Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2018-2019

April 1 2018 – March 31 2019

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 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 annuel du rendement des présentations de drogue – Exercice financier 2018-2019

To obtain additional information, please contact:

Health Canada
Address Locator 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9
Tel.: 613-941-7281
Fax: 613-941-0825
E-mail: hc.tpd.web.publications.sc@canada.ca

Publication date: June 2019

Cat H166-2E-PDF
ISSN 2561-7613
Pub 190067

Table of Contents

OVERVIEW

The Therapeutic Products Directorate's (TPD) Annual Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2014-2015 to 2018-2019.

Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report also includes detailed lists of Priority Submissions and New Active Substances approved during the 2018-2019 fiscal year (from April 1 2018 to March 31 2019).

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, Resource Management and Operations Directorate
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

The section of the report pertaining to Electronic Common Technical Document (eCTD) regulatory activity data (Appendix C) has been removed. Inquiries concerning Regulatory Activities in eCTD format may be directed to hc.ereview.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)

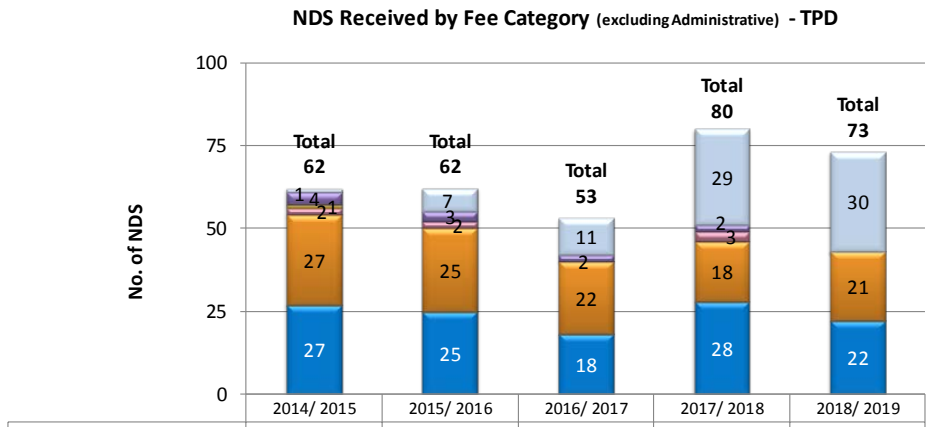
&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

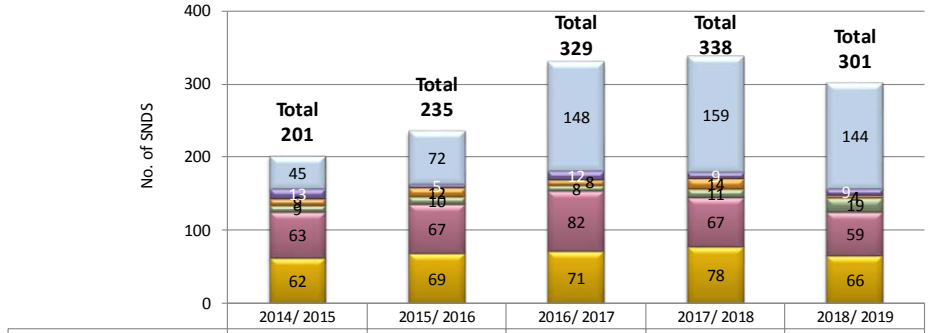
[9]

New Drug Submissions (NDS) Received by Fee Category



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Labelling Only	1	7	11	29	30
Comparative Studies	4	3	2	2	0
Clinical or Non-Clin Only	1	0	0	0	0
Chemistry & Manufacturing	2	2	0	3	0
Clinical or Non-Clin and C&M	27	25	22	18	21
New Active Substance	27	25	18	28	22
Total	62	62	53	80	73
Priority (subset)	8	8	5	10	6
NOC/c Class	2	4	1	2	4
Emergency Use (NDS)	1	0	0	0	0

Supplemental New Drug Submissions (SNDS) Received by Fee Category

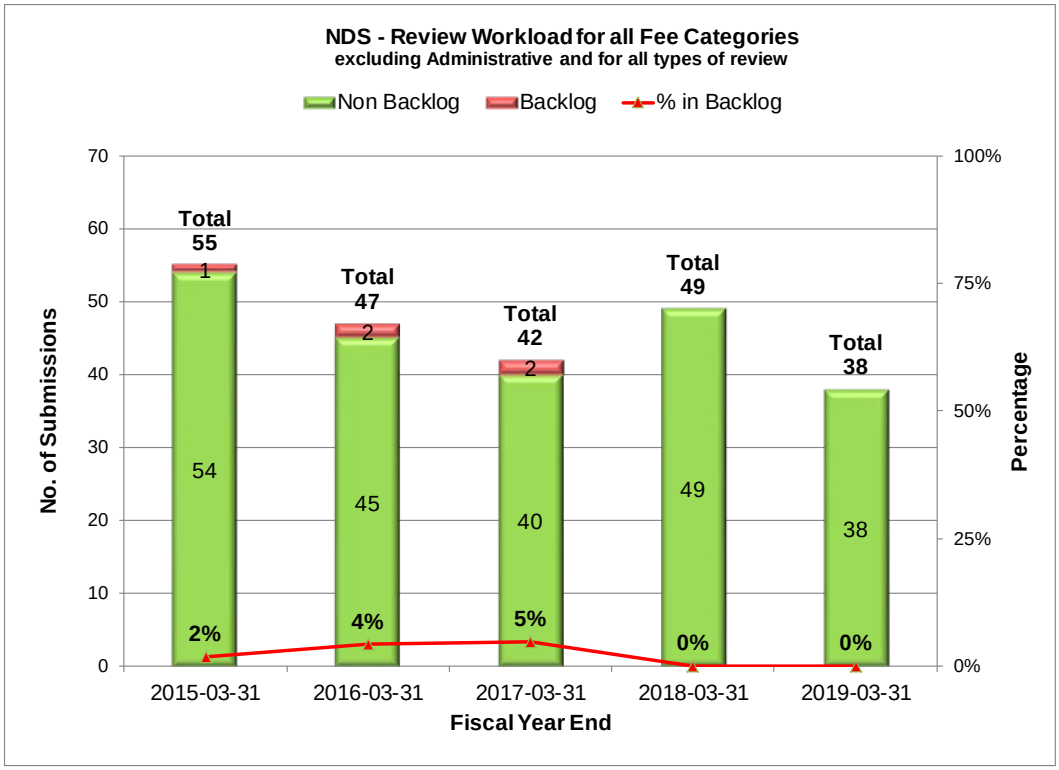


	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Labelling Only	45	72	148	159	144
Comparative Studies	13	5	12	9	9
Clinical or Non-Clin and C&M	9	12	8	14	4
Published Data Only	9	10	8	11	19
Chemistry & Manufacturing	63	67	82	67	59
Clinical or Non-Clin Only	62	69	71	78	66
Total	201	235	329	338	301
Priority (subset)	4	5	5	9	9
NOC/c Class	2	0	0	2	0
*SNDS Confirmatory	3	6	9	3	3

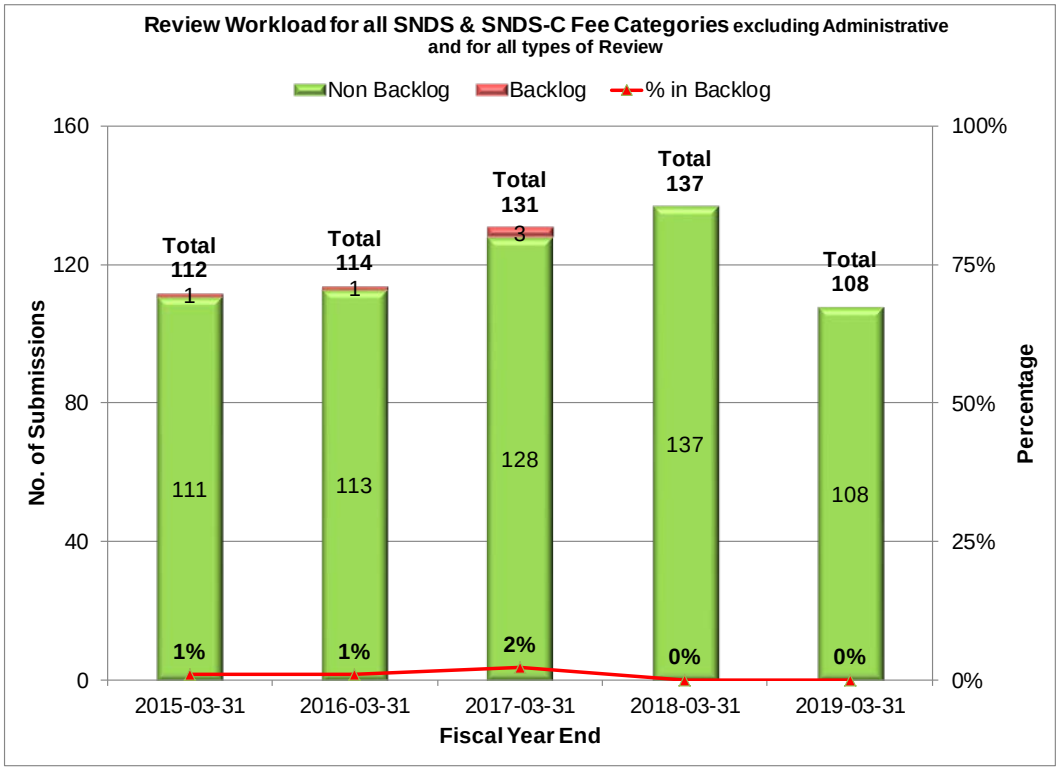
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

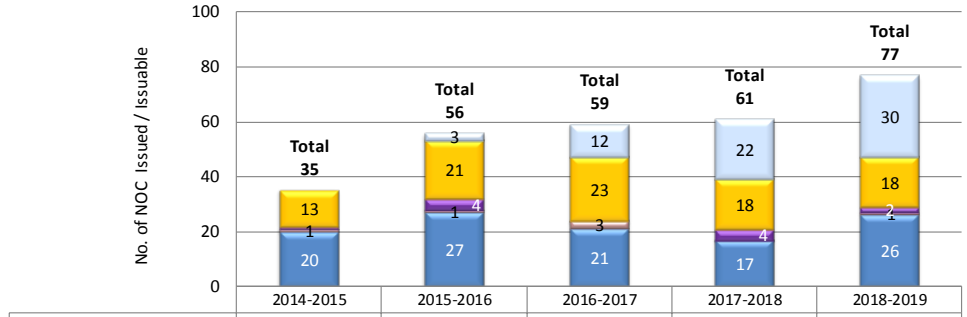
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	1	3	1	4	4
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	0	3	1	0
Backlog	*1*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	2	3	0	1	0
Backlog	*0*	*2*	*0*	*0*	*0*
Clinical or Non-Clin Only	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	26	24	19	18	15
Backlog	*0*	*0*	*1*	*0*	*0*
New Active Substance	23	17	19	25	19
Backlog	*0*	*0*	*1*	*0*	*0*
Total	**55**	**47**	**42**	**49**	**38**
Non Backlog	**54**	**45**	**40**	**49**	**38**
Backlog	**1**	**2**	**2**	**0**	**0**
% in Backlog	**2%**	**4%**	**5%**	**0%**	**0%**
Priority (subset)	4	4	6	6	3
Backlog	0	0	0	0	0

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

TPD SNDS and SNDS-C: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	**9**	**13**	**22**	**19**	**10**
Backlog	*0*	*1*	*1*	*0*	*0*
Comparative Studies	**8**	**1**	**7**	**4**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**29**	**31**	**34**	**30**	**29**
Backlog	*1*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**51**	**50**	**53**	**63**	**53**
Backlog	*0*	*0*	*2*	*0*	*0*
Clinical or Non-Clin and C&M	**9**	**12**	**8**	**11**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	**6**	**7**	**7**	**10**	**8**
Backlog	0	0	0	0	0
Total	**112**	**114**	**131**	**137**	**108**
Non Backlog	**111**	**113**	**128**	**137**	**108**
Backlog	**1**	**1**	**3**	**0**	**0**
% in Backlog	**1%**	**1%**	**2%**	**0%**	**0%**
Priority (subset)	2	5	4	7	4
Backlog	0	0	0	0	0
***SNDS-C (Confirmatory)**	3	6	6	3	2
Backlog	0	0	0	0	0

APPROVALS

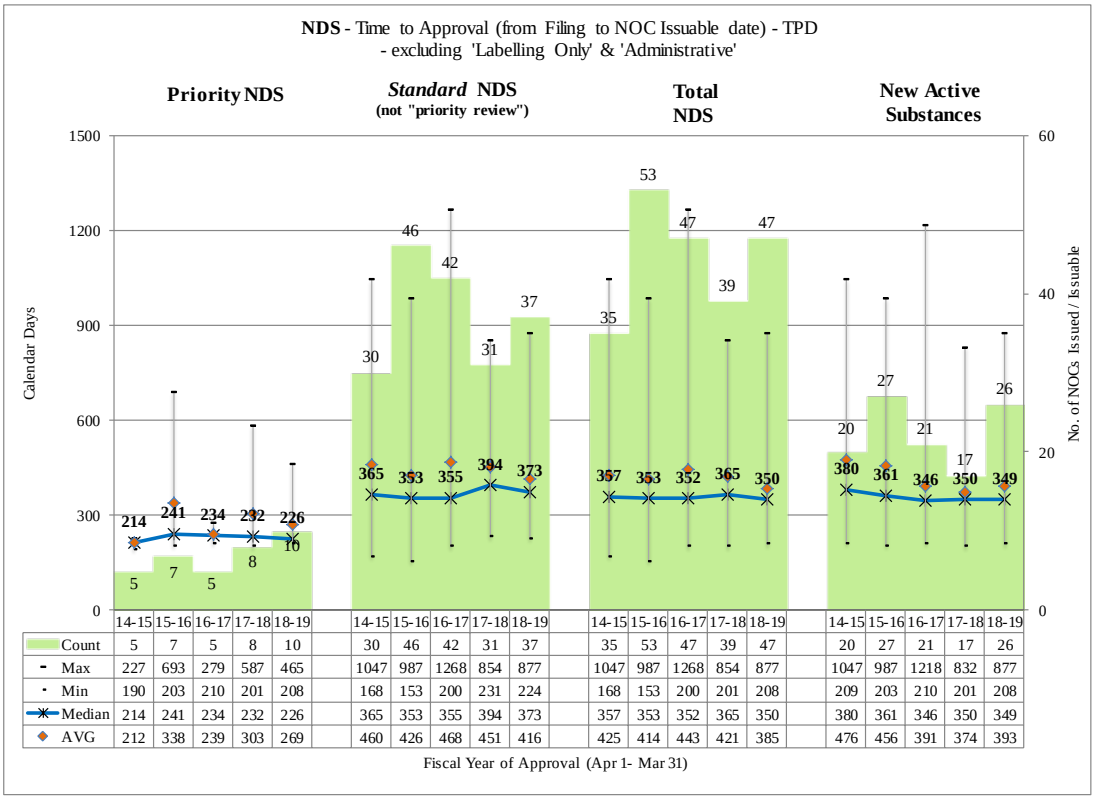
New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	0	3	12	22	30
Clinical or Non-Clin and C&M	13	21	23	18	18
Comparative Studies	1	4	0	4	2
Clinical or Non-Clin Only	0	0	0	0	0
Chemistry & Manufacturing	1	1	3	0	1
New Active Substance	20	27	21	17	26
Total	35	56	59	61	77
Notice of Compliance	32	49	53	57	72
NOC with Conditions	2	5	5	1	4
NOC on Hold (Patent)	1	1	1	3	1
NOC on Hold (Switch)	0	1	0	0	0
Priority (subset)	5	7	5	8	10
NOC-C Class	2	3	3	1	2

Fiscal Year

NDS Approval Times

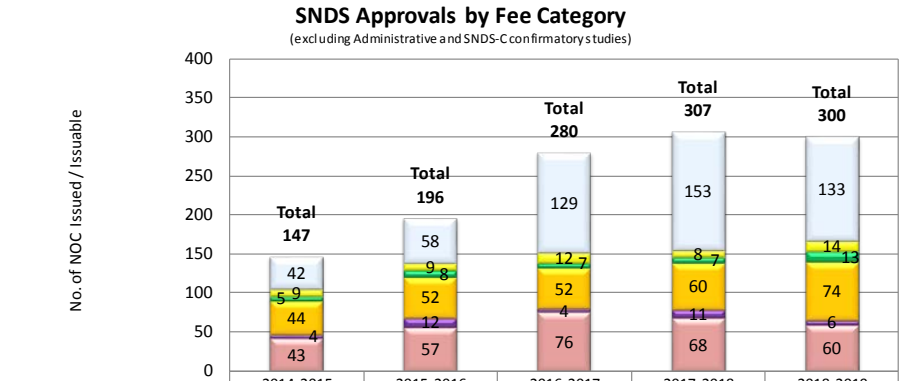


	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	5	7	5	8	10	30	46	42	31	37	35	53	47	39	47	20	27	21	17	26
Max	227	693	279	587	465	1047	987	1268	854	877	1047	987	1268	854	877	1047	987	1218	832	877
Min	190	203	210	201	208	168	153	200	231	224	168	153	200	201	208	209	203	210	201	208
Median	214	241	234	232	226	365	353	355	394	373	357	353	352	365	350	380	361	346	350	349
AVG	212	338	239	303	269	460	426	468	451	416	425	414	443	421	385	476	456	391	374	393

Fiscal Year of Approval (Apr 1- Mar 31)

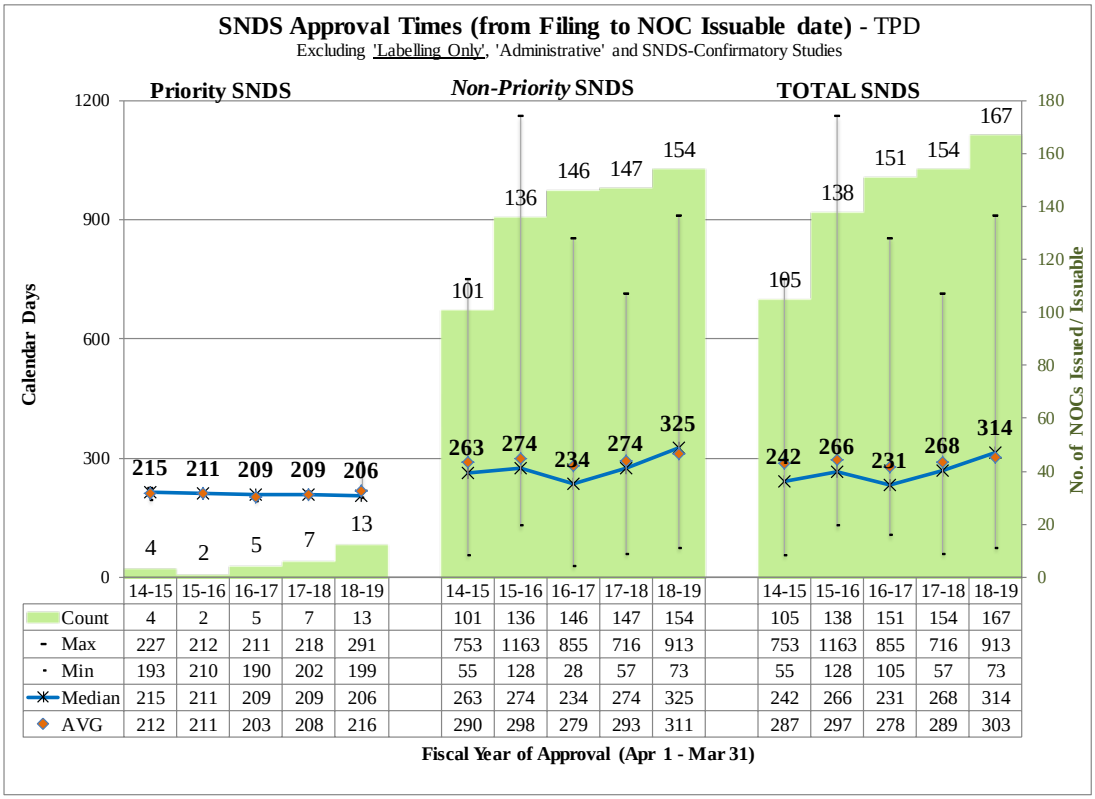
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor. Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review 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 .

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	42	58	129	153	133
Clinical or Non-Clin and C&M	9	9	12	8	14
Published Data Only	5	8	7	7	13
Clinical or Non-Clin Only	44	52	52	60	74
Comparative Studies	4	12	4	11	6
Chemistry & Manufacturing	43	57	76	68	60
Total	147	196	280	307	300
Notice of Compliance	141	190	279	304	297
NOC on Hold (Patent)	1	1	0	0	0
NOC on Hold (Switch)	0	0	0	0	0
NOC with Conditions	5	5	1	3	3
Priority (subset)	4	2 *correction from 0 to 2	5	7	13
NOC-C Class	1	1	0	0	2

SNDS Approval Times



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	4	2	5	7	13	101	136	146	147	154	105	138	151	154	167
Max	227	212	211	218	291	753	1163	855	716	913	753	1163	855	716	913
Min	193	210	190	202	199	55	128	28	57	73	55	128	105	57	73
Median	215	211	209	209	206	263	274	234	274	325	242	266	231	268	314
AVG	212	211	203	208	216	290	298	279	293	311	287	297	278	289	303

Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

New Active Substance (NAS) Approvals

And

Priority Submission Approvals

New Active Substance (NAS) Approvals - TPD - Fiscal Year 2018-2019

New Active Substance Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[10]) Date**	**Approval Date (dd-mon-yy)**
ALUNBRIG (Brigatinib) - is indicated as a monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non–small cell lung cancer (NSCLC) who have progressed on or who were intolerant to an ALK inhibitor (crizotinib).	NOC-C NAS	Takeda Canada Inc.	24-Oct-17	26-Jul-18 NOC-C
BELSOMRA (Suvorexant) - is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	NAS	Merck Canada Inc.	5-Jul-16	29-Nov-18
BIKTARVY (Bictegravir Sodium, Emtricitabine, Tenofovir Alafenamide Hemifumarate) - is indicated as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with no known substitution associated with resistance to the individual components of BIKTARVY.	NAS	Gilead Sciences Canada Inc.	26-Jul-17	10-Jul-18
CABOMETYX (Cabozantinib) - is indicated for: the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior vascular endothelial growth factor (VEGF)-targeted therapy.	PRIORITY -NAS	Ipsen Biopharmaceuticals Canada Inc.	6-Jun-17	14-Sep-18
CRESEMBA (Isavuconazonium Sulfate) - is an azole antifungal indicated for use in adults for the treatment of: • Invasive aspergillosis; • Invasive mucormycosis.	NAS	Avir Pharma Inc.	26-Oct-17	19-Dec-18

[10] The CR date is the date the submission is received and considered administratively complete by Health Canada.

New Active Substance Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[10]) Date**	**Approval Date (dd-mon-yy)**
DEMYLOCAN (Decitabine) - is indicated for the treatment of adult patients with: Myelodysplastic Syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups.	NAS	Pendopharm Division of Pharmascience Inc.	28-Dec-17	21-Jan-19
ERLEADA (Apalutamide) - is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).	PRIORITY -NAS	Janssen Inc.	7-Dec-17	3-Jul-18
EUCRISA (Crisaborole) - is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.	NAS	Pfizer Canada Inc.	23-Jun-17	7-Jun-18
FOLOTYN (Pralatrexate) - is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).	NAS	Servier Canada Inc.	18-Jul-17	26-Oct-18 NOC-C
IDHIFA (Enasidenib as Enasidenib Mesylate) - is indicated for the treatment of adult patients with relapsed or refractory Acute Myeloid Leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation.	PRIORITY -NAS	Celgene Inc.	15-Jun-18	6-Feb-19 NOC-C
LORBRENA (Lorlatinib) - is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on: crizotinib and at least one other ALK inhibitor, or patients who have progressed on ceritinib or alectinib.	NOC-C NAS	Pfizer Canada ULC	26-Apr-18	22 Feb-19 NOC-C

New Active Substance Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR^{10}) Date**	**Approval Date (dd-mon-yy)**
MONOFERRIC (Iron Isomaltoside 1000) - is indicated for the treatment of iron deficiency anemia in adult patients who have intolerance or unresponsiveness to oral iron therapy.	NAS	Pharmacosmos A/S	28-Apr-16	22-Jun-18
OLUMIANT (Baricitinib) - in combination with methotrexate (MTX), is indicated for reducing the signs and symptoms of moderate to severe rheumatoid arthritis (RA) in adult patients who have responded inadequately to one or more disease-modifying anti-rheumatic drugs (DMARDs).	NAS	Eli Lilly Canada Inc.	29-Mar-16	17-Aug-18
ONSTRYV (Safinamide as safinamide mesylate) - is indicated as an add-on therapy to a regimen that includes levodopa for the treatment of the signs and symptoms of idiopathic Parkinson's disease (PD) in patients experiencing "off" episodes while on a stable dose of levodopa.	NAS	Valeo Pharma Inc.	8-Noc-17	10-Jan-19
ORILISSA (Elagolix Sodium) - is indicated for the treatment of moderate to severe pain associated with endometriosis.	NAS	Abbvie Corporation	22-Sep-17	5-Oct-18
PIFELTRO (Doravirine) - is indicated, in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of viral resistance to doravirine.	NAS	Merck Canada Inc.	17-Nov-17	12-Oct-18
RADICAVA (Edaravone) - is indicated for the treatment of amyotrophic lateral sclerosis (ALS).	PRIORITY -NAS	Mitsubishi Tanabe Pharma Corporation	9-Mar-18	3-Oct-18
RAYALDEE (Calcifediol) - is a vitamin D3 analogue indicated for the treatment of secondary hyperparathyroidism (SHPT) in adults with Stage 3 or 4 chronic kidney disease (CKD) and low serum 25-hydroxyvitamin D levels [less than 75 nmol/L (30ng/mL) at initiation].	NAS	Vifor Fresenius Medical Care Renal Pharma Ltd.	9-May-17	10-Jul-18

New Active Substance Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[10]) Date**	**Approval Date (dd-mon-yy)**
STEGLATRO (Ertugliflozin) - Monotherapy: is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. Add-on combination: is indicated in adult patients with type 2 diabetes mellitus to improve glycemic control in combination with: metformin, metformin and sitagliptin when the therapy listed above, along with diet and exercise, does not provide adequate glycemic control.	NAS	Merck Canada Inc.	13-Apr-17	9-May-18
SYMDEKO (Tezacaftor, Ivacaftor) - is indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, D110H, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.	PRIORITY-NAS	Vertex Pharmaceuticals (Canada) Incorporated	17-Nov-17	27-Jun-18
TEGSEDI (Inotersen Sodium) - is indicated for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR)**.**	PRIORITY-NAS	Akcea Therapeutics Inc.	7-Mar-18	3-Oct-18
VELTASSA (Patiromer Sorbitex Calcium) - is indicated for: the treatment of hyperkalemia in adults with chronic kidney disease (eGFR ≥15mL/min/1.73m2).	NAS	Vifor Fresenius Medical Care Renal Pharma Ltd.	20-Oct-17	3-Oct-18
VIZIMPRO (Dacomitinib as Dacomitinib monohydrate) - is indicated for the first-line treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations.	NAS	Pfizer Canada ULC	16-Mar-18	26-Feb-19

New Active Substance Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[10]) Date**	**Approval Date (dd-mon-yy)**
VYZULTA (Latanoprostene Bunod) - is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	NAS	Bausch & Lomb Inc.	24-Jan-18	27-Dec-18
XERMELO (Telotristat Etiprate) - is indicated for the treatment of refractory carcinoid syndrome diarrhea, in combination with somatostatin analogue (SSA) therapy, in patients inadequately controlled by SSA therapy alone.	NAS	Ipsen Biopharmaceuticals Canada Inc.	1-Nov-17	10-Oct-18
XYDALBA (Dalbavancin) - is indicated for: treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus) and Enterococcus faecalis (vancomycin susceptible strains).	PRIORITY -NAS	Cipher Pharmaceuticals Inc.	21-Dec-17	4-Sep-18

Priority Submission Approvals - TPD - Fiscal Year 2018-2019

Priority Submission Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
ALECENSARO (Alectinib as alectinib hydrochloride) - new indication: for the first-line treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).	PRIORITY-CLIN ONLY	Hoffmann La Roche Limited	2-Nov-17	11 Jun-18
CABOMETYX (Cabozantinib) - is indicated for: the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior vascular endothelial growth factor (VEGF)-targeted therapy.	PRIORITY-NAS	Ipsen Biopharmaceuticals Canada Inc.	6-Jun-17	14-Sep-18
CYSTADROPS (Cysteamine as Cysteamine Hydrochloride) - is indicated for the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis.	PRIORITY-CLIN/C&M	Recordati Rare Diseases Canada Inc.	27-Nov-17	11-Feb-19
ERLEADA (Apalutamide) - is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).	PRIORITY-NAS	Janssen Inc.	7-Dec-17	3-Jul-18
GILENYA (Fingolimod Hydrochloride) - extension of the indication to include pediatric patients aged 10 to 18 years. Addition of a new 0.25mg capsule strength and formulation.	PRIORITY-CLIN/C&M	Novartis Pharmaceuticals Canada Inc.	12-Apr-18	7-Nov-18
IDHIFA (Enasidenib as Enasidenib Mesylate) - is indicated for the treatment of adult patients with relapsed or refractory Acute Myeloid Leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation.	PRIORITY-NAS	Celgene Inc.	15-Jun-18	6-Feb-19 NOC-C

Priority Submission Approvals – TPD
Fiscal Year 2018-2019
(April 1 2018 – March 31 2019)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
IMBRUVICA (Ibrutinib) - new indication: is indicated for the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.	PRIORITY-CLIN ONLY	Janssen Inc.	5-Jan-18	24-Jul-18
IMBRUVICA (Ibrutinib) - an extended indication of 420mg once daily in combination with Rituximab for the treatment of patients with Waldenstrom's macroglobulinemia.	PRIORITY-CLIN ONLY	Janssen Inc.	20-Jul-18	11-Feb-19
KALYDECO (Ivacaftor) - expansion of the indication for Kalydeco for the treatment of children with cystic fibrosis (CF) aged 12 months and older and weighing 7 kg to less than 25 kg who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.	PRIORITY-CLIN ONLY	Vertex Pharmaceuticals (Canada) Incorporated	10-Jul-18	25-Jan-19
LYNPARZA (Olaparib) - new indication: is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.	PRIORITY-CLIN/C&M	Astrazeneca Canada Inc.	13-Oct-17	8-May-18
MEKINIST (Trametinib) - expanded indication: in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	30-Oct-17	18-May-18

Priority Submission Approvals – TPD
Fiscal Year 2018-2019
(April 1 2018 – March 31 2019)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
ORKAMBI (Lumacaftor, Ivacaftor) - to expand the indication for Orkambi (Lumacaftor/Ivacaftor) for the treatment of cystic fibrosis (CF) in patients aged 2 through 5 years who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. A new dosage form, granules, is also being proposed for this patient population.	PRIORITY-CLIN/C&M	Vertex Pharmaceuticals (Canada) Incorporated	4-Apr-18	11-Dec-18
RADICAVA (Edaravone) - is indicated for the treatment of amyotrophic lateral sclerosis (ALS).	PRIORITY-NAS	Mitsubishi Tanabe Pharma Corporation	9-Mar-18	3-Oct-18
SUBLOCADE (Buprenorphine) - is indicated for the management of moderate to severe opioid use disorder in adult patients who have been inducted and clinically stabilized on a transmucosal buprenorphine-containing product.	PRIORITY-CLIN/C&M	Indivior UK Limited	26-Apr-18	21-Nov-18
SYMDEKO (Tezacaftor, Ivacaftor) - is indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, D110H, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.	PRIORITY-NAS	Vertex Pharmaceuticals (Canada) Incorporated	17-Nov-17	27-Jun-18
TAFINLAR (Dabrafenib) - expanded indication: in combination with trametinib for the treatment of patients with metastitic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	30-Oct-17	18-May-18

Priority Submission Approvals – TPD
Fiscal Year 2018-2019
(April 1 2018 – March 31 2019)

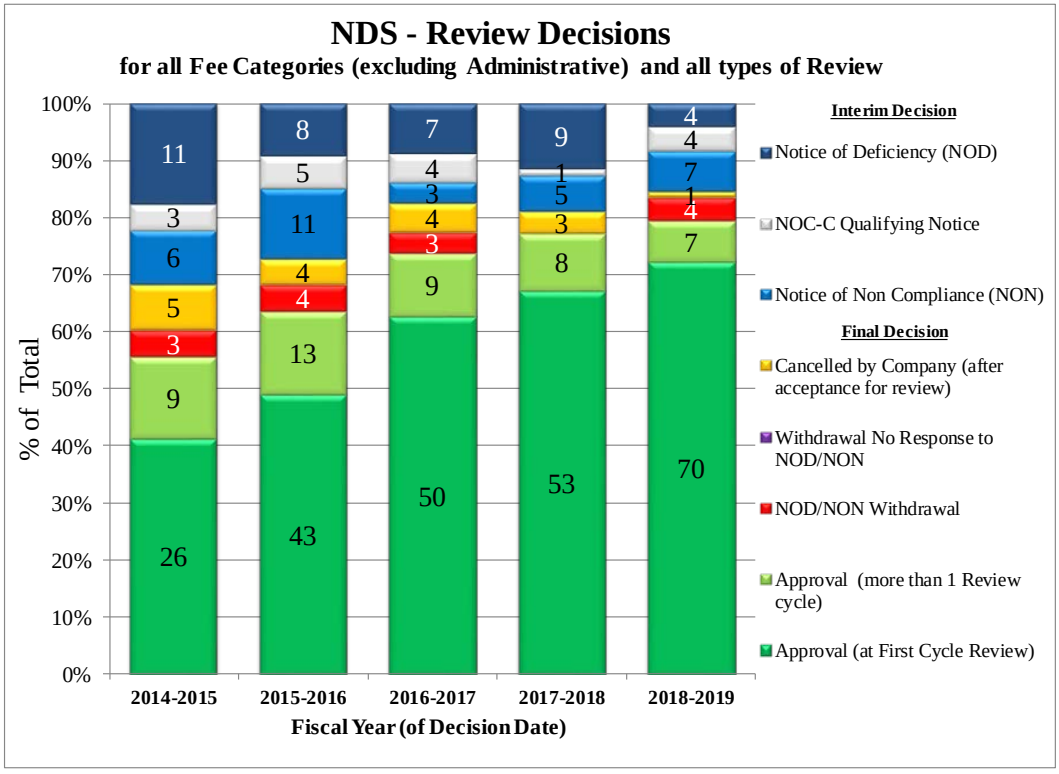
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
TAGRISSO (Osimertinib Mesylate) - new indication: is indicated for the first-line treatment of patients with locally advanced (not amenable to curative therapies) or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (either alone or in combination with the other EGFR mutations).	PRIORITY-CLIN ONLY	Astrazeneca Canada Inc.	13-Dec-17	10-Jul-18
TEGSEDI (Inotersen Sodium) - is indicated for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR)**.**	PRIORITY-NAS	Akcea Therapeutics Inc.	7-Mar-18	3-Oct-18
VENCLEXTA (Venetoclax) - new indication: in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy.	PRIORITY-CLIN ONLY	Abbvie Corporation	28-Feb-18	21-Sep-18
VERKAZIA (Cyclosporine) - is indicated for: Treatment of severe vernal keratoconjunctivitis in children from 4 years of age through adolescence.	PRIORITY-CLIN/C&M	Santen Incorporated	9-May-18	24-Dec-18
XARELTO (Rivaroxaban) - new indication and new strength (2.5mg): film-coated tablet (2.5 mg), in combination with 75 mg – 100 mg acetylsalicylic acid (ASA), is indicated for the: prevention of stroke, myocardial infarction and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with coronary artery disease (CAD) with or without peripheral artery disease (PAD).	PRIORITY-CLIN/C&M	Bayer Inc.	27-Nov-17	14-Sep-18
XTANDI (Enzalutamide) - new indication: is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).	PRIORITY-CLIN ONLY	Astellas Pharma Canada Inc.	29-May-18	20-Dec-18

Priority Submission Approvals – TPD Fiscal Year 2018-2019 (April 1 2018 – March 31 2019)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
XYDALBA (Dalbavancin) - is indicated for: treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus) and Enterococcus faecalis (vancomycin susceptible strains).	PRIORITY-NAS	Cipher Pharmaceuticals Inc.	21-Dec-17	4-Sep-18

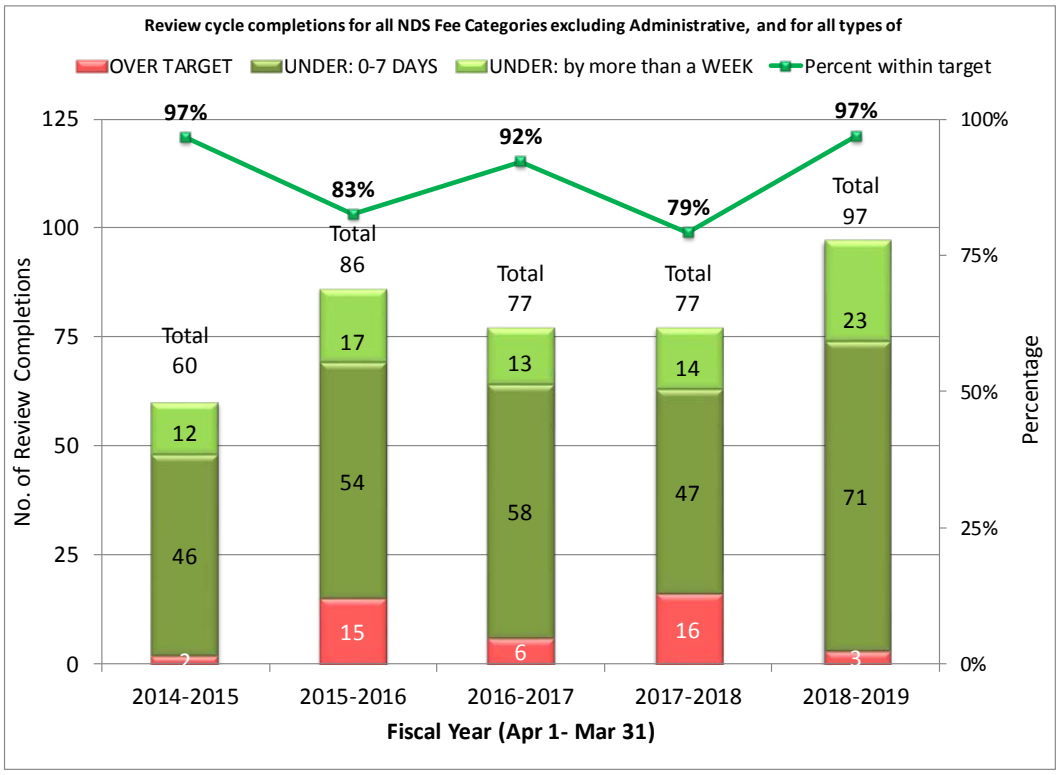
This page is left blank intentionally

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

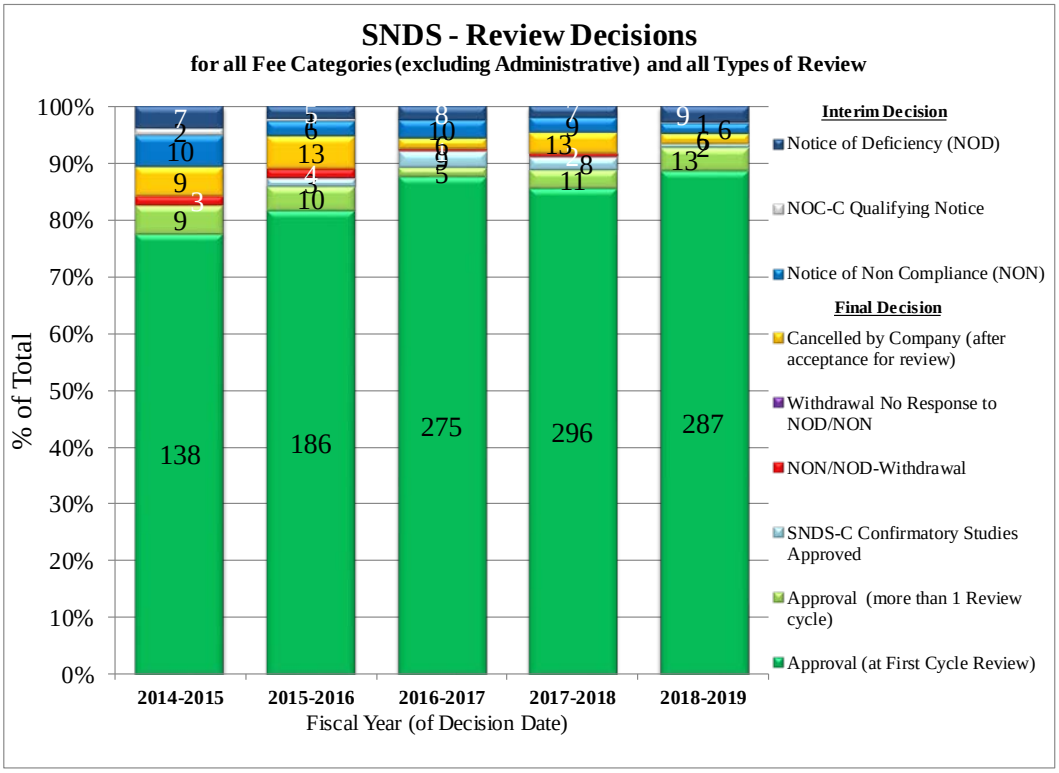


NDS - Review Cycle Completions Showing Percentage Within Target

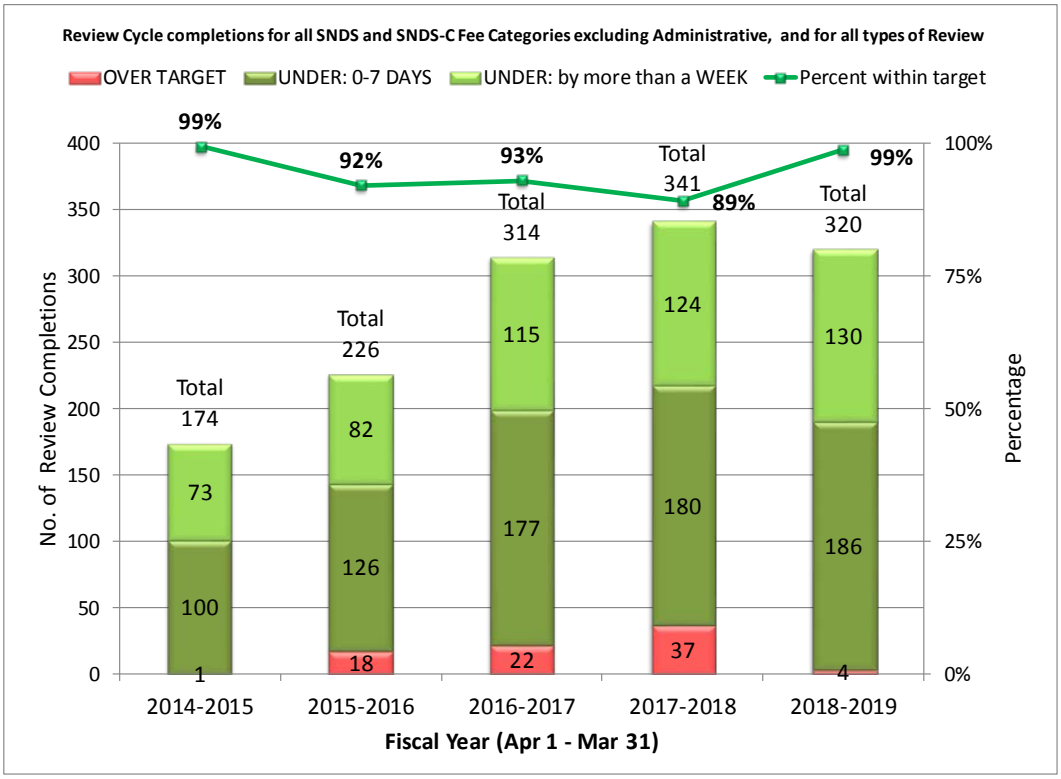


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

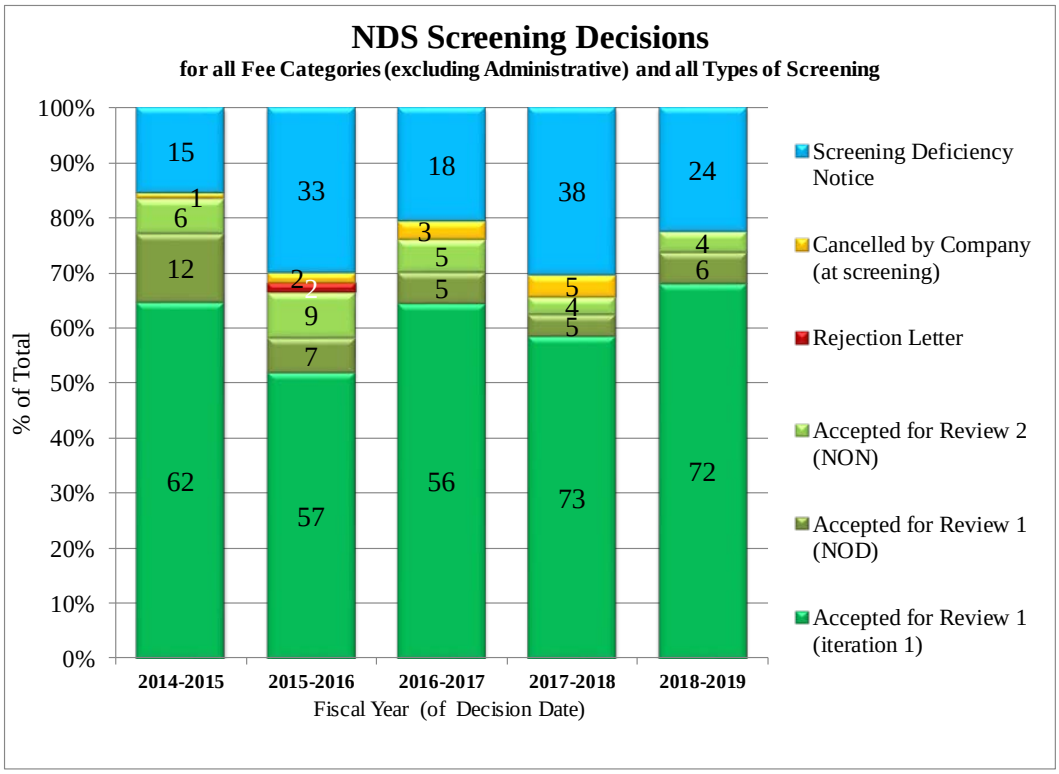


SNDS - Review Cycle Completions Showing Percentage Within Target

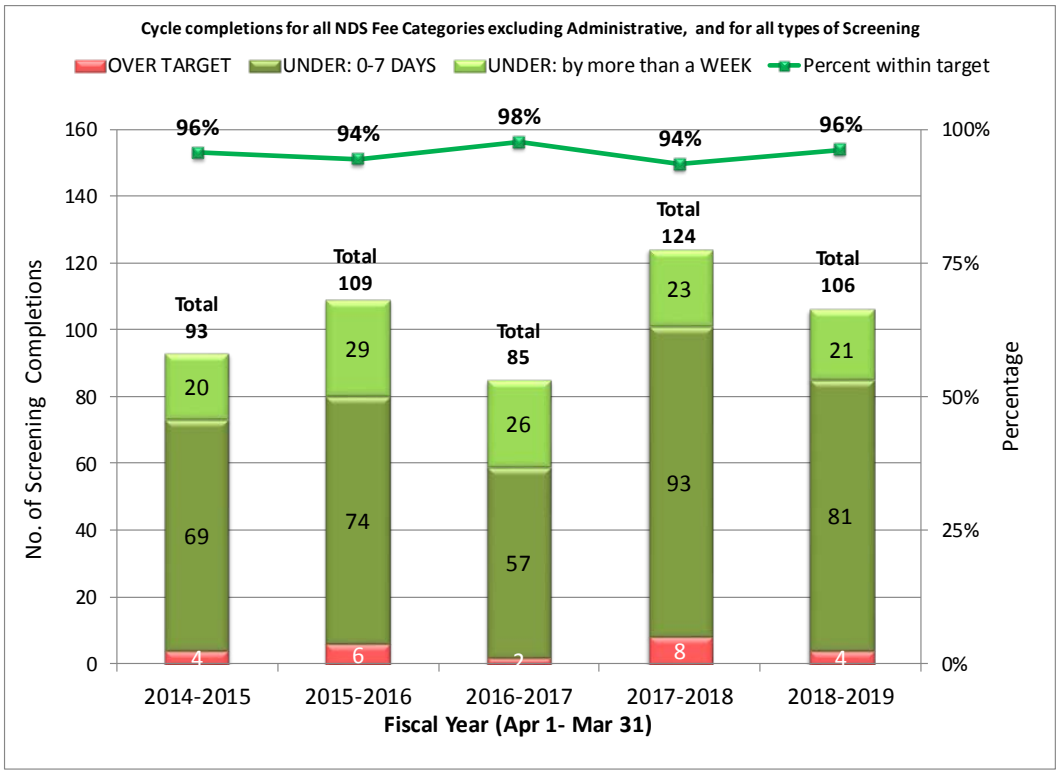


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

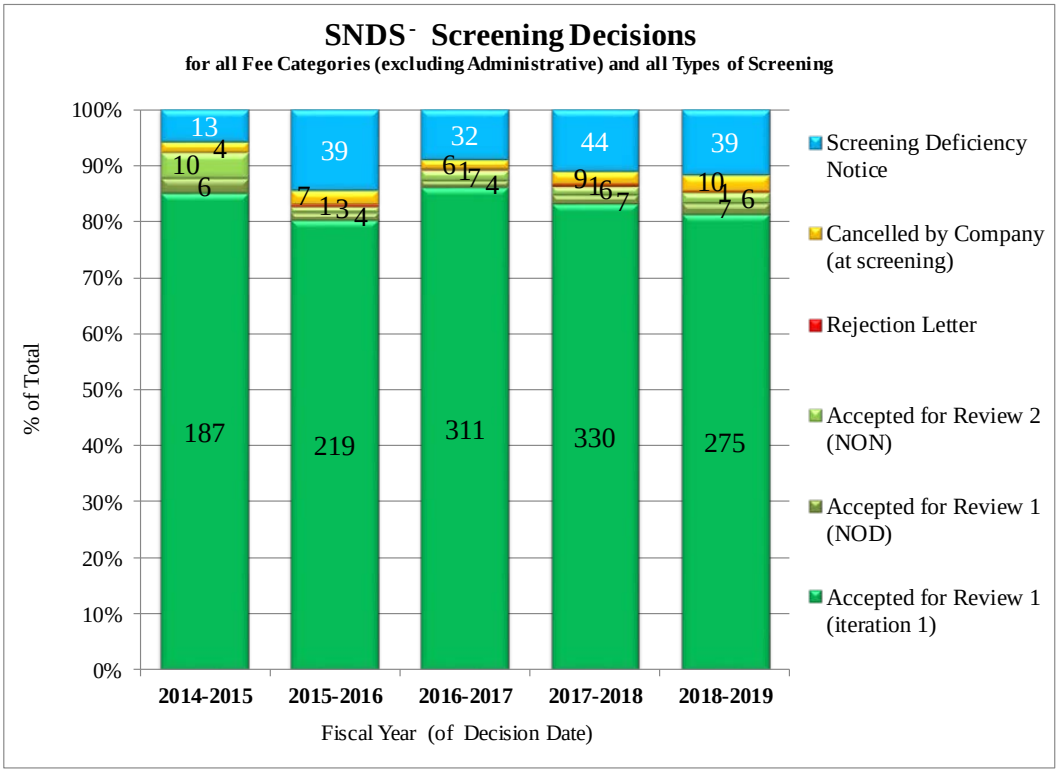


NDS - Screening Cycle Completions Showing Percentage Within Target

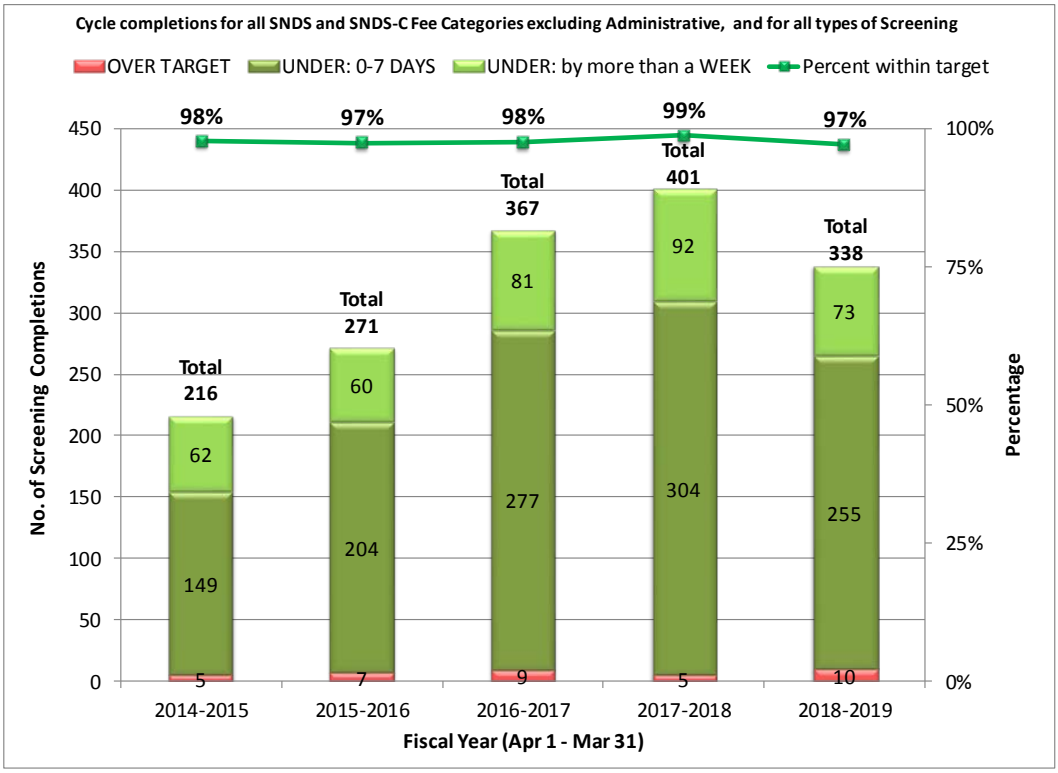


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



This page is left blank intentionally.

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – New Drug Submissions (NDS)

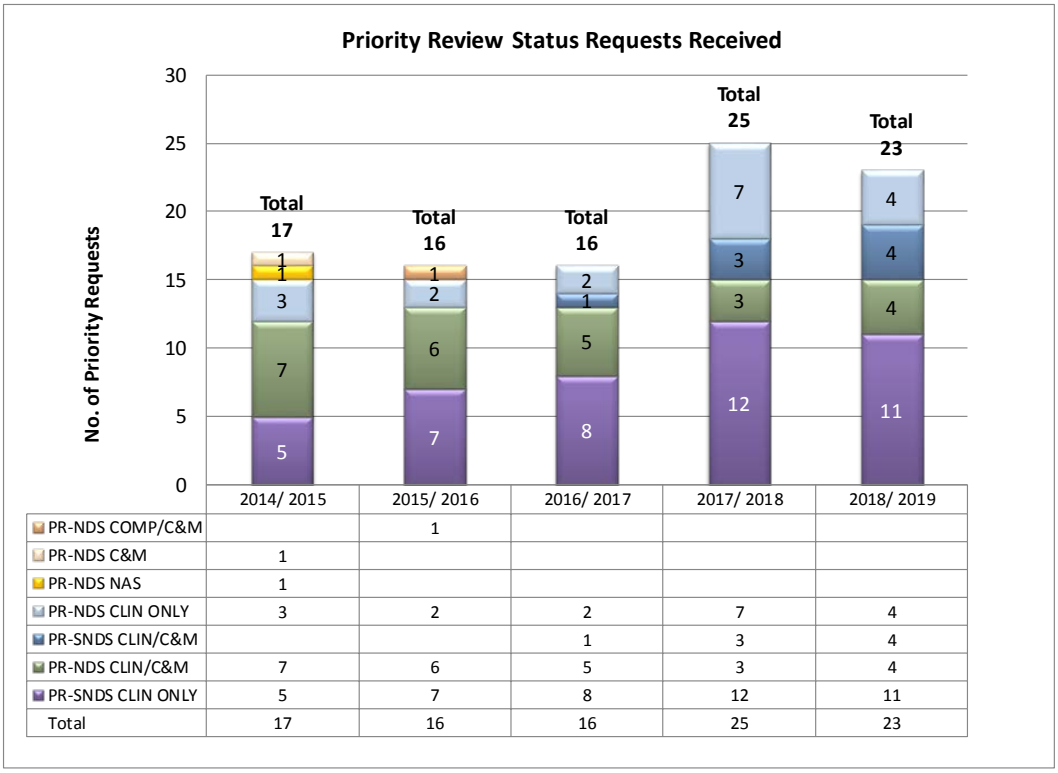
NDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**14-15**	**15-16**	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**NDS Status (as of May 2019)**
Total Received	**0**	**2**	**1**	**0**	**1**		
Total Pending	***0***	***0***	***0***	***0***	***0***		
Total Granted	***0***	***1***	***0***	***0***	***0***		
GRANTED	*0*	*1*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Total Denied	***0***	***1***	***1***	***0***	***1***		
DENIED	0	1	1	0	0	NOD-Withdrawal	Withdrawn
DENIED	0	0	0	0	1	NON-Withdrawal	Withdrawn

Requests for Reconsideration of Final Decisions – Supplemental New Drug Submissions (SNDS)

SNDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**14-15**	**15-16***	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**SNDS Status (as of May 2019)**
Total Received	**1**	**1**	**0**	**0**	**0**		
Total Denied	0	1	0	0	0	NOD-Withdrawal	Withdrawn
Total Granted	*1*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn

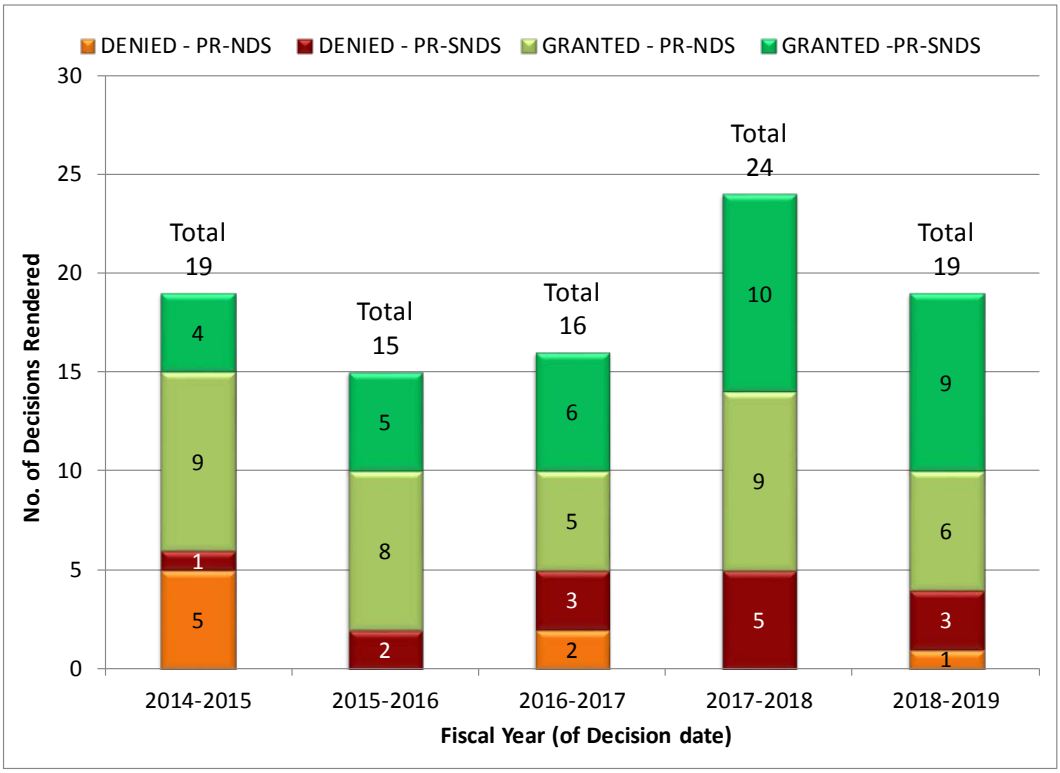
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



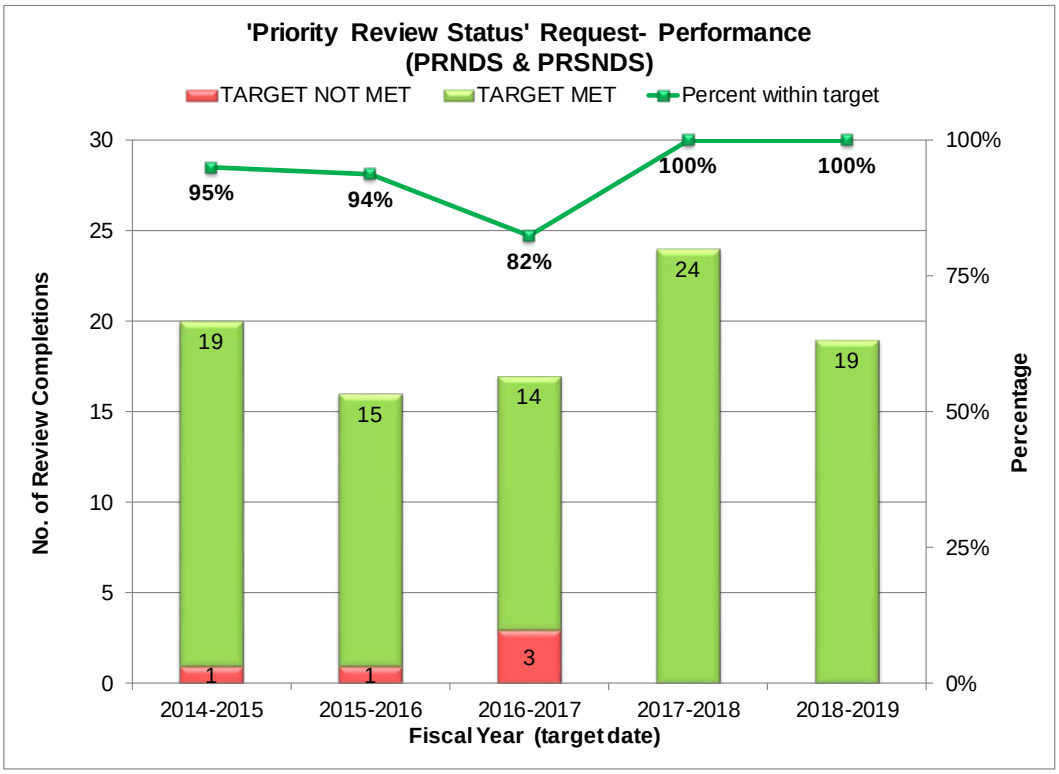
	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
PR-NDS COMP/C&M		1			
PR-NDS C&M	1				
PR-NDS NAS	1				
PR-NDS CLIN ONLY	3	2	2	7	4
PR-SNDS CLIN/C&M			1	3	4
PR-NDS CLIN/C&M	7	6	5	3	4
PR-SNDS CLIN ONLY	5	7	8	12	11
Total	17	16	16	25	23

Priority Review Status Requests: Decisions Rendered



PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Priority Review Requests (for NDS and SNDS)

"Priority Review Request" - Requests for Reconsideration of Final Decisions Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**14-15**	**15-16**	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**Submission Status (as of May 2019)**
Total Received	**0**	**0**	**0**	**1**	**0**		
Total Granted	***0***	***0***	***0***	***1***	***0***	Priority Review Request (for SNDS) Denied	Inactive-Reconsideration

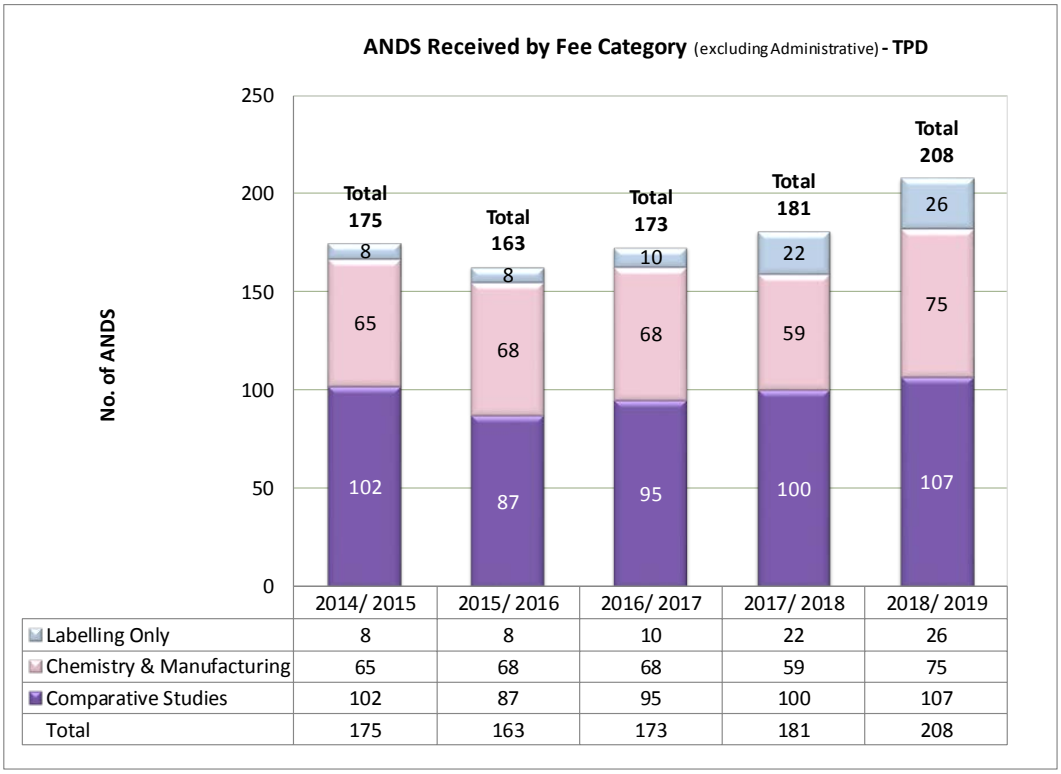
Abbreviated New Drug Submissions (ANDS)

&

Supplemental Abbreviated New Drug Submissions (SANDS)

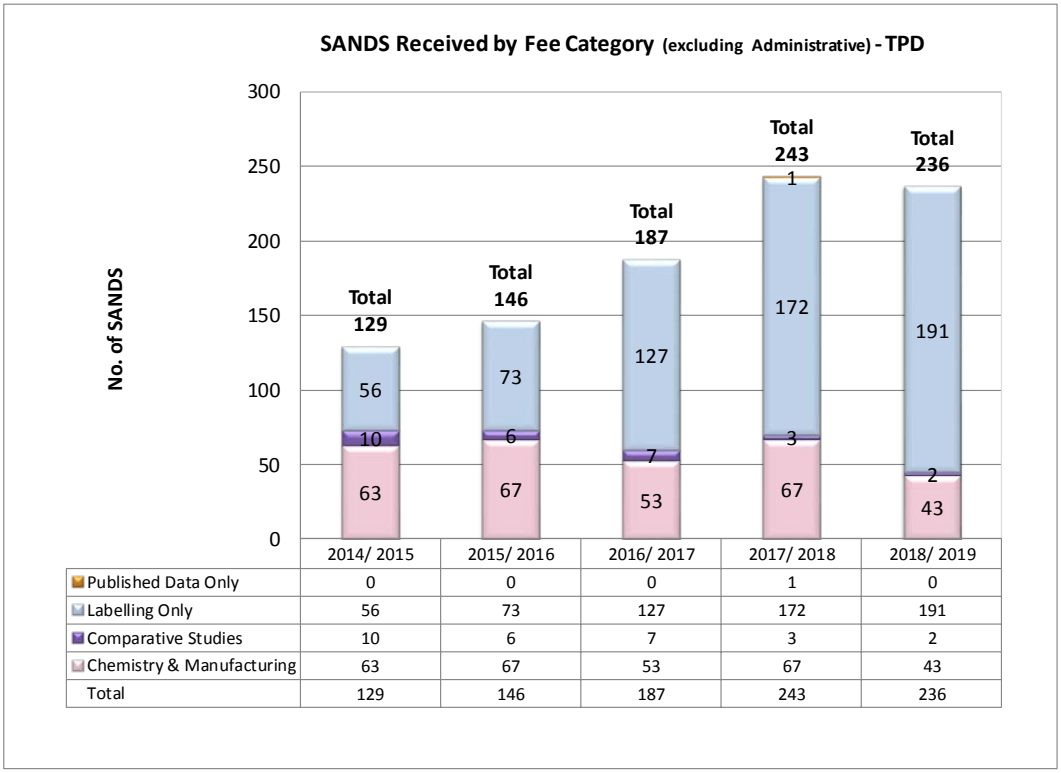
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Labelling Only	8	8	10	22	26
Chemistry & Manufacturing	65	68	68	59	75
Comparative Studies	102	87	95	100	107
Total	175	163	173	181	208

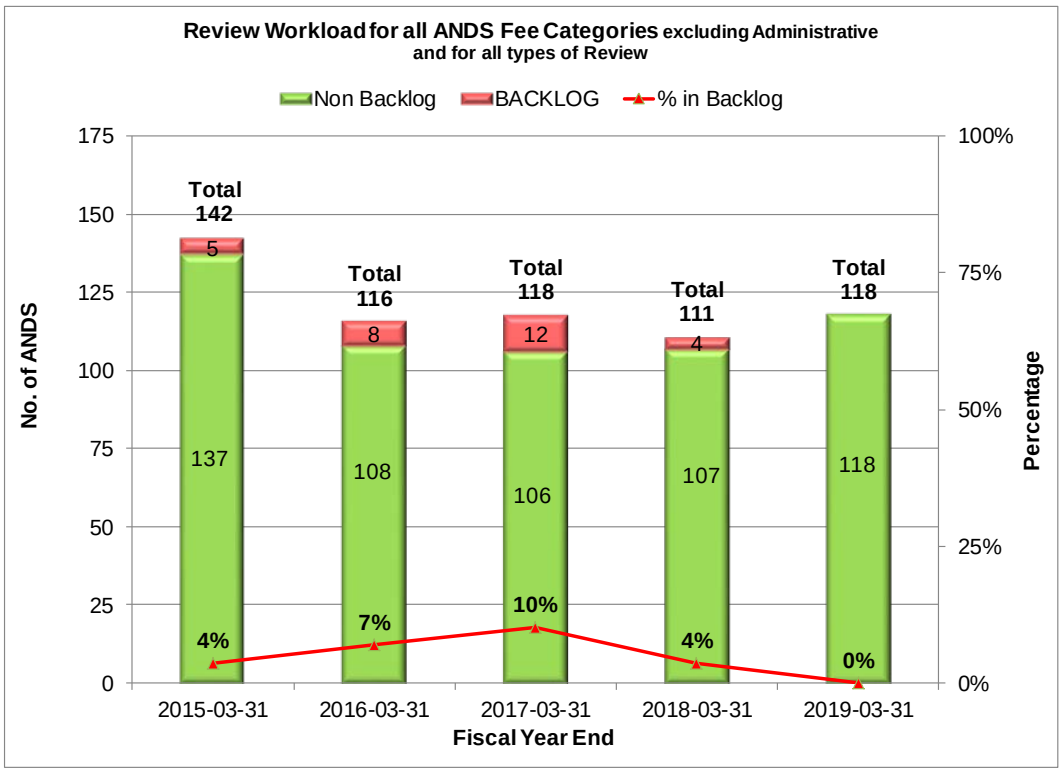
Supplemental Abbreviated New Drug Submission (SANDS) Received by Fee Category



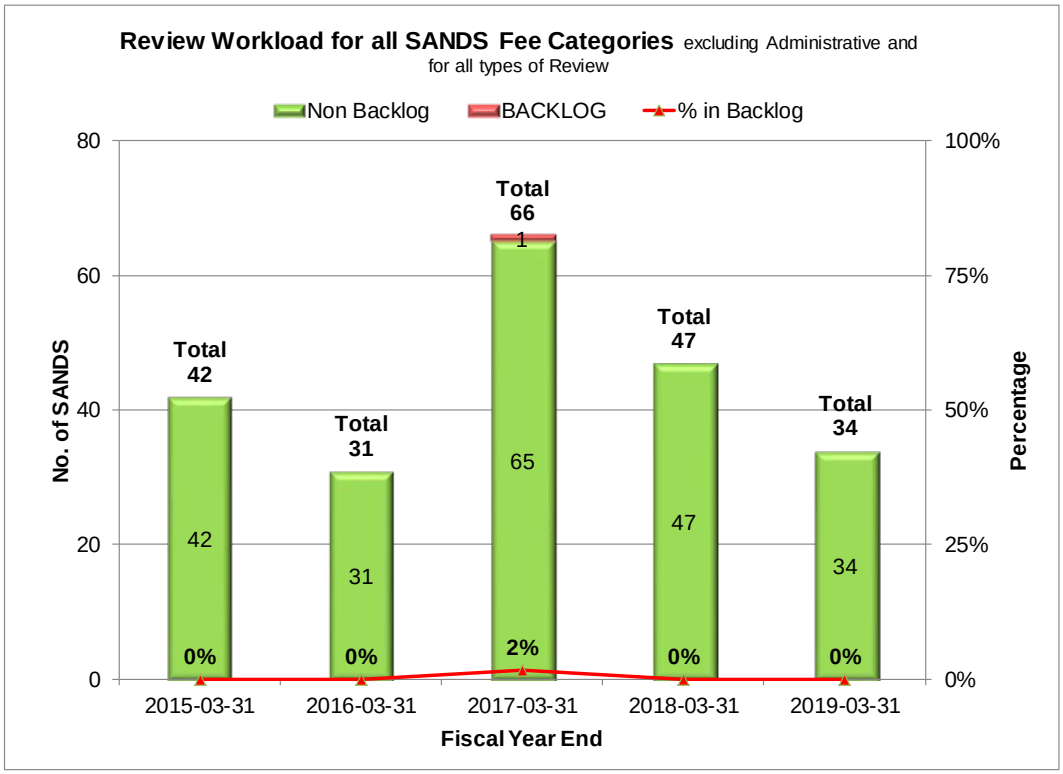
	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Published Data Only	0	0	0	1	0
Labelling Only	56	73	127	172	191
Comparative Studies	10	6	7	3	2
Chemistry & Manufacturing	63	67	53	67	43
Total	129	146	187	243	236

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

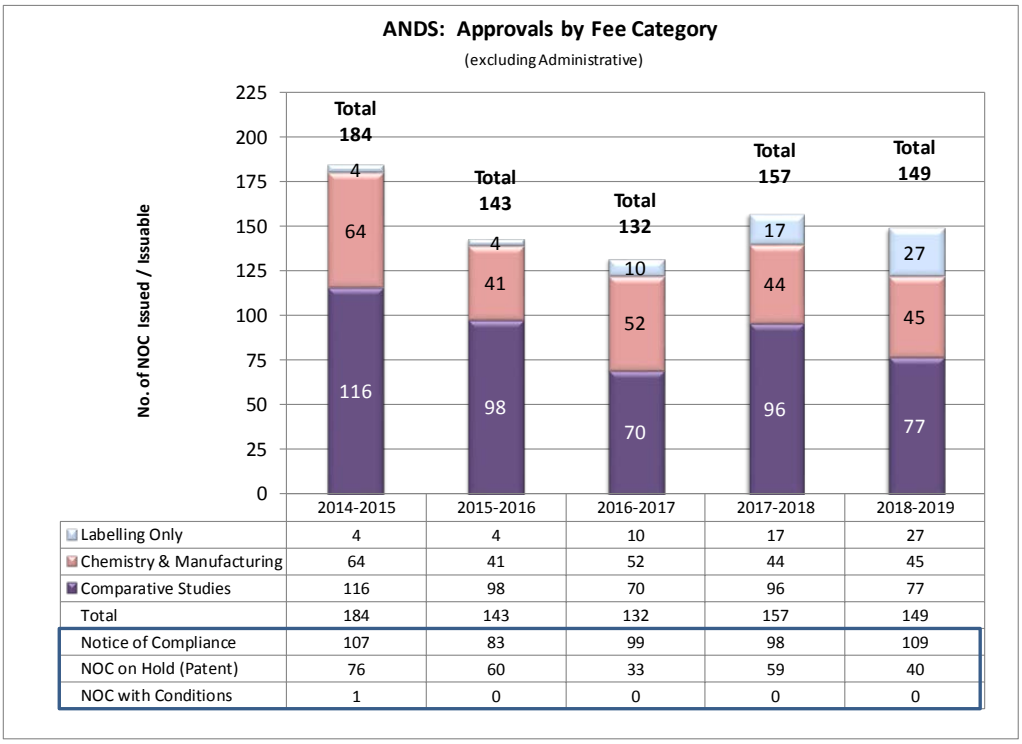
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Chemistry & Manufacturing	**59**	**49**	**46**	**43**	**38**
Backlog	*1*	*1*	*5*	*2*	*0*
Comparative Studies	**83**	**65**	**71**	**65**	**77**
Backlog	*4*	*7*	*7*	*2*	*0*
Labelling Only	**0**	**2**	**1**	**3**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**142**	**116**	**118**	**111**	**118**
Non Backlog	**137**	**108**	**106**	**107**	**118**
BACKLOG	**5**	**8**	**12**	**4**	**0**
% in Backlog	**4%**	**7%**	**10%**	**4%**	**0%**

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

TPD SANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Chemistry & Manufacturing	**27**	**24**	**32**	**26**	**22**
Backlog	*0*	*0*	*1*	*0*	*0*
Published Data Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**7**	**2**	**4**	**2**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**8**	**5**	**30**	**19**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**42**	**31**	**66**	**47**	**34**
Non Backlog	**42**	**31**	**65**	**47**	**34**
BACKLOG	**0**	**0**	**1**	**0**	**0**
% in Backlog	**0%**	**0%**	**2%**	**0%**	**0%**

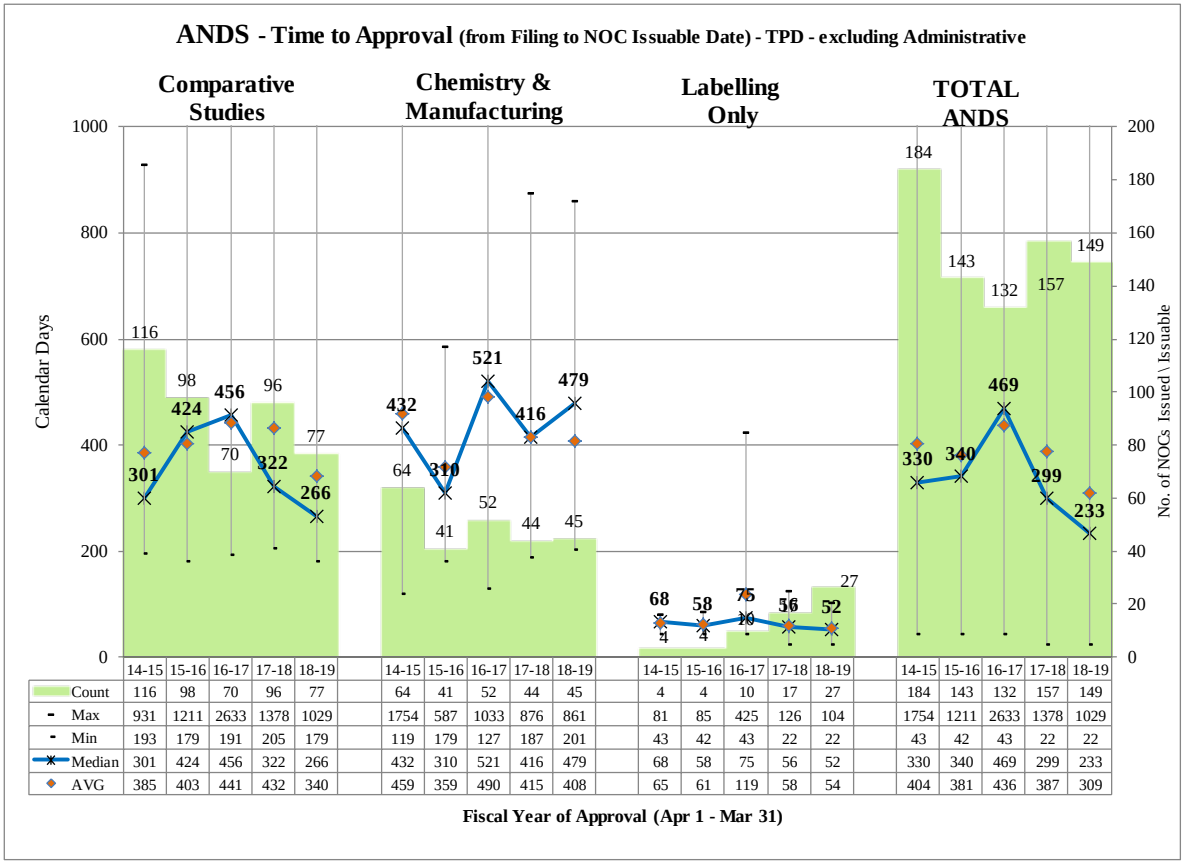
APPROVALS

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	4	4	10	17	27
Chemistry & Manufacturing	64	41	52	44	45
Comparative Studies	116	98	70	96	77
Total	184	143	132	157	149
Notice of Compliance	107	83	99	98	109
NOC on Hold (Patent)	76	60	33	59	40
NOC with Conditions	1	0	0	0	0

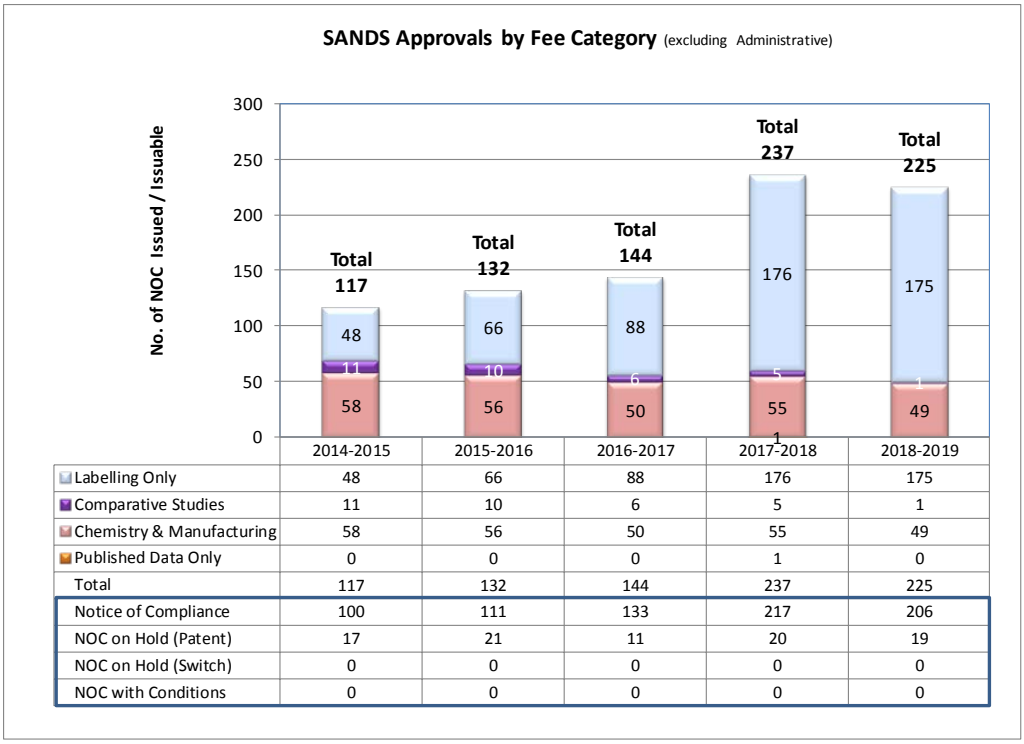
ANDS Approval Times



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	116	98	70	96	77	64	41	52	44	45	4	4	10	17	27	184	143	132	157	149
Max	931	1211	2633	1378	1029	1754	587	1033	876	861	81	85	425	126	104	1754	1211	2633	1378	1029
Min	193	179	191	205	179	119	179	127	187	201	43	42	43	22	22	43	42	43	22	22
Median	301	424	456	322	266	432	310	521	416	479	68	58	75	56	52	330	340	469	299	233
AVG	385	403	441	432	340	459	359	490	415	408	65	61	119	58	54	404	381	436	387	309

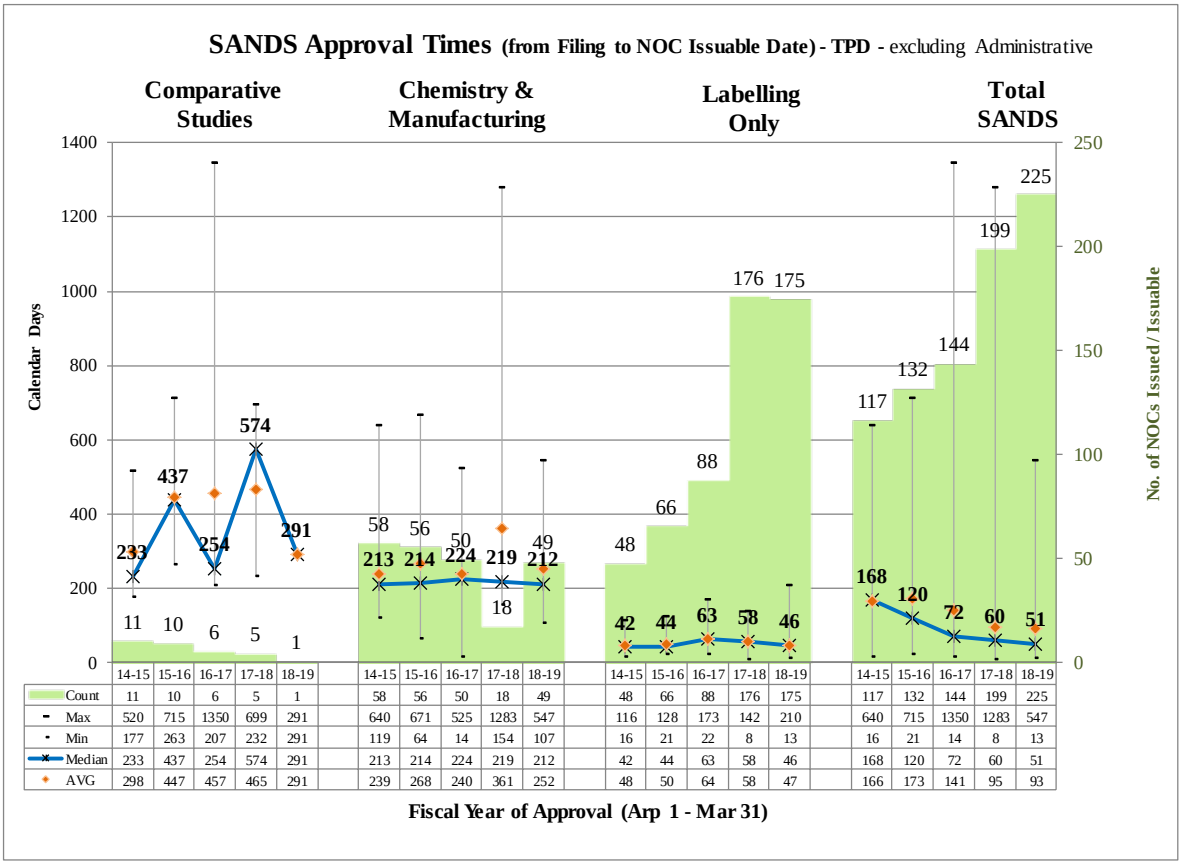
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Labelling Only	48	66	88	176	175
Comparative Studies	11	10	6	5	1
Chemistry & Manufacturing	58	56	50	55	49
Published Data Only	0	0	0	1	0
Total	117	132	144	237	225
Notice of Compliance	100	111	133	217	206
NOC on Hold (Patent)	17	21	11	20	19
NOC on Hold (Switch)	0	0	0	0	0
NOC with Conditions	0	0	0	0	0

SANDS Approval Times

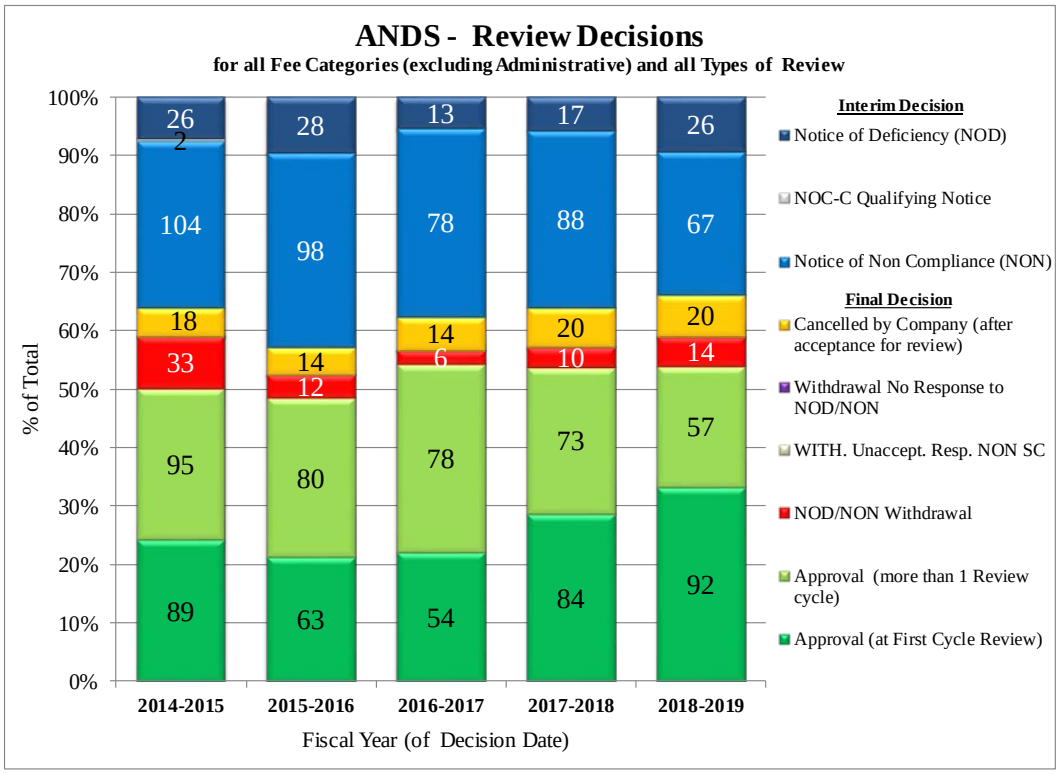


	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	11	10	6	5	1	58	56	50	18	49	48	66	88	176	175	117	132	144	199	225
Max	520	715	1350	699	291	640	671	525	1283	547	116	128	173	142	210	640	715	1350	1283	547
Min	177	263	207	232	291	119	64	14	154	107	16	21	22	8	13	16	21	14	8	13
Median	233	437	254	574	291	213	214	224	219	212	42	44	63	58	46	168	120	72	60	51
AVG	298	447	457	465	291	239	268	240	361	252	48	50	64	58	47	166	173	141	95	93

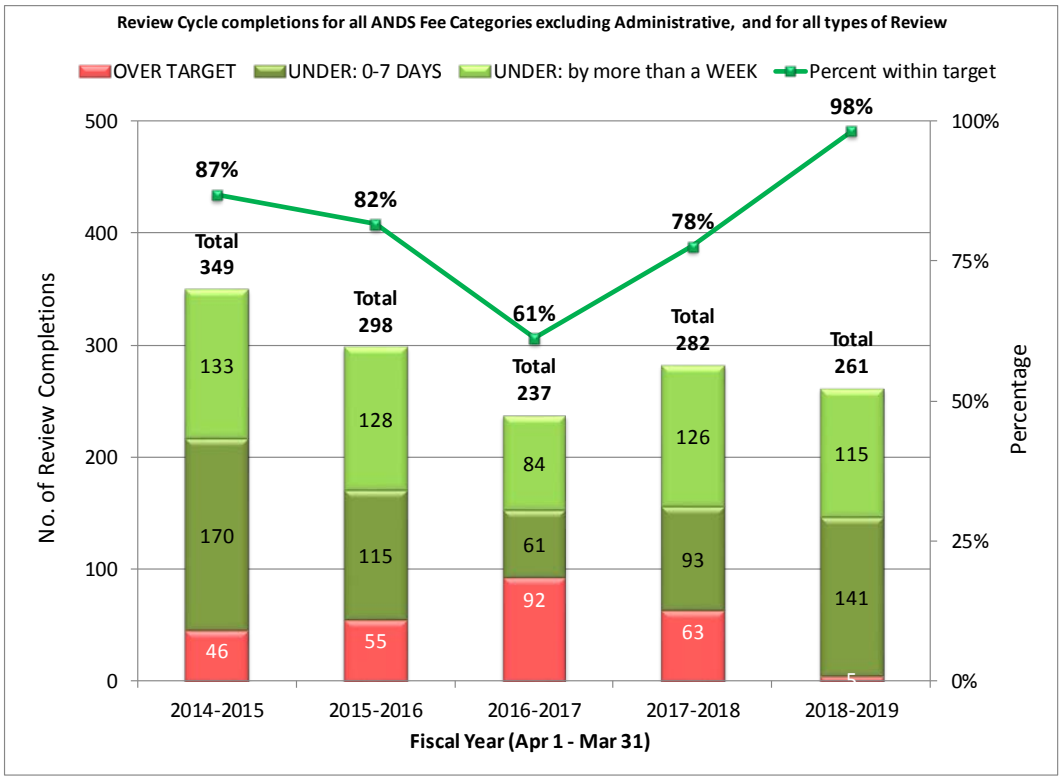
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

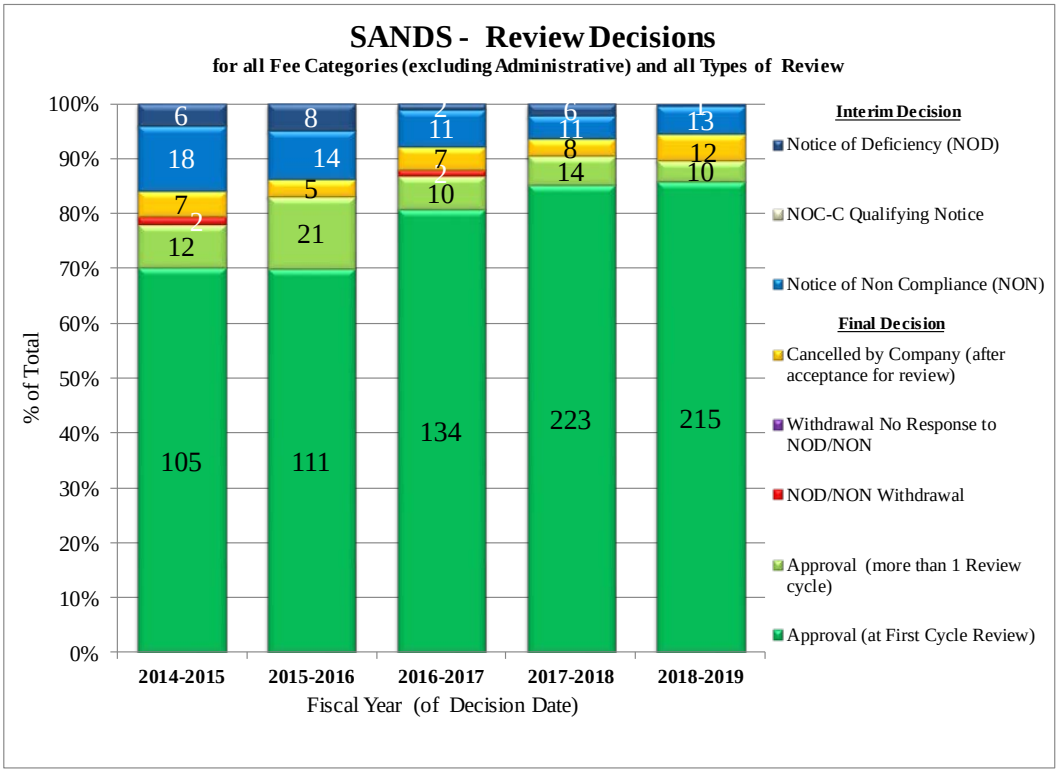


ANDS - Review Cycle Completions Showing Percentage Within Target

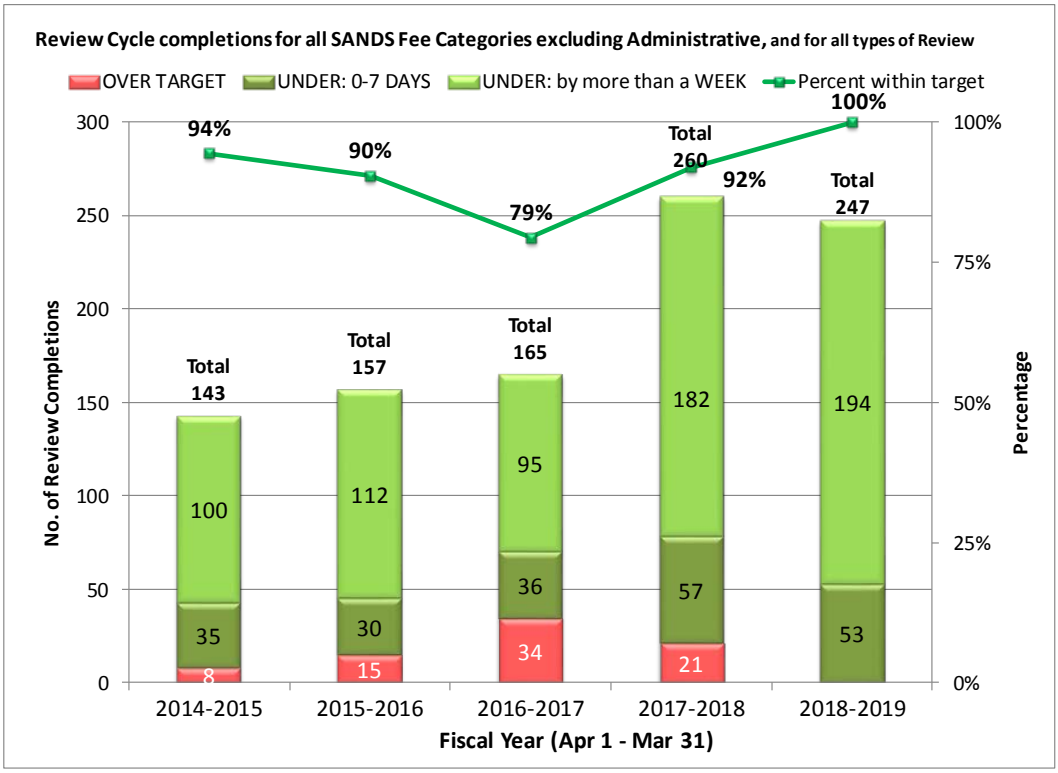


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

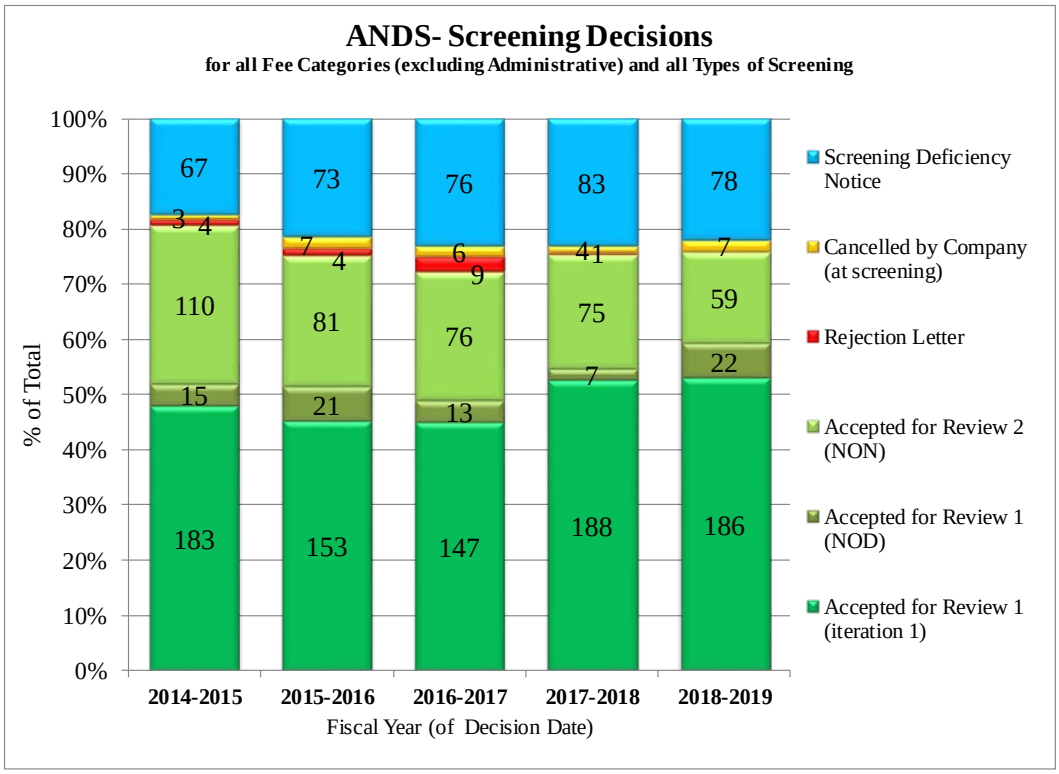


SANDS - Review Cycle Completions Showing Percentage Within Target

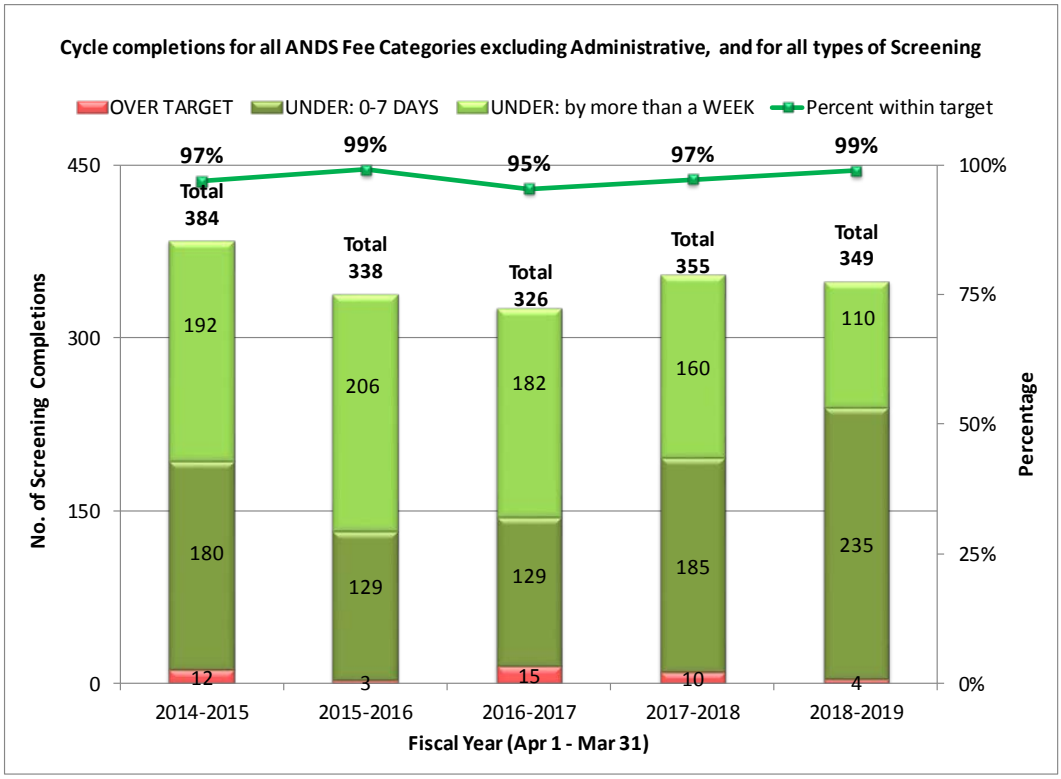


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

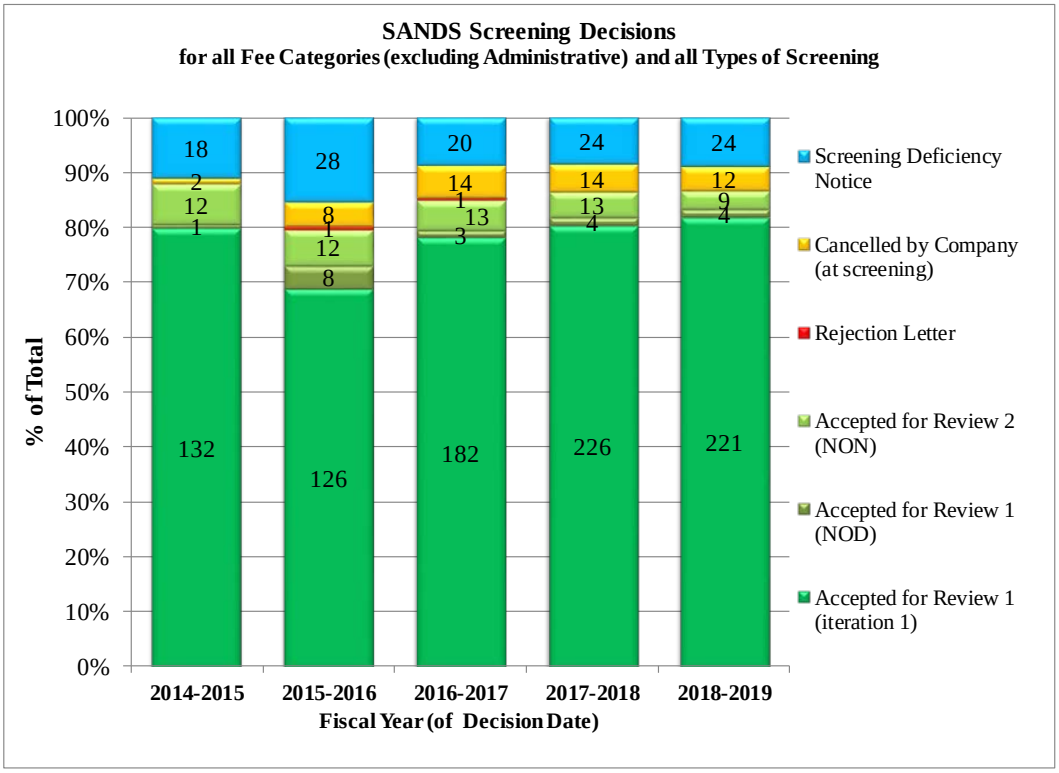


ANDS - Screening Cycle Completions Showing Percentage Within Target

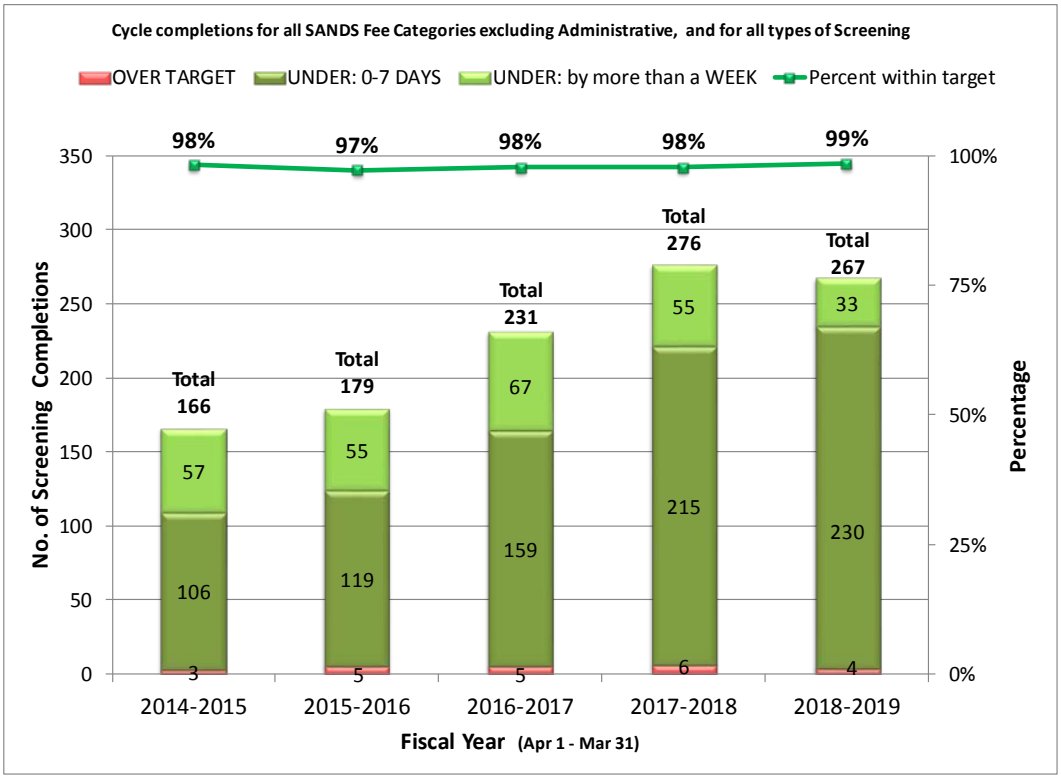


SCREENING CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Screening Decisions



SANDS - Screening Cycle Completions Showing Percentage Within Target



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Abbreviated New Drug Submissions (ANDS)

ANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	14-15	15-16	16-17	17-18	18-19	Final Decision in Dispute	ANDS Status (as of May 2019)
TOTAL Received	**8**	**3**	**2**	**0**	**3**		
Total Pending	***0***	***1***	***0***	***0***	***2***		
Pending	0	1	0	0	2	NON-Withdrawal	Under Reconsideration
Total Granted	***3***	***1***	***1***	***0***	***1***		
Granted	3	0	0	0	1	NON-Withdrawal	Cleared
Granted	0	1	0	0	0	NON-Withdrawal	Cleared
Granted	0	0	1	0	0	Rejection at Screening	Cleared
Total Denied	***1***	***1***	***0***	***0***	***0***		
Denied	0	0	0	0	0	NOD-Withdrawal	Withdrawn
Denied	1	1	0	0	0	NON-Withdrawal	Withdrawn
Total Cancelled	***4***	***0***	***1***	***0***	***0***		
Cancelled by Health Canada	1	0	0	0	0	NOD-Withdrawal	Withdrawn
Cancelled by Health Canada	2	0	0	0	0	NON-Withdrawal	Withdrawn
Cancelled by Health Canada	1	0	0	0	0	Rejection at Screening	Cleared
Cancelled by Company	0	0	1	0	0	NOD-Withdrawal	Withdrawn

Requests for Reconsideration of Final Decisions – Supplemental Abbreviated New Drug Submissions (SANDS)

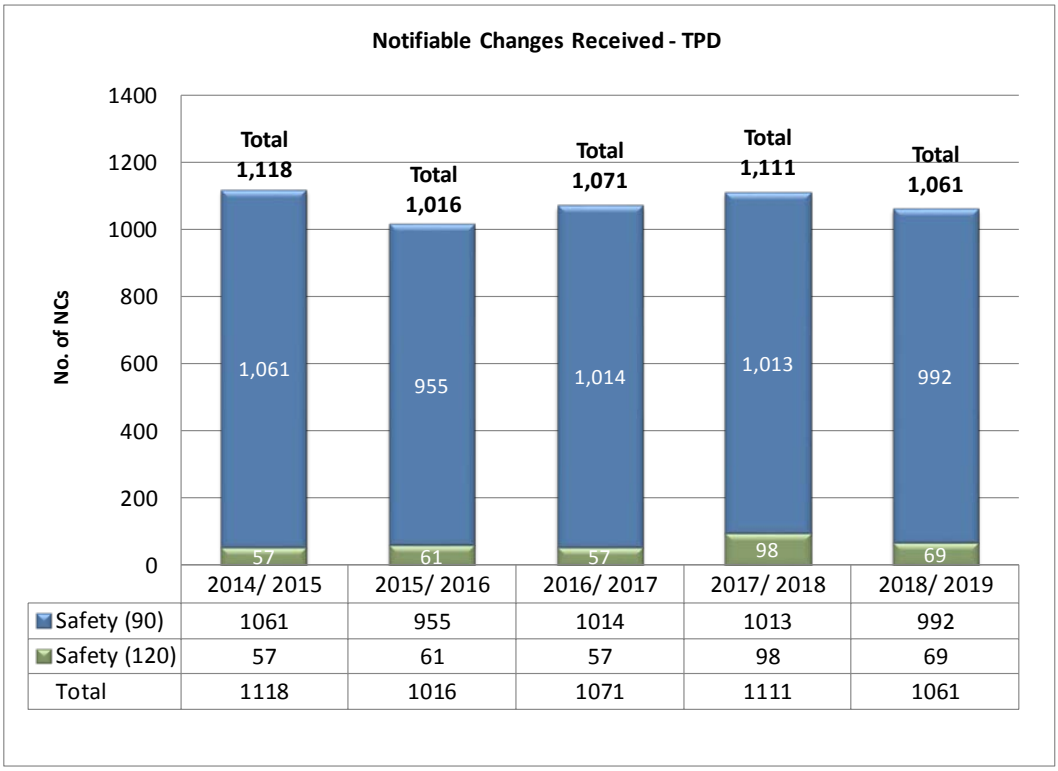
SANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31) *revised May 2019

Breakdown by Reconsideration Decision	14-15	15-16	16-17	17-18	18-19	Final Decision in Dispute	SANDS Status (as of May 2019)
Total Received	**0**	**1**	**1**	**0**	**0**		
Total Granted	***0***	***1***	***0***	***0***	***0***		
Granted	0	1	0	0	0	NOD-Withdrawal	Cleared
Total Cancelled	***0***	***0***	***1***	***0***	***0***		
Cancelled by Health Canada	0	0	1	0	0	NOD-Withdrawal	Withdrawn*

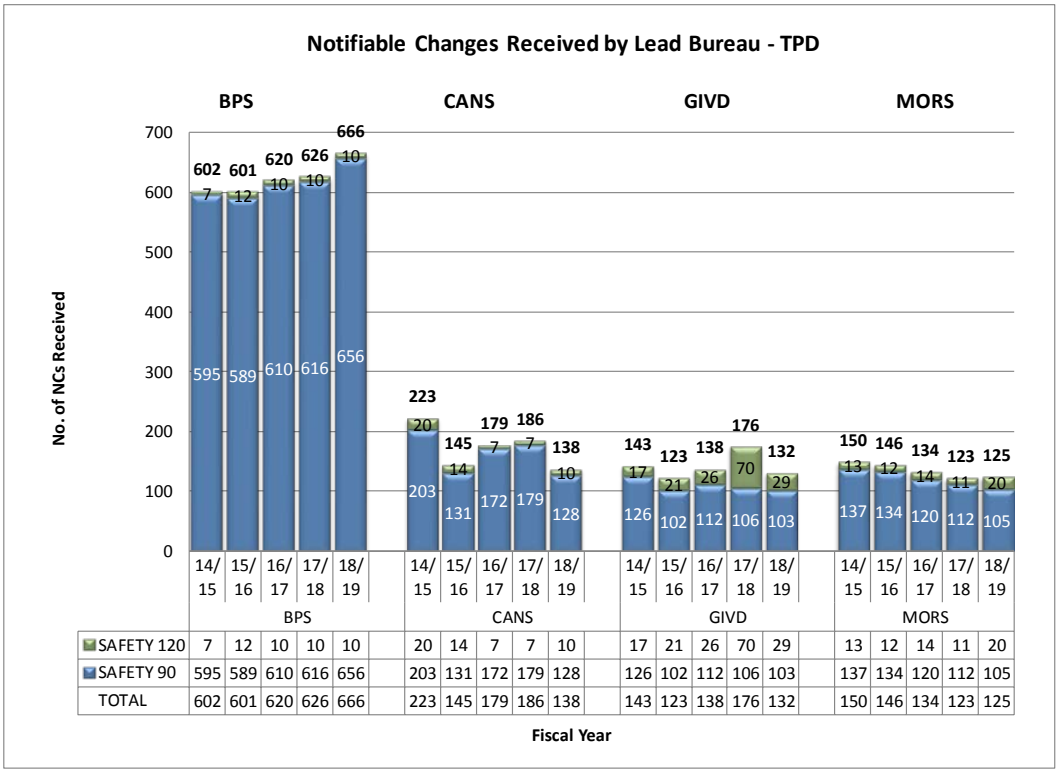
NOTIFIABLE CHANGES (NC)

Number Received - Notifiable Changes (NC)



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Safety (90)	1061	955	1014	1013	992
Safety (120)	57	61	57	98	69
Total	1118	1016	1071	1111	1061

Number Received by Lead Bureau- Notifiable Changes (NC)

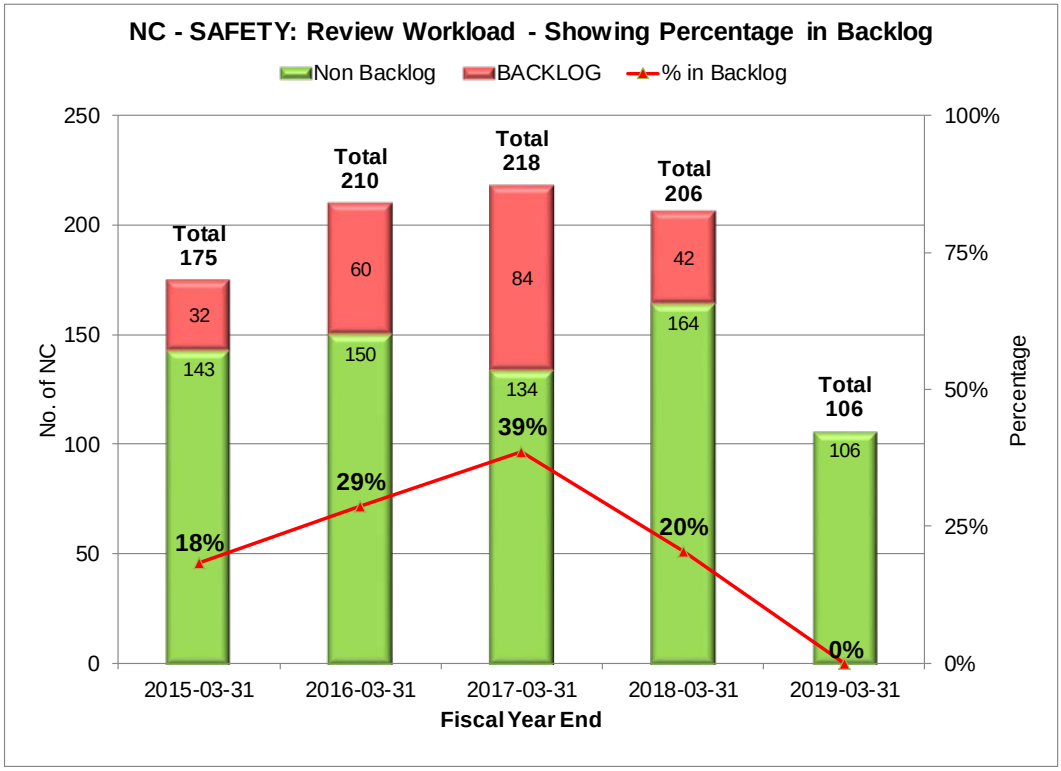


	BPS					CANS					GIVD					MORS				
	14/15	15/16	16/17	17/18	18/19	14/15	15/16	16/17	17/18	18/19	14/15	15/16	16/17	17/18	18/19	14/15	15/16	16/17	17/18	18/19
SAFETY 120	7	12	10	10	10	20	14	7	7	10	17	21	26	70	29	13	12	14	11	20
SAFETY 90	595	589	610	616	656	203	131	172	179	128	126	102	112	106	103	137	134	120	112	105
TOTAL	602	601	620	626	666	223	145	179	186	138	143	123	138	176	132	150	146	134	123	125

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



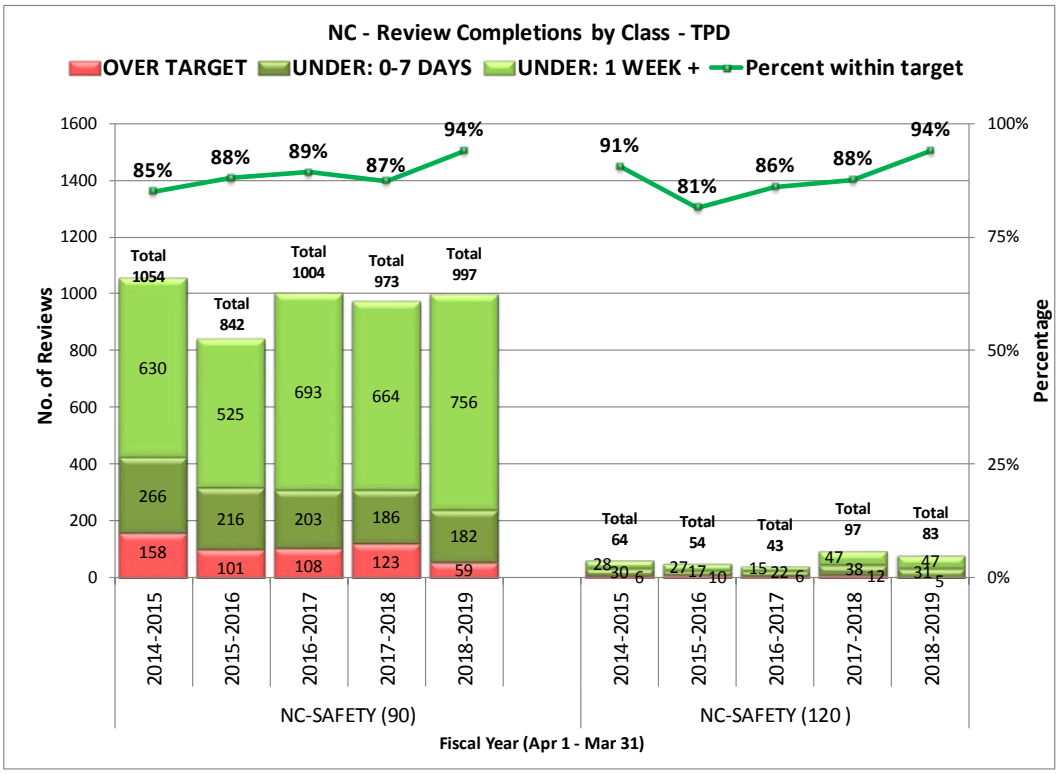
WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

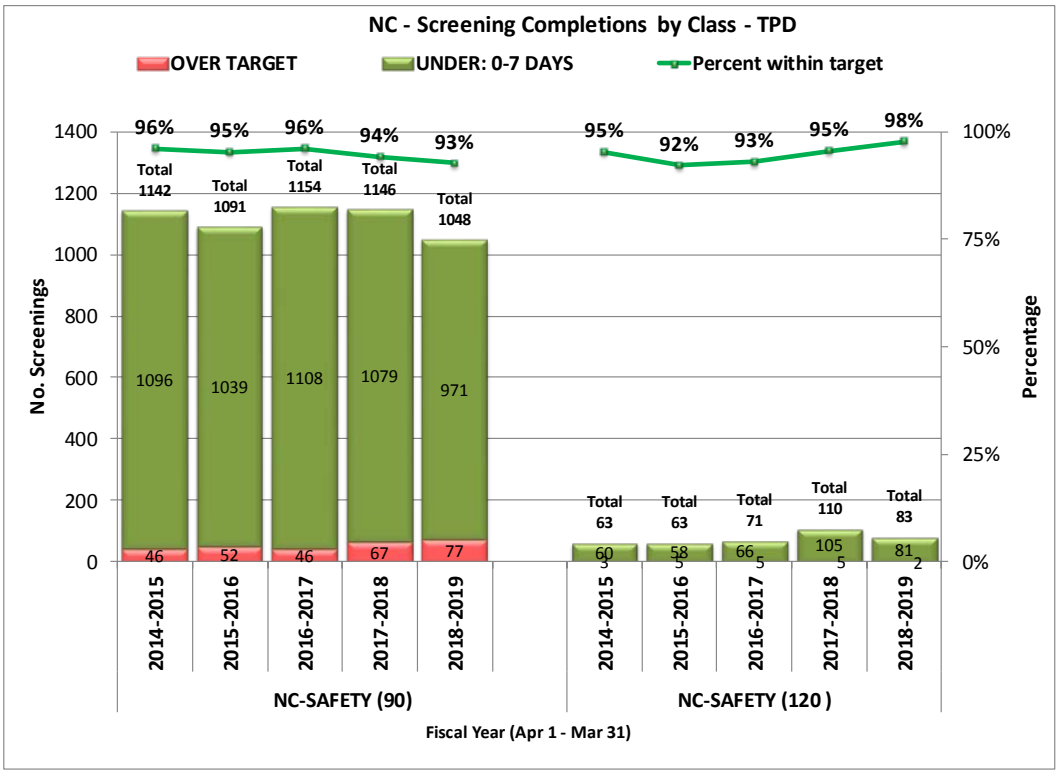
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2015-03-31**	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**
SAFETY - 90 day	**156**	**194**	**188**	**184**	**95**
Backlog	*32*	*60*	*78*	*39*	*0*
SAFETY - 120 day	**19**	**16**	**30**	**22**	**11**
Backlog	*0*	*0*	*6*	*3*	*0*
Total	**175**	**210**	**218**	**206**	**106**
Non Backlog	**143**	**150**	**134**	**164**	**106**
BACKLOG	**32**	**60**	**84**	**42**	**0**
% in Backlog	**18%**	**29%**	**39%**	**20%**	**0%**

PERFORMANCE

REVIEW Completions by Class - Notifiable Changes (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



DECISIONS

Decision Documents by Class - Notifiable Change (NC) Safety

NC - SAFETY (90)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	1065	834	954	990	977
CANCELLED BY COMPANY	49	62	65	66	63
NC - HOLD (PATENT)	34	45	69	46	35
SCREEN. DEFICIENCY NOTICE	85	197	136	161	115
REJECTION LETTER (SCR)	6	3	2	3	2
NOT SATISFACTORY NOTICE	5	1	2	0	1
SPONSOR SUB CHANGE ACCEPT	0	1	0	0	0

NC - SAFETY (120)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	63	54	43	90	81
NOT SATISFACTORY NOTICE	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	3	6	11	20	11
CANCELLED BY COMPANY	1	6	4	8	2
REJECTION LETTER (SCR)	0	1	0	0	0
NC - HOLD (PATENT)	0	0	0	0	1

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Notifiable Changes (NC)

Notifiable Changes - Requests for Reconsideration of Final Decisions

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	14-15	15-16	16-17	17-18	18-19	Final Decision in Dispute	NC's Status (as of May 2019)
Total Received	**0**	**0**	**0**	**0**	**0**		

This page is left blank intentionally.

Administrative Submissions

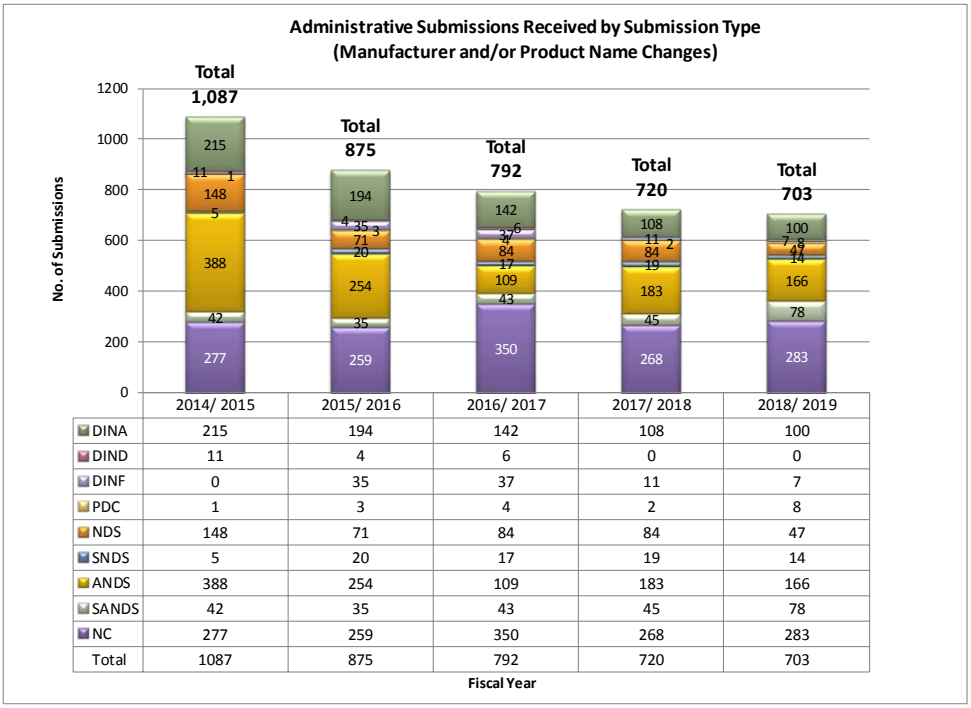
Submissions in support of a manufacturer or product name change.

Administrative Submissions

(Product & Manufacturer Name Changes) [11]

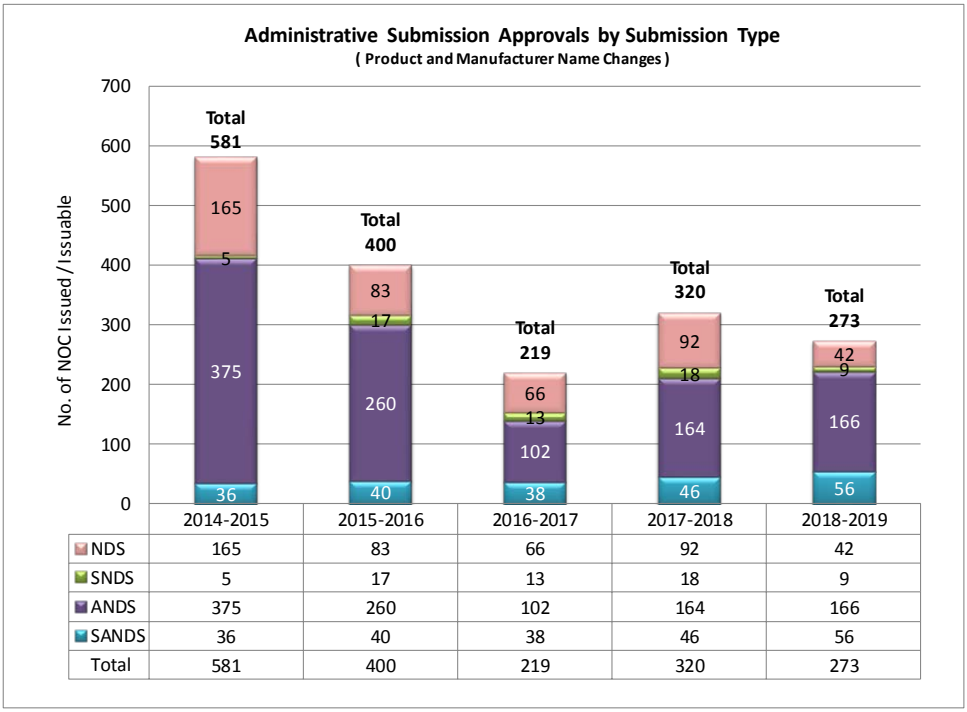
RECEIVED

Administrative Submissions Received by Submission Type



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
DINA	215	194	142	108	100
DIND	11	4	6	0	0
DINF	0	35	37	11	7
PDC	1	3	4	2	8
NDS	148	71	84	84	47
SNDS	5	20	17	19	14
ANDS	388	254	109	183	166
SANDS	42	35	43	45	78
NC	277	259	350	268	283
Total	1087	875	792	720	703

Administrative Submission Approvals for NDS, SNDS, ANDS and SANDS



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
NDS	165	83	66	92	42
SNDS	5	17	13	18	9
ANDS	375	260	102	164	166
SANDS	36	40	38	46	56
Total	581	400	219	320	273

[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 Disease (BGIVD) at TPD in December 2018.
(Admin Ncs are for cross-referenced changes)

Administrative Submissions

(Product & Manufacturer Name Changes) [12]

DECISIONS

Administrative Submissions/ Applications: DECISIONS

Administrative	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
NDS - Administrative					
NOTICE OF COMPLIANCE	165	77	65	92	42
NOC ON IP HOLD	0	6	1	0	0
NOC WITH CONDITIONS	0	2	0	0	0
SCREEN. DEFICIENCY NOTICE	0	0	6	5	0
CANCELLATION LETTER	0	0	1	3	4
PROCESSING HOLD LETTER	47	60	58	46	12
SNDS - Administrative					
NOTICE OF COMPLIANCE	5	17	12	18	9
NOC ON IP HOLD	0	0	1	0	0
CANCELLATION LETTER	0	1	2	1	7
PROCESSING HOLD LETTER	3	10	4	4	5
ANDS- Administrative					
NOTICE OF COMPLIANCE	335	157	77	157	165
NOC ON IP HOLD	40	103	25	3	1
SCREEN. DEFICIENCY NOTICE	0	0	10	1	5
CANCELLATION LETTER	20	9	3	8	6
PROCESSING HOLD LETTER	84	126	79	88	44
SANDS - Administrative					
NOTICE OF COMPLIANCE	35	36	36	46	56
NOC ON IP HOLD	2	4	2	0	0
SCREEN. DEFICIENCY NOTICE	0	0	2	0	2
CANCELLATION LETTER	1	0	1	2	9
PROCESSING HOLD LETTER	9	16	20	27	20
NC - Administrative					
NO OBJECTION LETTER	293	221	298	271	265
NC - HOLD (PATENT)	7	8	29	0	1
SCREEN. DEFICIENCY NOTICE	0	2	0	1	0
CANCELLATION LETTER	6	10	13	13	21
PROCESSING HOLD LETTER	9	5	6	2	16
DINA - Administrative					
NOTIFICATION FORM/DIN ISSUED	224	132	104	124	84
NO OBJECTION LETTER	0	2	0	0	2
SCREEN. DEFICIENCY NOTICE	0	0	63	11	8
CANCELLATION LETTER	0	4	4	8	11
PROCESSING HOLD LETTER	89	117	76	54	27
DIND - Administrative					
NOTIFICATION FORM/ DIN ISSUED	11	3	2	0	0
CANCELLATION LETTER	0	0	4	0	0
PROCESSING HOLD LETTER	9	3	9	0	0
DINF - Administrative					
NOTIFICATION FORM/ DIN ISSUED	0	35	29	9	0
NO OBJECTION LETTER	0	0	0	1	0
SCREEN. DEFICIENCY NOTICE	0	0	1	0	0
CANCELLATION LETTER	0	0	1	1	0
PROCESSING HOLD LETTER	0	27	24	16	7
PDC - Administrative					
NO OBJECTION LETTER	1	1	3	1	5
CANCELLATION LETTER	0	0	3	0	3
PROCESSING HOLD LETTER	1	0	1	0	2

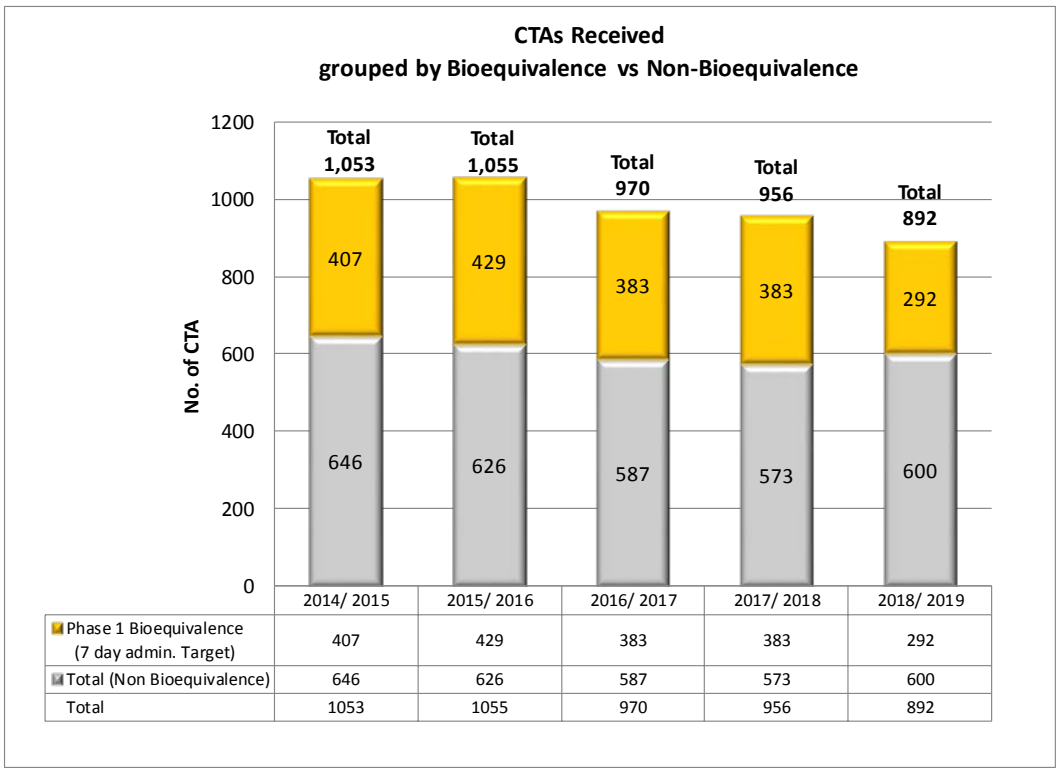
[12] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral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

Clinical Trial Applications and Amendments

(CTA & CTA-A)

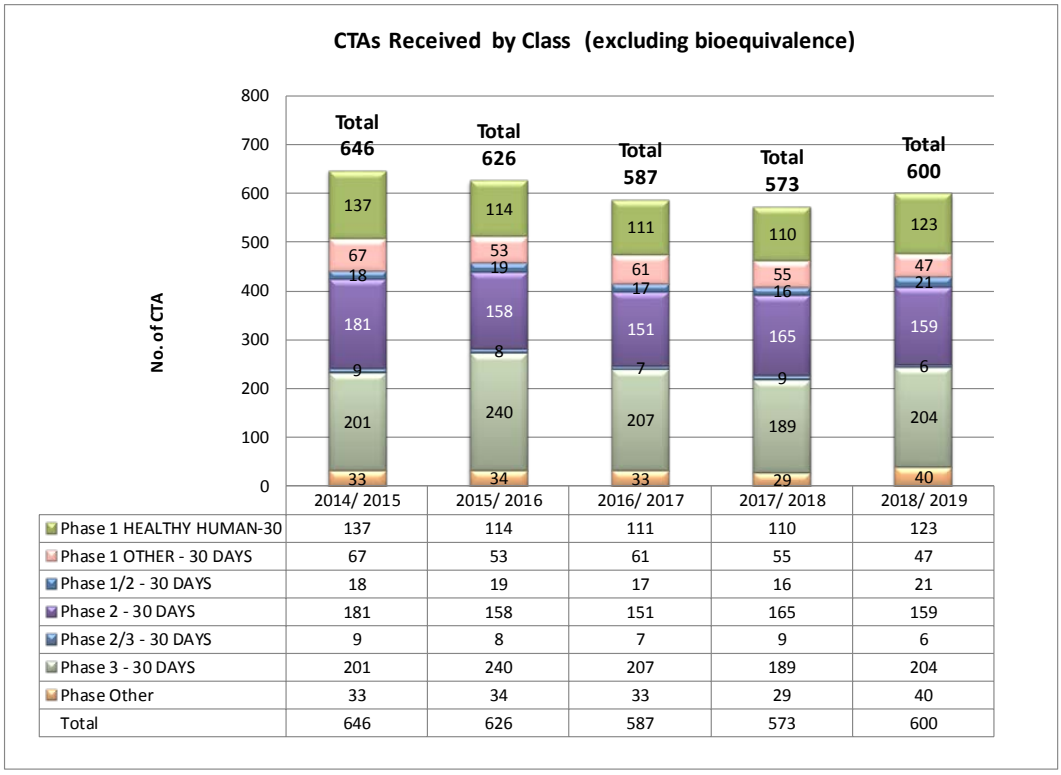
CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Phase 1 Bioequivalence (7 day admin. Target)	407	429	383	383	292
Total (Non Bioequivalence)	646	626	587	573	600
Total	1053	1055	970	956	892

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



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Phase 1 HEALTHY HUMAN-30	137	114	111	110	123
Phase 1 OTHER - 30 DAYS	67	53	61	55	47
Phase 1/2 - 30 DAYS	18	19	17	16	21
Phase 2 - 30 DAYS	181	158	151	165	159
Phase 2/3 - 30 DAYS	9	8	7	9	6
Phase 3 - 30 DAYS	201	240	207	189	204
Phase Other	33	34	33	29	40
Total	646	626	587	573	600

DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

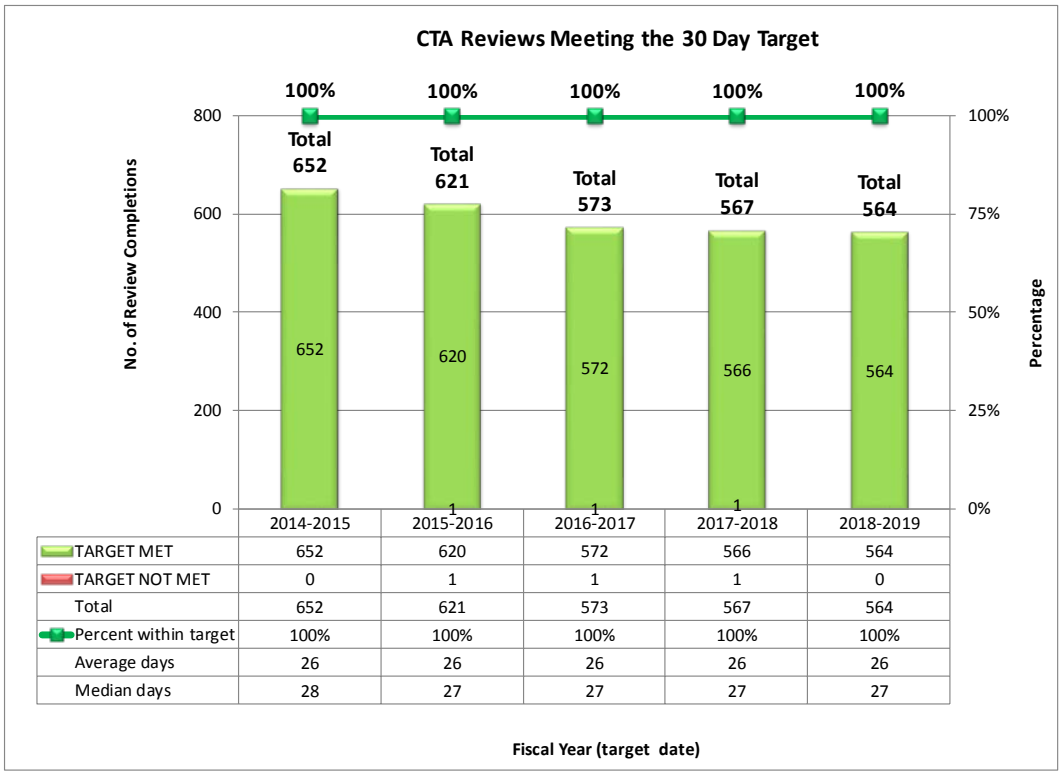
CTA (Total)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	1021	994	926	898	821
CANCELLED BY COMPANY DURING REVIEW	48	44	36	53	37
CANCELLED BY COMPANY AT PROCESSING	7	8	4	11	11

CTA (7 day administrative target) Phase 1 Bioequivalence					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	410	405	386	379	286
CANCELLED BY COMPANY DURING REVIEW	6	12	3	3	5
CANCELLED BY COMPANY AT PROCESSING	0	0	0	1	2

CTA (30 day target)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	611	589	540	519	535
CANCELLED BY COMPANY DURING REVIEW	42	32	33	50	32
CANCELLED BY COMPANY AT PROCESSING	7	8	4	10	9
NOT SATISFACTORY NOTICE	0	0	0	0	1

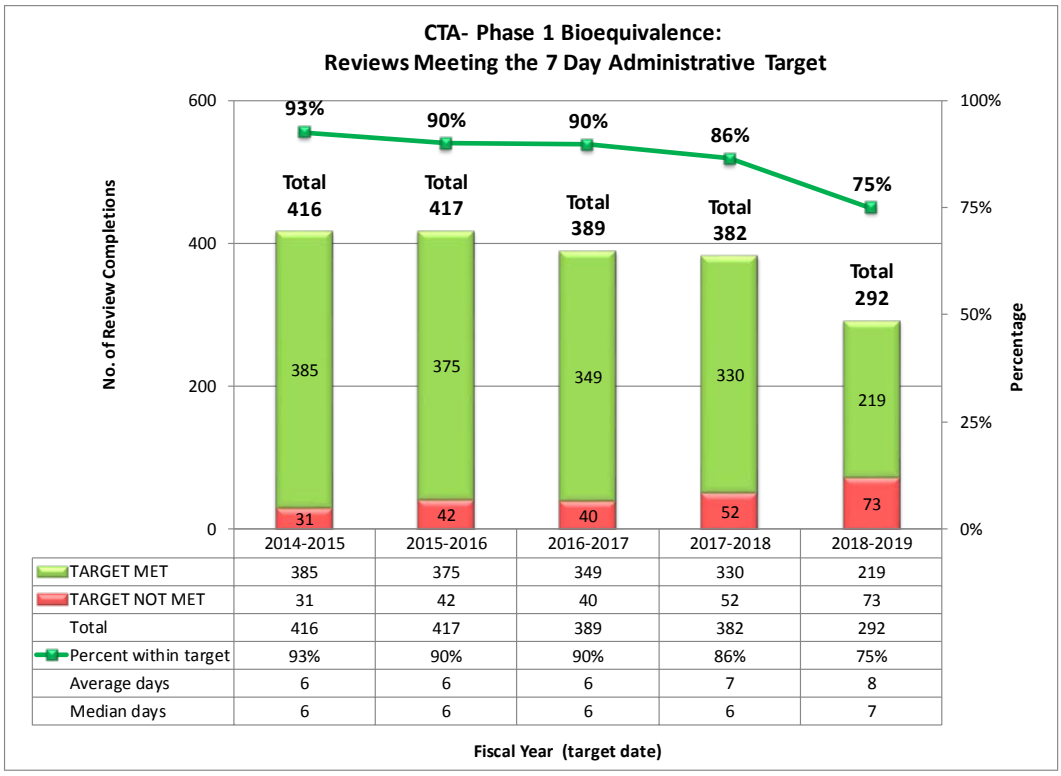
PERFORMANCE

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



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
TARGET MET	652	620	572	566	564
TARGET NOT MET	0	1	1	1	0
Total	652	621	573	567	564
Percent within target	100%	100%	100%	100%	100%
Average days	26	26	26	26	26
Median days	28	27	27	27	27

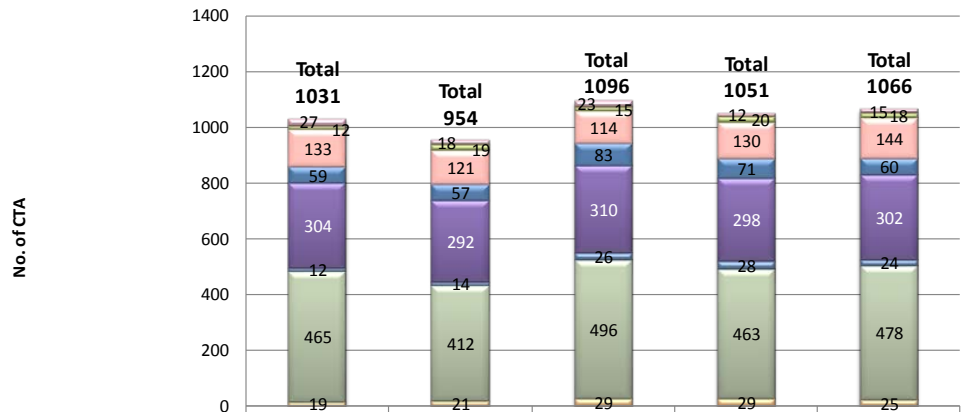
Performance – CTA Reviews Meeting the 7 Day Administrative Target



	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
TARGET MET	385	375	349	330	219
TARGET NOT MET	31	42	40	52	73
Total	416	417	389	382	292
Percent within target	93%	90%	90%	86%	75%
Average days	6	6	6	7	8
Median days	6	6	6	6	7

CLINICAL TRIAL APPLICATION-AMENDMENTS

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



	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Phase 1 BIOEQUIVALENCE-7	27	18	23	12	15
Phase 1 HEALTHY HUMAN-30	12	19	15	20	18
Phase 1 OTHER - 30 DAYS	133	121	114	130	144
Phase 1/2 - 30 DAYS	59	57	83	71	60
Phase 2 - 30 DAYS	304	292	310	298	302
Phase 2/3 - 30 DAYS	12	14	26	28	24
Phase 3 - 30 DAYS	465	412	496	463	478
Phase Other	19	21	29	29	25
Total	1031	954	1096	1051	1066

DECISION DOCUMENTS

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

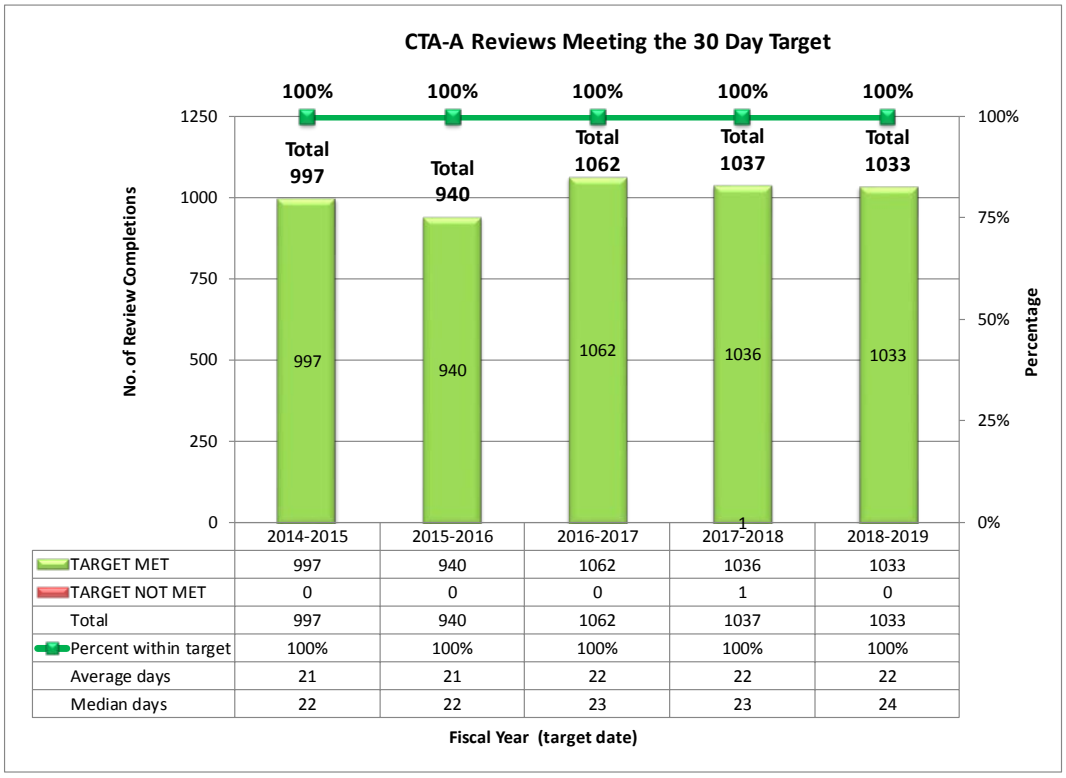
CTA-A (Total)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	1013	949	1070	1037	1032
CANCELLED BY COMPANY DURING REVIEW	11	9	15	11	15
CANCELLED BY COMPANY AT PROCESSING	4	0	0	1	3

CTA-A (7 day administrative target) Phase 1 Bioequivalence					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	26	18	23	12	12
CANCELLED BY COMPANY DURING REVIEW	0	0	0	0	2
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

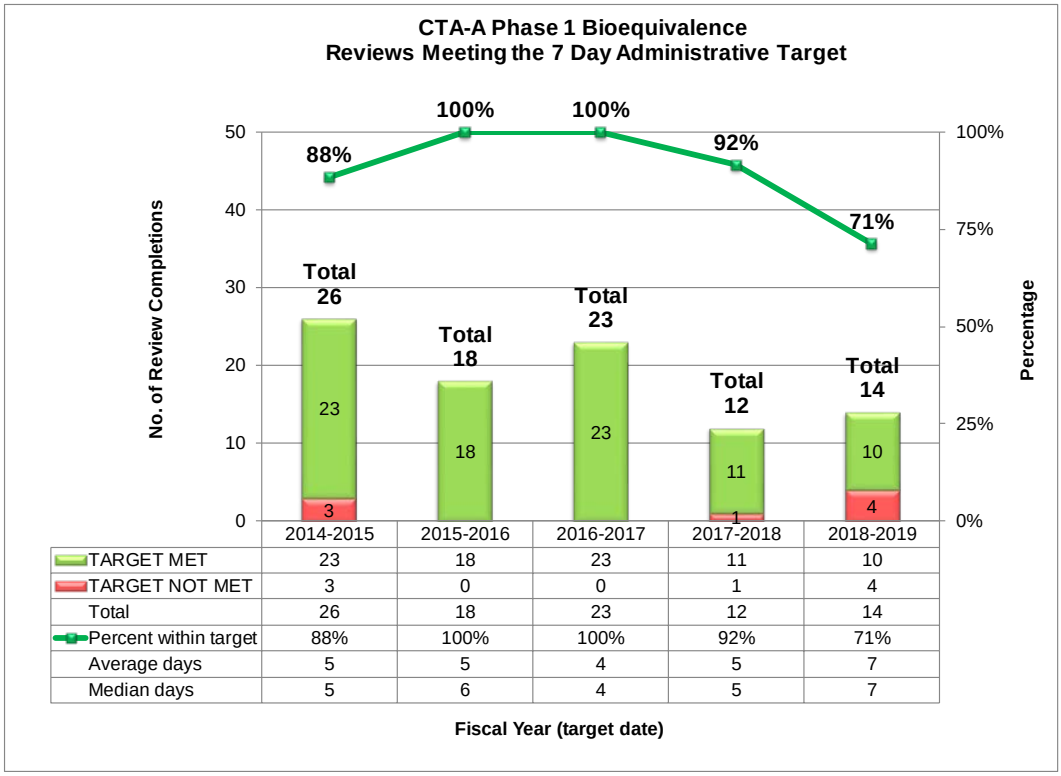
CTA-A (30 day target)					
DOCUMENT TYPE	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**
NO OBJECTION LETTER	987	931	1047	1025	1020
CANCELLED BY COMPANY DURING REVIEW	11	9	15	11	13
CANCELLED BY COMPANY AT PROCESSING	4	0	0	1	3

PERFORMANCE

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



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



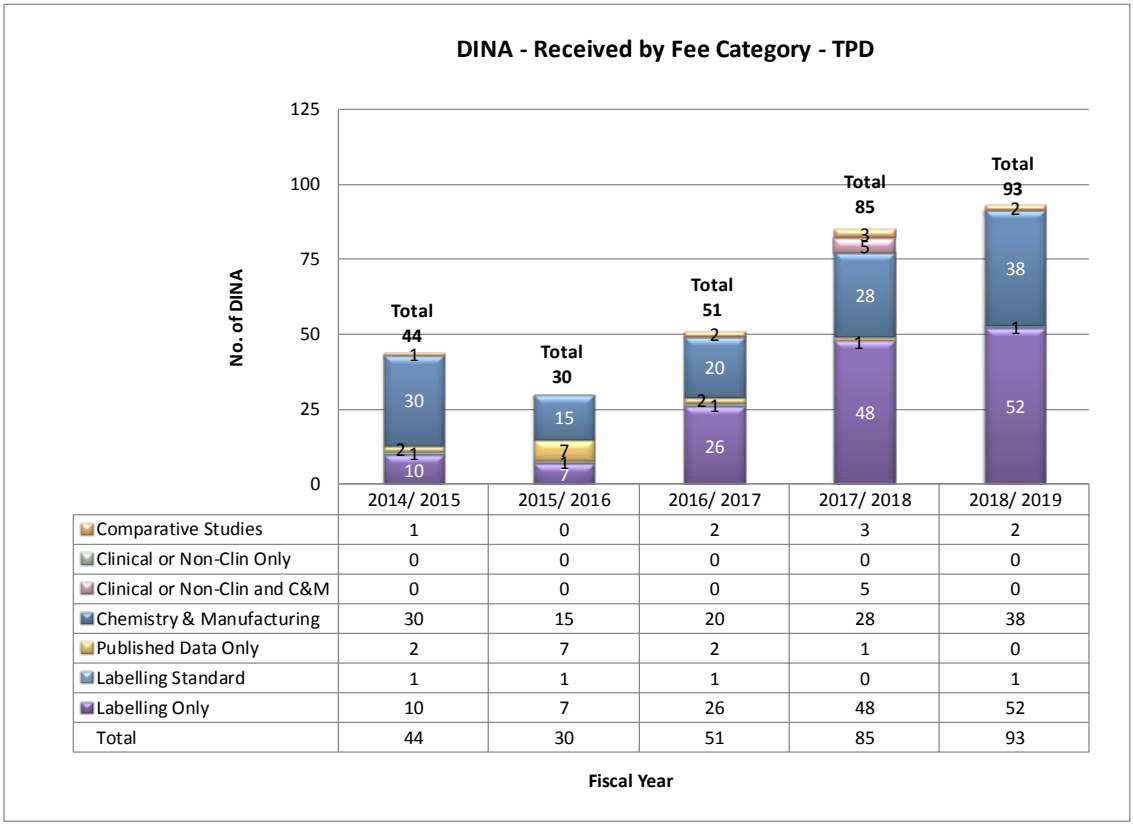
DINA

Application for a Drug Identification Number

Please note that TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report.

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

DINA: Number Received

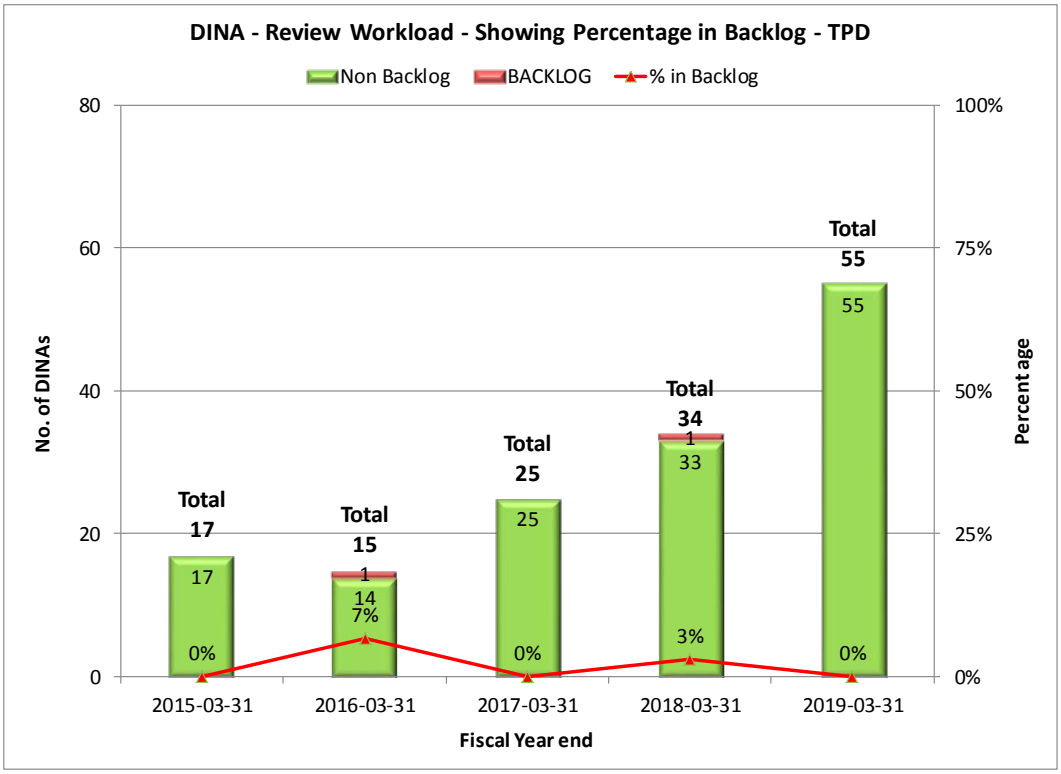


	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Comparative Studies	1	0	2	3	2
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	0	5	0
Chemistry & Manufacturing	30	15	20	28	38
Published Data Only	2	7	2	1	0
Labelling Standard	1	1	1	0	1
Labelling Only	10	7	26	48	52
Total	44	30	51	85	93

TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report.

REVIEW WORKLOAD

DINA: Review Workload / Backlog - Showing Percentage in Backlog

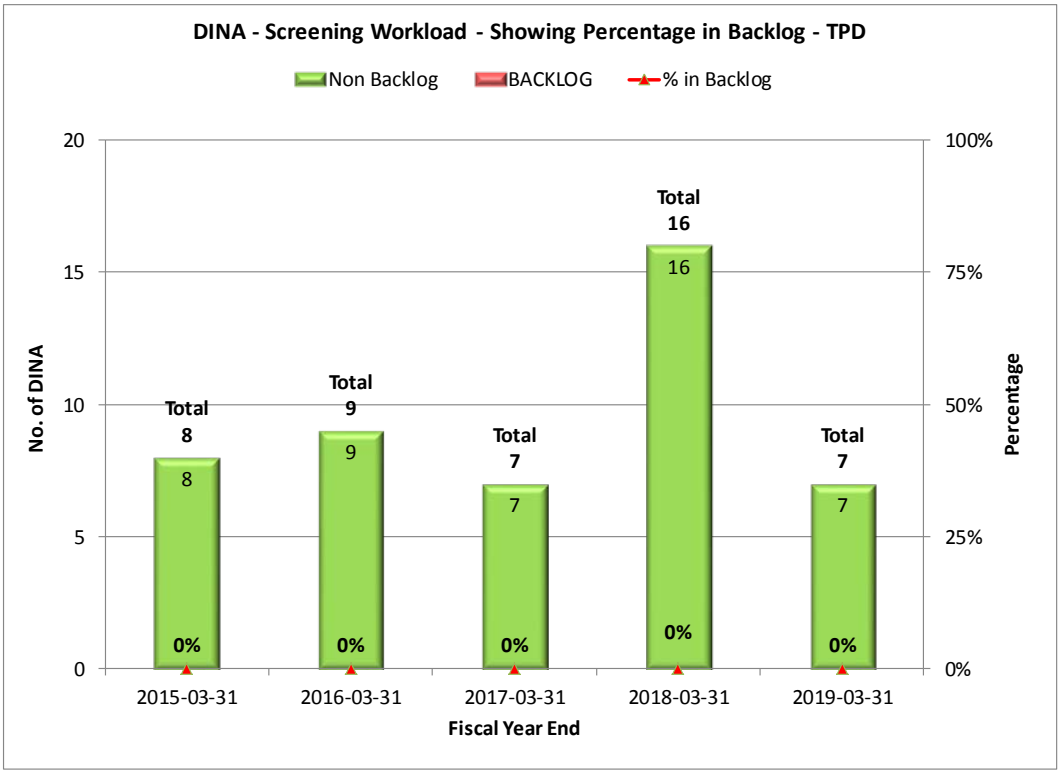


DINA: Review Workload by Class

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	**2**	**4**	**13**	**13**	**27**
Backlog	*0*	*0*	*0*	*1*	*0*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**14**	**9**	**12**	**19**	**26**
Backlog	*0*	*1*	*0*	*0*	*0*
Published Data	**0**	**1**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**1**	**0**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**17**	**15**	**25**	**34**	**55**
Non Backlog	**17**	**14**	**25**	**33**	**55**
BACKLOG	**0**	**1**	**0**	**1**	**0**
% in Backlog	**0%**	**7%**	**0%**	**3%**	**0%**

SCREENING WORKLOAD

DINA: Screening Workload Showing Percentage in Backlog



DINA: Screening Workload by Class

TPD DINA All SCREENING WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2015-03-31	2016-03-31	2017-03-31	2018-03-31	2019-03-31
Labelling Only	**3**	**1**	**4**	**8**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**5**	**2**	**4**	**3**
Backlog	**0**	**0**	**0**	**0**	**0**
Clinical or Non-Clinical Only	0	0	0	0	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	0	0	0	2	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	***1***	***3***	***0***	***0***	***0***
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**0**	**1**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**8**	**9**	**7**	**16**	**7**
Non Backlog	**8**	**9**	**7**	**16**	**7**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

CLASS	DOCUMENT TYPE	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
DINA - LABELLING ONLY	NOTIFICATION FORM/DIN ISSUED	4	1	3	12	9
	NO OBJECTION LETTER	6	5	4	25	29
	CANCELLED BY COMPANY		1	6	3	7
	DIN INCORR SUBTYPE-CLASS					
	NEW DRUG LETTER SCREEN					
	NON WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY	2		1		
	NOTICE OF NON-COMPLIANCE			1		2
	REJECTION LETTER (SCREENING)				1	
	SCREENING DEFICIENCY NOTICE	4	2	9	8	6
	SPONSOR SUB CHANGE ACCEPT					
DINA - LABELLING STANDARD	NOTIFICATION FORM/DIN ISSUED					
	NO OBJECTION LETTER					
	NEW DRUG LETTER SCREEN					
	REJECTION LETTER (SCREENING)			1		
	SCREENING DEFICIENCY NOTICE	1				
	SPONSOR SUB CHANGE ACCEPT					
	DIN INCORR SUBTYPE-CLASS					
	CANCELLED BY COMPANY	1				
DINA - PUBLISHED DATA ONLY	NO OBJECTION LETTER		3	2		1
	NOTICE OF DEFICIENCY					
	NON WITHDRAWAL LETTER					
	REJECTION LETTER (SCREENING)	1				
	SCREENING DEFICIENCY NOTICE				1	
	CANCELLED BY COMPANY		1	1		
	NOTICE OF NON-COMPLIANCE		1	1		
	NOT SATISFACTORY NOTICE			1		
DINA - CHEMISTRY & MANUFACTURING	NOTIFICATION FORM/DIN ISSUED	17	12	6	13	12
	NOD WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY	3	2	1	2	3
	REJECTION LETTER (SCREENING)			3		
	SCREENING DEFICIENCY NOTICE	11	12	17	9	7
	CANCELLED BY COMPANY		3	4	3	7
	NO OBJECTION LETTER	8	6	5	3	11
	NEW DRUG LETTER SCREEN					
	NEW DRUG LETTER REVIEW				1	
	NOTICE OF NON-COMPLIANCE	3	4	8	6	7
	NON WITHDRAWAL LETTER			1	2	2
DINA - CLINICAL OR NON CLINICAL DATA AND C&M	CANCELLED BY COMPANY				1	1
	SCREENING DEFICIENCY NOTICE				2	2
	NOTICE OF NON-COMPLIANCE					2
	NOTIFICATION FORM/DIN ISSUED					1
DINA - COMPARATIVE STUDIES	NOTIFICATION FORM/DIN ISSUED	2	1	2	1	2
	NO OBJECTION LETTER					
	NOTICE OF DEFICIENCY	1	1			
	NOTICE OF NON-COMPLIANCE				1	1
	SCREENING DEFICIENCY NOTICE			1	3	2
	NON WITHDRAWAL LETTER					1
	CANCELLED BY COMPANY					1

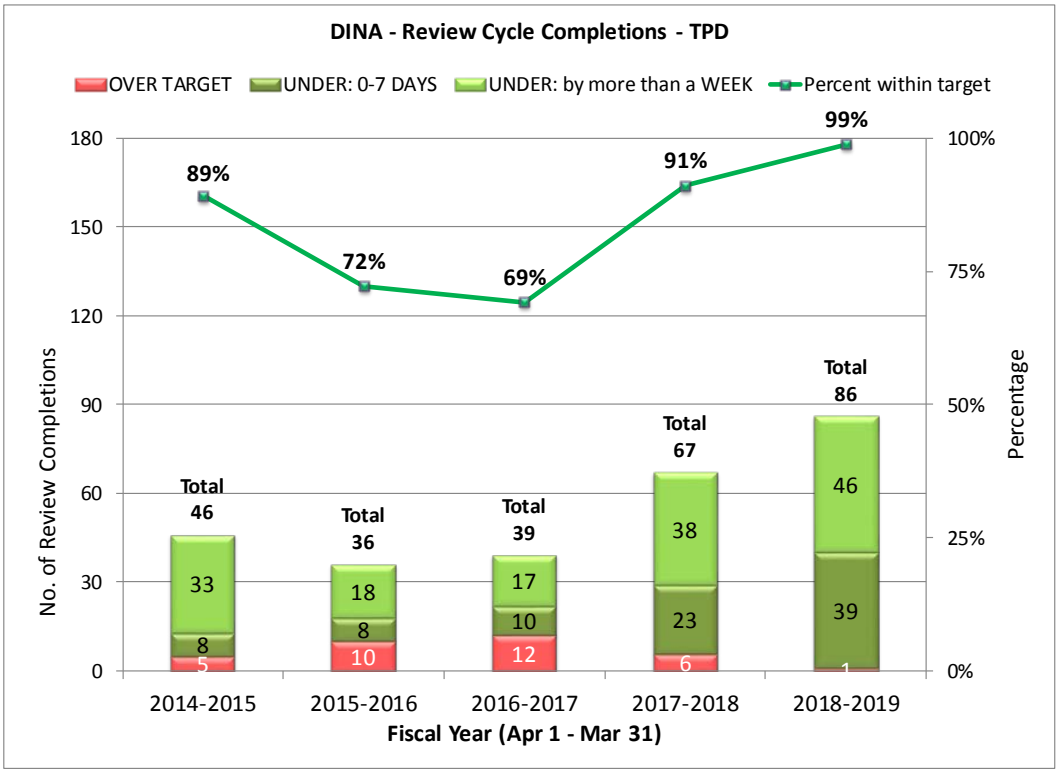
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Requests for Reconsideration of Final Decisions

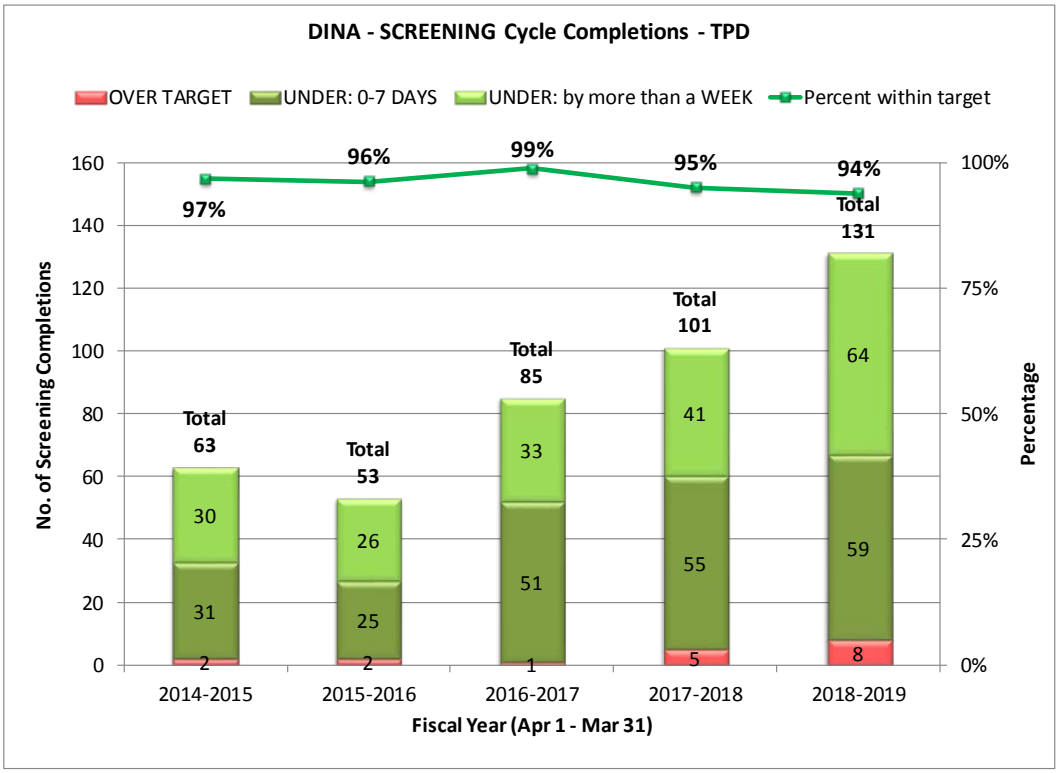
DINA - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**14-15**	**15-16**	**16-17**	**17-18**	**18-19**	**Final Decision in Dispute**	**Submission Status (as of May 2019)**
Total Received	**1**	**0**	**1**	**1**	**0**		
Total Granted	***0***	***0***	***1***	***1***	***0***		
	0	0	0	1	0	New Drug Letter	Cancelled by Company
	0	0	1	0	0	NON-Withdrawal	Cleared
Total Denied	***0***	***0***	***0***	***0***	***0***		
Total Cancelled	***1***	***0***	***0***	***0***	***0***		
Cancelled by Health Canada	1	0	0	0	0	New Drug Letter	Withdrawn

PERFORMANCE

DINA: Review Cycle Completions

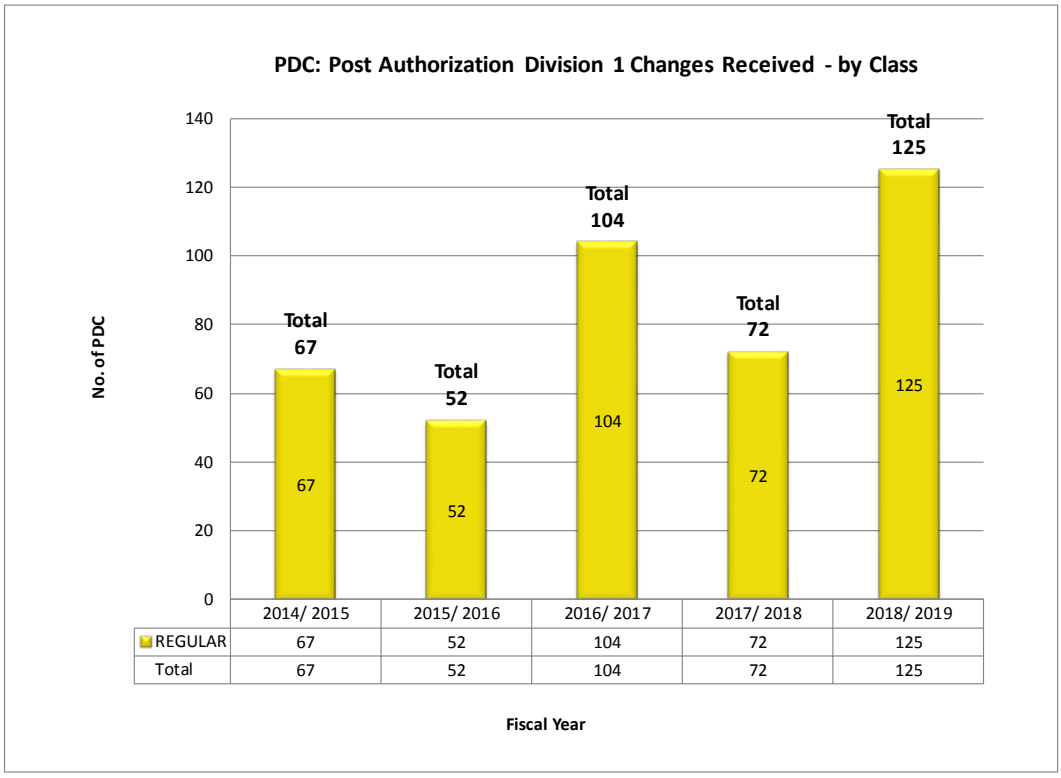


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGES

Post-Authorization Division 1 Changes (PDC) Received



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

DOCUMENT TYPE	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
REGULAR					
CANCELLED BY COMPANY	7	11	18	15	20
NO OBJECTION LETTER	67	43	80	35	131
NOT SATISFACTORY NOTICE			1		
NOTIFICATION FORM/DIN ISSUED					
REJECTION LETTER (SCREENING)					

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – Post-Authorization Division 1 Changes (PDC)

PDC - Reconsideration of Final Decisions by Year Requested

Fiscal Year of Request (April 1 - March 31)

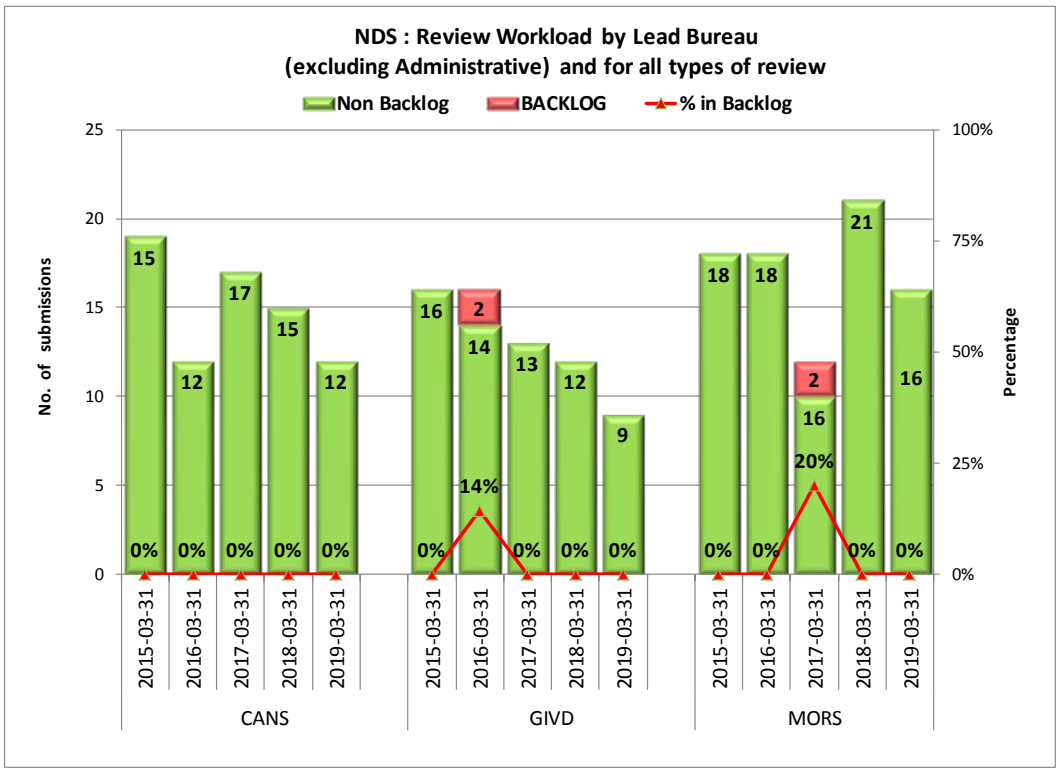
Breakdown by Reconsideration Decision	14-15	15-16	16-17	17-18	18-19	Final Decision in Dispute	Submission Status (as of May 2019)
Total Received	**0**	**0**	**0**	**0**	**0**		

APPENDIX A - Lead Bureau Summaries

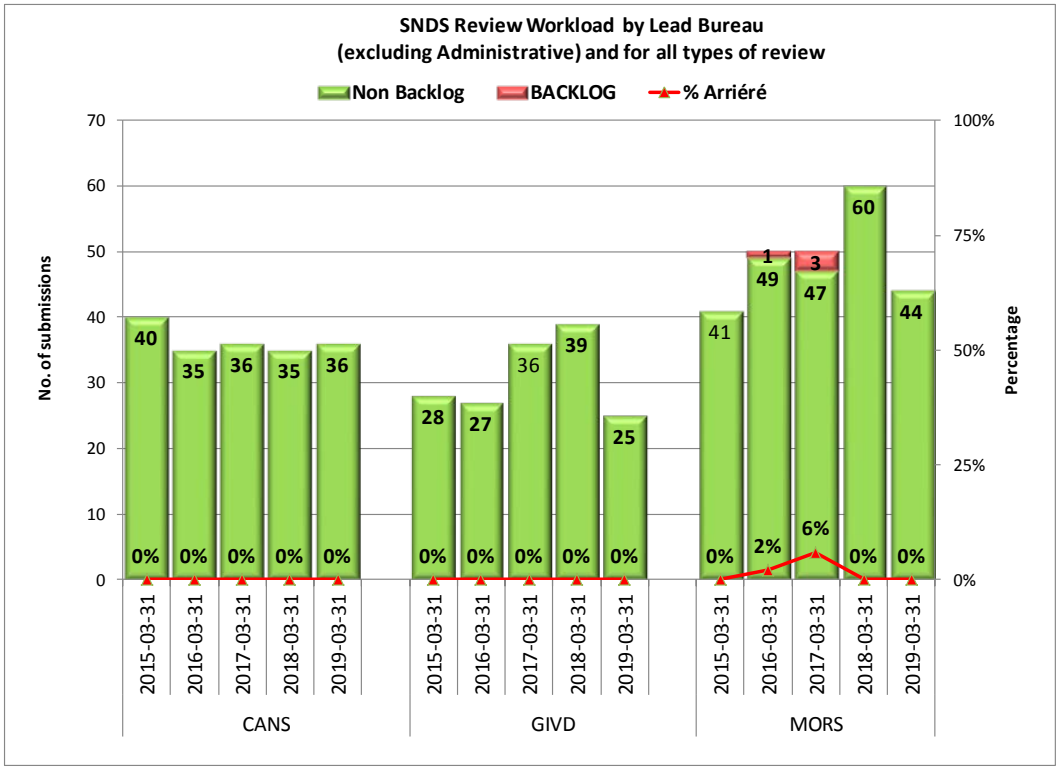
NDS & SNDS

WORKLOAD by Lead Bureau

NDS Review Workload by Lead Bureau

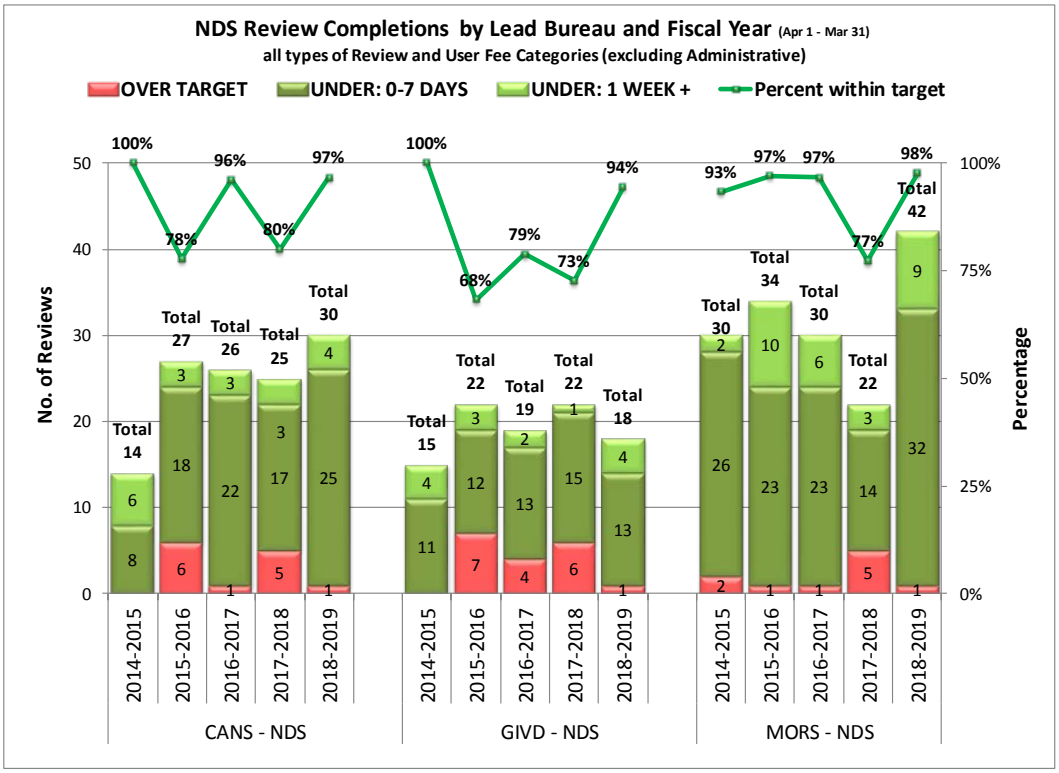


SNDS Review Workload by Lead Bureau

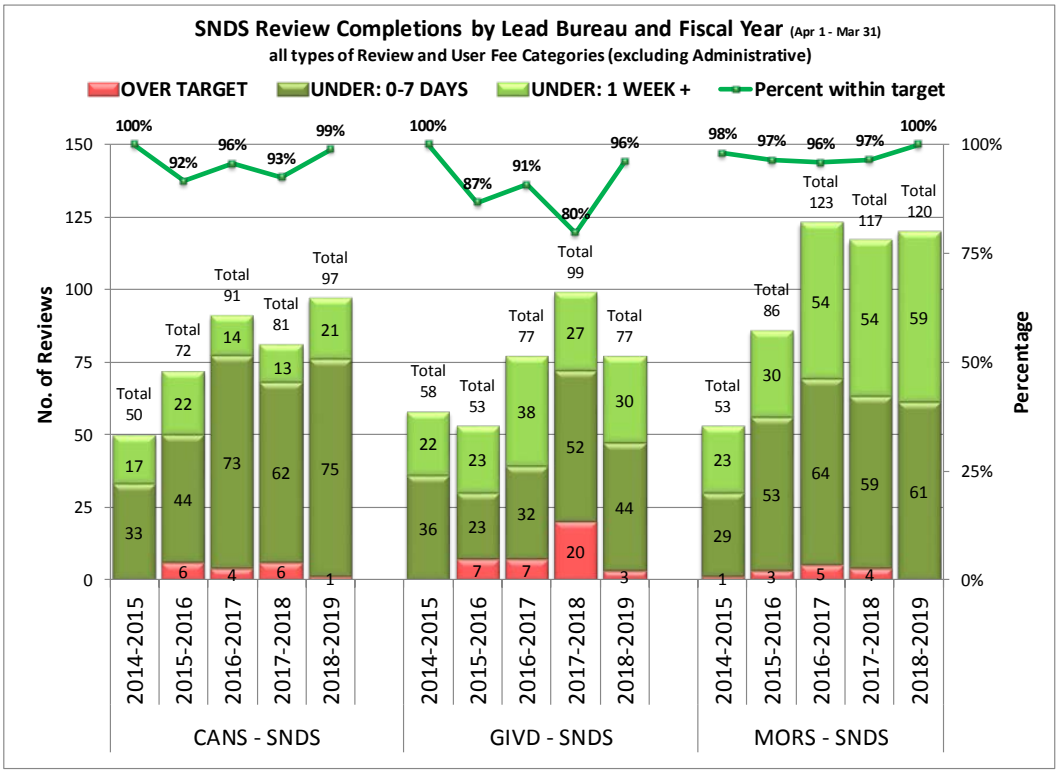


PERFORMANCE by Lead Bureau

NDS Review Performance by Lead Bureau

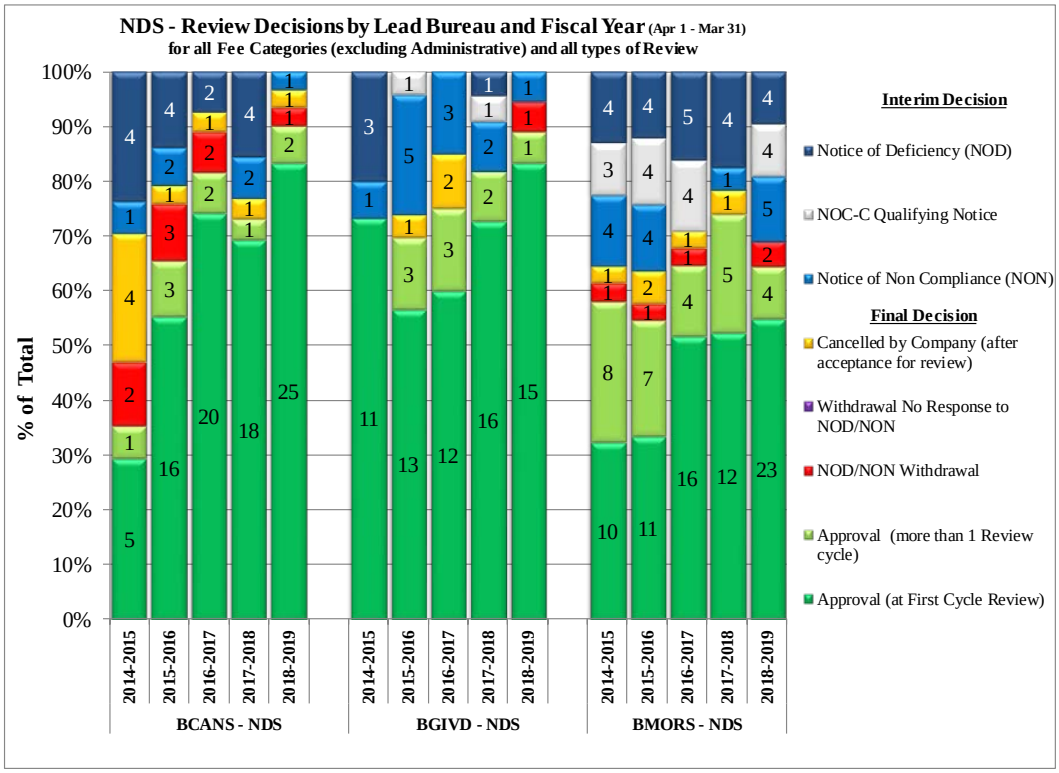


SNDS Review Performance by Lead Bureau

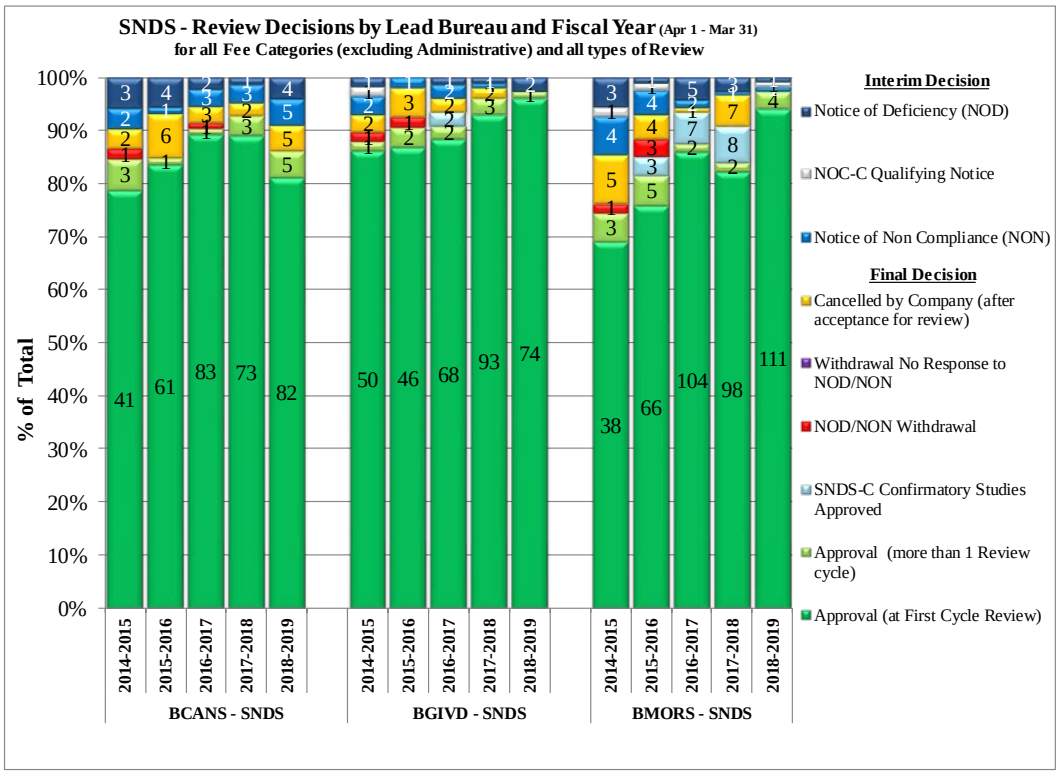


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

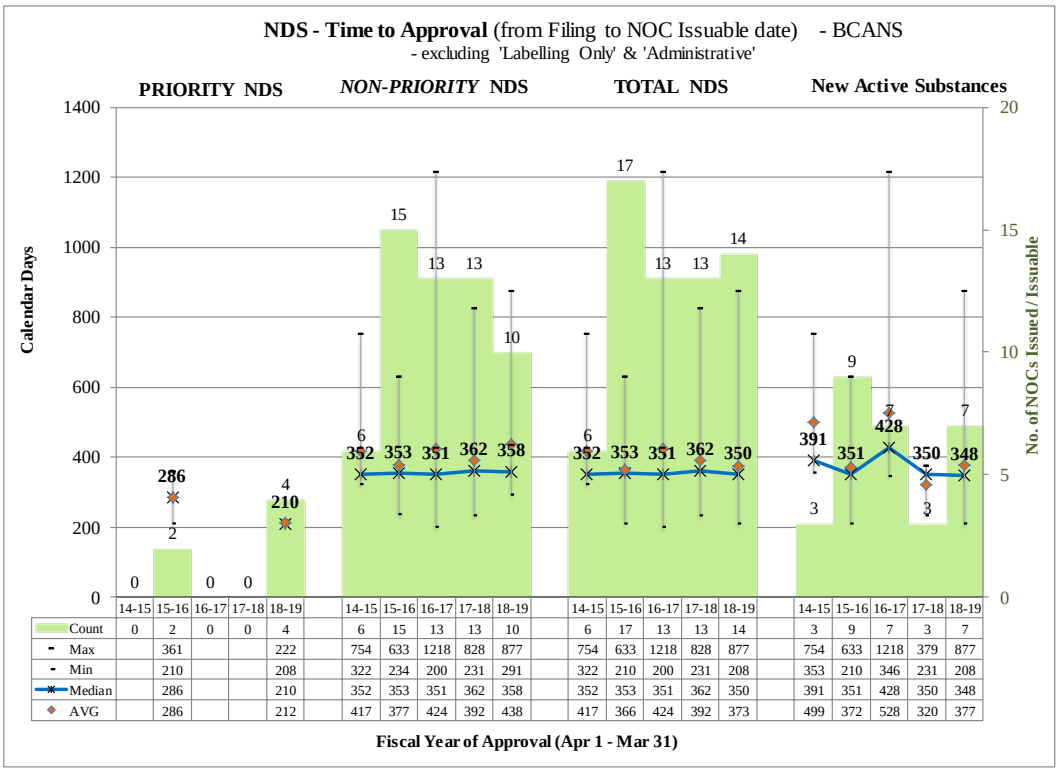


SNDS Review Decisions by Lead Bureau



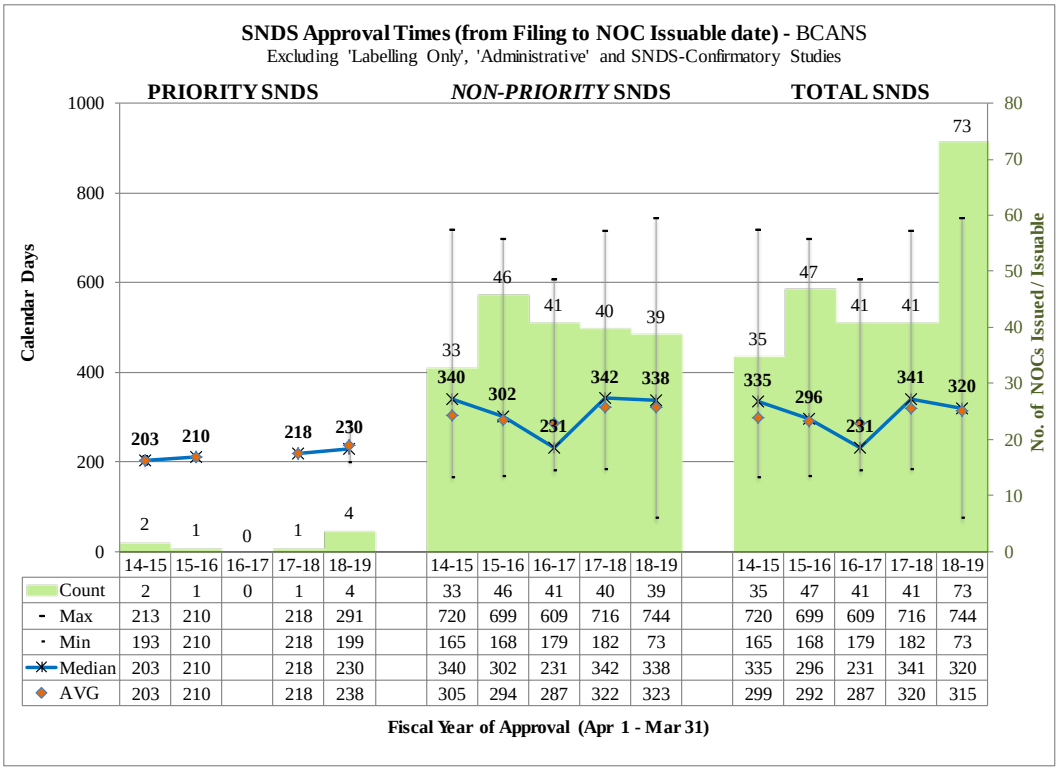
APPROVALS by Lead Bureau

NDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	0	2	0	0	4	6	15	13	13	10	6	17	13	13	14	3	9	7	3	7
Max		361			222	754	633	1218	828	877	754	633	1218	828	877	754	633	1218	379	877
Min		210			208	322	234	200	231	291	322	210	200	231	208	353	210	346	231	208
Median		286			210	352	353	351	362	358	352	353	351	362	350	391	351	428	350	348
AVG		286			212	417	377	424	392	438	417	366	424	392	373	499	372	528	320	377

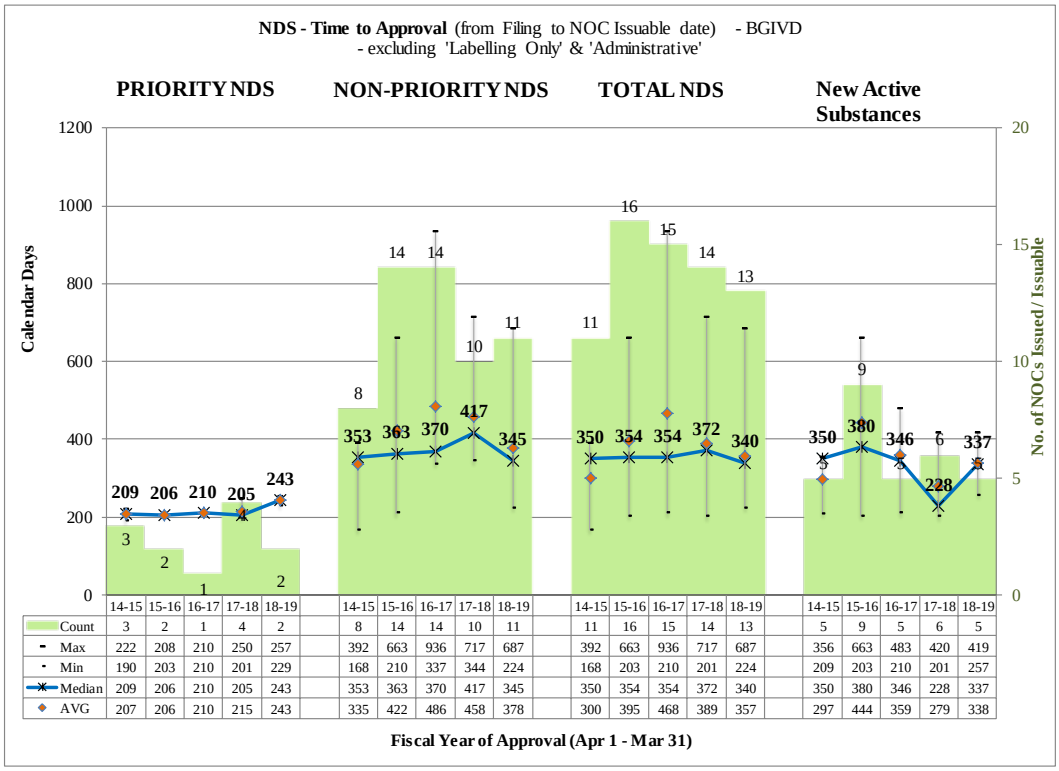
SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	2	1	0	1	4	33	46	41	40	39	35	47	41	41	73
Max	213	210		218	291	720	699	609	716	744	720	699	609	716	744
Min	193	210		218	199	165	168	179	182	73	165	168	179	182	73
Median	203	210		218	230	340	302	231	342	338	335	296	231	341	320
AVG	203	210		218	238	305	294	287	322	323	299	292	287	320	315

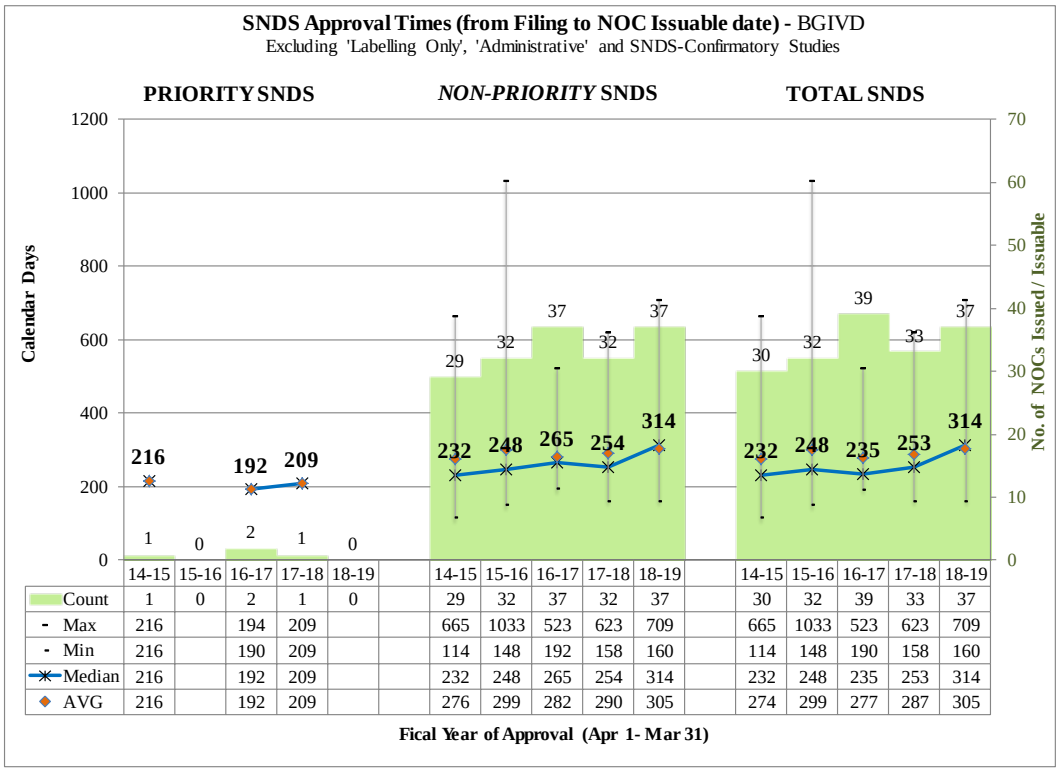
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

NDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	PRIORITY NDS					NON-PRIORITY NDS					TOTAL NDS					New Active Substances				
	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	3	2	1	4	2	8	14	14	10	11	11	16	15	14	13	5	9	5	6	5
Max	222	208	210	250	257	392	663	936	717	687	392	663	936	717	687	356	663	483	420	419
Min	190	203	210	201	229	168	210	337	344	224	168	203	210	201	224	209	203	210	201	257
Median	209	206	210	205	243	353	363	370	417	345	350	354	354	372	340	350	380	346	228	337
AVG	207	206	210	215	243	335	422	486	458	378	300	395	468	389	357	297	444	359	279	338

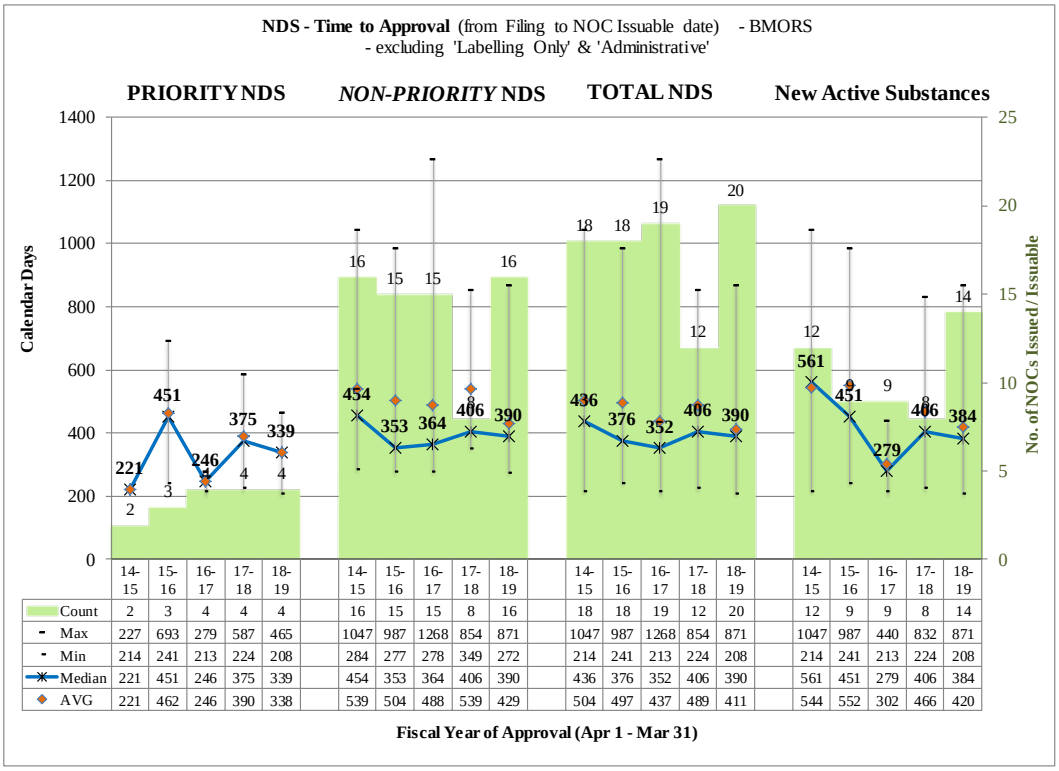
SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	PRIORITY SNDS					NON-PRIORITY SNDS					TOTAL SNDS				
	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	1	0	2	1	0	29	32	37	32	37	30	32	39	33	37
Max	216		194	209		665	1033	523	623	709	665	1033	523	623	709
Min	216		190	209		114	148	192	158	160	114	148	190	158	160
Median	216		192	209		232	248	265	254	314	232	248	235	253	314
AVG	216		192	209		276	299	282	290	305	274	299	277	287	305

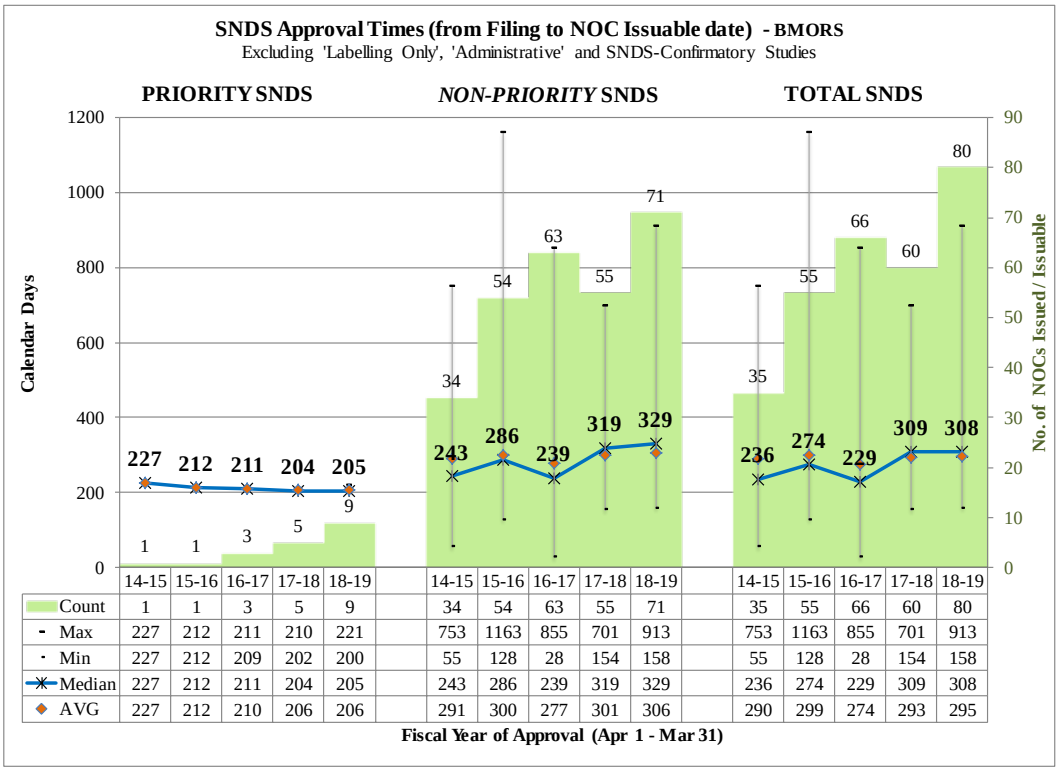
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	2	3	4	4	4	16	15	15	8	16	18	18	19	12	20	12	9	9	8	14
Max	227	693	279	587	465	1047	987	1268	854	871	1047	987	1268	854	871	1047	987	440	832	871
Min	214	241	213	224	208	284	277	278	349	272	214	241	213	224	208	214	241	213	224	208
Median	221	451	246	375	339	454	353	364	406	390	436	376	352	406	390	561	451	279	406	384
AVG	221	462	246	390	338	539	504	488	539	429	504	497	437	489	411	544	552	302	466	420

SNDS Approvals – Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)



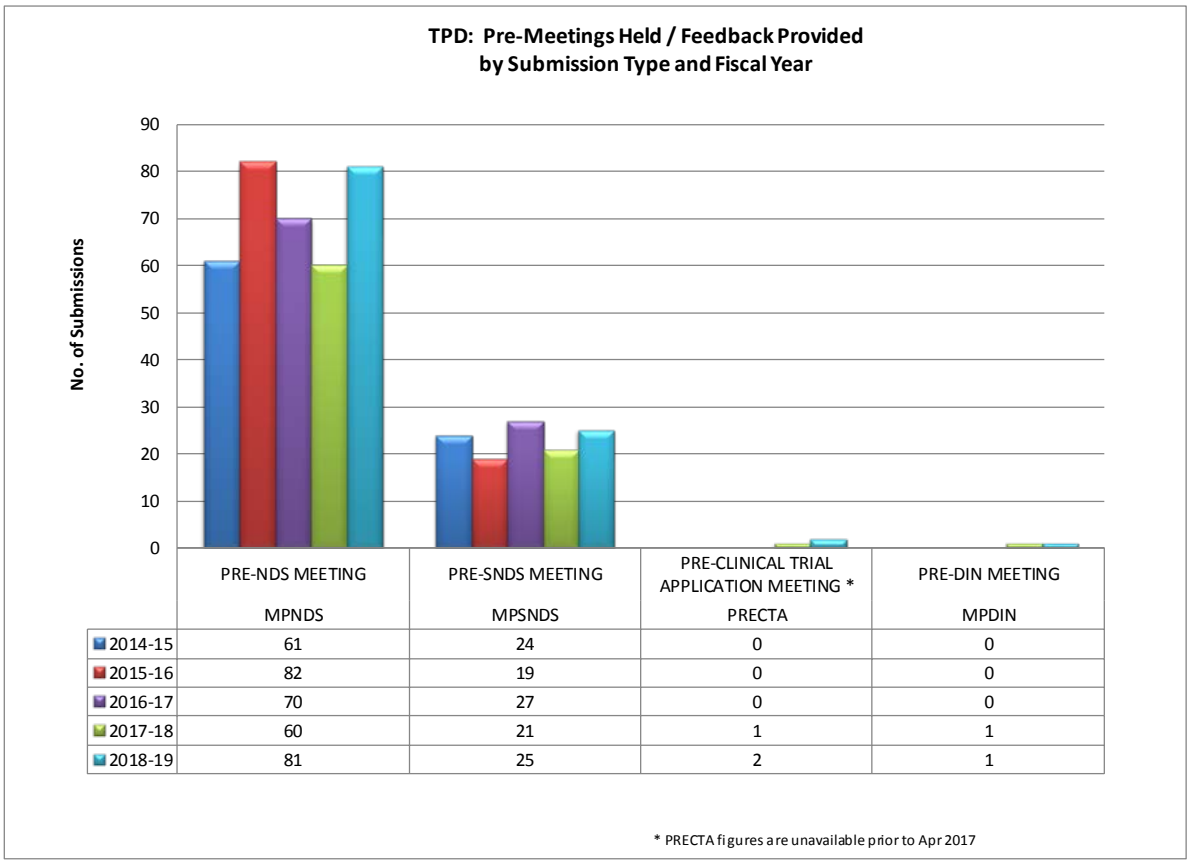
	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19	14-15	15-16	16-17	17-18	18-19
Count	1	1	3	5	9	34	54	63	55	71	35	55	66	60	80
Max	227	212	211	210	221	753	1163	855	701	913	753	1163	855	701	913
Min	227	212	209	202	200	55	128	28	154	158	55	128	28	154	158
Median	227	212	211	204	205	243	286	239	319	329	236	274	229	309	308
AVG	227	212	210	206	206	291	300	277	301	306	290	299	274	293	295

Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor

Appendix B: Pre-submission Meetings

13

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-CLINICAL TRIAL APPLICATION MEETING * PRECTA	PRE-DIN MEETING MPDIN
2014-15	61	24	0	0
2015-16	82	19	0	0
2016-17	70	27	0	0
2017-18	60	21	1	1
2018-19	81	25	2	1

.

[13] Prior to filing a submission, a sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the Guidance for Industry: Management of Drug Submissions

This page is left blank intentionally.