	24	35	30	31	18	30
SAFETY 120	2	1	7	5	5	1	3	4	2	5	12	4	1	9	12	7	3	5	0	5
SAFETY 90	136	154	167	145	126	28	28	37	20	22	18	15	38	7	12	28	27	26	18	25

[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

NC-SAFETY: Review Workload

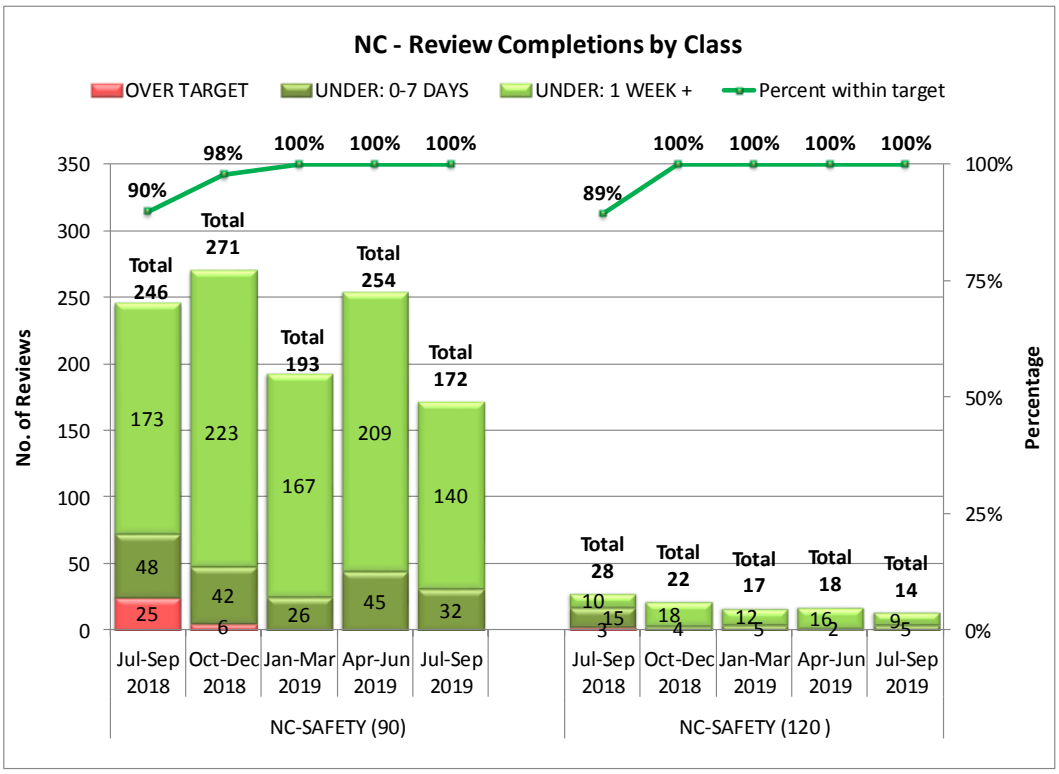


NC-SAFETY: Review Workload by Class

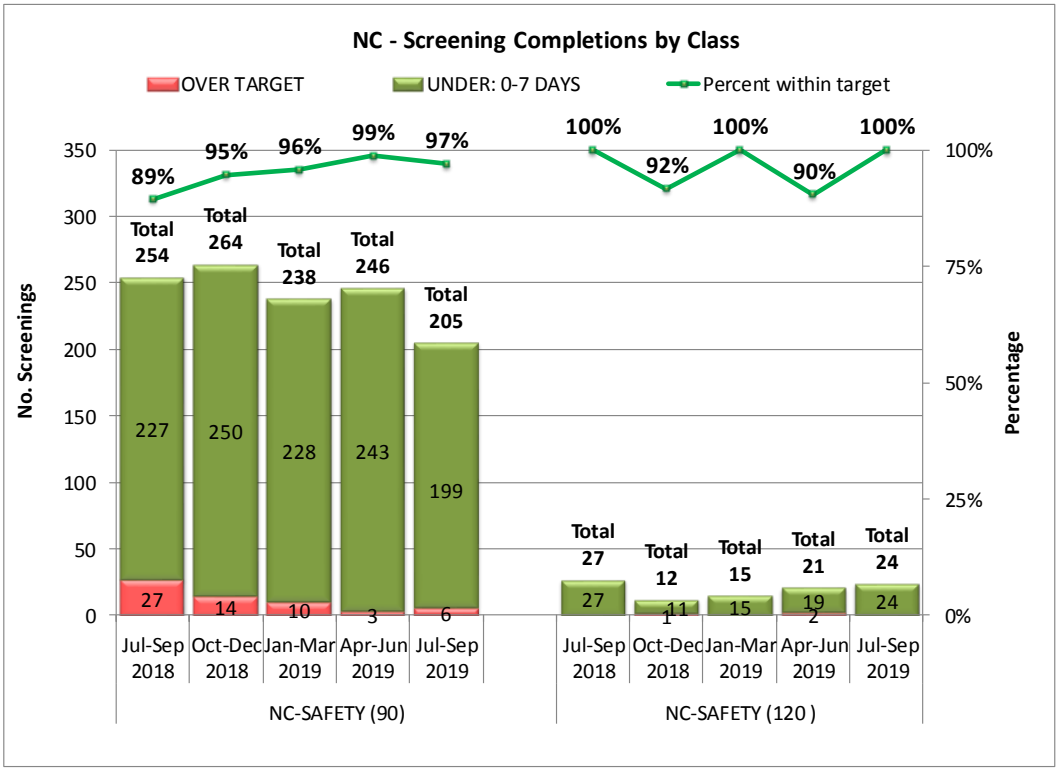
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
SAFETY - 90 day	119	78	95	64	64
Backlog	*5*	*0*	*0*	*0*	*1*
SAFETY - 120 day	25	14	11	13	23
Backlog	*0*	*0*	*0*	*0*	*0*
Total	144	92	106	77	87
Non Backlog	139	92	106	77	86
BACKLOG	5	0	0	0	1
% in Backlog	3%	0%	0%	0%	1%

PERFORMANCE

NC–SAFETY: Review Completions by Class



NC–SAFETY: Screening Completions by Class



NC–SAFETY: Number of Decisions by Class

NC - SAFETY (90)					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NO OBJECTION LETTER	234	270	195	245	176
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCR)	2	0	0	0	0
SCREENING DEFICIENCY NOTICE	25	32	20	20	26
CANCELLED BY COMPANY	10	10	18	12	17
NC - HOLD (PATENT)	14	9	6	9	2
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

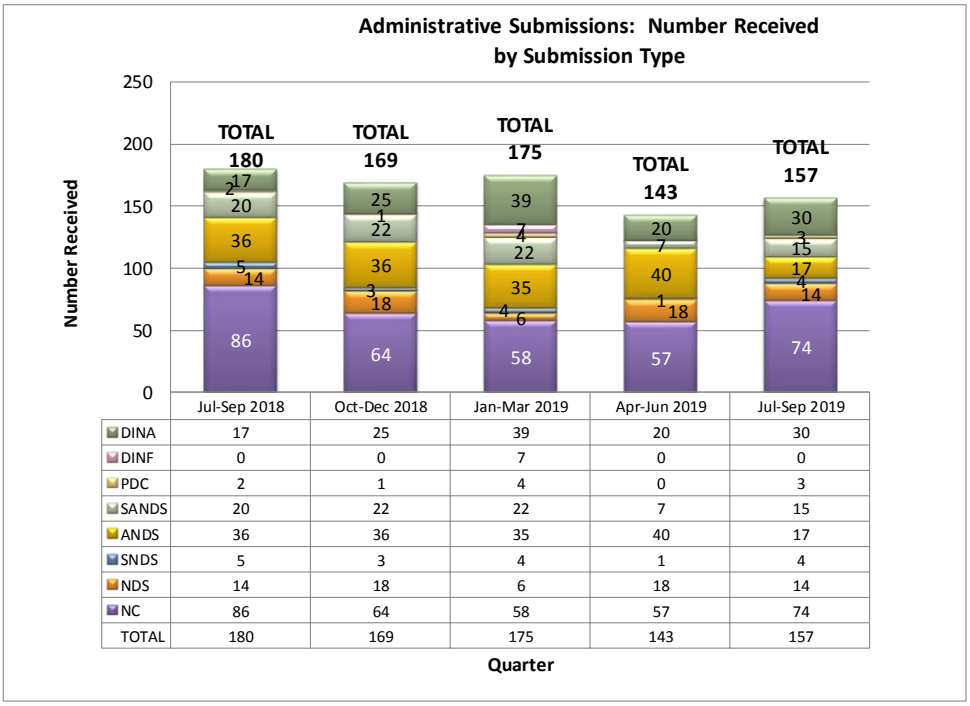
NC - SAFETY (120)					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NO OBJECTION LETTER	28	22	16	15	15
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	1	1	1	0
CANCELLED BY COMPANY	0	0	0	1	0
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD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

ADMINISTRATIVE SUBMISSIONS

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

RECEIVED

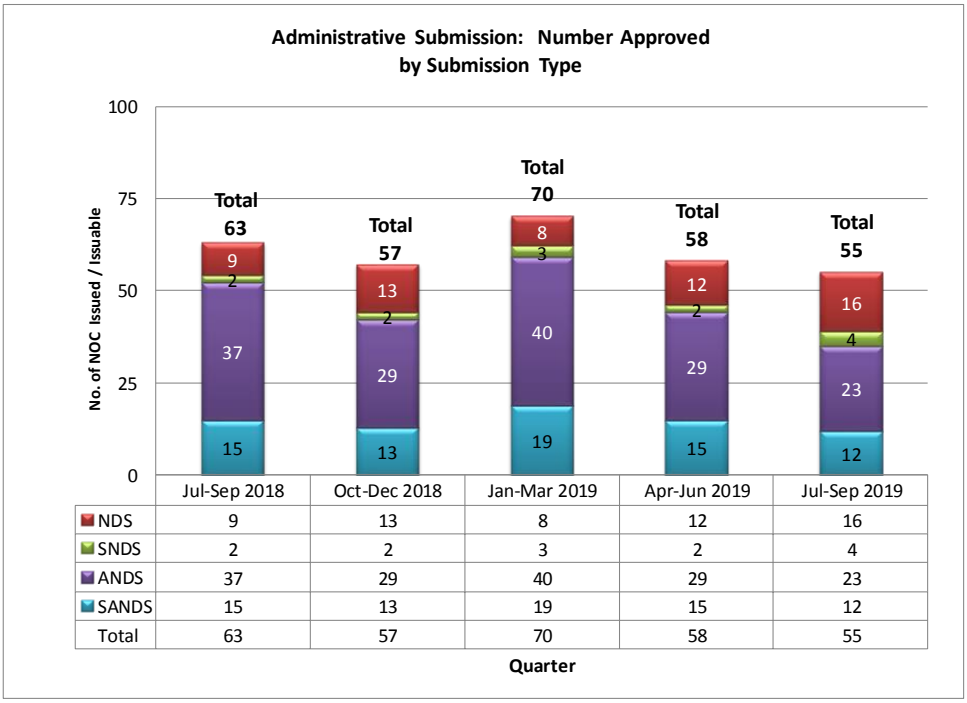
Administrative Submissions: Number Received by Submission Type



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
DINA	17	25	39	20	30
DINF	0	0	7	0	0
PDC	2	1	4	0	3
SANDS	20	22	22	7	15
ANDS	36	36	35	40	17
SNDS	5	3	4	1	4
NDS	14	18	6	18	14
NC	86	64	58	57	74
TOTAL	180	169	175	143	157

APPROVALS

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



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NDS	9	13	8	12	16
SNDS	2	2	3	2	4
ANDS	37	29	40	29	23
SANDS	15	13	19	15	12
Total	63	57	70	58	55

[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: Number of Decisions by Submission Type

NDS	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019*	Jul-Sep 2019
NOTICE OF COMPLIANCE	9	16	8	12	16
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	1	1	0	3	0
PROCESSING HOLD LETTER	3	7	2	3	6
SNDS	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NOTICE OF COMPLIANCE	2	2	3	2	4
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLATION LETTER	2	3	0	0	0
PROCESSING HOLD LETTER	3	1	0	0	0
ANDS	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NOTICE OF COMPLIANCE	37	31	40	29	23
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	2	0	0	0
CANCELLATION LETTER	0	0	2	7	5
PROCESSING HOLD LETTER	12	6	3	10	8
SANDS	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NOTICE OF COMPLIANCE	15	15	19	15	12
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
CANCELLATION LETTER	6	1	1	3	2
PROCESSING HOLD LETTER	5	5	3	3	7
NC	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NO OBJECTION LETTER	100	64	48	40	81
NC - HOLD (PATENT)	1	0	0	0	0
CANCELLATION LETTER	10	3	3	5	8
PROCESSING HOLD LETTER	4	4	4	4	6
DINA	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NOTIFICATION FORM / DIN ISSUED	10	13	41	11	21
NO OBJECTION LETTER	1	0	1	0	0
SCREENING DEFICIENCY NOTICE	1	7	0	0	0
CANCELLATION LETTER	2	2	5	9	11
PROCESSING HOLD LETTER	13	6	4	17	12
PDC	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019***	**Jul-Sep 2019**
NO OBJECTION LETTER	1	2	2	0	3
CANCELLATION LETTER	1	0	1	1	0
PROCESSING HOLD LETTER	0	0	0	0	0

*figures revised in Oct 2019

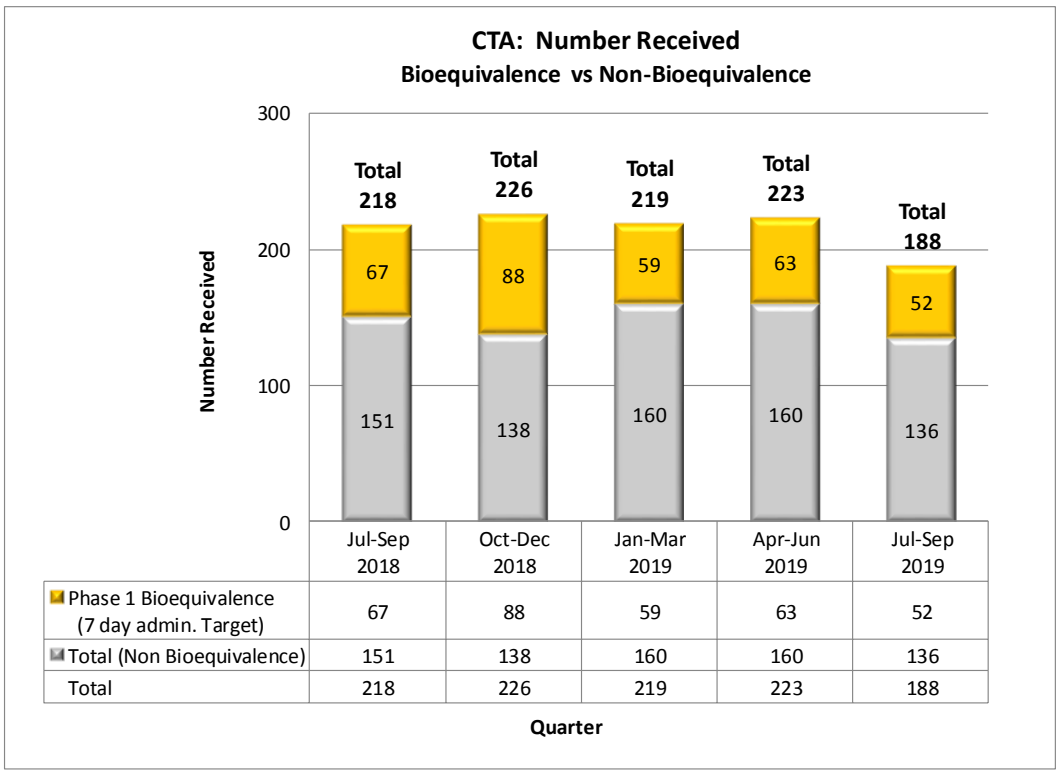
[12] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

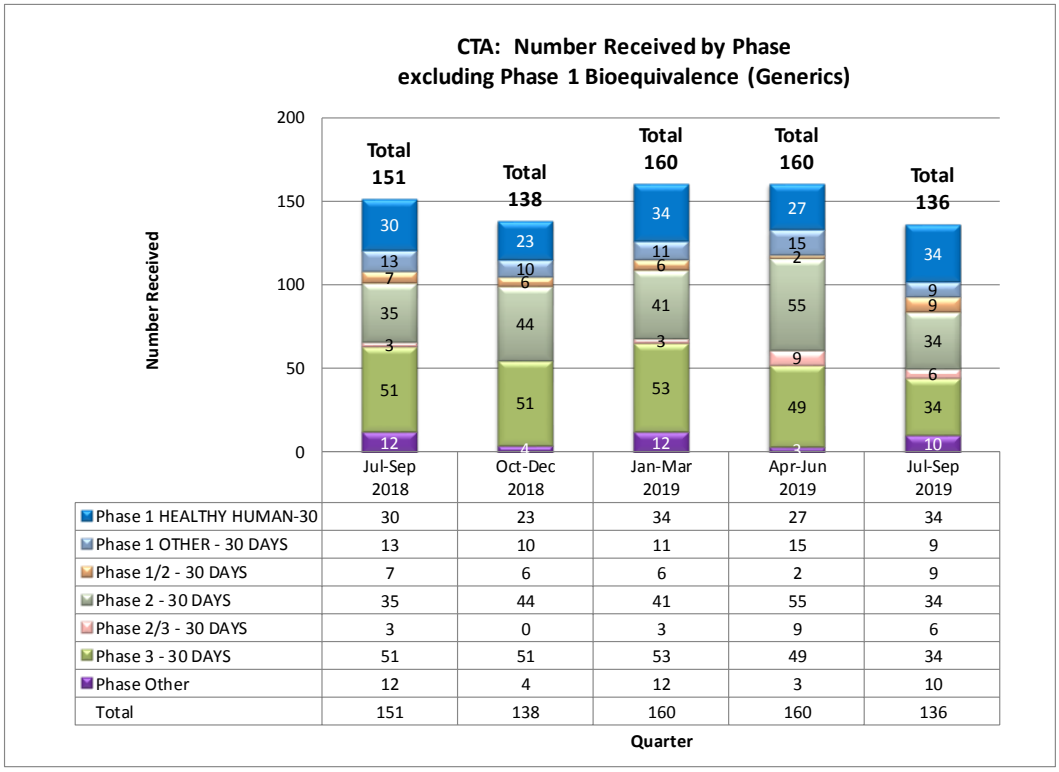
CTA: CLINICAL TRIAL APPLICATIONS

CTA: Number Received



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Phase 1 Bioequivalence (7 day admin. Target)	67	88	59	63	52
Total (Non Bioequivalence)	151	138	160	160	136
Total	218	226	219	223	188

CTA: Number Received by Phase



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Phase 1 HEALTHY HUMAN-30	30	23	34	27	34
Phase 1 OTHER - 30 DAYS	13	10	11	15	9
Phase 1/2 - 30 DAYS	7	6	6	2	9
Phase 2 - 30 DAYS	35	44	41	55	34
Phase 2/3 - 30 DAYS	3	0	3	9	6
Phase 3 - 30 DAYS	51	51	53	49	34
Phase Other	12	4	12	3	10
Total	151	138	160	160	136

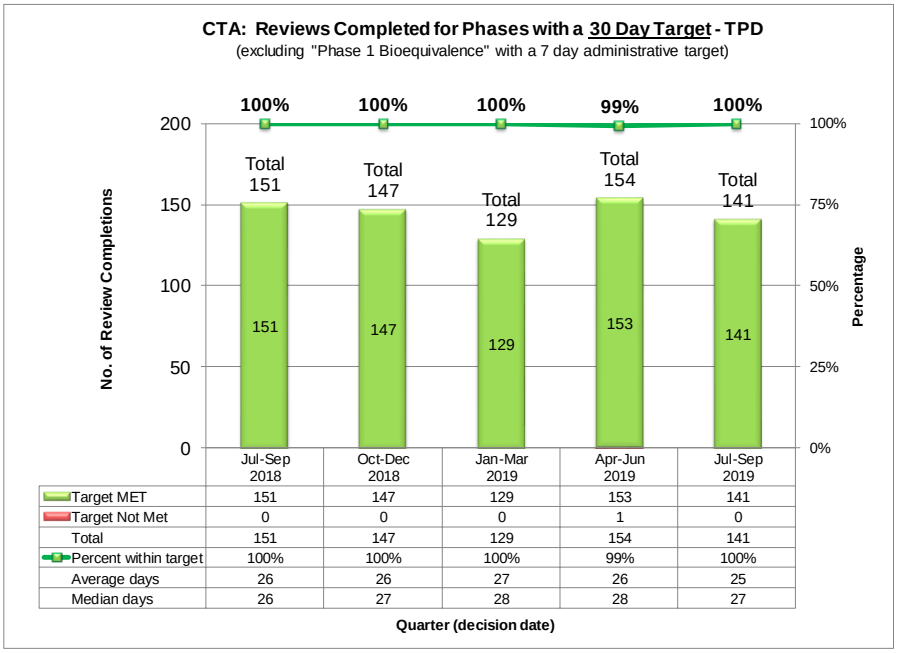
DECISION DOCUMENTS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NO OBJECTION LETTER	211	226	176	202	183
CANCELLED BY COMPANY DURING REVIEW	6	12	11	12	12
CANCELLED BY COMPANY AT PROCESSING	3	2	1	3	2
NOT SATISFACTORY NOTICE	0	0	1	0	0

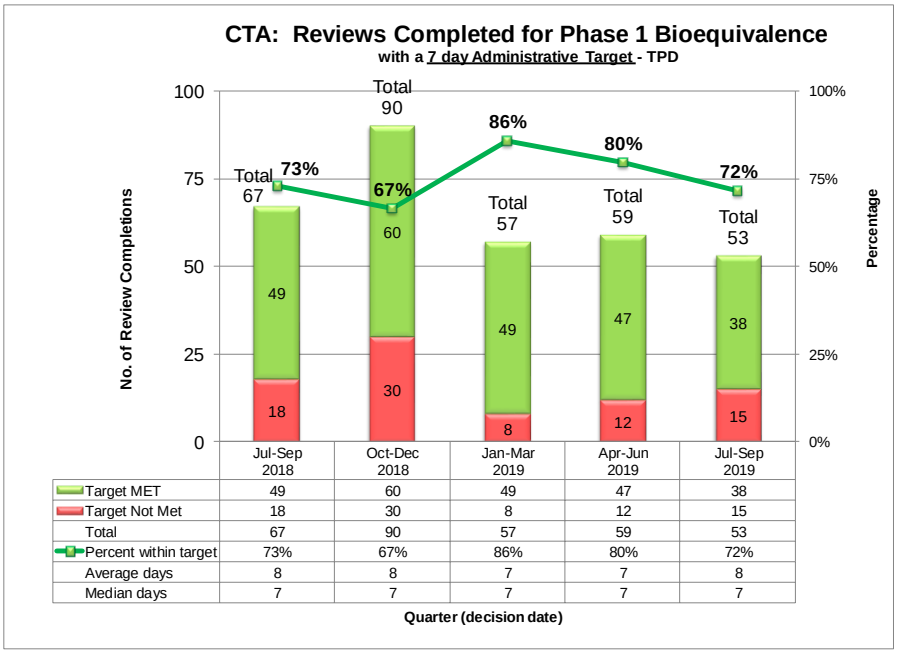
PERFORMANCE

CTA: Reviews Completed for Phases with a 30 Day Target



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Target MET	151	147	129	153	141
Target Not Met	0	0	0	1	0
Total	151	147	129	154	141
Percent within target	100%	100%	100%	99%	100%
Average days	26	26	27	26	25
Median days	26	27	28	28	27

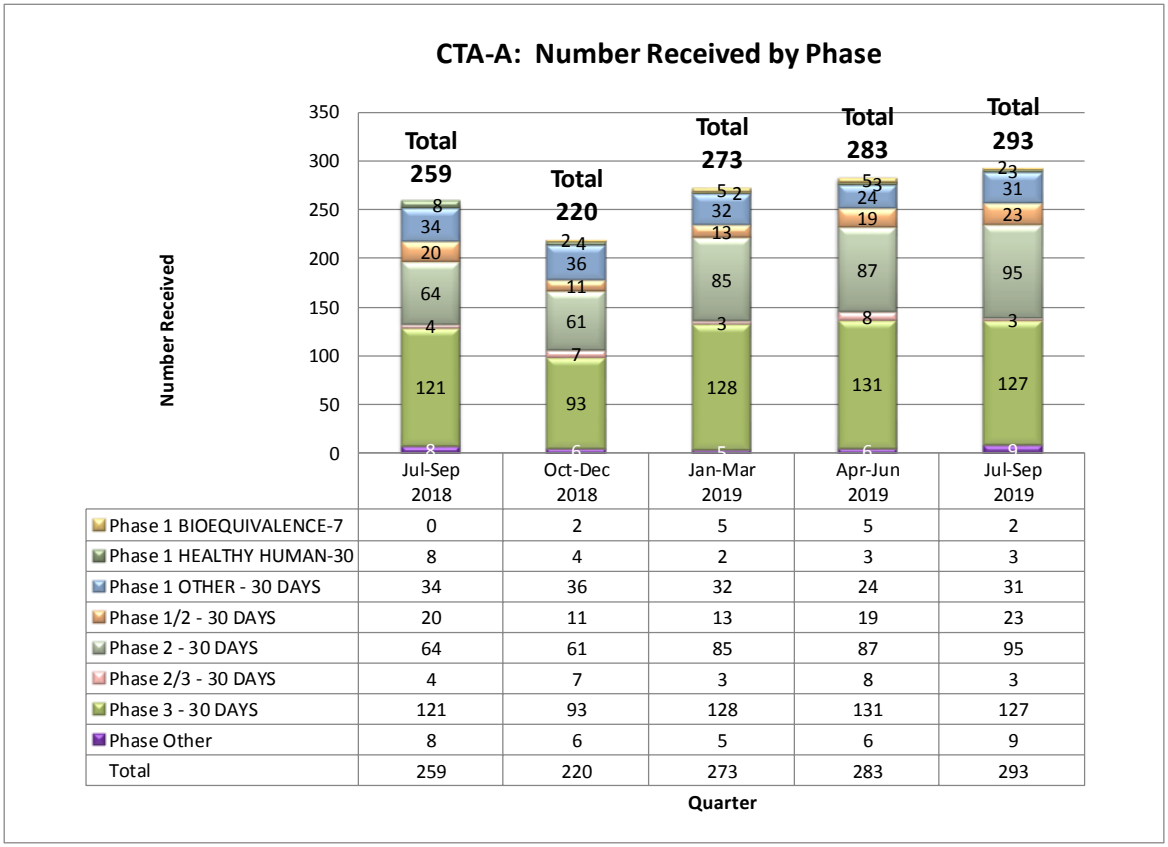
CTA: Reviews Completed for Phases with a 7 Day Administrative Target



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Target MET	49	60	49	47	38
Target Not Met	18	30	8	12	15
Total	67	90	57	59	53
Percent within target	73%	67%	86%	80%	72%
Average days	8	8	7	7	8
Median days	7	7	7	7	7

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

CTA-A: Number Received by Phase



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Phase 1 BIOEQUIVALENCE-7	0	2	5	5	2
Phase 1 HEALTHY HUMAN-30	8	4	2	3	3
Phase 1 OTHER - 30 DAYS	34	36	32	24	31
Phase 1/2 - 30 DAYS	20	11	13	19	23
Phase 2 - 30 DAYS	64	61	85	87	95
Phase 2/3 - 30 DAYS	4	7	3	8	3
Phase 3 - 30 DAYS	121	93	128	131	127
Phase Other	8	6	5	6	9
Total	259	220	273	283	293

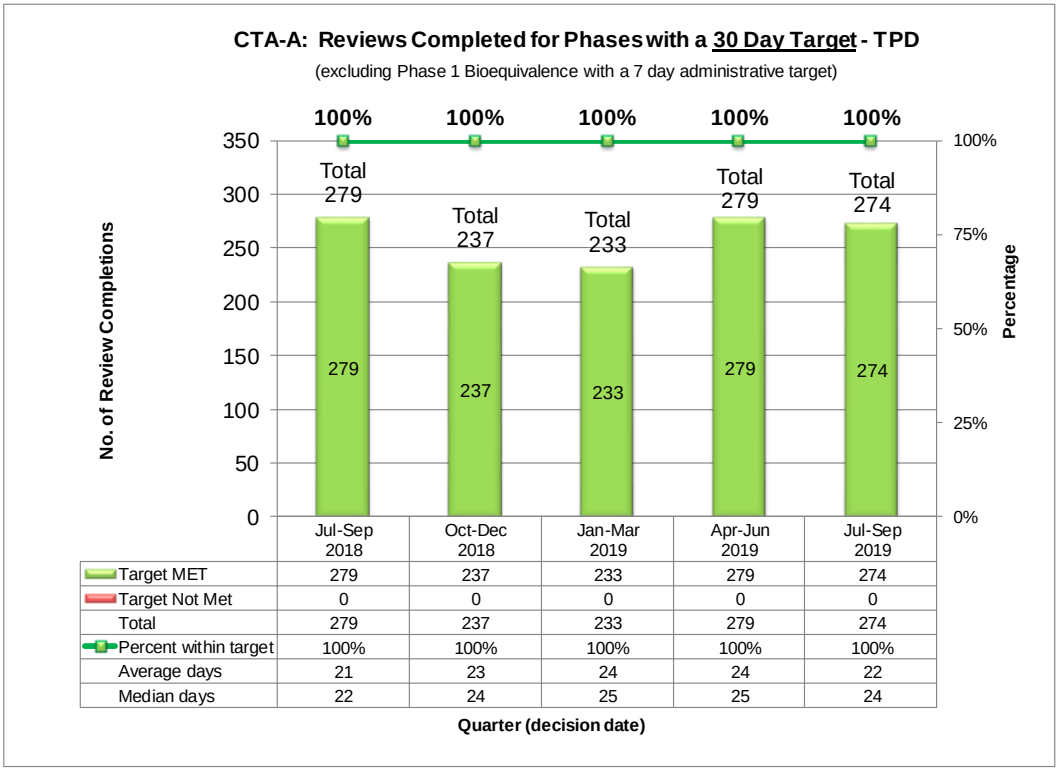
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NO OBJECTION LETTER	276	236	236	279	270
CANCELLED BY COMPANY DURING REVIEW	4	3	1	5	8
CANCELLED BY COMPANY AT PROCESSING	0	1	1	0	12
REJECTION LETTER (SCR)	0	0	0	1	0

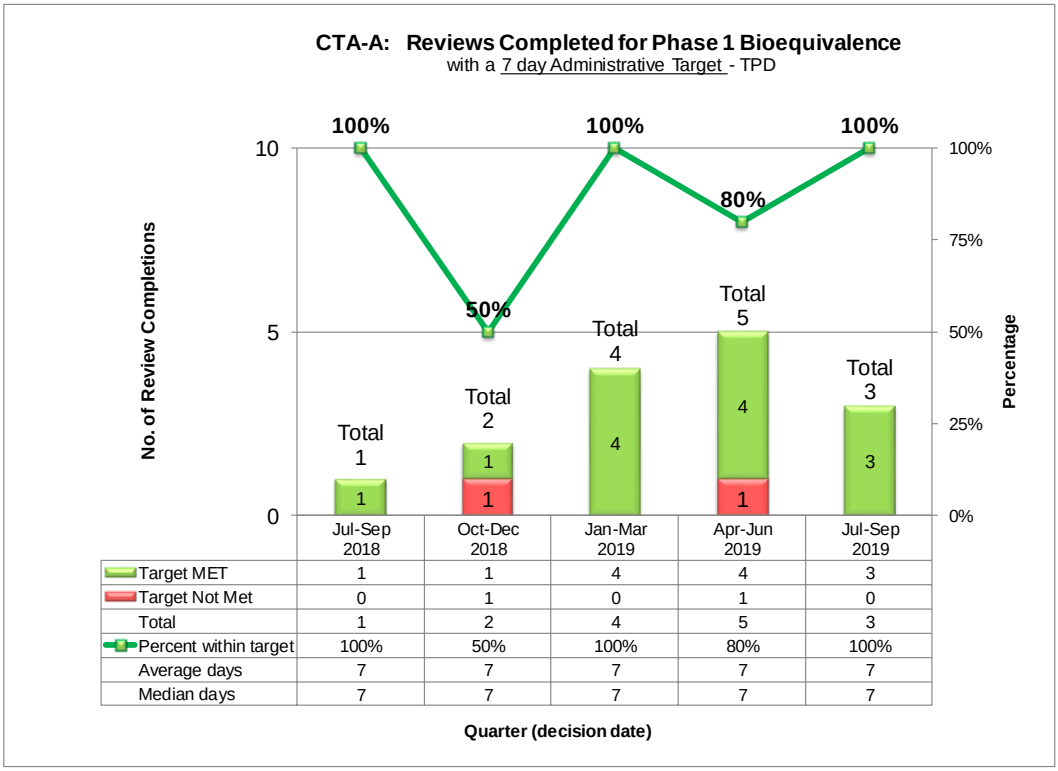
PERFORMANCE

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



	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Target MET	279	237	233	279	274
Target Not Met	0	0	0	0	0
Total	279	237	233	279	274
Percent within target	100%	100%	100%	100%	100%
Average days	21	23	24	24	22
Median days	22	24	25	25	24

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



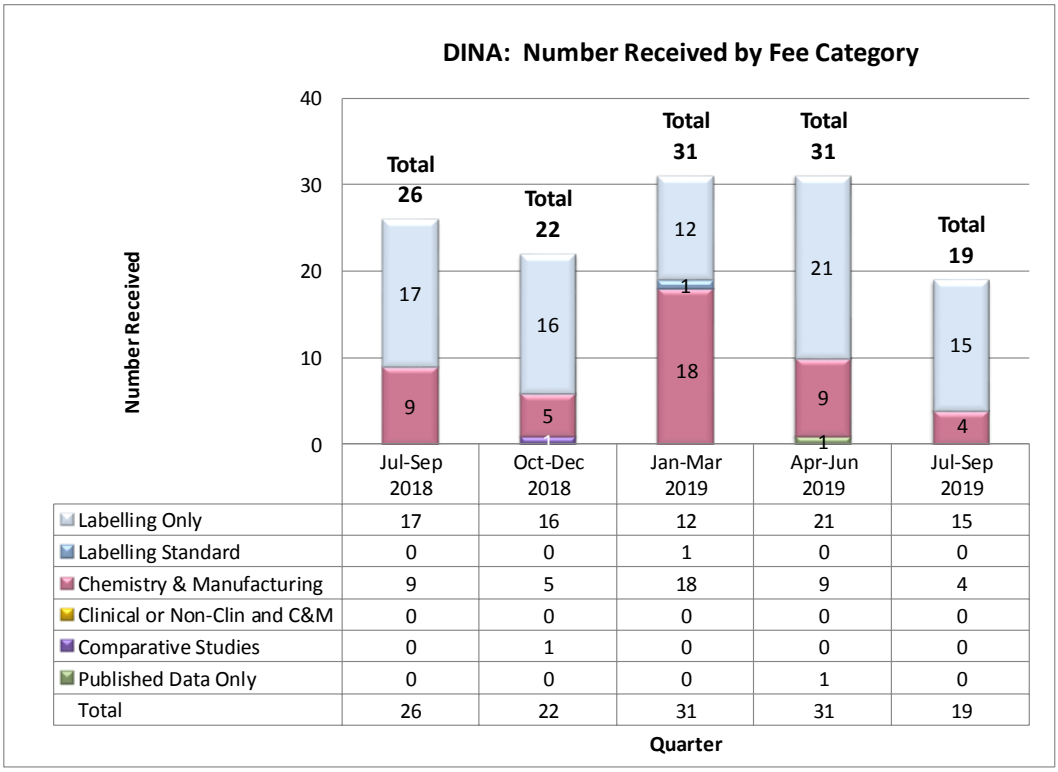
	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Target MET	1	1	4	4	3
Target Not Met	0	1	0	1	0
Total	1	2	4	5	3
Percent within target	100%	50%	100%	80%	100%
Average days	7	7	7	7	7
Median days	7	7	7	7	7

DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER[13]

DINA: Number Received by Fee Category

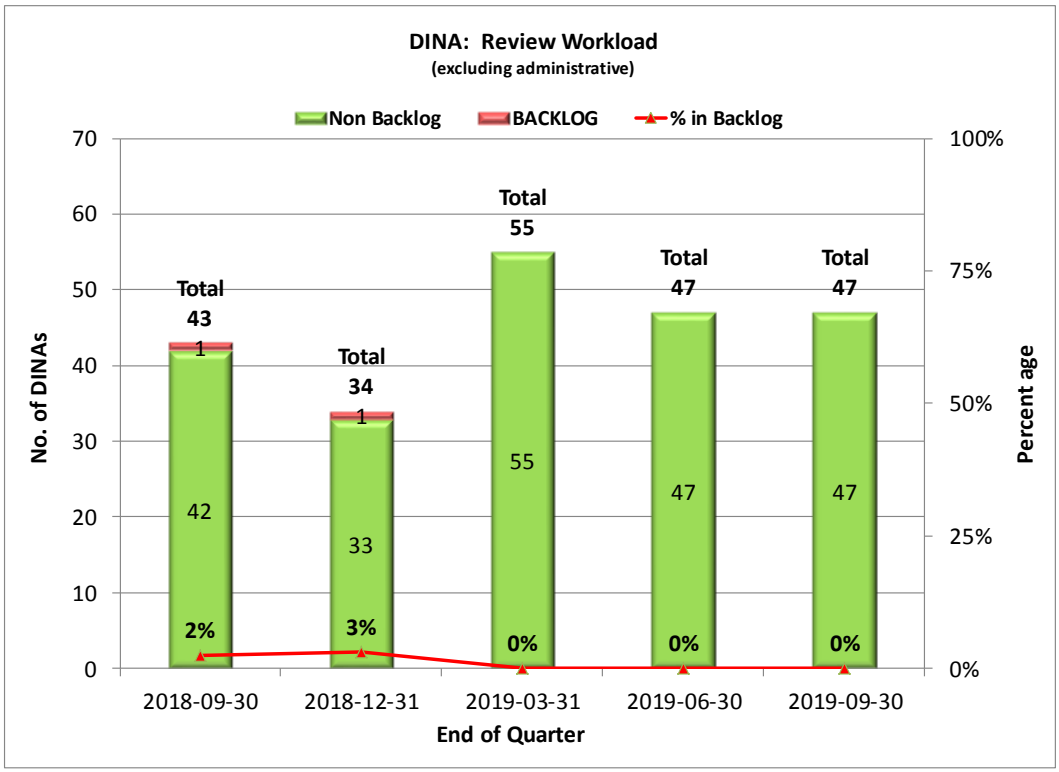


	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
Labelling Only	17	16	12	21	15
Labelling Standard	0	0	1	0	0
Chemistry & Manufacturing	9	5	18	9	4
Clinical or Non-Clin and C&M	0	0	0	0	0
Comparative Studies	0	1	0	0	0
Published Data Only	0	0	0	1	0
Total	26	22	31	31	19

[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

DINA: Review Workload

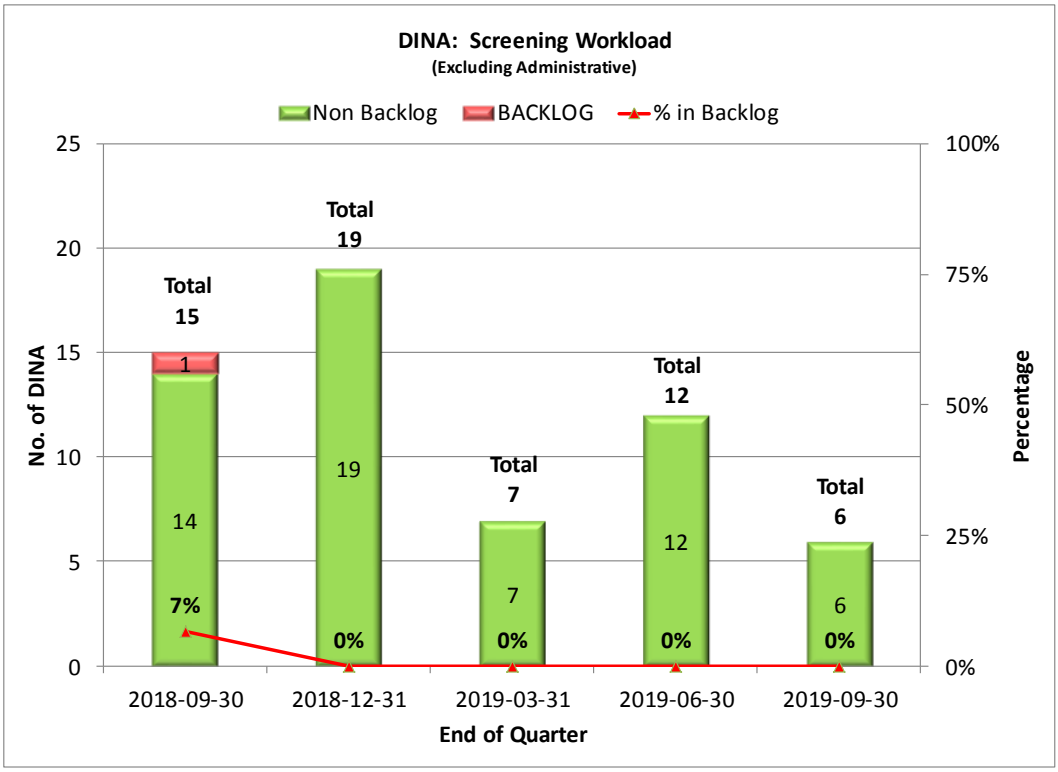


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Labelling Only	**17**	**19**	**27**	**22**	**30**
Backlog	*1*	*1*	*0*	*0*	*0*
Chemistry & Manufacturing	**20**	**13**	**26**	**24**	**17**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**4**	**1**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**2**	**1**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**43**	**34**	**55**	**47**	**47**
Non Backlog	**42**	**33**	**55**	**47**	**47**
BACKLOG	**1**	**1**	**0**	**0**	**0**
% in Backlog	**2%**	**3%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

DINA: Screening Workload



DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2018-09-30**	**2018-12-31**	**2019-03-31**	**2019-06-30**	**2019-09-30**
Labelling Only	**8**	**8**	**3**	**7**	**4**
Backlog	*1*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**7**	**9**	**3**	**5**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**2**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**15**	**19**	**7**	**12**	**6**
Non Backlog	**14**	**19**	**7**	**12**	**6**
BACKLOG	**1**	**0**	**0**	**0**	**0**
% in Backlog	**7%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINA: Number of Decisions by Fee Category

DINA - LABELLING ONLY					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NOTIFICATION FORM/DIN ISSUED	3	4	1	1	0
NO OBJECTION LETTER	7	8	9	18	10
CANCELLED BY COMPANY	1	3	0	0	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	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	2	0	1	1
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

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

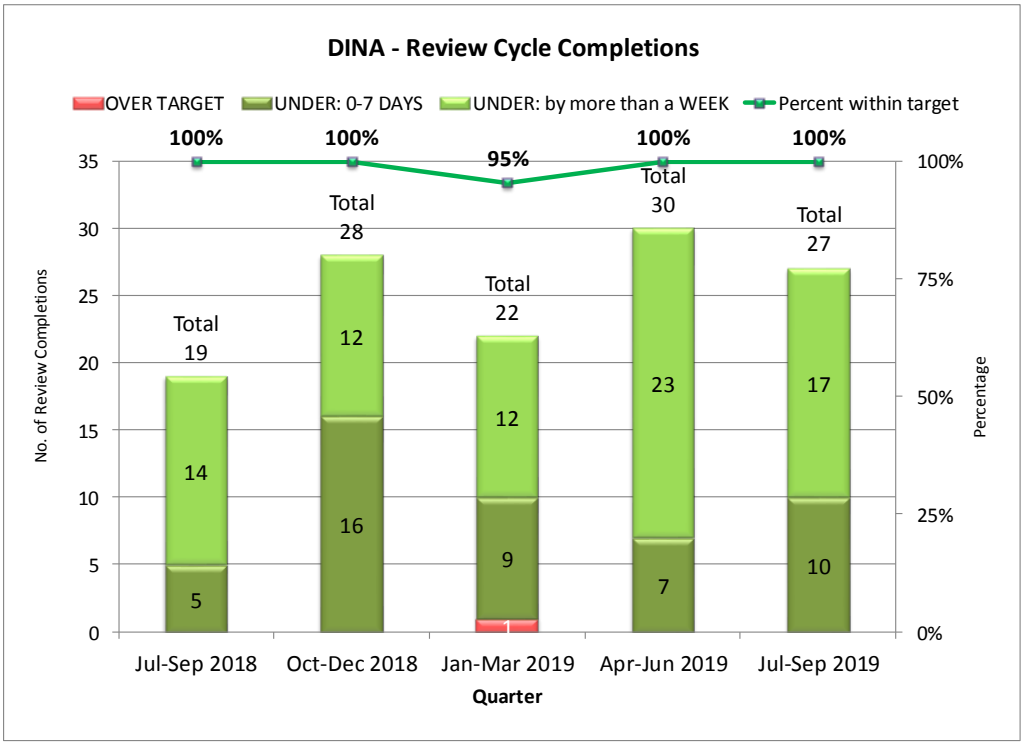
DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CANCELLED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

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
NOTIFICATION FORM/DIN ISSUED	1	0	1	1	0
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	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	1	0	0
CANCELLED BY COMPANY	0	0	1	0	0

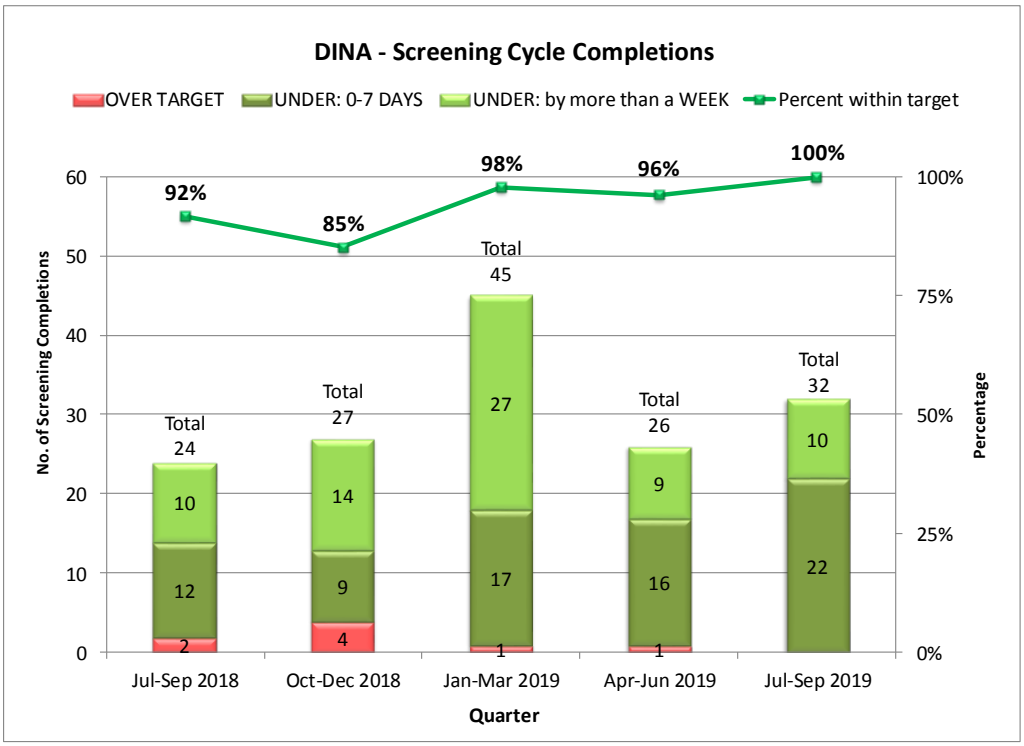
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
CANCELLED BY COMPANY	0	1	0	0	0
NOTICE OF NON-COMPLIANCE	0	1	1	0	0
NOTIFICATION FORM/DIN ISSUED	0	1	0	0	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

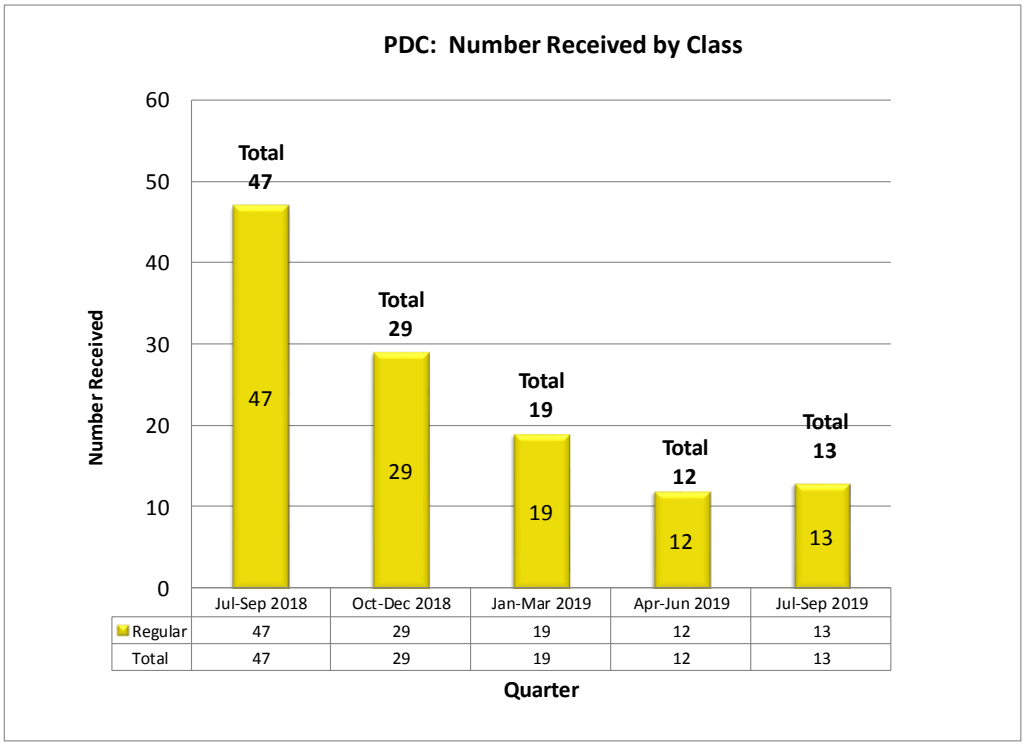


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE [14]

PDC: Number Received



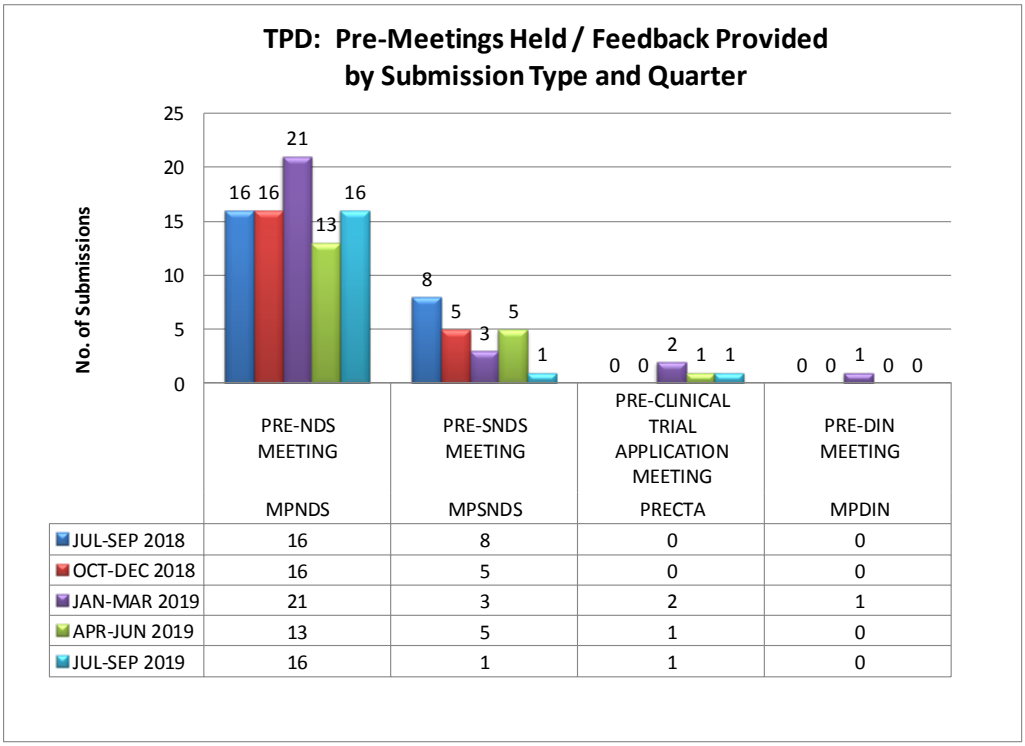
PDC: Number of Decisions by Type

PDC					
DOCUMENT TYPE	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**	**Jul-Sep 2019**
REGULAR					
CANCELLED BY COMPANY	7	4	6	6	4
NO OBJECTION LETTER	38	35	28	18	9
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 2018	16	8	0	0
OCT-DEC 2018	16	5	0	0
JAN-MAR 2019	21	3	2	1
APR-JUN 2019	13	5	1	0
JUL-SEP 2019	16	1	1	0

[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