Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Annual Report

Fiscal Year 2019-2020

April 1 2019 – March 31 2020

Canada

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Direction des produits thérapeutiques – Rapport annuel du rendement des présentations de drogue – Exercice financier 2019-2020

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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 2015-2016 to 2019-2020.

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 2019-2020 fiscal year (from April 1 2019 to March 31 2020).

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 Management of Drug Submissions and Applications Guidance document.

[2] Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further clarification refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

A **review cycle completion**[3] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set performance standard[4] which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

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

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

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[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 Management of Drug Submissions and Applications Guidance document. 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 Management of Drug Submissions and Applications Guidance document.

ACRONYMS

Submission Types

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

Documents

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

Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
Clinical or Non-Clinical Data and Chemistry and Manufacturing data	Submissions based on clinical or non-clinical data **and** chemistry and manufacturing data for a drug that does not include a NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[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.

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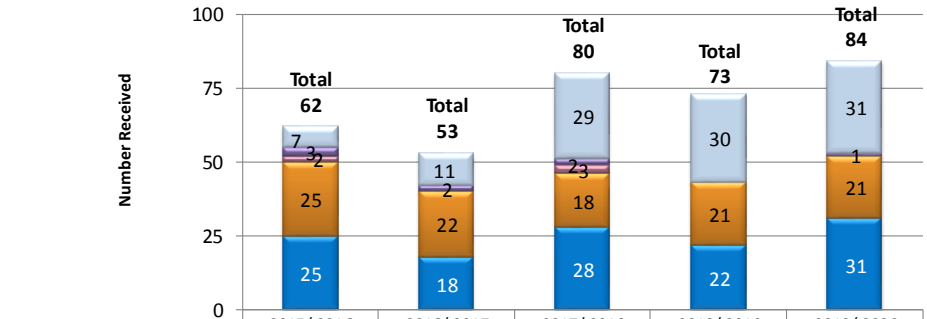
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)

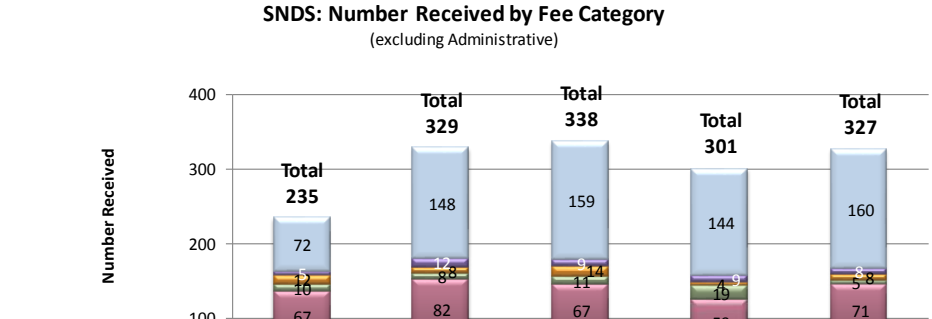
SUBMISSIONS RECEIVED [9]

NDS: Number Received by Fee Category



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	7	11	29	30	31
Comparative Studies	3	2	2	0	1
Chemistry & Manufacturing	2	0	3	0	0
Clinical or Non-Clin and C&M	25	22	18	21	21
New Active Substance	25	18	28	22	31
Total	62	53	80	73	84
Priority (subset)	8	5	10	6	12
NOC/c Class	4	1	2	4	1
Emergency Use (NDS)	0	0	0	0	0

SNDS: Number Received by Fee Category

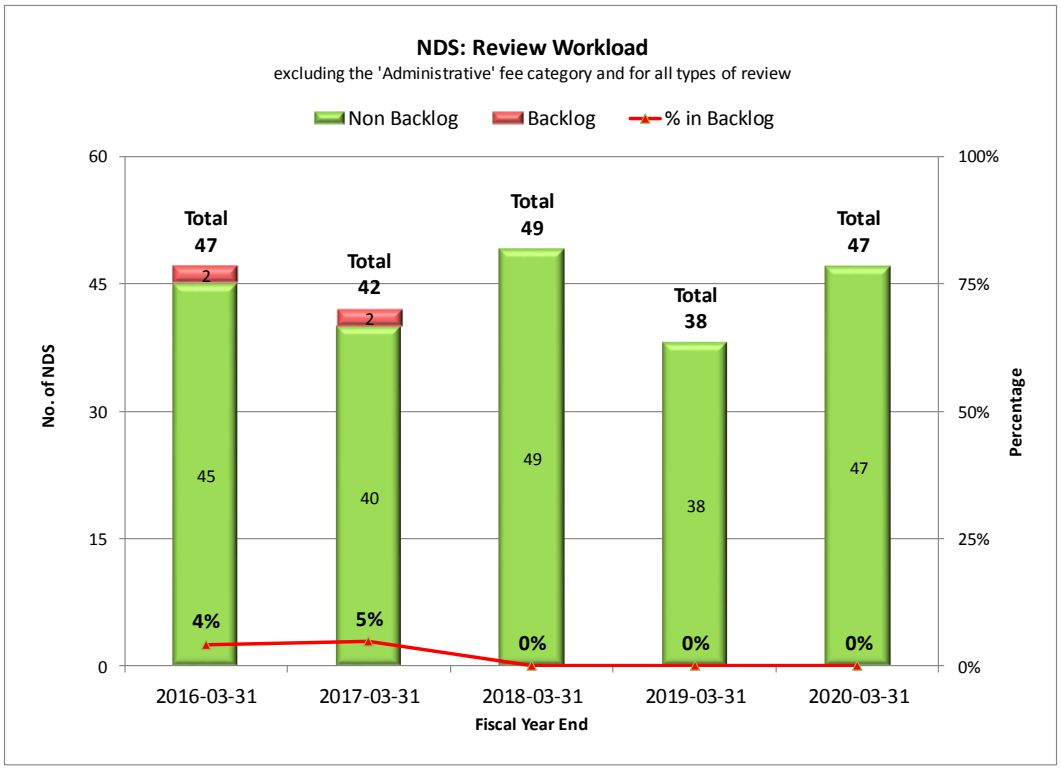


	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	72	148	159	144	160
Comparative Studies	5	12	9	9	8
Clinical or Non-Clin and C&M	12	8	14	4	8
Published Data Only	10	8	11	19	5
Chemistry & Manufacturing	67	82	67	59	71
Clinical or Non-Clin Only	69	71	78	66	75
Total	235	329	338	301	327
Priority (subset)	5	5	9	9	12
NOC/c Class	0	0	2	0	0
SNDS Confirmatory	6	9	3	3	1

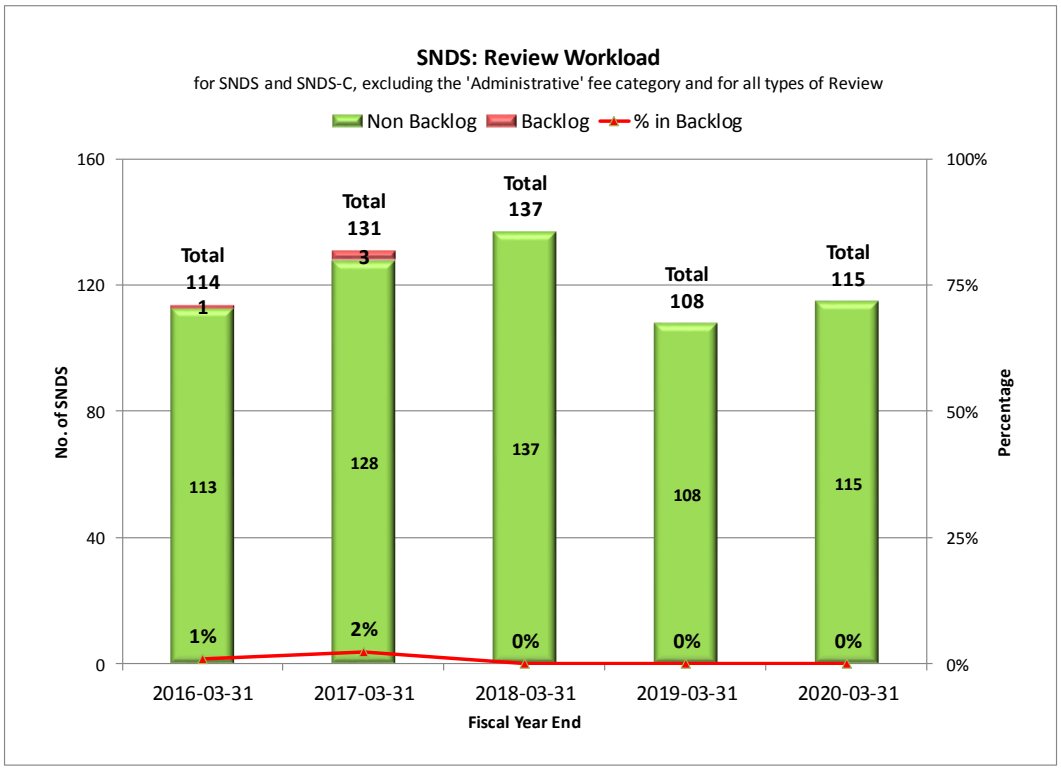
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions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

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

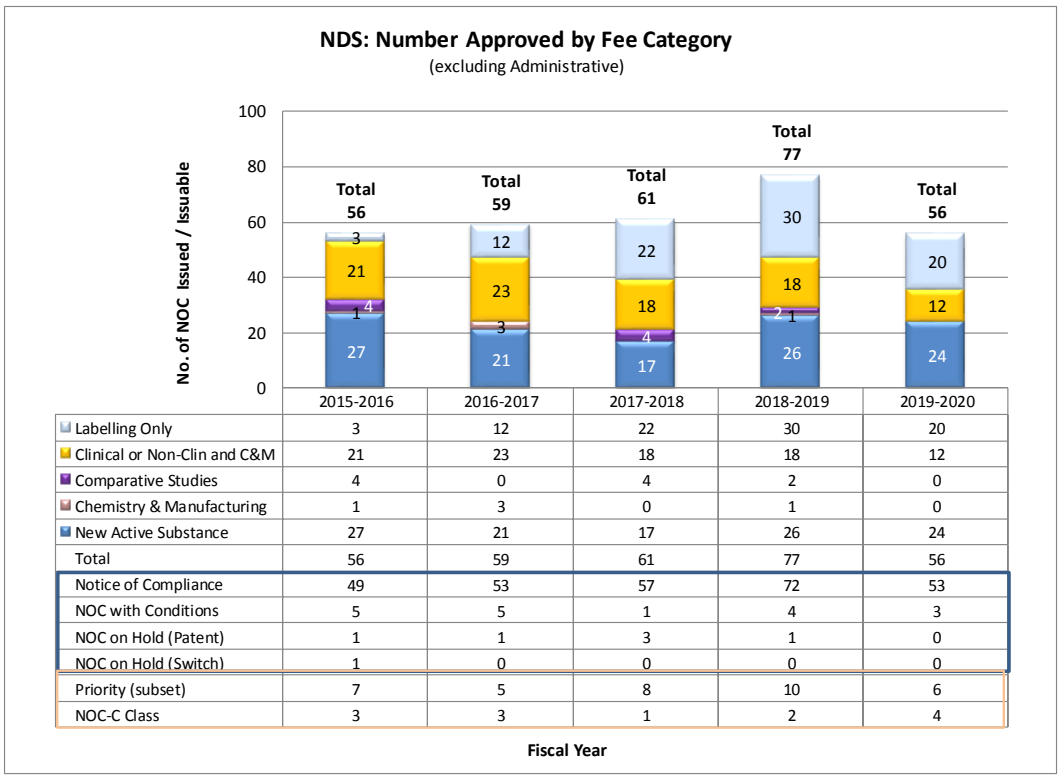
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Labelling Only	3	1	4	4	4
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	3	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	3	0	1	0	0
Backlog	*2*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	24	19	18	15	24
Backlog	*0*	*1*	*0*	*0*	*0*
New Active Substance	17	19	25	19	19
Backlog	*0*	*1*	*0*	*0*	*0*
Total	**47**	**42**	**49**	**38**	**47**
Non Backlog	**45**	**40**	**49**	**38**	**47**
Backlog	**2**	**2**	**0**	**0**	**0**
% in Backlog	**4%**	**5%**	**0%**	**0%**	**0%**
Priority (subset)	4	6	6	3	8
Backlog	0	0	0	0	0

SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Labelling Only	13	22	19	10	24
Backlog	*1*	*1*	*0*	*0*	*0*
Comparative Studies	1	7	4	7	5
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	31	34	30	29	26
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	50	53	63	53	49
Backlog	*0*	*2*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	12	8	11	1	8
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	7	7	10	8	3
Backlog	0	0	0	0	0
Total	**114**	**131**	**137**	**108**	**115**
Non Backlog	**113**	**128**	**137**	**108**	**115**
Backlog	**1**	**3**	**0**	**0**	**0**
% in Backlog	**1%**	**2%**	**0%**	**0%**	**0%**
Priority (subset)	5	4	7	4	5
Backlog	0	0	0	0	0
*SNDS-C (Confirmatory)	6	6	3	2	1
Backlog	0	0	0	0	0

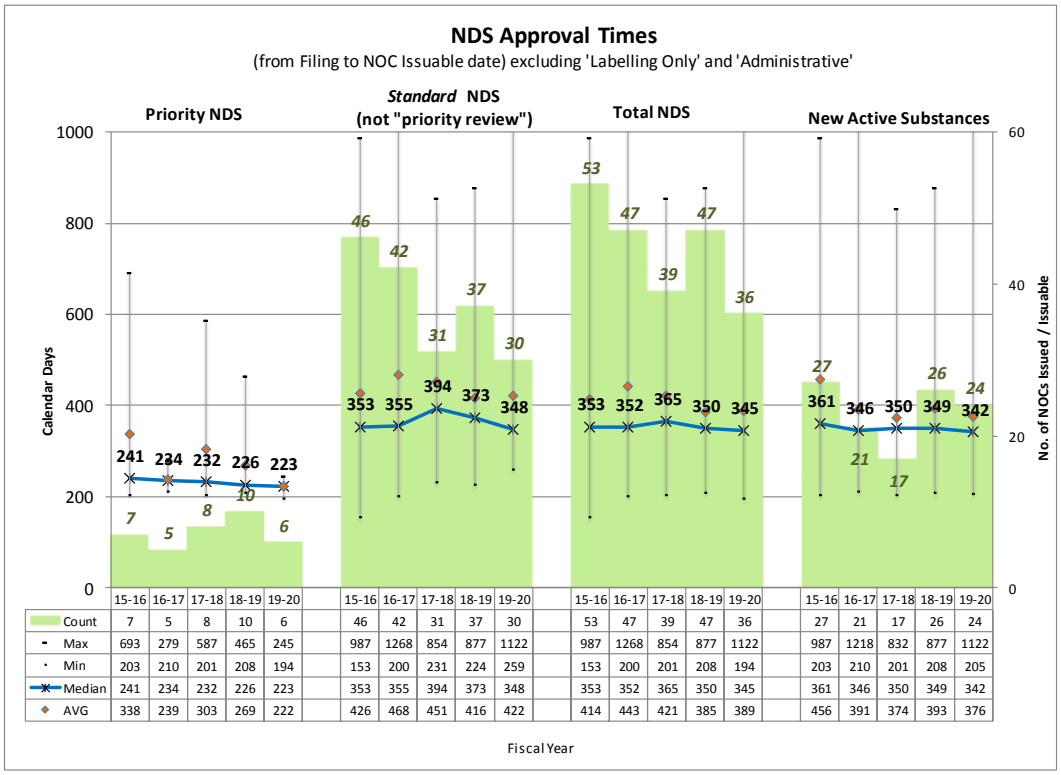
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Labelling Only	3	12	22	30	20
Clinical or Non-Clin and C&M	21	23	18	18	12
Comparative Studies	4	0	4	2	0
Chemistry & Manufacturing	1	3	0	1	0
New Active Substance	27	21	17	26	24
Total	56	59	61	77	56
Notice of Compliance	49	53	57	72	53
NOC with Conditions	5	5	1	4	3
NOC on Hold (Patent)	1	1	3	1	0
NOC on Hold (Switch)	1	0	0	0	0
Priority (subset)	7	5	8	10	6
NOC-C Class	3	3	1	2	4

NDS Approval Times

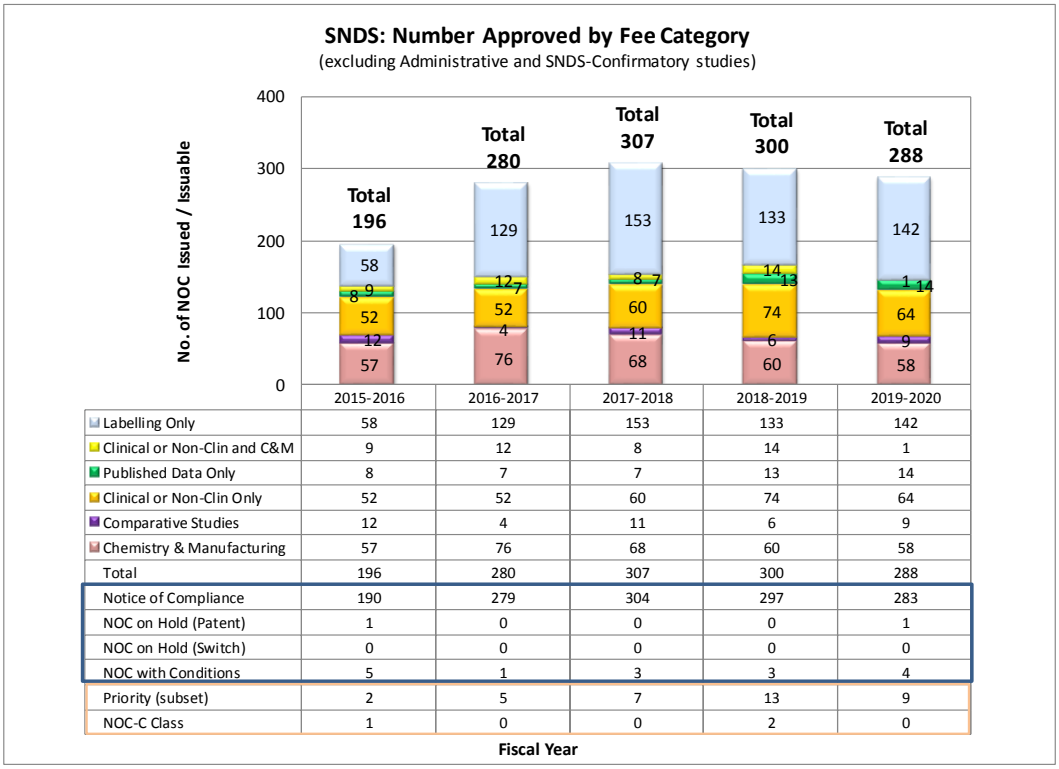


	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	7	5	8	10	6	46	42	31	37	30	53	47	39	47	36	27	21	17	26	24
Max	693	279	587	465	245	987	1268	854	877	1122	987	1268	854	877	1122	987	1218	832	877	1122
Min	203	210	201	208	194	153	200	231	224	259	153	200	201	208	194	203	210	201	208	205
Median	241	234	232	226	223	353	355	394	373	348	353	352	365	350	345	361	346	350	349	342
AVG	338	239	303	269	222	426	468	451	416	422	414	443	421	385	389	456	391	374	393	376

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 .

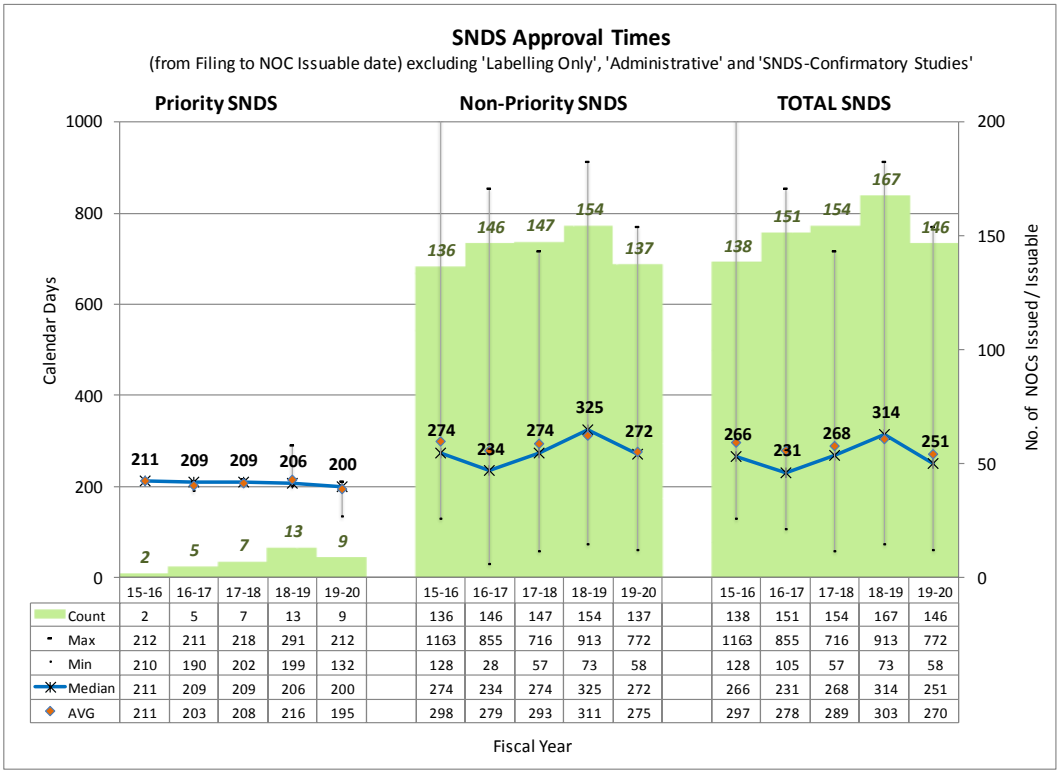
APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Labelling Only	58	129	153	133	142
Clinical or Non-Clin and C&M	9	12	8	14	1
Published Data Only	8	7	7	13	14
Clinical or Non-Clin Only	52	52	60	74	64
Comparative Studies	12	4	11	6	9
Chemistry & Manufacturing	57	76	68	60	58
Total	196	280	307	300	288
Notice of Compliance	190	279	304	297	283
NOC on Hold (Patent)	1	0	0	0	1
NOC on Hold (Switch)	0	0	0	0	0
NOC with Conditions	5	1	3	3	4
Priority (subset)	2	5	7	13	9
NOC-C Class	1	0	0	2	0

SNDS Approval Times



	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	2	5	7	13	9	136	146	147	154	137	138	151	154	167	146
Max	212	211	218	291	212	1163	855	716	913	772	1163	855	716	913	772
Min	210	190	202	199	132	128	28	57	73	58	128	105	57	73	58
Median	211	209	209	206	200	274	234	274	325	272	266	231	268	314	251
AVG	211	203	208	216	195	298	279	293	311	275	297	278	289	303	270

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.

NAS Approvals - TPD - Fiscal Year 2019-2020

New Active Substance Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
AKLIEF (trifarotene) - is indicated for the topical treatment of acne vulgaris of the face and/or trunk in patients 12 years of age and older.	NAS	Galderma Canada Inc.	14-Dec-18	25-Nov-19
BALVERSA (erdafitinib) - is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC): whose tumors have susceptible fibroblast growth factor receptor (FGFR)2 or FGFR3 genetic alterations and who have disease progression during or following at least one line of prior chemotherapy, including within 12 months of neoadjuvant or adjuvant chemotherapy.	NOC-C NAS	Janssen Inc.	8-Feb-19	25-Oct-19 NOC-C
CABENUVA (cabotegravir, rilpivirine), VOCABRIA (cabotegravir sodium) CABENUVA (cabotegravir and rilpivirine extended release injectable suspensions) is indicated: as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in patients who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL). VOCABRIA (cabotegravir tablets) is indicated, in combination with EDURANT (rilpivirine tablets), as a complete regimen for short-term treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL) as: • an oral lead-in to assess tolerability of cabotegravir prior to initiating CABENUVA • oral bridging therapy for missed CABENUVA injections	NAS	Viiv Healthcare ULC	29-Apr-19	18-Mar-20

[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 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
CALQUENCE (acalabrutinib) - is indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.	NOC-C NAS	AstraZeneca Canada Inc.	15-Mar-18	23-Aug-19
DACOGEN (decitabine) - is indicated for the treatment of adult patients with de novo or secondary Myelodysplastic Syndrome (MDS), untreated or previously treated with chemotherapy, who are not considered candidates for hematopoietic stem cell transplantation, including: • Intermediate-1, intermediate-2 and high-risk International Prognostic Scoring System (IPSS) groups, • All French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia (CMML)).	NAS	Otsuka Pharmaceutical Co. Ltd.	29-Jun-18	11-Jul-19
INTRAROSA (prasterone) - is indicated for the treatment of postmenopausal vulvovaginal atrophy.	NAS	Endoceutics Inc.	5-Oct-16	1-Nov-19
LOKELMA (sodium zirconium cyclosilicate) - is indicated for the treatment of hyperkalemia in adult patients.	NAS	AstraZeneca Canada Inc.	15-Aug-18	25-Jul-19
MAYZENT (siponimod) - is indicated for the treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features characteristic of multiple sclerosis inflammatory activity, to delay the progression of physical disability.	NAS	Novartis Pharmaceuticals Canada Inc.	21-Dec-18	20-Feb-20

New Active Substance Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
NERLYNX (neratinib as neratinib maleate) - is indicated for the extended adjuvant treatment of women with early-stage hormone receptor positive, HER2-overexpressed/amplified breast cancer within one year after completion of trastuzumab-based adjuvant therapy.	NAS	Puma Biotechnology Inc.	19-Jul-18	16-Jul-19
NUBEQA (darolutamide) - is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC).	NAS	Bayer Inc.	27-Mar-19	20-Feb-20
ONPATTRO (patisiran as patisiran sodium) - is indicated for the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis).	Priority-NAS	Alnylam Netherlands B.V.	14-Nov-18	7-Jun-19
PIQRAY (alpelisib) - in combination with fulvestrant, is indicated for the treatment of postmenopausal women, and men, with hormone receptor-positive, HER2-negative, PIK3CA- mutated advanced or metastatic breast cancer after disease progression following an endocrine-based regimen.	NAS	Novartis Pharmaceuticals Canada Inc.	17-Apr-19	11-Mar-20
RINVOQ (upadacitinib) - is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).	NAS	Abbvie Corporation	16-Jan-19	23-Dec-19

New Active Substance Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
ROZLYTREK (entrectinib) - is indicated for the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumours, including brain metastases, that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, and with no satisfactory treatment options.	NOC-C NAS	Hoffmann La Roche Limited	8-May-19	10-Feb-20 NOC-C
TALZENNA (talazoparib as talazoparib tosylate) - is indicated as a monotherapy for the treatment of adult patients with a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated human epidermal growth factor receptor 2 (HER2)-negative locally advanced (not amenable to curative radiation or surgery) or metastatic breast cancer, who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting, unless patients were inappropriate for these treatments.	NAS	Pfizer Canada Ulc	28-Sep-18	6-Sep-19
TIBELLA (tibolone) - is indicated for short-term treatment of vasomotor symptoms due to estrogen deficiency in postmenopausal women, more than one year after menopause.	NAS	Biosyent Pharma Inc.	1-Jun-17	10-May-19
TRULANCE (plecanatide) - is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.	NAS	Cipher Pharmaceuticals Inc.	20-Sep-18	10-Oct-19

New Active Substance Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
VASCEPA (icosapent ethyl) - is indicated to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor.	Priority-NAS	HLS Therapeutics Inc.	29-Apr-19	30-Dec-19
VERZENIO (abemaciclib) - is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer - in combination with an aromatase inhibitor in postmenopausal women as initial endocrine-based therapy. - in combination with fulvestrant in women with disease progression following endocrine therapy. Pre- or perimenopausal women must also be treated with a gonadotropin-releasing hormone (GnRH) agonist. - as a single agent in women with disease progression following endocrine therapy and at least 2 prior chemotherapy regimens. At least one chemotherapy regimen should have been administered in the metastatic setting, and at least one should have contained a taxane.	NAS	Eli Lilly Canada Inc.	16-Apr-18	5-Apr-19
VITRAKVI (larotrectinib as larotrectinib sulfate) - is indicated for the treatment of adult and pediatric patients with solid tumours that: • have a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory treatment options.	NOC-C NAS	Bayer Inc.	18-Sep-18	10-Jul-19 NOC-C

New Active Substance Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
VYNDAQEL (tafamidis meglumine) - is indicated for the treatment of adult patients with cardiomyopathy due to transthyretin-mediated amyloidosis, wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization.	Priority-NAS	Pfizer Canada Ulc	3-Jun-19	20-Jan-20
XOFLUZA (baloxavir marboxil) - is indicated for the treatment of uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza complications.	NAS	Hoffmann La Roche Limited	30-Apr-19	19-Feb-20
XOSPATA (gilterinitib fumarate) - is indicated in the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation.	Priority-NAS	Astellas Pharma Canada Inc.	22-May-19	23-Dec-19
ZEJULA (niraparib as niraparib tosylate) - is indicated as monotherapy for the maintenance treatment of female adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.	NAS	GlaxoSmith-Kline Inc.	4-Jun-18	27-Jun-19

Priority Submission Approvals - TPD - Fiscal Year 2019-2020

Priority Submission Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
ERLEADA (apalutamide) - new indication: is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).	PRIORITY-CLIN ONLY	Janssen Inc.	24-May-19	12-Dec-19
HYDROMORPHONE HP 10, HYDROMORPHONE HP 20, HYDROMORPHONE HP 50 and HYDROMORPHONE HP FORTE (hydromorphone hydrochloride) - new indication: supervised injectable opioid agonist therapy in adult patients with severe opioid use disorder who are using injectable opioids and have failed previous attempts at opioid agonist therapy.	PRIORITY-CLIN ONLY	Sandoz Canada Incorporated	20-Dec-18	1-May-19
INVOKANA (canagliflozin) - new indication: Patients with Diabetic Nephropathy: is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (>33.9 mg/mmol).	PRIORITY-CLIN ONLY	Janssen Inc.	26-Jun-19	24-Jan-20
IVOZFO (fosfomycin as fosfomycin sodium) - is indicated for the treatment of the following infections in adults and children including neonates: - Osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed above.	PRIORITY-CLIN/C&M	Verity Pharmaceuticals Inc	30-Aug-18	1-May-19

Priority Submission Approvals - TPD
Fiscal Year 2019-2020
(April 1 2019 - March 31 2020)

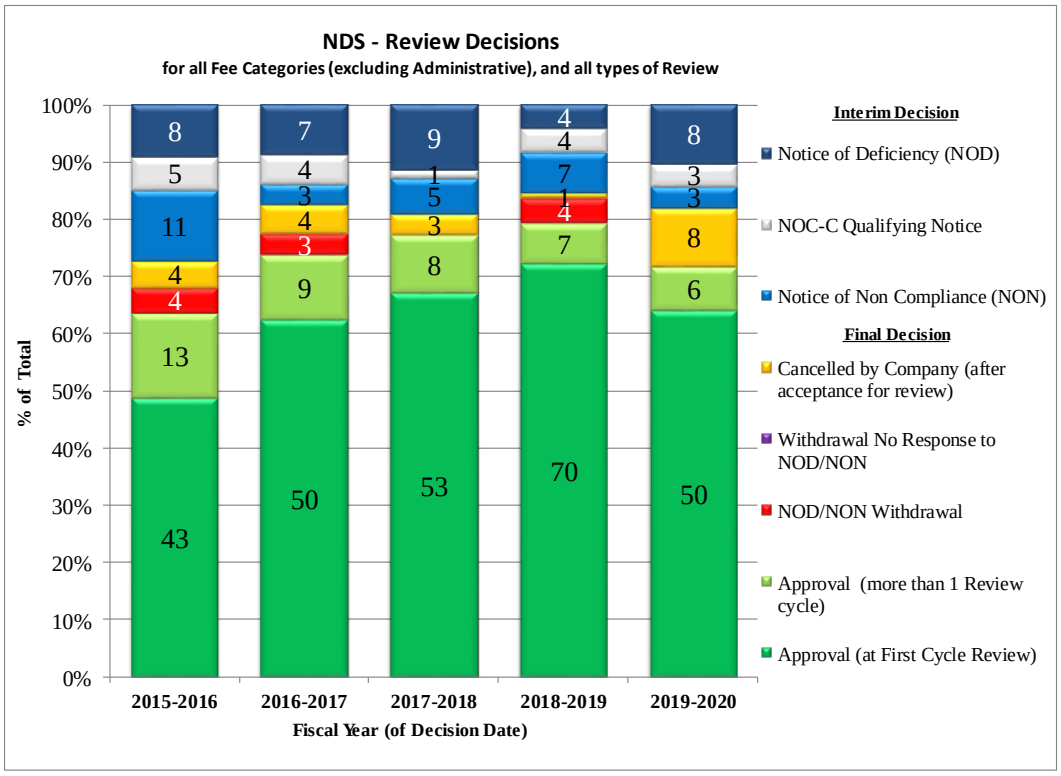
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
JORVEZA (budesonide) - is indicated for induction of clinico-pathological remission in adults with eosinophilic esophagitis (EoE).	PRIORITY-CLIN/C&M	Avir Pharma Inc.	26-Apr-19	6-Nov-19
LONSURF (tipiracil hydrochloride, trifluridine) - new indication: Lonsurf is a drug used to treat adults with some types of cancer that have spread to other parts of the body. These cancers are: • Colon or rectal cancer o Lonsurf is used when other treatments have not worked or when other treatments are not suitable for you. • A type of stomach cancer called gastric cancer or a type of esophageal cancer called gastroesophageal junction cancer. o Lonsurf is used after at least two other treatments.	PRIORITY-CLIN ONLY	Taiho Pharma Canada Inc.	23-Apr-19	19-Nov-19
LYNPARZA (olaparib) - new indication: as monotherapy for the maintenance treatment of adult patients with advanced BRCA-mutated high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to first-line platinum-based chemotherapy. Patients must have confirmation of BRCA mutation (identified by either germline or tumour testing) before LYNPARZA treatment is initiated.	PRIORITY-CLIN ONLY	AstraZeneca Canada Inc.	25-Oct-18	6-May-19
LYNPARZA (Ooaparib) - new indication: as monotherapy for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic adenocarcinoma of the pancreas whose disease has not progressed on a minimum of 16 weeks of first-line platinum-based chemotherapy. Germline BRCA mutation must be confirmed before LYNPARZA treatment is initiated.	PRIORITY-CLIN ONLY	AstraZeneca Canada Inc.	1-Aug-19	14-Feb-20

Priority Submission Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
MAVIRET (glecaprevir, pibrentasvir) - expand the treatment indication to include adolescent patients 12 years and older with chronic hepatitis C virus infection.	PRIORITY-CLIN ONLY	Abbvie Corporation	7-Dec-18	25-Jun-19
OFEV (nintedanib as nintedanib esilate) - new indication: Systemic Sclerosis-Associated Interstitial Lung Disease: is indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD).	PRIORITY-CLIN ONLY	Boehringer Ingelheim (Canada) Ltd Ltée	25-Apr-19	22-Nov-19
ONPATTRO (patisiran as patisiran sodium) - is indicated for the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis).	PRIORITY-NAS	Alnylam Netherlands B.V.	14-Nov-18	7-Jun-19
VASCEPA (icosapent ethyl) - is indicated to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor.	PRIORITY-NAS	HLS Therapeutics Inc.	29-Apr-19	30-Dec-19
VYNDAQEL (tafamidis meglumine) - is indicated for the treatment of adult patients with cardiomyopathy due to transthyretin-mediated amyloidosis, wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization.	PRIORITY-NAS	Pfizer Canada Ulc	3-Jun-19	20-Jan-20

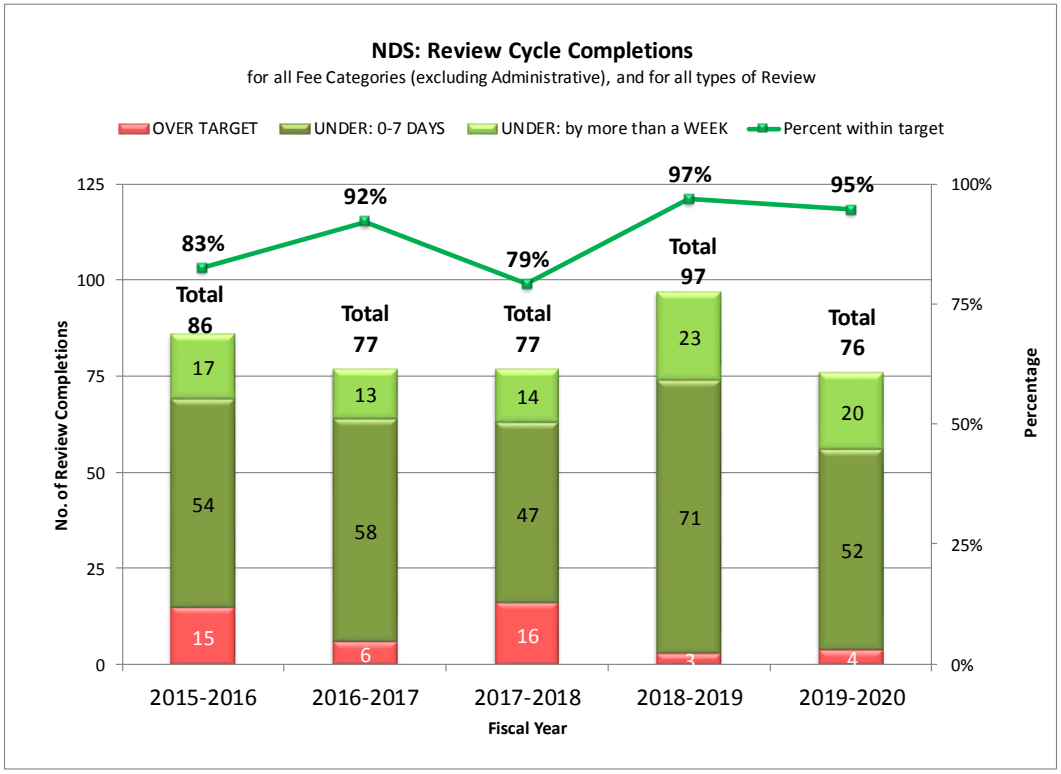
Priority Submission Approvals - TPD Fiscal Year 2019-2020 (April 1 2019 - March 31 2020)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
XOSPATA (gilterinitib fumarate) - is indicated in the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation.	PRIORITY-NAS	Astellas Pharma Canada Inc.	22-May-19	23-Dec-19
ZERBAXA (ceftolozane (as ceftolozane sulfate), tazobactam (as tazobactam sodium)) - new indication For the treatment of nosocomial pneumonia, including ventilator-associated pneumonia, caused by the following susceptible Gram-negative microorganisms: Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Serratia marcescens.	PRIORITY-CLIN ONLY	Merck Canada Inc.	15-Feb-19	30-Aug-19

REVIEW PERFORMANCE

NDS: Review Decisions by Type

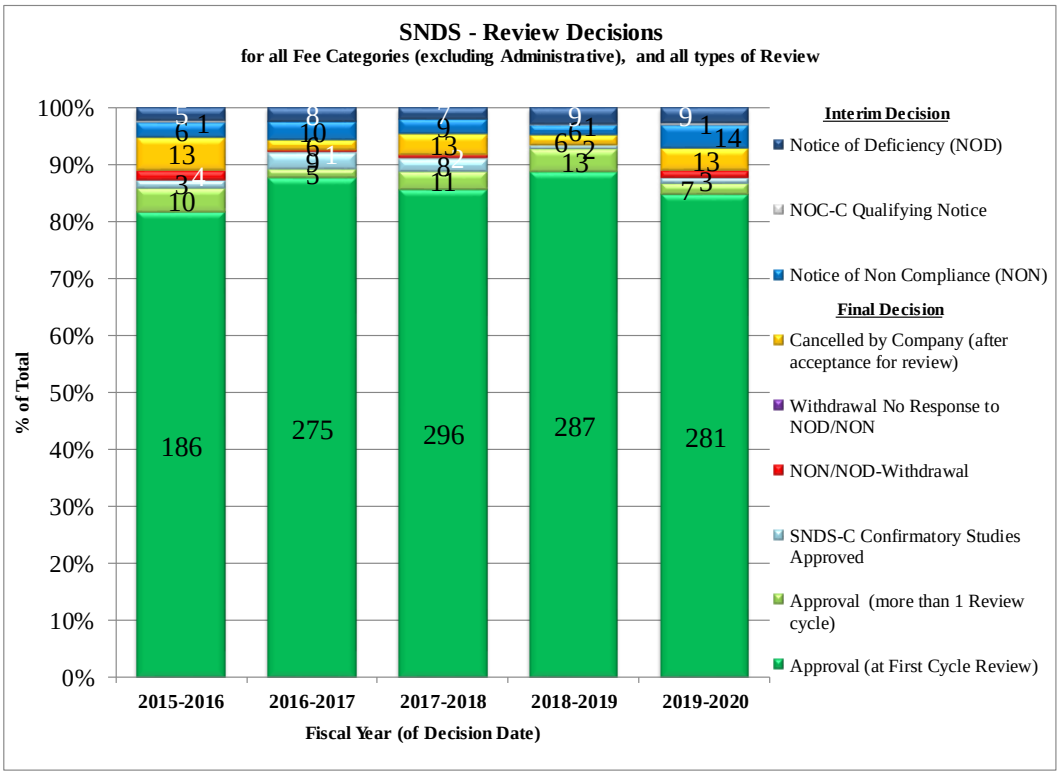


NDS: Review Cycle Completions



REVIEW PERFORMANCE

SNDS: Review Decisions by Type



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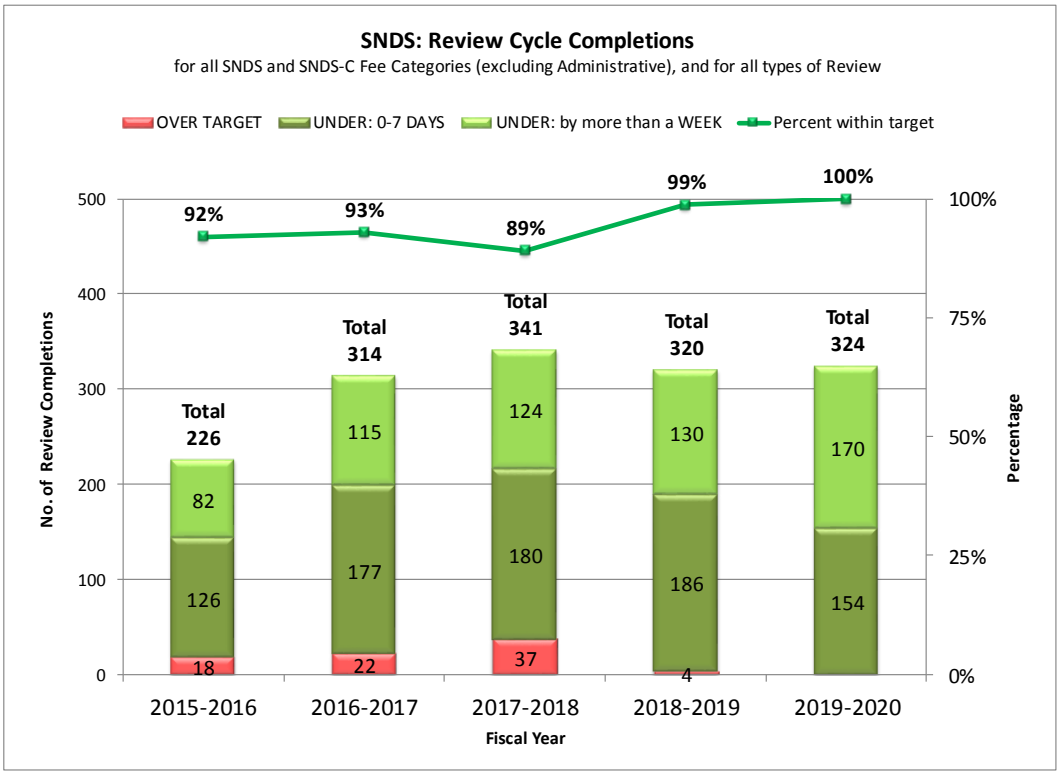
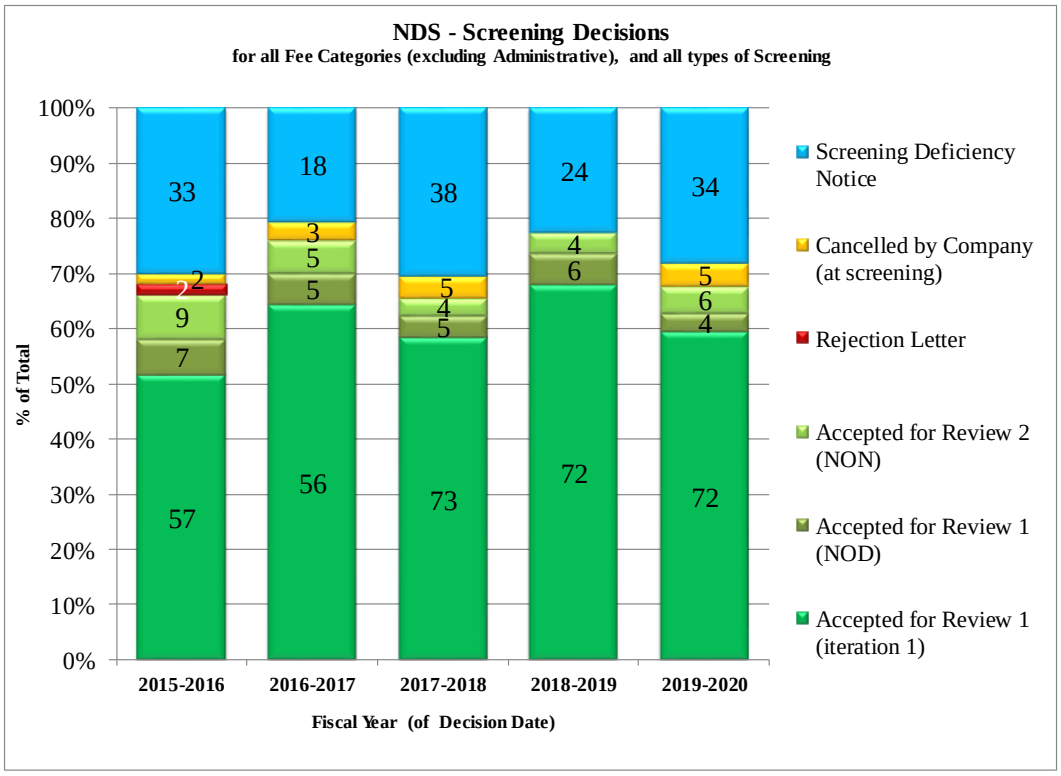


SCREENING PERFORMANCE

NDS: Screening Decisions by Type



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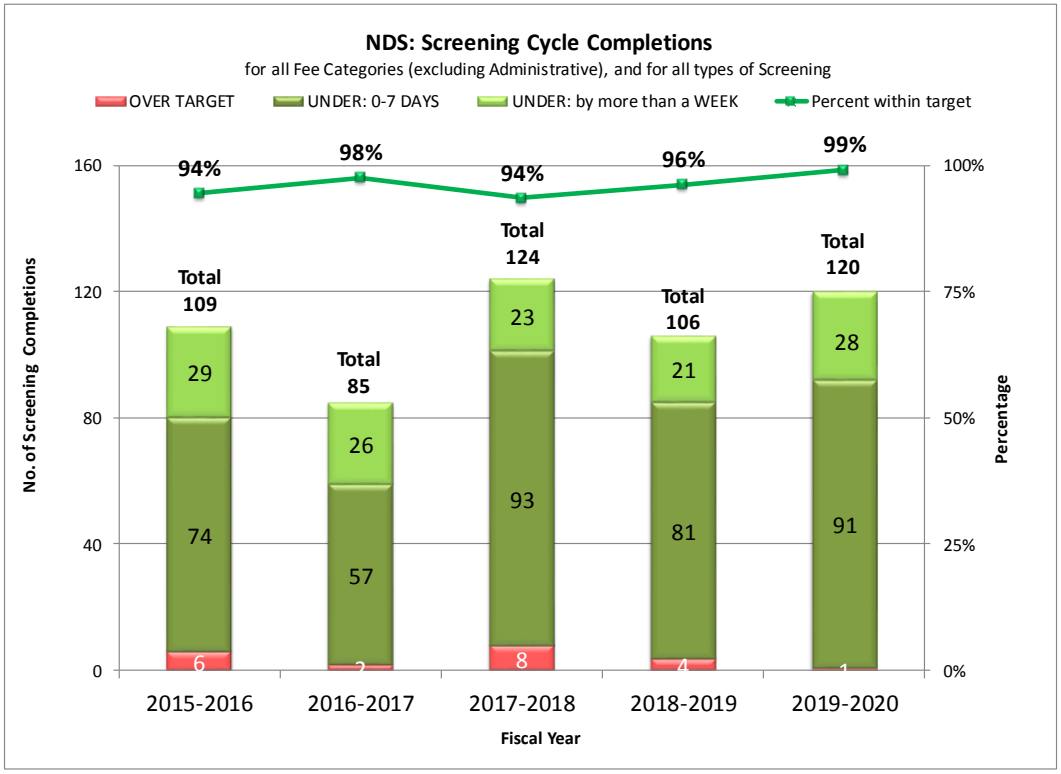
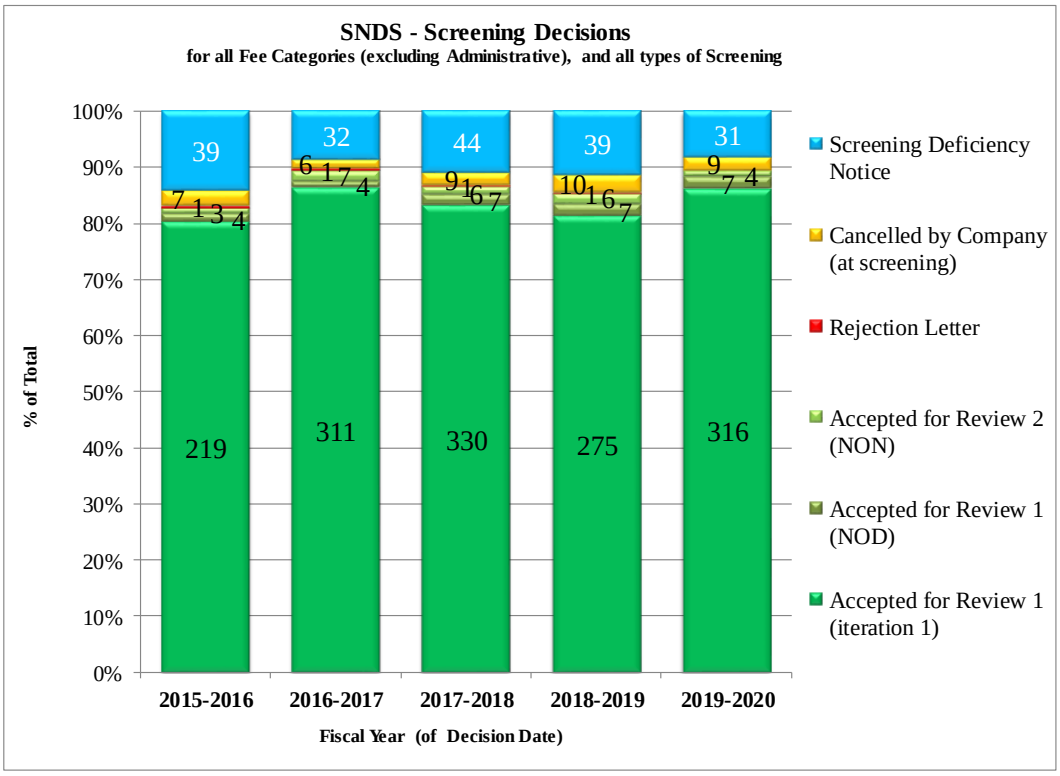
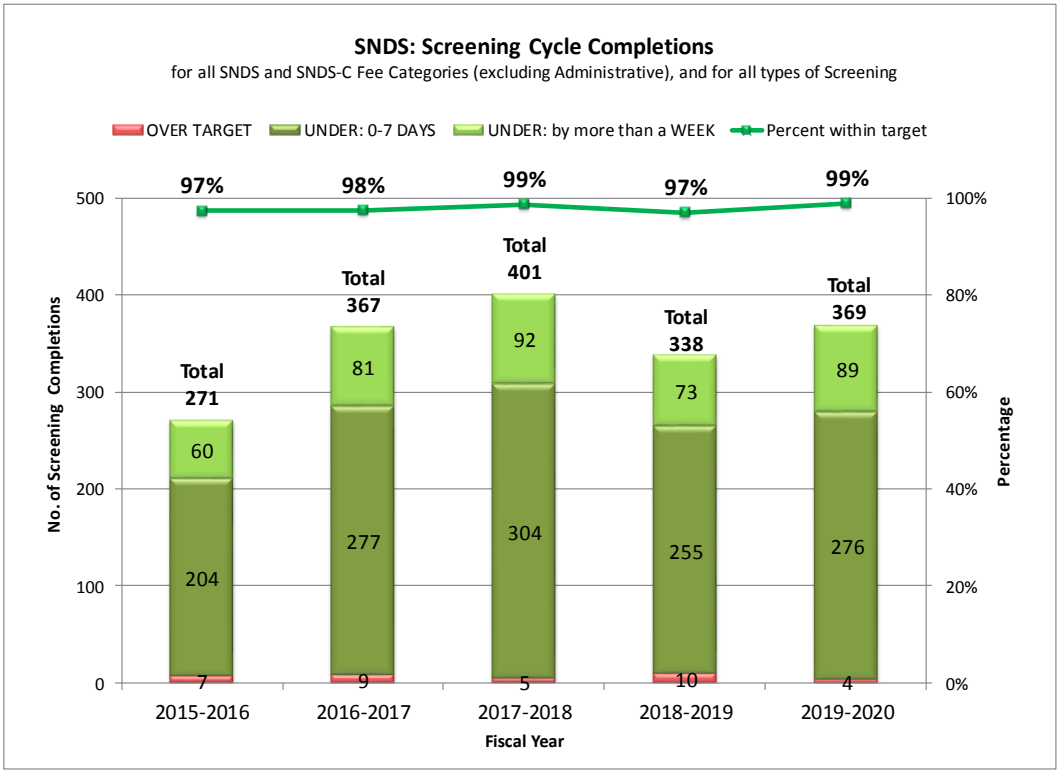


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

NDS: Request for Reconsideration of Final Decisions

NDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	NDS Status (as of May 2020)
Total Received	2	1	0	1	0		
Total Granted	*1*	*0*	*0*	*0*	*0*		
GRANTED	*1*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Total Denied	*1*	*1*	*0*	*1*	*0*		
DENIED	1	1	0	0	0	NOD-Withdrawal	Withdrawn
DENIED	0	0	0	1	0	NON-Withdrawal	Withdrawn

SNDS: Request for Reconsideration of Final Decisions

SNDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	SNDS Status (as of May 2020)
Total Received	1	0	0	0	0		
Total Denied	1	0	0	0	0	NOD-Withdrawal	Withdrawn

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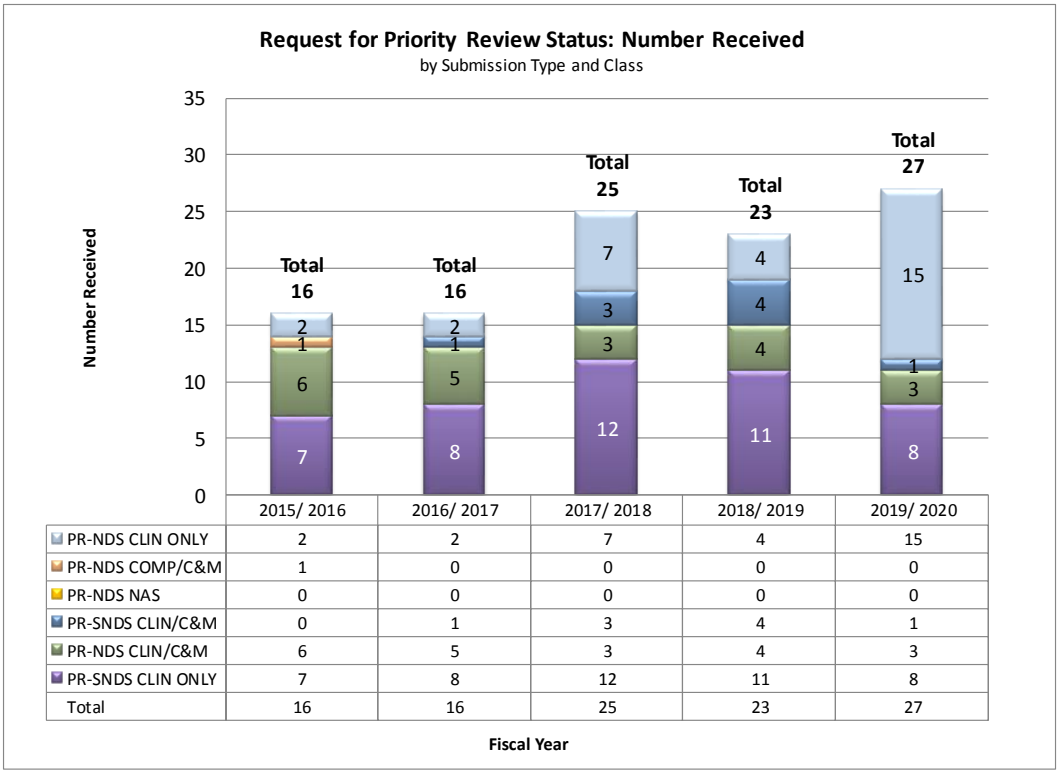
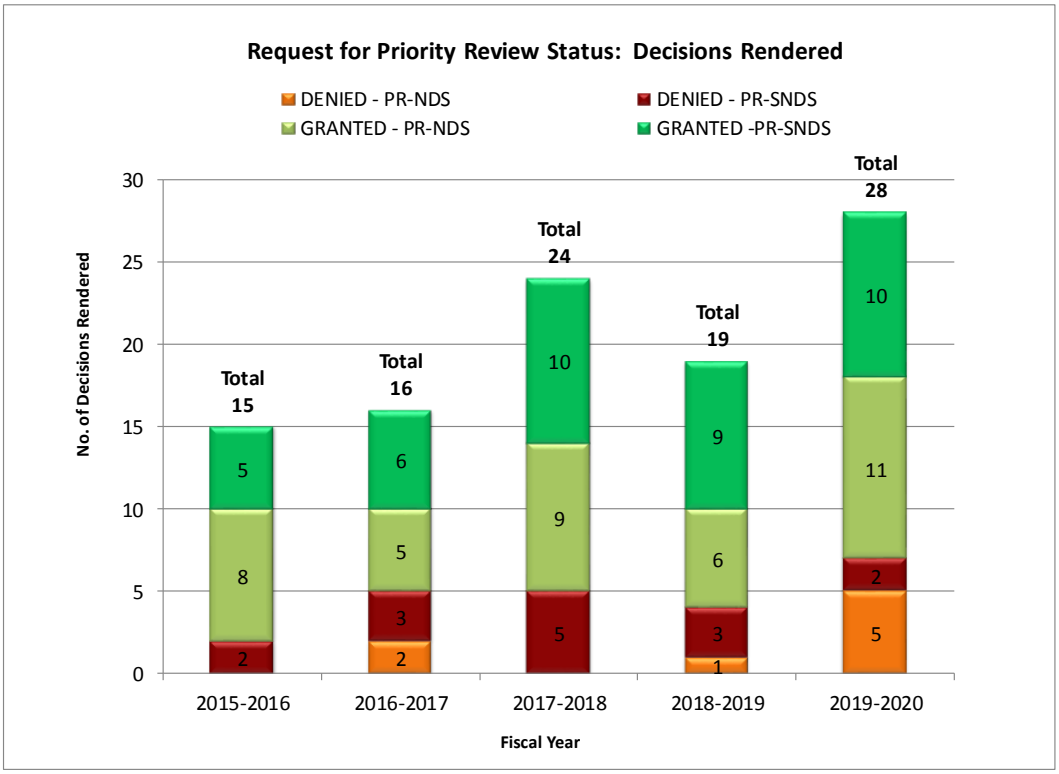
REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

Request for Priority Review Status: Number Received



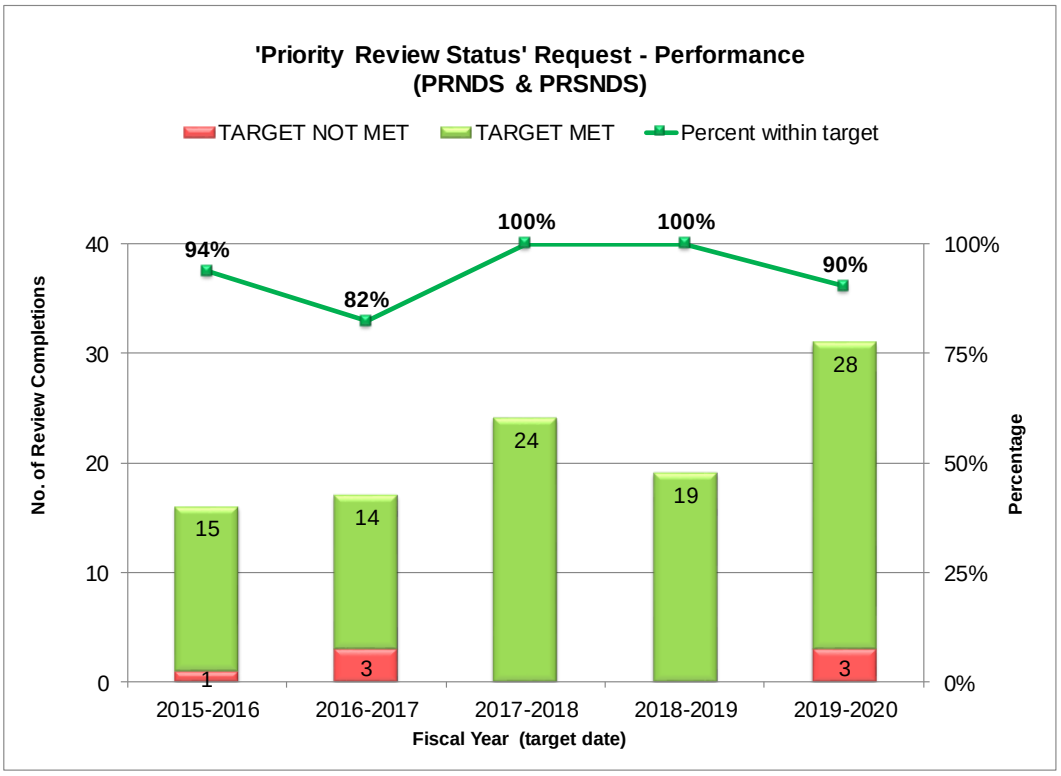
	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
PR-NDS CLIN ONLY	2	2	7	4	15
PR-NDS COMP/C&M	1	0	0	0	0
PR-NDS NAS	0	0	0	0	0
PR-SNDS CLIN/C&M	0	1	3	4	1
PR-NDS CLIN/C&M	6	5	3	4	3
PR-SNDS CLIN ONLY	7	8	12	11	8
Total	16	16	25	23	27

Request for Priority Review Status: Decisions Rendered



REQUEST FOR PRIORITY REVIEW STATUS

Request for Priority Review Status: Performance



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

Priority Review Requests: Request for Reconsideration of Final Decisions

"Priority Review Request" - Requests for Reconsideration of Final Decisions

Fiscal Year of Request (April 1 - March 31)

Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	Submission Status (as of May 2020)
Total Received	0	0	1	0	0		
Total Granted	*0*	*0*	*1*	*0*	*0*	Priority Review Request (for SNDS) Denied	Cleared

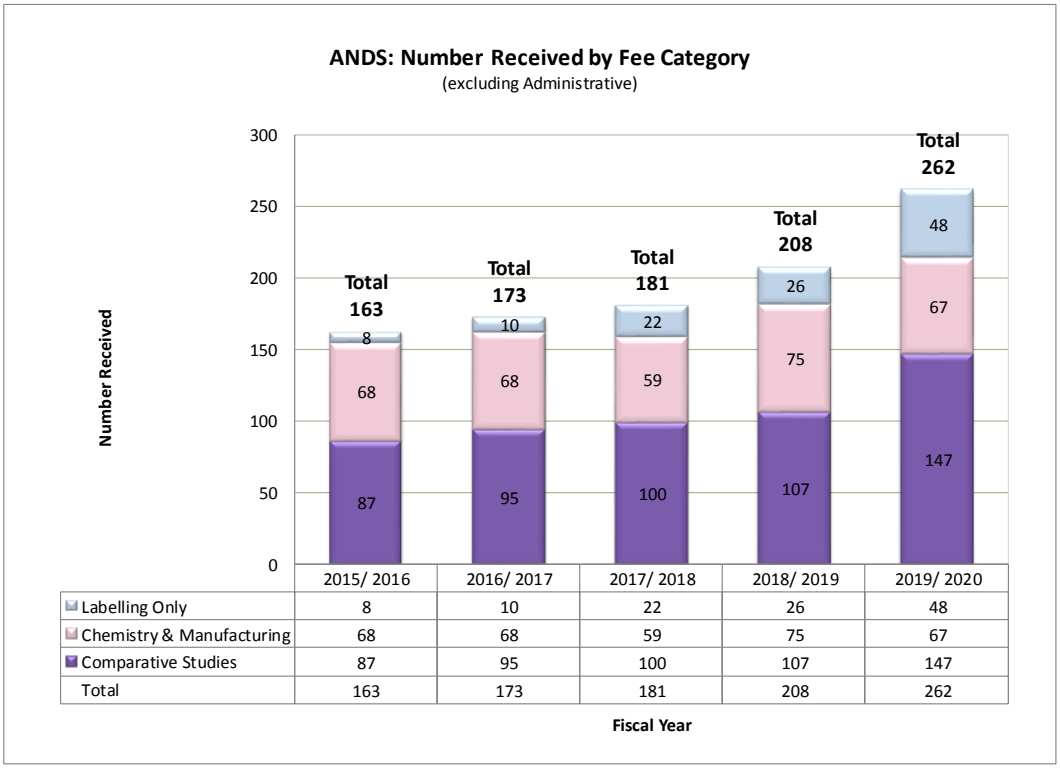
ABBREVIATED NEW DRUG SUBMISSIONS (ANDS)

&

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSIONS (SANDS)

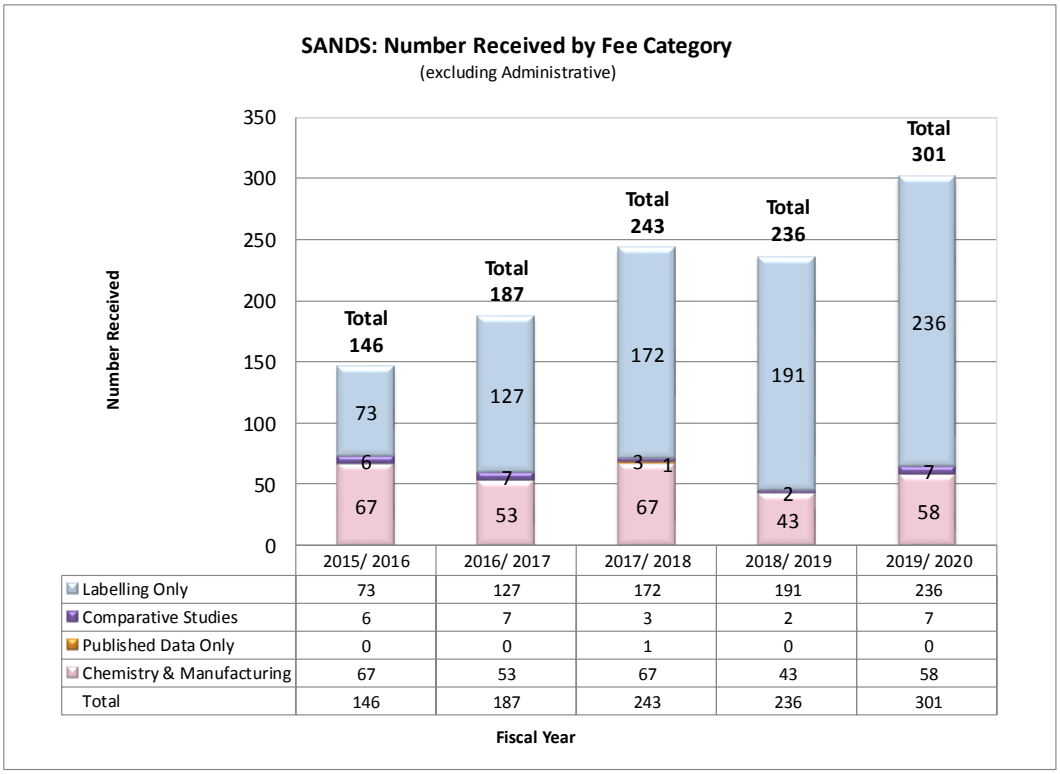
SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	8	10	22	26	48
Chemistry & Manufacturing	68	68	59	75	67
Comparative Studies	87	95	100	107	147
Total	163	173	181	208	262

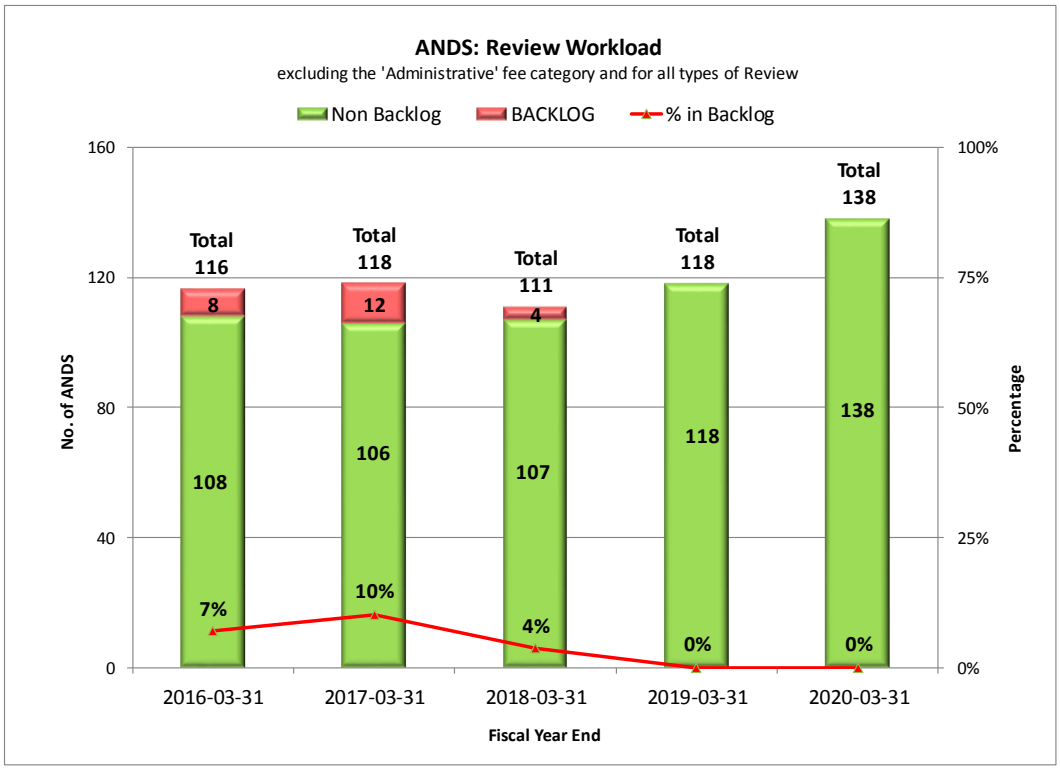
SANDS: Number Received by Fee Category



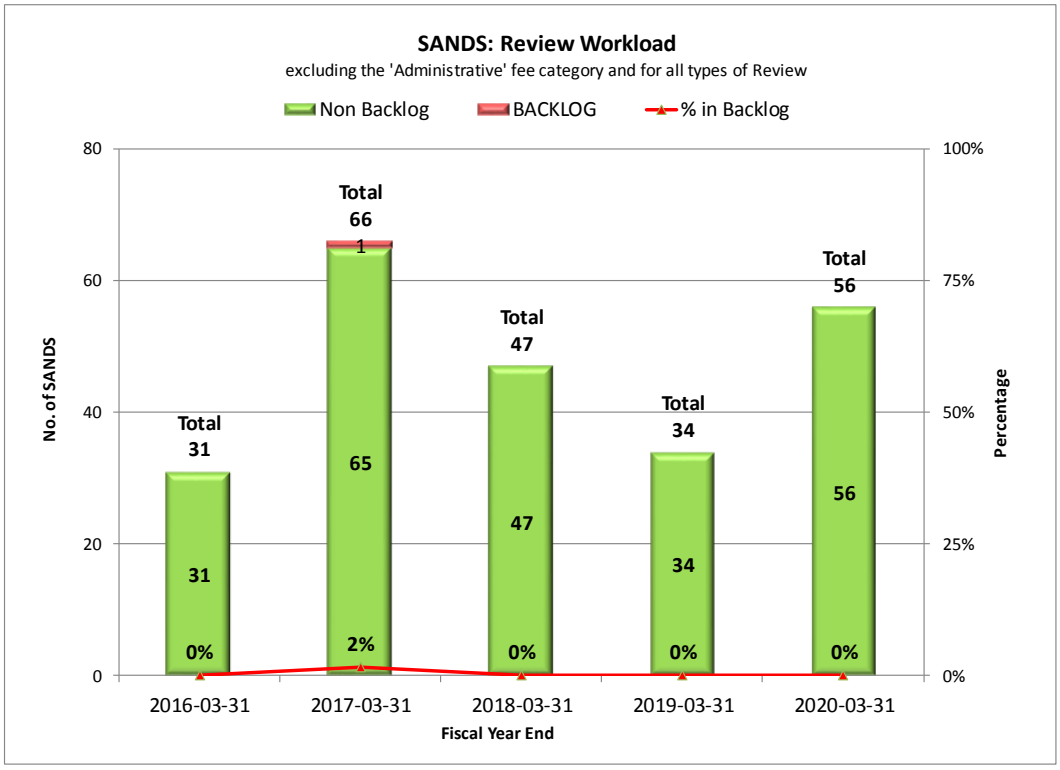
	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	73	127	172	191	236
Comparative Studies	6	7	3	2	7
Published Data Only	0	0	1	0	0
Chemistry & Manufacturing	67	53	67	43	58
Total	146	187	243	236	301

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

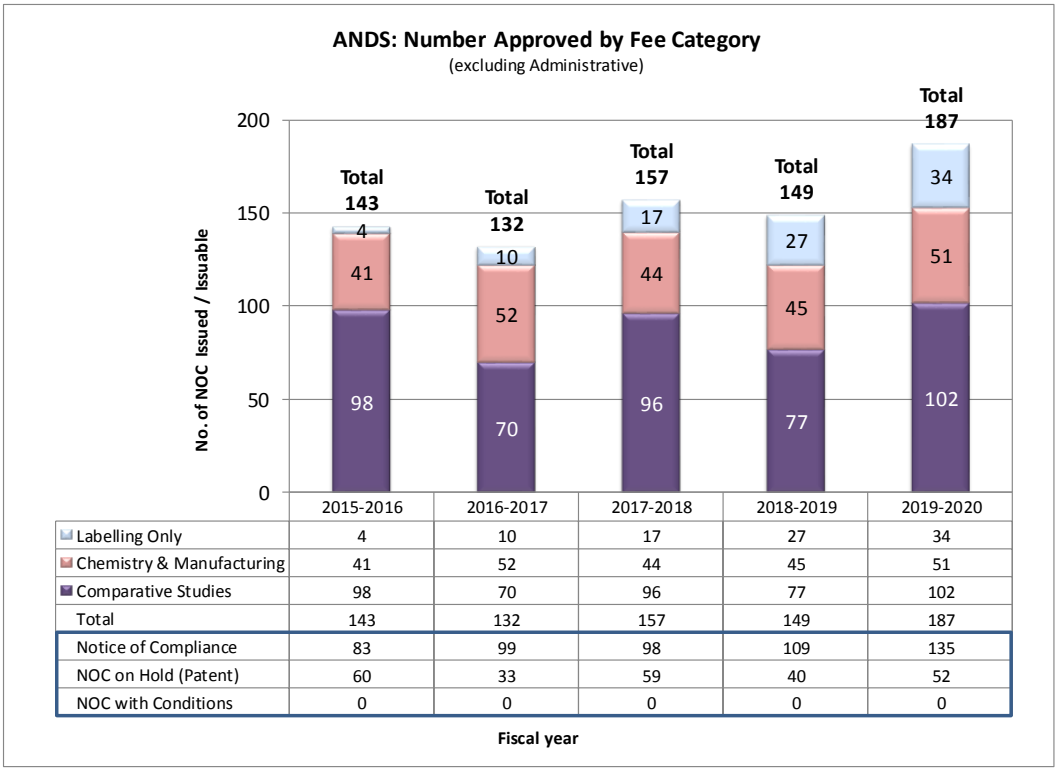
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Chemistry & Manufacturing	49	46	43	38	42
Backlog	*1*	*5*	*2*	*0*	*0*
Comparative Studies	65	71	65	77	88
Backlog	*7*	*7*	*2*	*0*	*0*
Labelling Only	2	1	3	3	8
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**116**	**118**	**111**	**118**	**138**
Non Backlog	**108**	**106**	**107**	**118**	**138**
BACKLOG	**8**	**12**	**4**	**0**	**0**
% in Backlog	**7%**	**10%**	**4%**	**0%**	**0%**

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Chemistry & Manufacturing	24	32	26	22	24
Backlog	*0*	*1*	*0*	*0*	*0*
Comparative Studies	2	4	2	2	3
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	5	30	19	10	29
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**31**	**66**	**47**	**34**	**56**
Non Backlog	**31**	**65**	**47**	**34**	**56**
BACKLOG	**0**	**1**	**0**	**0**	**0**
% in Backlog	**0%**	**2%**	**0%**	**0%**	**0%**

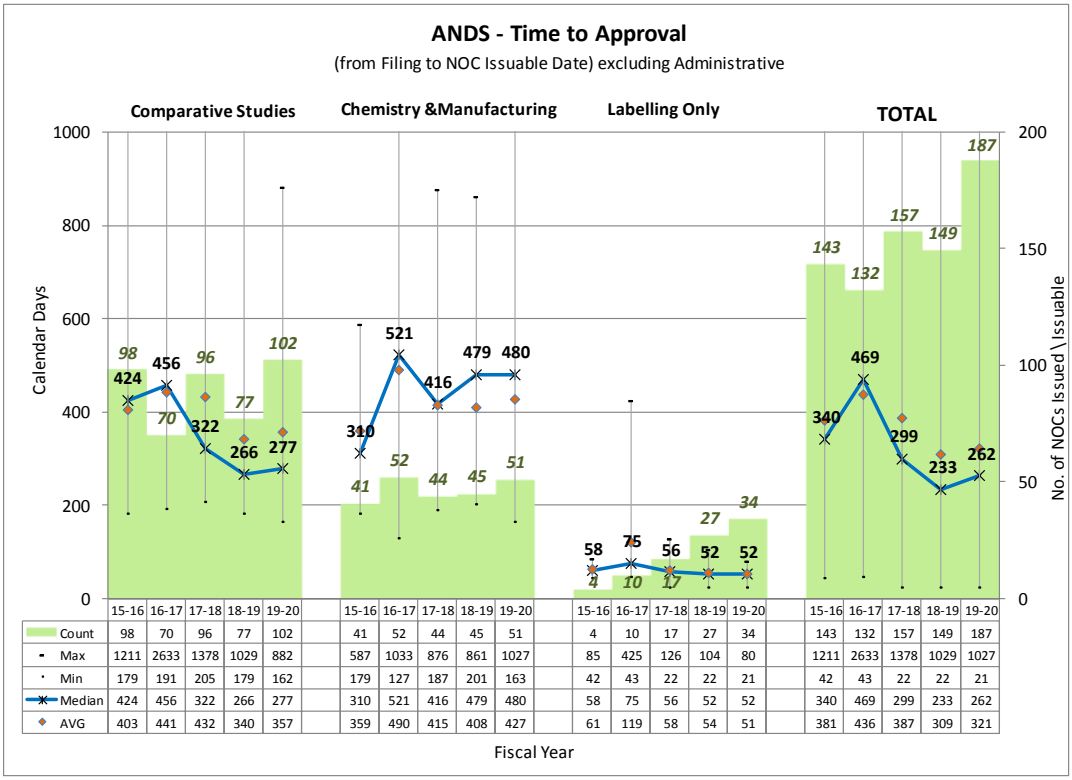
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Labelling Only	4	10	17	27	34
Chemistry & Manufacturing	41	52	44	45	51
Comparative Studies	98	70	96	77	102
Total	143	132	157	149	187
Notice of Compliance	83	99	98	109	135
NOC on Hold (Patent)	60	33	59	40	52
NOC with Conditions	0	0	0	0	0

ANDS Approval Times

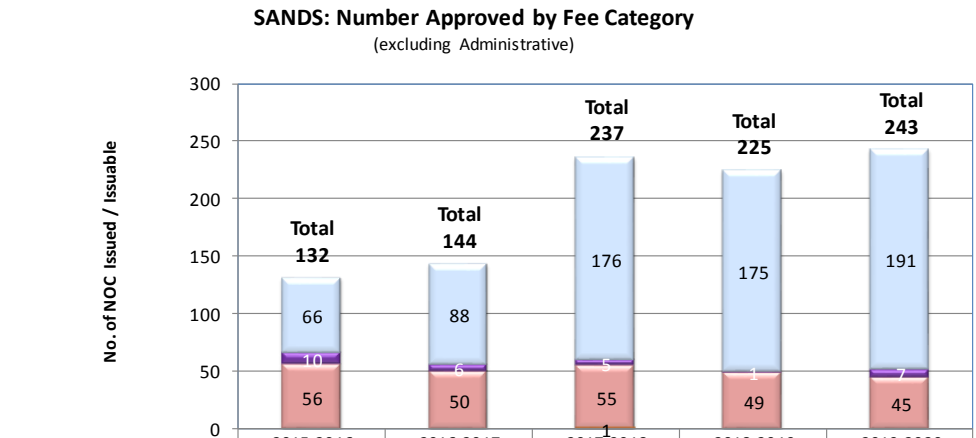


	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	98	70	96	77	102	41	52	44	45	51	4	10	17	27	34	143	132	157	149	187
Max	1211	2633	1378	1029	882	587	1033	876	861	1027	85	425	126	104	80	1211	2633	1378	1029	1027
Min	179	191	205	179	162	179	127	187	201	163	42	43	22	22	21	42	43	22	22	21
Median	424	456	322	266	277	310	521	416	479	480	58	75	56	52	52	340	469	299	233	262
AVG	403	441	432	340	357	359	490	415	408	427	61	119	58	54	51	381	436	387	309	321

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.

APPROVALS

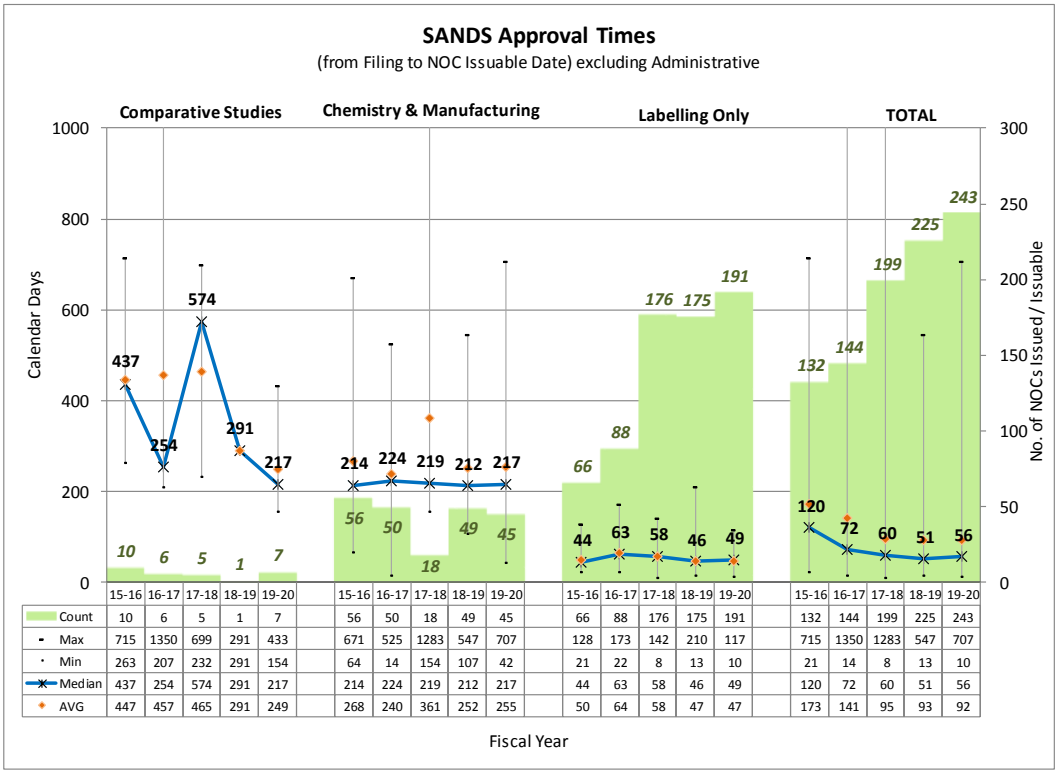
SANDS: Number Approved by Fee Category and by NOC Type



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Labelling Only	66	88	176	175	191
Comparative Studies	10	6	5	1	7
Chemistry & Manufacturing	56	50	55	49	45
Published Data Only	0	0	1	0	0
Total	132	144	237	225	243
Notice of Compliance	111	133	217	206	224
NOC on Hold (Patent)	21	11	20	19	19
NOC on Hold (Switch)	0	0	0	0	0
NOC with Conditions	0	0	0	0	0

Fiscal Year

SANDS Approval Times



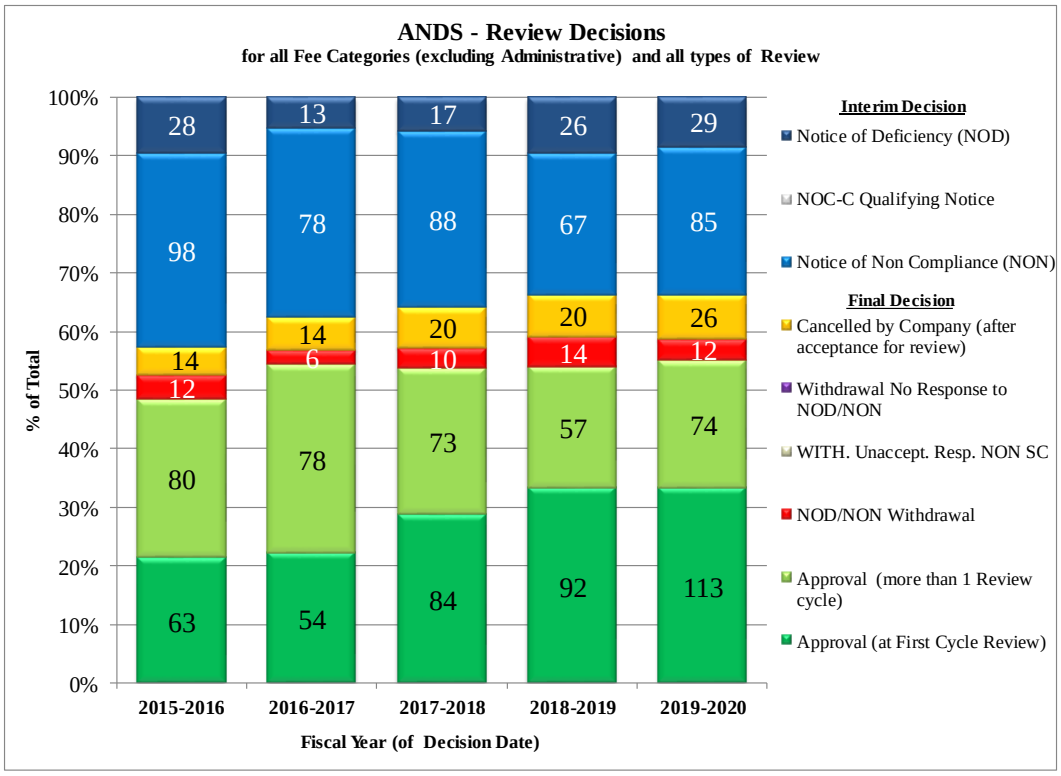
	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	10	6	5	1	7	56	50	18	49	45	66	88	176	175	191	132	144	199	225	243
Max	715	1350	699	291	433	671	525	1283	547	707	128	173	142	210	117	715	1350	1283	547	707
Min	263	207	232	291	154	64	14	154	107	42	21	22	8	13	10	21	14	8	13	10
Median	437	254	574	291	217	214	224	219	212	217	44	63	58	46	49	120	72	60	51	56
AVG	447	457	465	291	249	268	240	361	252	255	50	64	58	47	47	173	141	95	93	92

Fiscal Year

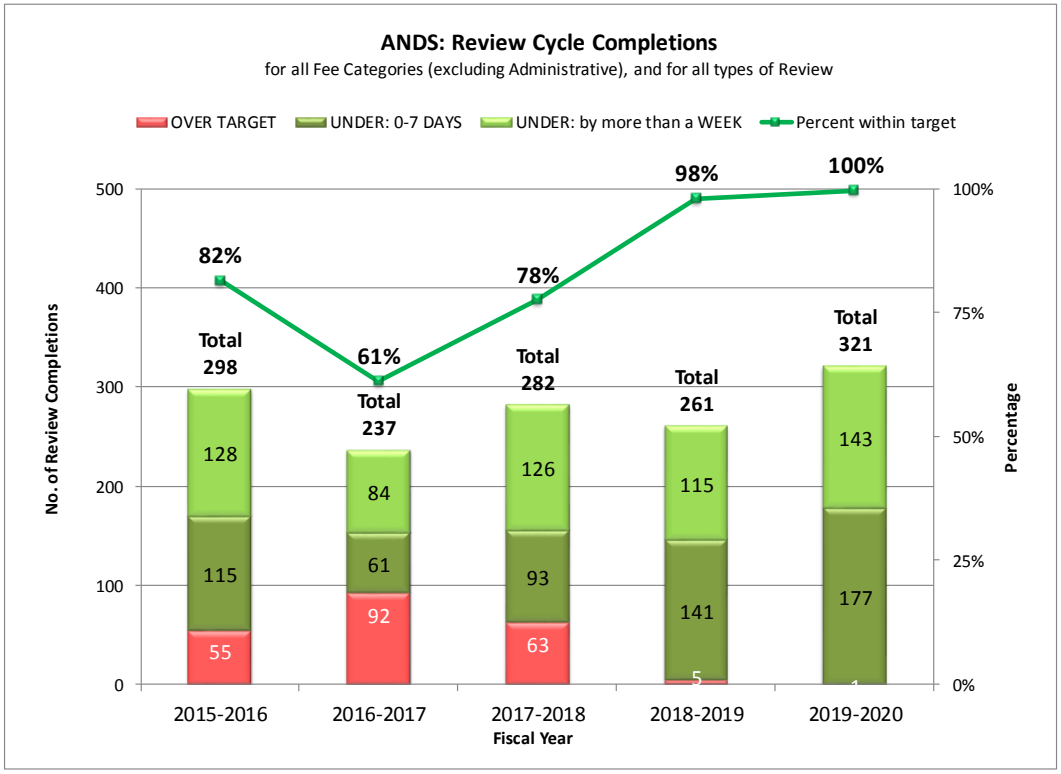
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW PERFORMANCE

ANDS: Review Decisions by Type

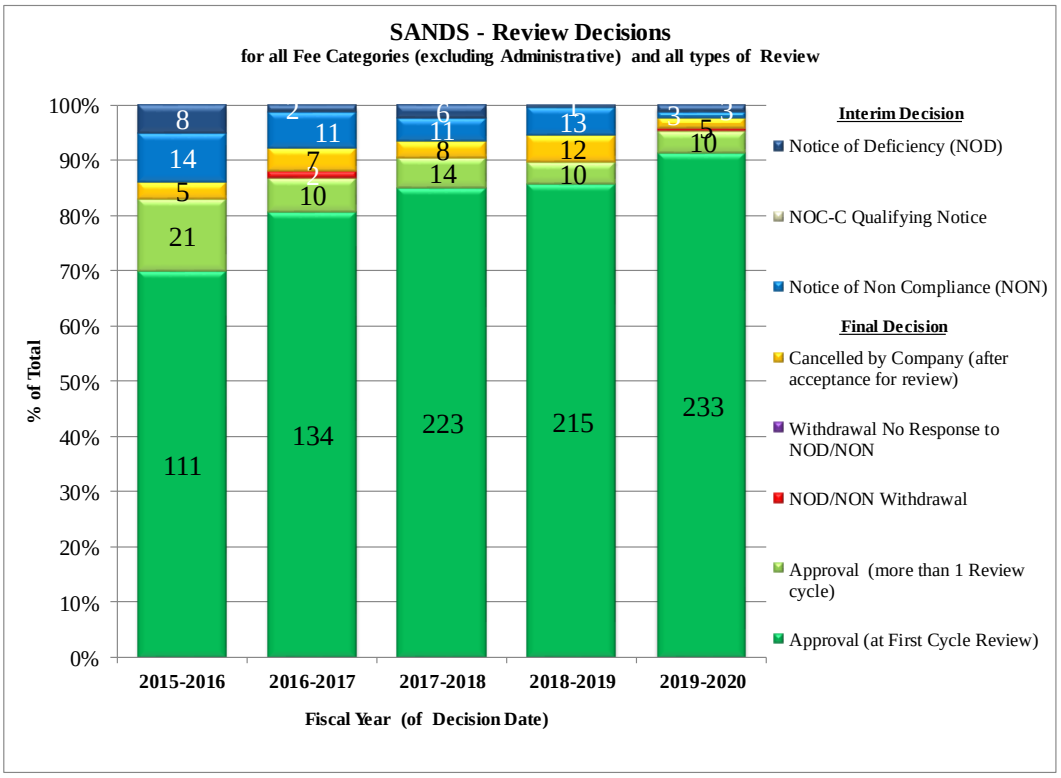


ANDS: Review Cycle Completions

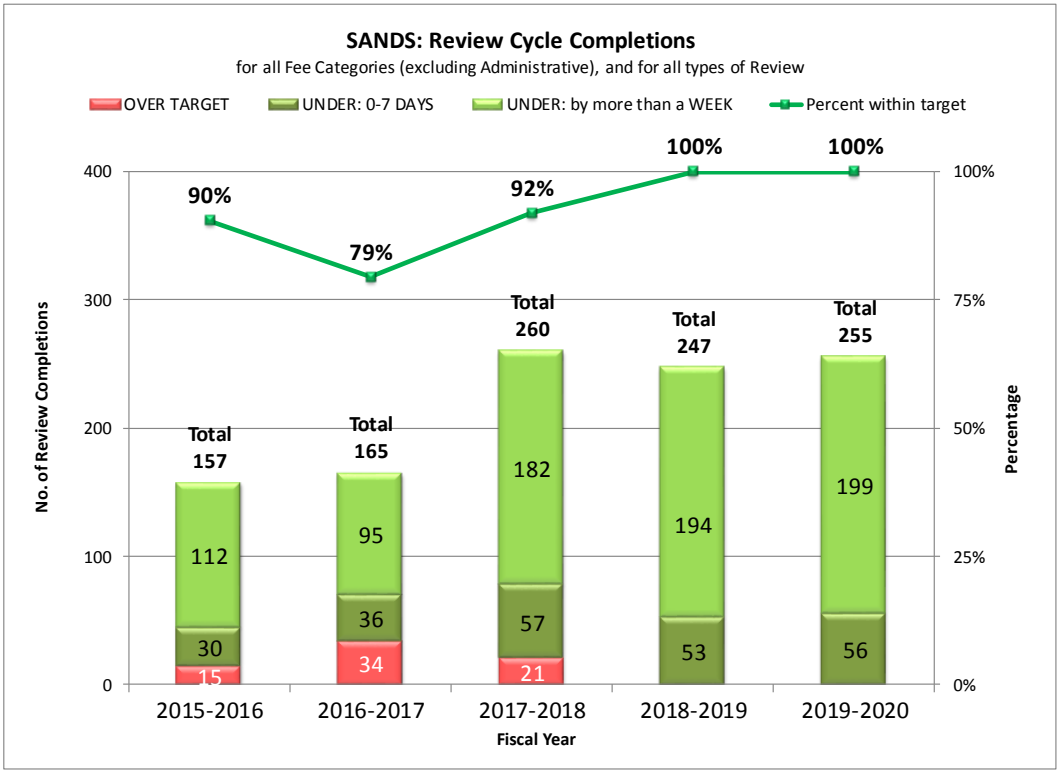


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

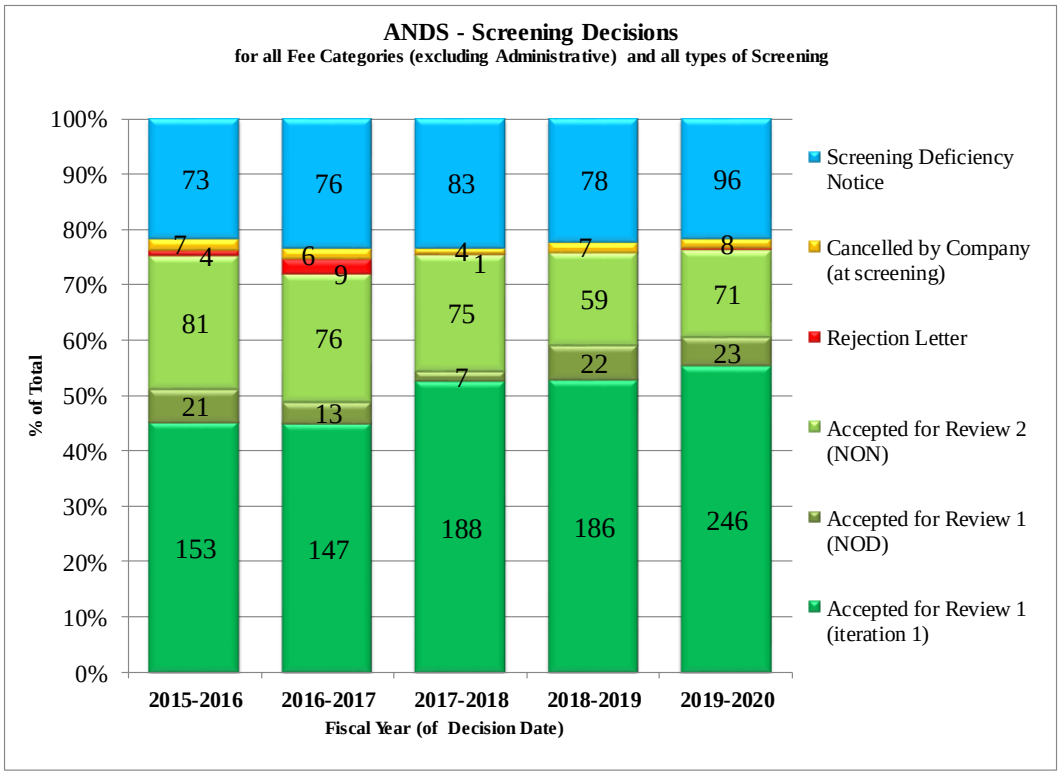


SANDS: Review Cycle Completions

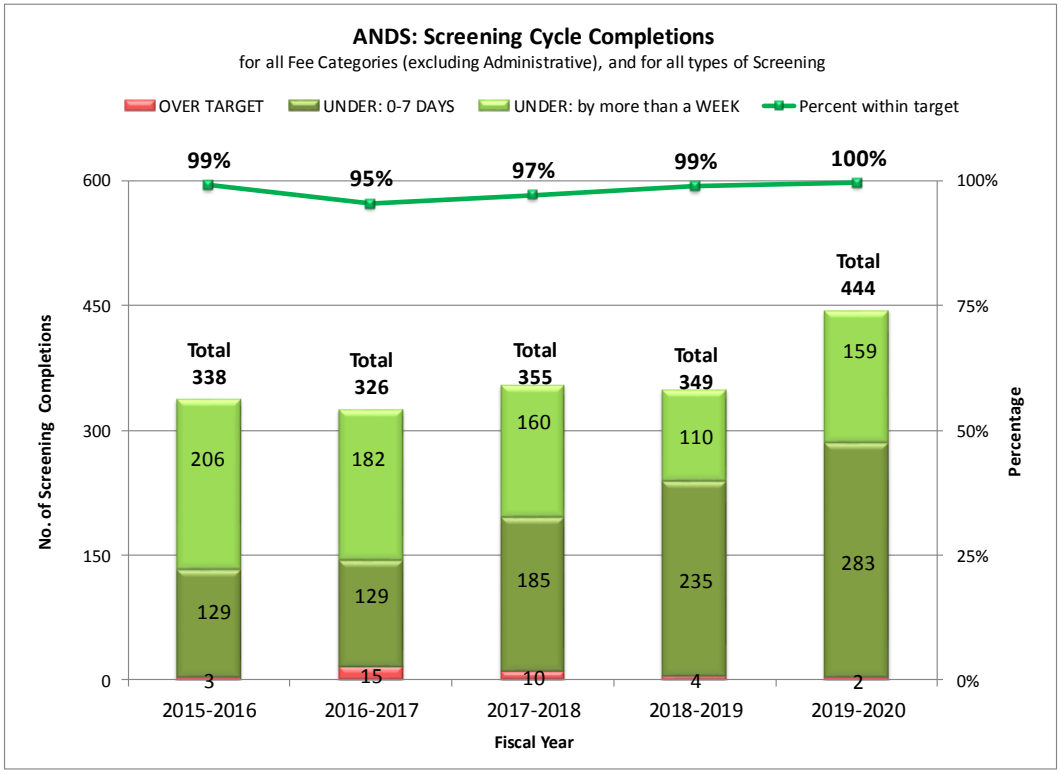


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

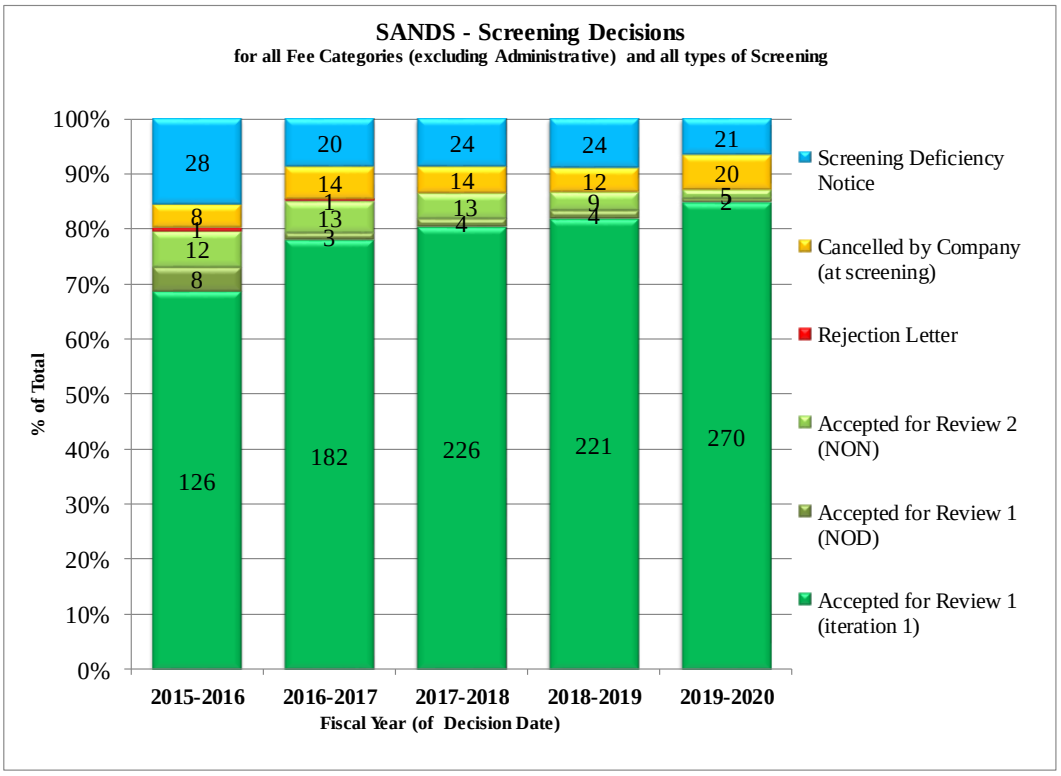


ANDS: Screening Cycle Completions

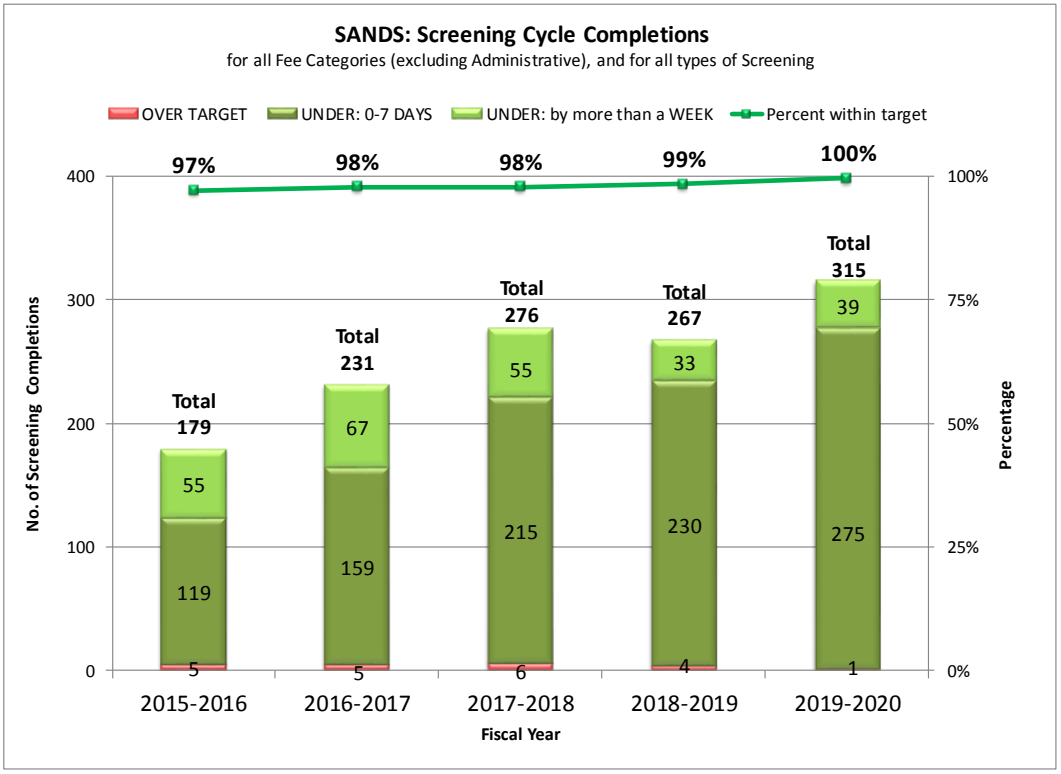


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type



SANDS: Screening Cycle Completions



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

ANDS: Request for Reconsideration of Final Decisions

ANDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	ANDS Status (as of May 2020)
TOTAL Received	**3**	**2**	**0**	**3**	**2**		
Total Pending	*1*	*0*	*0*	*1*	*0*		
Pending	1	0	0	1	0	NON-Withdrawal	Under Reconsideration
Total Granted	*1*	*1*	*0*	*2*	*0*		
Granted	1	0	0	2	0	NON-Withdrawal	Cleared
Granted	0	1	0	0	0	Rejection at Screening	Cleared
Total Denied	*1*	*0*	*0*	*0*	*0*		
Denied	1	0	0	0	0	NON-Withdrawal	Withdrawn
Total Cancelled	*0*	*1*	*0*	*0*	*2*		
Cancelled by Company	0	1	0	0	2	NOD-Withdrawal	Withdrawn

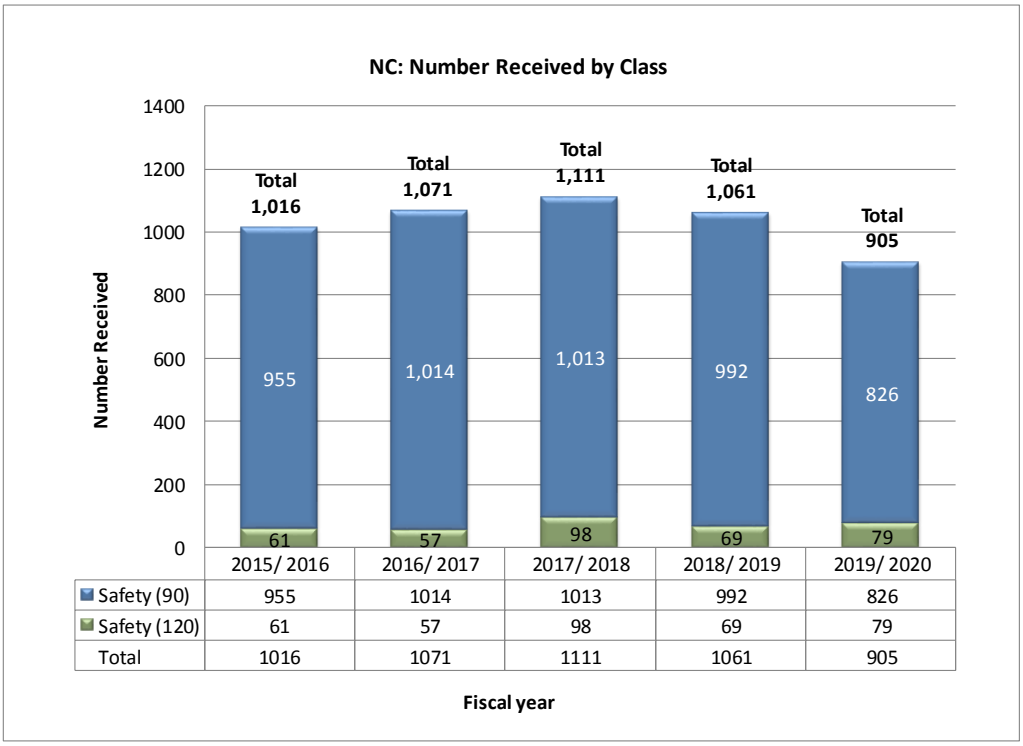
SANDS: Request for Reconsideration of Final Decisions

SANDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	SANDS Status (as of May 2020)
Total Received	**1**	**1**	**0**	**0**	**0**		
Total Granted	*1*	*0*	*0*	*0*	*0*		
Granted	1	0	0	0	0	NOD-Withdrawal	Cleared
Total Cancelled	*0*	*1*	*0*	*0*	*0*		
Cancelled by Health Canada	0	1	0	0	0	NOD-Withdrawal	Withdrawn

NC: NOTIFIABLE CHANGE

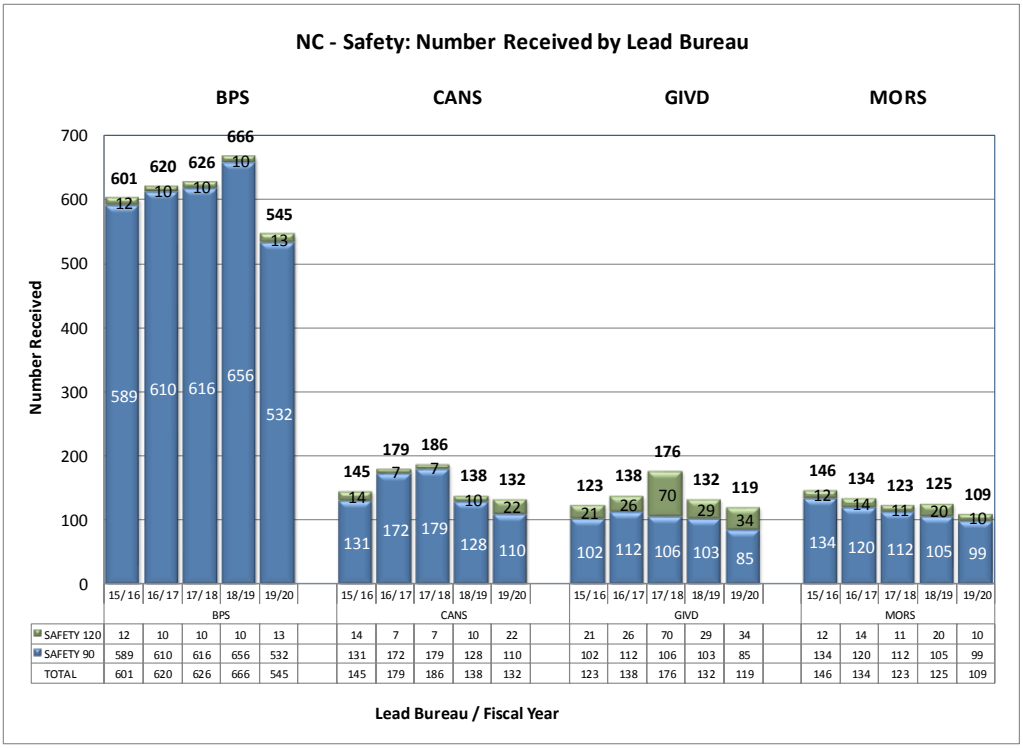
NOTIFIABLE CHANGES RECEIVED

NC: Number Received by Class



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Safety (90)	955	1014	1013	992	826
Safety (120)	61	57	98	69	79
Total	1016	1071	1111	1061	905

NC-SAFETY: Number Received by Lead Bureau

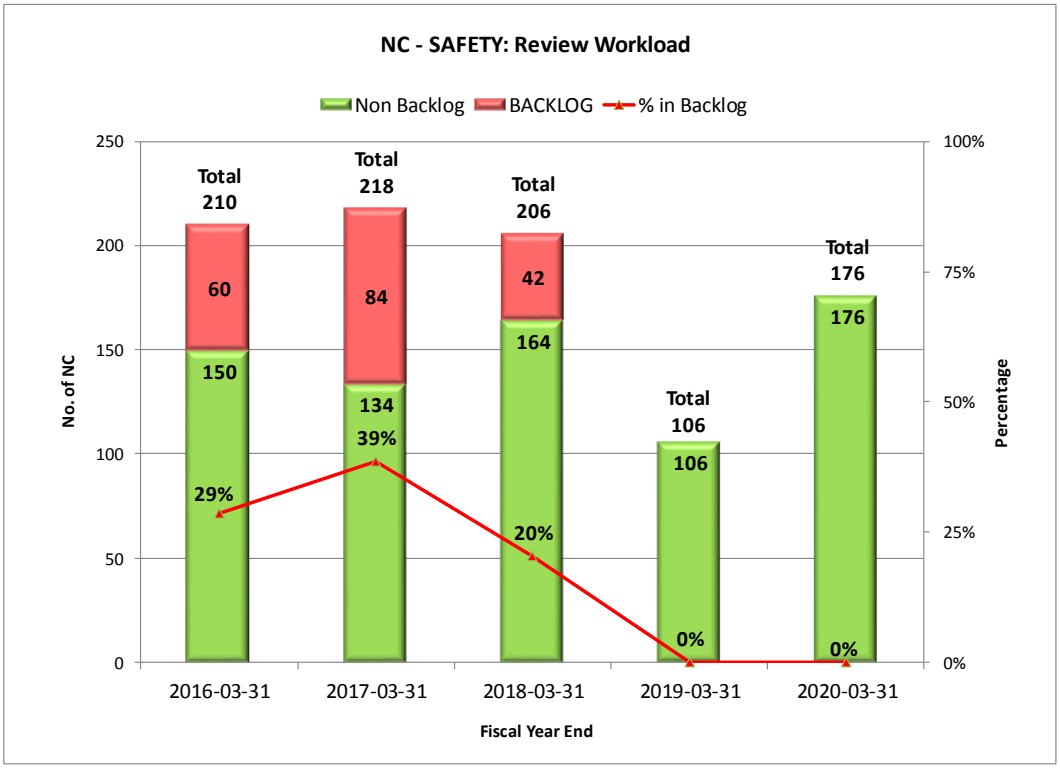


	BPS					CANS					GIVD					MORS				
	15/16	16/17	17/18	18/19	19/20	15/16	16/17	17/18	18/19	19/20	15/16	16/17	17/18	18/19	19/20	15/16	16/17	17/18	18/19	19/20
SAFETY 120	12	10	10	10	13	14	7	7	10	22	21	26	70	29	34	12	14	11	20	10
SAFETY 90	589	610	616	656	532	131	172	179	128	110	102	112	106	103	85	134	120	112	105	99
TOTAL	601	620	626	666	545	145	179	186	138	132	123	138	176	132	119	146	134	123	125	109

In February 2013 the Safety Labelling Changes to the Product Monographs of Brand Name Pharmaceutical Drug Products process was introduced to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals and Canadians.

WORKLOAD

NC-SAFETY: Review Workload

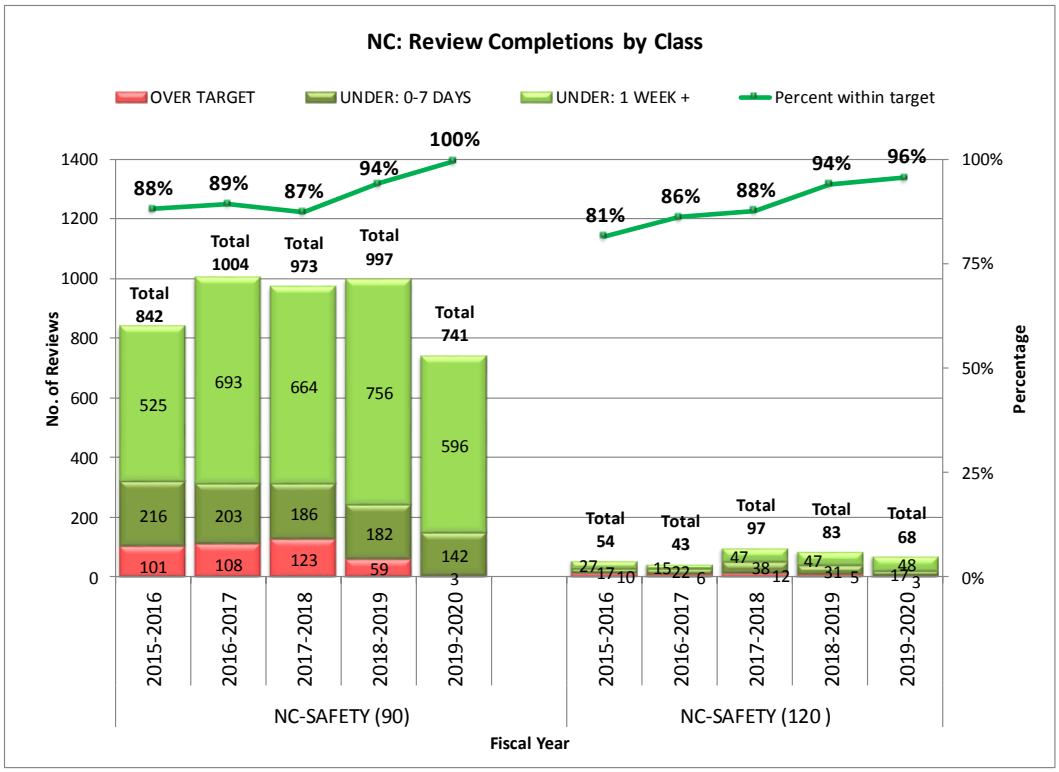


NC-SAFETY: Review Workload by Class

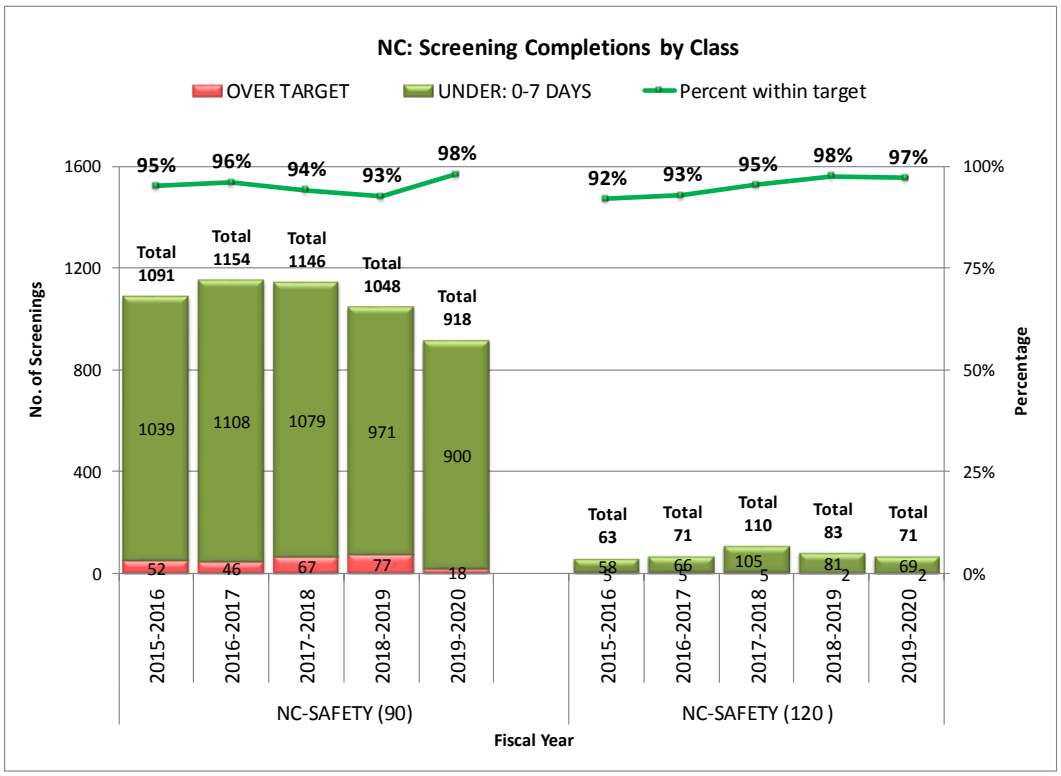
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
SAFETY - 90 day	194	188	184	95	166
Backlog	*60*	*78*	*39*	*0*	*0*
SAFETY - 120 day	16	30	22	11	10
Backlog	*0*	*6*	*3*	*0*	*0*
Total	**210**	**218**	**206**	**106**	**176**
Non Backlog	**150**	**134**	**164**	**106**	**176**
BACKLOG	60	84	42	0	0
% in Backlog	**29%**	**39%**	**20%**	0%	0%

PERFORMANCE

NC-SAFETY: Review Completions by Class



NC-SAFETY: Screening Completions by Class



DECISIONS

NC-SAFETY: Number of Decisions by Class

NC - SAFETY (90)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	834	954	990	977	736
CANCELLED BY COMPANY	62	65	66	63	43
NC - HOLD (PATENT)	45	69	46	35	23
SCREEN. DEFICIENCY NOTICE	197	136	161	115	90
REJECTION LETTER (SCR)	3	2	3	2	1
NOT SATISFACTORY NOTICE	1	2	0	1	0
NC - SAFETY (120)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	54	43	90	81	62
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	6	11	20	11	4
CANCELLED BY COMPANY	6	4	8	2	7
REJECTION LETTER (SCR)	1	0	0	0	0
NC - HOLD (PATENT)	0	0	0	1	2

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

NC: Request for Reconsideration of Final Decisions

NC - Requests for Reconsideration of Final Decisions					
	Fiscal Year of Request (April 1 - March 31)				
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total Received	0	0	0	0	0

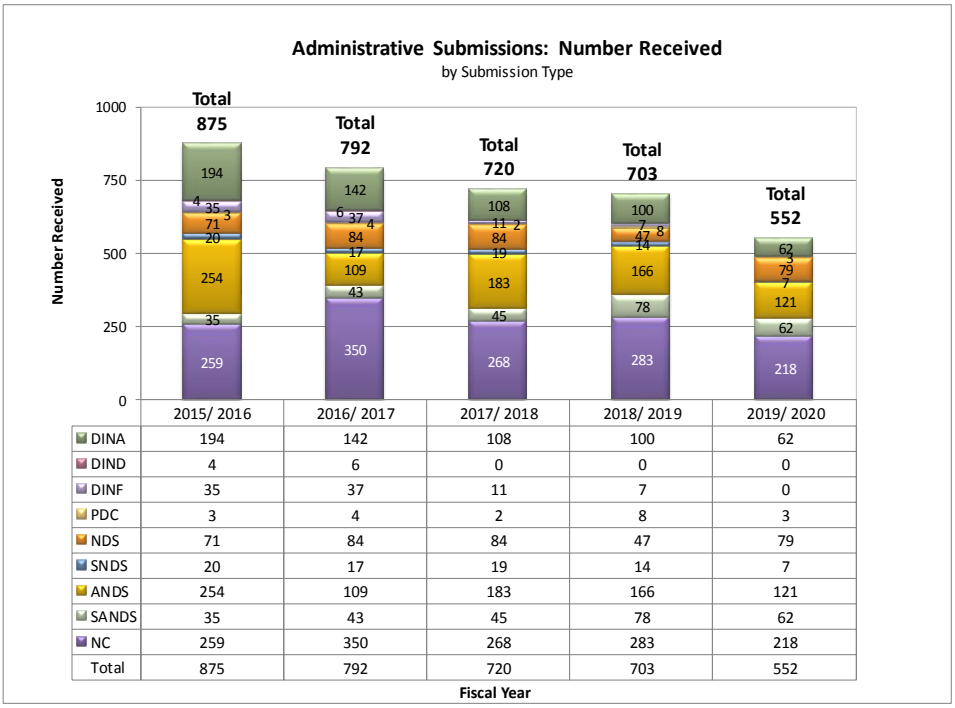
ADMINISTRATIVE SUBMISSIONS

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS[11]

RECEIVED

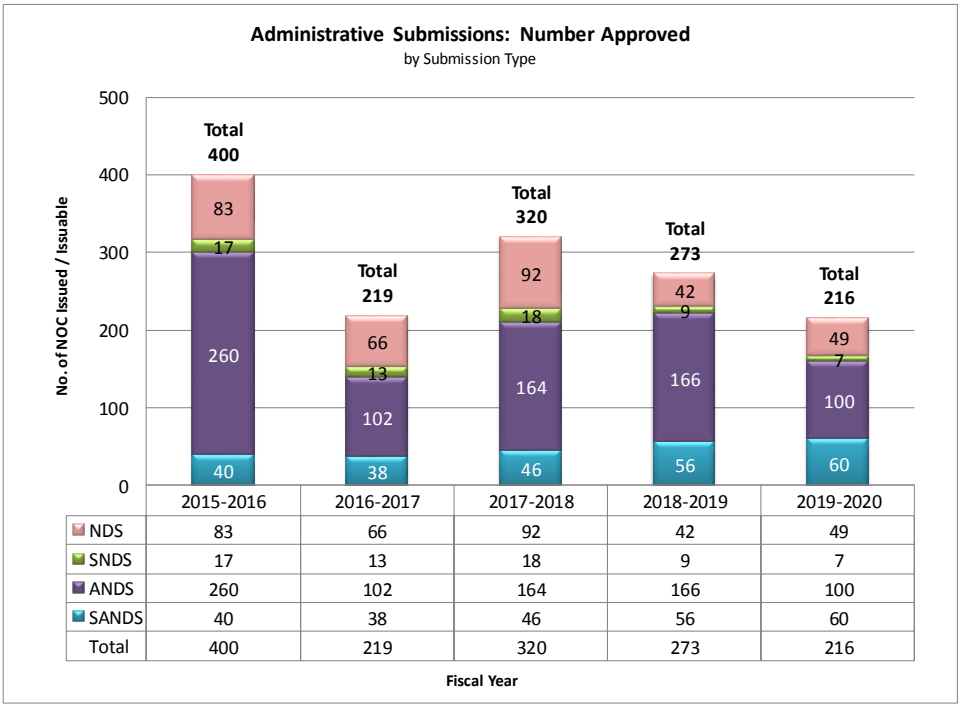
Administrative Submissions: Number Received by Submission Type



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
DINA	194	142	108	100	62
DIND	4	6	0	0	0
DINF	35	37	11	7	0
PDC	3	4	2	8	3
NDS	71	84	84	47	79
SNDS	20	17	19	14	7
ANDS	254	109	183	166	121
SANDS	35	43	45	78	62
NC	259	350	268	283	218
Total	875	792	720	703	552

APPROVALS

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



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
NDS	83	66	92	42	49
SNDS	17	13	18	9	7
ANDS	260	102	164	166	100
SANDS	40	38	46	56	60
Total	400	219	320	273	216

[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 areas of the Bureau of Gastroenterology, Infection and Viral Disease (BGIVD) at TPD in December 2018 and to the NNHPD for non-prescription products.

DECISIONS

Administrative Submissions (Division 8): Number of Decisions

SUBMISSION TYPE - DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
NDS - Administrative					
NOTICE OF COMPLIANCE	77	65	92	42	49
NOC ON IP HOLD	6	1	0	0	0
NOC WITH CONDITIONS	2	0	0	0	0
SCREEN. DEFICIENCY NOTICE	0	6	5	0	0
CANCELLATION LETTER	0	1	3	4	6
PROCESSING HOLD LETTER	60	58	46	12	22
SNDS - Administrative					
NOTICE OF COMPLIANCE	17	12	18	9	7
NOC ON IP HOLD	0	1	0	0	0
CANCELLATION LETTER	1	2	1	7	1
PROCESSING HOLD LETTER	10	4	4	5	1
ANDS - Administrative					
NOTICE OF COMPLIANCE	157	77	157	165	99
NOC ON IP HOLD	103	25	3	1	1
SCREEN. DEFICIENCY NOTICE	0	10	1	5	0
CANCELLATION LETTER	9	3	8	6	23
PROCESSING HOLD LETTER	126	79	88	44	34
SANDS - Administrative					
NOTICE OF COMPLIANCE	36	36	46	56	60
NOC ON IP HOLD	4	2	0	0	0
SCREEN. DEFICIENCY NOTICE	0	2	0	2	0
CANCELLATION LETTER	0	1	2	9	10
PROCESSING HOLD LETTER	16	20	27	20	16
NC - Administrative					
NO OBJECTION LETTER	221	298	271	265	196
NC - HOLD (PATENT)	8	29	0	1	0
SCREEN. DEFICIENCY NOTICE	2	0	1	0	0
CANCELLATION LETTER	10	13	13	21	32
PROCESSING HOLD LETTER	5	6	2	16	12

DECISIONS

Administrative DIN Applications (Division 1): Number of Decisions

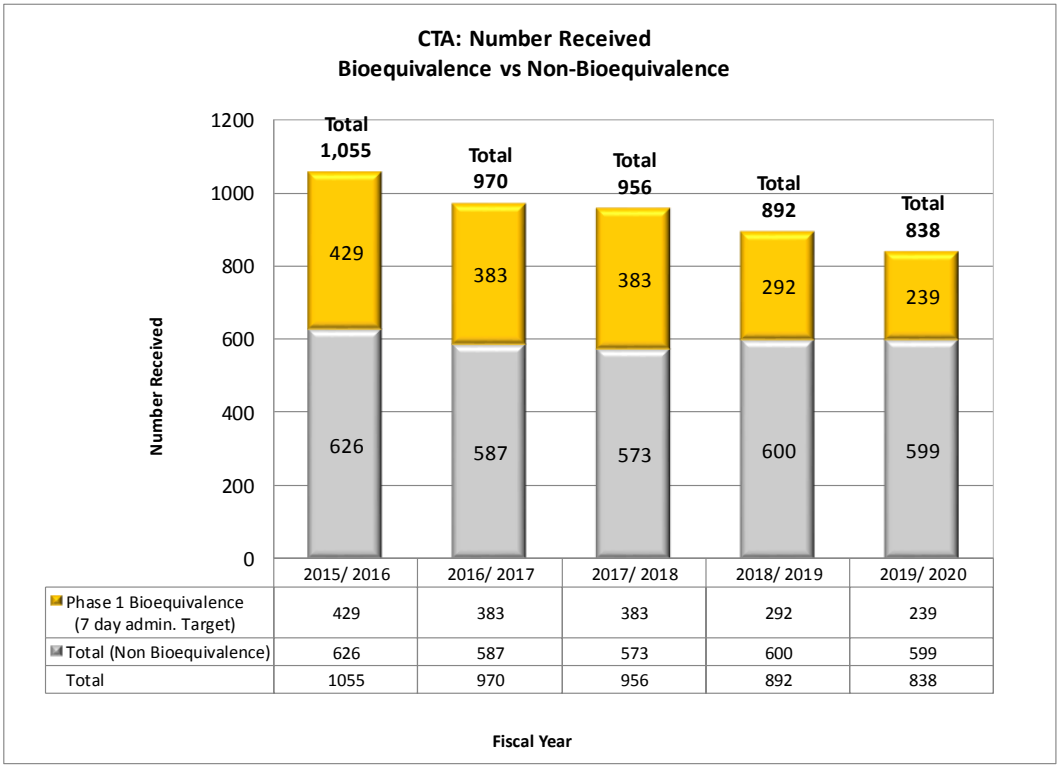
SUBMISSION TYPE - DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
DINA - Administrative					
NOTIFICATION FORM/DIN ISSUED	132	104	124	84	37
NO OBJECTION LETTER	2	0	0	2	1
SCREEN. DEFICIENCY NOTICE	0	63	11	8	0
CANCELLATION LETTER	4	4	8	11	20
PROCESSING HOLD LETTER	117	76	54	27	30
DIND - Administrative					
NOTIFICATION FORM/ DIN ISSUED	3	2	0	0	0
CANCELLATION LETTER	0	4	0	0	0
PROCESSING HOLD LETTER	3	9	0	0	0
DINF - Administrative					
NOTIFICATION FORM/ DIN ISSUED	35	29	9	0	7
NO OBJECTION LETTER	0	0	1	0	0
SCREEN. DEFICIENCY NOTICE	0	1	0	0	0
CANCELLATION LETTER	0	1	1	0	0
PROCESSING HOLD LETTER	27	24	16	7	0
PDC - Administrative					
NO OBJECTION LETTER	1	3	1	5	3
CANCELLATION LETTER	0	3	0	3	1
PROCESSING HOLD LETTER	0	1	0	2	0

Clinical Trial Applications and Amendments

(CTA & CTA-A)

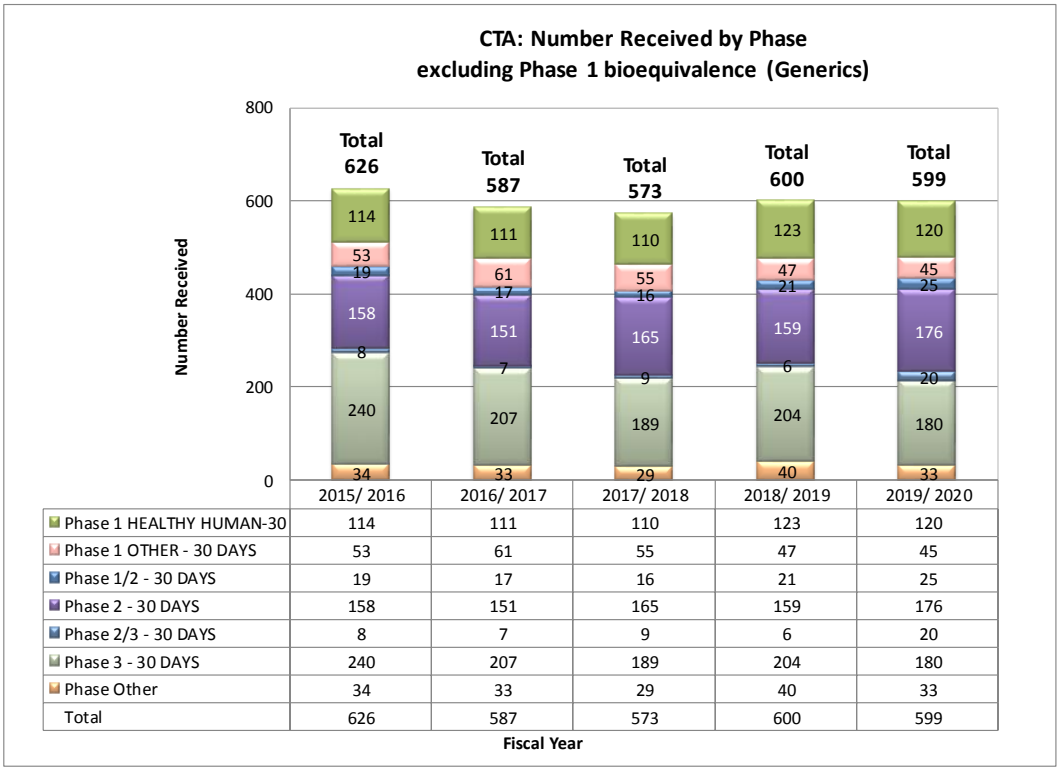
CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

CTA: Number Received



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Phase 1 Bioequivalence (7 day admin. Target)	429	383	383	292	239
Total (Non Bioequivalence)	626	587	573	600	599
Total	1055	970	956	892	838

CTA: Number Received by Phase excluding Bioequivalence (Generics)



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Phase 1 HEALTHY HUMAN-30	114	111	110	123	120
Phase 1 OTHER - 30 DAYS	53	61	55	47	45
Phase 1/2 - 30 DAYS	19	17	16	21	25
Phase 2 - 30 DAYS	158	151	165	159	176
Phase 2/3 - 30 DAYS	8	7	9	6	20
Phase 3 - 30 DAYS	240	207	189	204	180
Phase Other	34	33	29	40	33
Total	626	587	573	600	599

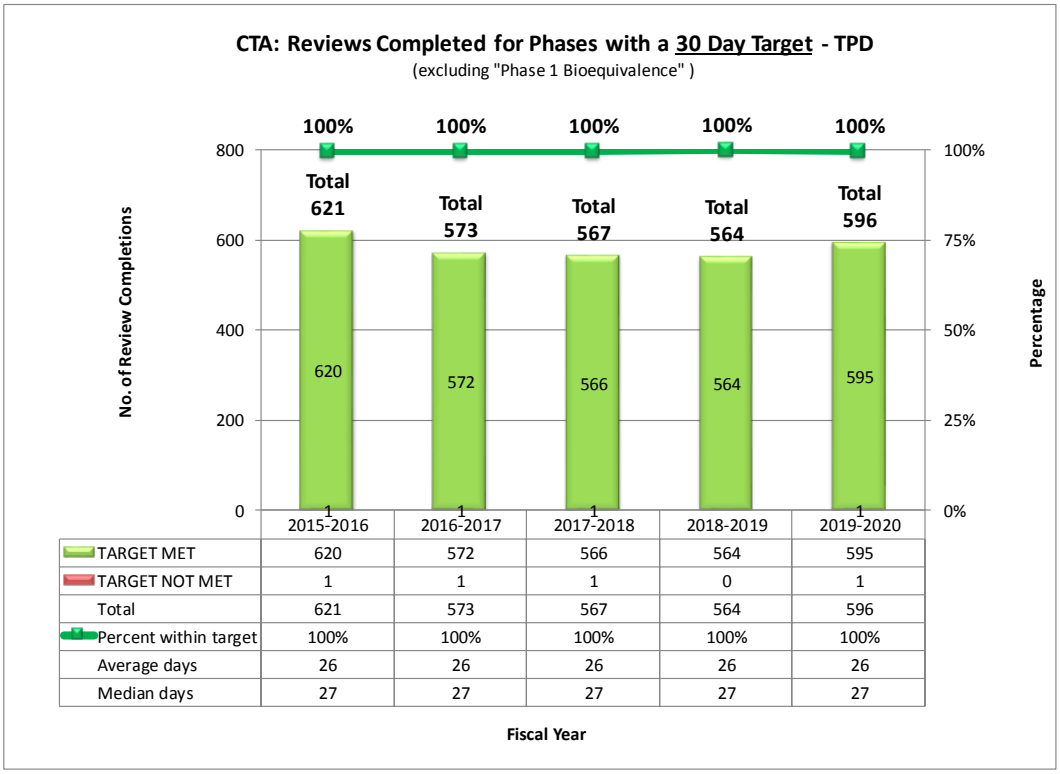
DECISION DOCUMENTS

CTA: Number of Decisions by Type

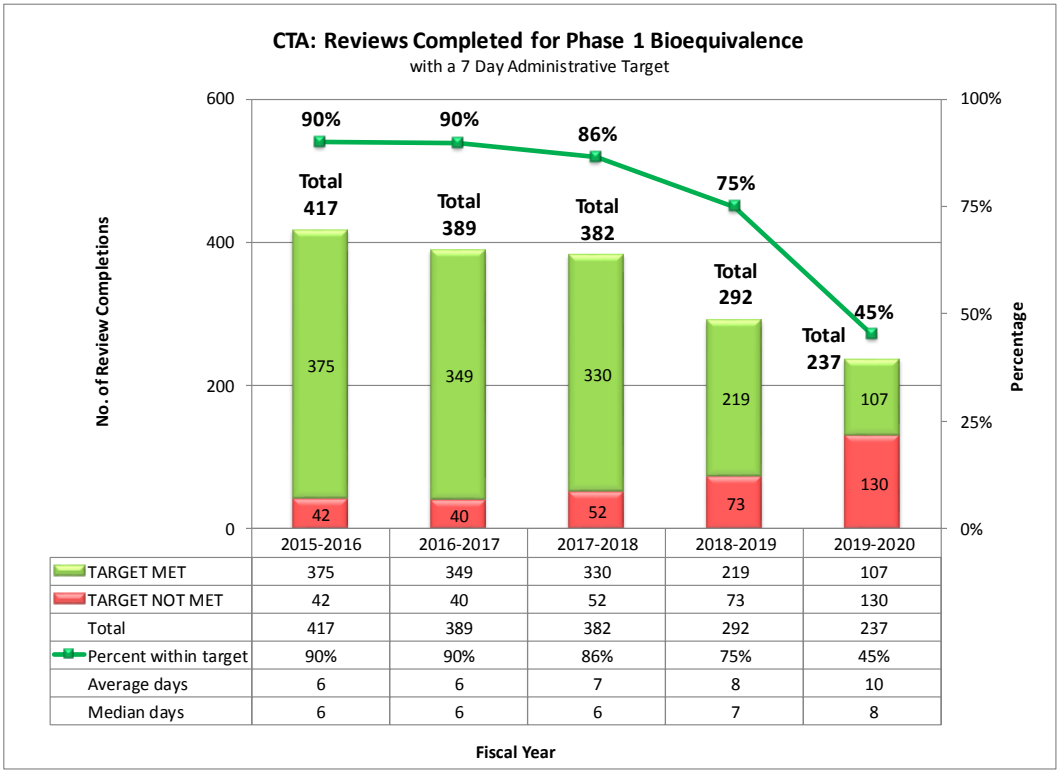
CTA (Total)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	994	926	898	821	775
CANCELLED BY COMPANY DURING REVIEW	44	36	53	37	60
CANCELLED BY COMPANY AT PROCESSING	8	4	11	11	15
CTA Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	405	386	379	286	229
CANCELLED BY COMPANY DURING REVIEW	12	3	3	5	8
CANCELLED BY COMPANY AT PROCESSING	0	0	1	2	2
CTA (30 day target)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	589	540	519	535	546
CANCELLED BY COMPANY DURING REVIEW	32	33	50	32	52
CANCELLED BY COMPANY AT PROCESSING	8	4	10	9	13
NOT SATISFACTORY NOTICE	0	0	0	1	0

PERFORMANCE

CTA: Reviews Completed for Phases with a 30 Day Target

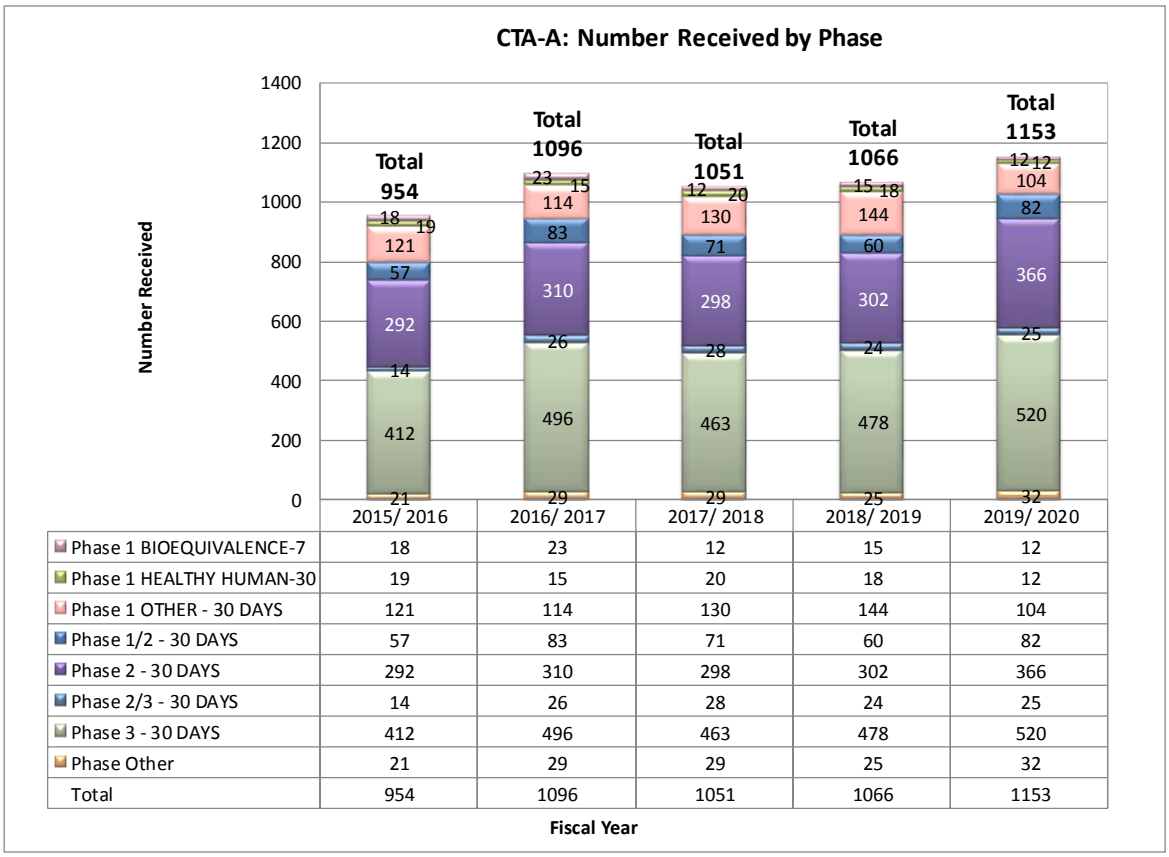


CTA: Reviews Completed for Phases with a 7 Day Administrative Target



CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Phase 1 BIOEQUIVALENCE-7	18	23	12	15	12
Phase 1 HEALTHY HUMAN-30	19	15	20	18	12
Phase 1 OTHER - 30 DAYS	121	114	130	144	104
Phase 1/2 - 30 DAYS	57	83	71	60	82
Phase 2 - 30 DAYS	292	310	298	302	366
Phase 2/3 - 30 DAYS	14	26	28	24	25
Phase 3 - 30 DAYS	412	496	463	478	520
Phase Other	21	29	29	25	32
Total	954	1096	1051	1066	1153

DECISIONS

CTA-A: Number of Decisions by Type

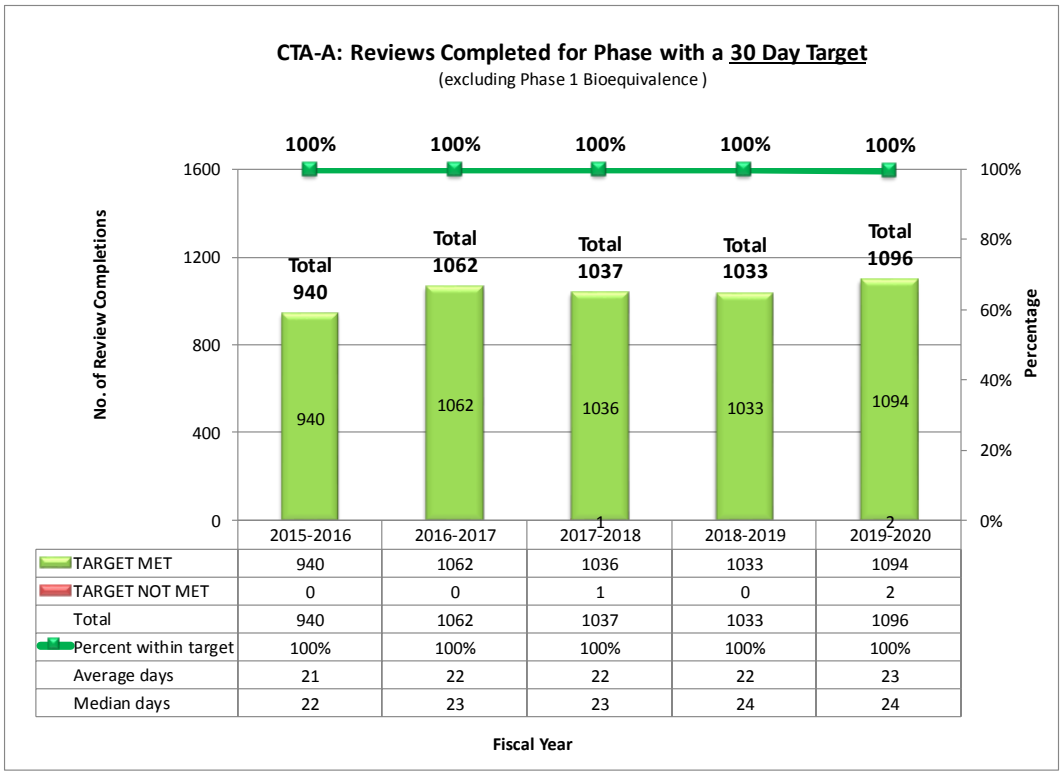
CTA-A (Total)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	949	1070	1037	1032	1079
CANCELLED BY COMPANY DURING REVIEW	9	15	11	15	30
CANCELLED BY COMPANY AT PROCESSING	0	0	1	3	33

CTA-A Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	18	23	12	12	13
CANCELLED BY COMPANY DURING REVIEW	0	0	0	2	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

CTA-A (30 day target)					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
NO OBJECTION LETTER	931	1047	1025	1020	1066
CANCELLED BY COMPANY DURING REVIEW	9	15	11	13	30
CANCELLED BY COMPANY AT PROCESSING	0	0	1	3	33
NOT SATISFACTORY NOTICE	0	0	0	0	1
REJECTION LETTER (SCR)	0	0	0	0	1

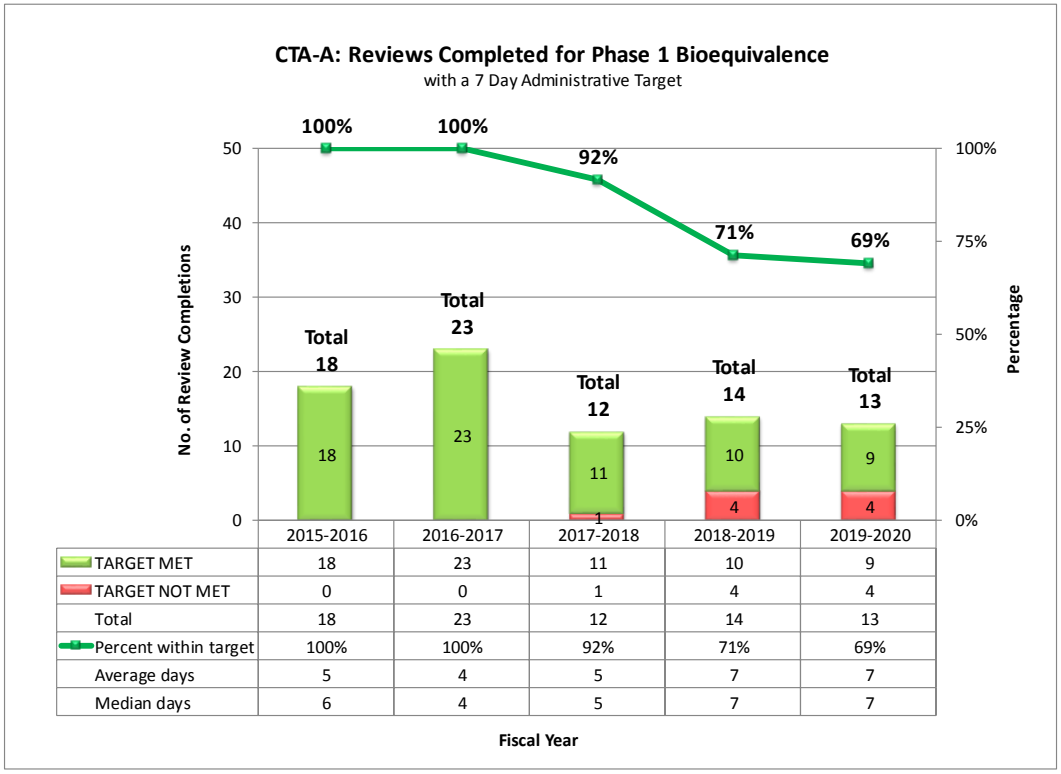
PERFORMANCE

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



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
TARGET MET	940	1062	1036	1033	1094
TARGET NOT MET	0	0	1	0	2
Total	940	1062	1037	1033	1096
Percent within target	100%	100%	100%	100%	100%
Average days	21	22	22	22	23
Median days	22	23	23	24	24

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



	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
TARGET MET	18	23	11	10	9
TARGET NOT MET	0	0	1	4	4
Total	18	23	12	14	13
Percent within target	100%	100%	92%	71%	69%
Average days	5	4	5	7	7
Median days	6	4	5	7	7

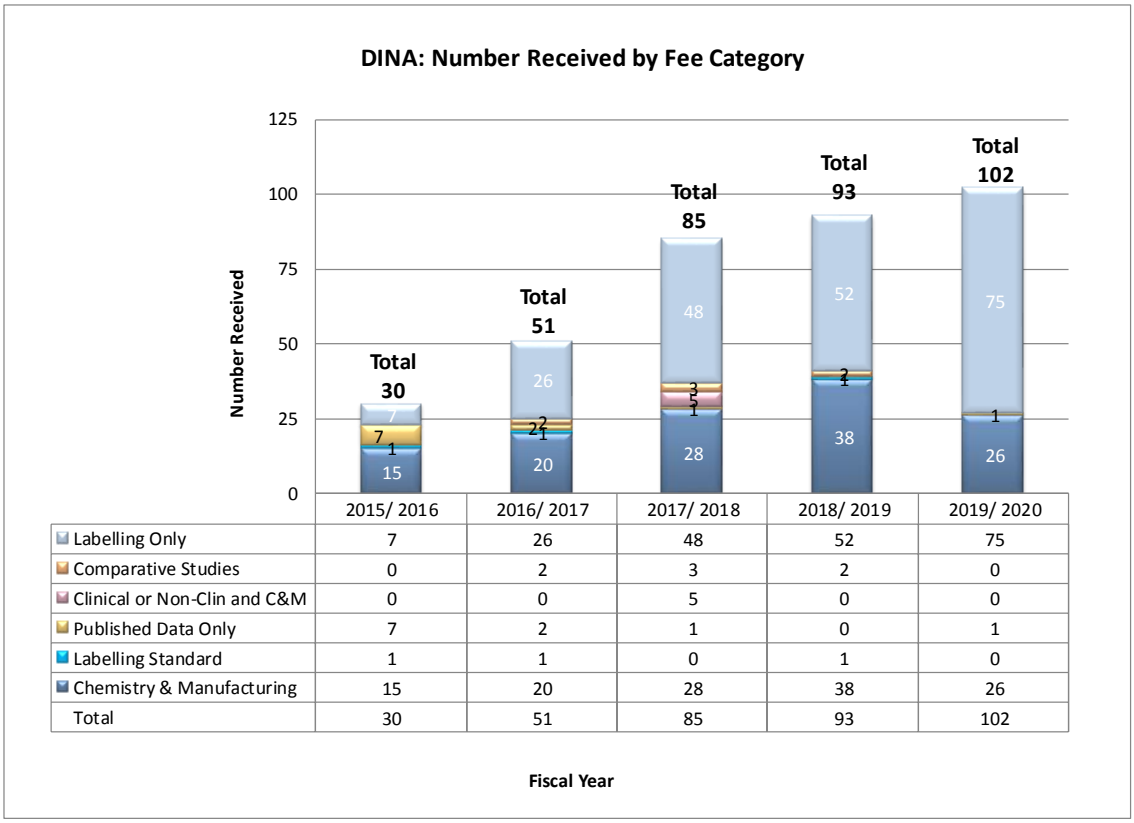
DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

RECEIVED

DINA: Number Received by Fee Category

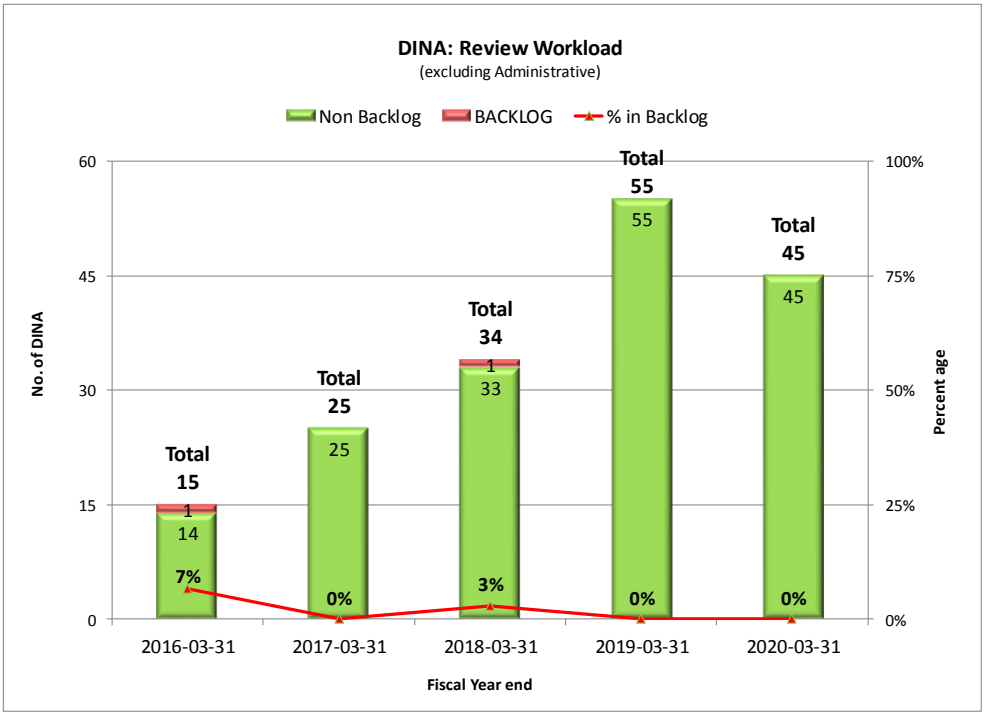


	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Labelling Only	7	26	48	52	75
Comparative Studies	0	2	3	2	0
Clinical or Non-Clin and C&M	0	0	5	0	0
Published Data Only	7	2	1	0	1
Labelling Standard	1	1	0	1	0
Chemistry & Manufacturing	15	20	28	38	26
Total	30	51	85	93	102

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

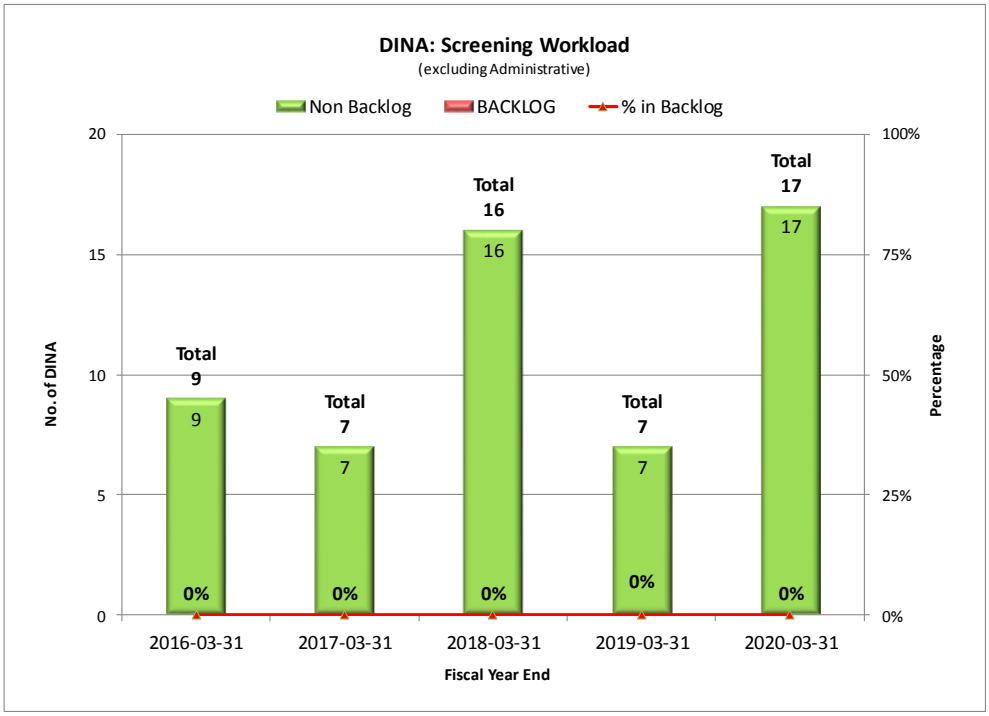


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Labelling Only	4	13	13	27	29
Backlog	*0*	*0*	*1*	*0*	*0*
Clinical or Non-Clin and C&M	0	0	0	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	9	12	19	26	15
Backlog	*1*	*0*	*0*	*0*	*0*
Published Data	1	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	0	1	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**15**	**25**	**34**	**55**	**45**
Non Backlog	**14**	**25**	**33**	**55**	**45**
BACKLOG	**1**	**0**	**1**	**0**	**0**
% in Backlog	**7%**	**0%**	**3%**	**0%**	**0%**

SCREENING WORKLOAD

DINA: Screening Workload



DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2016-03-31**	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**
Labelling Only	1	4	8	3	11
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	0	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	5	2	4	3	6
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	2	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	3	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	1	2	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**9**	**7**	**16**	**7**	**17**
Non Backlog	**9**	**7**	**16**	**7**	**17**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINA: Number of Decisions by Fee Category

CATEGORY / DOCUMENT TYPE	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
DINA - LABELLING ONLY					
NOTIFICATION FORM/DIN ISSUED	1	3	12	9	2
NO OBJECTION LETTER	5	4	25	29	59
CANCELLED BY COMPANY	1	6	3	7	2
NOTICE OF DEFICIENCY	-	1	-	-	-
NOTICE OF NON-COMPLIANCE	-	1	-	2	-
REJECTION LETTER (SCREENING)	-	-	1	-	-
SCREENING DEFICIENCY NOTICE	2	9	8	6	4
DINA - PUBLISHED DATA ONLY					
NO OBJECTION LETTER	3	2	-	1	-
SCREENING DEFICIENCY NOTICE	-	-	1	-	-
CANCELLED BY COMPANY	1	1	-	-	1
NOTICE OF NON-COMPLIANCE	1	1	-	-	-
NOT SATISFACTORY NOTICE	-	1	-	-	-
DINA - CHEMISTRY & MANUFACTURING					
NOTIFICATION FORM/DIN ISSUED	12	6	13	12	15
NOTICE OF DEFICIENCY	2	1	2	3	-
REJECTION LETTER (SCREENING)	-	3	-	-	-
SCREENING DEFICIENCY NOTICE	12	17	9	7	8
CANCELLED BY COMPANY	3	4	3	7	2
NO OBJECTION LETTER	6	5	3	11	20
NEW DRUG LETTER REVIEW	-	-	1	-	-
NOTICE OF NON-COMPLIANCE	4	8	6	7	6
NON WITHDRAWAL LETTER	-	1	2	2	-
DINA - CLINICAL & NON CLINICAL DATA & C&M					
CANCELLED BY COMPANY	-	-	1	1	-
SCREENING DEFICIENCY NOTICE	-	-	2	2	-
NOTICE OF NON-COMPLIANCE	-	-	-	2	-
NOTIFICATION FORM/DIN ISSUED	-	-	-	1	1
DINA - COMPARATIVE STUDIES					
NOTIFICATION FORM/DIN ISSUED	1	2	1	2	1
NO OBJECTION LETTER	-	-	-	-	-
NOTICE OF DEFICIENCY	1	-	-	-	-
NOTICE OF NON-COMPLIANCE	-	-	1	1	-
SCREENING DEFICIENCY NOTICE	-	1	3	2	-
NON WITHDRAWAL LETTER	-	-	-	1	-
CANCELLED BY COMPANY	-	-	-	1	-

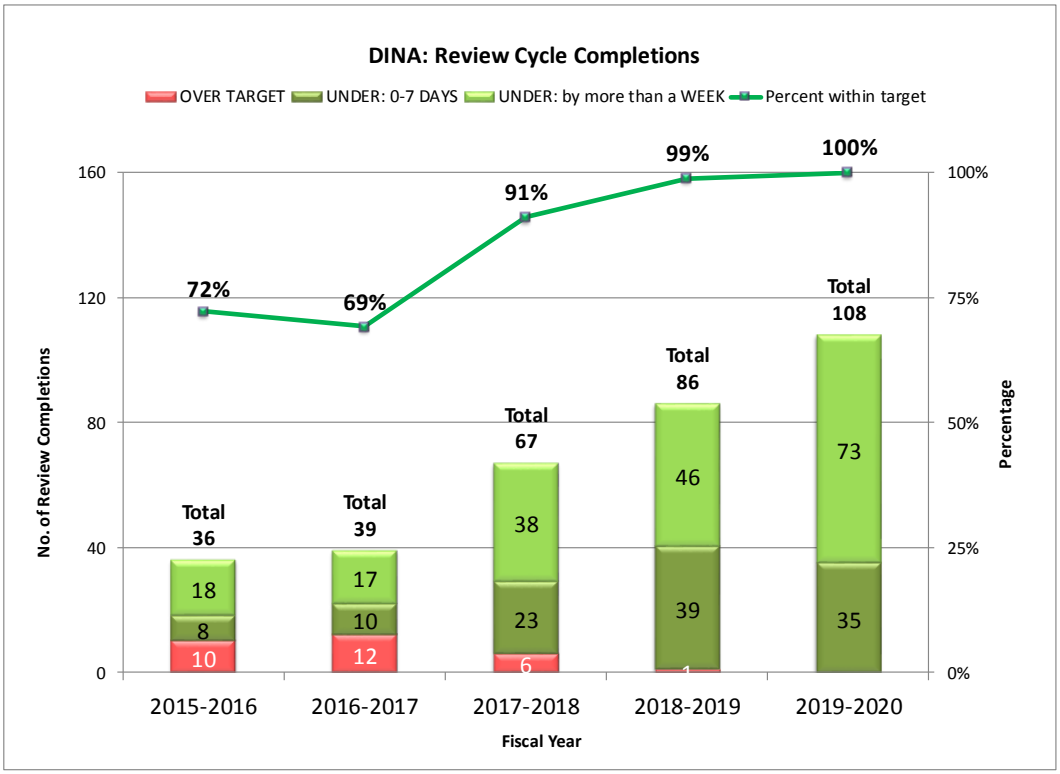
REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Request for Reconsideration of Final Decisions

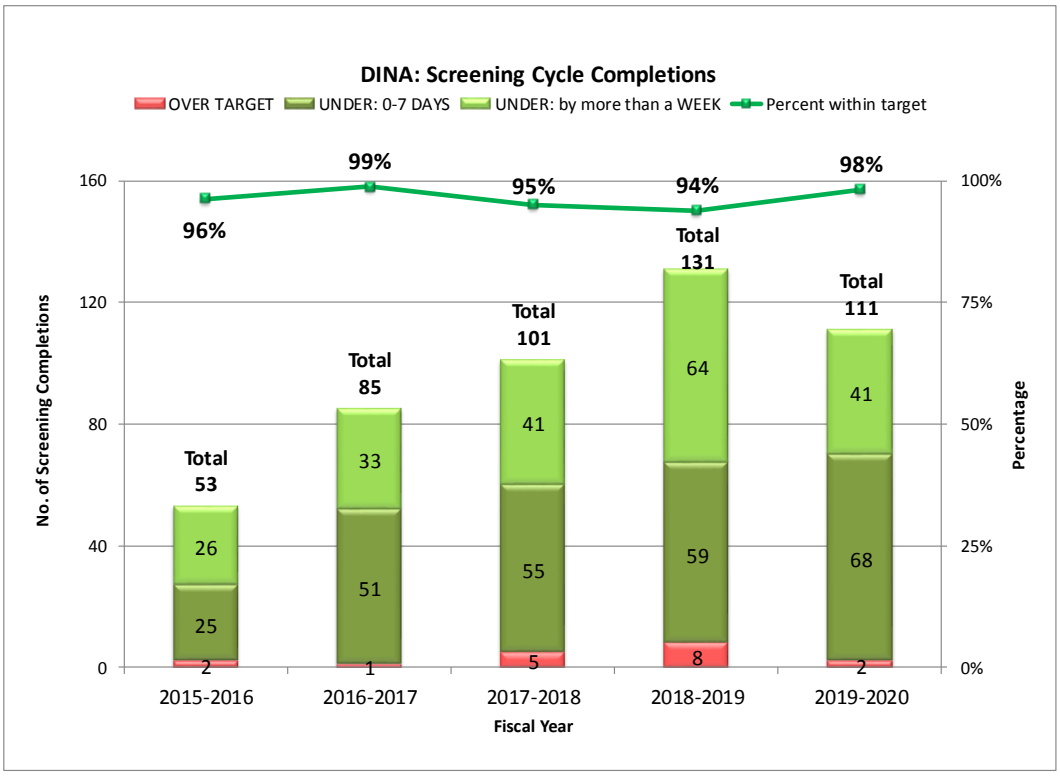
DINA - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	Final Decision in Dispute	Submission Status (as of May 2020)
Total Received	0	1	1	0	0		
Total Granted	*0*	*1*	*1*	*0*	*0*		
Granted	0	0	1	0	0	New Drug Letter	Cancelled by Company
Granted	0	1	0	0	0	NON-Withdrawal	Cleared

PERFORMANCE

DINA: Review Cycle Completions



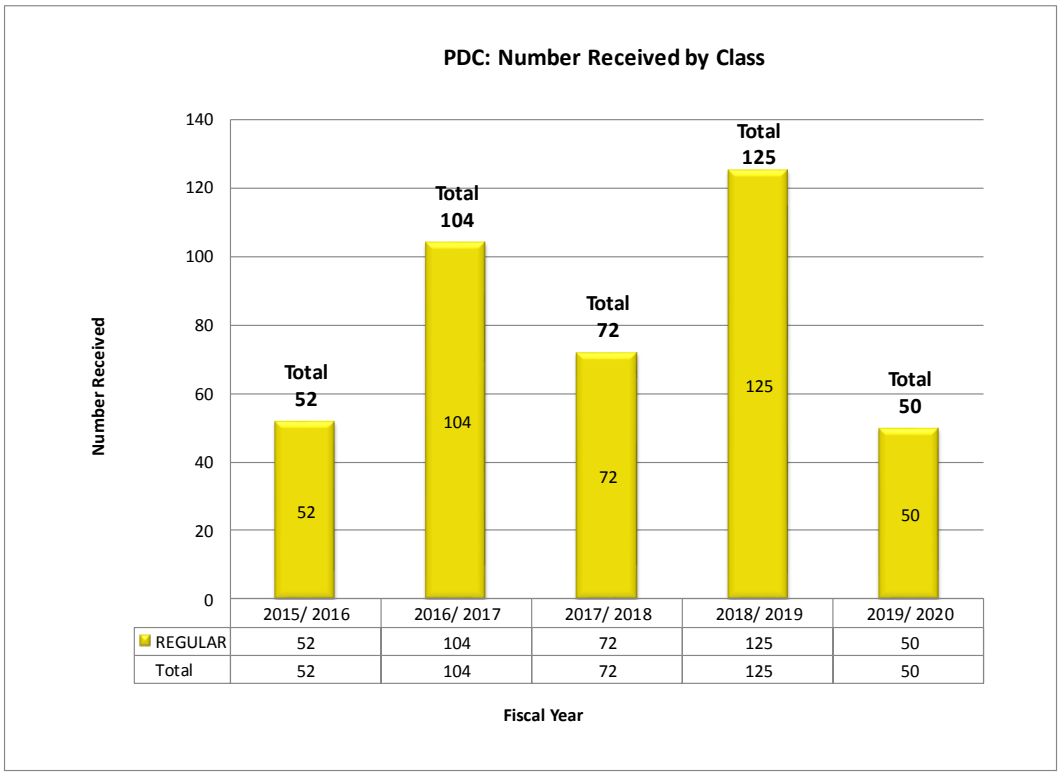
DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

RECEIVED

PDC: Number Received



DECISIONS

PDC: Number of Decision by Type

PDC- Regular					
DOCUMENT TYPE	**2015-2016**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**
CANCELLED BY COMPANY	11	18	15	20	18
NO OBJECTION LETTER	43	80	35	131	39
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCREENING)	0	0	0	0	0

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

PDC: Request for Reconsideration of Final Decisions

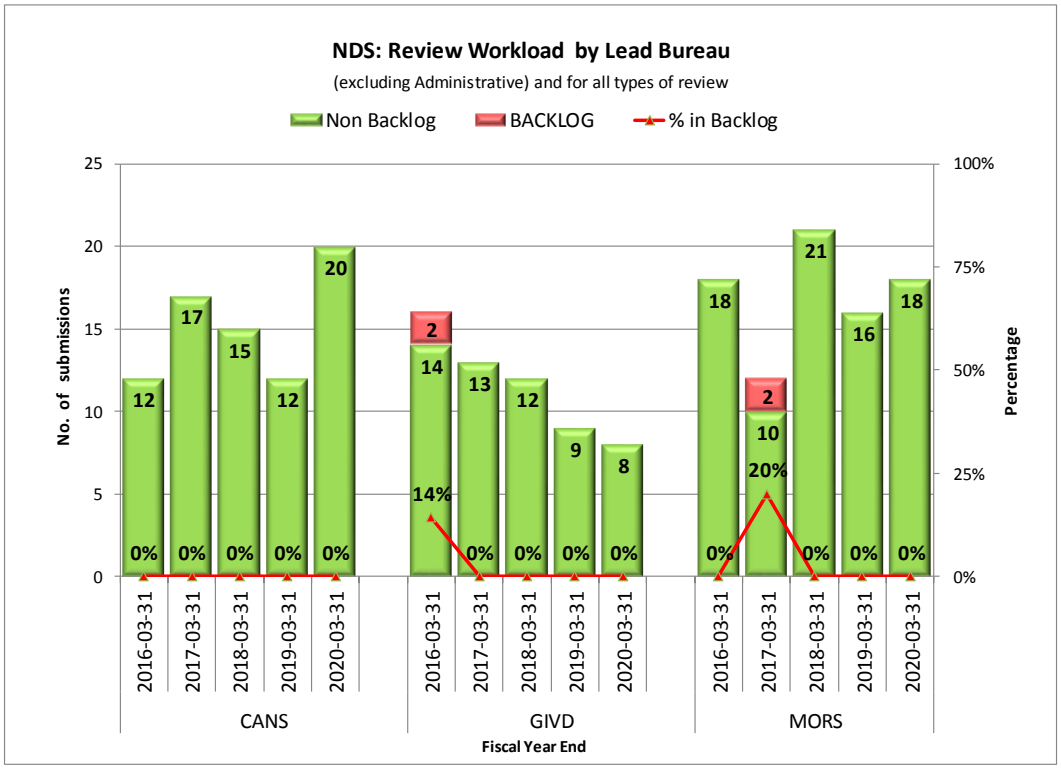
PDC - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)					
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Total Received	0	0	0	0	0

APPENDIX A - Lead Bureau Summaries

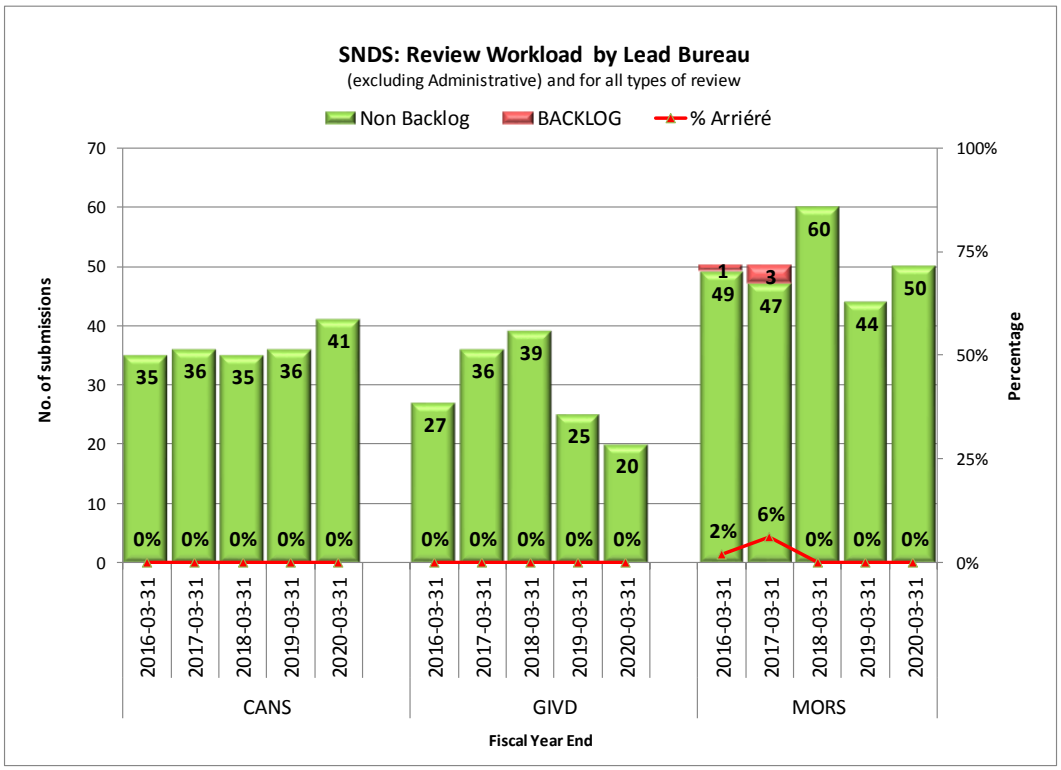
NDS & SNDS

WORKLOAD by Lead Bureau

NDS: Review Workload by Lead Bureau

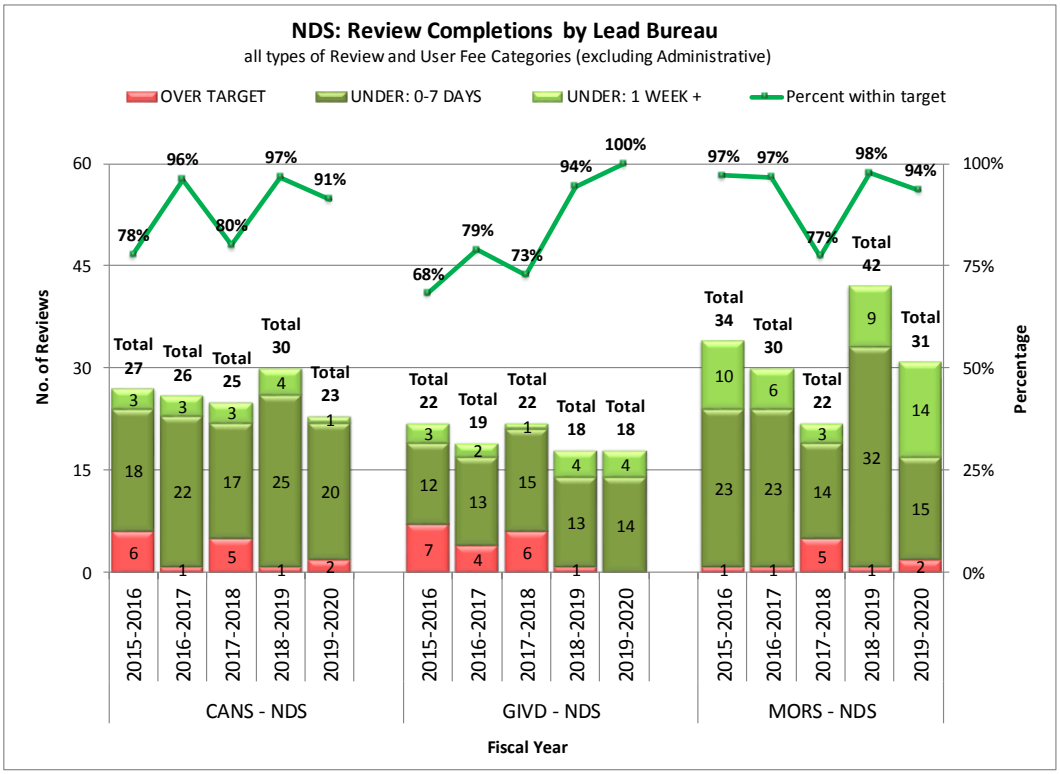


SNDS: Review Workload by Lead Bureau

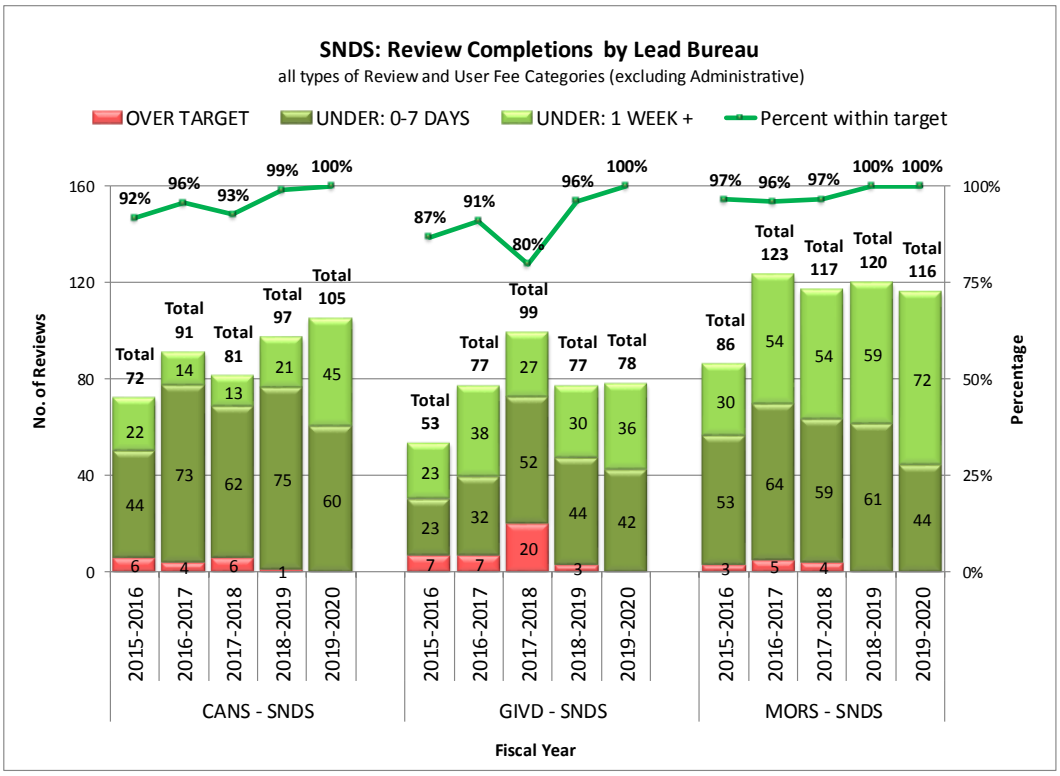


PERFORMANCE by Lead Bureau

NDS: Review Performance by Lead Bureau

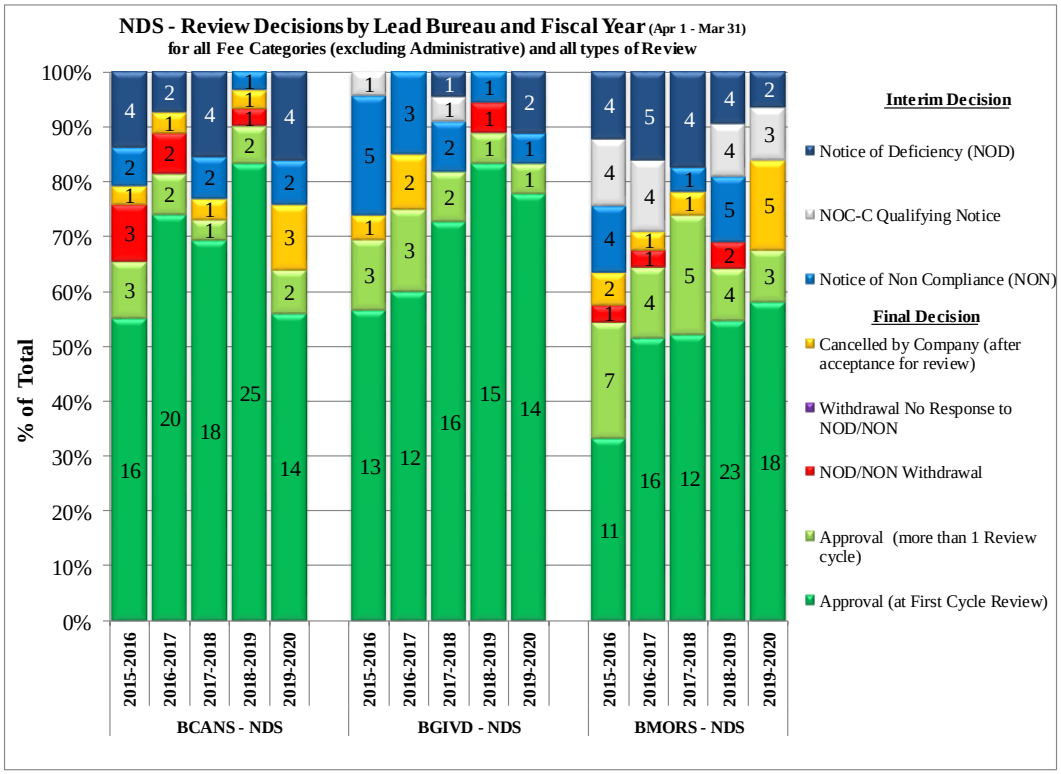


SNDS: Review Performance by Lead Bureau

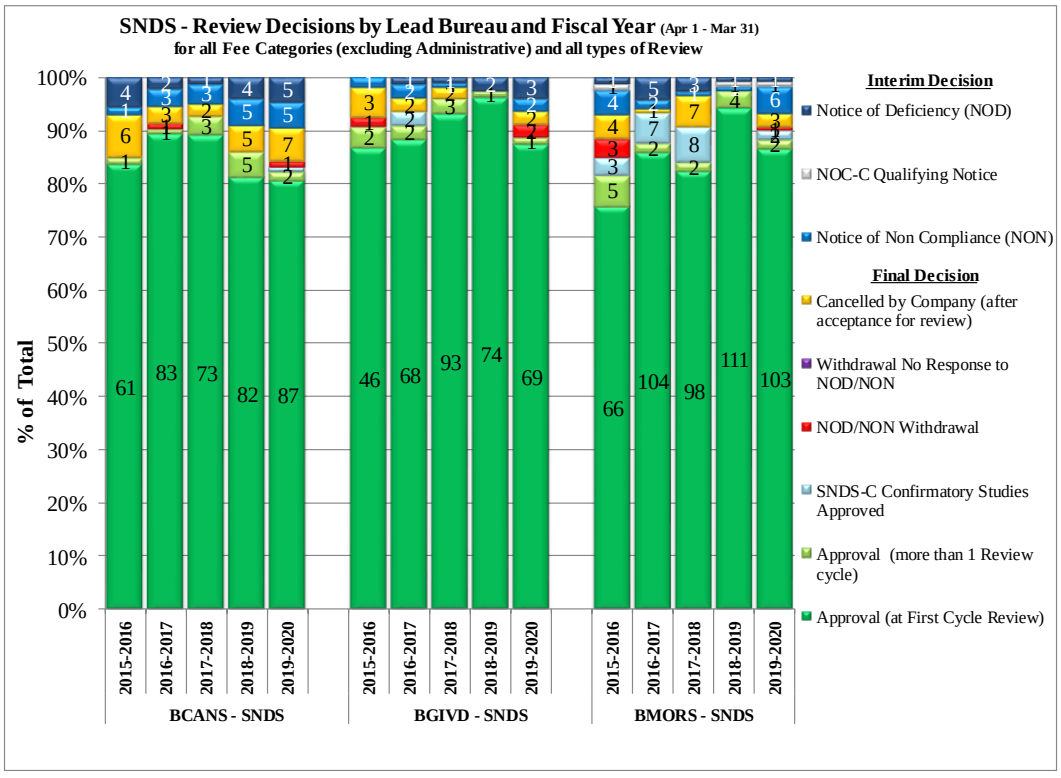


REVIEW DECISIONS by Lead Bureau

NDS: Review Decisions by Lead Bureau

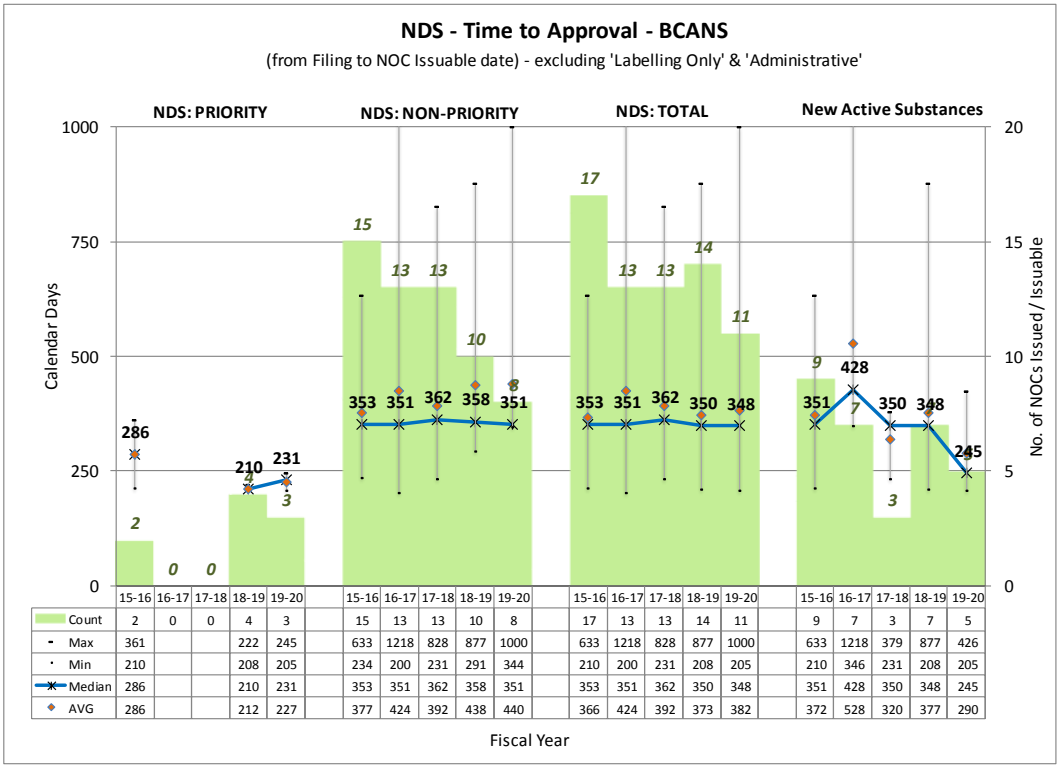


SNDS: Review Decisions by Lead Bureau



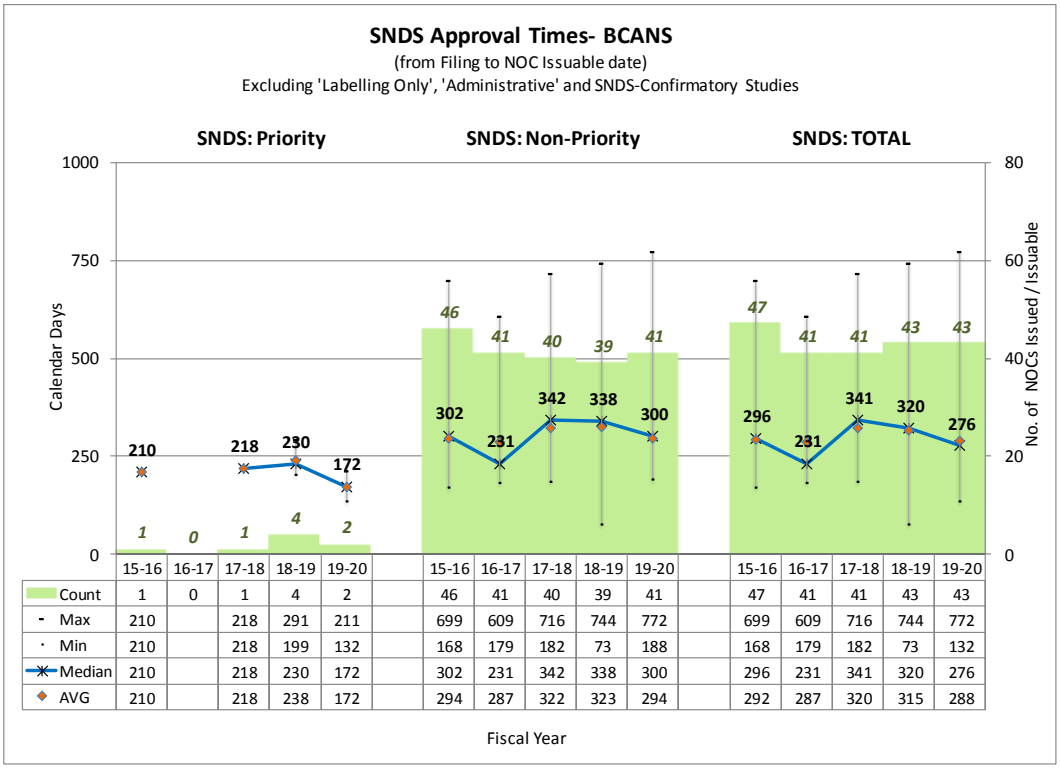
APPROVALS: Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)

NDS Time to Approval: BCANS



	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	2	0	0	4	3	15	13	13	10	8	17	13	13	14	11	9	7	3	7	5
Max	361			222	245	633	1218	828	877	1000	633	1218	828	877	1000	633	1218	379	877	426
Min	210			208	205	234	200	231	291	344	210	200	231	208	205	210	346	231	208	205
Median	286			210	231	353	351	362	358	351	353	351	362	350	348	351	428	350	348	245
AVG	286			212	227	377	424	392	438	440	366	424	392	373	382	372	528	320	377	290

SNDS Time to Approval: BCANS

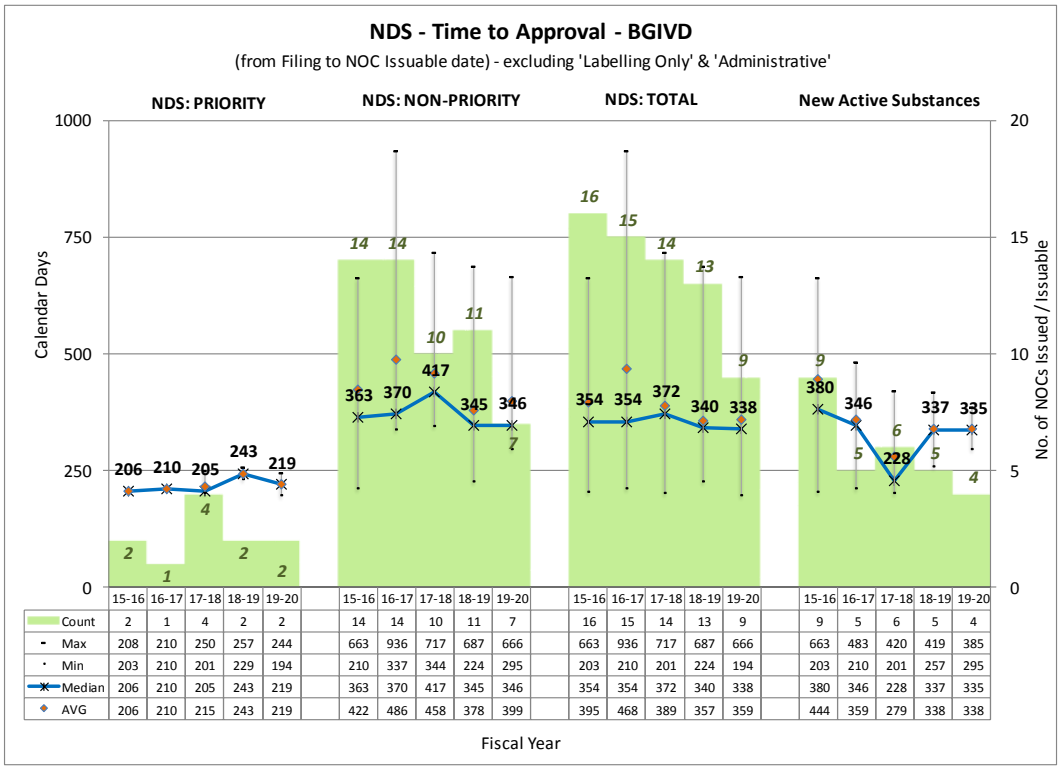


	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	1	0	1	4	2	46	41	40	39	41	47	41	41	43	43
Max	210		218	291	211	699	609	716	744	772	699	609	716	744	772
Min	210		218	199	132	168	179	182	73	188	168	179	182	73	132
Median	210		218	230	172	302	231	342	338	300	296	231	341	320	276
AVG	210		218	238	172	294	287	322	323	294	292	287	320	315	288

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.

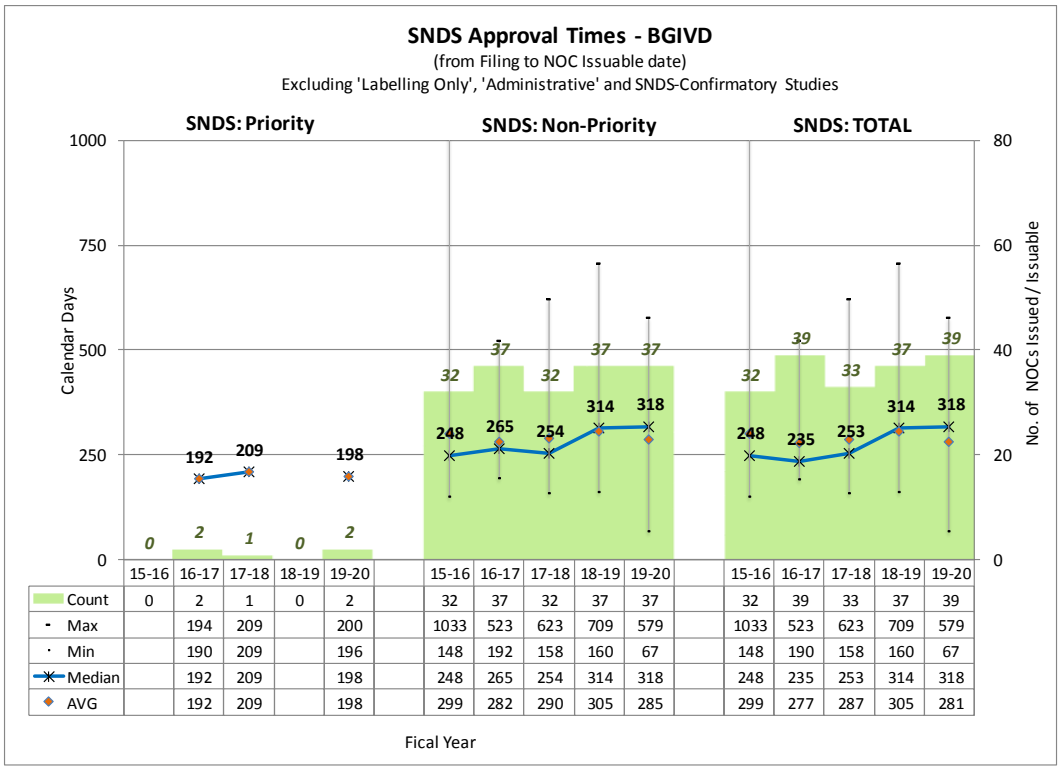
APPROVALS: Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)

NDS Time to Approval: BGIVD



	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	2	1	4	2	2	14	14	10	11	7	16	15	14	13	9	9	5	6	5	4
Max	208	210	250	257	244	663	936	717	687	666	663	936	717	687	666	663	483	420	419	385
Min	203	210	201	229	194	210	337	344	224	295	203	210	201	224	194	203	210	201	257	295
Median	206	210	205	243	219	363	370	417	345	346	354	354	372	340	338	380	346	228	337	335
AVG	206	210	215	243	219	422	486	458	378	399	395	468	389	357	359	444	359	279	338	338

SNDS Time to Approval: BGIVD

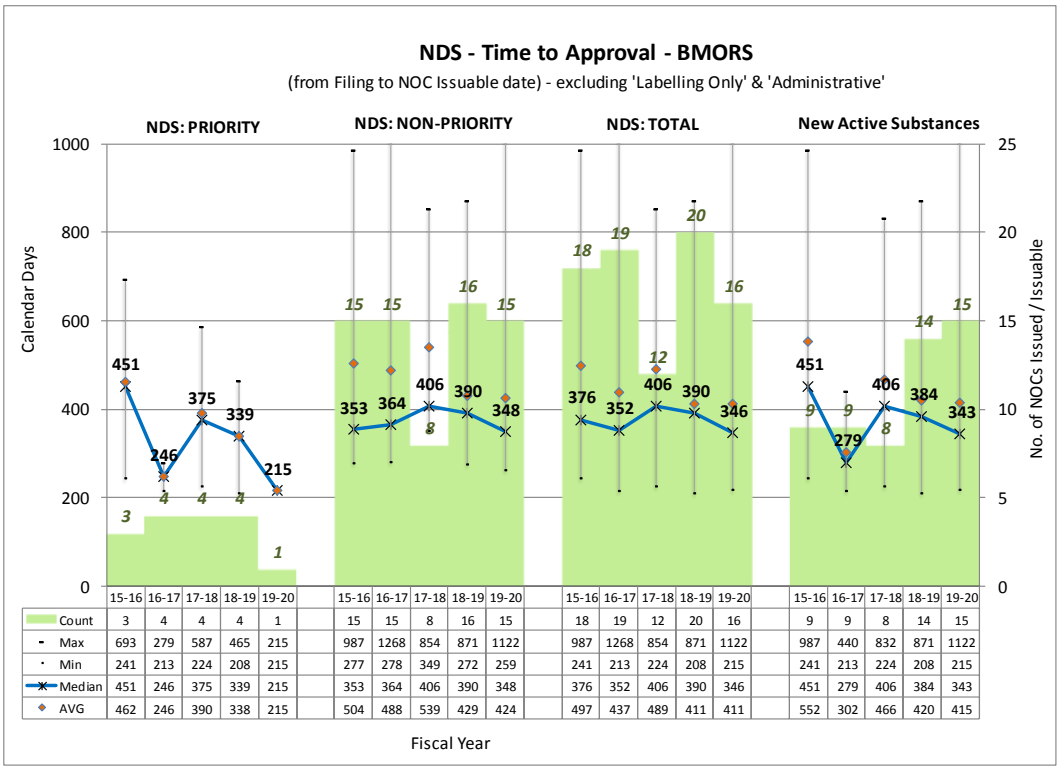


	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	0	2	1	0	2	32	37	32	37	37	32	39	33	37	39
Max		194	209		200	1033	523	623	709	579	1033	523	623	709	579
Min		190	209		196	148	192	158	160	67	148	190	158	160	67
Median		192	209		198	248	265	254	314	318	248	235	253	314	318
AVG		192	209		198	299	282	290	305	285	299	277	287	305	281

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.

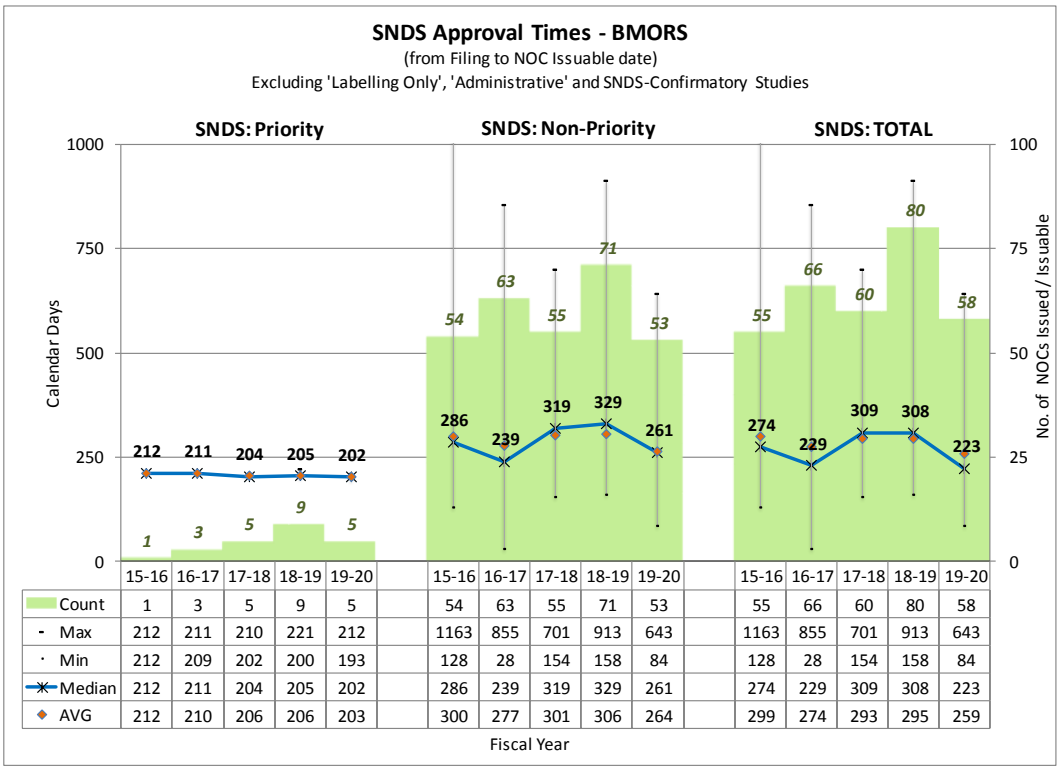
APPROVALS - Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)

NDS Time to Approval: BMORS



	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	3	4	4	4	1	15	15	8	16	15	18	19	12	20	16	9	9	8	14	15
Max	693	279	587	465	215	987	1268	854	871	1122	987	1268	854	871	1122	987	440	832	871	1122
Min	241	213	224	208	215	277	278	349	272	259	241	213	224	208	215	241	213	224	208	215
Median	451	246	375	339	215	353	364	406	390	348	376	352	406	390	346	451	279	406	384	343
AVG	462	246	390	338	215	504	488	539	429	424	497	437	489	411	411	552	302	466	420	415

SNDS Time to Approval: BMORS



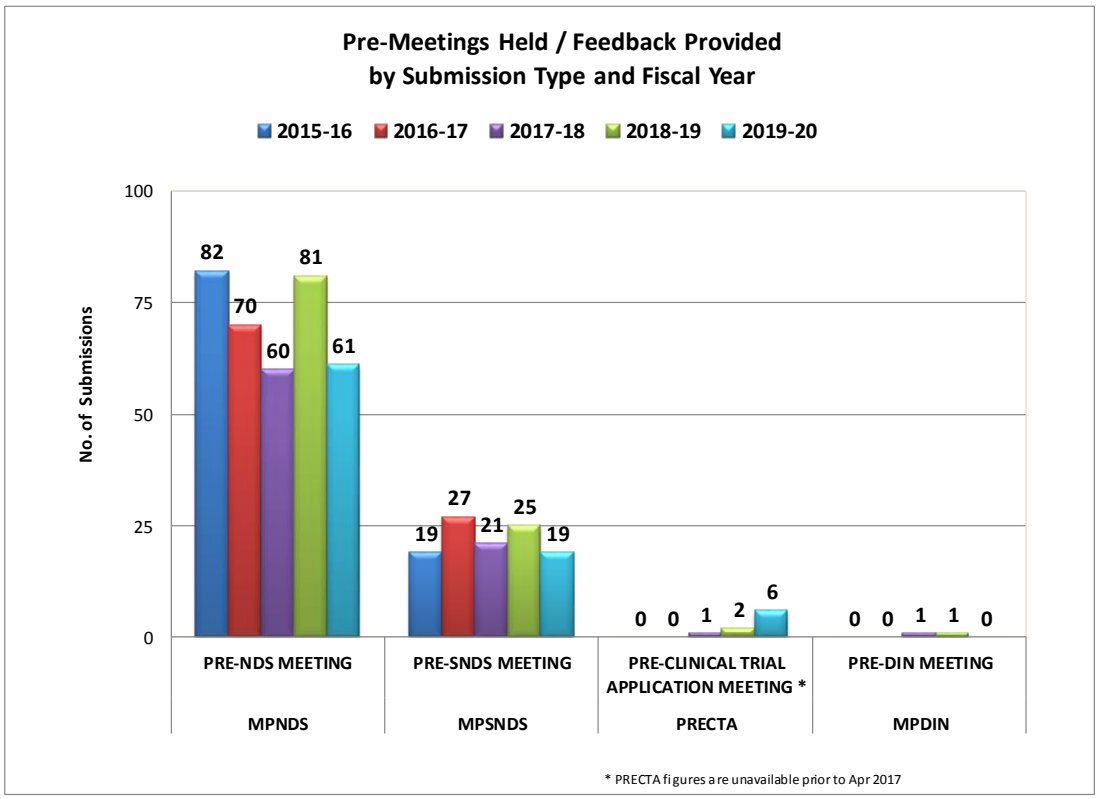
	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20	15-16	16-17	17-18	18-19	19-20
Count	1	3	5	9	5	54	63	55	71	53	55	66	60	80	58
Max	212	211	210	221	212	1163	855	701	913	643	1163	855	701	913	643
Min	212	209	202	200	193	128	28	154	158	84	128	28	154	158	84
Median	212	211	204	205	202	286	239	319	329	261	274	229	309	308	223
AVG	212	210	206	206	203	300	277	301	306	264	299	274	293	295	259

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



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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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