Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2017-2018

April 1 2017 – March 31 2018

Canada

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Également disponible en français sous le titre :
Direction des produits thérapeutiques – Rapport annuel du rendement des présentations de drogue – Exercice financier 2017-2018

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Publication date: May 2018

Cat H166-2E-PDF
ISSN 2561-7613
Pub 180077

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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 2013-2014 to 2017-2018.

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 2017-2018 fiscal year (from April 1 2017 to March 31 2018).

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, Therapeutic Products 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)

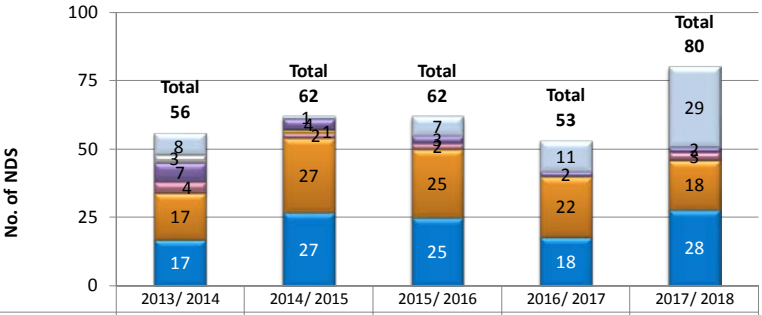
&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED

[9] [10]

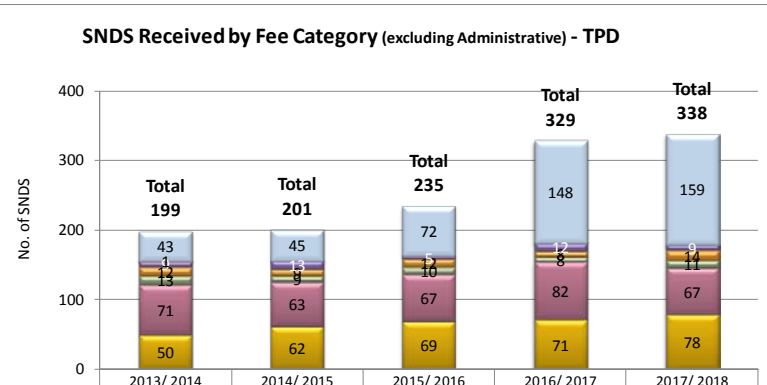
New Drug Submissions (NDS) Received by Fee Category



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Only	8	1	7	11	29
Disinfectants	3				
Comparative Studies	7	4	3	2	2
Clinical or Non-Clin Only		1			
Chemistry & Manufacturing	4	2	2		3
Clinical or Non-Clin and C&M	17	27	25	22	18
New Active Substance	17	27	25	18 *	28
Total	56	62	62	53	80
Priority (subset)	6	8	8	5	10
NOC/c Class	1	2	4	1	2
Emergency Use (NDS)	0	1	0	0	0

*revised Apr 2018

Supplemental New Drug Submissions (SNDS) Received by Fee Category



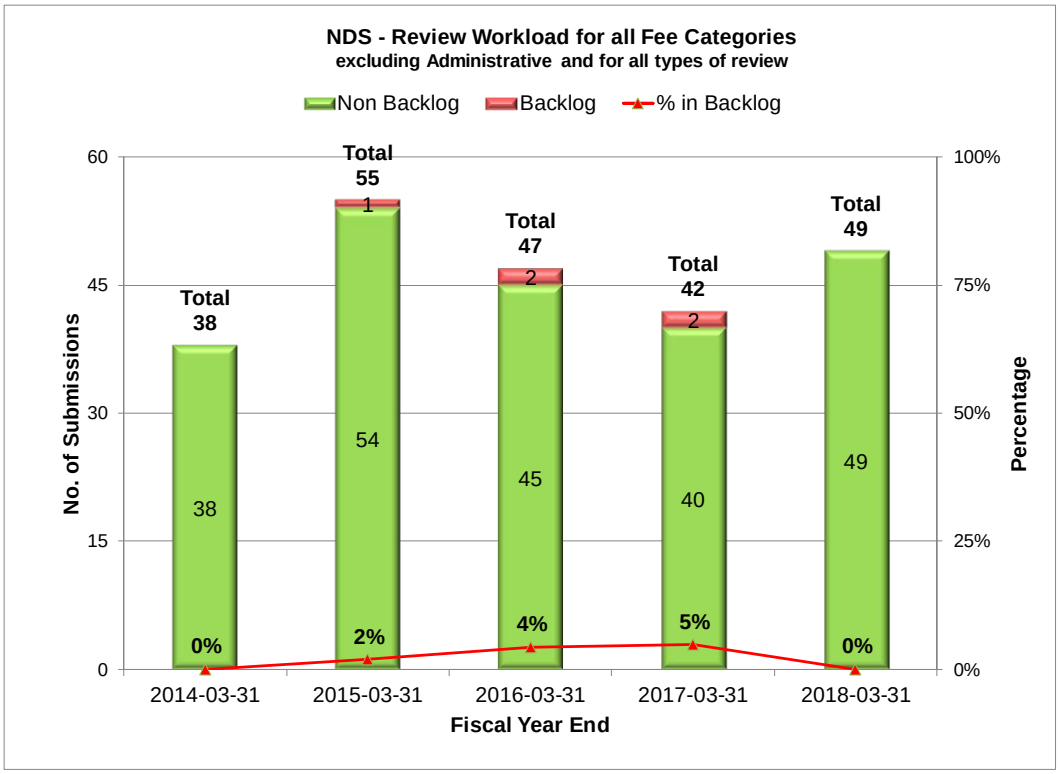
	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Only	43	45	72	148	159
Switch from Rx to OTC	1				
Disinfectants	0	0	0	0	0
Comparative Studies	9	13	5	12	9
Clinical or Non-Clin and C&M	12	9	12	8	14
Published Data Only	13	9	10	8	11
Chemistry & Manufacturing	71	63	67	82	67
Clinical or Non-Clin Only	50	62	69	71	78
Total	199	201	235	329	338
Priority (subset)	2	4	5	5	9
NOC/c Class	0	2	0	0	2
*SNDS Confirmatory	1	3	6	9	3

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

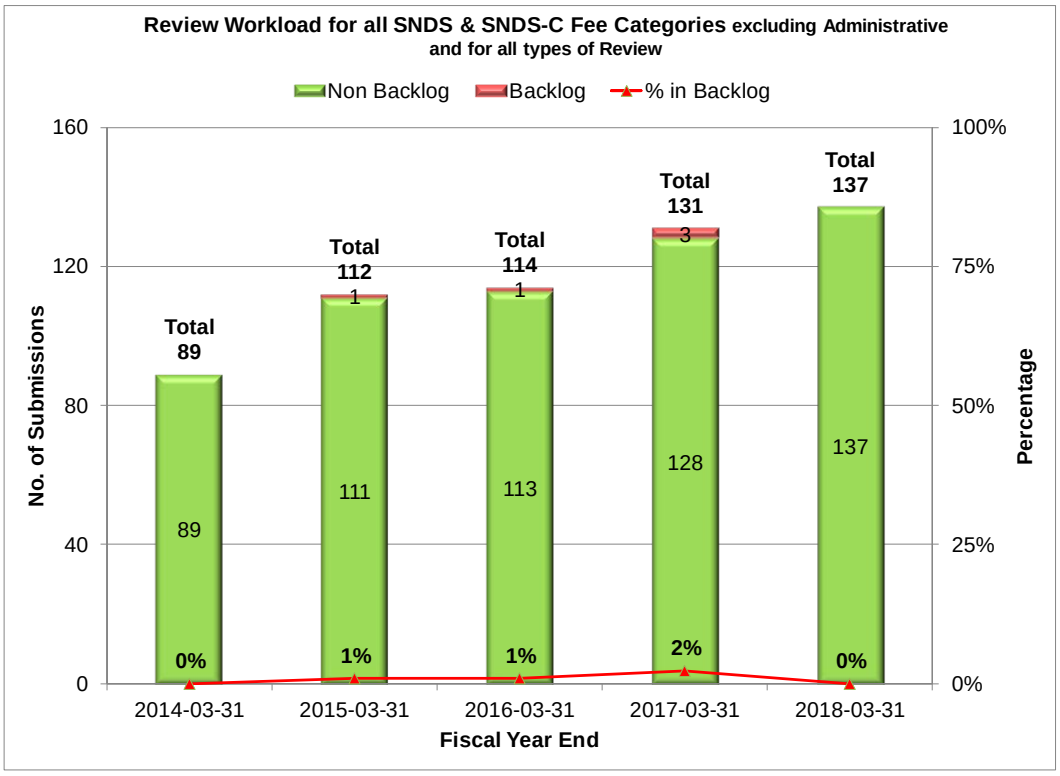
[10] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

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

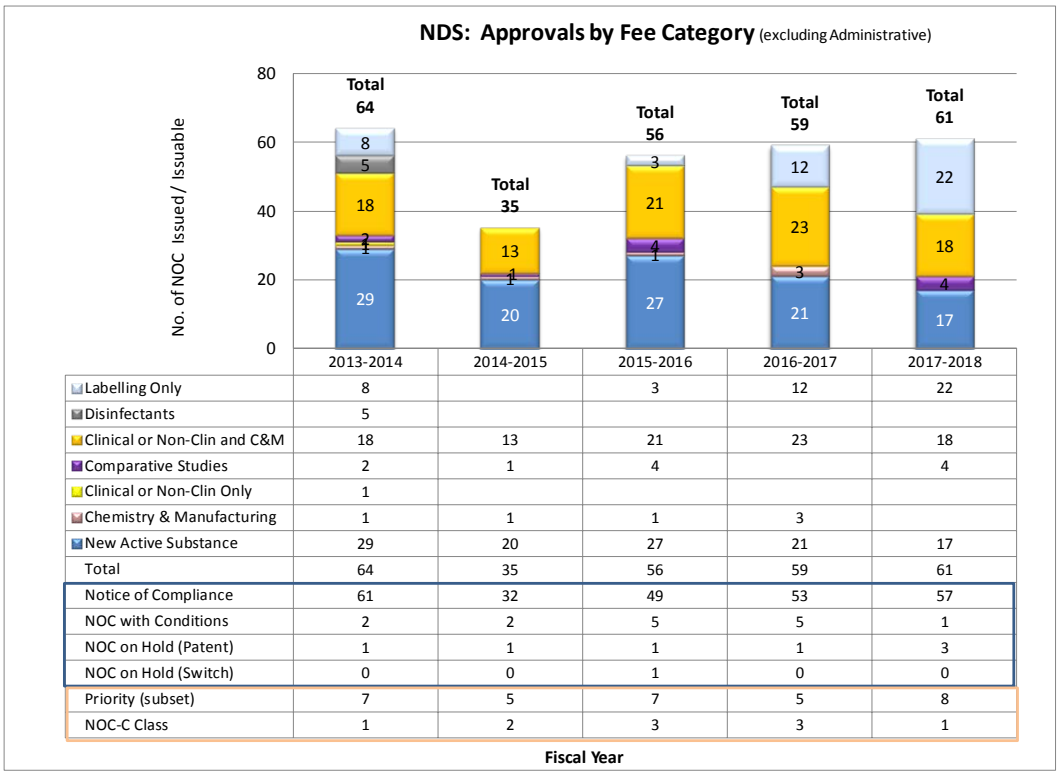
TPD NDS: All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	0	1	3	1	4
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	3	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	3	2	0	3	1
Backlog	*0*	*1*	*0*	*0*	*0*
Chemistry & Manufacturing	3	2	3	0	1
Backlog	*0*	*0*	*2*	*0*	*0*
Clinical or Non-Clin Only	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	15	26	24	19	18
Backlog	*0*	*0*	*0*	*1*	*0*
New Active Substance	14	23	17	19	25
Backlog	*0*	*0*	*0*	*1*	*0*
Total	**38**	**55**	**47**	**42**	**49**
Non Backlog	**38**	**54**	**45**	**40**	**49**
Backlog	**0**	**1**	**2**	**2**	**0**
% in Backlog	**0%**	**2%**	**4%**	**5%**	**0%**
Priority (subset)	0	4	4	6	6
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					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**7**	**9**	**13**	**22**	**19**
Backlog	*0*	*0*	*1*	*1*	*0*
Comparative Studies	**4**	**8**	**1**	**7**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**22**	**29**	**31**	**34**	**30**
Backlog	*0*	*1*	*0*	*0*	*0*
Clinical or Non-Clin Only	**39**	**51**	**50**	**53**	**63**
Backlog	*0*	*0*	*0*	*2*	*0*
Clinical or Non-Clin and C&M	**10**	**9**	**12**	**8**	**11**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	**7**	**6**	**7**	**7**	**10**
Backlog	0	0	0	0	0
Total	**89**	**112**	**114**	**131**	**137**
Non Backlog	**89**	**111**	**113**	**128**	**137**
Backlog	**0**	**1**	**1**	**3**	**0**
% in Backlog	**0%**	**1%**	**1%**	**2%**	**0%**
Priority (subset)	1	2	5	4	7
Backlog	0	0	0	0	0
***SNDS-C (Confirmatory)**	0	3	6	6	3
Backlog	0	0	0	0	0

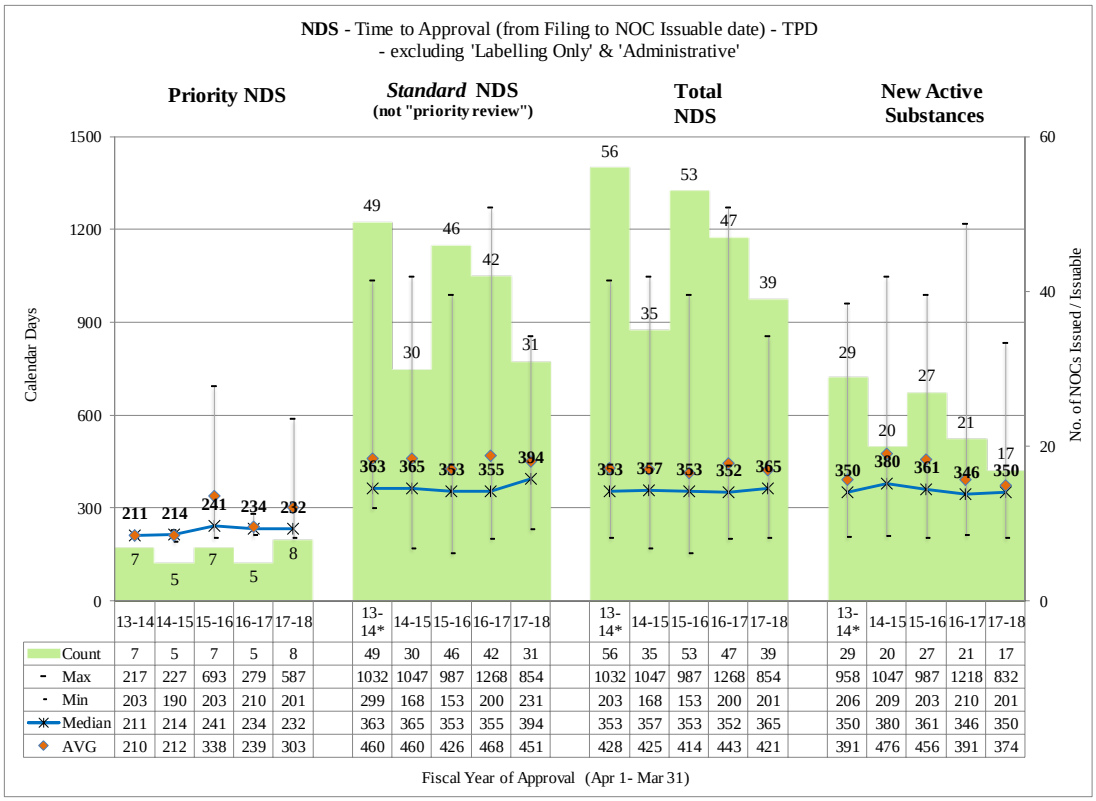
APPROVALS

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only	8		3	12	22
Disinfectants	5				
Clinical or Non-Clin and C&M	18	13	21	23	18
Comparative Studies	2	1	4		4
Clinical or Non-Clin Only	1				
Chemistry & Manufacturing	1	1	1	3	
New Active Substance	29	20	27	21	17
Total	64	35	56	59	61
Notice of Compliance	61	32	49	53	57
NOC with Conditions	2	2	5	5	1
NOC on Hold (Patent)	1	1	1	1	3
NOC on Hold (Switch)	0	0	1	0	0
Priority (subset)	7	5	7	5	8
NOC-C Class	1	2	3	3	1

NDS Approval Times

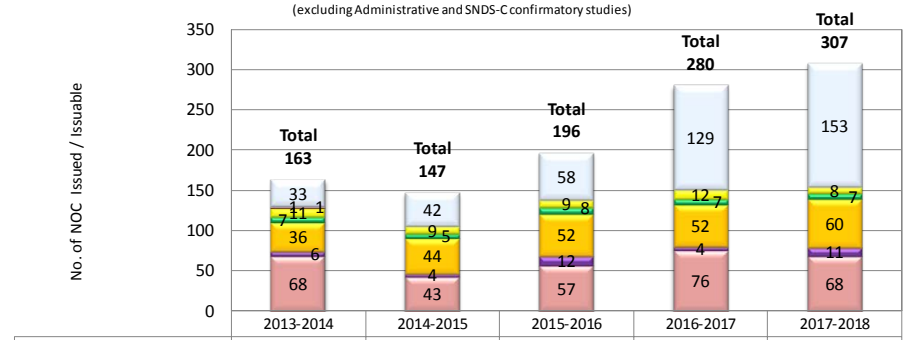


	13-14	14-15	15-16	16-17	17-18	13-14*	14-15	15-16	16-17	17-18	13-14*	14-15	15-16	16-17	17-18	13-14*	14-15	15-16	16-17	17-18
Count	7	5	7	5	8	49	30	46	42	31	56	35	53	47	39	29	20	27	21	17
Max	217	227	693	279	587	1032	1047	987	1268	854	1032	1047	987	1268	854	958	1047	987	1218	832
Min	203	190	203	210	201	299	168	153	200	231	203	168	153	200	201	206	209	203	210	201
Median	211	214	241	234	232	363	365	353	355	394	353	357	353	352	365	350	380	361	346	350
AVG	210	212	338	239	303	460	460	426	468	451	428	425	414	443	421	391	476	456	391	374

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.

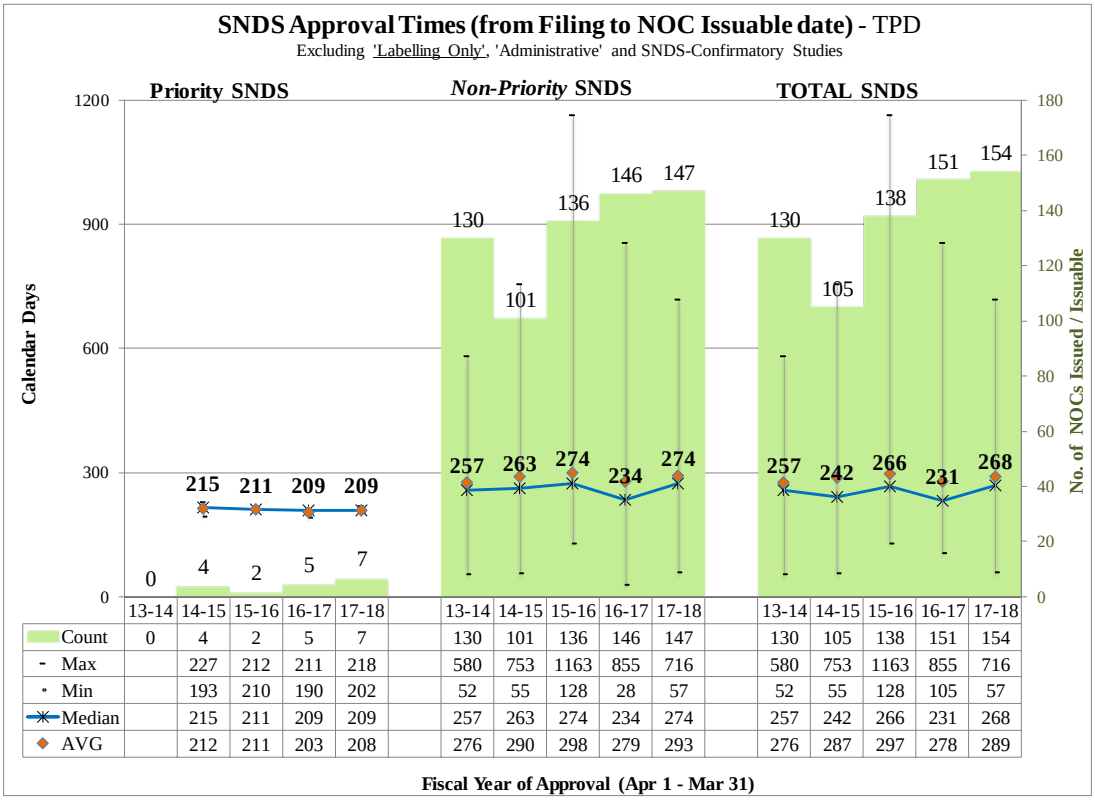
*One outlier is included for fiscal year 2013-14. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this "outlier NDS", the dates used to calculate the time to approval are the date the screening resumed and the date the submission was placed on intellectual property hold.

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only	33	42	58	129	153
Disinfectants	1				
Switch from Rx to OTC	1				
Clinical or Non-Clin and C&M	11	9	9	12	8
Published Data Only	7	5	8	7	7
Clinical or Non-Clin Only	36	44	52	52	60
Comparative Studies	6	4	12	4	11
Chemistry & Manufacturing	68	43	57	76	68
Total	163	147	196	280	307
Notice of Compliance	156	141	190	279	304
NOC on Hold (Patent)	1	1	1	0	0
NOC on Hold (Switch)	4	0	0	0	0
NOC with Conditions	2	5	5	1	3
Priority (subset)	0	4	2 *correction from 0 to 2	5	7
NOC-C Class	0	1	1	0	0

SNDS Approval Times



	13-14	14-15	15-16	16-17	17-18		13-14	14-15	15-16	16-17	17-18		13-14	14-15	15-16	16-17	17-18
Count	0	4	2	5	7		130	101	136	146	147		130	105	138	151	154
Max		227	212	211	218		580	753	1163	855	716		580	753	1163	855	716
Min		193	210	190	202		52	55	128	28	57		52	55	128	105	57
Median		215	211	209	209		257	263	274	234	274		257	242	266	231	268
AVG		212	211	203	208		276	290	298	279	293		276	287	297	278	289

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 .

New Active Substance (NAS) Approvals

And

Priority Submission Approvals

New Active Substance (NAS) Approvals - TPD - Fiscal Year 2017-2018

New Active Substance Approvals – TPD Fiscal Year 2017-2018 (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[11]) Date**	**Approval Date (dd-mon-yy)**
ADDYI (Flibanserin) - is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire for a minimum of 6 months, which occurs 75-100% of the time, that causes marked distress or interpersonal difficulty and is NOT due to: a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.	NAS	Sprout Pharmaceuticals Inc.	18-Nov-15	27-Feb-18
ADLYXINE (Lixisenatide) - is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus in combination with: metformin, a sulfonylurea (alone or with metformin), pioglitazone (alone or with metformin), a basal insulin (alone or with metformin), when the therapy listed above does not provide adequate glycemic control.	NAS	Sanofi-Aventis Canada Inc.	26-Apr-16	25-May-17
AKYNZEO (Netupitant, Palonosetron (as Palonosetron Hydrochloride) - in combination with dexamethasone, is indicated for once-per-cycle treatment in adult patients for: prevention of acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of acute nausea and vomiting associated with moderately emetogenic cancer therapy that is uncontrolled by a 5-HT3 receptor antagonist alone.	NAS	Purdue Pharma	13-Oct-16	28-Sep-17
CERDELGA (Eliglustat as Eliglustat Tartrate) - is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolizers (PMs), intermediate metabolizers (IMs) or extensive metabolizers (EMs), as determined by CYP2D6 genotype testing.	NAS	Sanofi Genzyme, a Division of Sanofi-Aventis Canada Inc.	19-Mar-15	21-Apr-17
GALAFOLD **(Migalastat as Migalastat Hydrochloride)** - is indicated for long-term treatment of adults with a confirmed diagnosis of Fabry disease [deficiency of α-galactosidase (α-Gal A)] and who have an α-Gal A mutation determined to be amenable by an in vitro assay.	NAS	Amicus Therapeutics UK Ltd.	15-Jul-16	5-Sep-17

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

New Active Substance Approvals – TPD
Fiscal Year 2017-2018
(April 1 2017 – March 31 2018)

Brand Name (Active Ingredient(s) - Indication(s))	Class	Company	Filing (CR[11]) Date	Approval Date (dd-mon-yy)
KISQALI (Ribociclib as Ribiciclib Succinate) - is indicated: in combination with letrozole for the treatment of postmenopausal women with hormonereceptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negativeadvanced or metastatic breast cancer as an initial endocrine-based therapy.	NAS	Novartis Pharmaceuticals Canada Inc.	17-Mar-17	2-Mar-18
LONSURF (Trifluridine, Tipiracil Hydrochloride) - is indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.	PRIORITY-NAS	Taiho Pharma Canada, Inc.	30-May-17	25-Jan-18
MAVIRET (Pibrentasvir, Glecaprevir) - is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis. This includes patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors.	PRIORITY-NAS	Abbvie Corporation	24-Jan-17	16-Aug-17
OCALIVA (Obeticholic Acid) - is indicated for the treatment of primary biliary cholangitis1 (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	PRIORITY-NAS	Intercept Pharmaceuticals Inc.	16-Sep-16	24-May-17 NOC-C
OZANEX (Ozenoxacin) - is indicated for the topical treatment of impetigo in patients aged 2 months and older.	NAS	Ferrer Internacional SA	1-Apr-16	1-May-17
PREVYMIS (Letermovir) - is indicated for the prophylaxis of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).	PRIORITY-NAS	Merck Canada Inc.	10-Apr-17	1-Nov-17
PROCYSBI **(Cysteamine as Cysteamine Bitartrate)** - is indicated for the treatment of nephropathic cystinosis.	PRIORITY-NAS	Horizon Pharma Ireland Ltd.	21-Jan-16	13-Jun-17

New Active Substance Approvals – TPD Fiscal Year 2017-2018 (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s) - Indication(s))	**Class**	**Company**	**Filing (CR[11]) Date**	**Approval Date (dd-mon-yy)**
RYDAPT (Midostaurin) - is indicated in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy for the treatment of adult patients with newly diagnosed FLT3-mutated acute myeloid leukemia (AML).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	9-Dec-16	21-Jul-17
SPINRAZA (Nusinersen as Nusinersen Sodium) - is indicated for the treatment of 5q Spinal Muscular Atrophy (SMA).	NOC-C-NAS	Biogen Canada Inc.	10-Nov-16	29-Jun-17 NOC (no conditions)
VELPHORO (Sucroferric Oxyhydroxide) - is indicated for the control of serum phosphorus levels in adult patients with end-stage renal disease (ESRD) on dialysis.	NAS	Vifor Fresenius Medical Care Renal Pharma Ltd.	22-Dec-16	5-Jan-18
VOSEVI (Sofosbuvir, Velpatasvir, Voxilaprevir) - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adult patients, without cirrhosis or with compensated cirrhosis, who have: • genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; • genotype 1, 2, 3, or 4 infection and have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.	PRIORITY-NAS	Gilead Sciences Canada Inc.	27-Jan-17	16-Aug-17
XIIDRA (Lifitegrast) - is indicated for the treatment of the signs and symptoms of dry eye disease.	NAS	Shire Pharma Canada ULC	28-Oct-16	22-Dec-17

Priority Submission Approvals - TPD - Fiscal Year 2017-2018

Priority Submission Approvals – TPD Fiscal Year 2017-2018 (April 1 2017 – March 31 2018)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR) Date**	**Approval Date**
HARVONI (Ledipasvir, Sofosbuvir) - treatment indication to include adolescent patients (from 12 years of age) with chronic hepatitis C virus genotype 1 infection, without cirrhosis or with compensated cirrhosis.	PRIORITY-CLIN ONLY	Gilead Sciences Canada Inc.	27-Oct-16	24-May-17
IMBRUVICA (Ibrutinib) - new indication: for the treatment of patients with steroid dependent or refractory chronic graft versus host disease (cGVHD).	PRIORITY-CLIN ONLY	Janssen Inc.	4-Apr-17	25-Oct-17
LONSURF **(Trifluridine, Tipiracil Hydrochloride)** - is indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.	PRIORITY-NAS	Taiho Pharma Canada, Inc.	30-May-17	25-Jan-18
MAVIRET (Pibrentasvir, Glecaprevir) - is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis. This includes patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors.	PRIORITY-NAS	Abbvie Corporation	24-Jan-17	16-Aug-17
MEKINIST (Trametinib) - new indication: in combination with Dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation whose disease has progressed following systemic therapy.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	18-Oct-16	16-May-17

Priority Submission Approvals – TPD
Fiscal Year 2017-2018
(April 1 2017 – March 31 2018)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
OCALIVA (Obeticholic Acid) - is indicated for the treatment of primary biliary cholangitis1 (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	PRIORITY-NAS	Intercept Pharmaceuticals Inc.	16-Sep-16	24-May-17 NOC-C
ONIVYDE (Irinotecan Hydrochloride) - is indicated for the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have disease progression following gemcitabine-based therapy.	PRIORITY-CLIN/C&M	Baxalta Canada Corporation	31-Dec-15	9-Aug-17
ORKAMBI (Lumacaftor, Ivacaftor) - new indication: for the treatment of cystic fibrosis (CF) in patients 6 years of age and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. New strength: 100 mg Lumacaftor/125mg Ivacaftor for children 6-11 years old..	PRIORITY-CLIN/C&M	Vertex Pharmaceuticals (Canada) Incorporated	12-Sep-16	18-Apr-17
PREVYMIS (Letermovir) - is indicated for the prophylaxis of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).	PRIORITY-NAS	Merck Canada Inc.	10-Apr-17	1-Nov-17
PROCYSBI **(Cysteamine as Cysteamine Bitartrate)** - is indicated for the treatment of nephropathic cystinosis.	PRIORITY-NAS	Horizon Pharma Ireland Ltd.	21-Jan-16	13-Jun-17
RYDAPT (Midostaurin) - is indicated in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy for the treatment of adult patients with newly diagnosed FLT3-mutated acute myeloid leukemia (AML).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	9-Dec-16	21-Jul-17
STIVARGA (Regorafenib) - new indication: for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.	PRIORITY-CLIN ONLY	Bayer Inc.	28-Feb-17	18-Sep-17

Priority Submission Approvals – TPD
Fiscal Year 2017-2018
(April 1 2017 – March 31 2018)

Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR) Date	Approval Date
TAFINLAR **(Dabrafenib as Dabrafenib Mesylate)** - new indication: in combination with trametinib is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation whose disease has progressed following systemic therapy.	PRIORITY-CLIN ONLY	Novartis Pharmaceuticals Canada Inc.	18-Oct-16	16-May-17
VOSEVI **(Sofosbuvir, Velpatasvir, Voxilaprevir)** - is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adult patients, without cirrhosis or with compensated cirrhosis, who have: • genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; • genotype 1, 2, 3, or 4 infection and have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.	PRIORITY-NAS	Gilead Sciences Canada Inc.	27-Jan-17	16-Aug-17
ZYTIGA (Abiraterone Acetate) - new indication: in combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed hormone-sensitive high-risk metastatic prostate cancer who may have received up to 3 months of prior ADT.	PRIORITY-CLIN ONLY	Janssen Inc.	26-Jul-17	13-Feb-18

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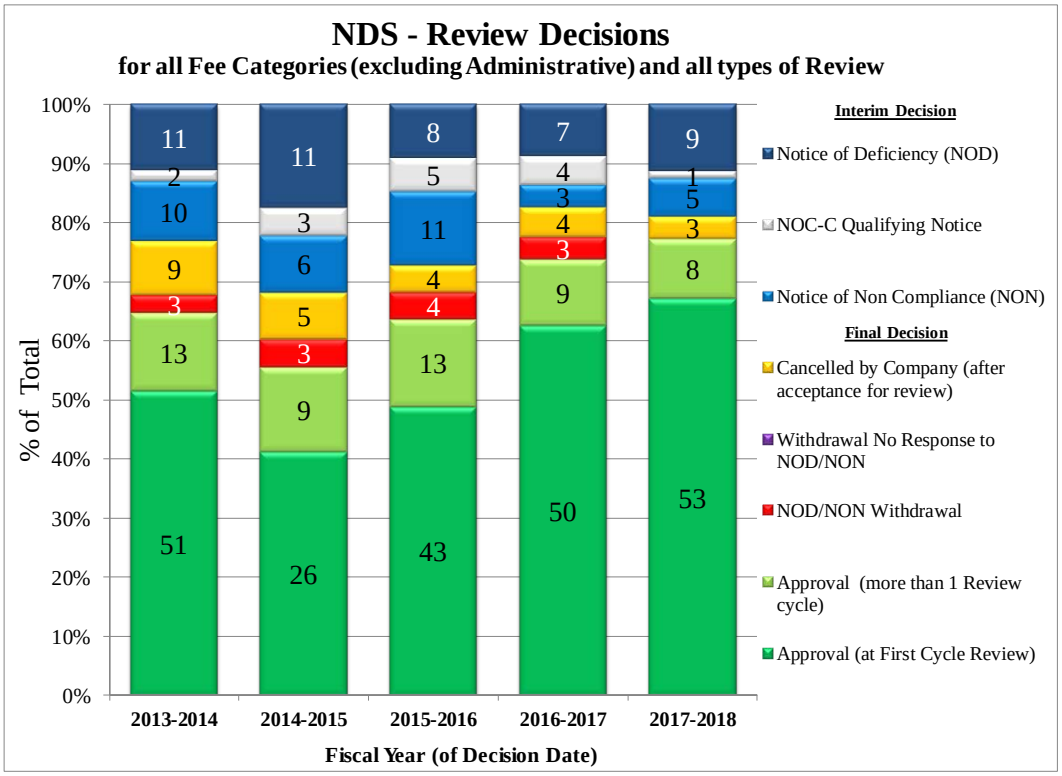
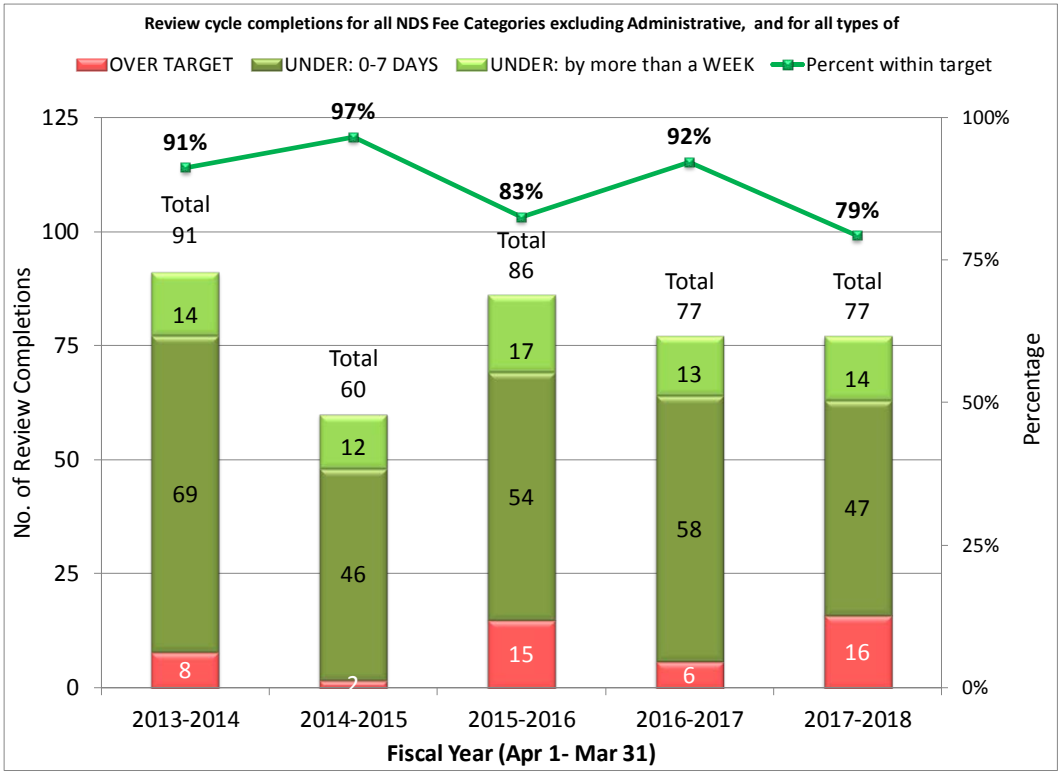
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

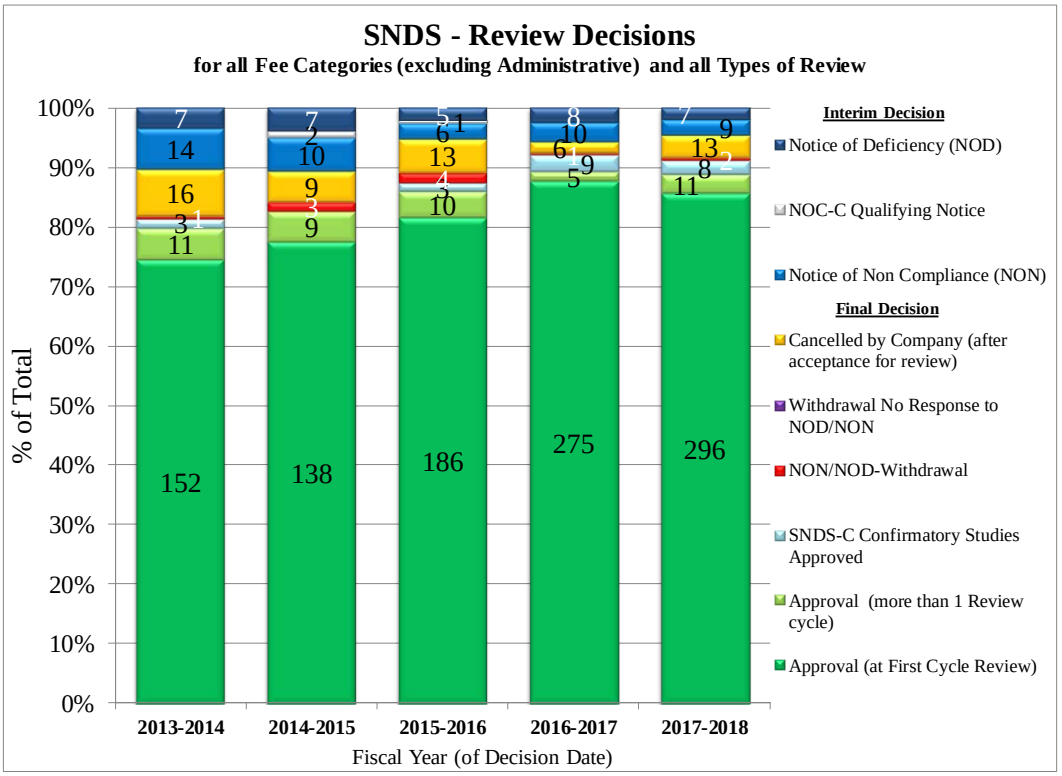


NDS - Review Cycle Completions Showing Percentage Within Target

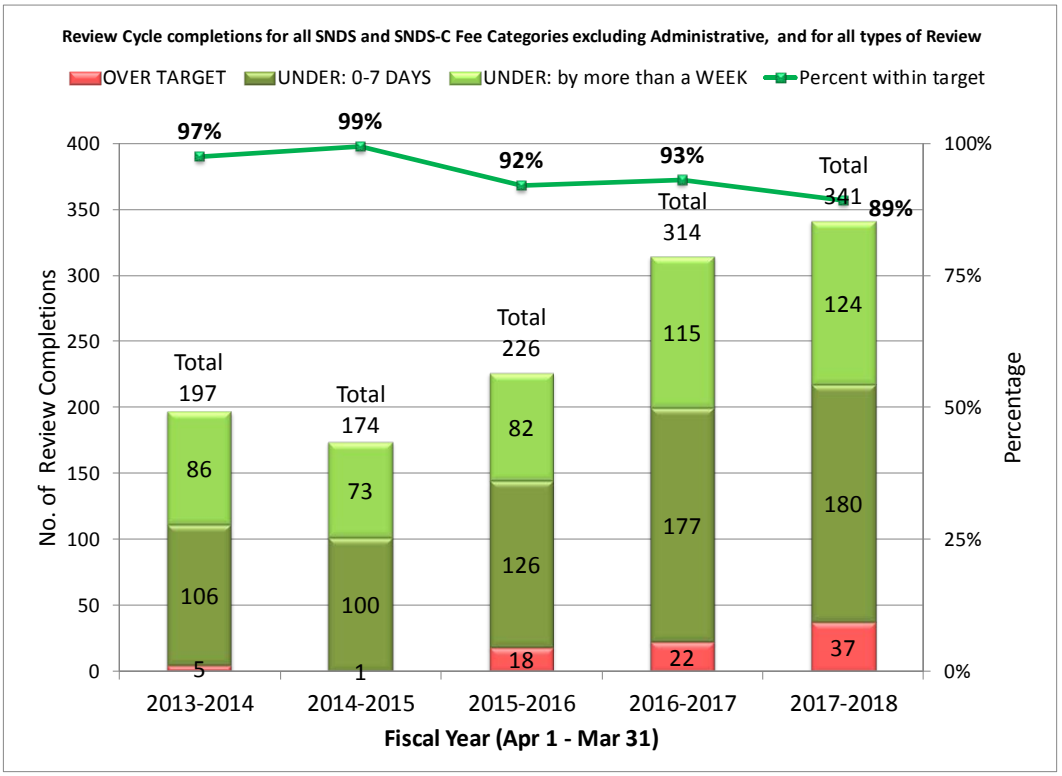


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

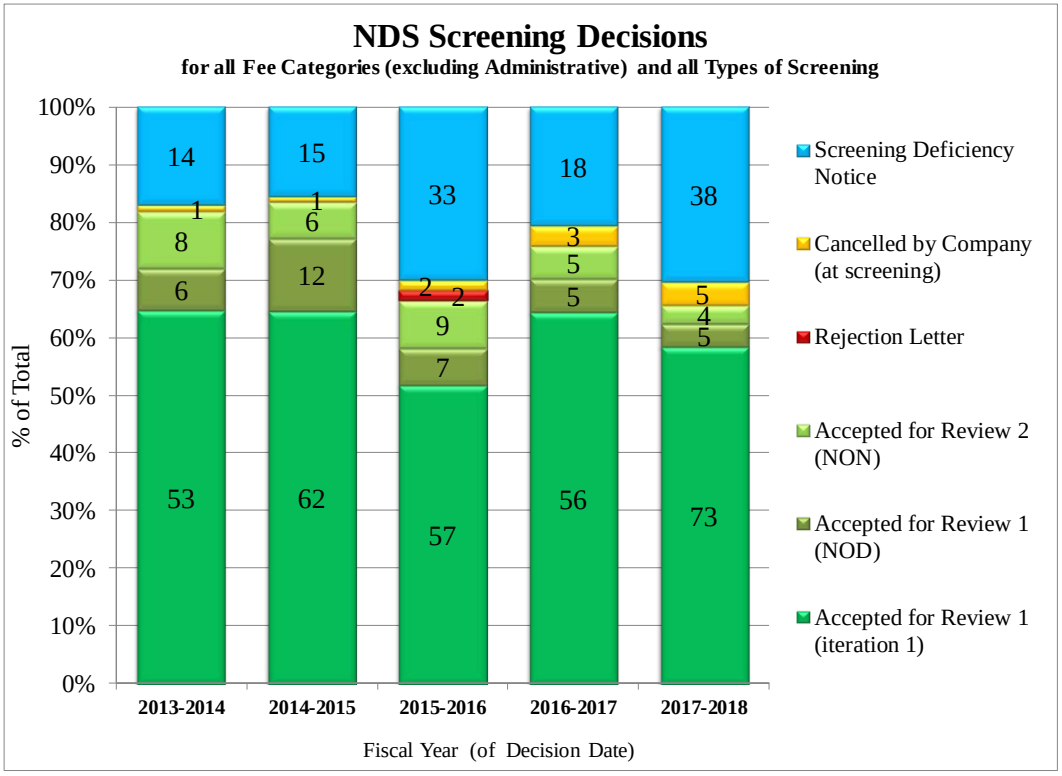


SNDS - Review Cycle Completions Showing Percentage Within Target

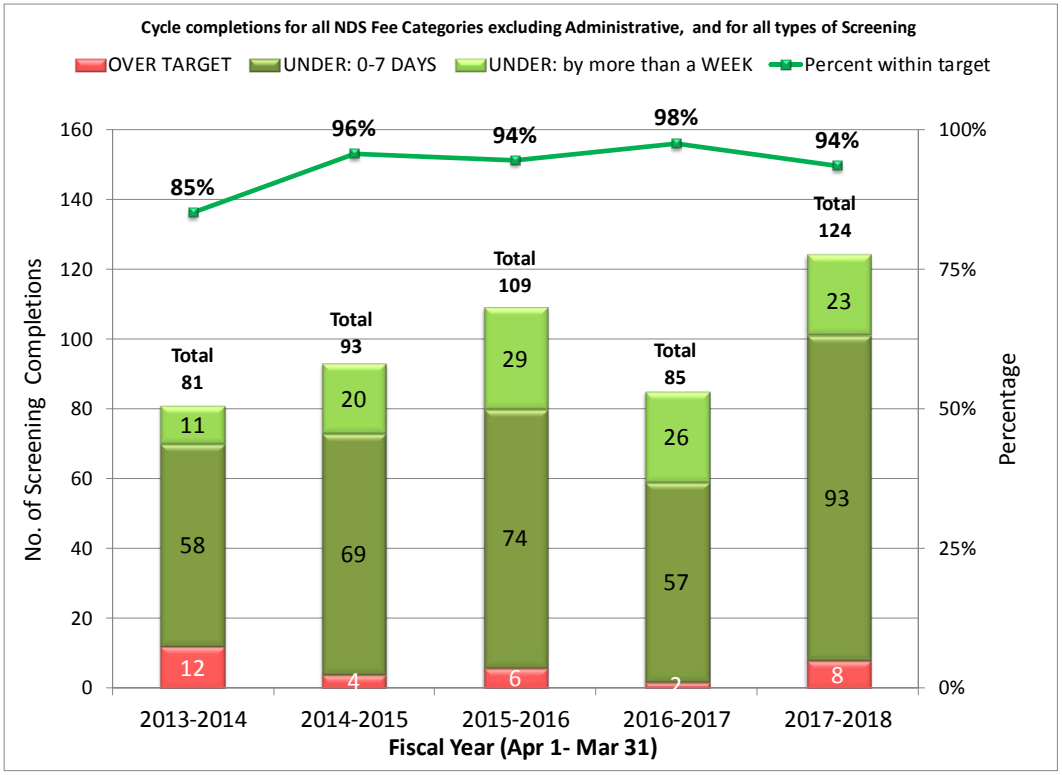


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

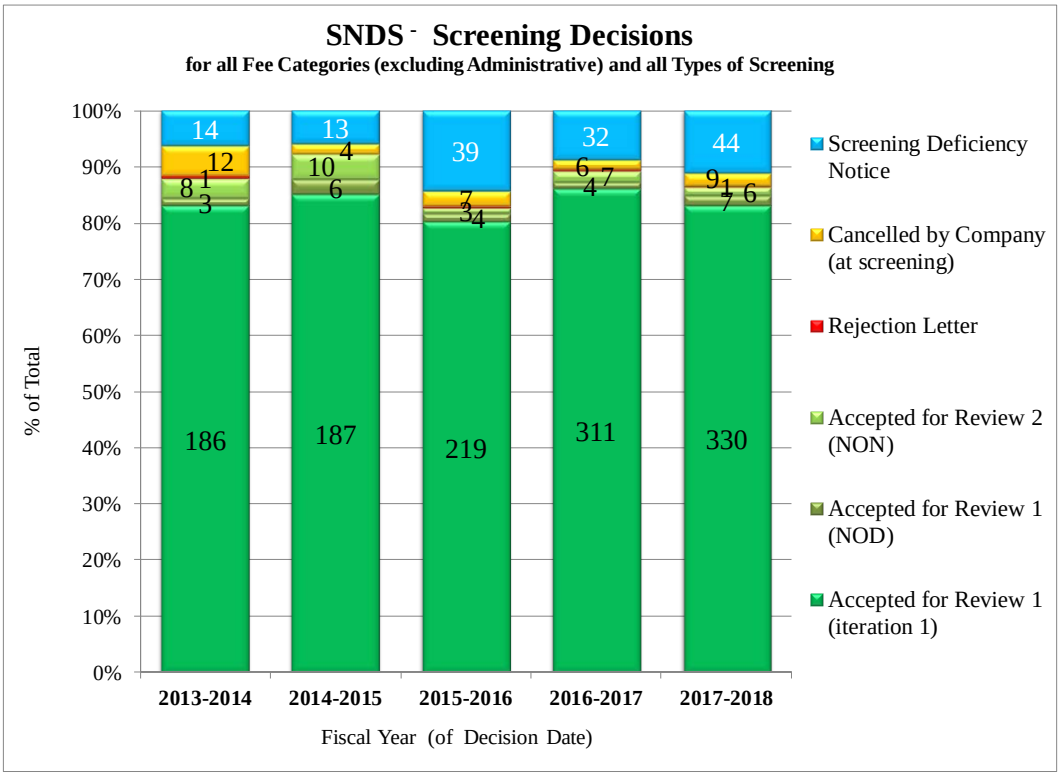


NDS - Screening Cycle Completions Showing Percentage Within Target

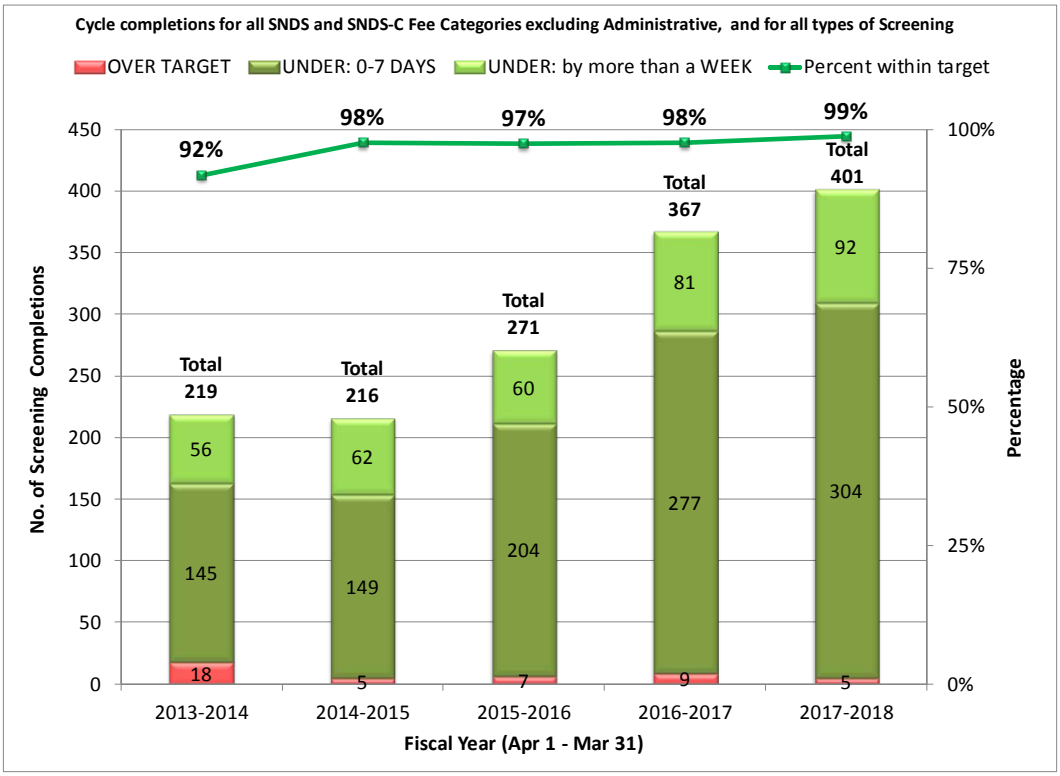


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions



SNDS - Screening Cycle Completions Showing Percentage Within Target



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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	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	NDS Status (as of May 2018)
Total Received	**1**	**0**	**2**	**1**	**0**		
Total Pending	***0***	***0***	***0***	***0***	***0***		
Total Granted	***1***	***0***	***1***	***0***	***0***		
GRANTED	1					NON-Withdrawal	Cleared
GRANTED			*1*			NOD-Withdrawal	Cleared
Total Denied	***0***	***0***	***1***	***1***	***0***		
DENIED			1	1		NOD-Withdrawal	Withdrawn

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

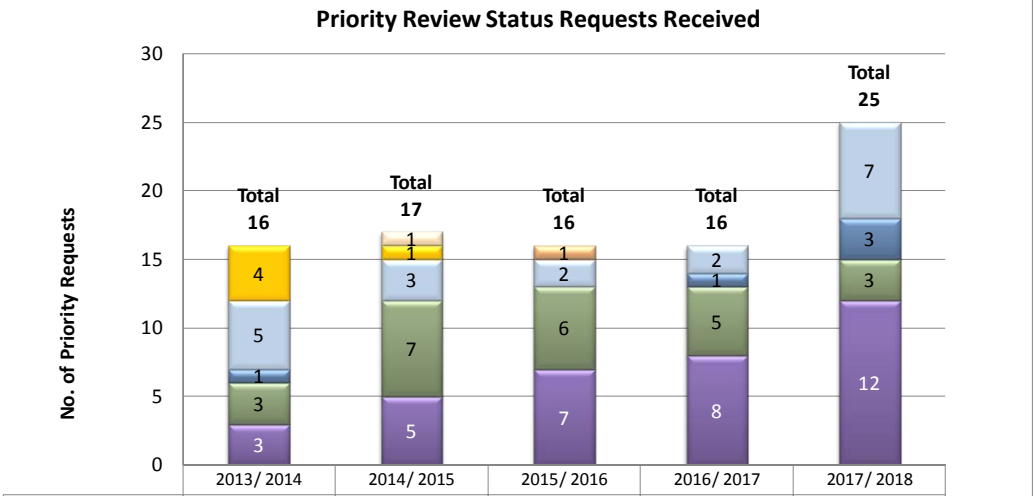
SNDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31) * revised May 2018

Breakdown by Reconsideration Decision	13-14	14-15	15-16*	16-17	17-18	Final Decision in Dispute	SNDS Status (as of May 2018)
Total Received	**0**	**1**	**1**	**0**	**0**		
Total Pending			***1***			NOD-Withdrawal	Under Reconsideration
Total Granted		***1***				NOD-Withdrawal	Withdrawn

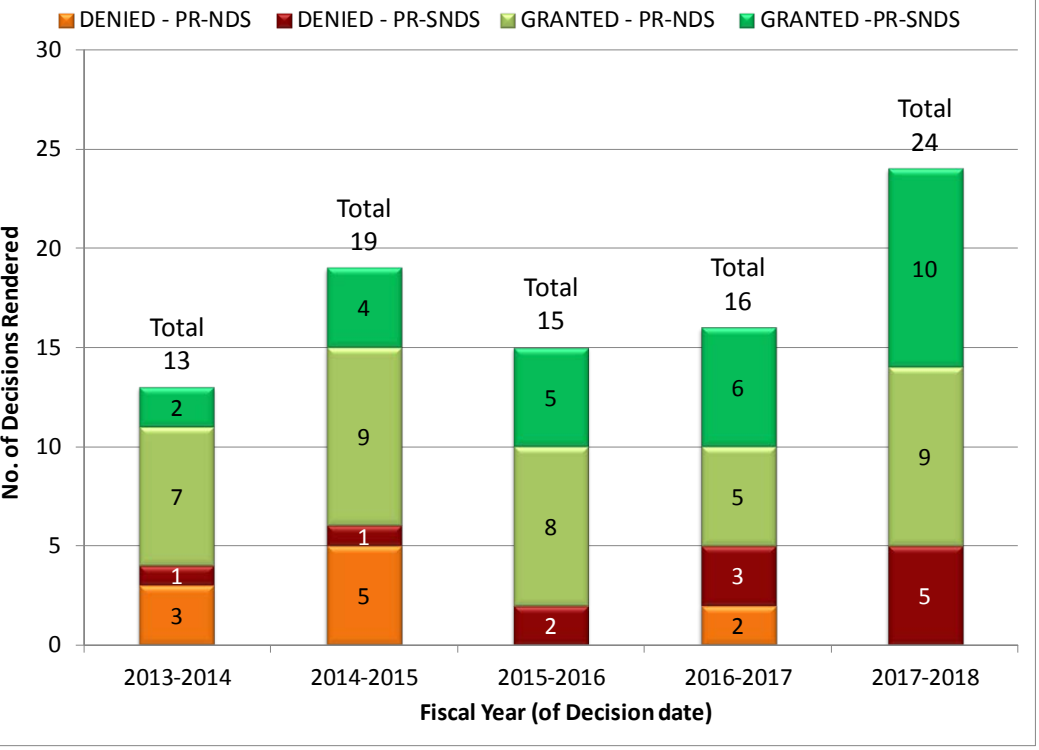
PRIORITY REVIEW STATUS REQUEST (for NDS & SNDS)

Priority Review Status Requests Received



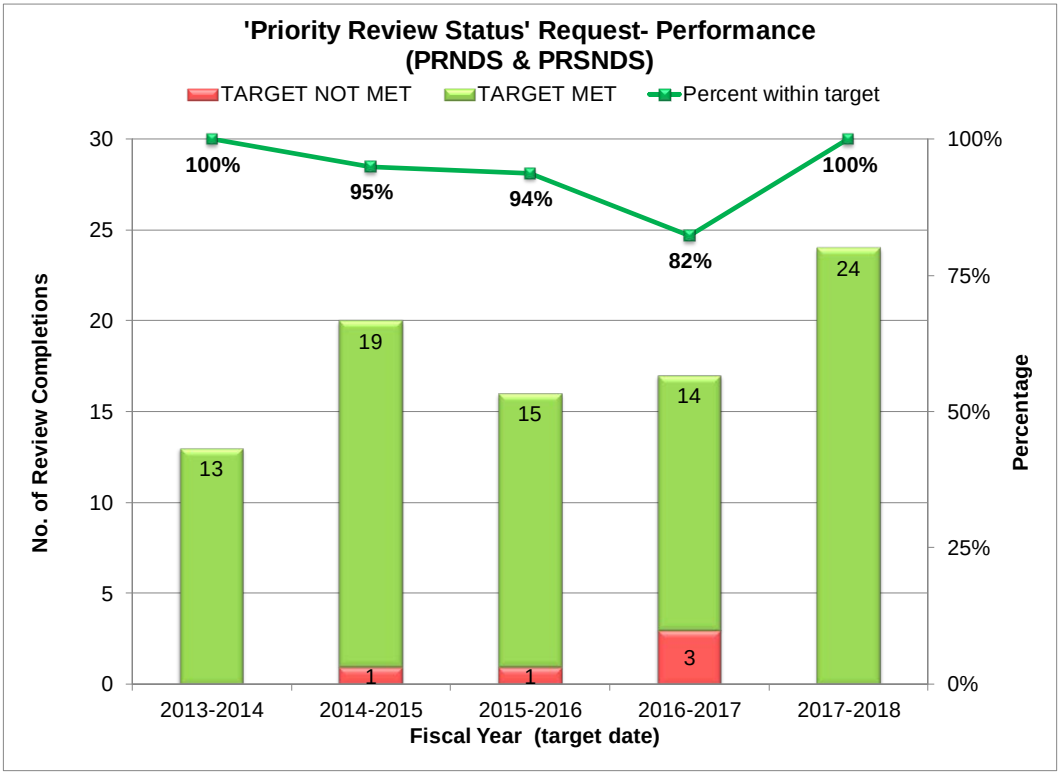
	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
PR-NDS COMP/C&M			1		
PR-NDS C&M		1			
PR-NDS NAS	4	1			
PR-NDS CLIN ONLY	5	3	2	2	7
PR-SNDS CLIN/C&M	1			1	3
PR-NDS CLIN/C&M	3	7	6	5	3
PR-SNDS CLIN ONLY	3	5	7	8	12
Total	16	17	16	16	25

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	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
Total Received	**0**	**0**	**0**	**0**	**1**		
Total Granted	***0***	***0***	***0***	***0***	***1***	Priority Review Request (for SNDS) Denied	Inactive-Reconsideration

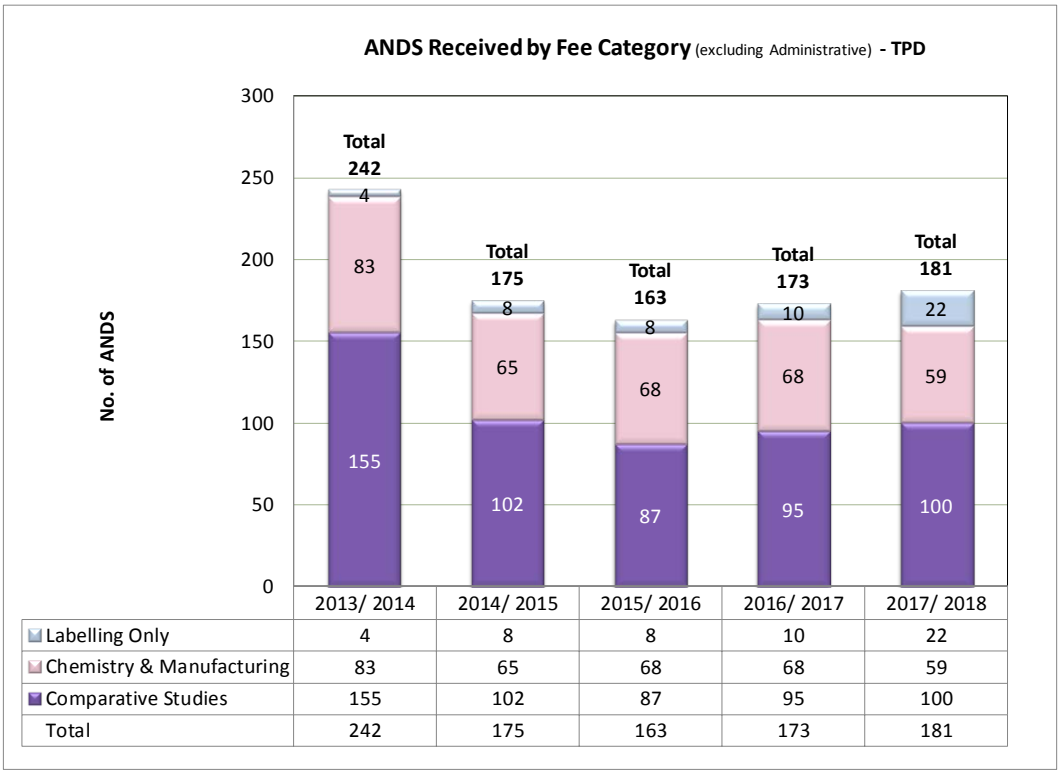
Abbreviated New Drug Submissions (ANDS)

&

Supplemental Abbreviated New Drug Submissions (SANDS)

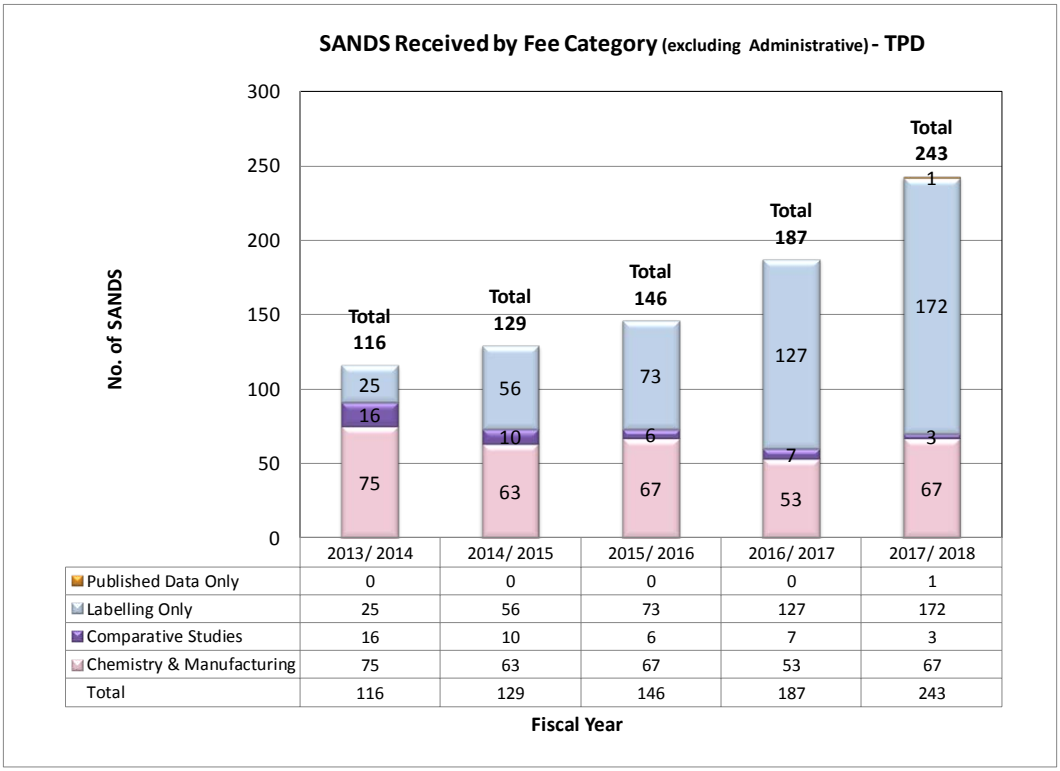
SUBMISSIONS RECEIVED

Abbreviated New Drug Submissions (ANDS) Received by Fee Category



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Only	4	8	8	10	22
Chemistry & Manufacturing	83	65	68	68	59
Comparative Studies	155	102	87	95	100
Total	242	175	163	173	181

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

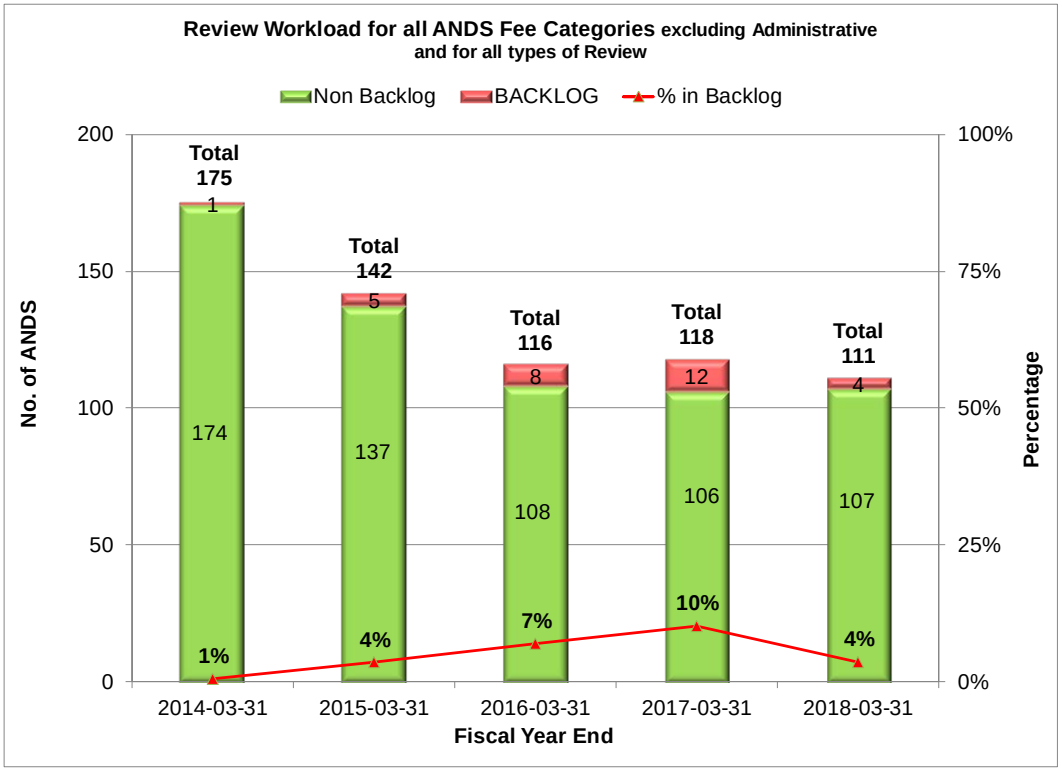


	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Published Data Only	0	0	0	0	1
Labelling Only	25	56	73	127	172
Comparative Studies	16	10	6	7	3
Chemistry & Manufacturing	75	63	67	53	67
Total	116	129	146	187	243

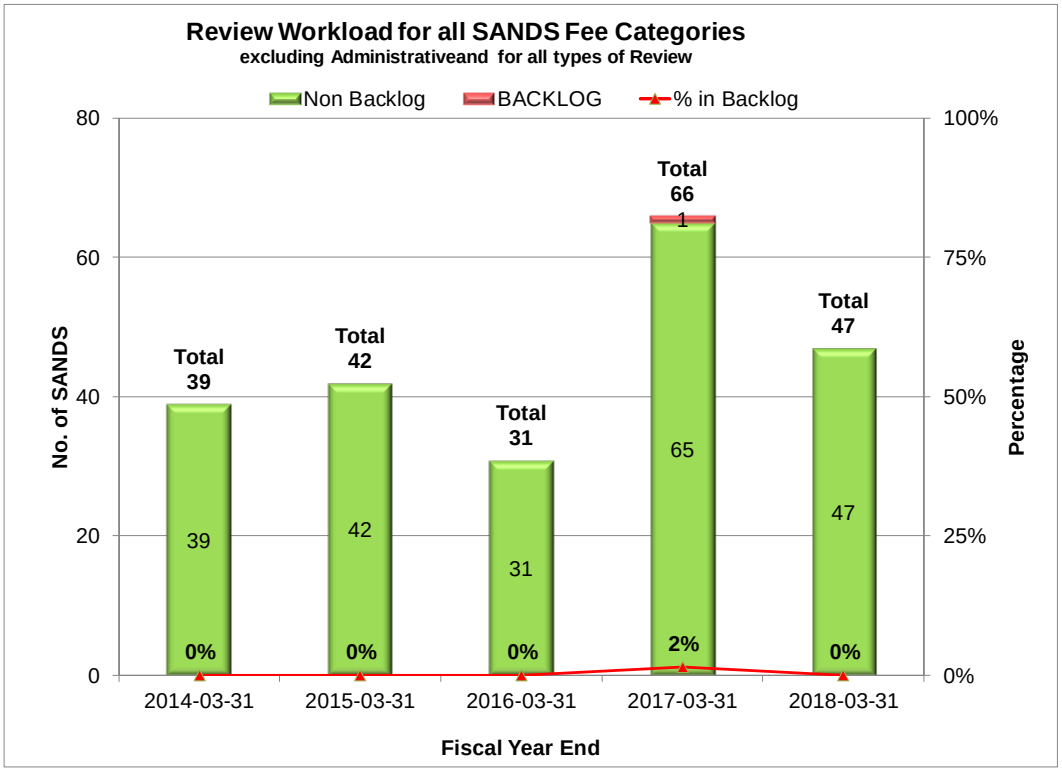
Fiscal Year

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

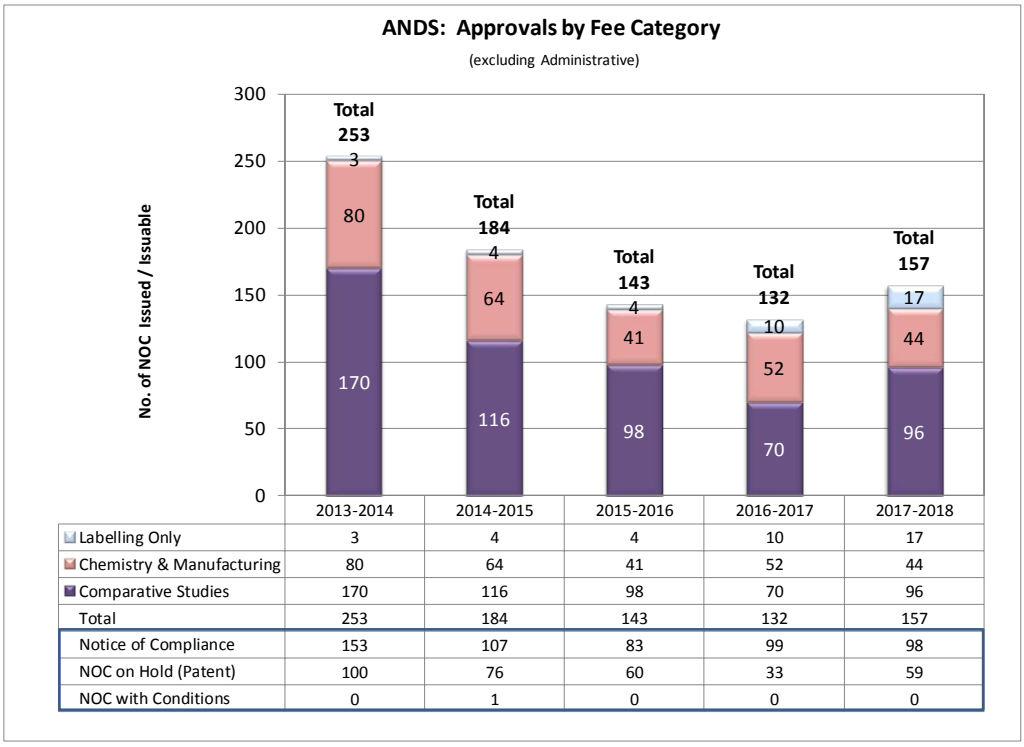
TPD ANDS All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Chemistry & Manufacturing	**58**	**59**	**49**	**46**	**43**
Backlog	*1*	*1*	*1*	*5*	*2*
Comparative Studies	**117**	**83**	**65**	**71**	**65**
Backlog	*0*	*4*	*7*	*7*	*2*
Labelling Only	**0**	**0**	**2**	**1**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**175**	**142**	**116**	**118**	**111**
Non Backlog	**174**	**137**	**108**	**106**	**107**
BACKLOG	**1**	**5**	**8**	**12**	**4**
% in Backlog	**1%**	**4%**	**7%**	**10%**	**4%**

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					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Chemistry & Manufacturing	**27**	**27**	**24**	**32**	**26**
Backlog	*0*	*0*	*0*	*1*	*0*
Published Data Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**10**	**7**	**2**	**4**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**2**	**8**	**5**	**30**	**19**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**39**	**42**	**31**	**66**	**47**
Non Backlog	**39**	**42**	**31**	**65**	**47**
BACKLOG	**0**	**0**	**0**	**1**	**0**
% in Backlog	**0%**	**0%**	**0%**	**2%**	**0%**

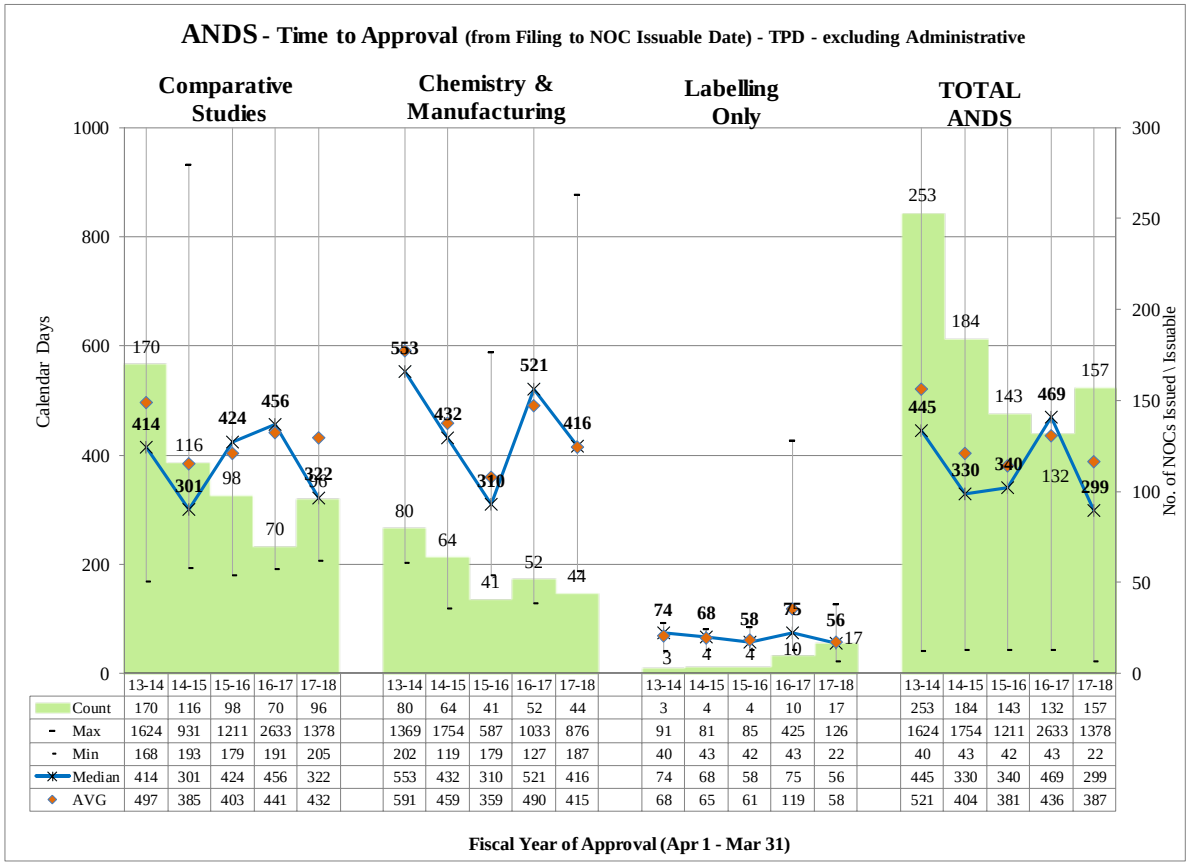
APPROVALS

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only	3	4	4	10	17
Chemistry & Manufacturing	80	64	41	52	44
Comparative Studies	170	116	98	70	96
Total	253	184	143	132	157
Notice of Compliance	153	107	83	99	98
NOC on Hold (Patent)	100	76	60	33	59
NOC with Conditions	0	1	0	0	0

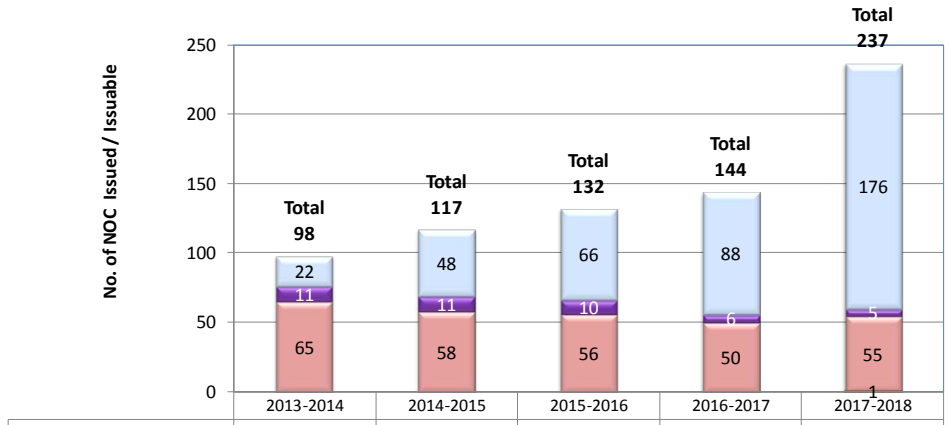
ANDS Approval Times



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	170	116	98	70	96	80	64	41	52	44	3	4	4	10	17	253	184	143	132	157
Max	1624	931	1211	2633	1378	1369	1754	587	1033	876	91	81	85	425	126	1624	1754	1211	2633	1378
Min	168	193	179	191	205	202	119	179	127	187	40	43	42	43	22	40	43	42	43	22
Median	414	301	424	456	322	553	432	310	521	416	74	68	58	75	56	445	330	340	469	299
AVG	497	385	403	441	432	591	459	359	490	415	68	65	61	119	58	521	404	381	436	387

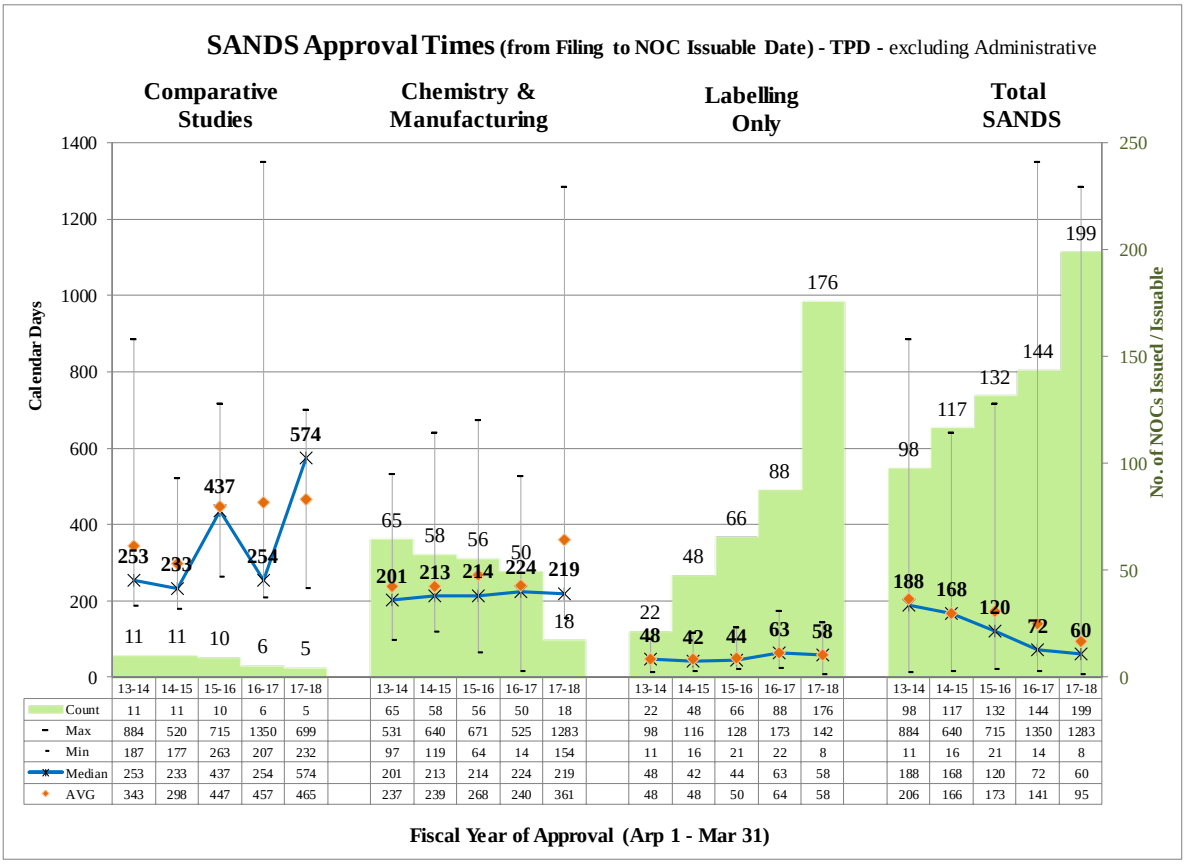
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
Labelling Only	22	48	66	88	176
Comparative Studies	11	11	10	6	5
Chemistry & Manufacturing	65	58	56	50	55
Published Data Only					1
Total	98	117	132	144	237
Notice of Compliance	78	100	111	133	217
NOC on Hold (Patent)	20	17	21	11	20
NOC on Hold (Switch)	0	0	0	0	0
NOC with Conditions	0	0	0	0	0

SANDS Approval Times

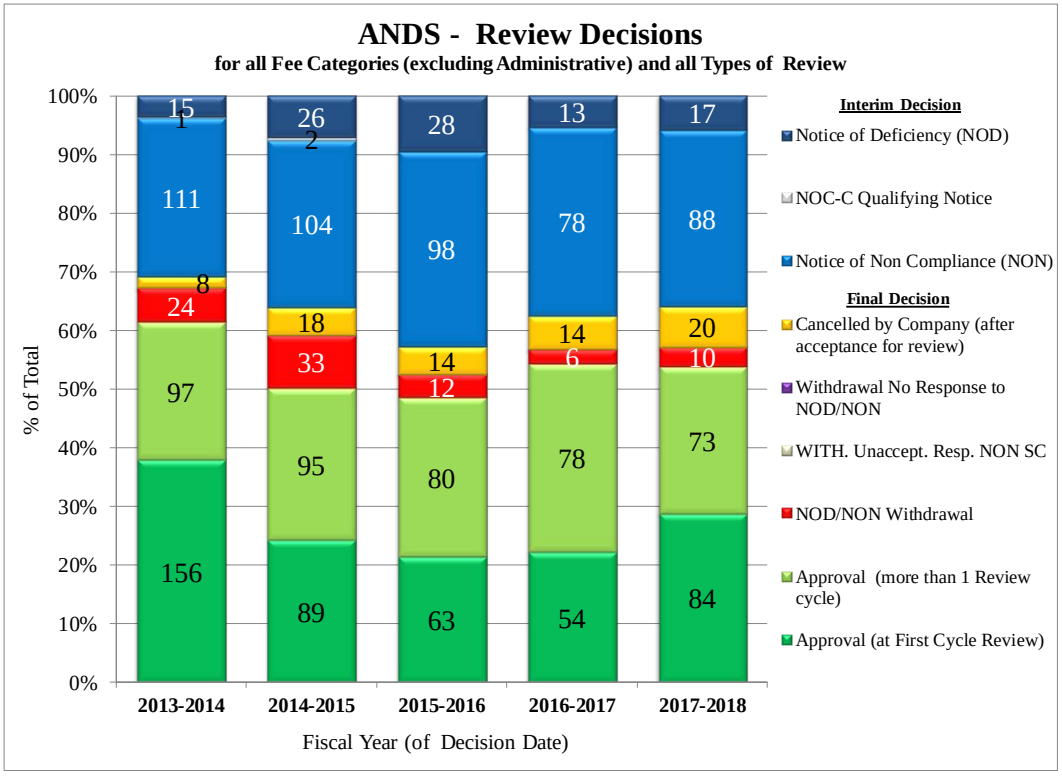


	Comparative Studies					Chemistry & Manufacturing					Labelling Only					Total SANDS				
	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	11	11	10	6	5	65	58	56	50	18	22	48	66	88	176	98	117	132	144	199
Max	884	520	715	1350	699	531	640	671	525	1283	98	116	128	173	142	884	640	715	1350	1283
Min	187	177	263	207	232	97	119	64	14	154	11	16	21	22	8	11	16	21	14	8
Median	253	233	437	254	574	201	213	214	224	219	48	42	44	63	58	188	168	120	72	60
AVG	343	298	447	457	465	237	239	268	240	361	48	48	50	64	58	206	166	173	141	95

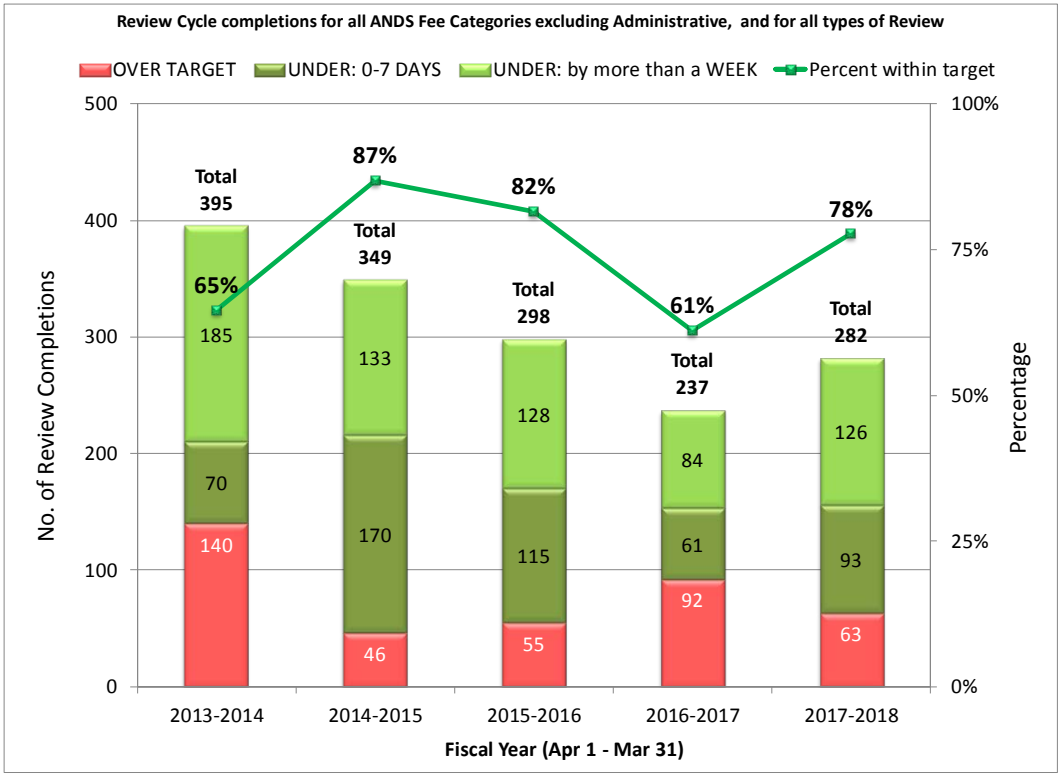
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Review Decisions

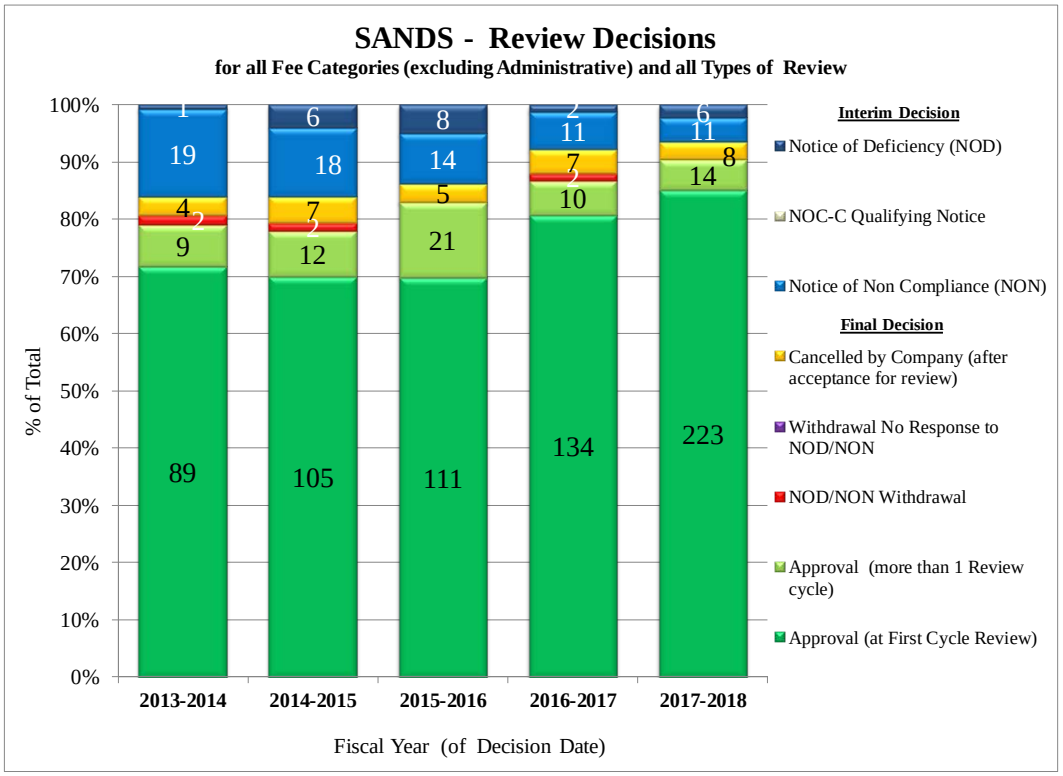


ANDS - Review Cycle Completions Showing Percentage Within Target

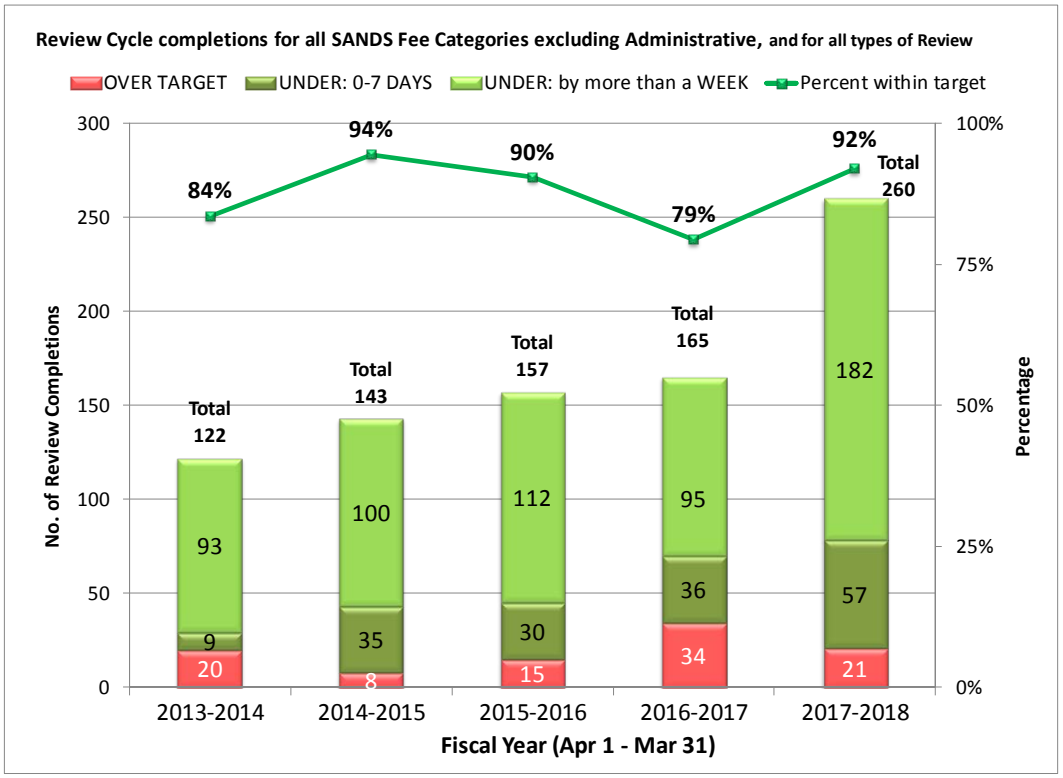


REVIEW CYCLE DECISIONS

Supplemental Abbreviated New Drug Submission (SANDS) Review Decisions

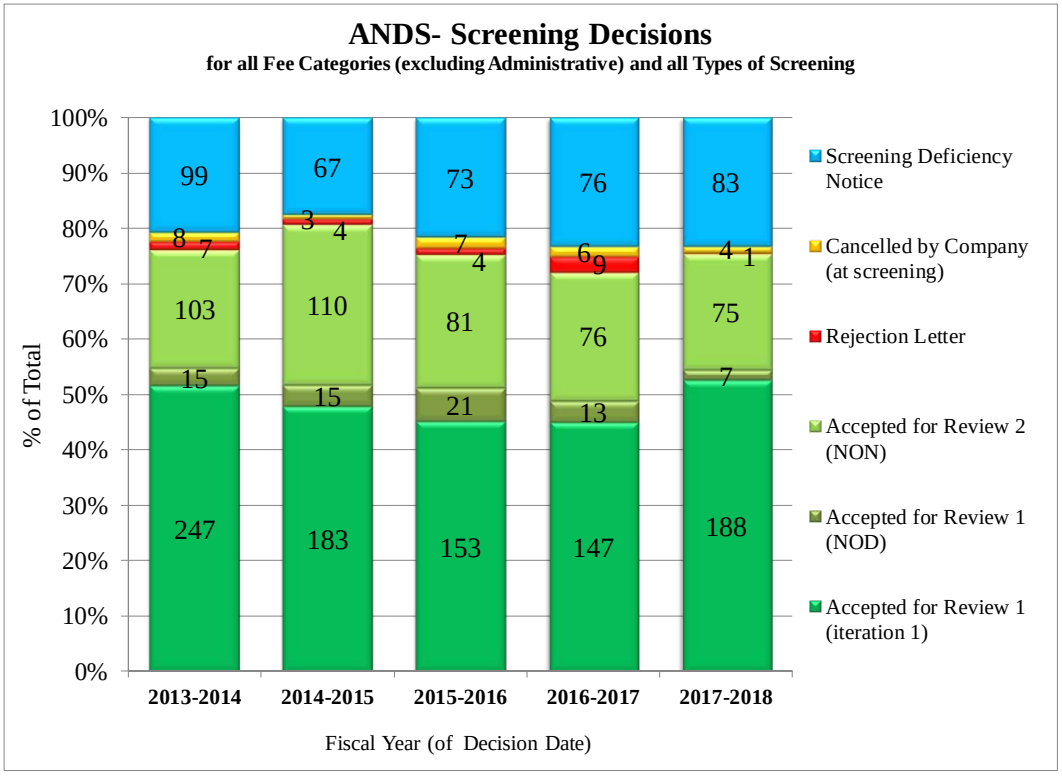


SANDS - Review Cycle Completions Showing Percentage Within Target

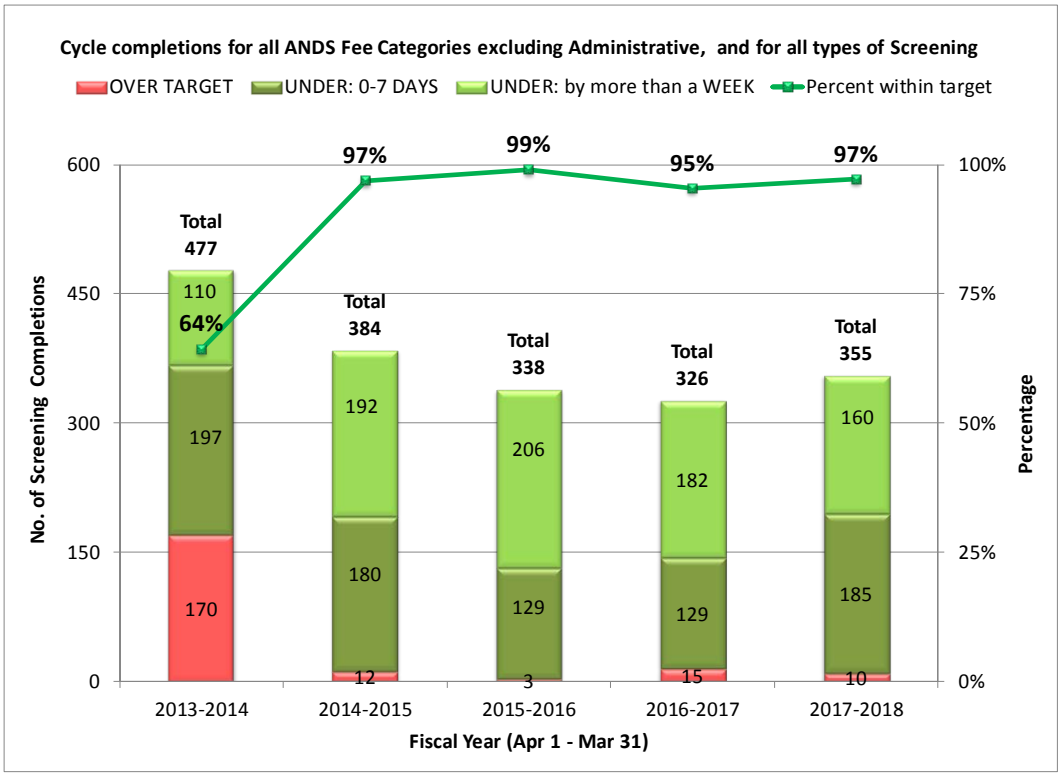


SCREENING CYCLE DECISIONS

Abbreviated New Drug Submission (ANDS) Screening Decisions

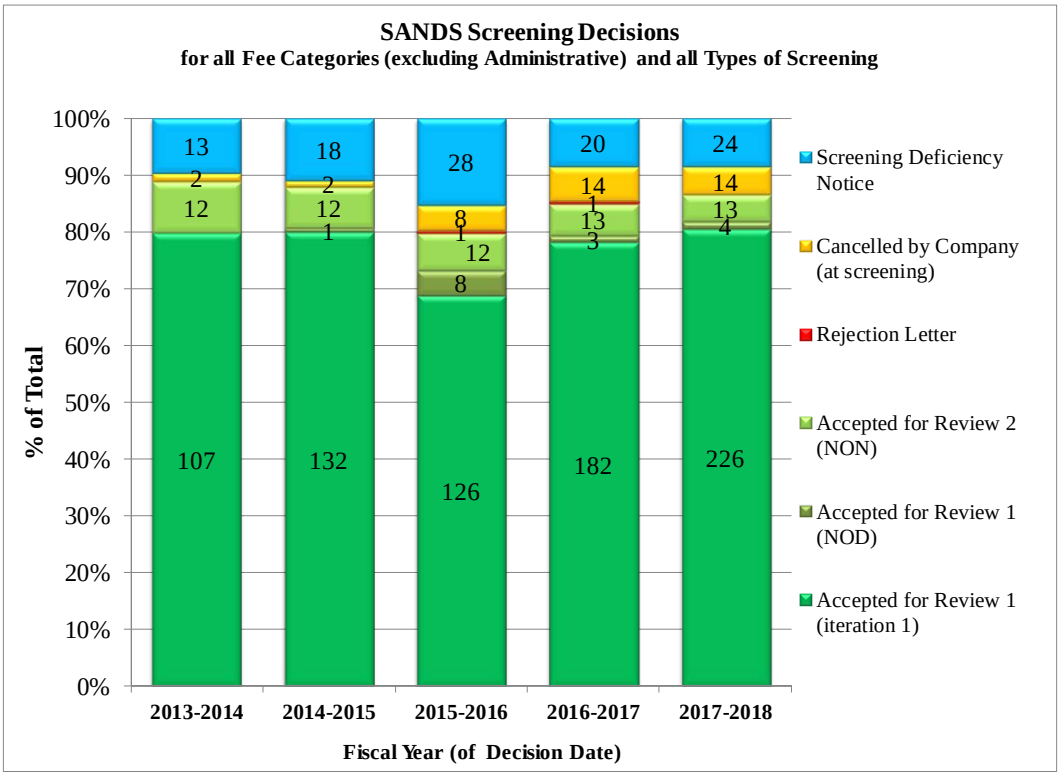


ANDS - Screening Cycle Completions Showing Percentage Within Target

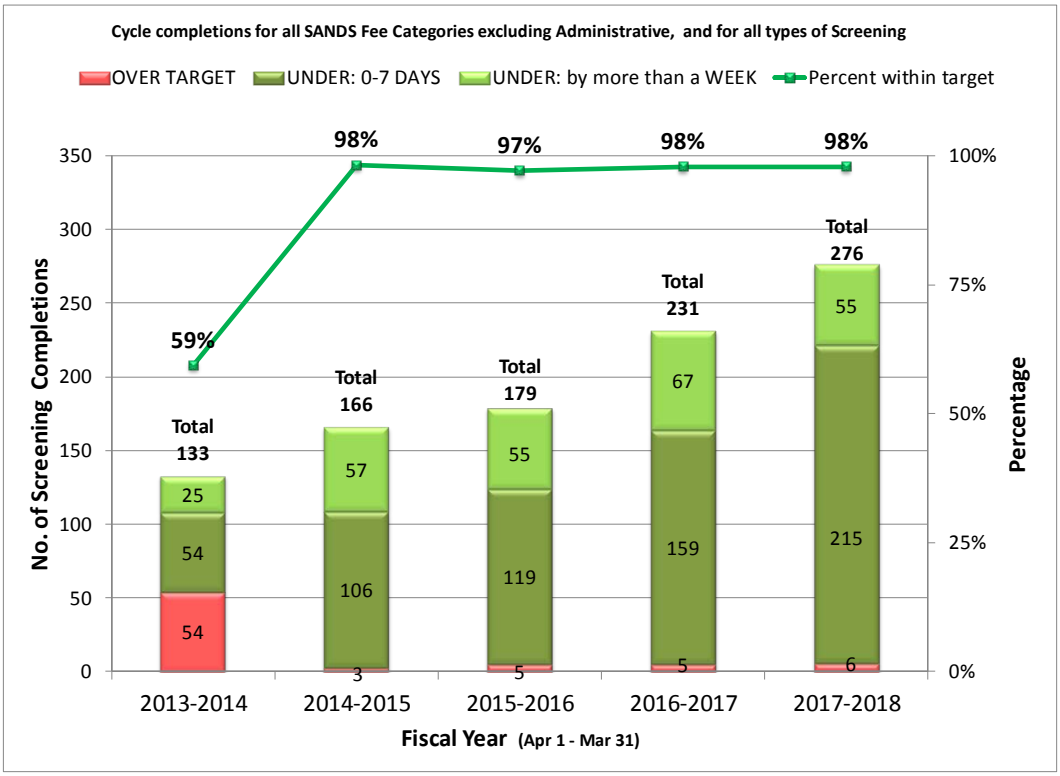


SCREENING CYCLE DECISIONS

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	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	ANDS Status (as of May 2018)
TOTAL Received	**8**	**8**	**3**	**2**	**0**		
Total Pending	***0***	***0***	***1***	***0***	***0***		
Pending			1			NON-Withdrawal	Under Reconsideration
Total Granted	***1***	***3***	***1***	***1***	***0***		
Granted	1	3				NON-Withdrawal	Cleared
Granted			1			NON-Withdrawal	Cleared
Granted				1		Rejection at Screening	Cleared
Total Denied	***3***	***1***	***1***	***0***	***0***		
Denied	2					NOD-Withdrawal	Withdrawn
Denied	1	1	1			NON-Withdrawal	Withdrawn
Total Cancelled	***4***	***4***	***0***	***1***	***0***		
Cancelled by Health Canada	1					NOD-Withdrawal	Cleared
Cancelled by Health Canada		1				NOD-Withdrawal	Withdrawn
Cancelled by Health Canada	2					NON-Withdrawal	Cleared
Cancelled by Health Canada		2				NON-Withdrawal	Withdrawn
Cancelled by Health Canada		1				Rejection at Screening	Cleared
Cancelled by Company				1		NOD-Withdrawal	Withdrawn
Cancelled by Company	1					NON-Withdrawal	Withdrawn

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

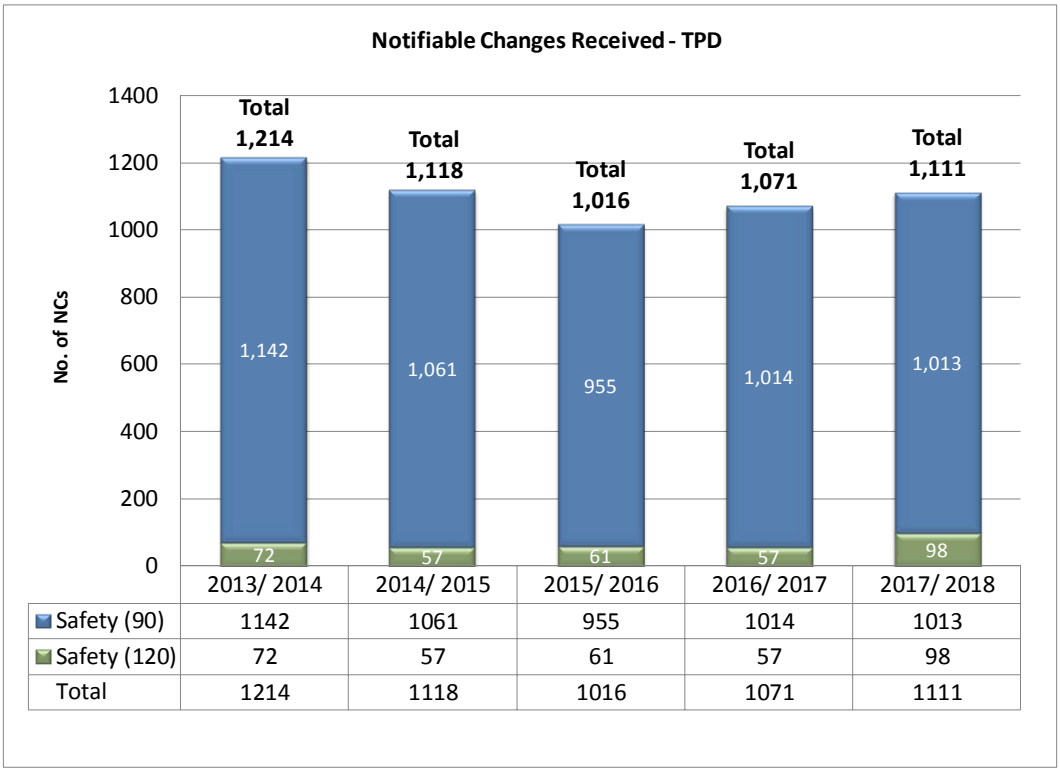
SANDS - Reconsideration of Final Decisions Requests Received

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	SANDS Status (as of May 2018)
Total Received	**0**	**0**	**1**	**1**	**0**		
Total Granted	***0***	***0***	***1***	***0***	***0***		
Granted			1			NOD-Withdrawal	Cleared
Total Cancelled	***0***	***0***	***0***	***1***	***0***		
Cancelled by Health Canada				1		NOD-Withdrawal	Cleared

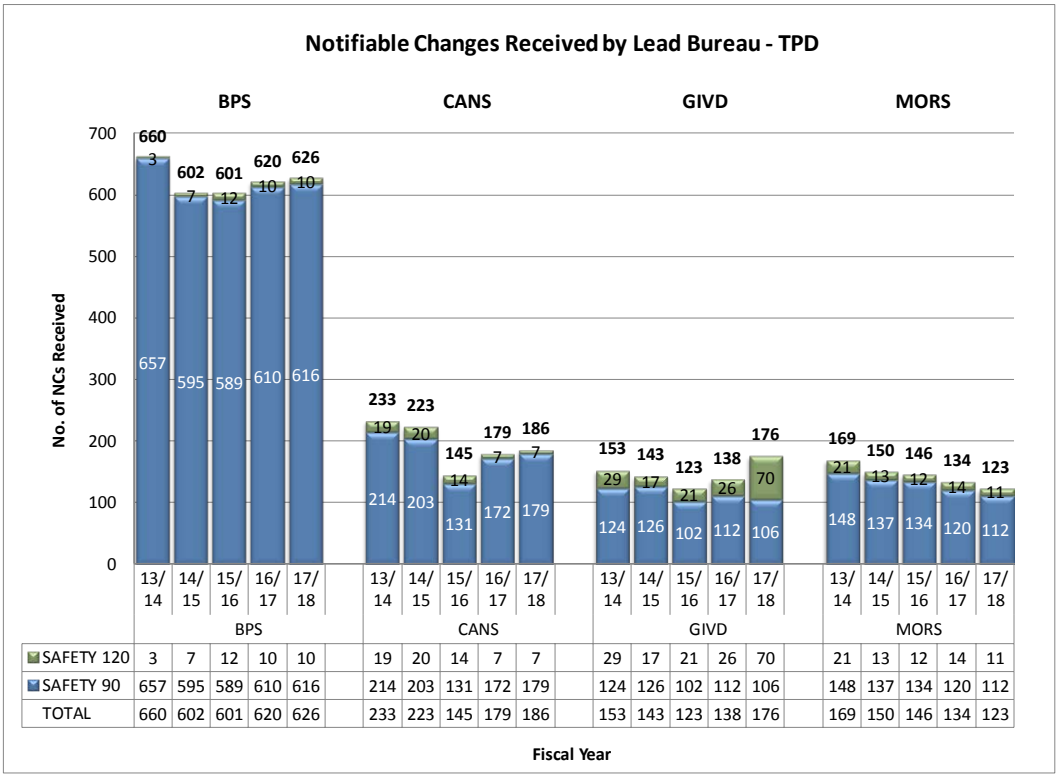
NOTIFIABLE CHANGES (NC)

Number Received - Notifiable Changes (NC)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Safety (90)	1142	1061	955	1014	1013
Safety (120)	72	57	61	57	98
Total	1214	1118	1016	1071	1111

Number Received by Lead Bureau- Notifiable Changes (NC)

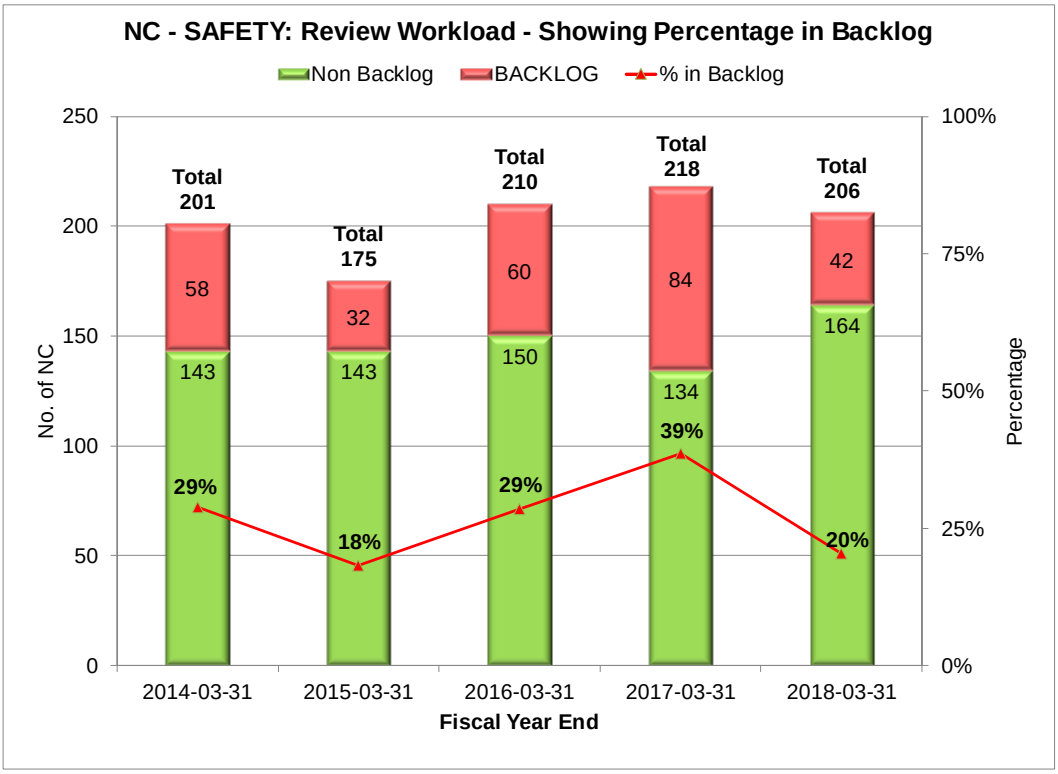


	BPS					CANS					GIVD					MORS				
	13/14	14/15	15/16	16/17	17/18	13/14	14/15	15/16	16/17	17/18	13/14	14/15	15/16	16/17	17/18	13/14	14/15	15/16	16/17	17/18
SAFETY 120	3	7	12	10	10	19	20	14	7	7	29	17	21	26	70	21	13	12	14	11
SAFETY 90	657	595	589	610	616	214	203	131	172	179	124	126	102	112	106	148	137	134	120	112
TOTAL	660	602	601	620	626	233	223	145	179	186	153	143	123	138	176	169	150	146	134	123

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



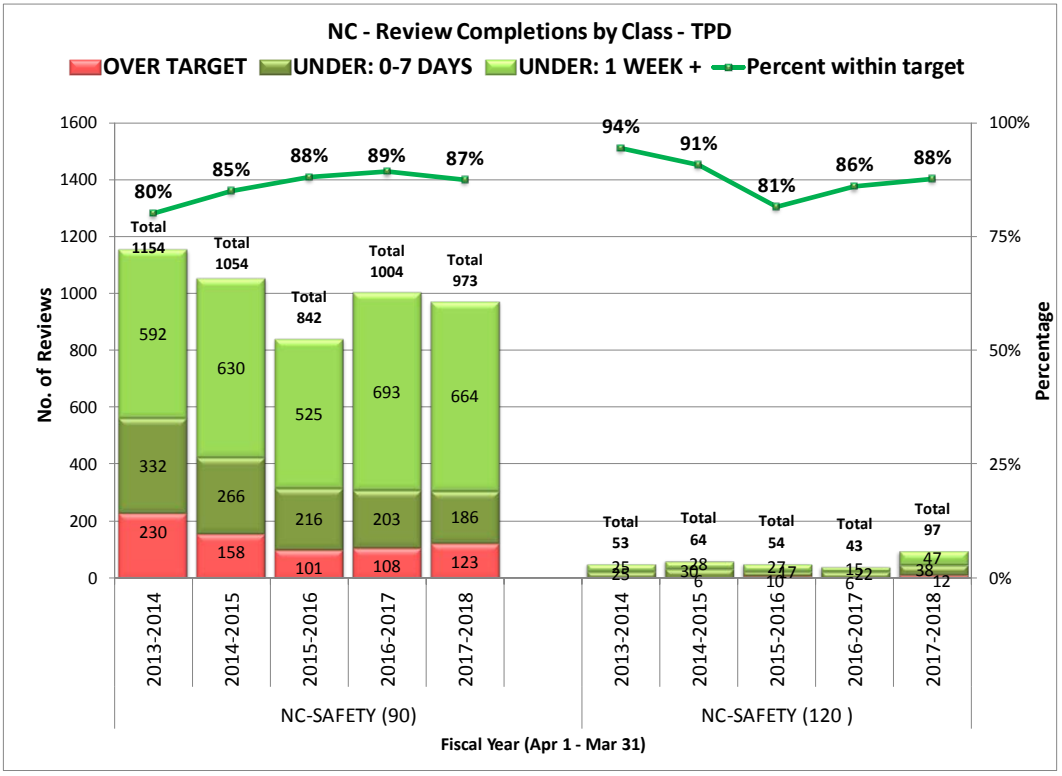
WORKLOAD

Notifiable Change (NC) SAFETY: Review Workload by Class

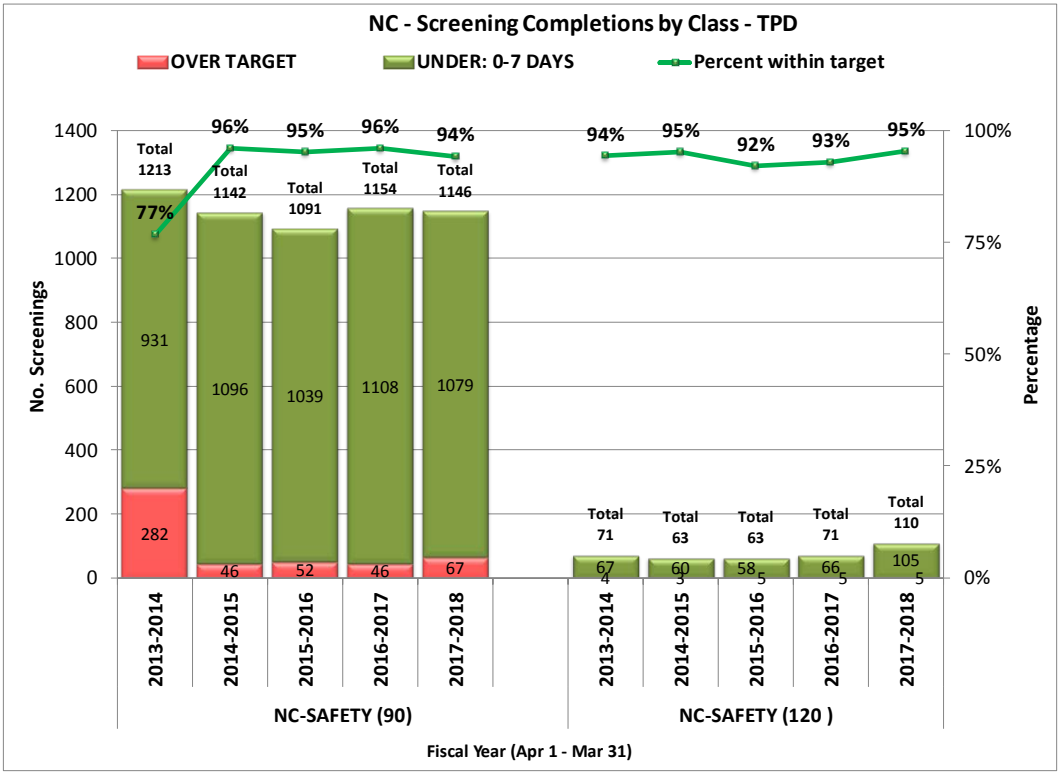
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
SAFETY - 90 day	177	156	194	188	184
Backlog	*57*	*32*	*60*	*78*	*39*
SAFETY - 120 day	24	19	16	30	22
Backlog	*1*	*0*	*0*	*6*	*3*
Total	201	175	210	218	206
Non Backlog	143	143	150	134	164
BACKLOG	58	32	60	84	42
% in Backlog	29%	18%	29%	39%	20%

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	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	1098	1065	834	954	990
CANCELLED BY COMPANY	42	49	62	65	66
NC - HOLD (PATENT)	72	34	45	69	46
SCREEN. DEFICIENCY NOTICE	91	85	197	136	161
REJECTION LETTER (SCR)	5	6	3	2	3
NOT SATISFACTORY NOTICE	2	5	1	2	
SPONSOR SUB CHANGE ACCEPT			1		

NC - SAFETY (120)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	49	63	54	43	90
NOT SATISFACTORY NOTICE	1	1			
SCREENING DEFICIENCY NOTICE	1	3	6	11	20
CANCELLED BY COMPANY	7	1	6	4	8
REJECTION LETTER (SCR)	1		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	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	NC's Status (as of May 2018)
Total Received	**0**	**0**	**0**	**0**	**0**		

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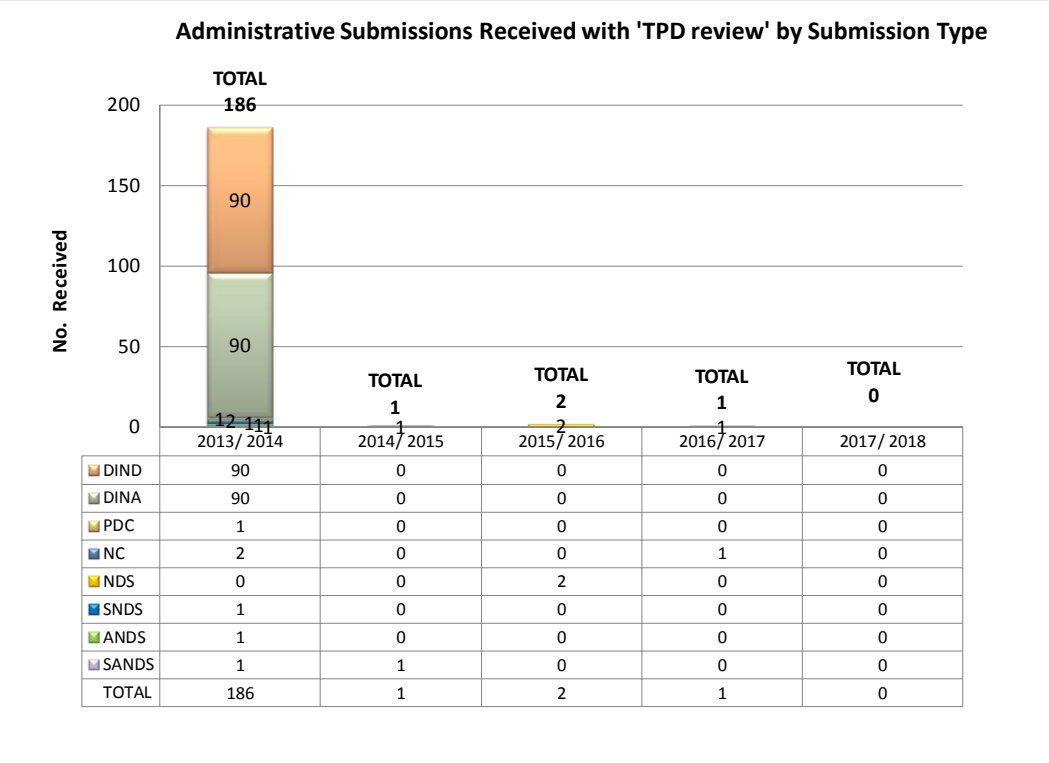
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS with TPD review

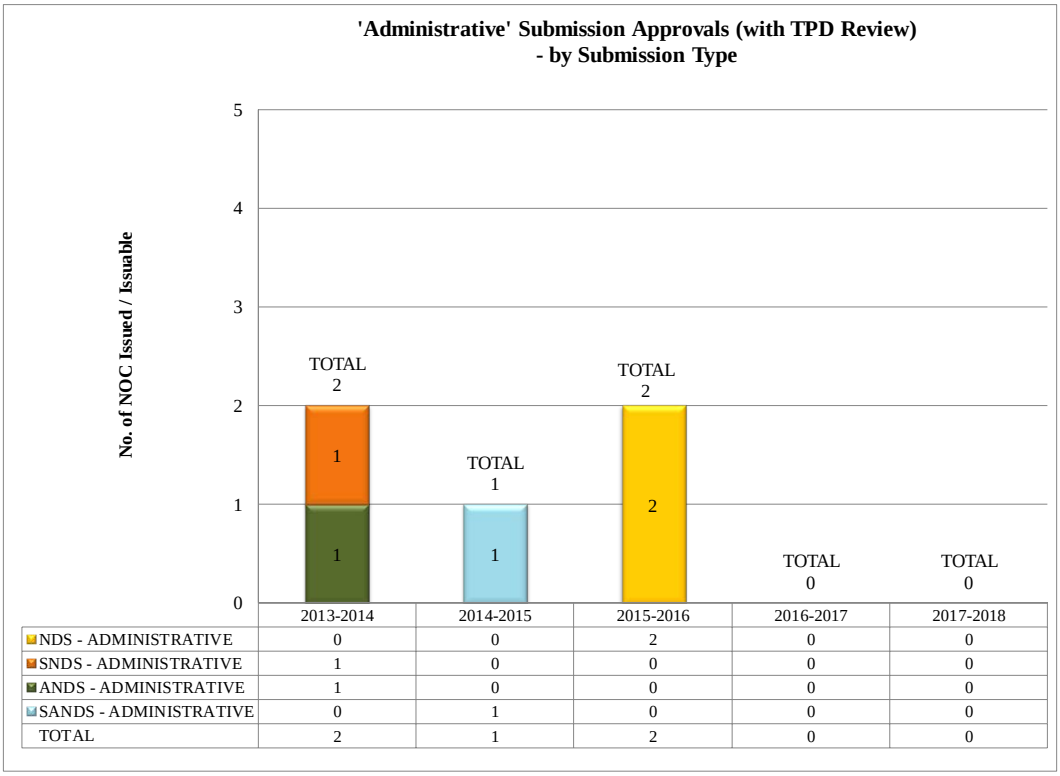
(such as product name change that requires a drug name review)

Administrative Submissions Received (with TPD review)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
DIND	90	0	0	0	0
DINA	90	0	0	0	0
PDC	1	0	0	0	0
NC	2	0	0	1	0
NDS	0	0	2	0	0
SNDS	1	0	0	0	0
ANDS	1	0	0	0	0
SANDS	1	1	0	0	0
TOTAL	186	1	2	1	0

Administrative Submission Approvals (with TPD Review)

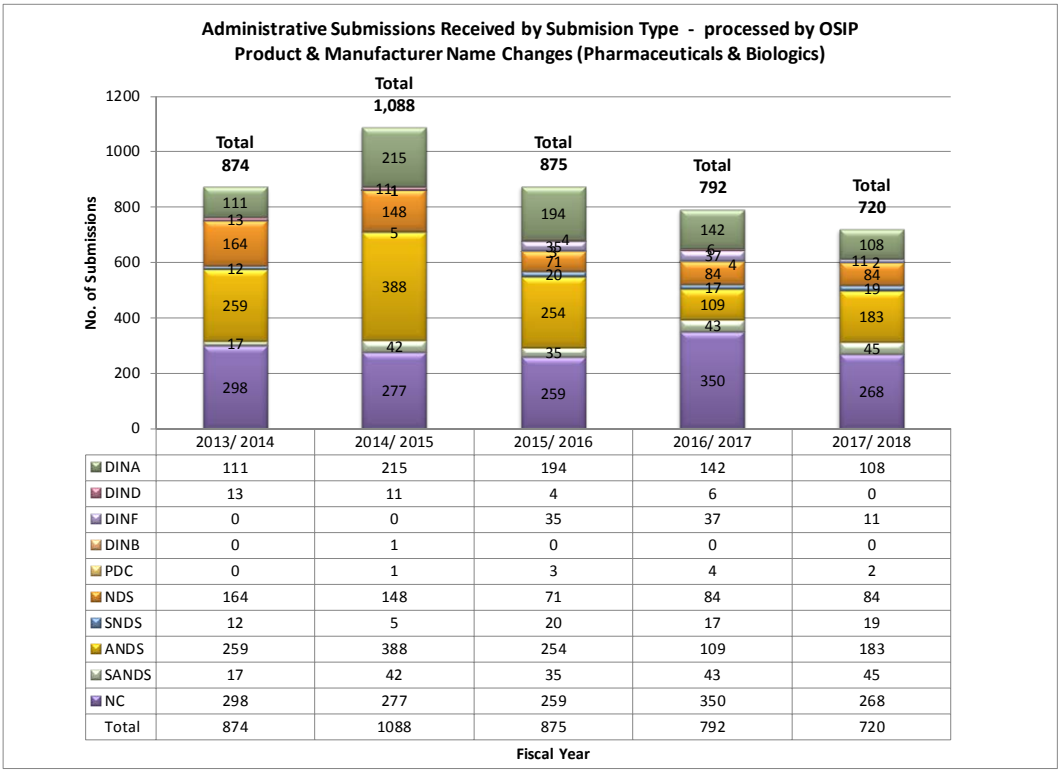


	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NDS - ADMINISTRATIVE	0	0	2	0	0
SNDS - ADMINISTRATIVE	1	0	0	0	0
ANDS - ADMINISTRATIVE	1	0	0	0	0
SANDS - ADMINISTRATIVE	0	1	0	0	0
TOTAL	2	1	2	0	0

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

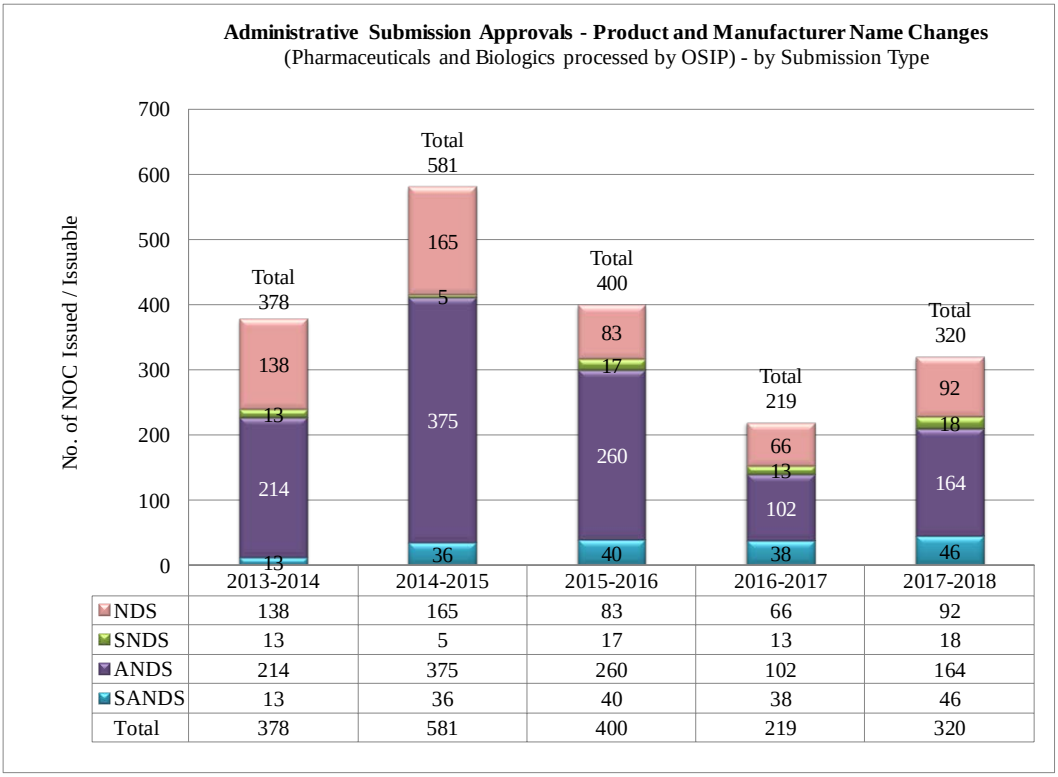
(Product & Manufacturer Name Changes)
(Admin Ncs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
DINA	111	215	194	142	108
DIND	13	11	4	6	0
DINF	0	0	35	37	11
DINB	0	1	0	0	0
PDC	0	1	3	4	2
NDS	164	148	71	84	84
SNDS	12	5	20	17	19
ANDS	259	388	254	109	183
SANDS	17	42	35	43	45
NC	298	277	259	350	268
Total	874	1088	875	792	720

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



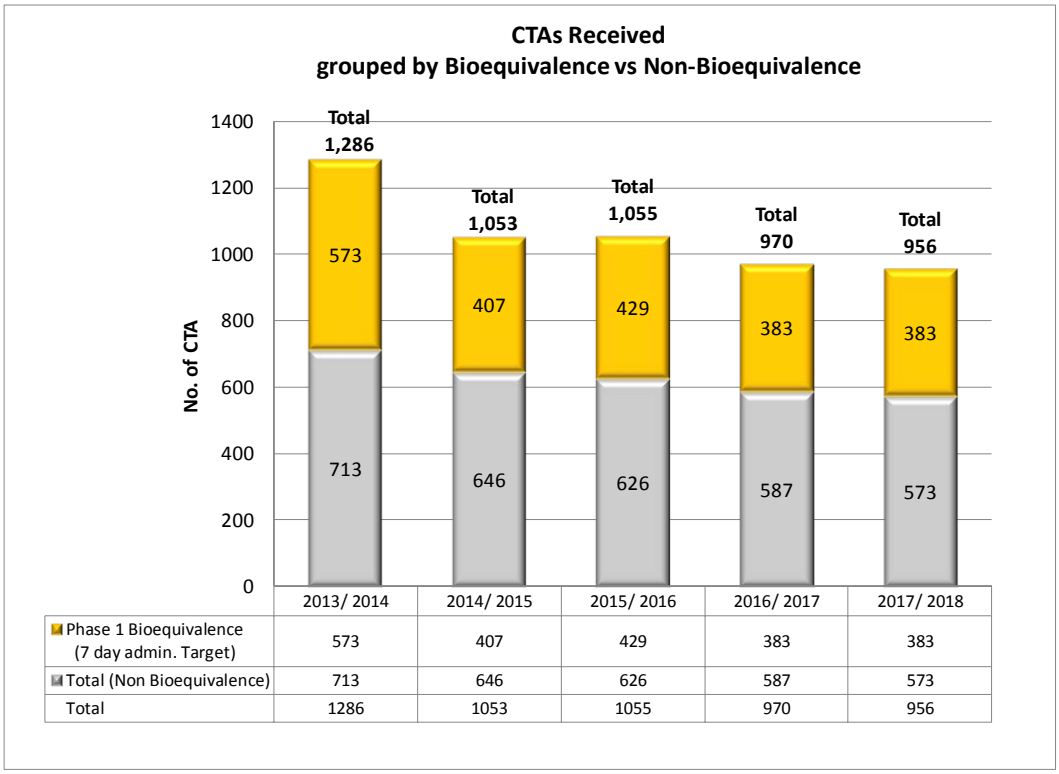
	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
NDS	138	165	83	66	92
SNDS	13	5	17	13	18
ANDS	214	375	260	102	164
SANDS	13	36	40	38	46
Total	378	581	400	219	320

Clinical Trial Applications and Amendments

(CTA & CTA-A)

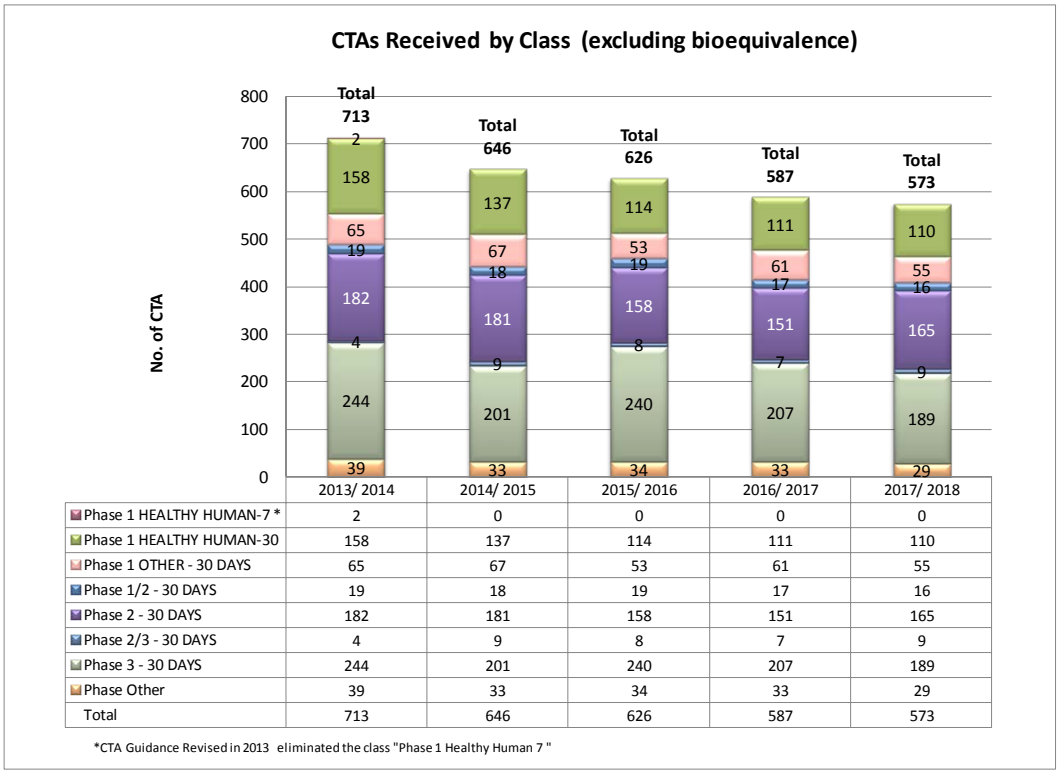
CLINICAL TRIAL APPLICATIONS

Number Received - Clinical Trial Application (CTA)



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Phase 1 Bioequivalence (7 day admin. Target)	573	407	429	383	383
Total (Non Bioequivalence)	713	646	626	587	573
Total	1286	1053	1055	970	956

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



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Phase 1 HEALTHY HUMAN-7 *	2	0	0	0	0
Phase 1 HEALTHY HUMAN-30	158	137	114	111	110
Phase 1 OTHER - 30 DAYS	65	67	53	61	55
Phase 1/2 - 30 DAYS	19	18	19	17	16
Phase 2 - 30 DAYS	182	181	158	151	165
Phase 2/3 - 30 DAYS	4	9	8	7	9
Phase 3 - 30 DAYS	244	201	240	207	189
Phase Other	39	33	34	33	29
Total	713	646	626	587	573

*CTA Guidance Revised in 2013 eliminated the class "Phase 1 Healthy Human 7 "

DECISION DOCUMENTS

Decision Documents - Clinical Trial Application (CTA)

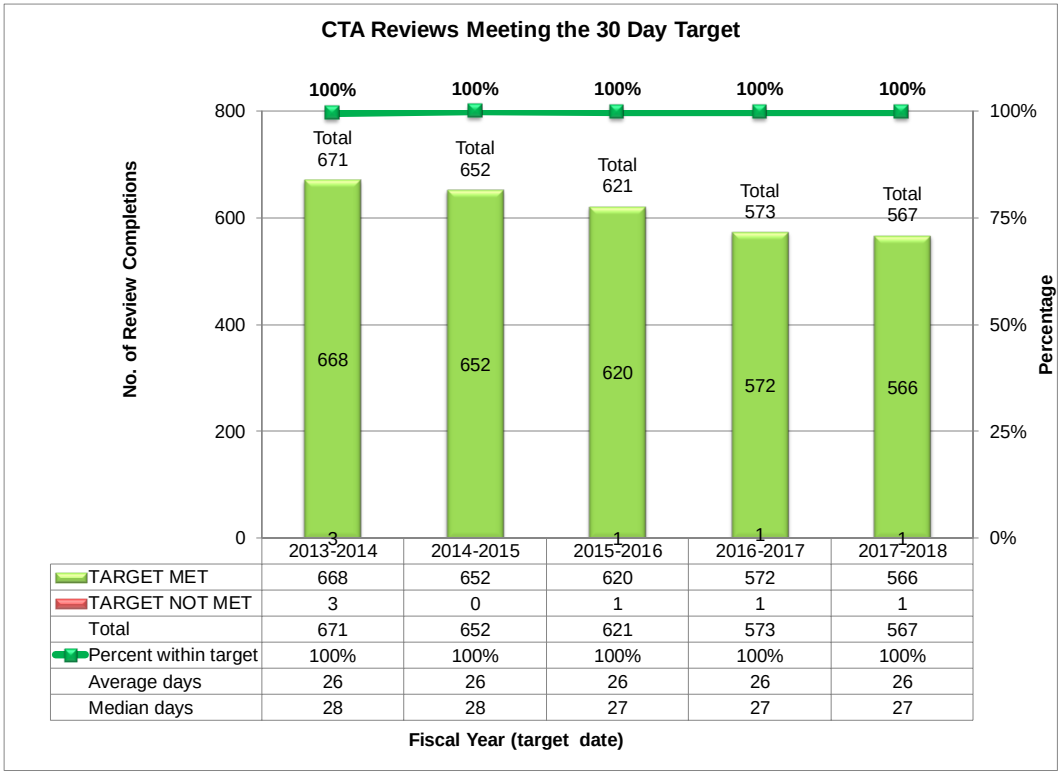
CTA (Total)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	1186	1021	994	926	898
CANCELLED BY COMPANY DURING REVIEW	54	48	44	36	53
CANCELLED BY COMPANY AT PROCESSING	17	7	8	4	11

CTA (7 day administrative target*)	*Phase 1 Bioequivalence (Class Phase 1 Healthy Human 7 eliminated in 2013)				
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	553	410	405	386	379
CANCELLED BY COMPANY DURING REVIEW	16	6	12	3	3
CANCELLED BY COMPANY AT PROCESSING	2	0	0	0	1

CTA (30 day target)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	633	611	589	540	519
CANCELLED BY COMPANY DURING REVIEW	38	42	32	33	50
CANCELLED BY COMPANY AT PROCESSING	15	7	8	4	10

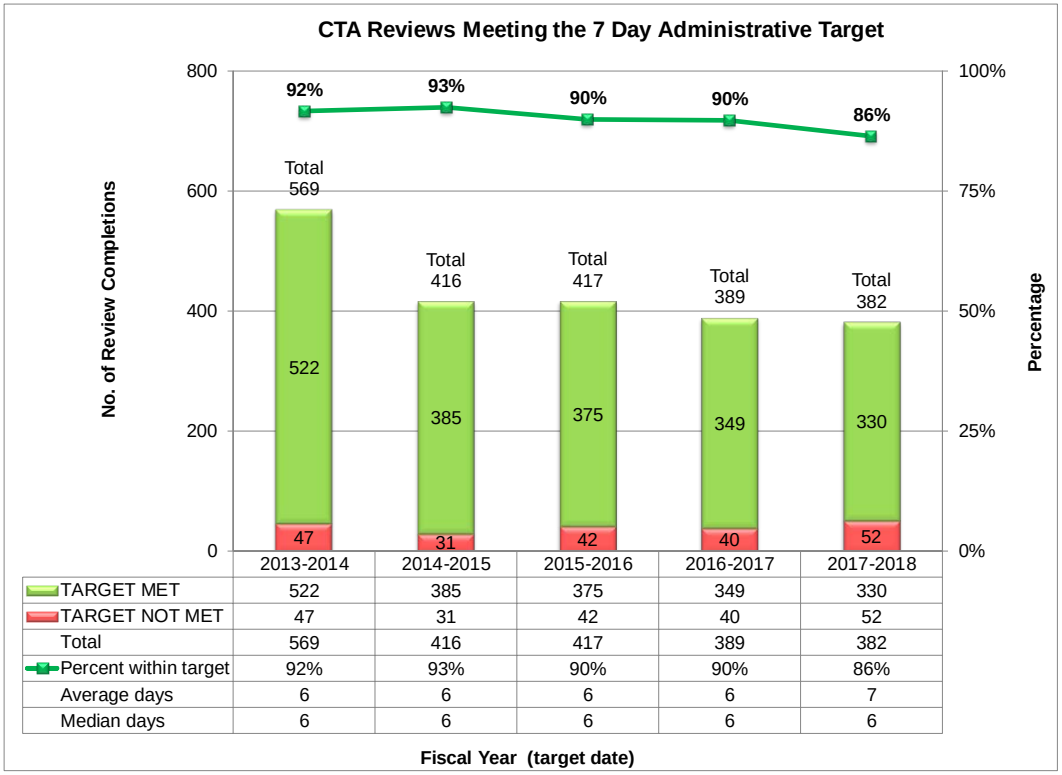
PERFORMANCE

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	668	652	620	572	566
TARGET NOT MET	3	0	1	1	1
Total	671	652	621	573	567
Percent within target	100%	100%	100%	100%	100%
Average days	26	26	26	26	26
Median days	28	28	27	27	27

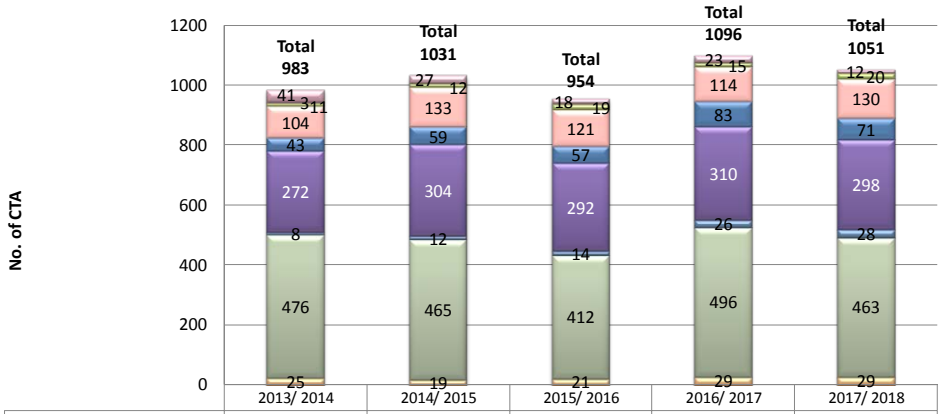
Performance – CTA Reviews Meeting the 7 Day Administrative Target



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	522	385	375	349	330
TARGET NOT MET	47	31	42	40	52
Total	569	416	417	389	382
Percent within target	92%	93%	90%	90%	86%
Average days	6	6	6	6	7
Median days	6	6	6	6	6

CLINICAL TRIAL APPLICATION-AMENDMENTS

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



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Phase 1 BIOEQUIVALENCE-7	41	27	18	23	12
Phase 1 HEALTHY HUMAN -7*	3	0	0	0	0
Phase 1 HEALTHY HUMAN-30	11	12	19	15	20
Phase 1 OTHER - 30 DAYS	104	133	121	114	130
Phase 1/2 - 30 DAYS	43	59	57	83	71
Phase 2 - 30 DAYS	272	304	292	310	298
Phase 2/3 - 30 DAYS	8	12	14	26	28
Phase 3 - 30 DAYS	476	465	412	496	463
Phase Other	25	19	21	29	29
Total	983	1031	954	1096	1051

*CTA Guidance Revised in 2013 eliminated the class "Phase 1 Healthy Human 7 "

DECISION DOCUMENTS

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

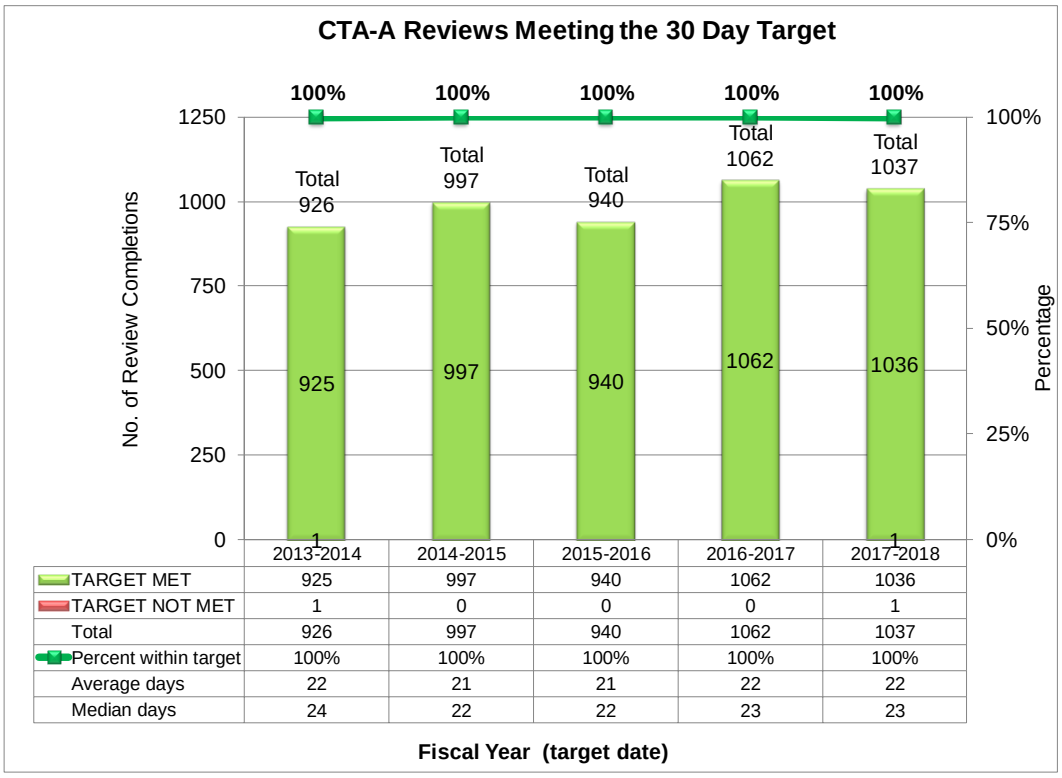
CTA-A (Total)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	963	1013	949	1070	1037
CANCELLED BY COMPANY DURING REVIEW	8	11	9	15	11
CANCELLED BY COMPANY AT PROCESSING	0	4	0	0	1

CTA-A (7 day administrative target)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	43	26	18	23	12
CANCELLED BY COMPANY DURING REVIEW	0	0	0	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

CTA-A (30 day target)					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NO OBJECTION LETTER	920	987	931	1047	1025
CANCELLED BY COMPANY DURING REVIEW	8	11	9	15	11
CANCELLED BY COMPANY AT PROCESSING	0	4	0	0	1

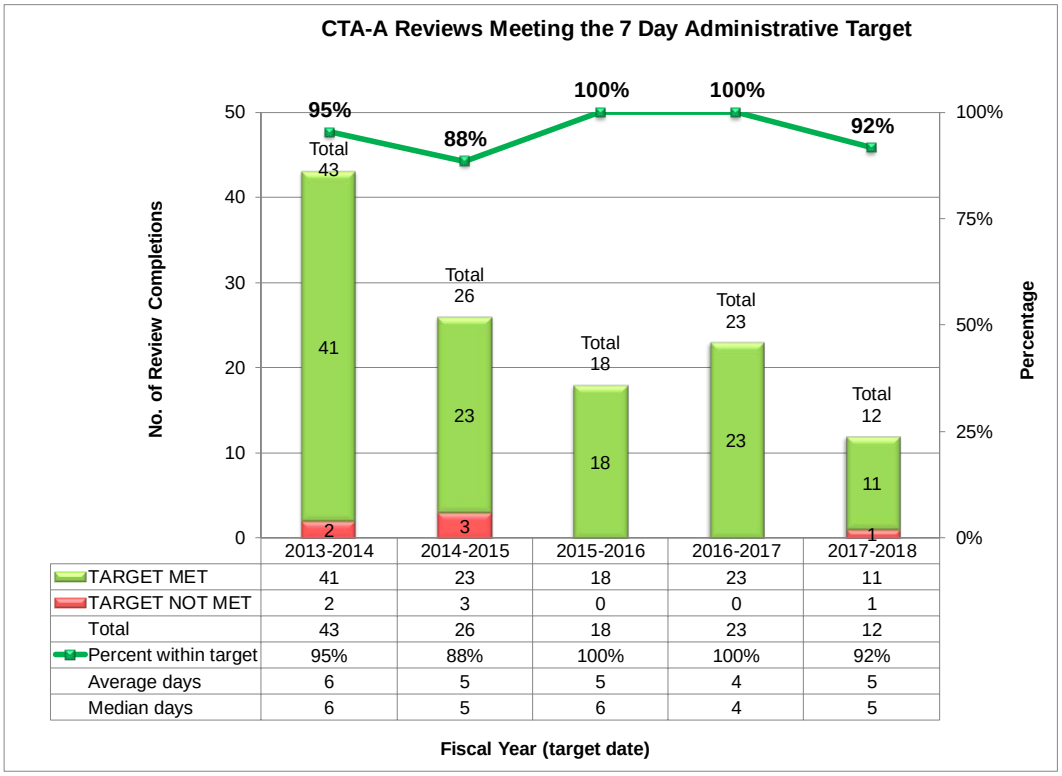
PERFORMANCE

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	925	997	940	1062	1036
TARGET NOT MET	1	0	0	0	1
Total	926	997	940	1062	1037
Percent within target	100%	100%	100%	100%	100%
Average days	22	21	21	22	22
Median days	24	22	22	23	23

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



	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
TARGET MET	41	23	18	23	11
TARGET NOT MET	2	3	0	0	1
Total	43	26	18	23	12
Percent within target	95%	88%	100%	100%	92%
Average days	6	5	5	4	5
Median days	6	5	6	4	5

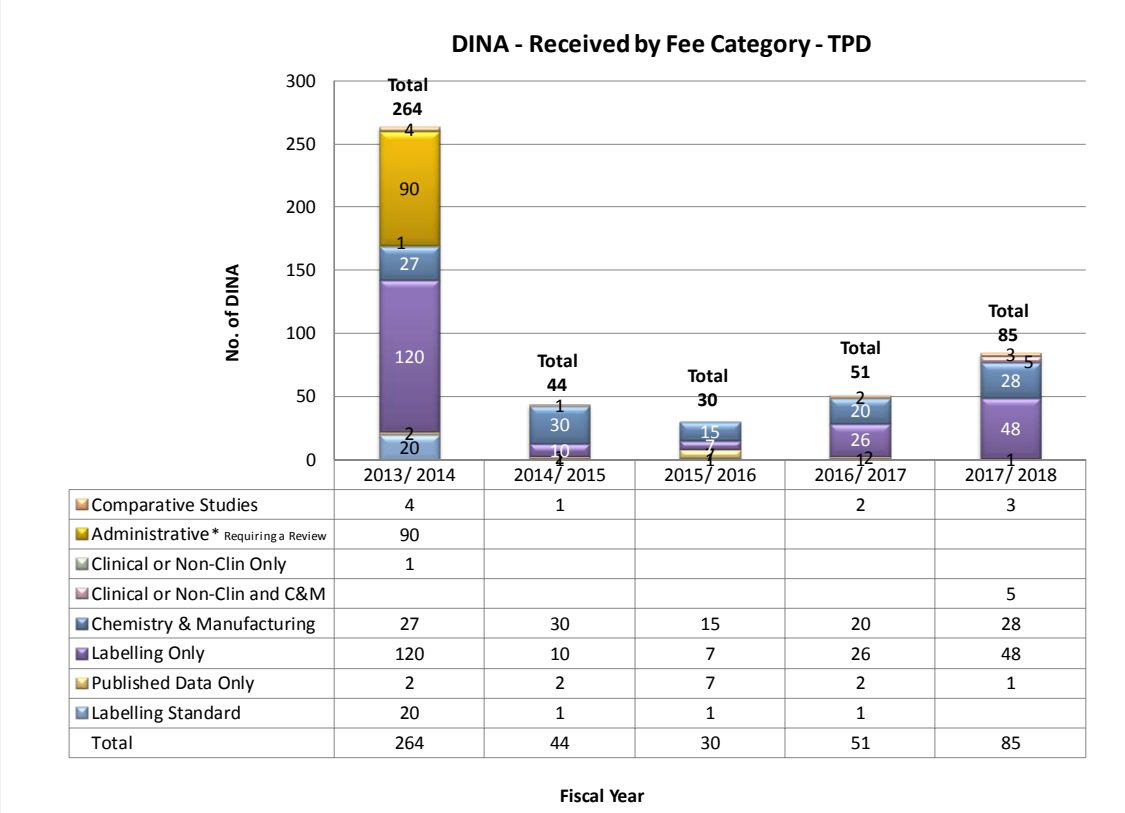
DINA

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

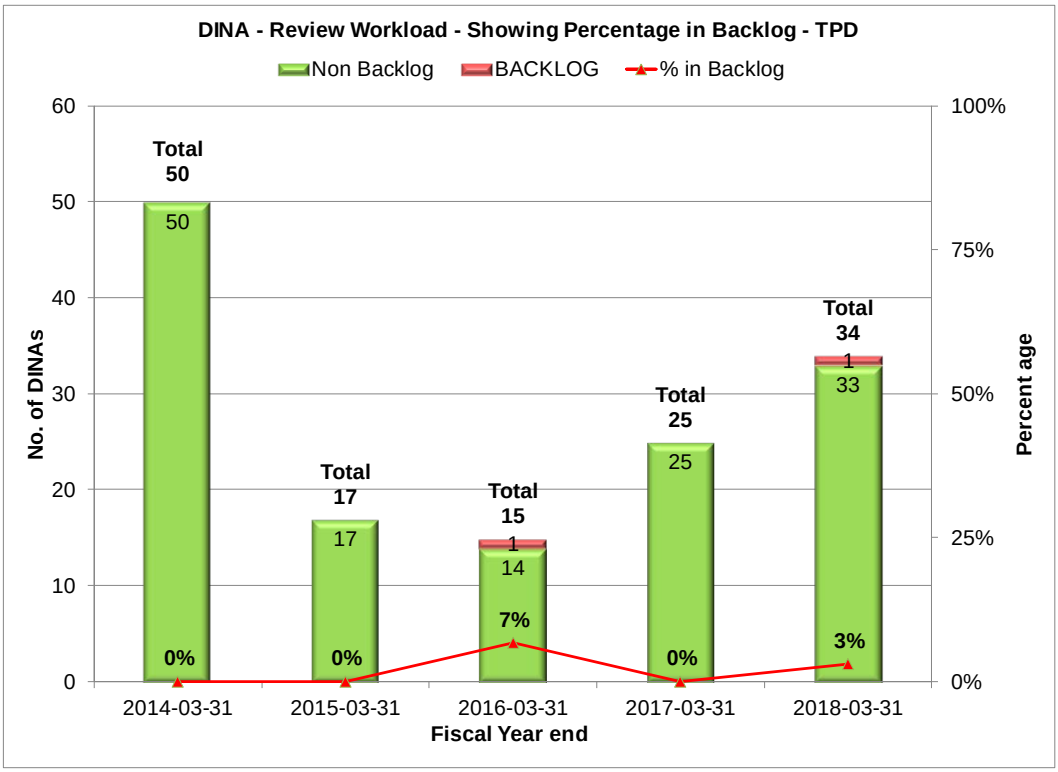


	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Comparative Studies	4	1		2	3
Administrative* Requiring a Review	90				
Clinical or Non-Clin Only	1				
Clinical or Non-Clin and C&M					5
Chemistry & Manufacturing	27	30	15	20	28
Labelling Only	120	10	7	26	48
Published Data Only	2	2	7	2	1
Labelling Standard	20	1	1	1	
Total	264	44	30	51	85

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

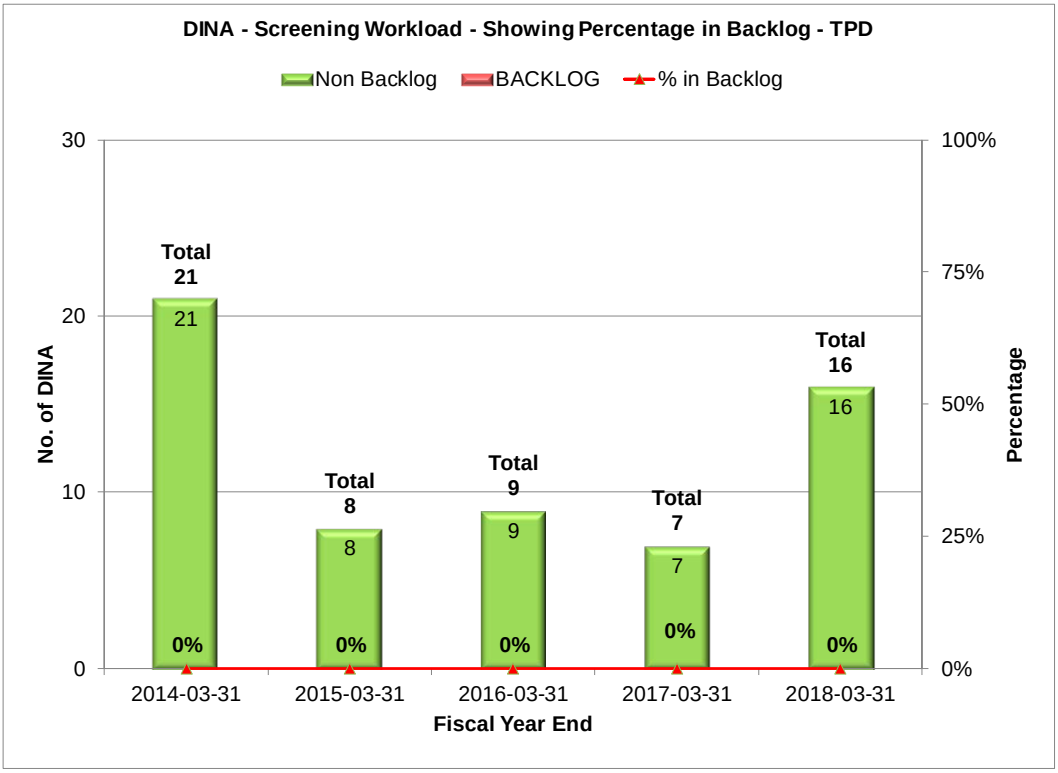


DINA: Review Workload by Class

TPD DINA All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**32**	**2**	**4**	**13**	**13**
Backlog	*0*	*0*	*0*	*0*	*1*
Clinical or Non-Clin Only	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**15**	**14**	**9**	**12**	**19**
Backlog	*0*	*0*	*1*	*0*	*0*
Published Data	**0**	**0**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**2**	**1**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**50**	**17**	**15**	**25**	**34**
Non Backlog	**50**	**17**	**14**	**25**	**33**
BACKLOG	**0**	**0**	**1**	**0**	**1**
% in Backlog	**0%**	**0%**	**7%**	**0%**	**3%**

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					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**13**	**3**	**1**	**4**	**8**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**4**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**3**	**5**	**2**	**4**
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	0	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	***0***	***1***	***3***	***0***	***0***
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**1**	**0**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**21**	**8**	**9**	**7**	**16**
Non Backlog	**21**	**8**	**9**	**7**	**16**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

CLASS	DOCUMENT TYPE	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018
DINA - LABELLING ONLY	NOTIFICATION FORM/DIN ISSUED	92	4	1	3	12
	NO OBJECTION LETTER	21	6	5	4	25
	CANCELLED BY COMPANY	10		1	6	3
	DIN INCORR SUBTYPE-CLASS	17				
	NEW DRUG LETTER SCREEN	3				
	NON WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY		2		1	
	NOTICE OF NON-COMPLIANCE	8			1	
	REJECTION LETTER (SCREENING)					1
	SCREENING DEFICIENCY NOTICE	17	4	2	9	8
	SPONSOR SUB CHANGE ACCEPT	10				
DINA - ADMINISTRATIVE	NOTIFICATION FORM/DIN ISSUED	87	-	-	-	-
	NO OBJECTION LETTER	1	-	-	-	-
	REJECTION LETTER (SCREENING)	10	-	-	-	-
	SCREENING DEFICIENCY NOTICE	6	-	-	-	-
	CANCELLED BY COMPANY	2	-	-	-	-
DINA - LABELLING STANDARD	NOTIFICATION FORM/DIN ISSUED	16				-
	NO OBJECTION LETTER					-
	NEW DRUG LETTER SCREEN	1				-
	REJECTION LETTER (SCREENING)				1	-
	SCREENING DEFICIENCY NOTICE	1	1			-
	SPONSOR SUB CHANGE ACCEPT					-
	DIN INCORR SUBTYPE-CLASS					-
	CANCELLED BY COMPANY	1	1			-
DINA - PUBLISHED DATA ONLY	NO OBJECTION LETTER			3	2	
	NOTICE OF DEFICIENCY					
	NON WITHDRAWAL LETTER					
	REJECTION LETTER (SCREENING)		1			
	SCREENING DEFICIENCY NOTICE					1
	CANCELLED BY COMPANY	2		1	1	
	NOTICE OF NON-COMPLIANCE			1	1	
	NOT SATISFACTORY NOTICE				1	
DINA - CHEMISTRY & MANUFACTURING	NOTIFICATION FORM/DIN ISSUED	8	17	12	6	13
	NOD WITHDRAWAL LETTER					
	NOTICE OF DEFICIENCY		3	2	1	2
	REJECTION LETTER (SCREENING)	3			3	
	SCREENING DEFICIENCY NOTICE	15	11	12	17	9
	CANCELLED BY COMPANY	5		3	4	3
	NO OBJECTION LETTER	3	8	6	5	3
	NEW DRUG LETTER SCREEN	1				
	NEW DRUG LETTER REVIEW					1
	NOTICE OF NON-COMPLIANCE	6	3	4	8	6
	NON WITHDRAWAL LETTER				1	2
DINA - CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM/DIN ISSUED	1				
	NOTICE OF DEFICIENCY					
	NO OBJECTION LETTER	3				
DINA - CLINICAL OR NON CLINICAL DATA AND C&M	CANCELLED BY COMPANY					1
	SCREENING DEFICIENCY NOTICE					2
DINA - COMPARATIVE STUDIES	NOTIFICATION FORM/DIN ISSUED	1	2	1	2	1
	NO OBJECTION LETTER	1				
	NOTICE OF DEFICIENCY	1	1	1		
	NOTICE OF NON-COMPLIANCE					1
	SCREENING DEFICIENCY NOTICE	1			1	3

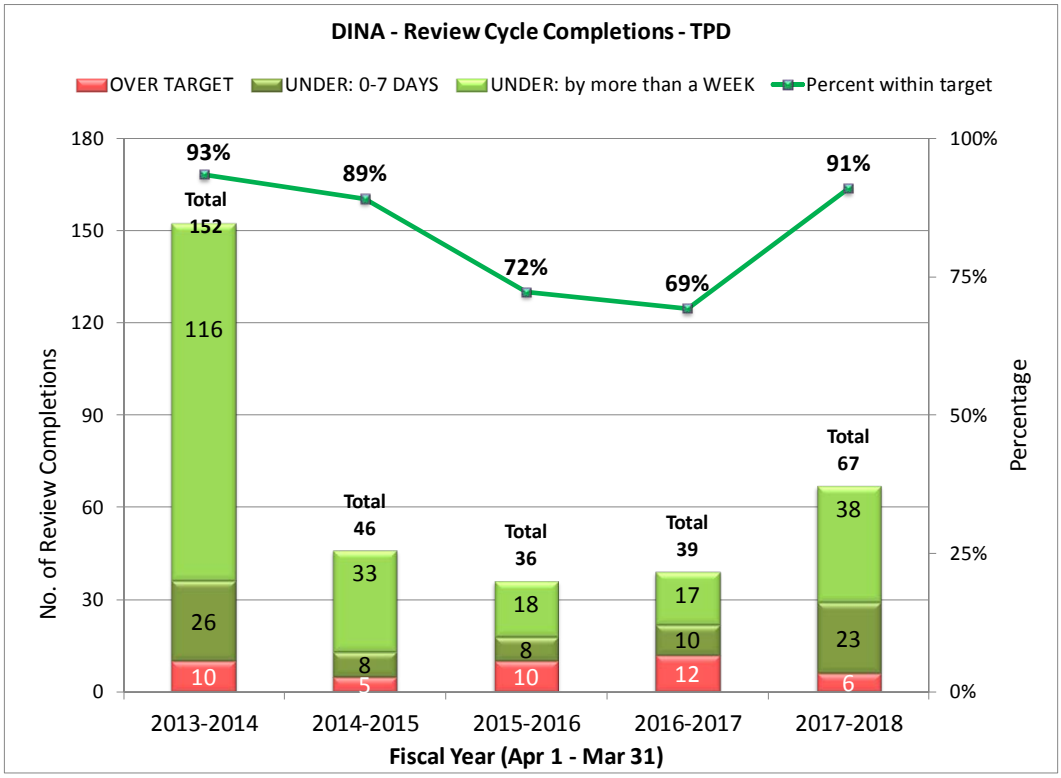
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Requests for Reconsideration of Final Decisions

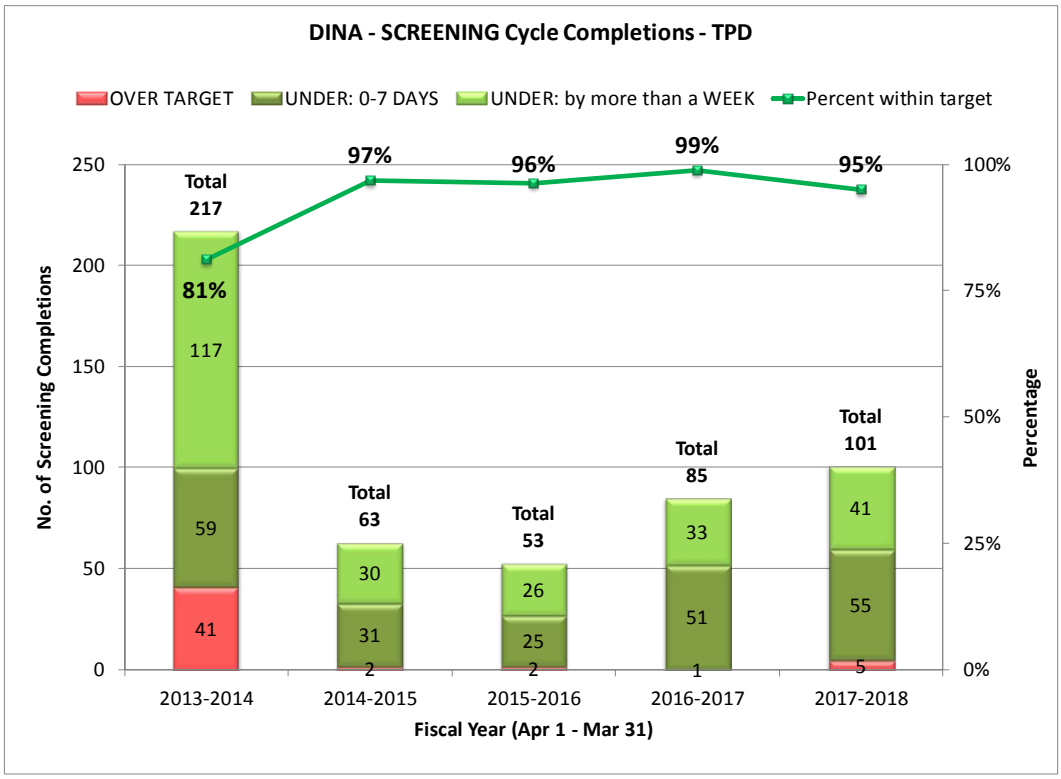
DINA - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**13-14**	**14-15**	**15-16**	**16-17**	**17-18**	**Final Decision in Dispute**	**Submission Status (as of May 2018)**
Total Received	**0**	**1**	**0**	**1**	**0**		
Total Granted	***0***	***0***	***0***	***1***	***0***	NON-Withdrawal	Cleared
Total Cancelled	***0***	***1***	***0***	***0***	***0***		
Cancelled by Health Canada		1				New Drug Letter	Withdrawn

PERFORMANCE

DINA: Review Cycle Completions

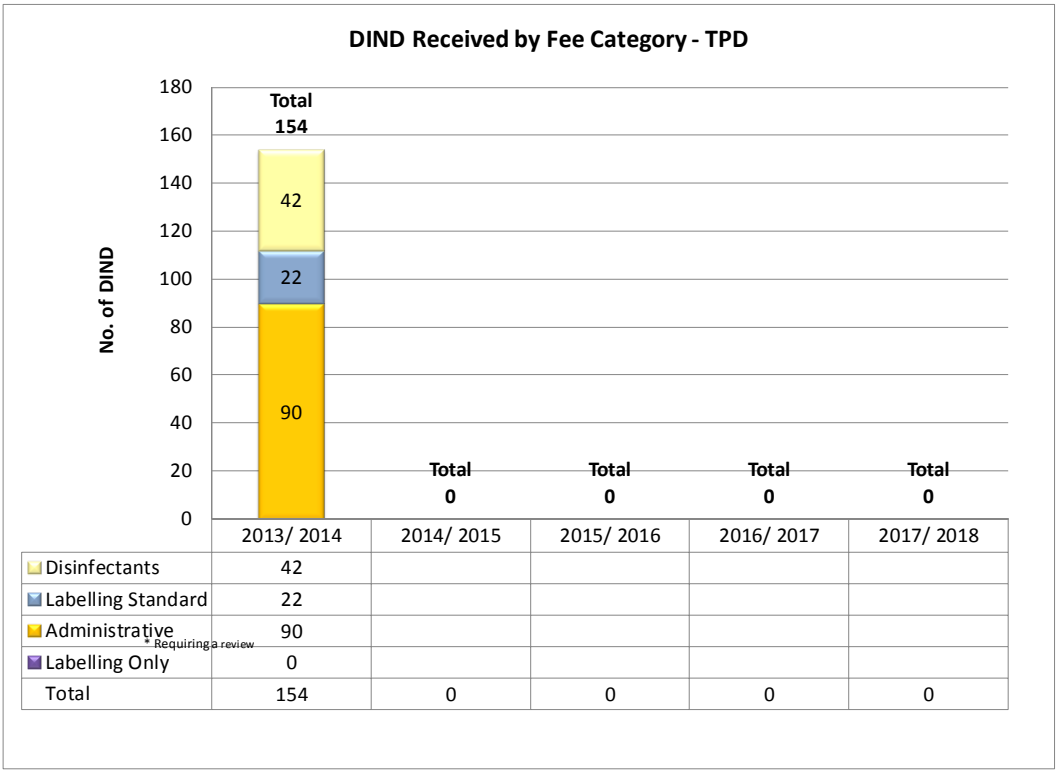


DINA: Screening Cycle Completions



DIND: Application for a Drug Identification Number - DISINFECTANT PRODUCT

DIND: Number Received

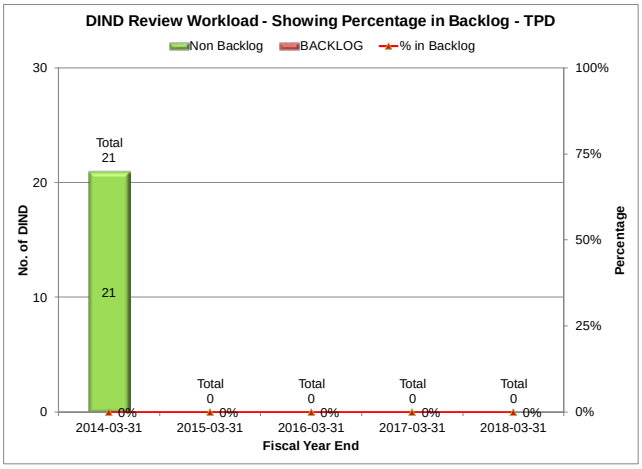


	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Disinfectants	42				
Labelling Standard	22				
Administrative * Requiring a review	90				
Labelling Only	0				
Total	154	0	0	0	0

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

DIND: Review Workload Showing Percentage in Backlog

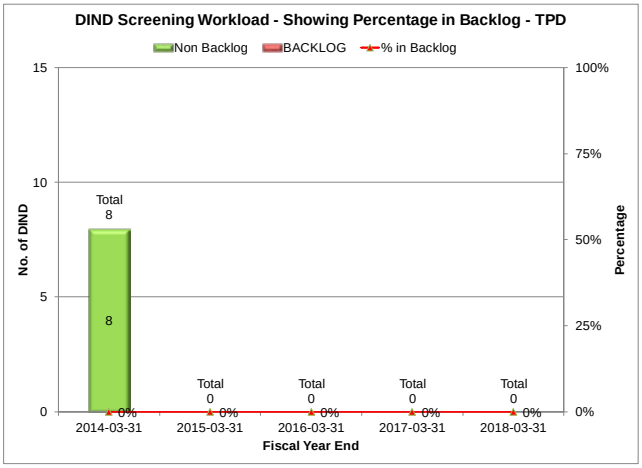


DIND: Review Workload by User Fee Category

TPD DIND All REVIEW WORKLOAD BY FEE CATEGORY (excluding administrative) and Fiscal Year End					
	2014-03-31	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Disinfectant	**21**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**21**	**0**	**0**	**0**	**0**
Non Backlog	**21**	*0*	*0*	*0*	*0*
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

DIND: Screening Workload Showing Percentage in Backlog



DIND: Screening Workload by Class

TPD DIND All SCREENING WORKLOAD BY User Fee Category (excluding administrative) and Fiscal Year End					
CLASS	**2014-03-31**	**2015-03-31**	**2016-03-31**	**2017-03-31**	**2018-03-31**
Labelling Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Disinfectant	**7**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**8**	0	0	0	0
Non Backlog	8	0	0	0	0
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

DIND: Decision Documents by Class

DIND - ADMINISTRATIVE					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NOTIFICATION FORM/DIN ISSUED	75	-	-	-	-
NO OBJECTION LETTER	1	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE	18	-	-	-	-

DIND - LABELLING STANDARD					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NOTIFICATION FORM/DIN ISSUED	25	-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE	17	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
NEW DRUG LETTER SCREEN	1	-	-	-	-

DIND - DIS NONCLIN/CLINICAL					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NOTIFICATION FORM/DIN ISSUED	24	-	-	-	-
DIN INCORR SUBTYPE-CLASS		-	-	-	-
NO OBJECTION LETTER	7	-	-	-	-
NOTICE OF NON-COMPLIANCE	4	-	-	-	-
REJECTION LETTER (SCREENING)		-	-	-	-
SCREENING DEFICIENCY NOTICE		-	-	-	-
SPONSOR SUB CHANGE ACCEPT		-	-	-	-
CANCELLED BY COMPANY	1	-	-	-	-
NON WITHDRAWAL LETTER	1	-	-	-	-

DIND - DISINFECT LABEL ONLY					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
SCREENING DEFICIENCY NOTICE	2	-	-	-	-
CANCELLED BY COMPANY		-	-	-	-

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DIND: Requests for Reconsideration of Final Decisions

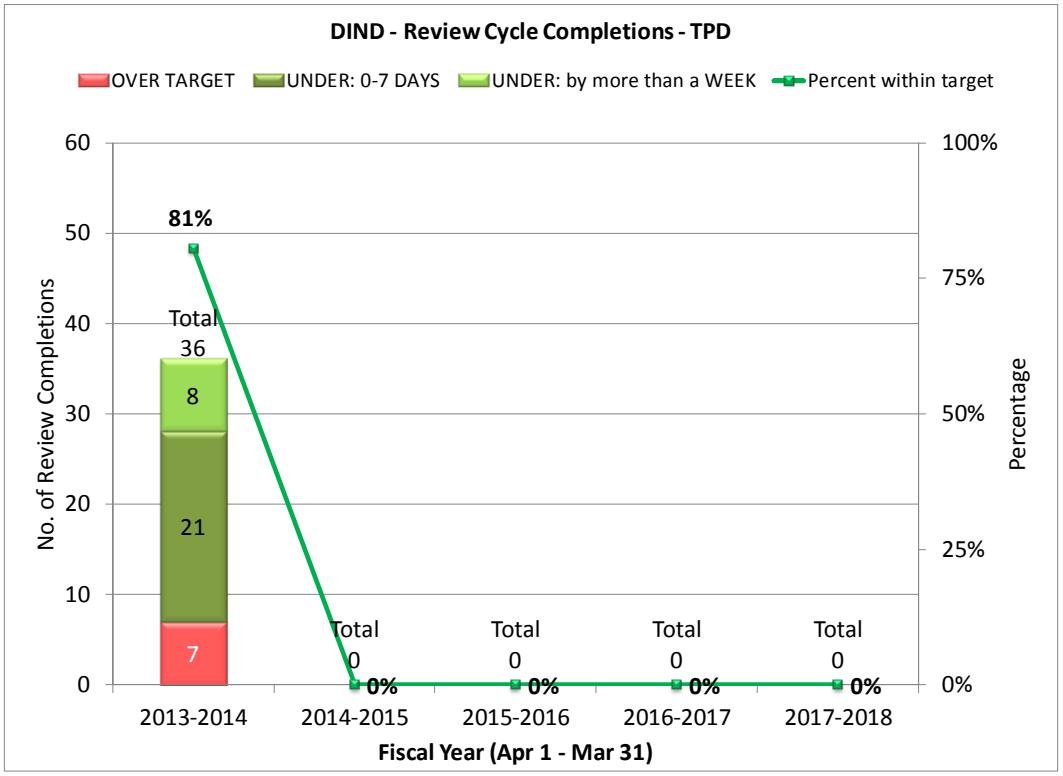
DIND - Reconsideration of Final Decisions by Year Requested

Fiscal Year of Request (April 1 - March 31)

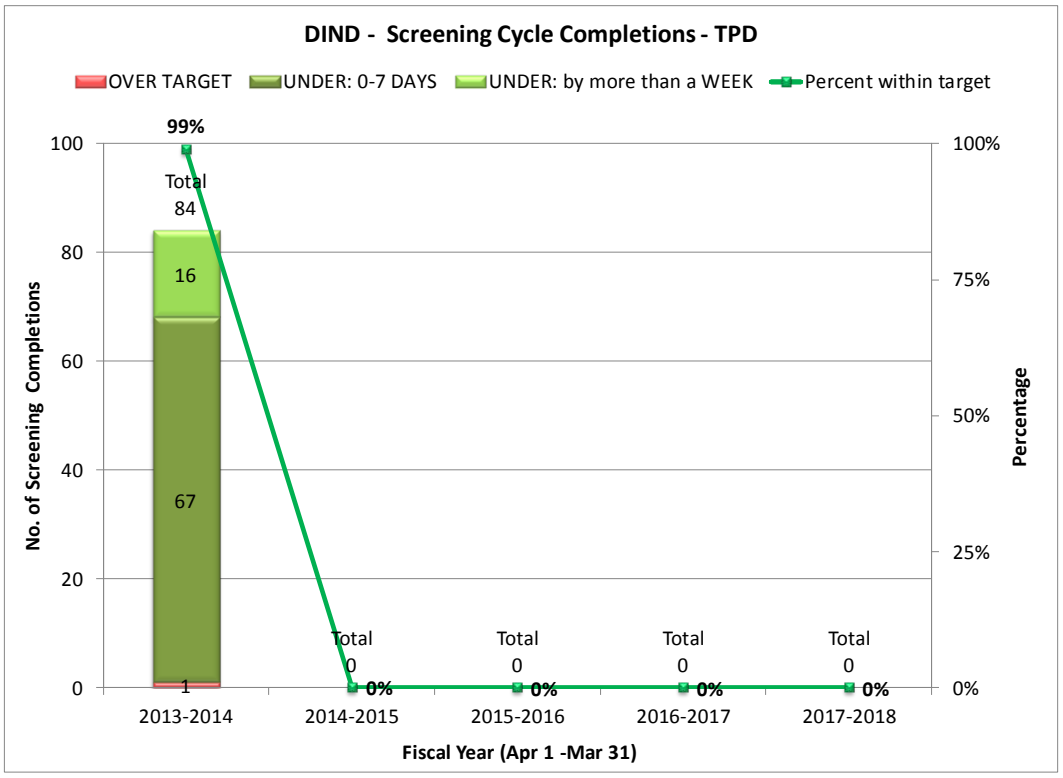
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
Total Received	**0**	**0**	**0**	**0**	**0**		

PERFORMANCE

DIND: Review Cycle Completions

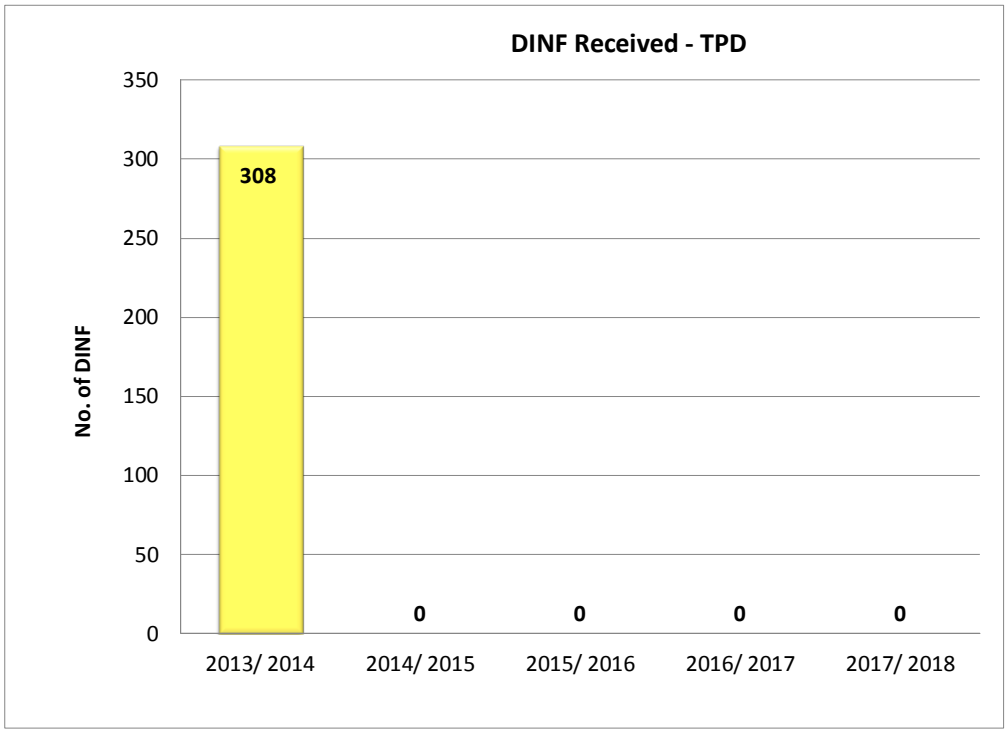


DIND: Screening Cycle Completions

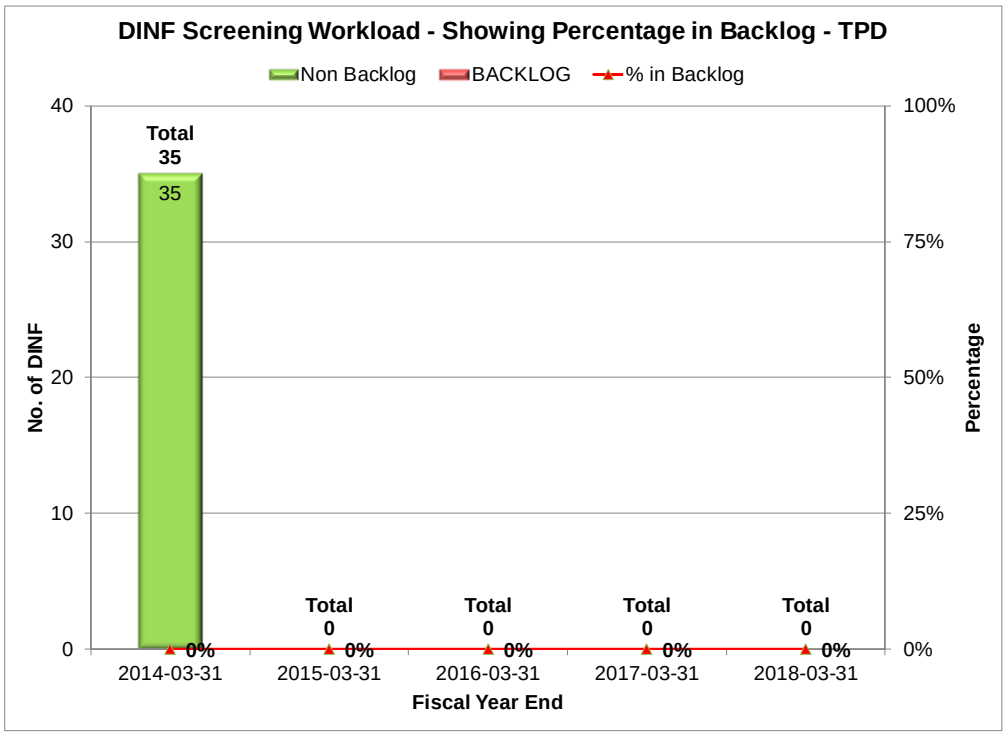


DINF: CATEGORY IV PRODUCT - (LABELLING STANDARD)

DINF: Number Received



DINF: Screening Workload Showing Percentage in Backlog



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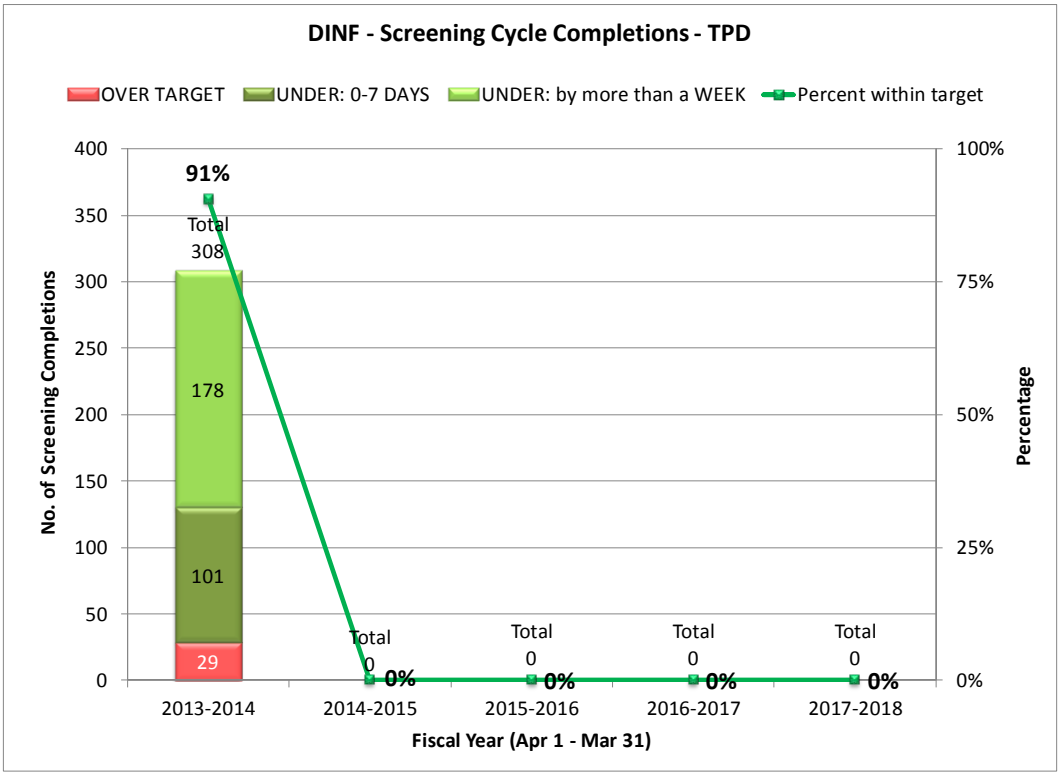
PERFORMANCE

DINF: Screening Cycle Completions



DECISION DOCUMENTS

DINF: Decision Documents

DINF - LABELLING STANDARD					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
NOTIFICATION FORM/DIN ISSUED	286	-	-	-	-
NO OBJECTION LETTER	1	-	-	-	-
CANCELLED BY COMPANY	11	-	-	-	-
DIN INCORR SUBTYPE-CLASS	1	-	-	-	-
NEW DRUG LETTER SCREEN		-	-	-	-
NOT SATISFACTORY NOTICE		-	-	-	-
REJECTION LETTER (SCREENING)	8	-	-	-	-
SCREENING DEFICIENCY NOTICE	12	-	-	-	-
SPONSOR SUB CHANGE ACCEPT	1	-	-	-	-

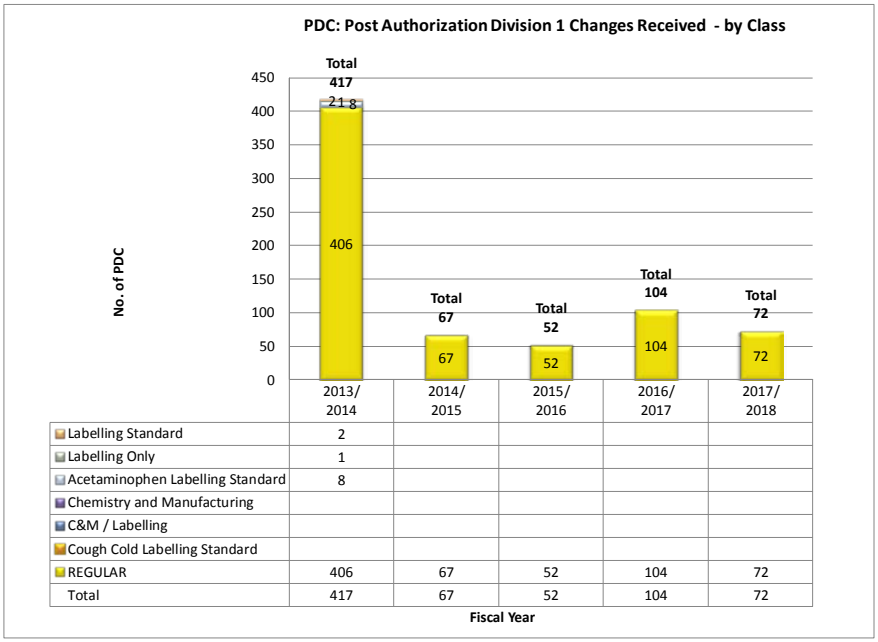
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions – DINF

DINF - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	**13-14**	**14-15**	**15-16**	**16-17**	**17-18**	**Final Decision in Dispute**	**Submission Status (as of May 2018)**
Total Received	**0**	**0**	**0**	**0**	**0**		

PDC: POST-AUTHORIZATION DIVISION 1 CHANGES

Post-Authorization Division 1 Changes (PDC) Received



	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Labelling Standard	2				
Labelling Only	1				
Acetaminophen Labelling Standard	8				
Chemistry and Manufacturing					
C&M / Labelling					
Cough Cold Labelling Standard					
REGULAR	406	67	52	104	72
Total	417	67	52	104	72

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

PDC					
DOCUMENT TYPE	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2017-2018**
COUGH COLD LABELLING STANDARD					
NO OBJECTION LETTER					
NOT SATISFACTORY NOTICE					
ACETAMINOPHEN LS					
CANCELLED BY COMPANY					
NO OBJECTION LETTER	10				
NOT SATISFACTORY NOTICE					
REGULAR					
CANCELLED BY COMPANY	16	7	11	18	15
NO OBJECTION LETTER	362	67	43	80	35
NOT SATISFACTORY NOTICE	15			1	
NOTIFICATION FORM/DIN ISSUED					
REJECTION LETTER (SCREENING)					
C&M ONLY					
NO OBJECTION LETTER					
CANCELLED BY COMPANY					
C&M LABELLING					
NO OBJECTION LETTER					
CANCELLED BY COMPANY					
NOT SATISFACTORY NOTICE					
LABELLING ONLY					
NO OBJECTION LETTER	1				
LABELLING STANDARD					
NO OBJECTION LETTER	2				

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)

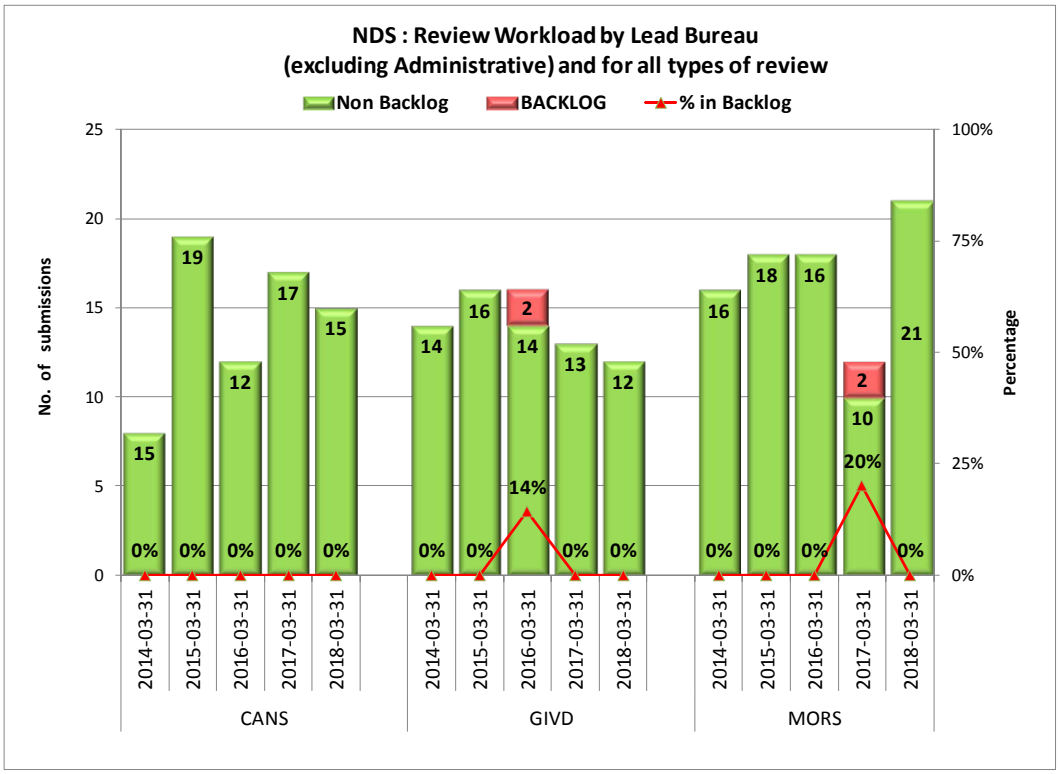
Breakdown by Reconsideration Decision	13-14	14-15	15-16	16-17	17-18	Final Decision in Dispute	Submission Status (as of May 2018)
Total Received	**2**	**0**	**0**	**0**	**0**		
Total Cancelled by Company	***2***					Not Satisfactory Notice	Rejected

APPENDIX A - Lead Bureau Summaries

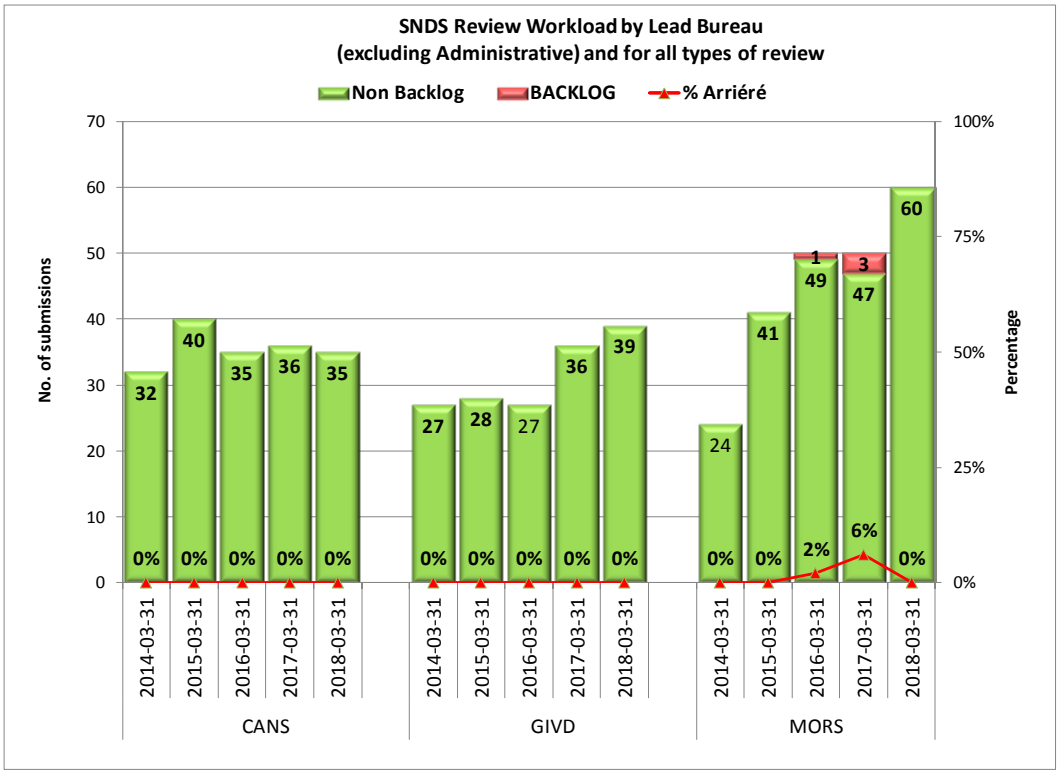
NDS & SNDS

WORKLOAD by Lead Bureau

NDS Review Workload by Lead Bureau

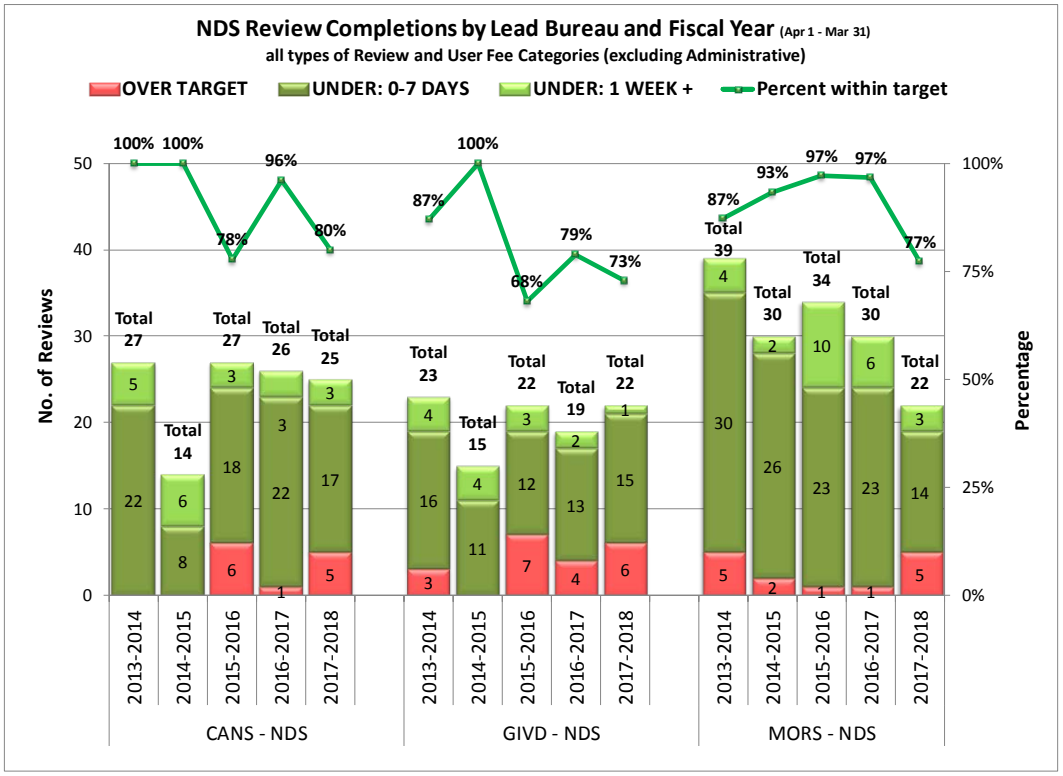


SNDS Review Workload by Lead Bureau

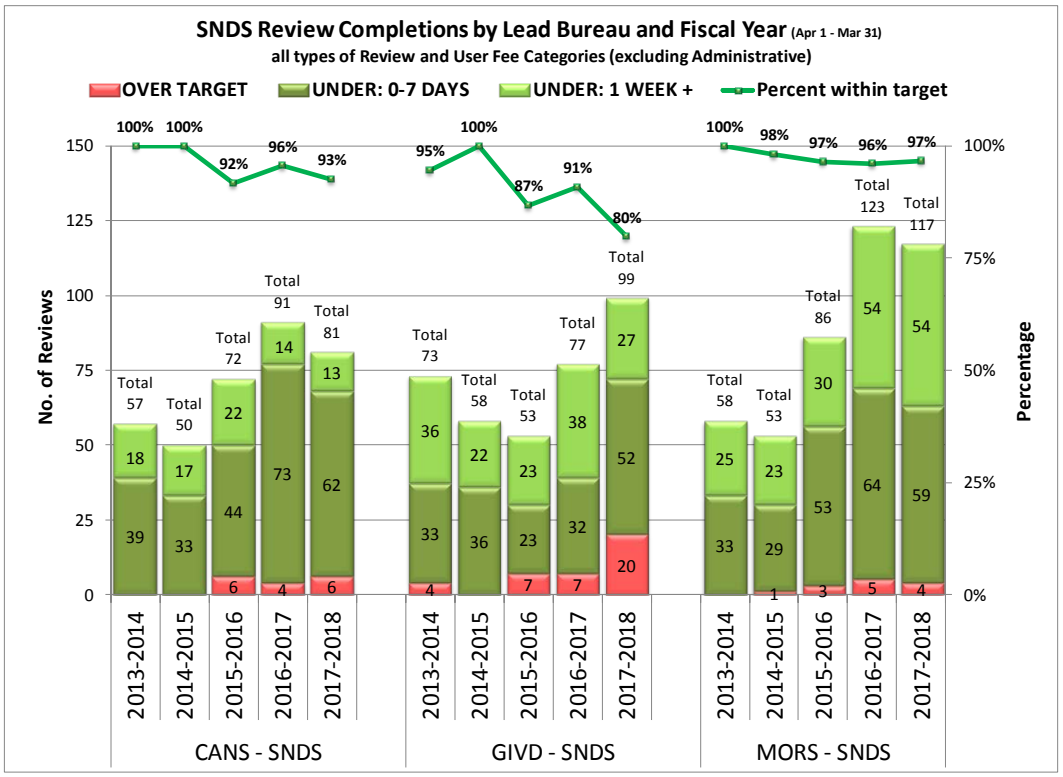


PERFORMANCE by Lead Bureau

NDS Review Performance by Lead Bureau

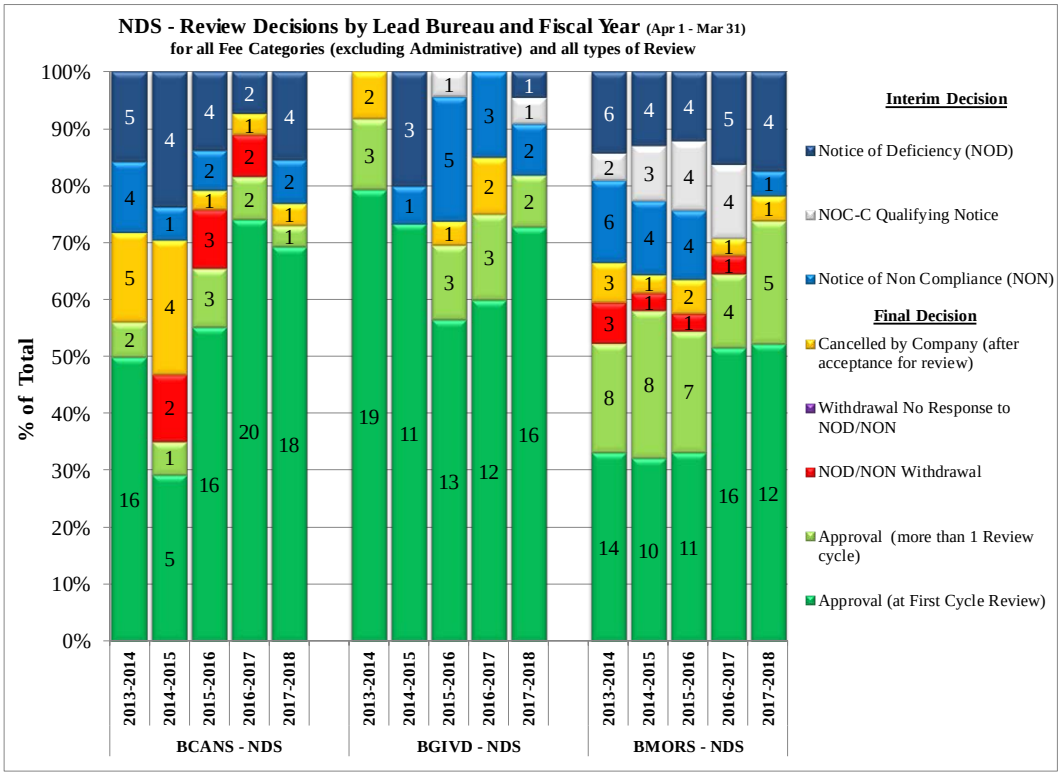


SNDS Review Performance by Lead Bureau

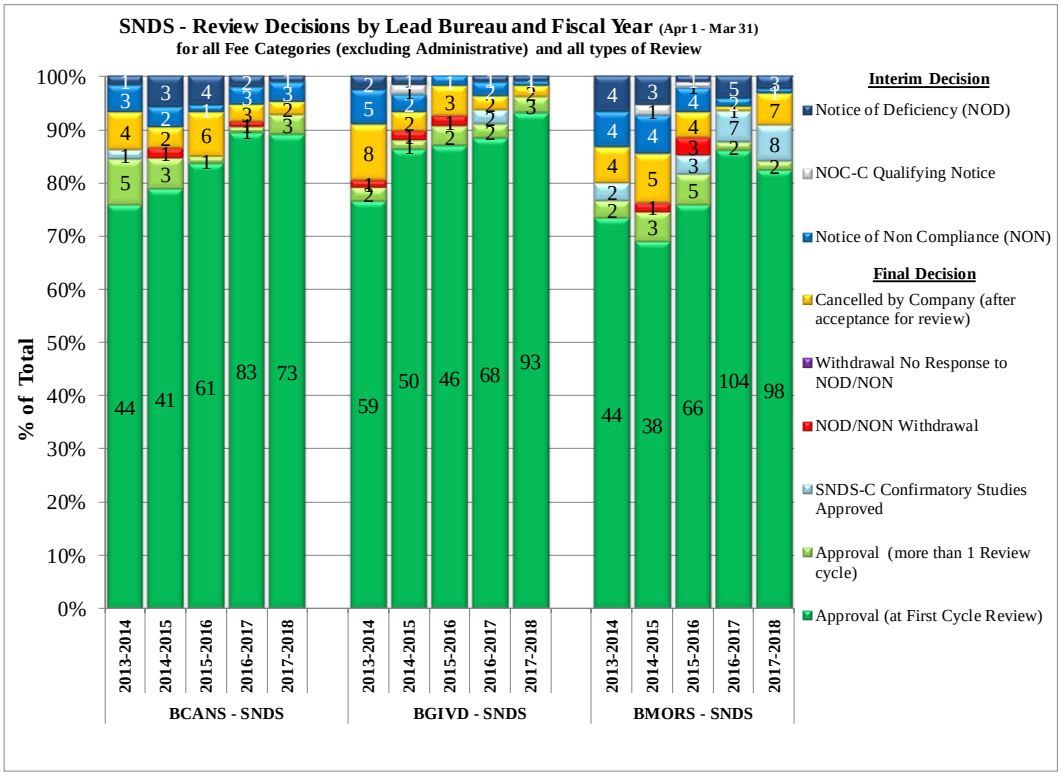


REVIEW DECISIONS by Lead Bureau

NDS Review Decisions by Lead Bureau

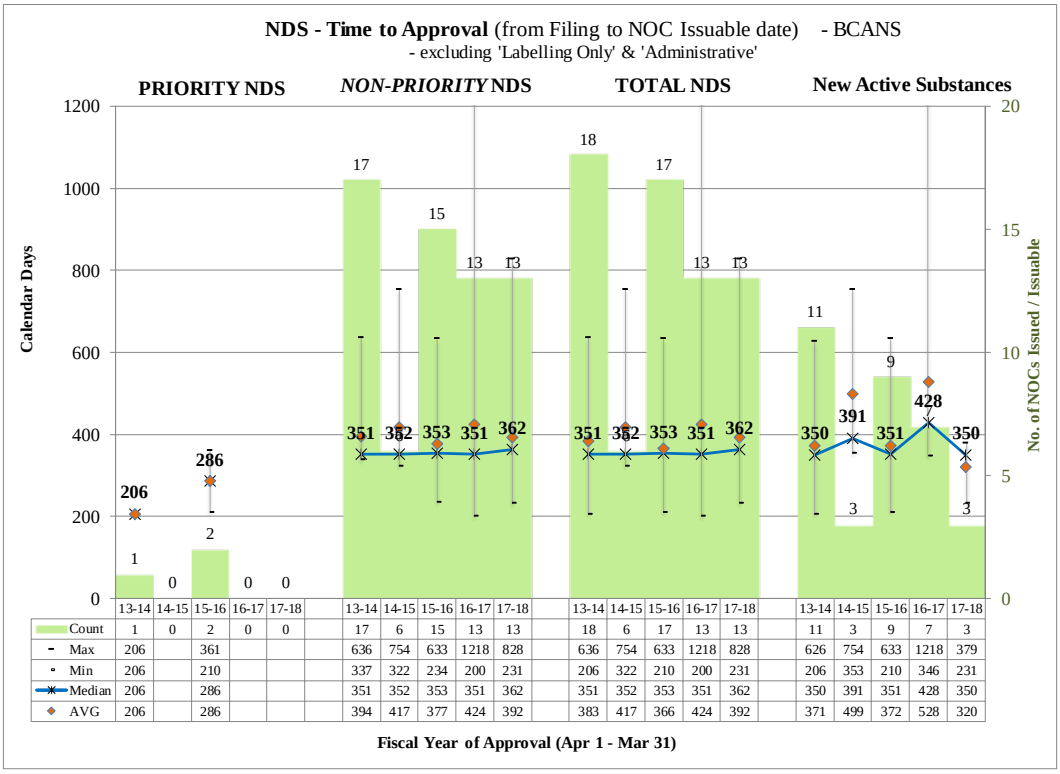


SNDS Review Decisions by Lead Bureau



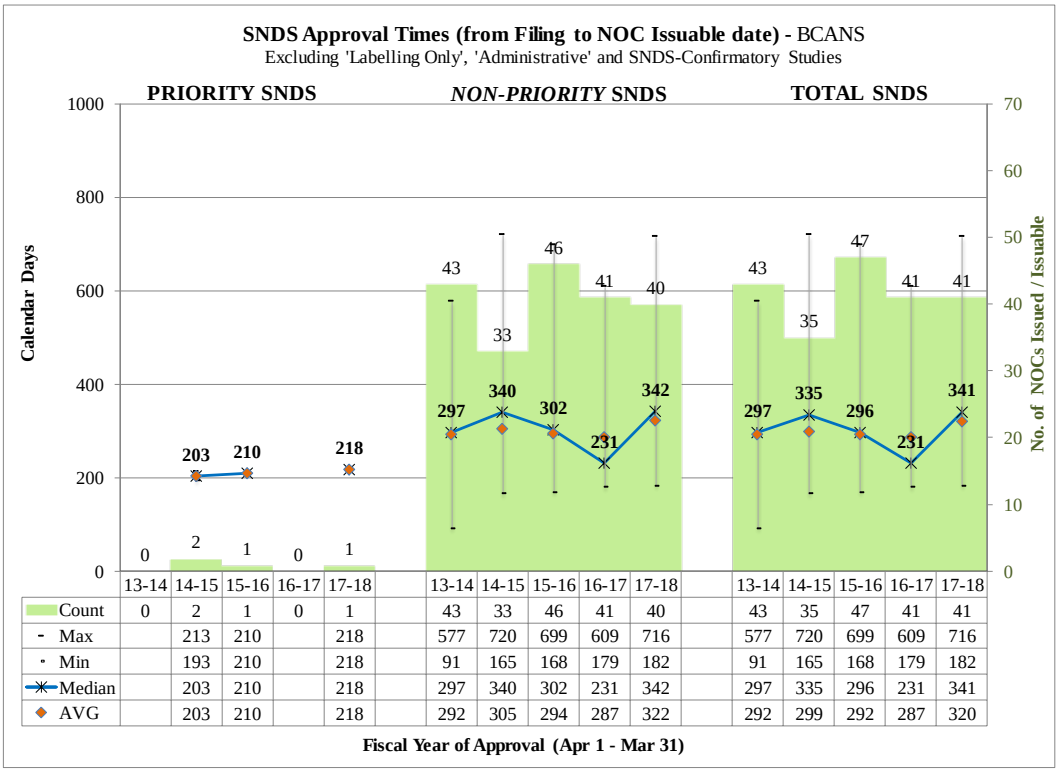
APPROVALS by Lead Bureau

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



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	1	0	2	0	0	17	6	15	13	13	18	6	17	13	13	11	3	9	7	3
Max	206		361			636	754	633	1218	828	636	754	633	1218	828	626	754	633	1218	379
Min	206		210			337	322	234	200	231	206	322	210	200	231	206	353	210	346	231
Median	206		286			351	352	353	351	362	351	352	353	351	362	350	391	351	428	350
AVG	206		286			394	417	377	424	392	383	417	366	424	392	371	499	372	528	320

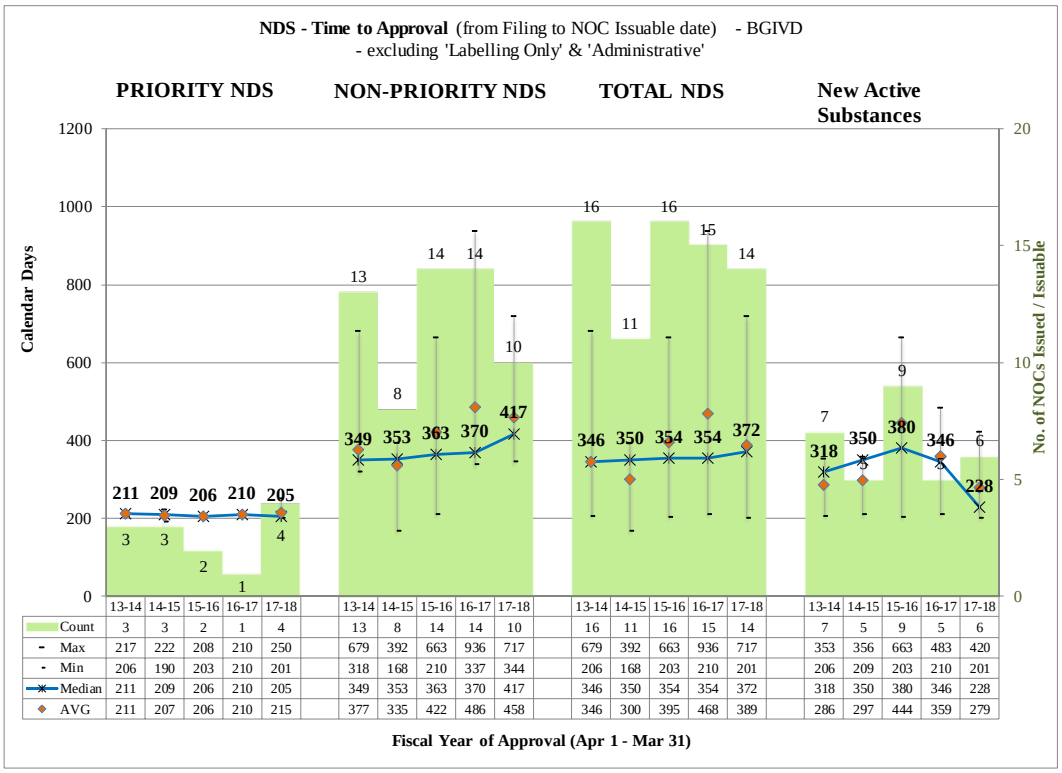
SNDS Approvals – Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	0	2	1	0	1	43	33	46	41	40	43	35	47	41	41
Max		213	210		218	577	720	699	609	716	577	720	699	609	716
Min		193	210		218	91	165	168	179	182	91	165	168	179	182
Median		203	210		218	297	340	302	231	342	297	335	296	231	341
AVG		203	210		218	292	305	294	287	322	292	299	292	287	320

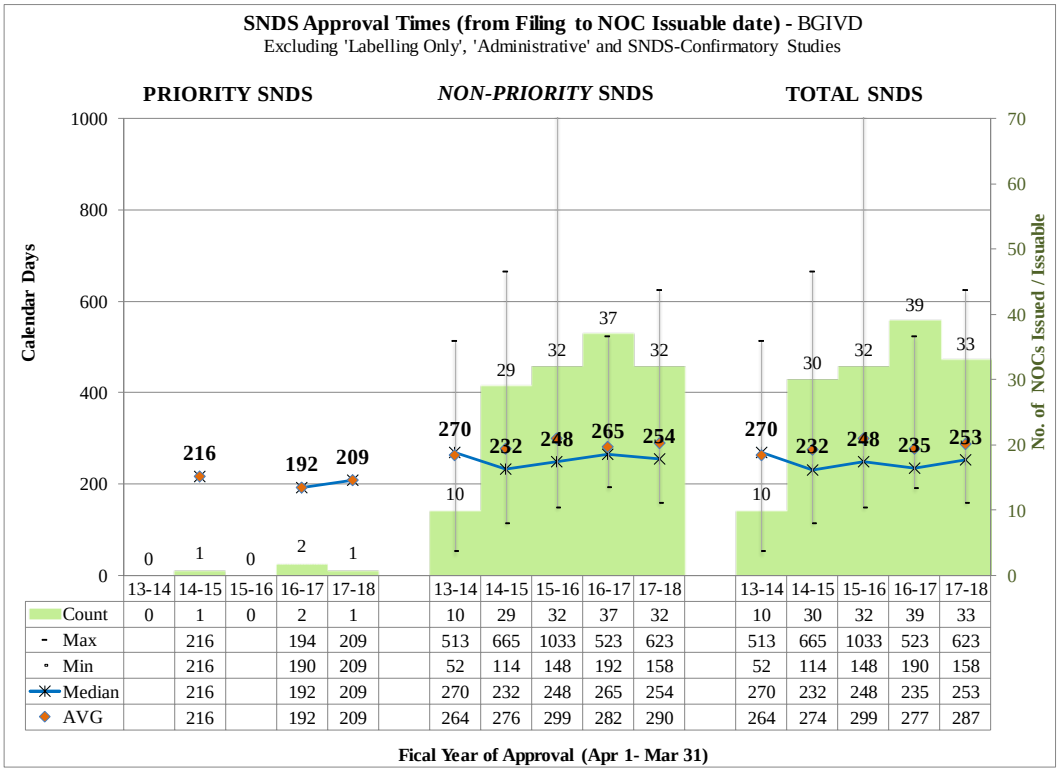
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	3	3	2	1	4	13	8	14	14	10	16	11	16	15	14	7	5	9	5	6
Max	217	222	208	210	250	679	392	663	936	717	679	392	663	936	717	353	356	663	483	420
Min	206	190	203	210	201	318	168	210	337	344	206	168	203	210	201	206	209	203	210	201
Median	211	209	206	210	205	349	353	363	370	417	346	350	354	354	372	318	350	380	346	228
AVG	211	207	206	210	215	377	335	422	486	458	346	300	395	468	389	286	297	444	359	279

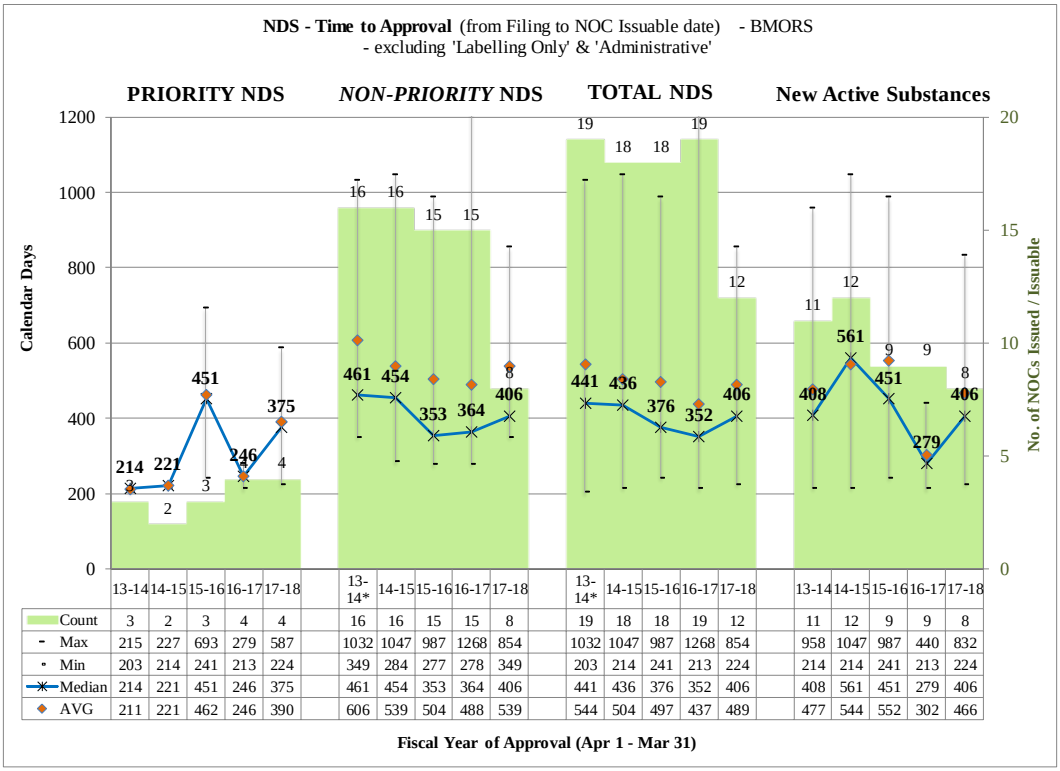
SNDS Approvals – Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)



	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	0	1	0	2	1	10	29	32	37	32	10	30	32	39	33
Max		216		194	209	513	665	1033	523	623	513	665	1033	523	623
Min		216		190	209	52	114	148	192	158	52	114	148	190	158
Median		216		192	209	270	232	248	265	254	270	232	248	235	253
AVG		216		192	209	264	276	299	282	290	264	274	299	277	287

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.

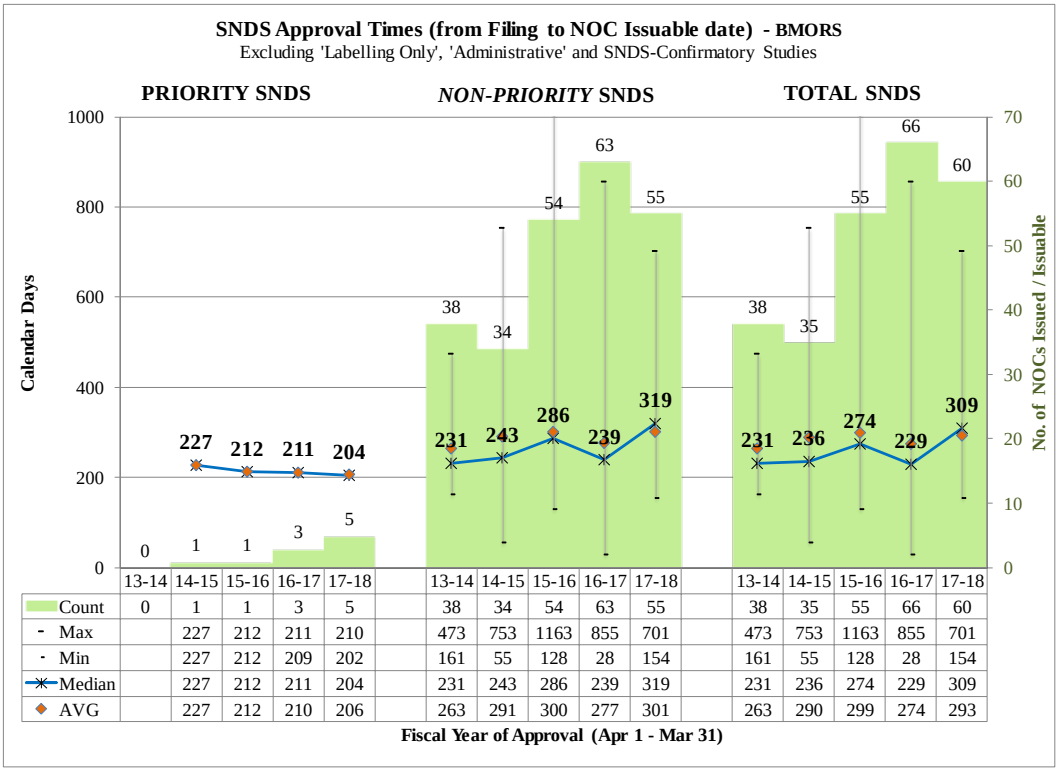
NDS Approvals – Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)



	13-14	14-15	15-16	16-17	17-18	13-14*	14-15	15-16	16-17	17-18	13-14*	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	3	2	3	4	4	16	16	15	15	8	19	18	18	19	12	11	12	9	9	8
Max	215	227	693	279	587	1032	1047	987	1268	854	1032	1047	987	1268	854	958	1047	987	440	832
Min	203	214	241	213	224	349	284	277	278	349	203	214	241	213	224	214	214	241	213	224
Median	214	221	451	246	375	461	454	353	364	406	441	436	376	352	406	408	561	451	279	406
AVG	211	221	462	246	390	606	539	504	488	539	544	504	497	437	489	477	544	552	302	466

*One outlier for fiscal year 2013-14 is included. The NDS was in rejected status for over 4 years but following a judicial review decision, screening was resumed. For this "outlier NDS", the dates used to calculate the time to approval are the date the screening resumed and the date the submission was placed on intellectual property hold.

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



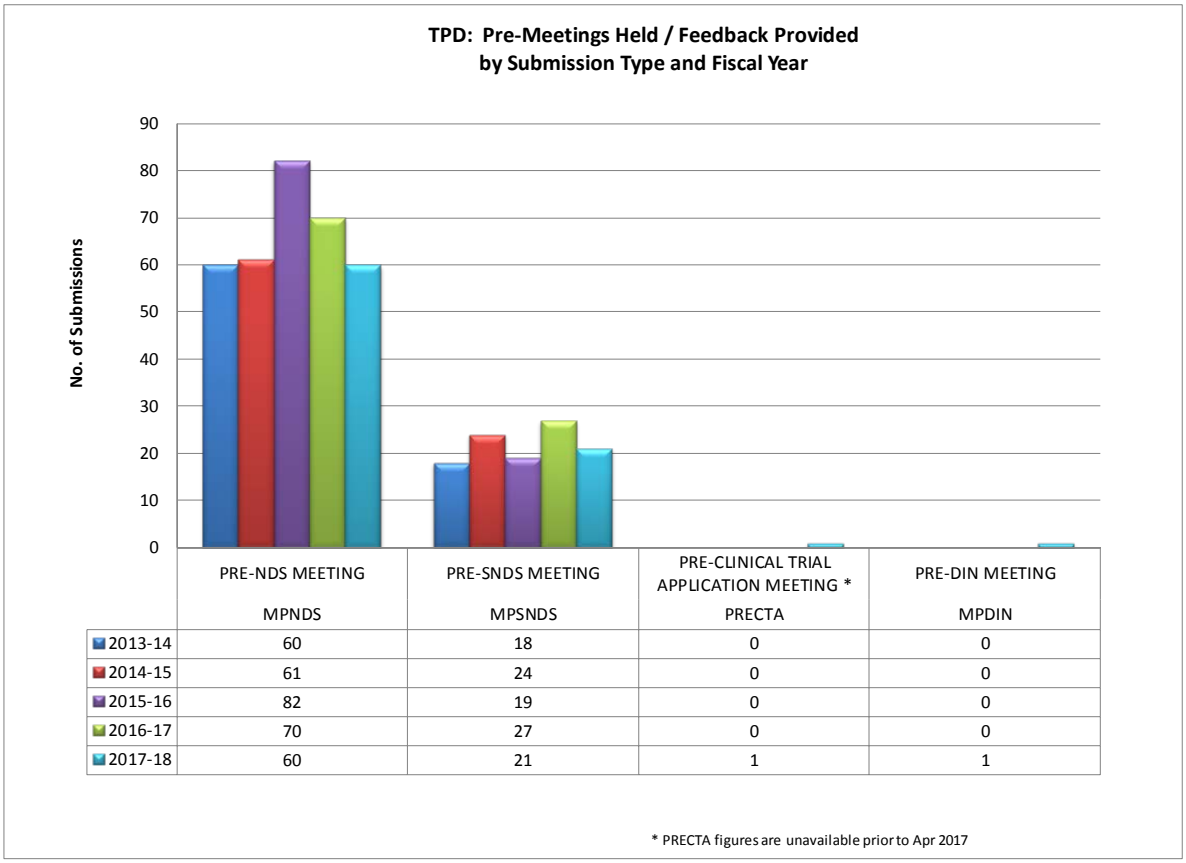
	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18	13-14	14-15	15-16	16-17	17-18
Count	0	1	1	3	5	38	34	54	63	55	38	35	55	66	60
Max		227	212	211	210	473	753	1163	855	701	473	753	1163	855	701
Min		227	212	209	202	161	55	128	28	154	161	55	128	28	154
Median		227	212	211	204	231	243	286	239	319	231	236	274	229	309
AVG		227	212	210	206	263	291	300	277	301	263	290	299	274	293

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

12

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-CLINICAL TRIAL APPLICATION MEETING * PRECTA	PRE-DIN MEETING MPDIN
2013-14	60	18	0	0
2014-15	61	24	0	0
2015-16	82	19	0	0
2016-17	70	27	0	0
2017-18	60	21	1	1

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[12] 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

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