Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

October-December

2017

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre :
Direction des produits thérapeutiques – Rapport trimestriel du rendement des présentations de drogue – Octobre – Décembre 2017

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OVERVIEW

The Therapeutic Products Directorate's (TPD) Quarterly Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive quarters: from October – December 2016 to October – December 2017. 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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101 Tunney's Pasture Driveway, Tunney's Pasture
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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[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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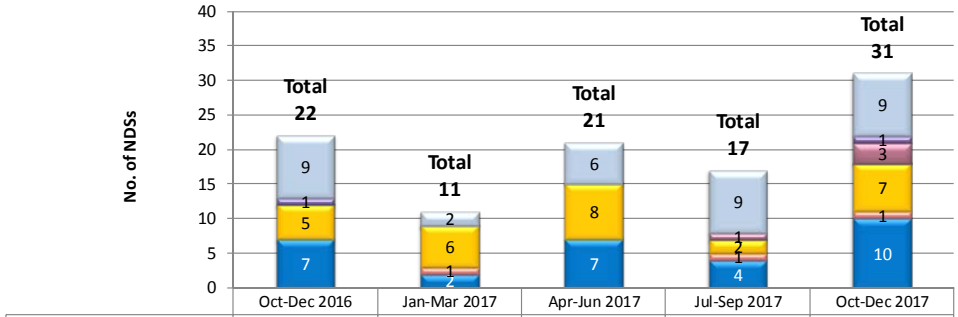
Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

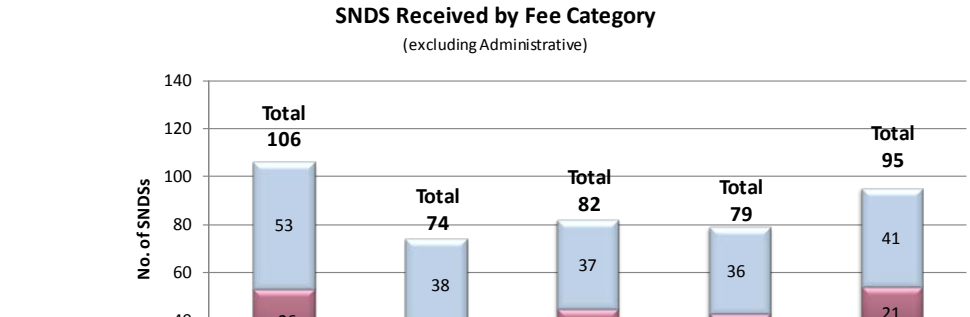
[9]

New Drug Submissions (NDS) Received by Fee Category



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	9	2	6	9	9
Comparative Studies	1	0	0	0	1
Chemistry & Manufacturing	0	0	0	1	3
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	5	6	8	2	7
Unassigned	0	1	0	1	1
New Active Substance	7	2	7	4	10
Total	22	11	21	17	31
Priority Class	1	2	1	1	5
NOC-C Class	0	1	0	0	1
Emergency Use (NDS)	0	0	0	0	0

Supplemental New Drug Submissions (SNDS) Received by Fee Category

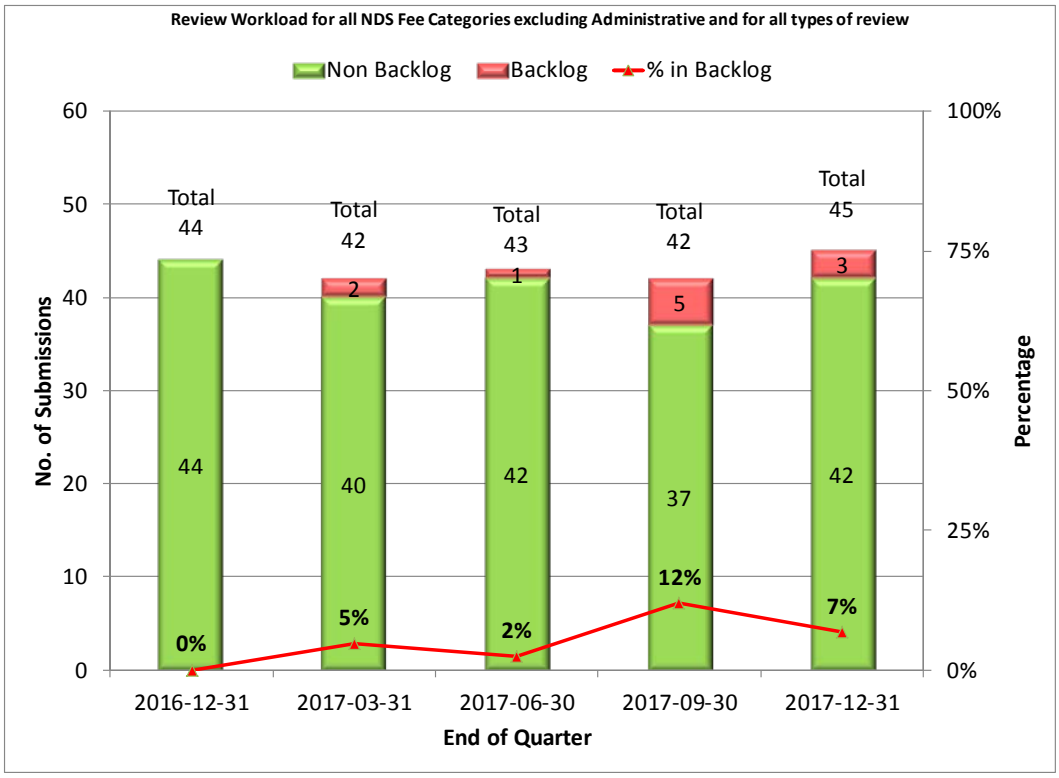


	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	53	38	37	36	41
Chemistry & Manufacturing	26	16	19	14	21
Clinical or Non-Clin Only	18	16	18	22	18
Published Data Only	2	3	1	3	6
Comparative Studies	4	1	5	1	0
Clinical or Non-Clin and C&M	3	0	2	3	9
Total	106	74	82	79	95
Priority Class	3	1	1	1	5
NOC-C Class	0	0	0	0	0
SNDS Confirmatory	3	2	1	1	1

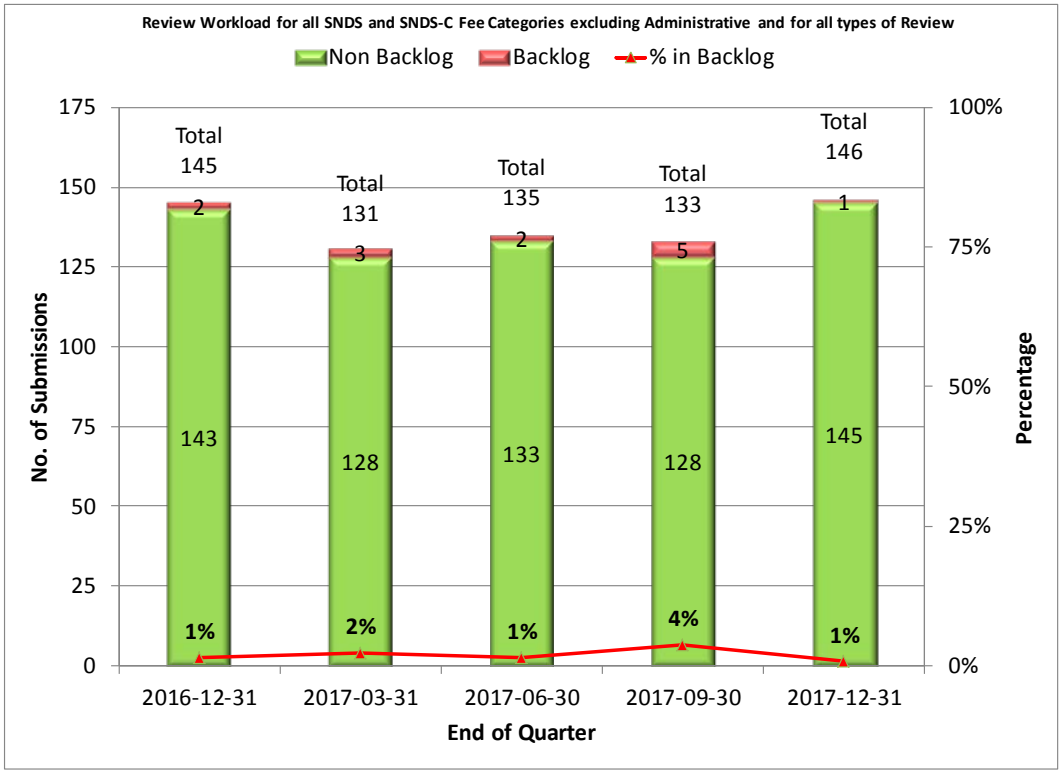
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

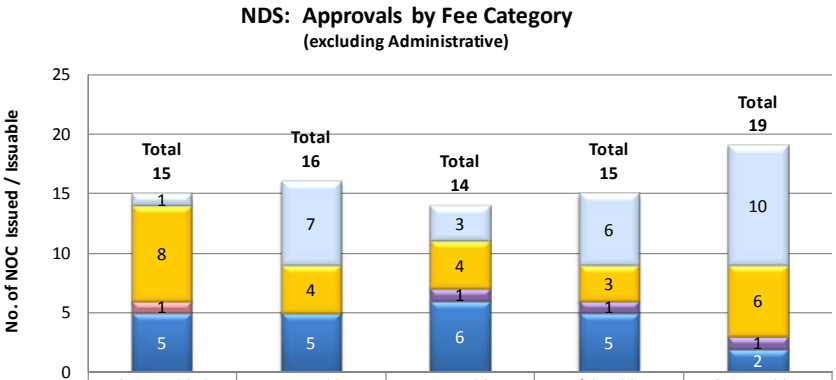
TPD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Labelling Only	**6**	**1**	**4**	**2**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**3**	**2**	**3**	**1**
Backlog	*0*	*0*	*0*	*1*	*0*
Chemistry & Manufacturing	**0**	**0**	**0**	**0**	**1**
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**	**19**	**23**	**24**	**20**
Backlog	*0*	*1*	*0*	*3*	*2*
New Active Substance	**21**	**19**	**14**	**13**	**20**
Backlog	*0*	*1*	*1*	*1*	*1*
Total	**44**	**42**	**43**	**42**	**45**
Non Backlog	**44**	**40**	**42**	**37**	**42**
Backlog	**0**	**2**	**1**	**5**	**3**
% in Backlog	**0%**	**5%**	**2%**	**12%**	**7%**
Priority (subset)	**2**	**6**	**5**	**3**	**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					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Labelling Only	**35**	**22**	**23**	**23**	**28**
Backlog	*0*	*1*	*1*	*2*	*0*
Comparative Studies	**5**	**7**	**7**	**8**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**33**	**34**	**37**	**38**	**34**
Backlog	*0*	*0*	*0*	*2*	*1*
Clinical or Non-Clin Only	**62**	**53**	**55**	**53**	**63**
Backlog	*1*	*2*	*1*	*1*	*0*
Clinical or Non-Clin and C&M	**7**	**8**	**5**	**6**	**9**
Backlog	*1*	*0*	*0*	*0*	*0*
Switch from Rx to OTC	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**3**	**7**	**8**	**5**	**8**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**145**	**131**	**135**	**133**	**146**
Non Backlog	**143**	**128**	**133**	**128**	**145**
Backlog	**2**	**3**	**2**	**5**	**1**
% in Backlog	**1%**	**2%**	**1%**	**4%**	**1%**
Priority (subset)	**4**	**4**	**2**	**2**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**4**	**6**	**7**	**6**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*

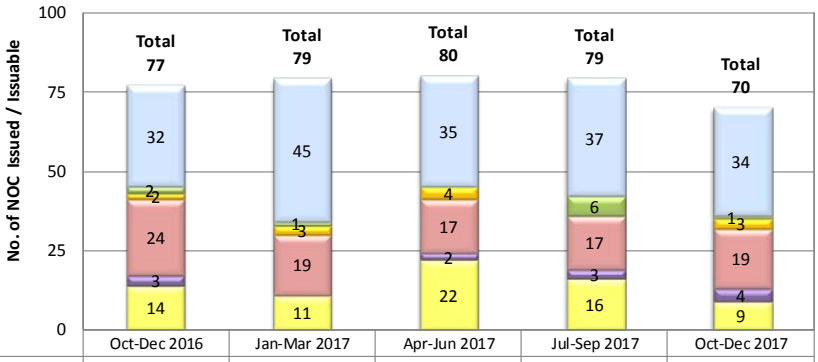
APPROVALS[10]

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	1	7	3	6	10
Clinical or Non-Clin and C&M	8	4	4	3	6
Clinical or Non-Clin Only	0	0	0	0	0
Comparative Studies	0	0	1	1	1
Chemistry & Manufacturing	1	0	0	0	0
New Active Substance	5	5	6	5	2
Total	15	16	14	15	19
Notice of Compliance	15	14	12	14	19
NOC with Conditions	0	1	1	0	0
NOC on Hold (Patent)	0	1	1	1	0
Priority Class	2	0	2	4	1
NOC-C Class	0	0	1	0	0

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	32	45	35	37	34
Published Data Only	2	1	0	6	1
Clinical or Non-Clin and C&M	2	3	4	0	3
Chemistry & Manufacturing	24	19	17	17	19
Comparative Studies	3	0	2	3	4
Clinical or Non-Clin Only	14	11	22	16	9
Total	77	79	80	79	70
Notice of Compliance	77	79	79	78	70
NOC with Conditions	0	0	1	1	0
NOC on Hold (Patent)	0	0	0	0	0
Priority Class	0	0	4	1	1
NOC-C Class	0	0	1	0	0

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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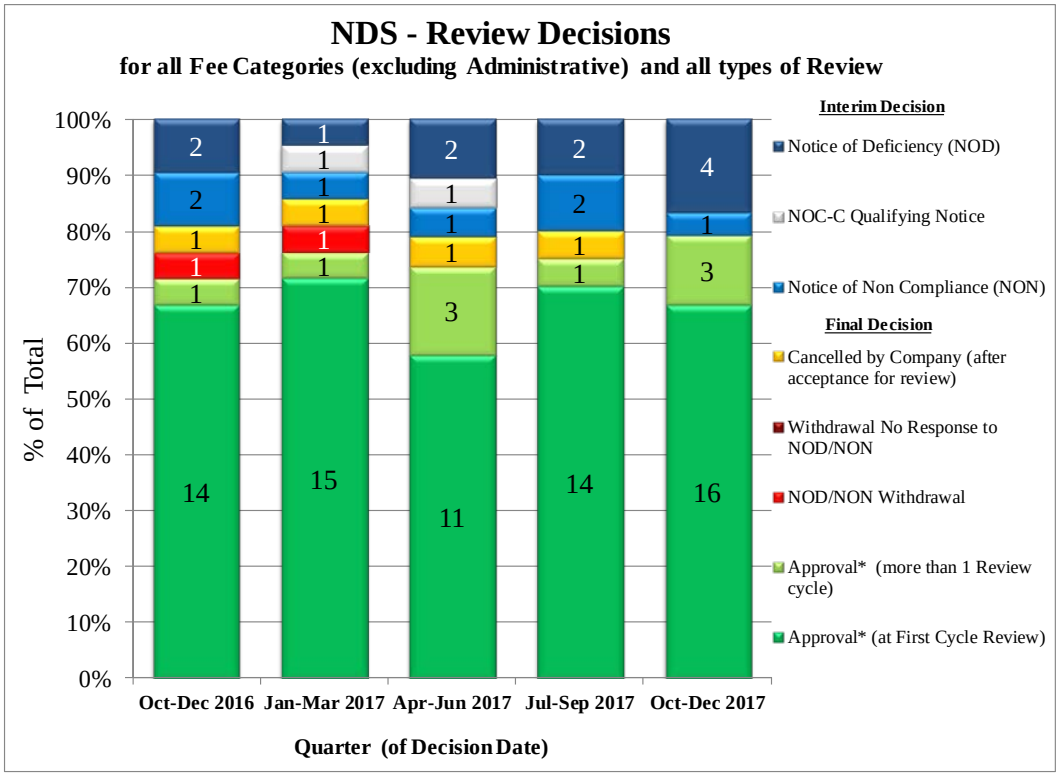
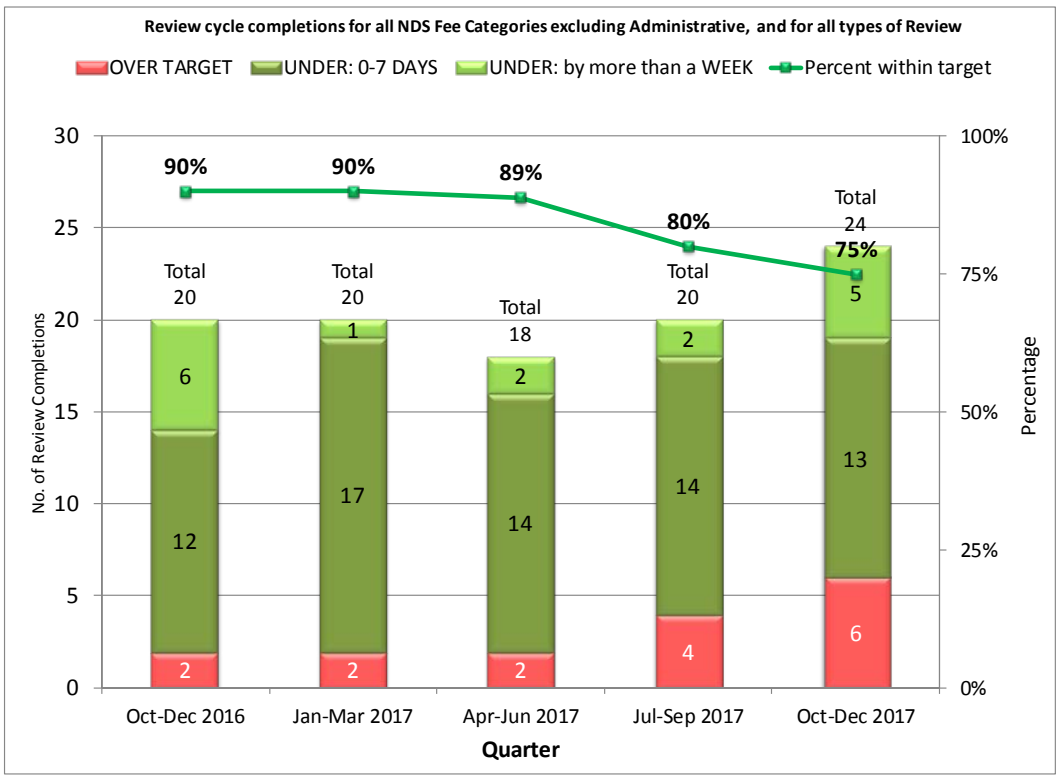
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

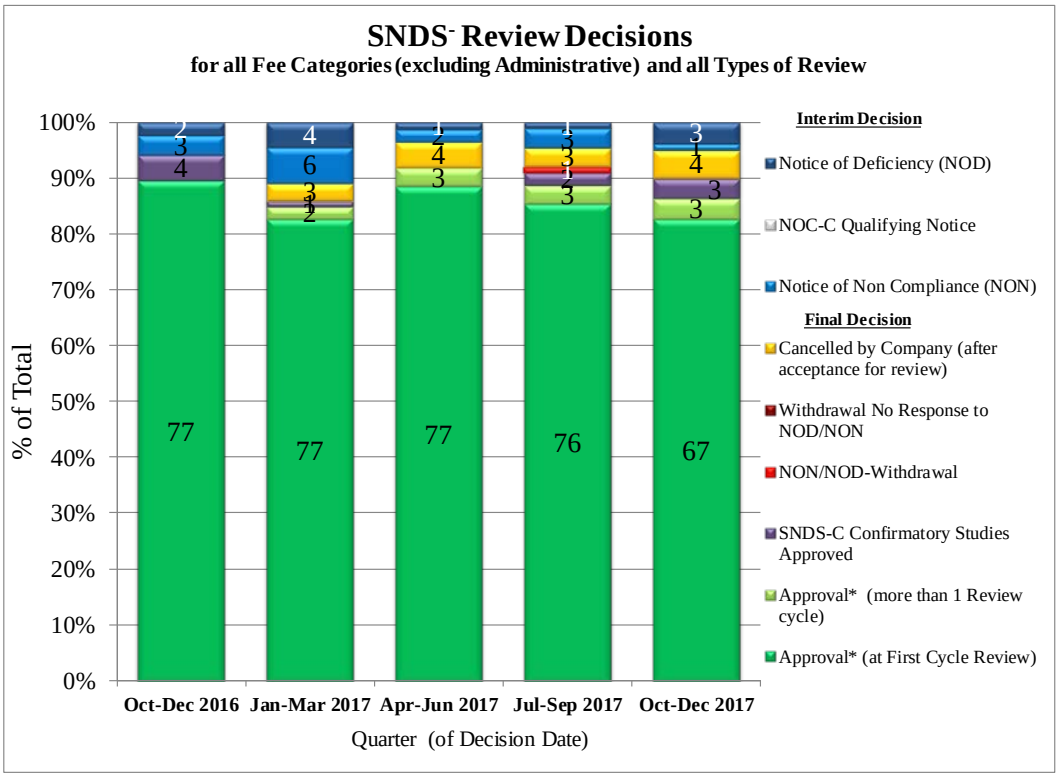


NDS - Review Cycle Completions Showing Percentage Within Target

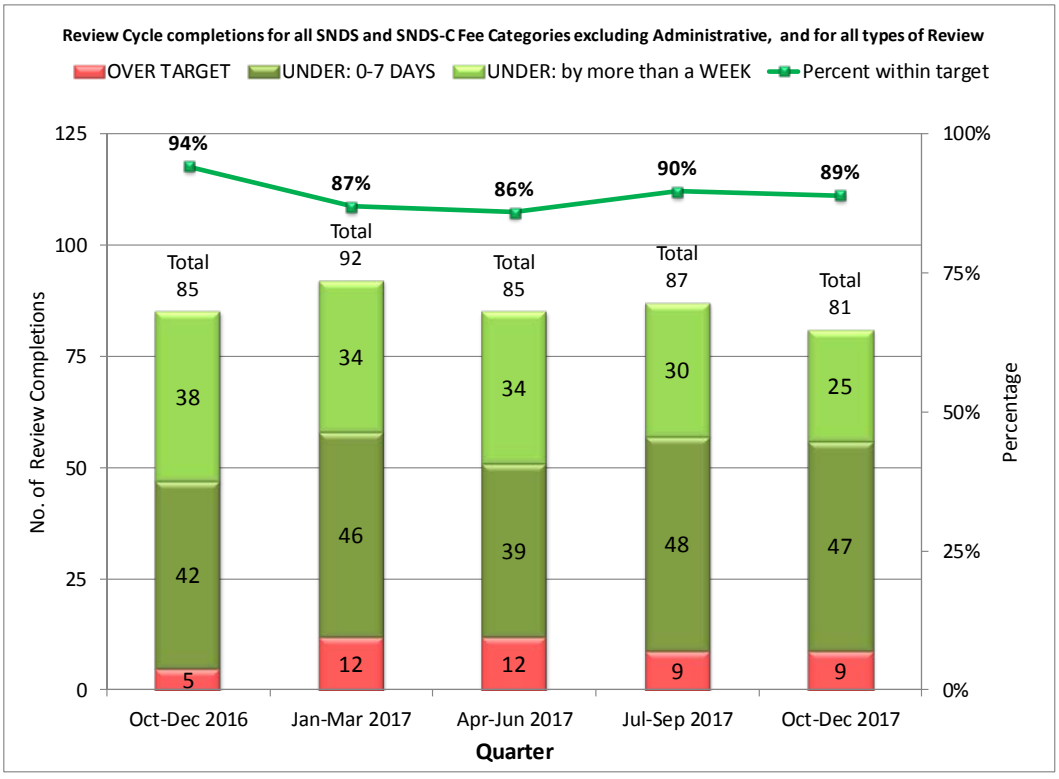


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

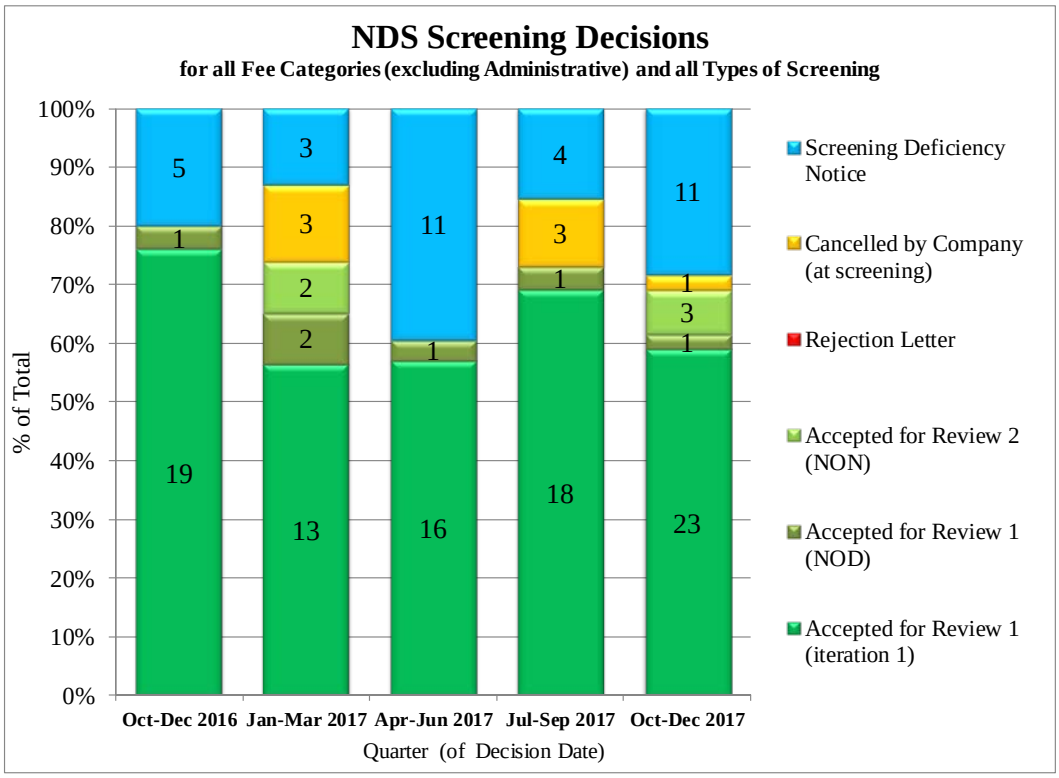


SNDS - Review Cycle Completions Showing Percentage Within Target

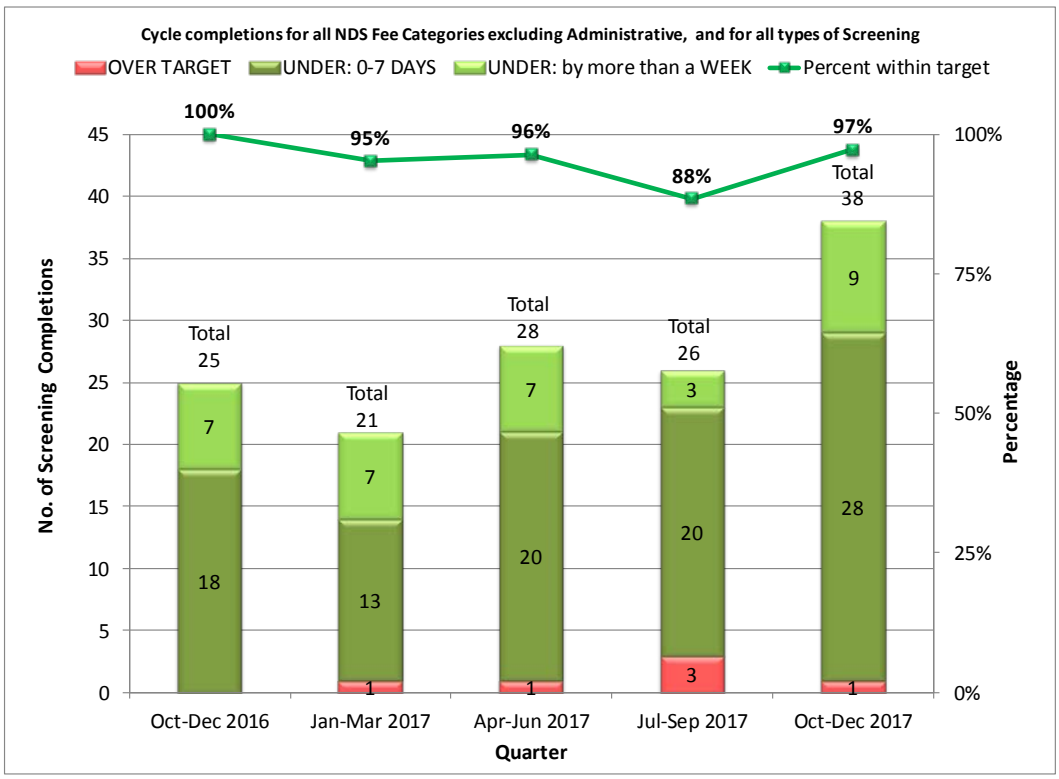


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

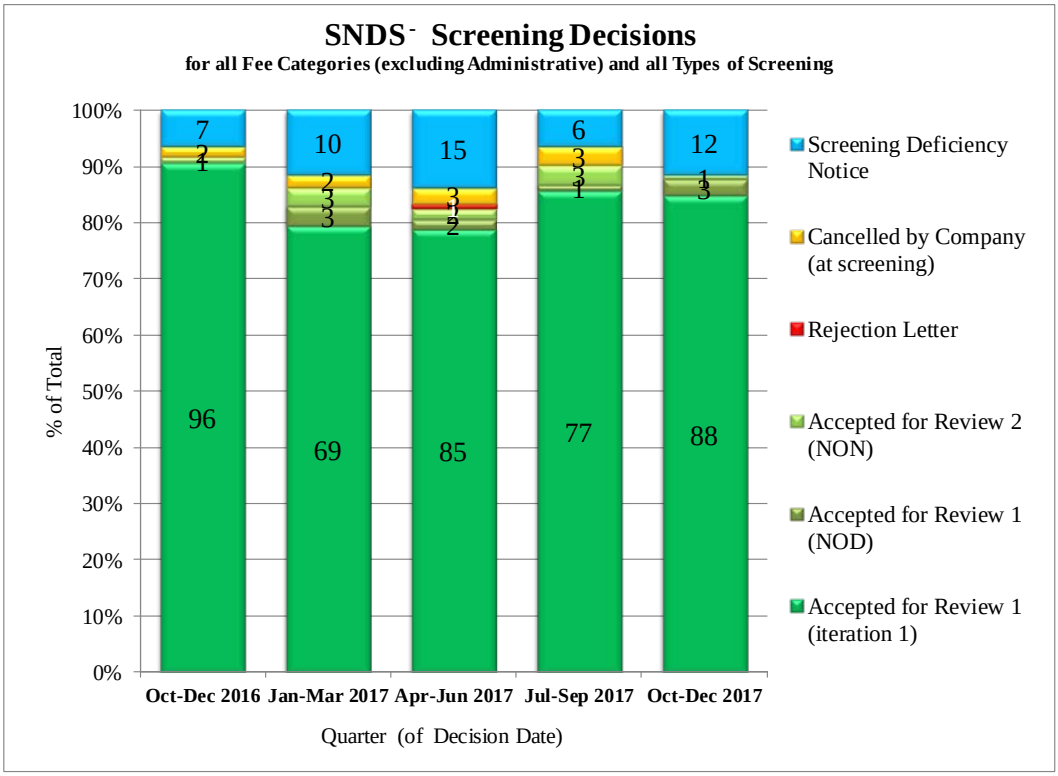


NDS - Screening Cycle Completions Showing Percentage Within Target

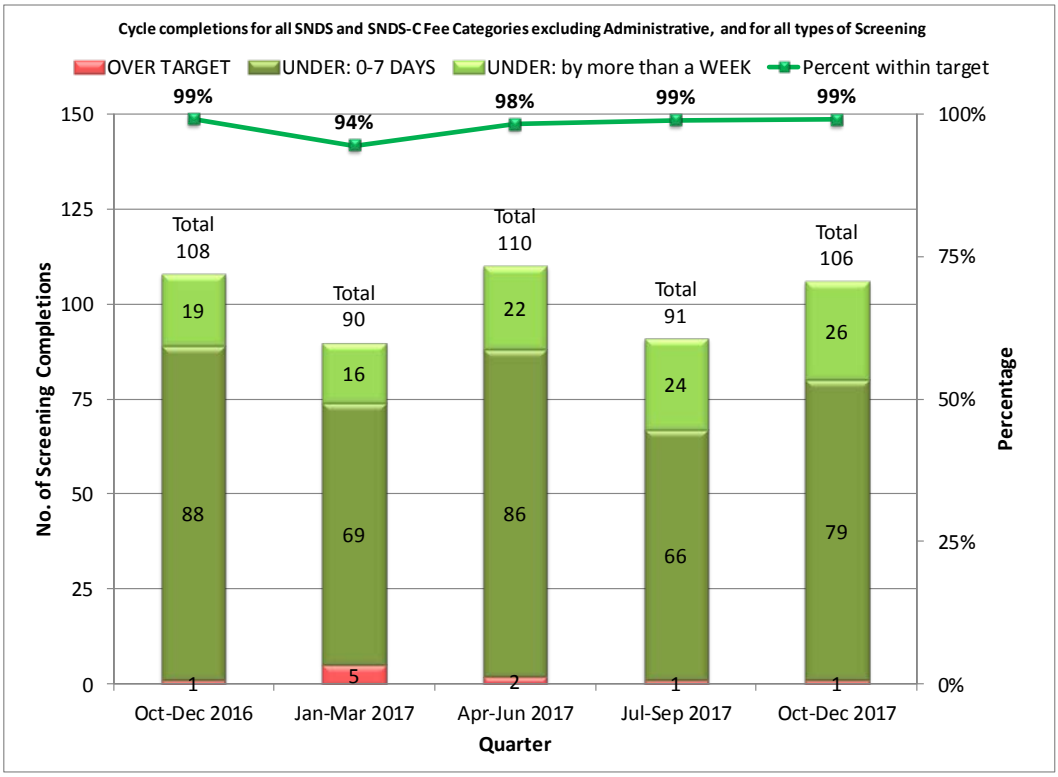


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



Abbreviated New Drug Submissions (ANDS)

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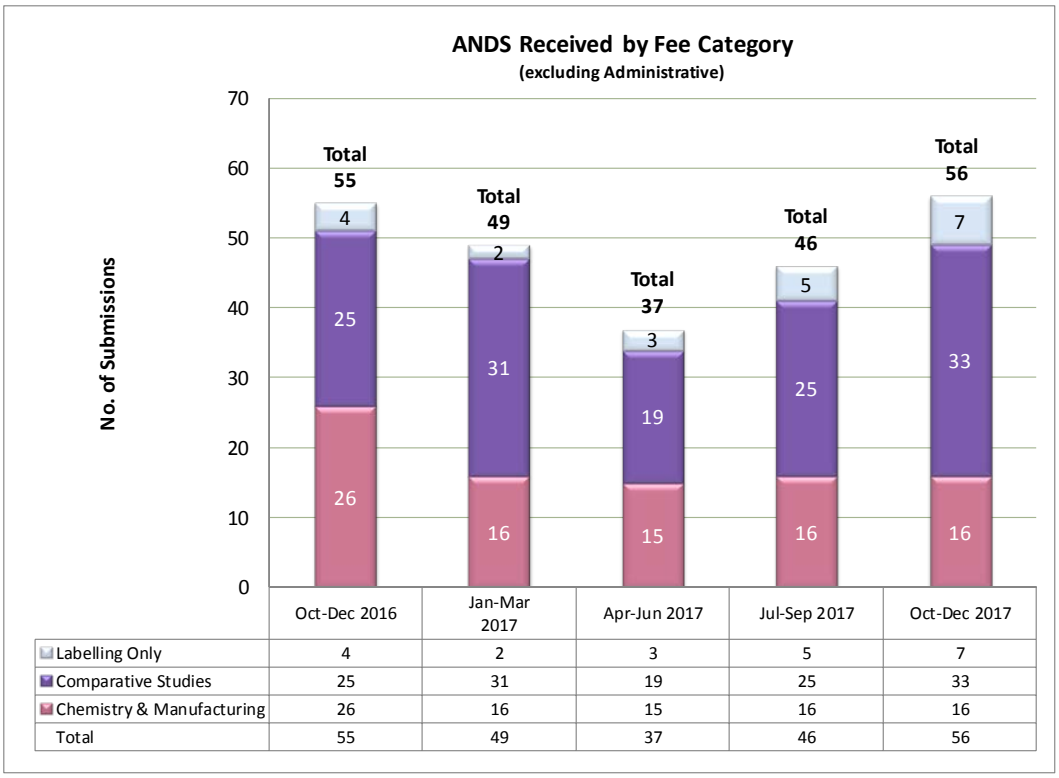
Supplemental Abbreviated New Drug Submissions

(SANDS)

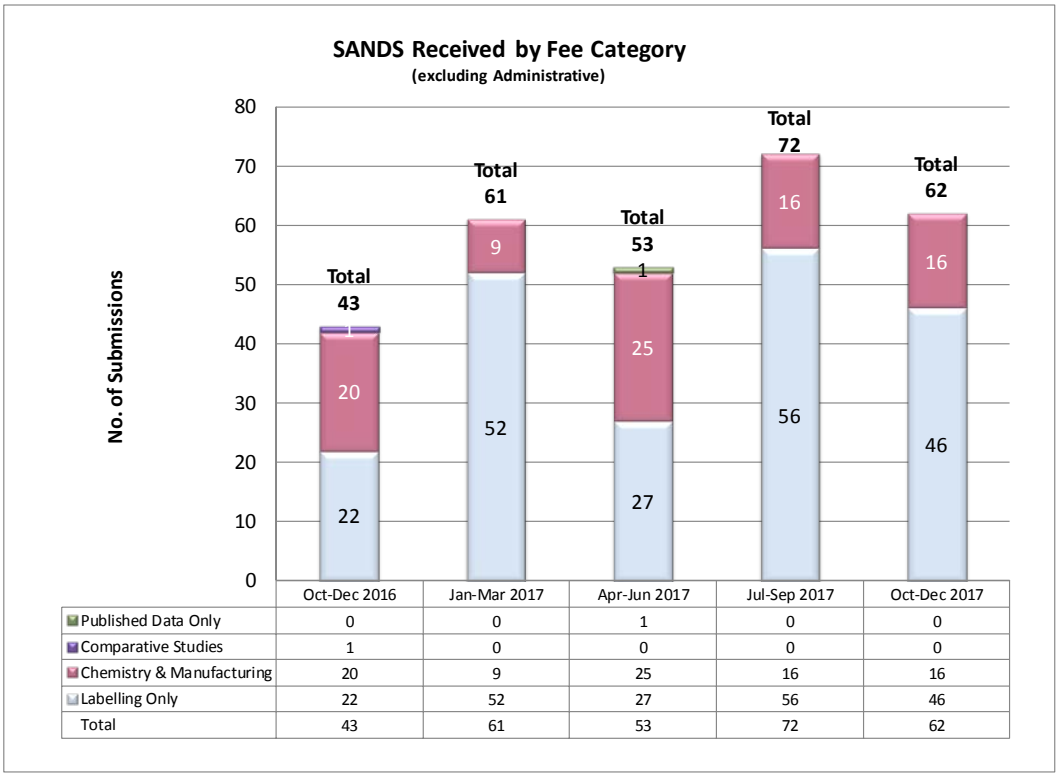
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	4	2	3	5	7
Comparative Studies	25	31	19	25	33
Chemistry & Manufacturing	26	16	15	16	16
Total	55	49	37	46	56

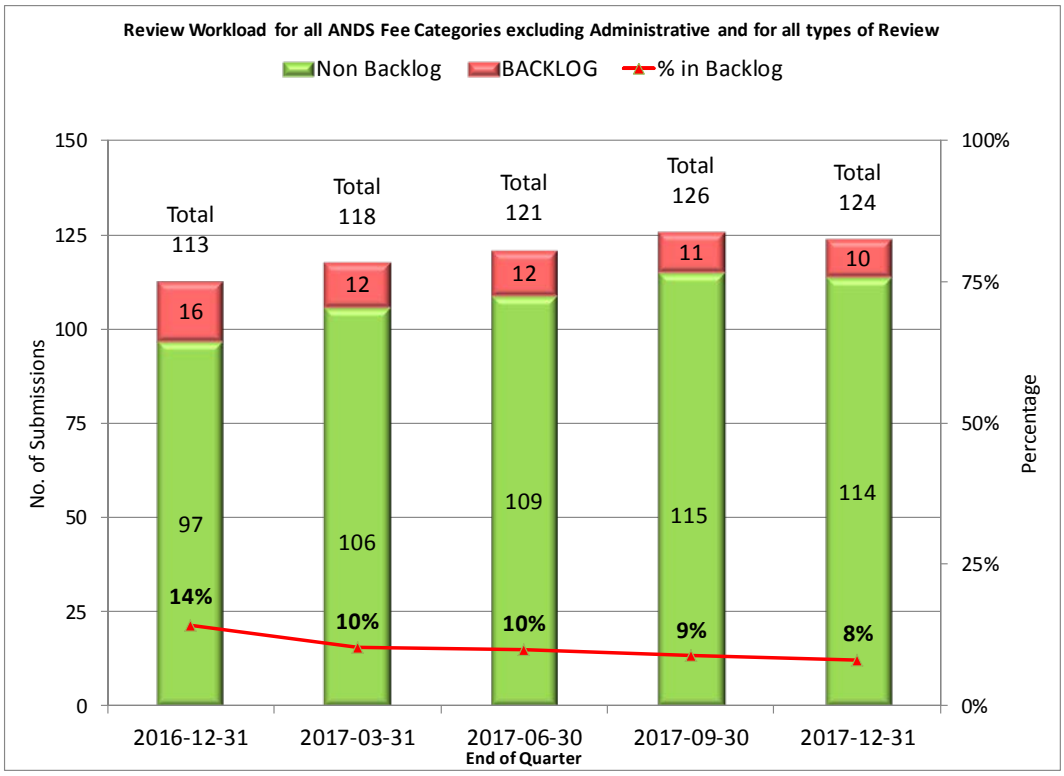
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



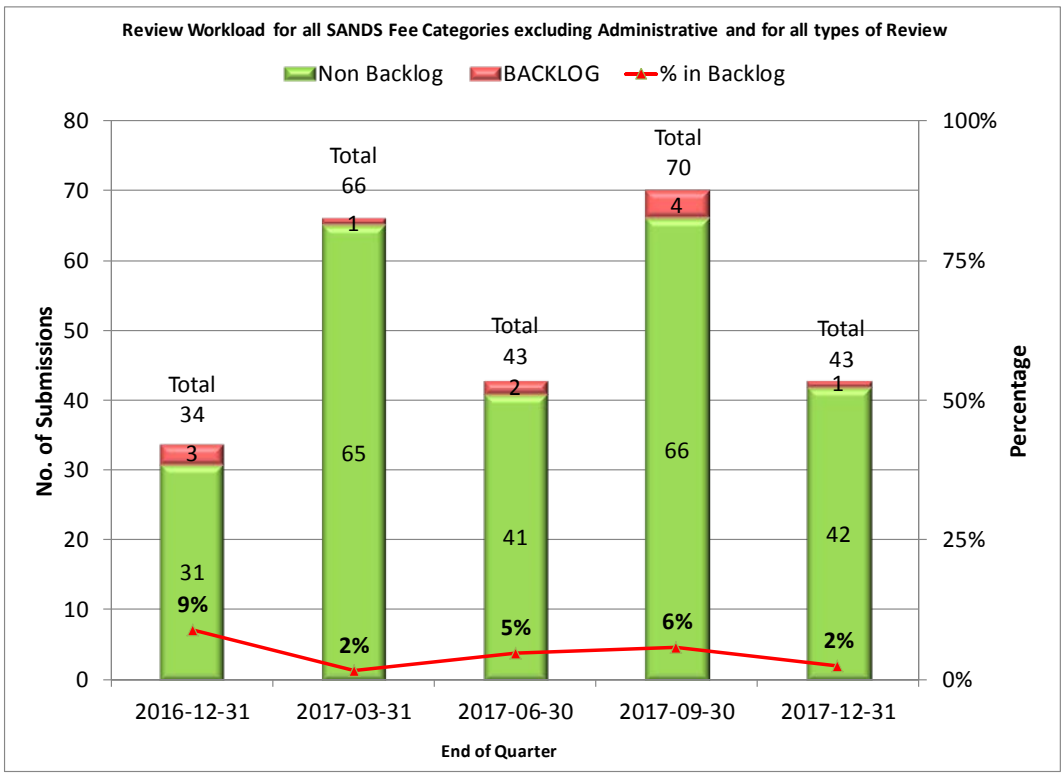
	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Published Data Only	0	0	1	0	0
Comparative Studies	1	0	0	0	0
Chemistry & Manufacturing	20	9	25	16	16
Labelling Only	22	52	27	56	46
Total	43	61	53	72	62

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

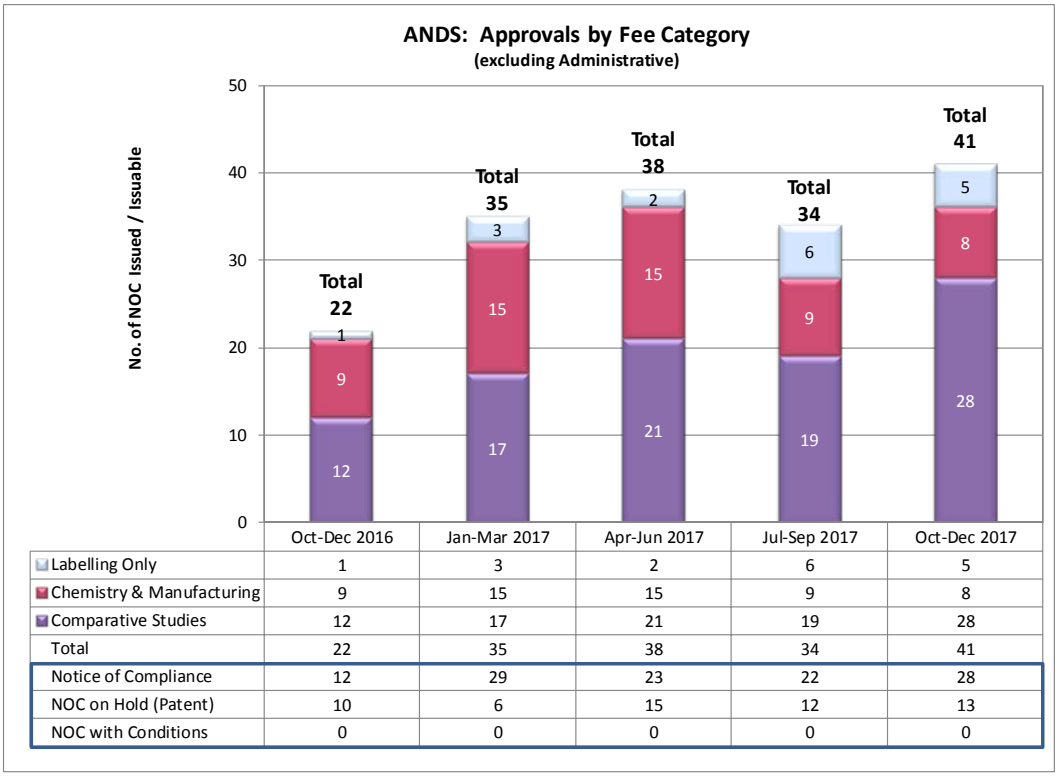
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Chemistry & Manufacturing	**48**	**46**	**46**	**46**	**49**
Backlog	*9*	*5*	*5*	*5*	*4*
Comparative Studies	**63**	**71**	**73**	**79**	**73**
Backlog	*7*	*7*	*7*	*6*	*6*
Labelling Only	**2**	**1**	**2**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**113**	**118**	**121**	**126**	**124**
Non Backlog	97	106	109	115	114
BACKLOG	16	12	12	11	10
% in Backlog	14%	10%	10%	9%	8%

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

TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Chemistry & Manufacturing	**19**	**32**	**26**	**38**	**27**
Backlog	*2*	*1*	*1*	*2*	*1*
Comparative Studies	**6**	**4**	**2**	**3**	**0**
Backlog	*1*	*0*	*0*	*1*	*0*
Published Data	**0**	**0**	**1**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**9**	**30**	**14**	**28**	**15**
Backlog	*0*	*0*	*1*	*1*	*0*
Total	**34**	**66**	**43**	**70**	**43**
Non Backlog	31	65	41	66	42
BACKLOG	3	1	2	4	1
% in Backlog	9%	2%	5%	6%	2%

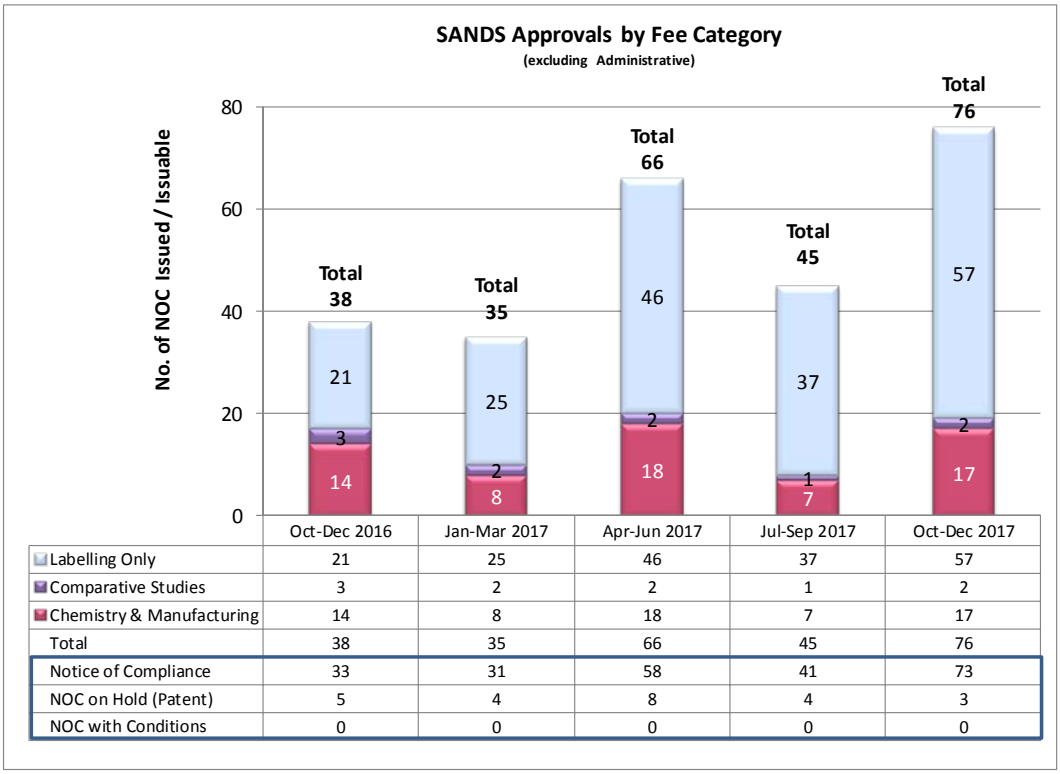
APPROVALS

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	1	3	2	6	5
Chemistry & Manufacturing	9	15	15	9	8
Comparative Studies	12	17	21	19	28
Total	22	35	38	34	41
Notice of Compliance	12	29	23	22	28
NOC on Hold (Patent)	10	6	15	12	13
NOC with Conditions	0	0	0	0	0

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	21	25	46	37	57
Comparative Studies	3	2	2	1	2
Chemistry & Manufacturing	14	8	18	7	17
Total	38	35	66	45	76
Notice of Compliance	33	31	58	41	73
NOC on Hold (Patent)	5	4	8	4	3
NOC with Conditions	0	0	0	0	0

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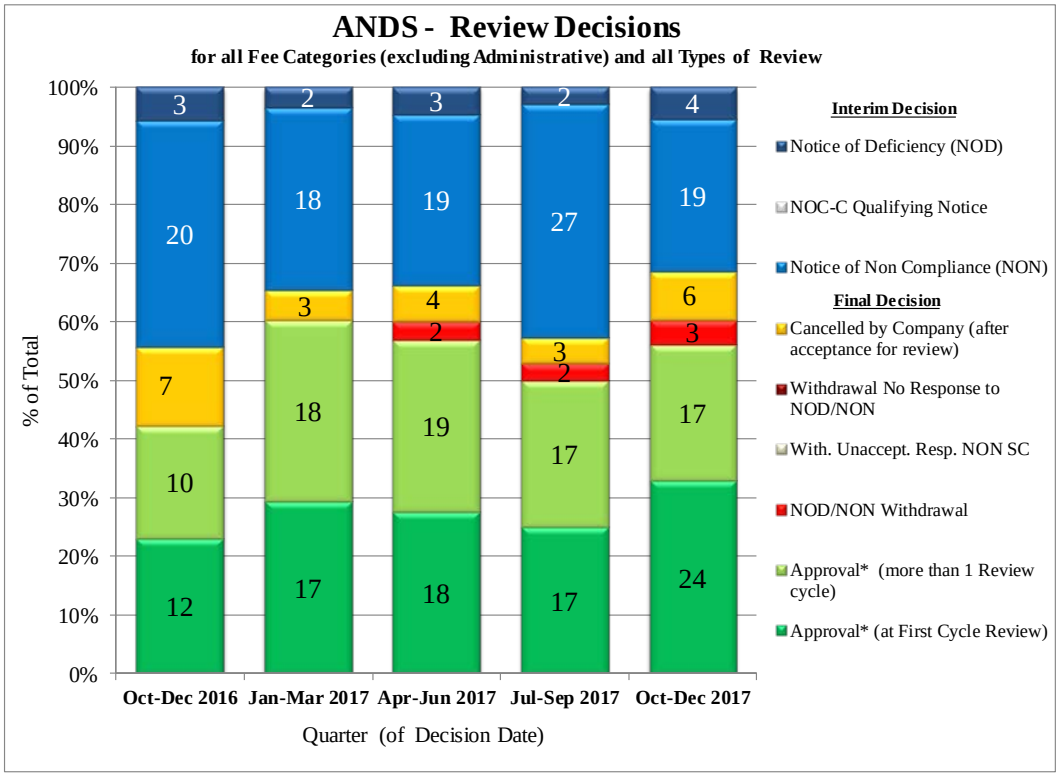
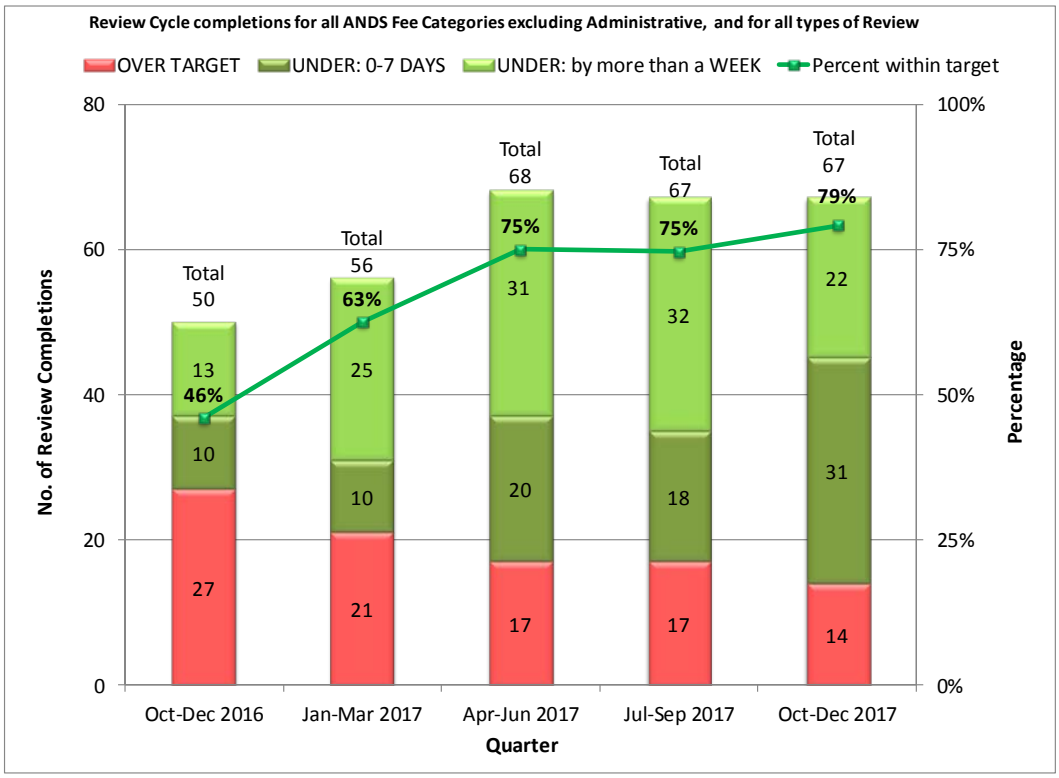
REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

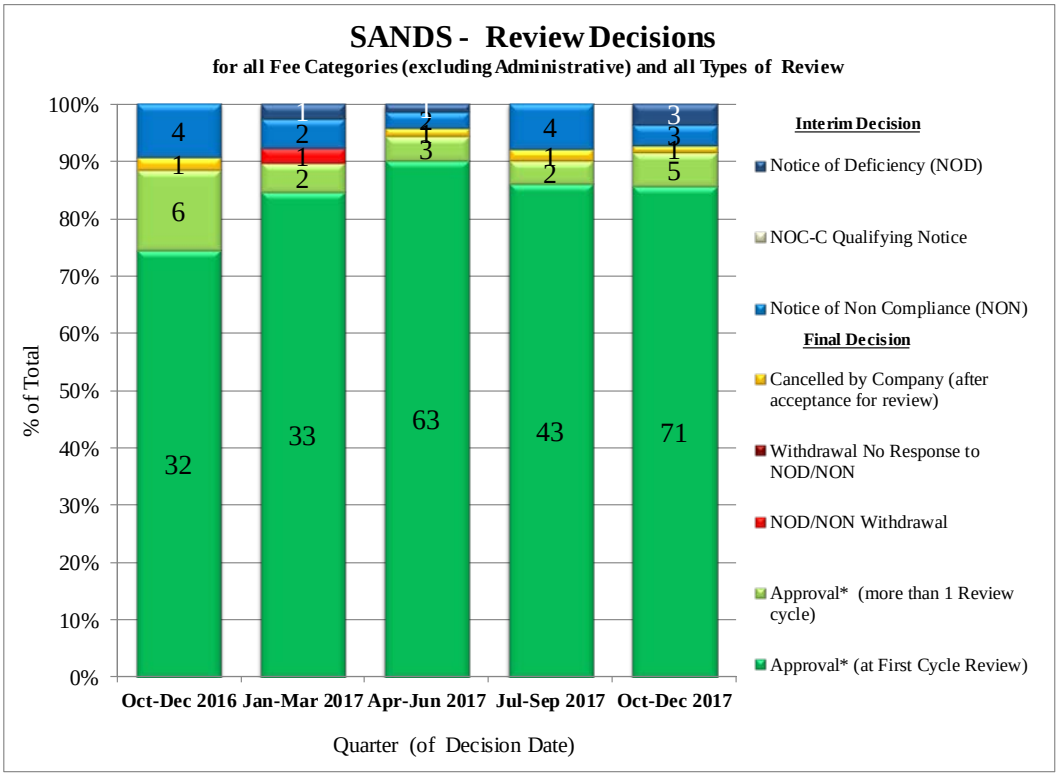


ANDS - Review Cycle Completions Showing Percentage Within Target

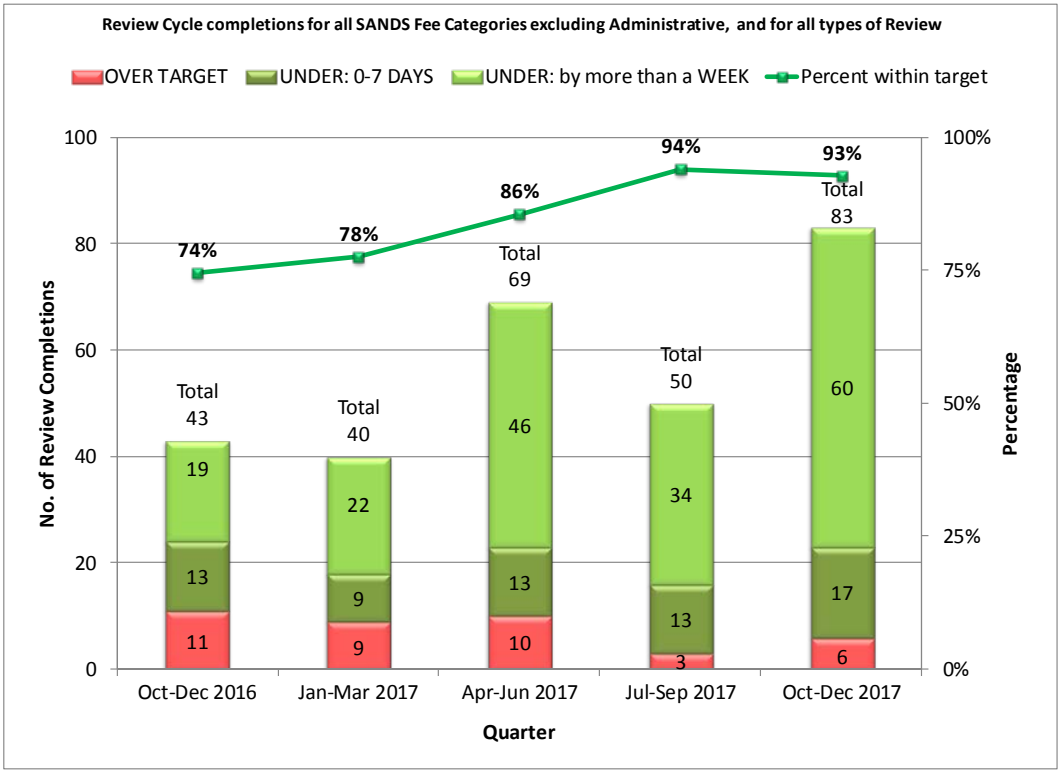


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

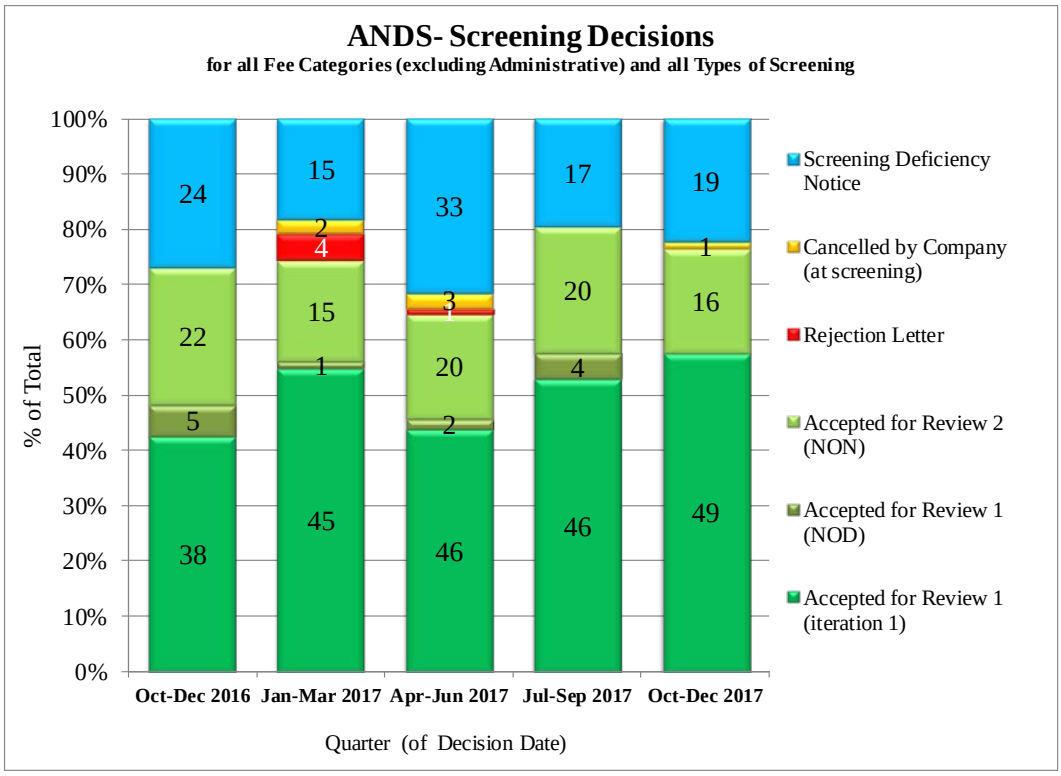


SANDS - Review Cycle Completions Showing Percentage Within Target

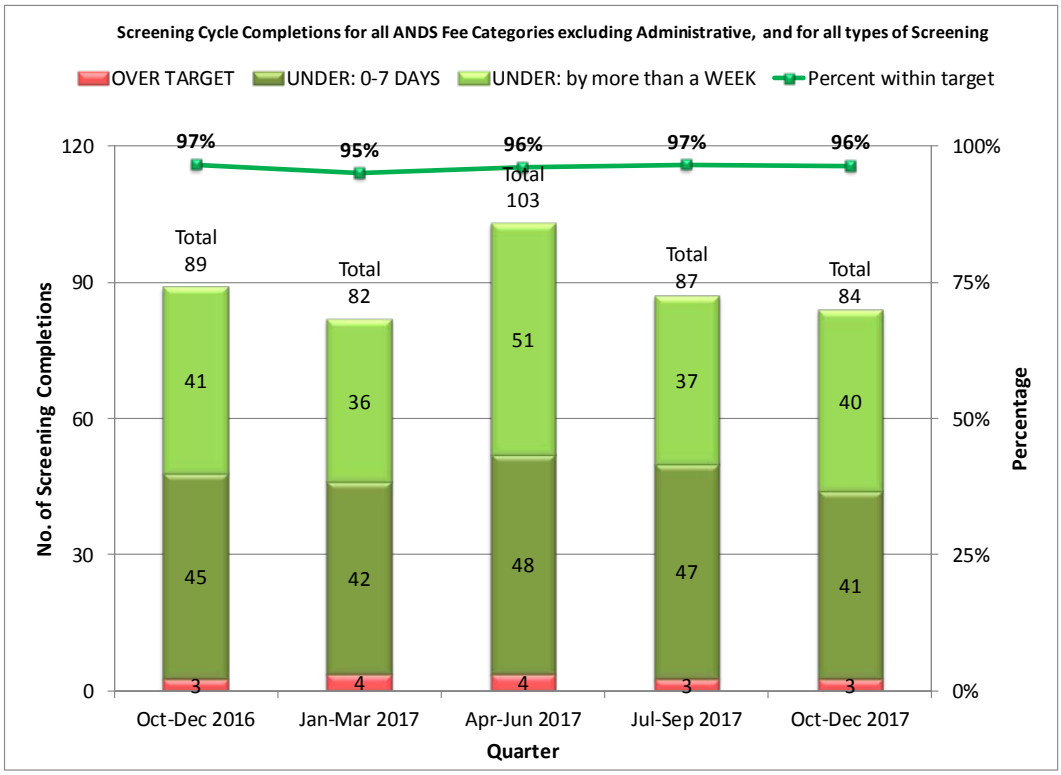


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

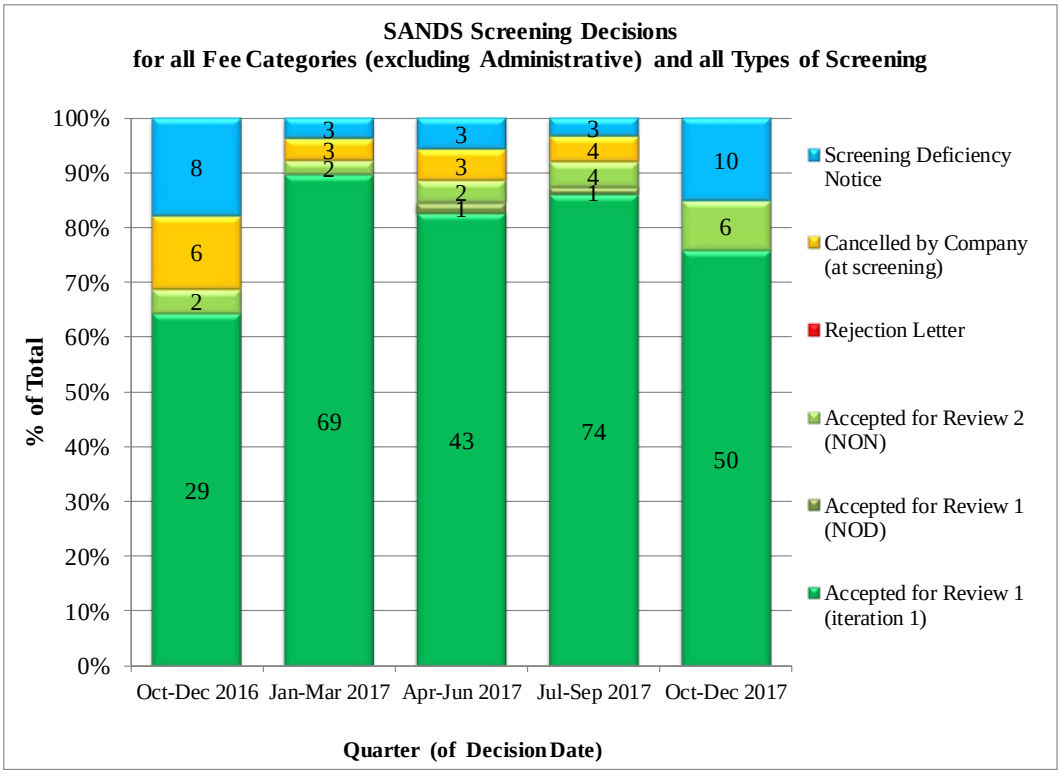


ANDS - Screening Cycle Completions Showing Percentage Within Target

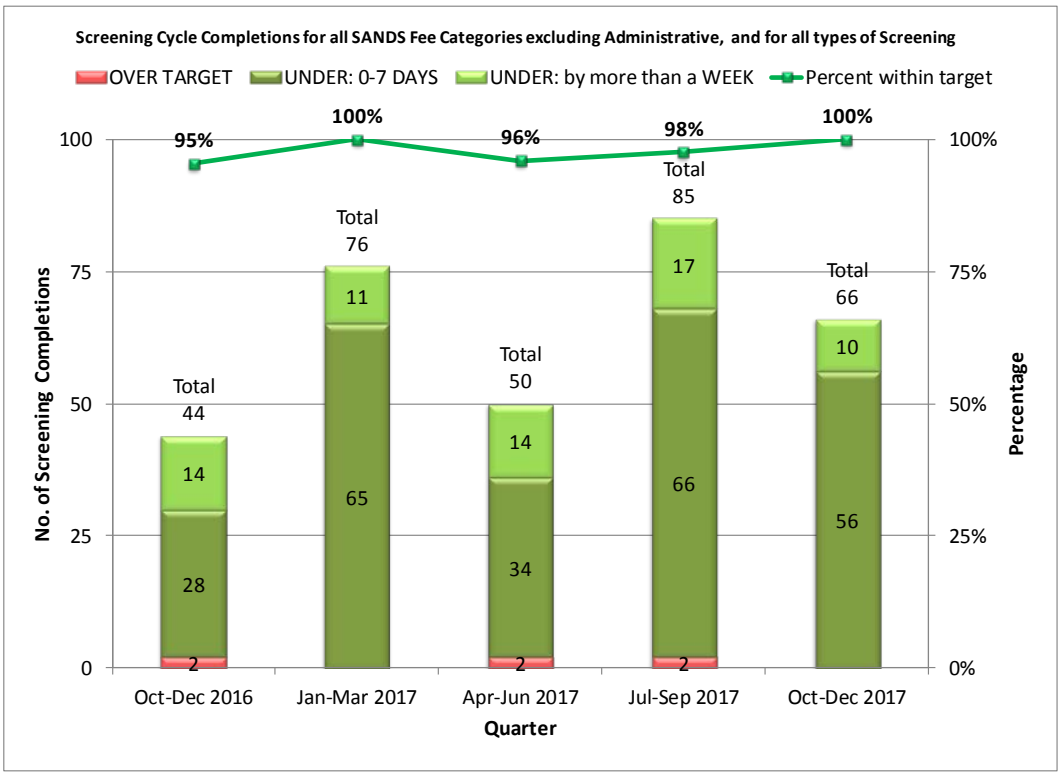


SCREENING CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions

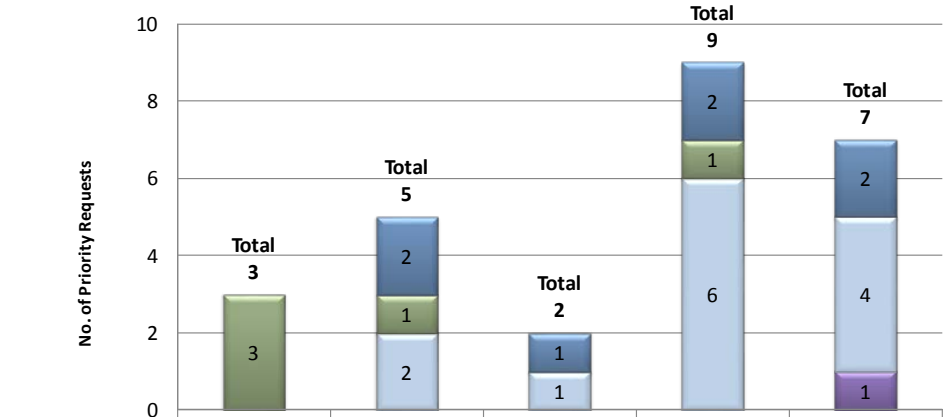


SANDS - Screening Cycle Completions Showing Percentage Within Target



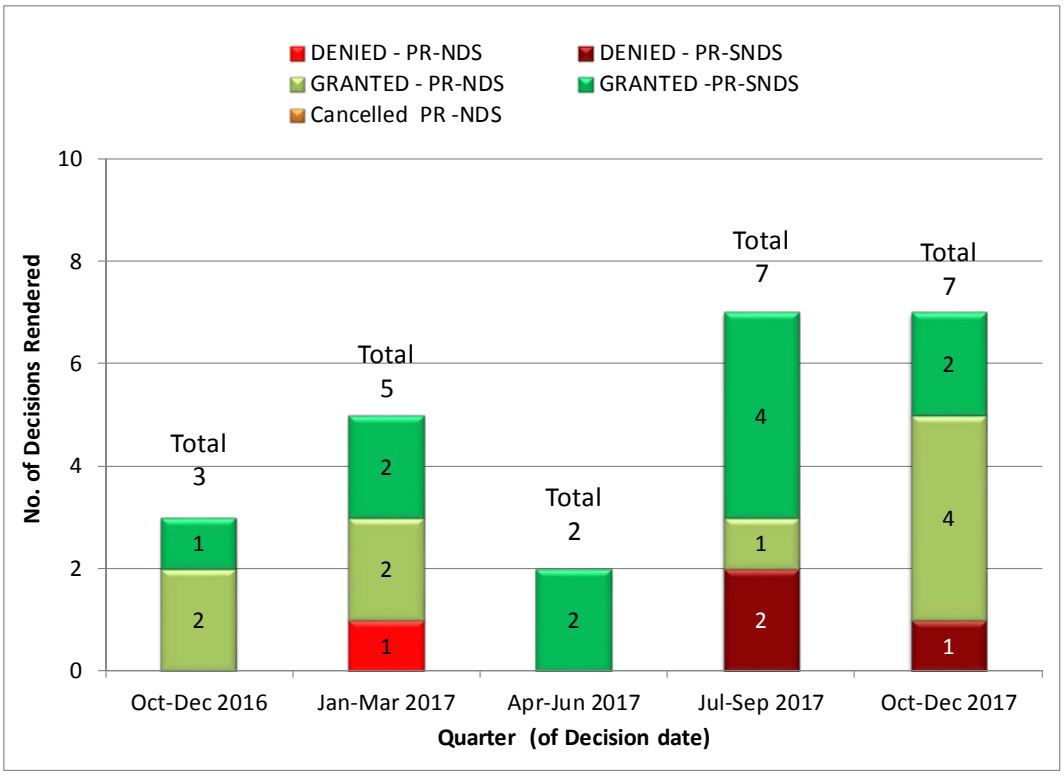
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

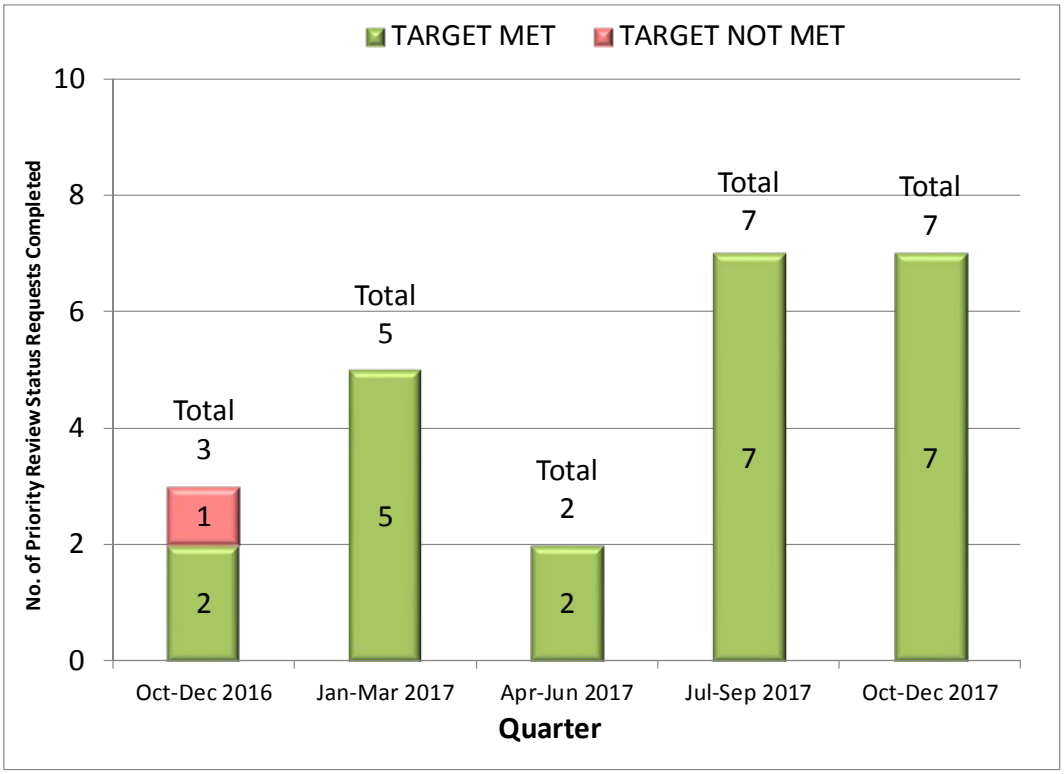


	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
PR-NDS COMP	0	0	0	0	0
PR-NDS C&M	0	0	0	0	0
PR-NDS CLIN ONLY	0	2	1	2	2
PR-NDS CLIN/C&M	3	1	0	1	0
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN ONLY	0	2	1	6	4
PR-SNDS CLIN/C&M	0	0	0	0	1
Total	3	5	2	9	7

Priority Review Status Requests: Decisions Rendered



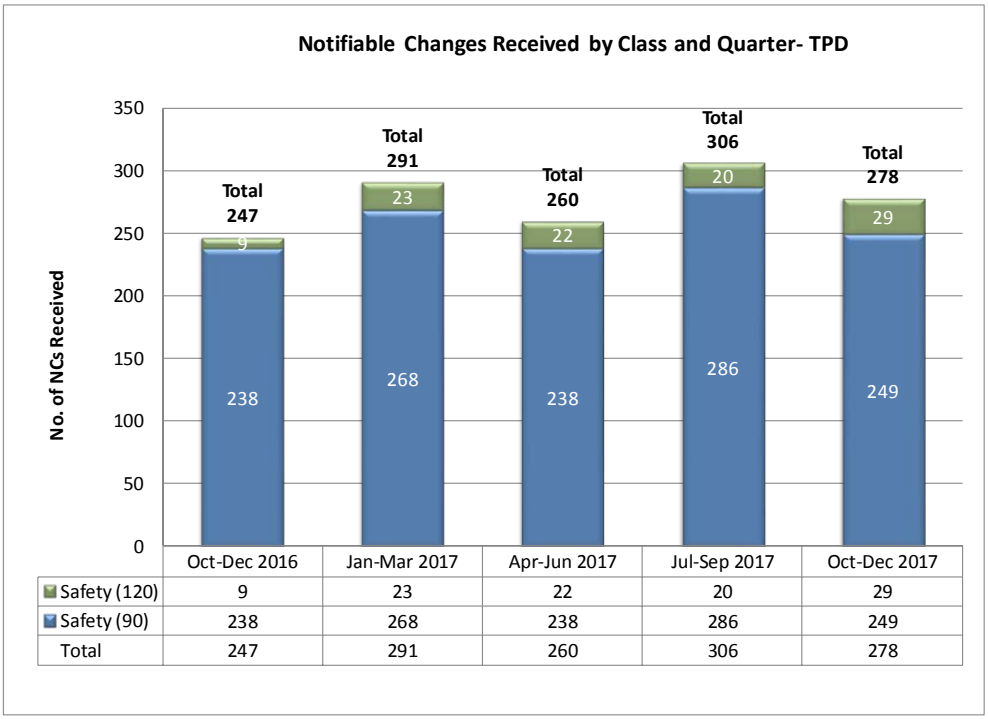
Priority Review Status Requests: Performance



NOTIFIABLE CHANGES (NC)

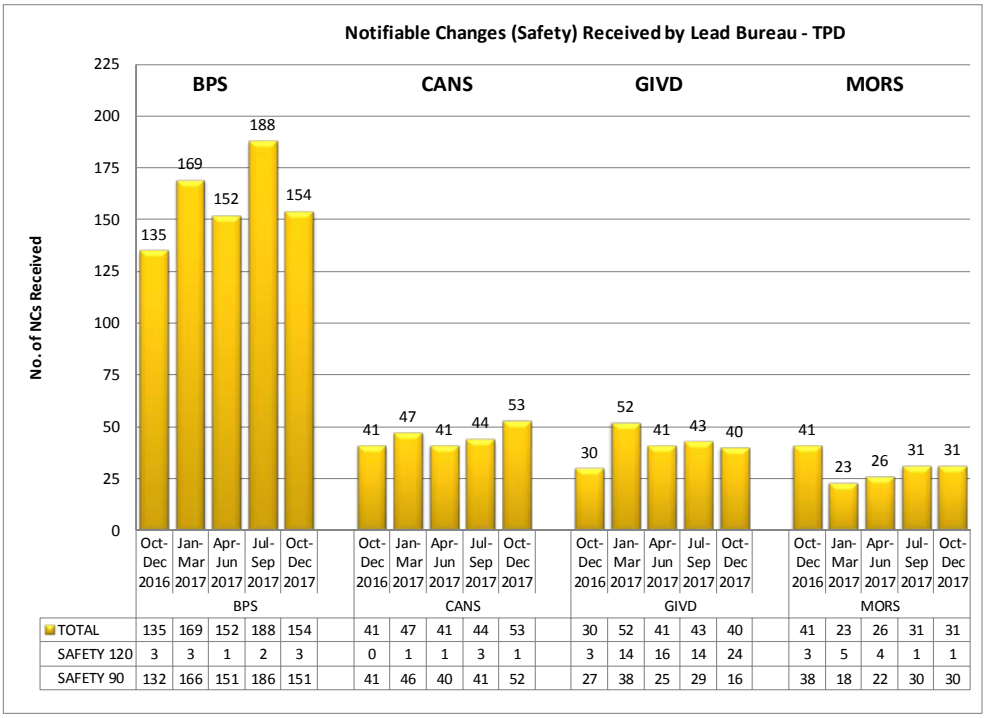
NOTIFIABLE CHANGES[11]
SUBMISSIONS RECEIVED

Number Received - Notifiable Changes (NC) - by Class



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Safety (120)	9	23	22	20	29
Safety (90)	238	268	238	286	249
Total	247	291	260	306	278

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

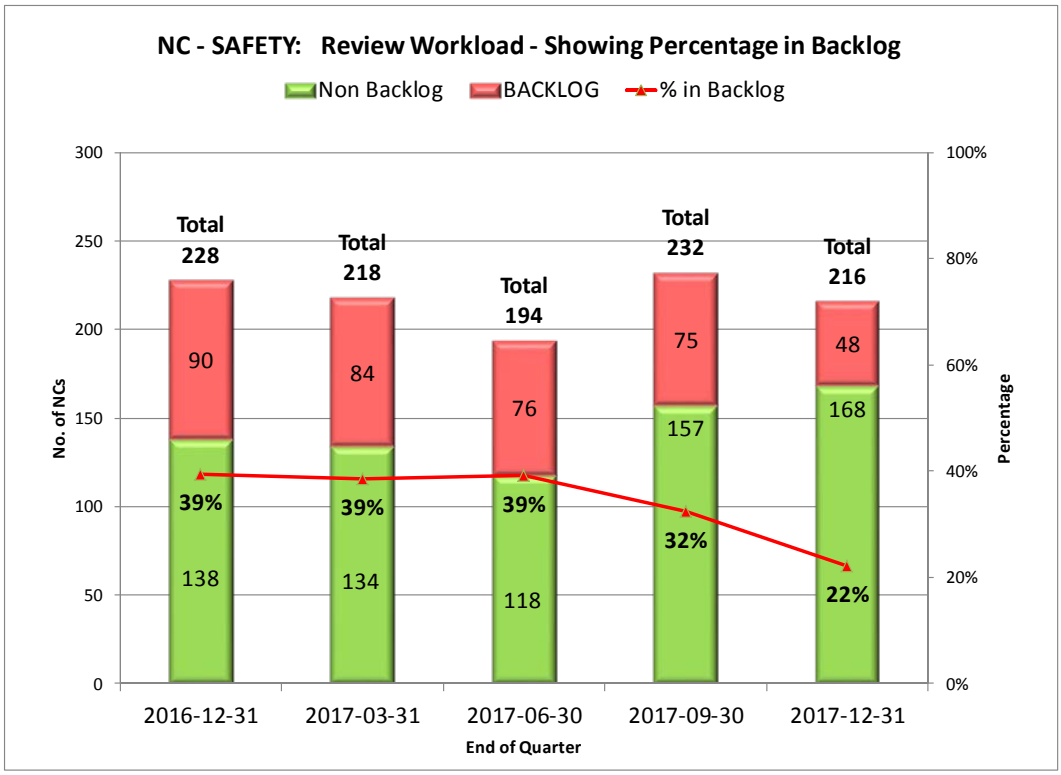


	BPS					CANS					GIVD					MORS				
	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
TOTAL	135	169	152	188	154	41	47	41	44	53	30	52	41	43	40	41	23	26	31	31
SAFETY 120	3	3	1	2	3	0	1	1	3	1	3	14	16	14	24	3	5	4	1	1
SAFETY 90	132	166	151	186	151	41	46	40	41	52	27	38	25	29	16	38	18	22	30	30

[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

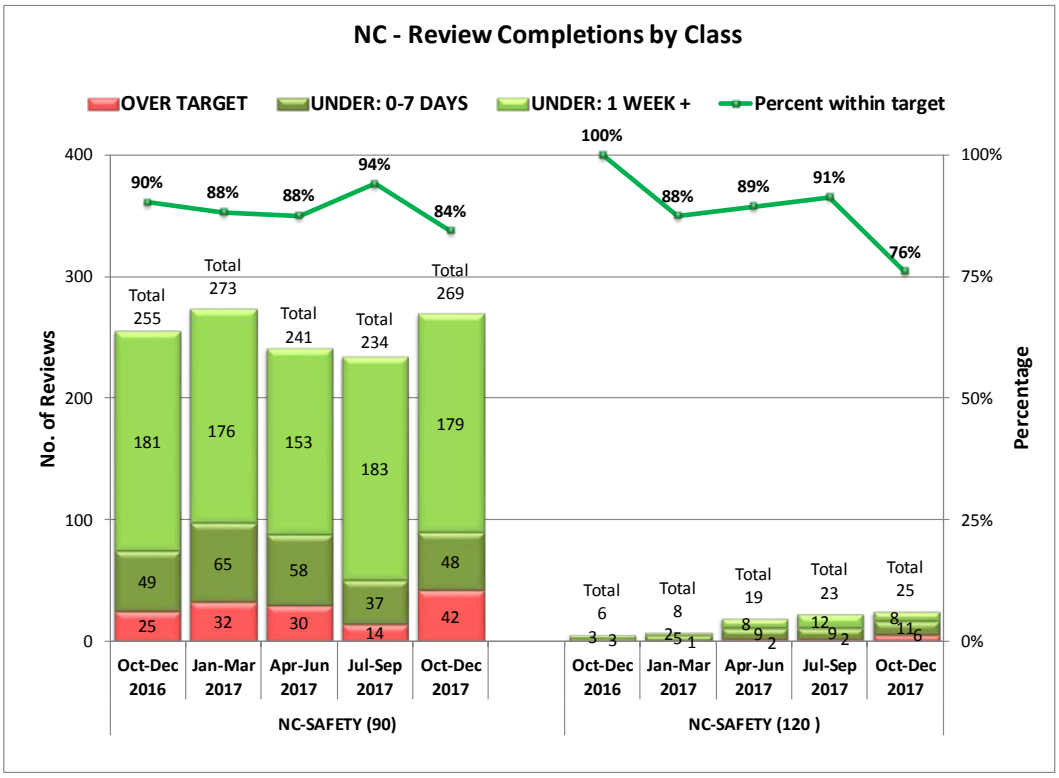


Notifiable Change (NC) SAFETY: Review Workload by Class

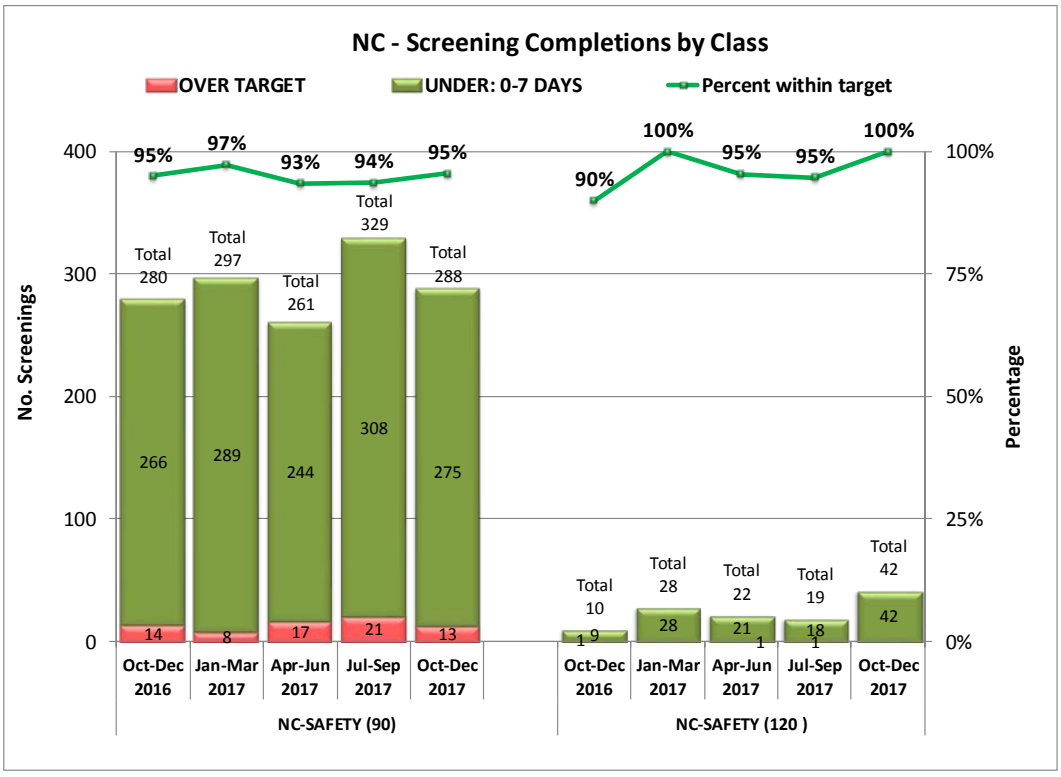
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
SAFETY - 90 day	214	188	161	206	181
Backlog	*86*	*78*	*69*	*70*	*43*
SAFETY - 120 day	14	30	33	26	35
Backlog	*4*	*6*	*7*	*5*	*5*
Total	228	218	194	232	216
Non Backlog	138	134	118	157	168
BACKLOG	90	84	76	75	48
% in Backlog	39%	39%	39%	32%	22%

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



Decision Documents by Class - Notifiable Change (NC)

NC - SAFETY (90)					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NO OBJECTION LETTER	251	244	243	255	261
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCR)	0	0	0	2	0
SCREENING DEFICIENCY NOTICE	26	46	43	44	40
CANCELLED BY COMPANY	14	27	17	20	18
NC - HOLD (PATENT)	9	18	12	11	3
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

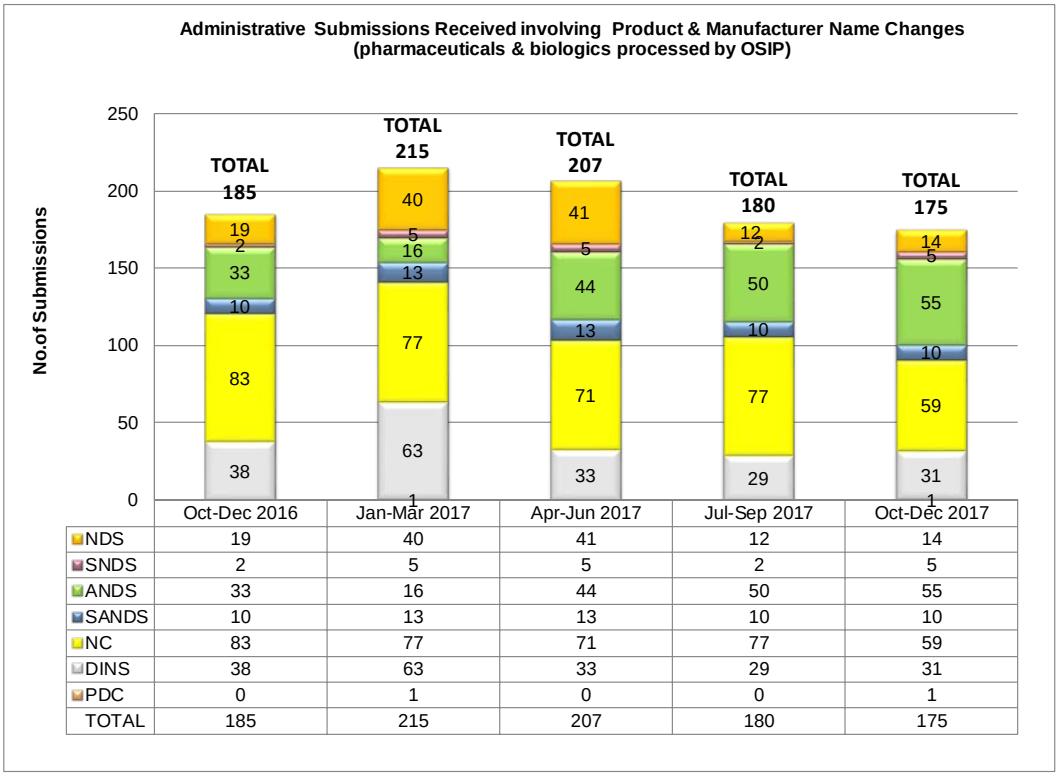
NC - SAFETY (120)					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NO OBJECTION LETTER	6	8	14	22	24
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	4	0	4	8
CANCELLED BY COMPANY	1	0	5	1	1
REJECTION LETTER (SCR)	0	0	0	0	0

NC - ADMINISTRATIVE					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NO OBJECTION LETTER	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

Administrative Submissions

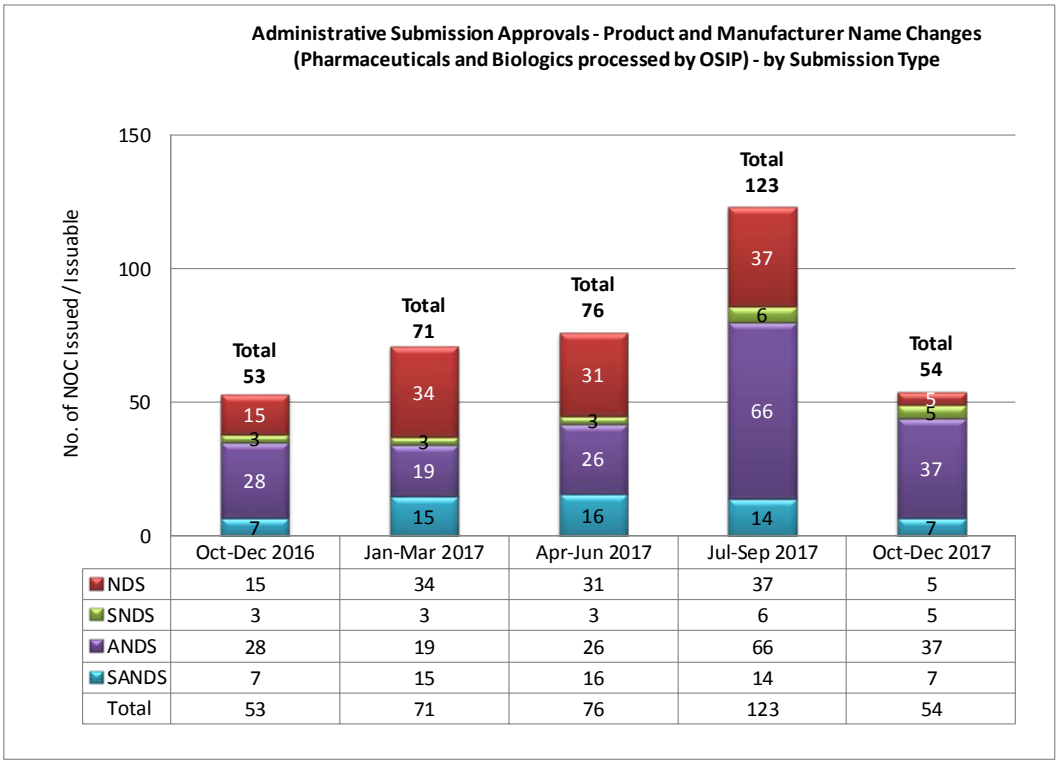
(Product & Manufacturer Name Changes[12])

Administrative Submissions Received by Submission Type (OSIP)



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
NDS	19	40	41	12	14
SNDS	2	5	5	2	5
ANDS	33	16	44	50	55
SANDS	10	13	13	10	10
NC	83	77	71	77	59
DINS	38	63	33	29	31
PDC	0	1	0	0	1
TOTAL	185	215	207	180	175

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
NDS	15	34	31	37	5
SNDS	3	3	3	6	5
ANDS	28	19	26	66	37
SANDS	7	15	16	14	7
Total	53	71	76	123	54

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

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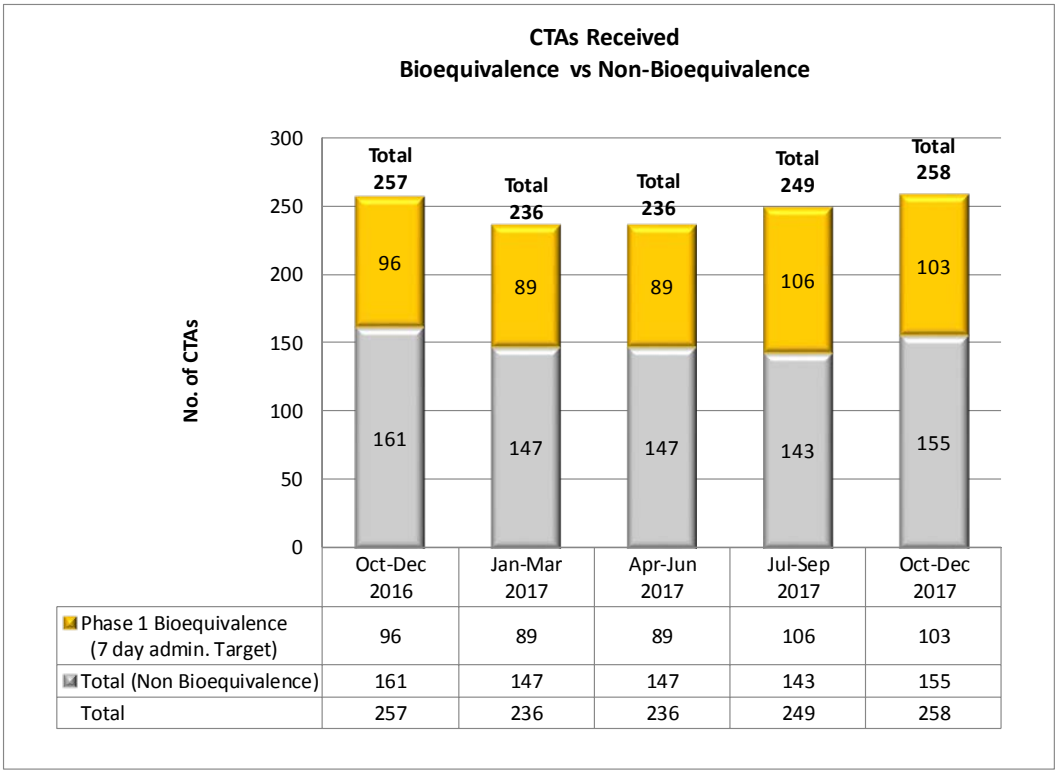
Clinical Trial Applications and Amendments

(CTA & CTA-A)

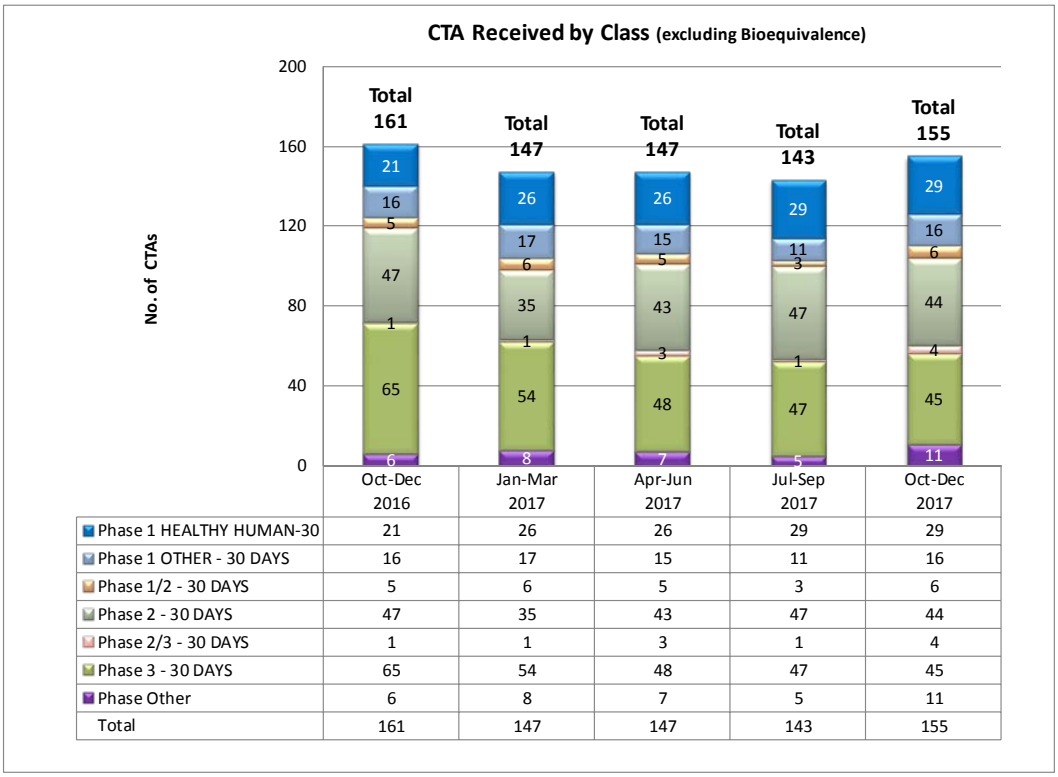
Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Phase 1 Bioequivalence (7 day admin. Target)	96	89	89	106	103
Total (Non Bioequivalence)	161	147	147	143	155
Total	257	236	236	249	258

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Phase 1 HEALTHY HUMAN-30	21	26	26	29	29
Phase 1 OTHER - 30 DAYS	16	17	15	11	16
Phase 1/2 - 30 DAYS	5	6	5	3	6
Phase 2 - 30 DAYS	47	35	43	47	44
Phase 2/3 - 30 DAYS	1	1	3	1	4
Phase 3 - 30 DAYS	65	54	48	47	45
Phase Other	6	8	7	5	11
Total	161	147	147	143	155

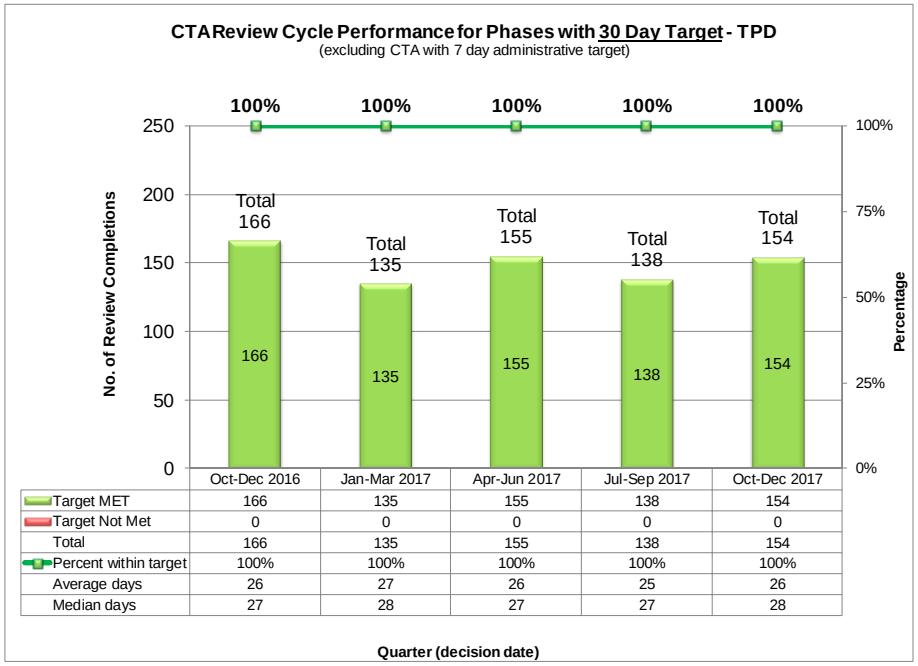
DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NO OBJECTION LETTER	246	216	235	238	237
CANCELLED BY COMPANY	13	11	15	9	20

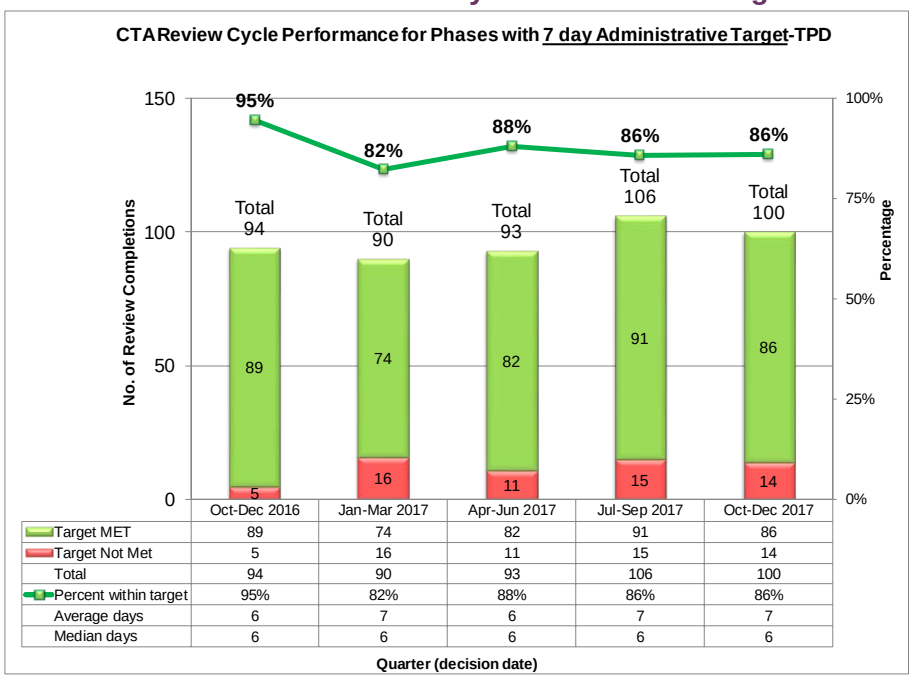
PERFORMANCE

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Target MET	166	135	155	138	154
Target Not Met	0	0	0	0	0
Total	166	135	155	138	154
Percent within target	100%	100%	100%	100%	100%
Average days	26	27	26	25	26
Median days	27	28	27	27	28

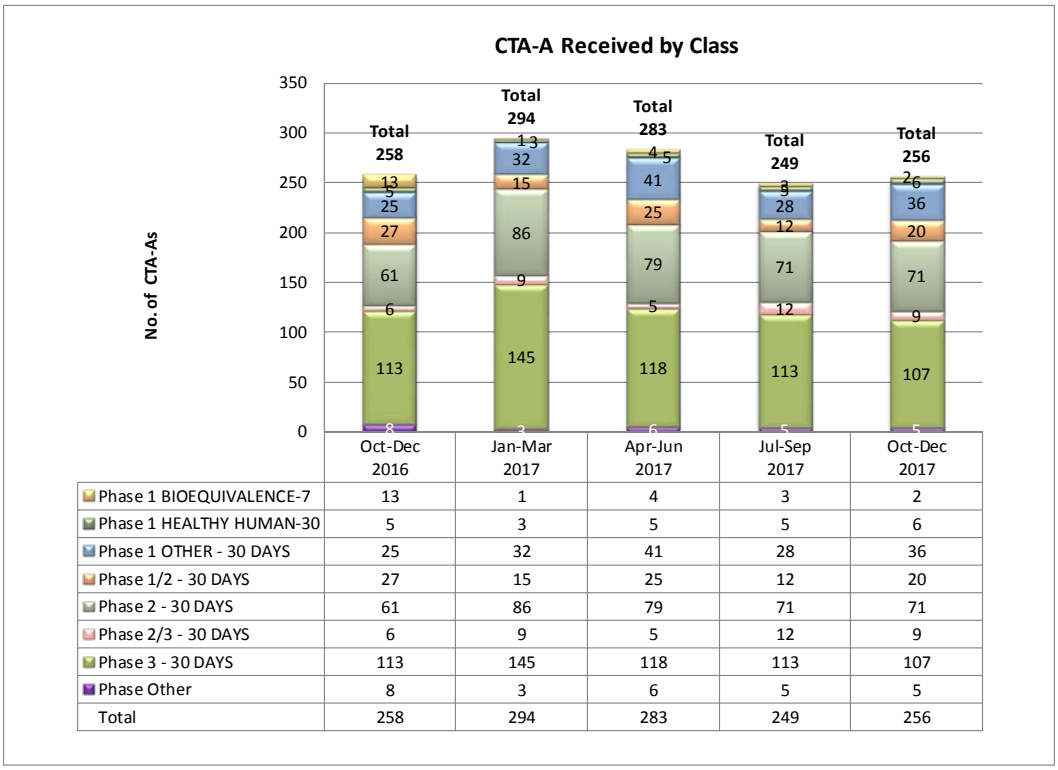
Performance – CTA Review: 7 Day Administrative Target



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Target MET	89	74	82	91	86
Target Not Met	5	16	11	15	14
Total	94	90	93	106	100
Percent within target	95%	82%	88%	86%	86%
Average days	6	7	6	7	7
Median days	6	6	6	6	6

Clinical Trial Application – Amendments (CTA–A)

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



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Phase 1 BIOEQUIVALENCE-7	13	1	4	3	2
Phase 1 HEALTHY HUMAN-30	5	3	5	5	6
Phase 1 OTHER - 30 DAYS	25	32	41	28	36
Phase 1/2 - 30 DAYS	27	15	25	12	20
Phase 2 - 30 DAYS	61	86	79	71	71
Phase 2/3 - 30 DAYS	6	9	5	12	9
Phase 3 - 30 DAYS	113	145	118	113	107
Phase Other	8	3	6	5	5
Total	258	294	283	249	256

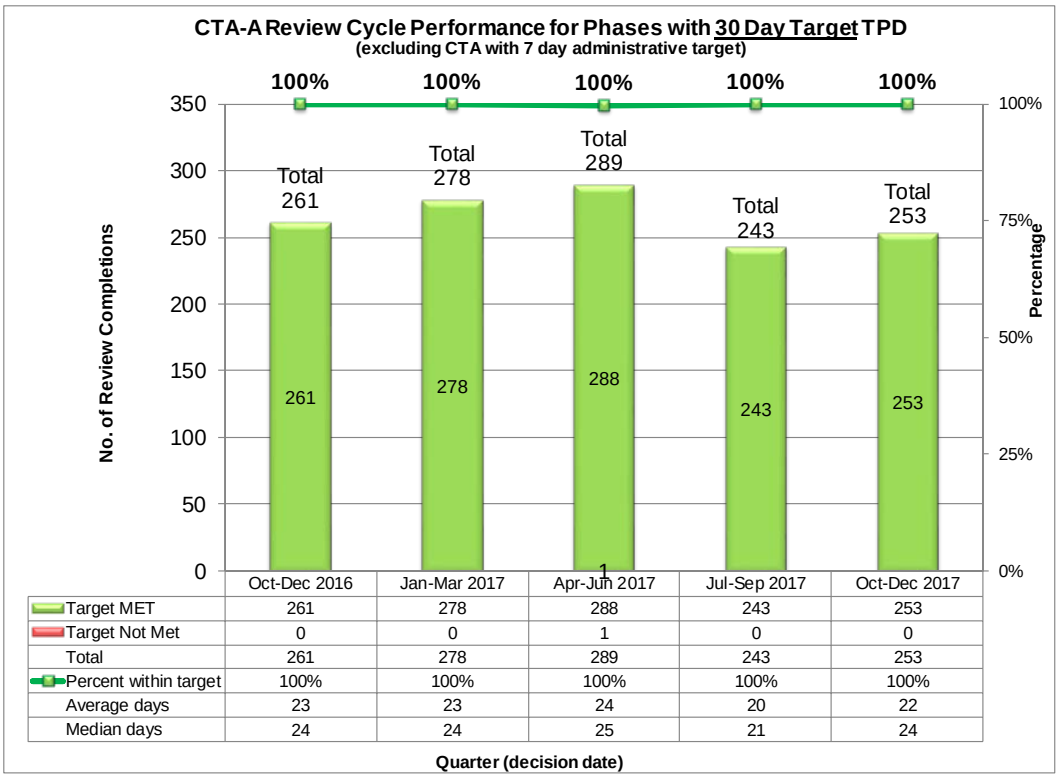
DECISION DOCUMENTS

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

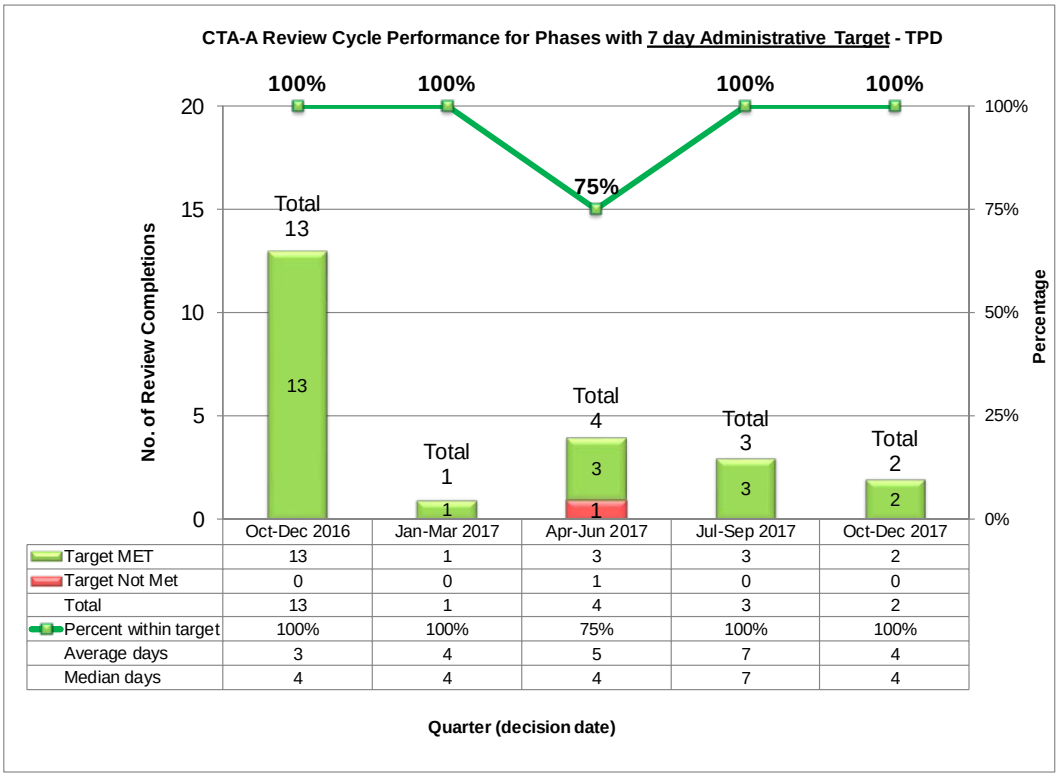
CTA-A					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NO OBJECTION LETTER	272	269	290	245	251
CANCELLED BY COMPANY	2	10	3	1	5
NOT SATISFACTORY NOTICE	0	0	0	0	0

PERFORMANCE

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



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



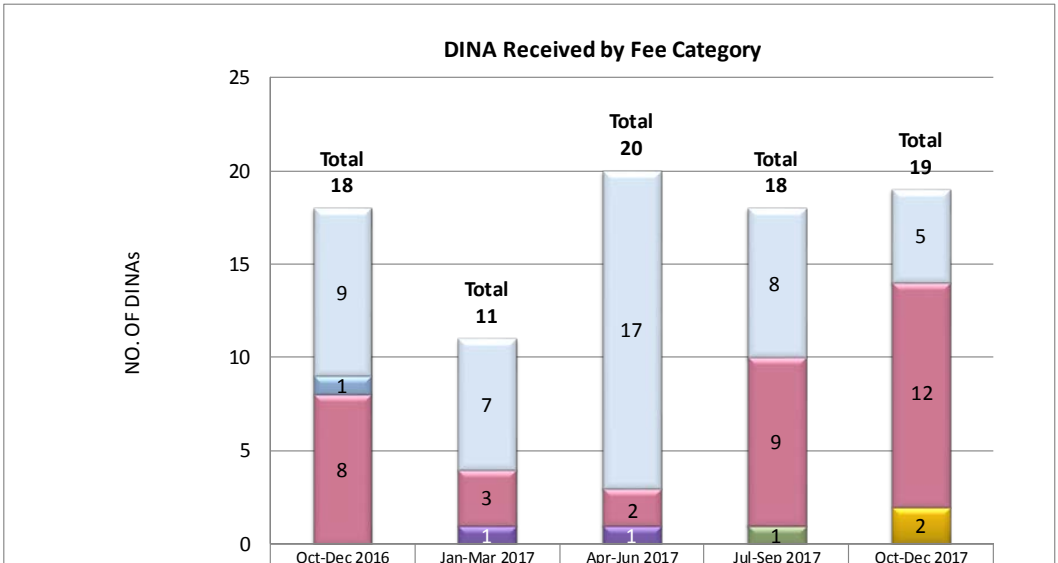
DINA

Application for a Drug Identification Number

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

DINA : Application for a Drug Identification Number[13]

Number Received – DINA

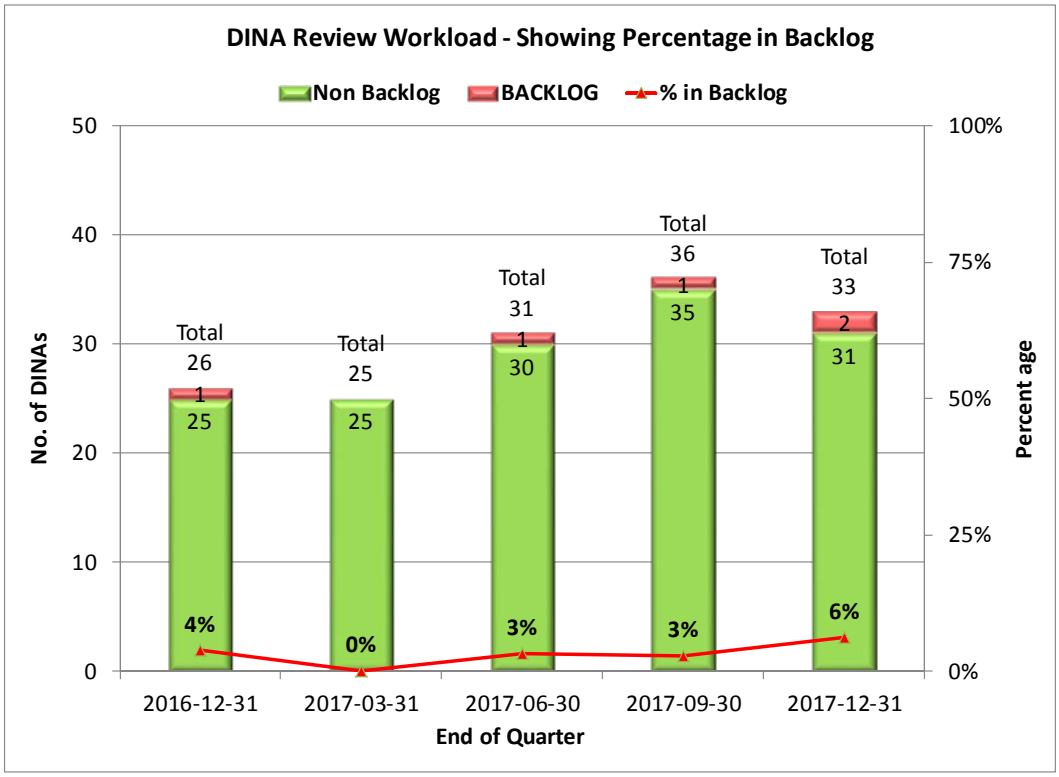


	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	9	7	17	8	5
Labelling Standard	1	0	0	0	0
Chemistry & Manufacturing	8	3	2	9	12
Clinical or Non-Clin and C&M	0	0	0	0	2
Comparative Studies	0	1	1	0	0
Published Data Only	0	0	0	1	0
Total	18	11	20	18	19

[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

Review Workload / Backlog - Showing Percentage in Backlog – DINA

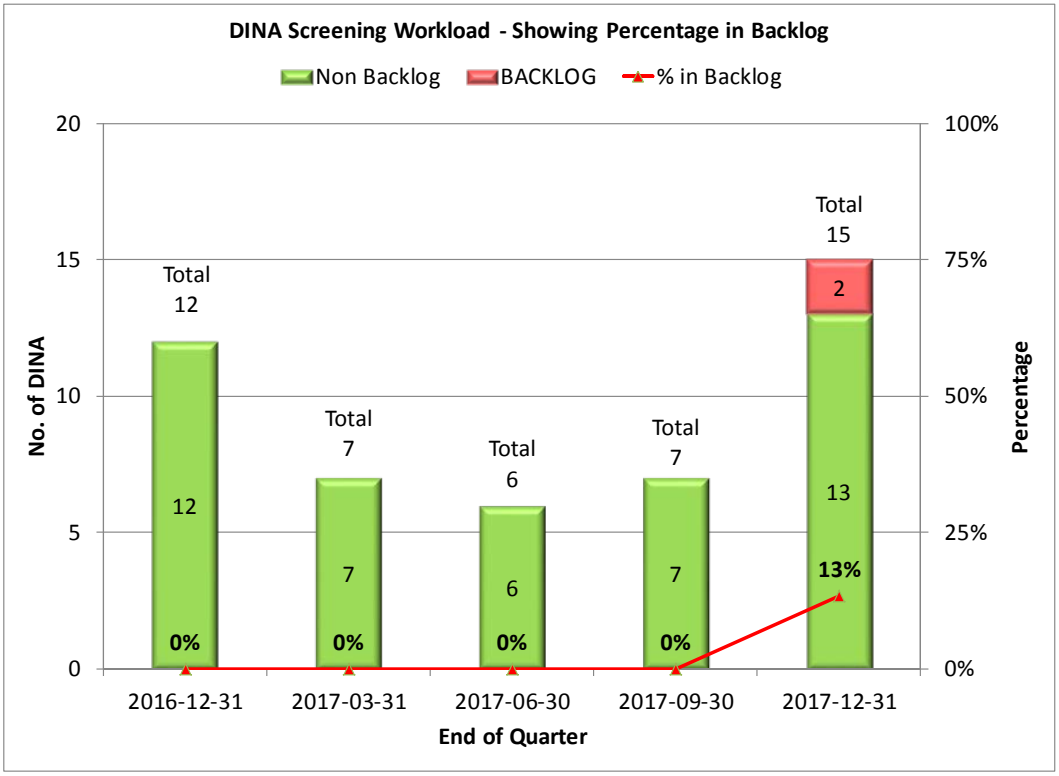


Review Workload by Fee Category – DINA

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Labelling Only	**11**	**13**	**18**	**20**	**14**
Backlog	*0*	*0*	*1*	*0*	*1*
Chemistry & Manufacturing	**14**	**12**	**12**	**14**	**17**
Backlog	*1*	*0*	*0*	*1*	*1*
Published Data	**0**	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**0**	**1**	**2**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**26**	**25**	**31**	**36**	**33**
Non Backlog	**25**	**25**	**30**	**35**	**31**
BACKLOG	**1**	**0**	**1**	**1**	**2**
% in Backlog	**4%**	**0%**	**3%**	**3%**	**6%**

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					
	2016-12-31	2017-03-31	2017-06-30	2017-09-30	2017-12-31
Labelling Only	**5**	**4**	**4**	**3**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*1*
Chemistry & Manufacturing	**5**	**2**	**1**	**3**	**10**
Backlog	*0*	*0*	*0*	*0*	*1*
Published Data	**1**	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**0**	**1**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**12**	**7**	**6**	**7**	**15**
Non Backlog	**12**	**7**	**6**	**7**	**13**
BACKLOG	**0**	**0**	**0**	**0**	**2**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**13%**

DECISION DOCUMENTS

Decision Documents – DINA by Fee Category

DINA - Labelling Only					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NOTIFICATION FORM/DIN ISSUED	1	0	3	1	5
NO OBJECTION LETTER	1	2	8	4	6
CANCELLED BY COMPANY	1	4	1	0	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	1	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	1
SCREENING DEFICIENCY NOTICE	1	3	1	3	1
SPONSOR SUB CHANGE ACCEPT	0	0	0	0	0

DINA - LABELLING STANDARD					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	0	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

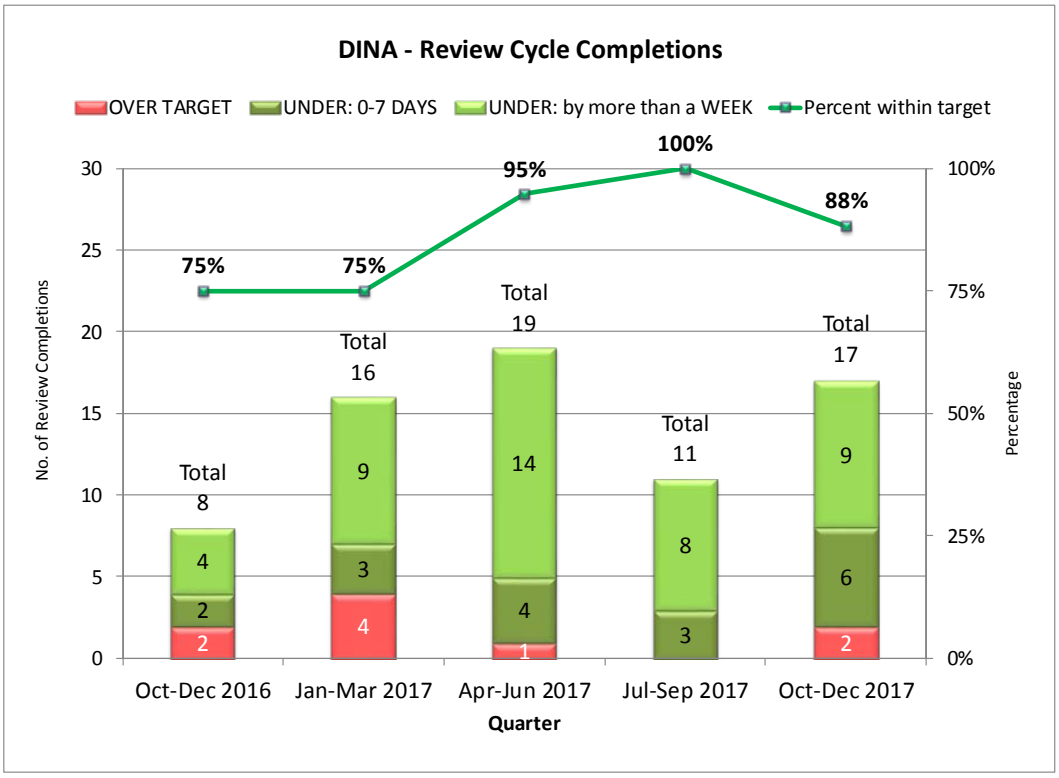
DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NOTIFICATION FORM/DIN ISSUED	1	3	3	2	4
NO OBJECTION LETTER	1	1	0	2	0
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	1	0	1	0	0
NOTICE OF DEFICIENCY	1	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	5	2	2	1
NEW DRUG LETTER REVIEW	0	0	1	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	2	0	0	0	0
SCREENING DEFICIENCY NOTICE	3	2	1	2	0
CANCELLED BY COMPANY	0	3	0	0	0

DINA - PUBLISHED DATA ONLY					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
SCREENING DEFICIENCY NOTICE	0	0	0	1	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	1	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	1	0	0	0

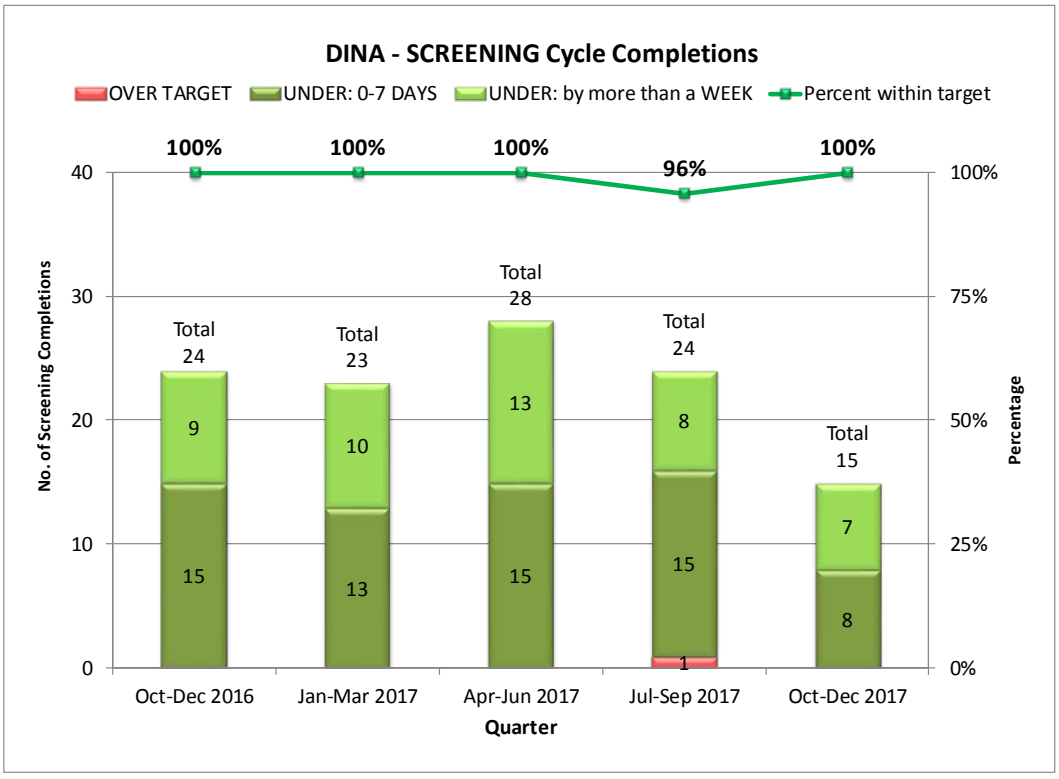
DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
NOTIFICATION FORM/DIN ISSUED	0	1	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	1
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	2	0	0

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target – DINA

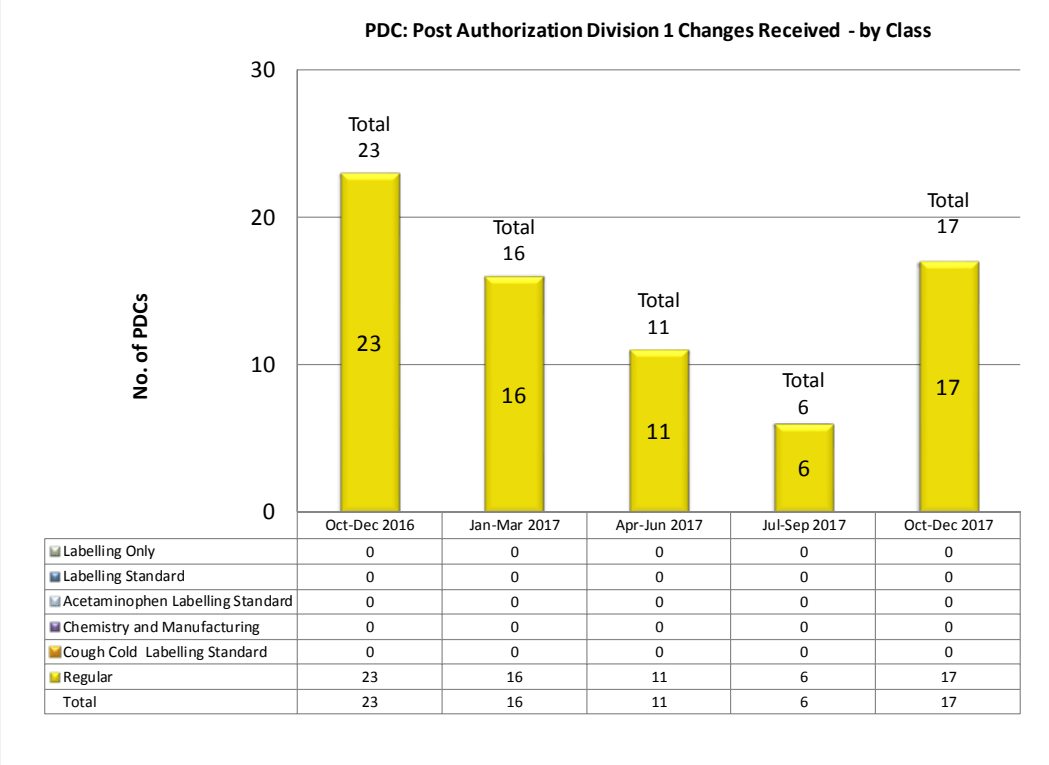


Performance Screening Cycle Completions Showing Percentage Within Target – DINA



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

Post-Authorization Division 1 Changes (PDC) Received



	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017
Labelling Only	0	0	0	0	0
Labelling Standard	0	0	0	0	0
Acetaminophen Labelling Standard	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	0
Cough Cold Labelling Standard	0	0	0	0	0
Regular	23	16	11	6	17
Total	23	16	11	6	17

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

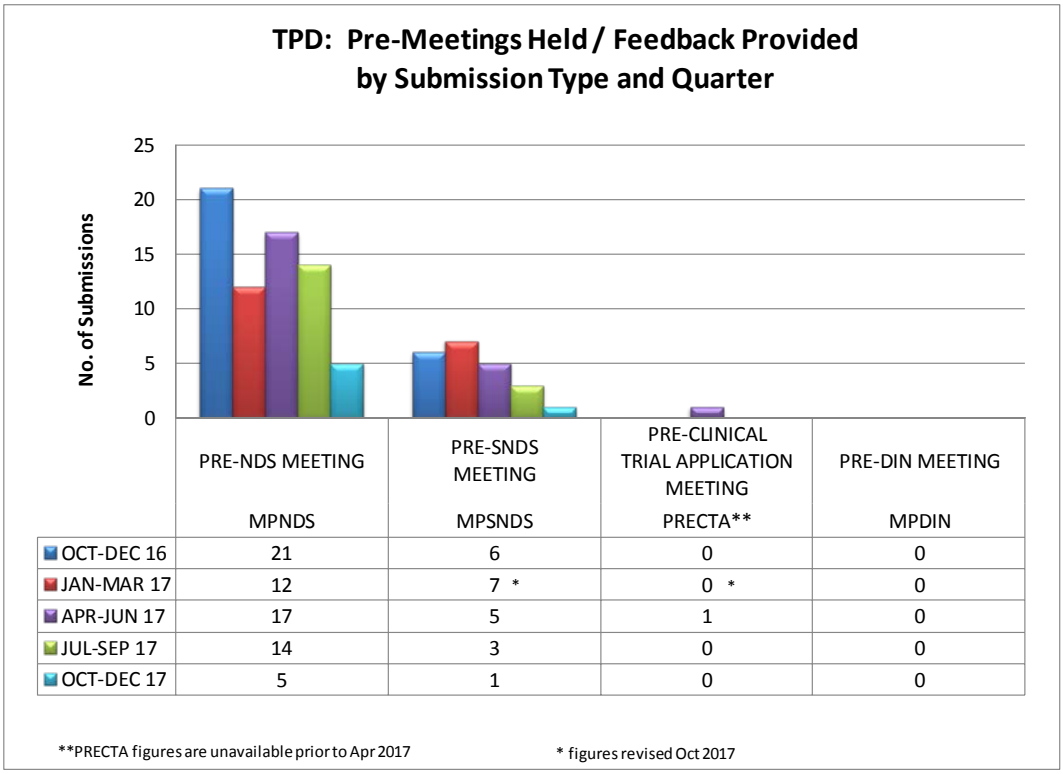
PDC					
DOCUMENT TYPE	**Oct-Dec 2016**	**Jan-Mar 2017**	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**
COUGH COLD LABELLING STANDARD					
NO OBJECTION LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REGULAR					
CANCELLED BY COMPANY	5	5	3	3	5
NO OBJECTION LETTER	39	17	9	2	9
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
ACETAMINOPHEN LS					
CANCELLED BY COMPANY	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	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
OCT-DEC 16	21	6	0	0
JAN-MAR 17	12	7 *	0 *	0
APR-JUN 17	17	5	1	0
JUL-SEP 17	14	3	0	0
OCT-DEC 17	5	1	0	0

**PRECTA figures are unavailable prior to Apr 2017

* figures revised Oct 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