Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Annual Report

Fiscal Year 2020-2021

April 1 2020 - March 31 2021

Canada

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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, Ontario K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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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 2016-2017 to 2020-2021.

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 2020-2021 fiscal year (from April 1 2020 to March 31 2021).

Several significant events occurred during the spring of 2020 including the COVID-19 Pandemic and the implementation of revised fees in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124).*

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately, in 2019, HPFB had implemented new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format. 1 This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.

- An Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was approved and on August 13, 2020 the Minister of Health approved an order to temporarily extend the default period to review clinical trial applications and amendments from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. The number of CTA and CTAAs received under orders are included in this report.

- The Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report.

- There was a significant increase in the volume of Drug Identification Number Applications for Disinfectant products (DIND) received (see the Annual Drug Submission Performance Report for the Natural and Non-Prescription Health Products Directorate (NNHPD)).

- On April 1, 2020, revised fees were implemented in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*. In addition, submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as an NC).

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.

Authorization means an authorization issued under section 5 of the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD Interim Order).

[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.

Performance for all submissions or applications filed after April 1, 2020 is tracked individually.

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

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

Office of Submissions and Intellectual Property
Resource Management and Operations Directorate
Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: hc.osip-bppi.sc@canada.ca

[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
COV19	-	Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
COV19A	-	Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
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
IO_NOA	-	Notice of Authorization
IO-NOA_TC	-	Notice of Authorization with Terms and 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 biosimilar biologic drug 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.
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance.
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.

[6] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling.

Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment.
Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug.
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.

[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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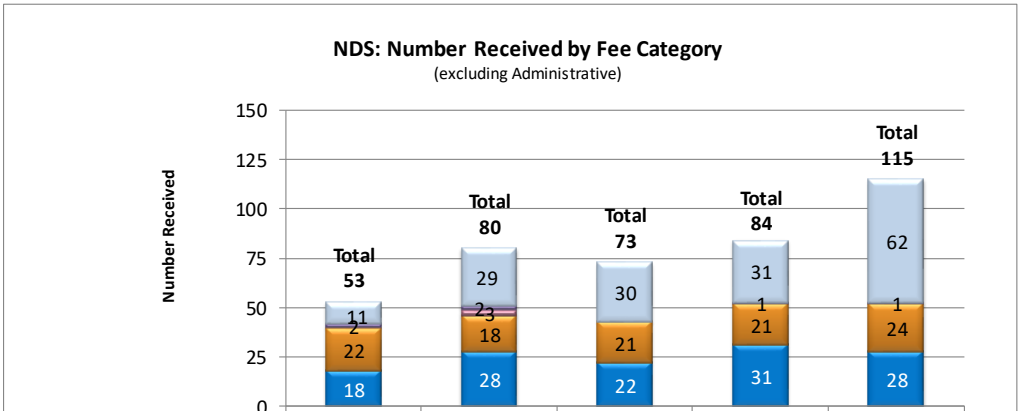
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)

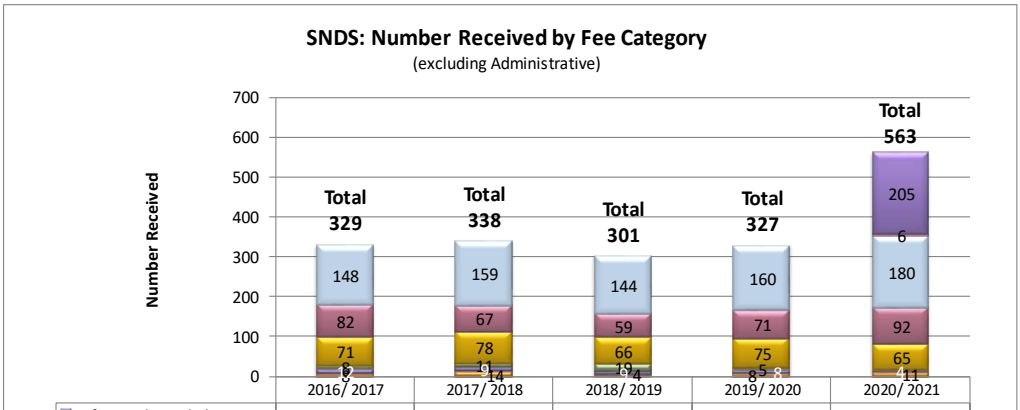
SUBMISSIONS RECEIVED [9]

NDS: Number Received by Fee Category



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Labelling Only	11	29	30	31	62
Comparative Studies	2	2	0	1	1
Chemistry & Manufacturing	0	3	0	0	0
Clinical or Non-Clin and C&M	22	18	21	21	24
New Active Substance	18	28	22	31	28
Total	53	80	73	84	115
Priority (subset)	5	10	6	12	11
NOC/c Class	1	2	4	1	6
Emergency Use (NDS)	0	0	0	0	1

SNDS: Number Received by Fee Category

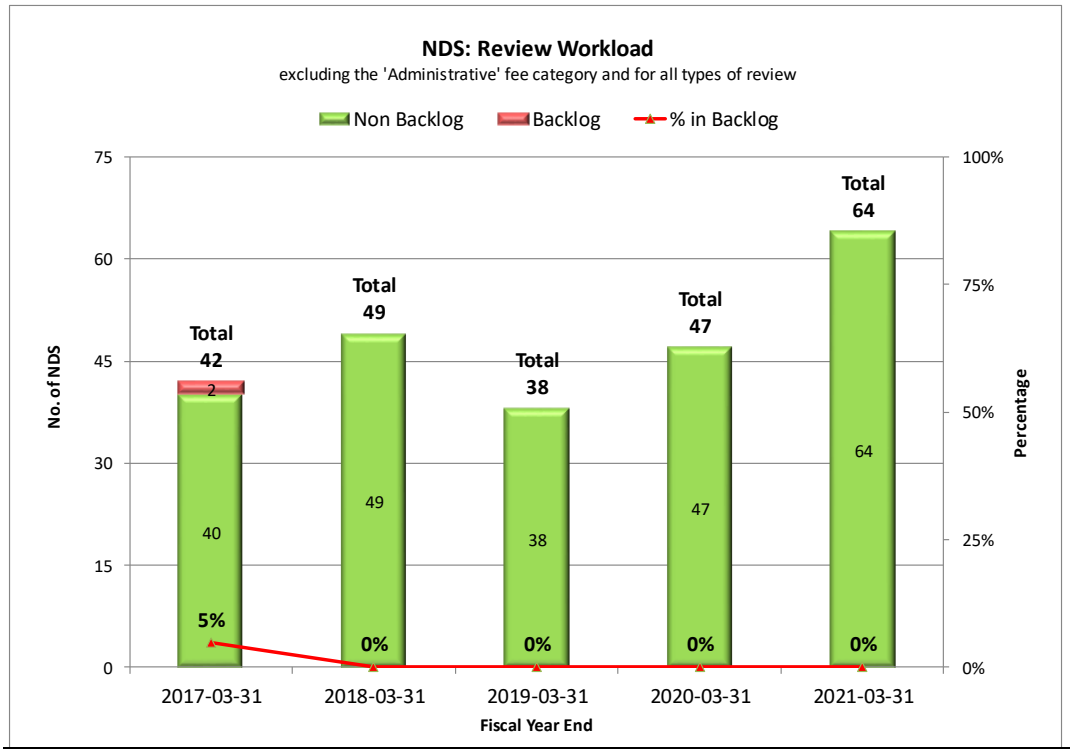


	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Safety Update Label	0	0	0	0	205
Label Update Generic	0	0	0	0	6
Labelling Only	148	159	144	160	180
Chemistry & Manufacturing	82	67	59	71	92
Clinical or Non-Clin Only	71	78	66	75	65
Published Data Only	8	11	19	5	0
Comparative Studies	12	9	9	8	4
Clinical or Non-Clin and C&M	8	14	4	8	11
Total	329	338	301	327	563
Priority (subset)	5	9	9	12	3
NOC/c Class	0	2	0	0	0
SNDS Confirmatory	9	3	3	1	2

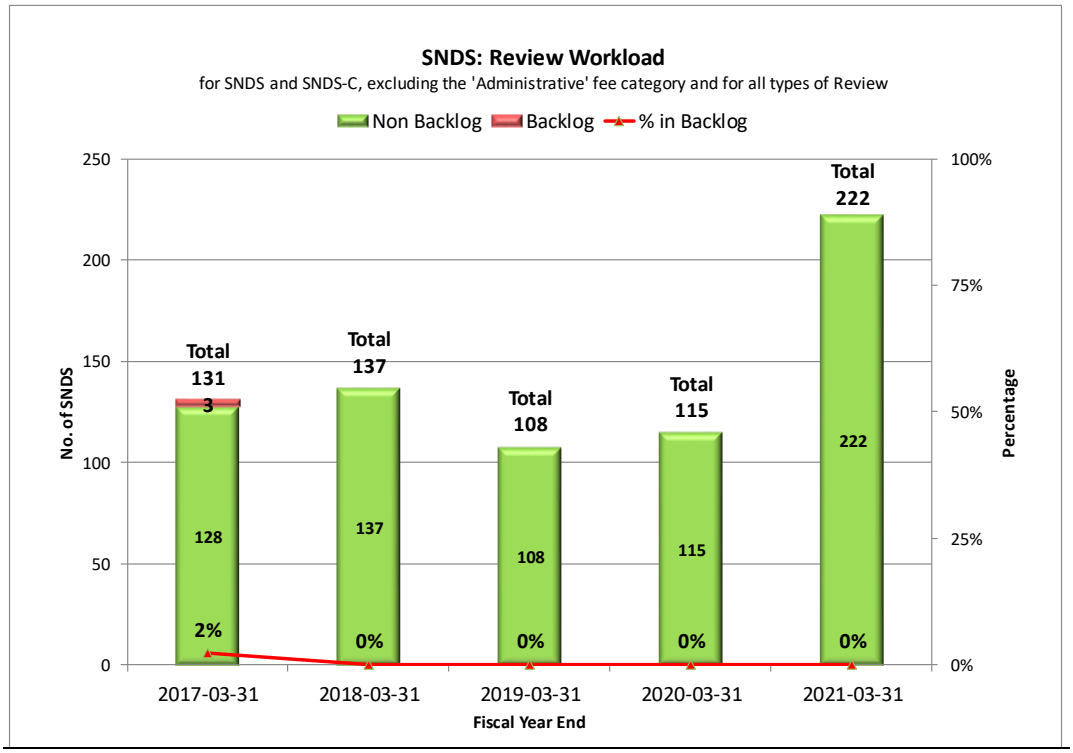
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions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

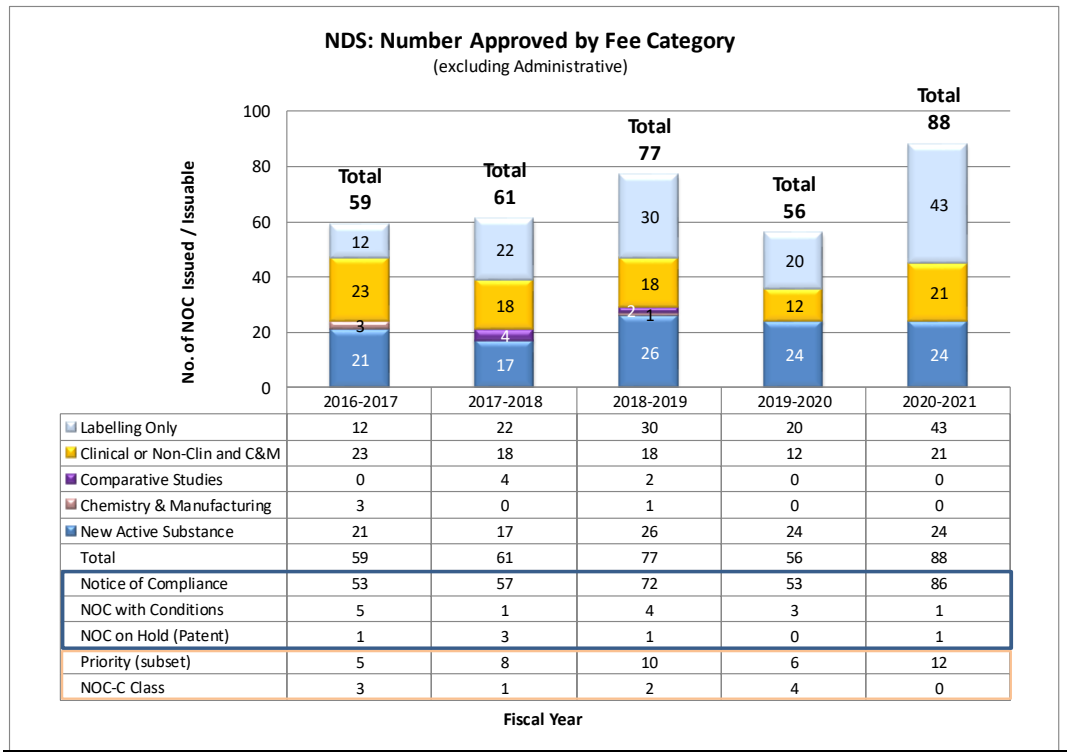
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Labelling Only	1	4	4	4	17
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	3	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	19	18	15	24	22
Backlog	*1*	*0*	*0*	*0*	*0*
New Active Substance	19	25	19	19	25
Backlog	*1*	*0*	*0*	*0*	*0*
Total	**42**	**49**	**38**	**47**	**64**
Non Backlog	**40**	**49**	**38**	**47**	**64**
Backlog	**2**	**0**	**0**	**0**	**0**
% in Backlog	**5%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	6	6	3	8	6
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	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Labelling Only	22	19	10	24	49
Backlog	*1*	*0*	*0*	*0*	*0*
Comparative Studies	7	4	7	5	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	34	30	29	26	47
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	53	63	53	49	53
Backlog	*2*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	8	11	1	8	9
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	7	10	8	3	0
Backlog	0	0	0	0	0
Label Update Generic	0	0	0	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	61
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**131**	**137**	**108**	**115**	**222**
Non Backlog	**128**	**137**	**108**	**115**	**222**
Backlog	**3**	**0**	**0**	**0**	**0**
% in Backlog	**2%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	4	7	4	5	2
Backlog	0	0	0	0	0
*SNDS-C (Confirmatory)	6	3	2	1	1
Backlog	0	0	0	0	0

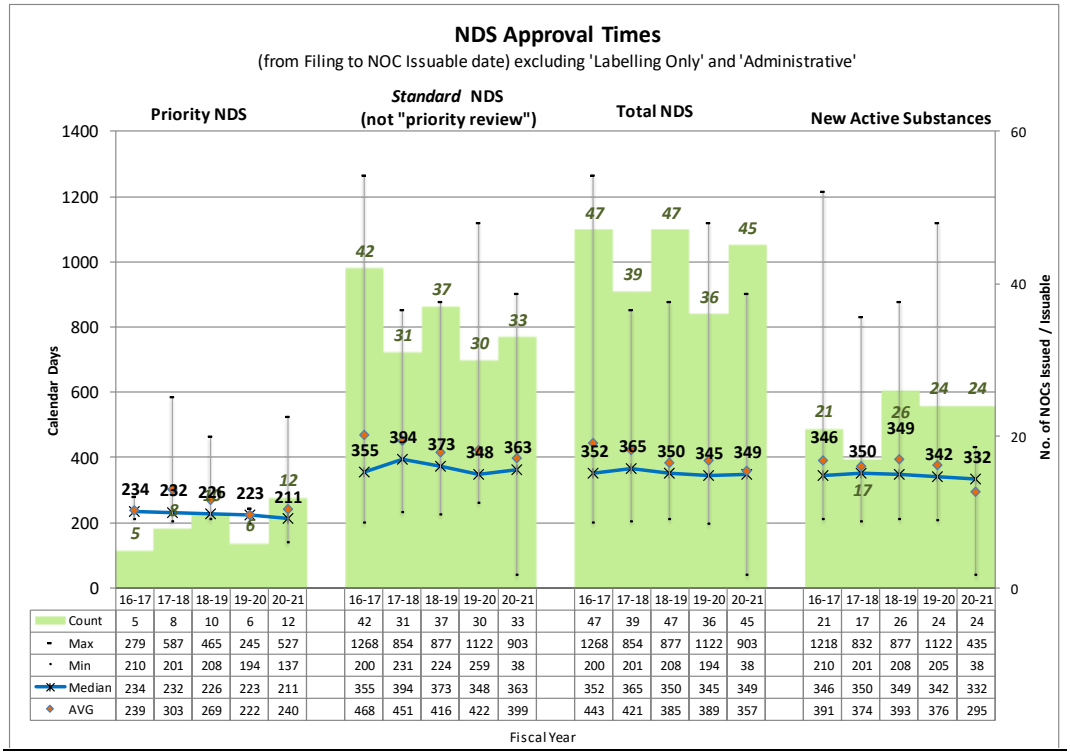
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Labelling Only	12	22	30	20	43
Clinical or Non-Clin and C&M	23	18	18	12	21
Comparative Studies	0	4	2	0	0
Chemistry & Manufacturing	3	0	1	0	0
New Active Substance	21	17	26	24	24
Total	59	61	77	56	88
Notice of Compliance	53	57	72	53	86
NOC with Conditions	5	1	4	3	1
NOC on Hold (Patent)	1	3	1	0	1
Priority (subset)	5	8	10	6	12
NOC-C Class	3	1	2	4	0

NDS Approval Times

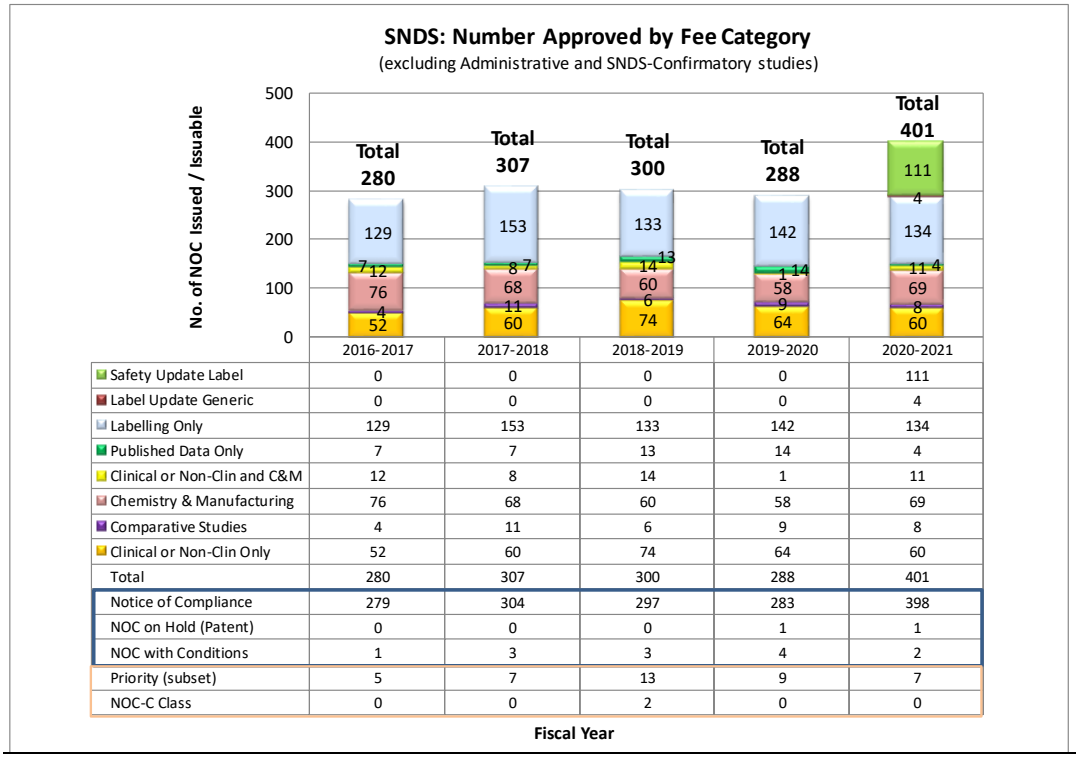


	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	5	8	10	6	12	42	31	37	30	33	47	39	47	36	45	21	17	26	24	24
Max	279	587	465	245	527	1268	854	877	1122	903	1268	854	877	1122	903	1218	832	877	1122	435
Min	210	201	208	194	137	200	231	224	259	38	200	201	208	194	38	210	201	208	205	38
Median	234	232	226	223	211	355	394	373	348	363	352	365	350	345	349	346	350	349	342	332
AVG	239	303	269	222	240	468	451	416	422	399	443	421	385	389	357	391	374	393	376	295

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

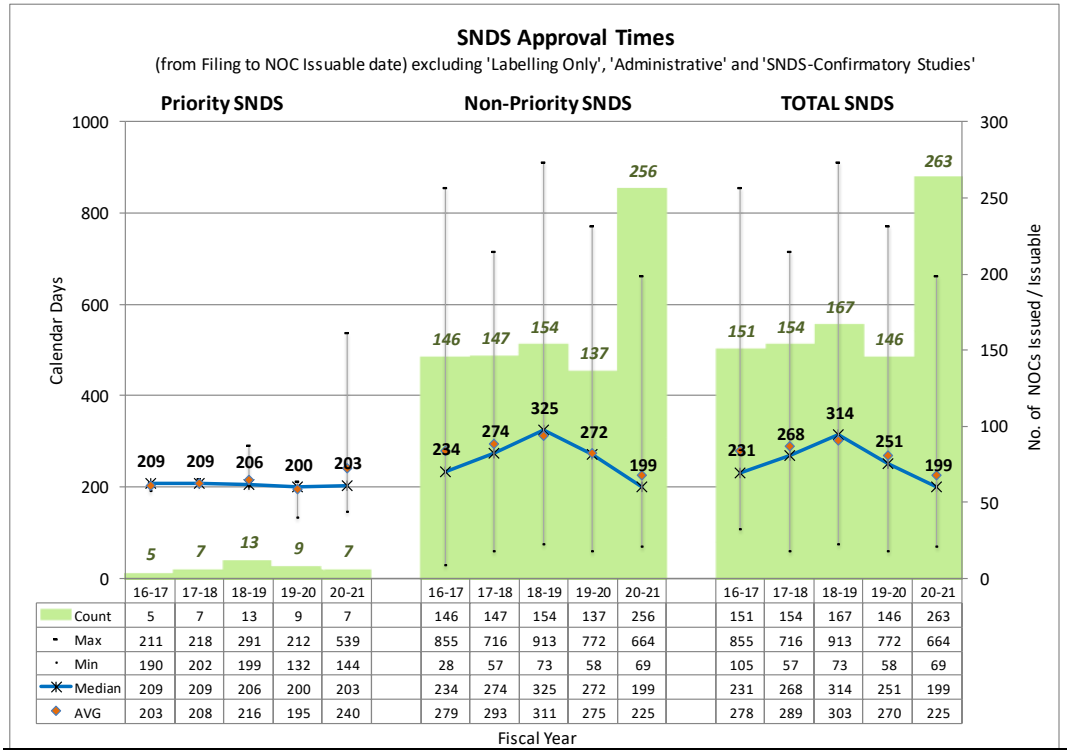
APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Safety Update Label	0	0	0	0	111
Label Update Generic	0	0	0	0	4
Labelling Only	129	153	133	142	134
Published Data Only	7	7	13	14	4
Clinical or Non-Clin and C&M	12	8	14	1	11
Chemistry & Manufacturing	76	68	60	58	69
Comparative Studies	4	11	6	9	8
Clinical or Non-Clin Only	52	60	74	64	60
Total	280	307	300	288	401
Notice of Compliance	279	304	297	283	398
NOC on Hold (Patent)	0	0	0	1	1
NOC with Conditions	1	3	3	4	2
Priority (subset)	5	7	13	9	7
NOC-C Class	0	0	2	0	0

SNDS Approval Times



	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	5	7	13	9	7	146	147	154	137	256	151	154	167	146	263
Max	211	218	291	212	539	855	716	913	772	664	855	716	913	772	664
Min	190	202	199	132	144	28	57	73	58	69	105	57	73	58	69
Median	209	209	206	200	203	234	274	325	272	199	231	268	314	251	199
AVG	203	208	216	195	240	279	293	311	275	225	278	289	303	270	225

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 2020-2021

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
BRAFTOVI (ENCORAFENIB) BRAFTOVI is used with a drug called binimetinib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body, or cannot be removed by surgery. BRAFTOVI is also used with a drug called cetuximab to treat adults with a type of large intestine cancer called metastatic colorectal cancer (mCRC). This type of intestine cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body and has already been treated with other cancer drugs	NAS	Pfizer Canada ULC	20-Mar-20	2-Mar-21
BRUKINSA (ZANUBRUTINIB) BRUKINSA is used in adults to treat patients with a kind of cancer called Waldenström's Macroglobulinemia (WM).	PRIORITY-NAS	Beigene Switzerland Gmbh	12-Aug-20	1-Mar-21
CORZYNA (RANOLAZINE) Corzyna is a medicine used to treat chest pain (stable angina) in adults. It is used along with other medicines in patients who cannot tolerate other antianginal therapies or for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers).	PRIORITY-NAS	KYE Pharmaceuticals Inc.	27-May-20	31-Dec-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 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
DAURISMO (GLASDEGIB as Glasdegib Maleate) Daurismo is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed and previously untreated acute myeloid leukemia (AML) in adult patients who are age ≥75 years or who are not eligible to receive intensive induction chemotherapy.	NAS	Pfizer Canada ULC	15-Mar-19	28-Apr-20
DAYVIGO (LEMBOREXANT) Dayvigo is used in adults who have trouble falling asleep and/or staying asleep (insomnia). Dayvigo is not for use in children under the age of 18 years.	NAS	Eisai Limited	3-Sep-19	4-Nov-20
DOJOLVI (TRIHEPTANOIN) Dojolvi is indicated as a source of calories and fatty acids for the treatment of adult and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).	PRIORITY-NAS	Ultragenyx Pharmaceutical Inc.	28-Jul-20	15-Feb-21
FIRDAPSE (AMIFAMPRIDINE (as Amifampridine Phosphate) Firdapse is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	PRIORITY-NAS	KYE Pharmaceuticals Inc.	6-Nov-19	31-Jul-20
GIVLAARI (GIVOSIRAN as Givosiran Sodium) Givlaari is used to treat acute hepatic porphyria in adults.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-Mar-20	9-Oct-20
IBSRELA (TENAPANOR as Tenapanor Hydrochloride) Ibsrela is used in adults (18 years of age and older) to treat a condition called irritable bowel syndrome with constipation (IBS-C).	NAS	Knight Therapeutics Inc.	26-Feb-19	15-Apr-20

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
INQOVI (CEDAZURIDINE, DECITABINE) Inqovi is used to treat adults with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). In MDS and CMML, the bone marrow does not make enough healthy mature blood cells. MDS and CMML are types of cancer.	NAS	Otsuka Pharmaceutical Co. Ltd.	31-Dec-19	7-Jul-20
INREBIC (FEDRATINIB as Fedratinib Hydrochloride) Inrebic is a prescription medicine. It is used to treat adults with an enlarged spleen and/or the associated symptoms caused by certain types of myelofibrosis. Myelofibrosis is a rare form of blood cancer.	NAS	Celgene Inc.	19-Jul-19	27-Jul-20
MAR-TRIENTINE (TRIENTINE HYDROCHLORIDE) MAR-Trientine is used for the treatment of Wilson's disease. It is used in patients who cannot take the drug penicillamine.	NAS	Marcan Pharmaceuticals Inc.	7-Aug-19	14-Sep-20
MEKTOVI (BINIMETINIB) MEKTOVI is used with a drug called encorafenib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body, or cannot be removed by surgery.	NAS	Pfizer Canada ULC	20-Mar-20	2-Mar-21
NEXTSTELLIS (DROSPIRENONE, ESTETROL MONOHYDRATE) Nextstellis is indicated to prevent pregnancy.	NAS	Searchlight Pharma Inc.	18-Feb-20	5-Mar-21

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
ODOMZO (SONIDEGIB (as Sonidegib Phosphate) Odomzo is used to treat adults with a type of skin cancer, called basal cell carcinoma. It is used when the cancer has spread to surrounding areas (called "locally advanced" basal cell carcinoma (BCC)) and it cannot be treated with surgery or radiation.	NAS	Sun Pharma Global FZE	4-Jul-19	12-Jun-20
QINLOCK (RIPRETINIB) Qinlock is used to treat adults with gastrointestinal stromal tumor (GIST), which is a type of soft tissue cancer (sarcoma). The cancer must have been treated before with other cancer drugs for GIST including imatinib, sunitinib, and regorafenib.	PRIORITY-NAS	Deciphera Pharmaceuticals. LLC	23-Dec-19	19-Jun-20
RUZURGI (AMIFAMPRIDINE) Ruzurgi is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older. It is not known if Ruzurgi works or is safe in children less than 6 years old.	PRIORITY-NAS	Medunik Canada	20-Dec-19	10-Aug-20
TAVALISSE (FOSTAMATINIB (as Fostamatinib Disodium) Tavalisse is used to treat adults with a bleeding disorder known as chronic immune thrombocytopenia when other treatments have not worked well enough.	NAS	Rigel Pharmaceuticals Inc.	30-Sep-19	19-Nov-20
TISSUEBLUE (BRILLIANT BLUE G) TISSUEBLUE is used as an aid in eye surgery. It is used to stain a part of your eye called the internal limiting membrane (ILM).	NAS	Dutch Ophthalmic Research Center International BV	7-Nov-19	15-Jan-21

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
TOMVI (ETOMIDATE) Tomvi is an anesthetic that is used in adults: • to help make you asleep (unconscious) for a surgery or other medical procedure. • with other anesthetics to help keep you asleep for a short surgery.	NAS	Sterimax Inc.	30-Aug-19	15-Jul-20
TUKYSA (TUCATINIB) Tukysa is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that: • is positive for human epidermal growth factor receptor 2 (HER2 positive), • cannot be removed by surgery, • has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and • has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine.	PRIORITY-NAS	Seattle Genetics Inc.	20-Jan-20	5-Jun-20
VEKLURY (REMDESIVIR) Veklury is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen.	NAS	Gilead Sciences Canada Inc.	19-Jun-20	27-Jul-20 NOC-C

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
XENLETA (LEFAMULIN as Lefamulin Acetate) Xenleta is used: • In adults • To treat an infection of the lungs called Community-acquired pneumonia (CAP) • CAP develops in adults with limited or no contact with hospitals or healthcare centers • Adults with CAP get infected in a community setting • Antibacterial drugs like Xenleta treat only bacterial infections. They do not treat viral infections.	PRIORITY-NAS	Sunovion Pharmaceuticals Canada Inc.	7-Nov-19	10-Jul-20
ZEPOSIA (OZANIMOD as Ozanimod Hydrochloride) Zeposia is used to treat adult patients with the relapsing and remitting form of multiple sclerosis (RRMS). Zeposia is not authorized for use in children.	NAS	Celgene Inc.	25-Oct-19	2-Oct-20

Priority Submission Approvals - TPD - Fiscal Year 2020-2021

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
BRUKINSA (ZANUBRUTINIB) BRUKINSA is used in adults to treat patients with a kind of cancer called Waldenström's Macroglobulinemia (WM).	PRIORITY-NAS	Beigene Switzerland Gmbh	12-Aug-20	1-Mar-21
CARBAGLU (CARGLUMIC ACID) NEW INDICATIONS: **Acute hyperammonemia due to Propionic Acidemia (PA):** CARBAGLU is indicated, in pediatric and adult patients, for the treatment of acute hyperammonemic episodes due to propionic acidemia (PA), as an adjunctive treatment to other ammonia lowering therapies. **Acute hyperammonemia due to Methylmalonic Acidemia (MMA)**: CARBAGLU is indicated, in pediatric and adult patients, for the treatment of acute hyperammonemic episodes due to methylmalonic acidemia (MMA), as an adjunctive treatment to other ammonia lowering therapies.	PRIORITY-CLIN ONLY	Recordati Rare Diseases	17-May-19	6-Nov-20
CORZYNA (RANOLAZINE) Corzyna is a medicine used to treat chest pain (stable angina) in adults. It is used along with other medicines in patients who cannot tolerate other antianginal therapies or for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers).	PRIORITY-NAS	KYE Pharmaceuticals Inc.	27-May-20	31-Dec-20

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
DOJOLVI (TRIHEPTANOIN) Dojolvi is indicated as a source of calories and fatty acids for the treatment of adult and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).	PRIORITY-NAS	Ultragenyx Pharmaceutical Inc.	28-Jul-20	15-Feb-21
FIRDAPSE (AMIFAMPRIDINE (as Amifampridine Phosphate) Firdapse is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	PRIORITY-NAS	KYE Pharmaceuticals Inc.	6-Nov-19	31-Jul-20
FORXIGA (DAPAGLIFLOZIN as Dapagliflozin Propanediol Monohydrate) **Heart Failure** FORXIGA can be used in adults along with other heart failure medicines when your heart is unable to pump blood as well as normal to: • reduce your risk of cardiovascular death, • reduce your risk of hospitalization or urgent visits for heart failure.	PRIORITY-CLIN ONLY	Astrazeneca Canada Inc.	10-Dec-19	30-Jun-20
GIVLAARI (GIVOSIRAN as Givosiran Sodium) Givlaari is used to treat acute hepatic porphyria in adults.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-Mar-20	9-Oct-20
GLEOLAN (AMINOLEVULINIC ACID HYDROCHLORIDE) Gleolan is used to help visualize certain brain tumours (called malignant glioma) during tumour surgery.	PRIORITY-CLIN/C&M	Medexus Inc.	23-Dec-19	9-Sep-20

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
LYNPARZA (OLAPARIB) NEW INDICATION: Prostate Cancer Lynparza is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA or ATM mutated metastatic castrationresistant Prostate Cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent. BRCA or ATM mutations must be confirmed before LYNPARZA treatment is initiated.	PRIORITY-CLIN ONLY	Astrazeneca Canada Inc.	31-Jan-20	21-Aug-20
OFEV (NINTEDANIB as Nintedanib Esilate) Use OFEV to treat adults with: • Interstitial Lung Diseases (ILDs) where lung fibrosis continues to worsen (progress). May also be know as progressive fibrosing ILD (PF-ILD).	PRIORITY-CLIN ONLY	Boehringer Ingelheim (Canada) Ltd Ltee	28-Oct-19	20-May-20
ONUREG (AZACITIDINE) Onureg is a nucleoside metabolic inhibitor indicated for: • maintenance therapy in adult patients with acute myeloid leukemia (AML) who achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy with or without consolidation treatment, and who are not eligible for hematopoietic stem cell transplantation (HSCT).	PRIORITY-CLIN/C&M	Celgene Inc.	15-Jun-20	5-Jan-21

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
QINLOCK (RIPRETINIB) Qinlock is used to treat adults with gastrointestinal stromal tumor (GIST), which is a type of soft tissue cancer (sarcoma). The cancer must have been treated before with other cancer drugs for GIST including imatinib, sunitinib, and regorafenib.	PRIORITY-NAS	Deciphera Pharmaceuticals. LLC	23-Dec-19	19-Jun-20
RUZURGI (AMIFAMPRIDINE) Ruzurgi is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older. It is not known if Ruzurgi works or is safe in children less than 6 years old.	PRIORITY-NAS	Medunik Canada	20-Dec-19	10-Aug-20

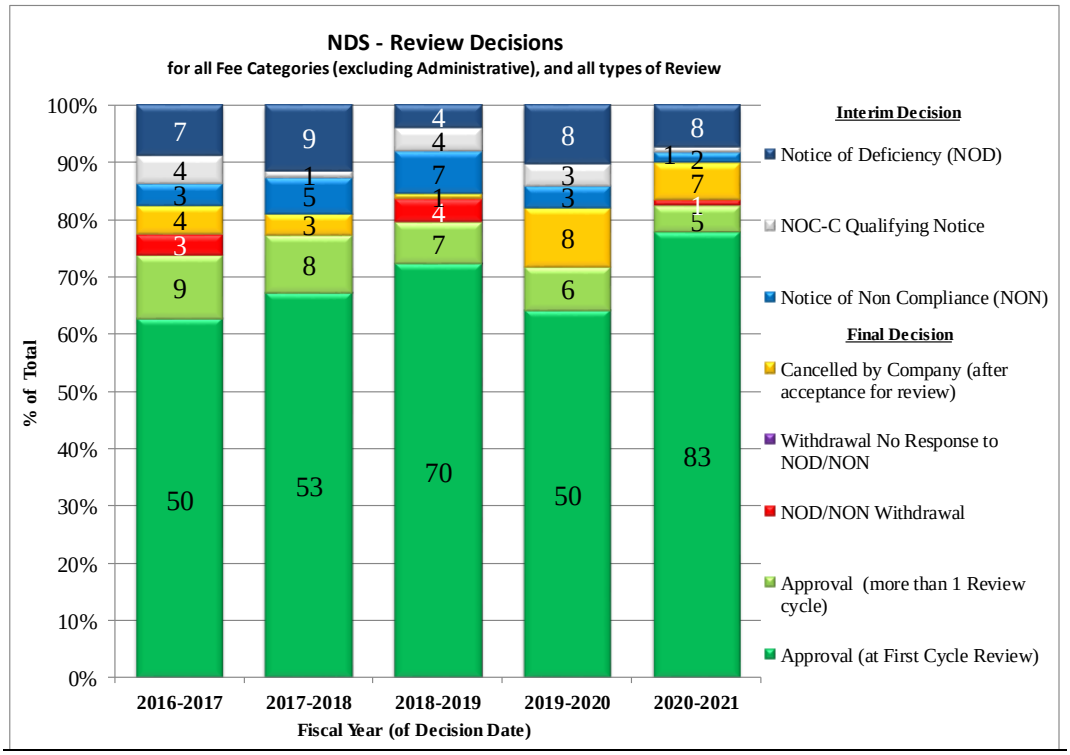
Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
SPRAVATO (ESKETAMINE as Esketamine Hydrochloride) Spravato is a nasal spray used to treat adults with major depressive disorder that: • is moderate to severe in intensity and • has not responded to two or more separate courses of treatment in the current episode of depression. Separate courses refers to previous treatment with different antidepressants, each given at adequate doses for an adequate amount of time. Spravato nasal spray is used together with an antidepressant taken by mouth that is either: • a selective serotonin reuptake inhibitor (SSRI) or • a serotonin and norepinephrine reuptake inhibitor (SNRI) Spravato is not for use in children or adolescents. If you are 65 years or older, talk to your doctor before starting Spravato. Spravato may not be an effective treatment for you and you may be more sensitive to experiencing side effects.	PRIORITY-CLIN/C&M	Janssen Inc.	10-Dec-18	20-May-20
TAGRISSO (OSIMERTINIB as Osimertinib Mesylate) is indicated as adjuvant therapy after tumour resection in patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.	PRIORITY-CLIN/C&M	Astrazeneca Canada Inc.	27-Aug-20	18-Jan-21

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
TUKYSA (TUCATINIB) Tukysa is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that: • is positive for human epidermal growth factor receptor 2 (HER2 positive), • cannot be removed by surgery, • has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and • has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine.	PRIORITY-NAS	Seattle Genetics Inc.	20-Jan-20	5-Jun-20
XENLETA (LEFAMULIN as Lefamulin Acetate) Xenleta is used: • In adults • To treat an infection of the lungs called Community-acquired pneumonia (CAP) • CAP develops in adults with limited or no contact with hospitals or healthcare centers • Adults with CAP get infected in a community setting • Antibacterial drugs like Xenleta treat only bacterial infections. They do not treat viral infections.	PRIORITY-NAS	Sunovion Pharmaceuticals Canada Inc.	7-Nov-19	10-Jul-20
XTANDI (ENZALUTAMIDE) NEW INDICATION: Xtandi is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).	PRIORITY-CLIN ONLY	Astellas Pharma Canada Inc.	18-Nov-19	2-Jun-20

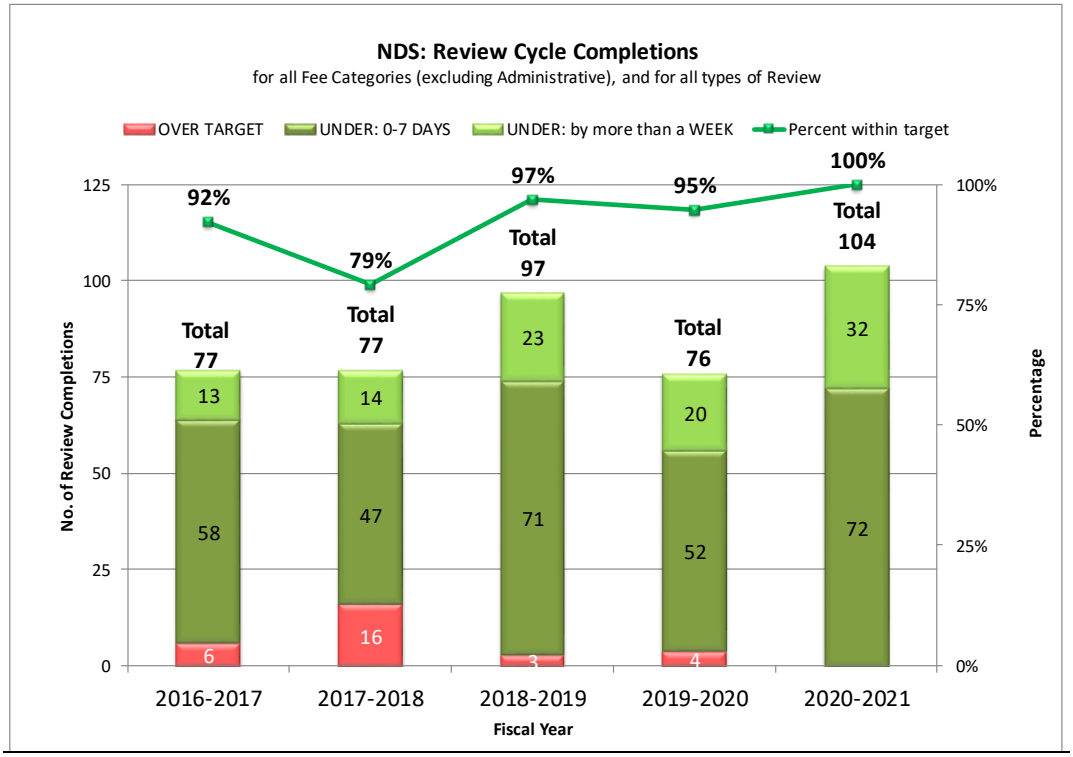
Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
ZEJULA (NIRAPARIB as Niraparib Tosylate) ZEJULA is used in adult women for the maintenance treatment of ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (the membrane that lines the inside of the abdomen).	PRIORITY-CLIN ONLY	GlaxoSmithKline Inc.	27-Mar-20	2-Oct-20

REVIEW PERFORMANCE

NDS: Review Decisions by Type

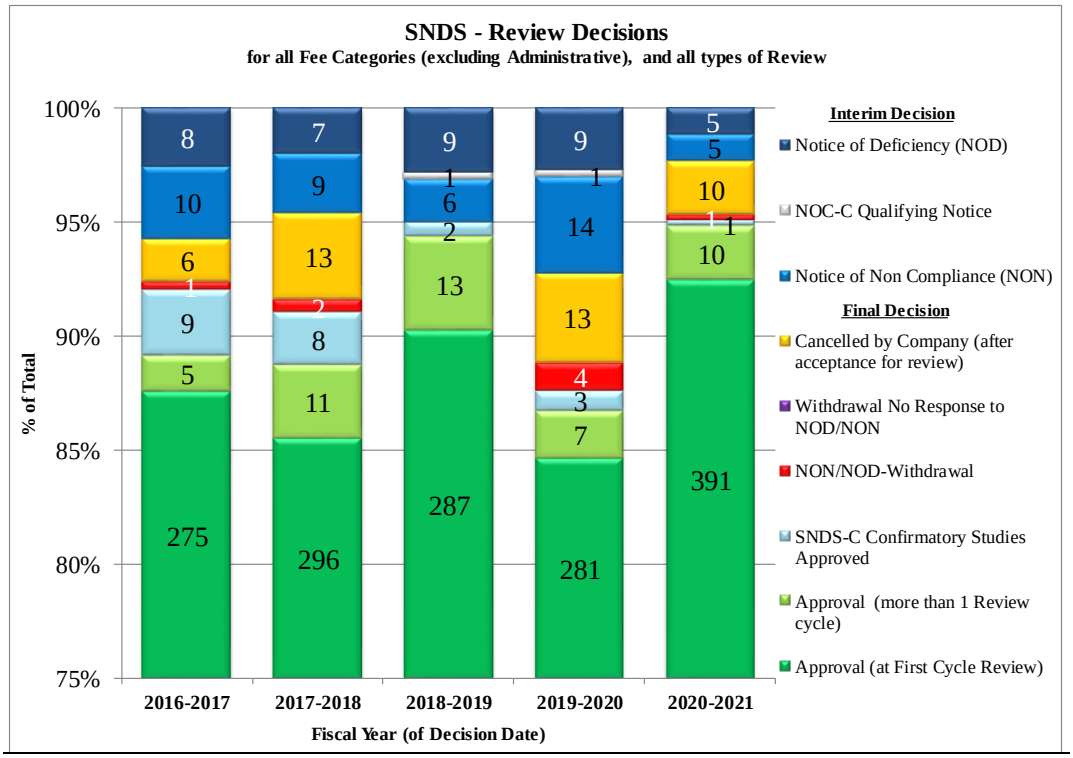


NDS: Review Cycle Completions

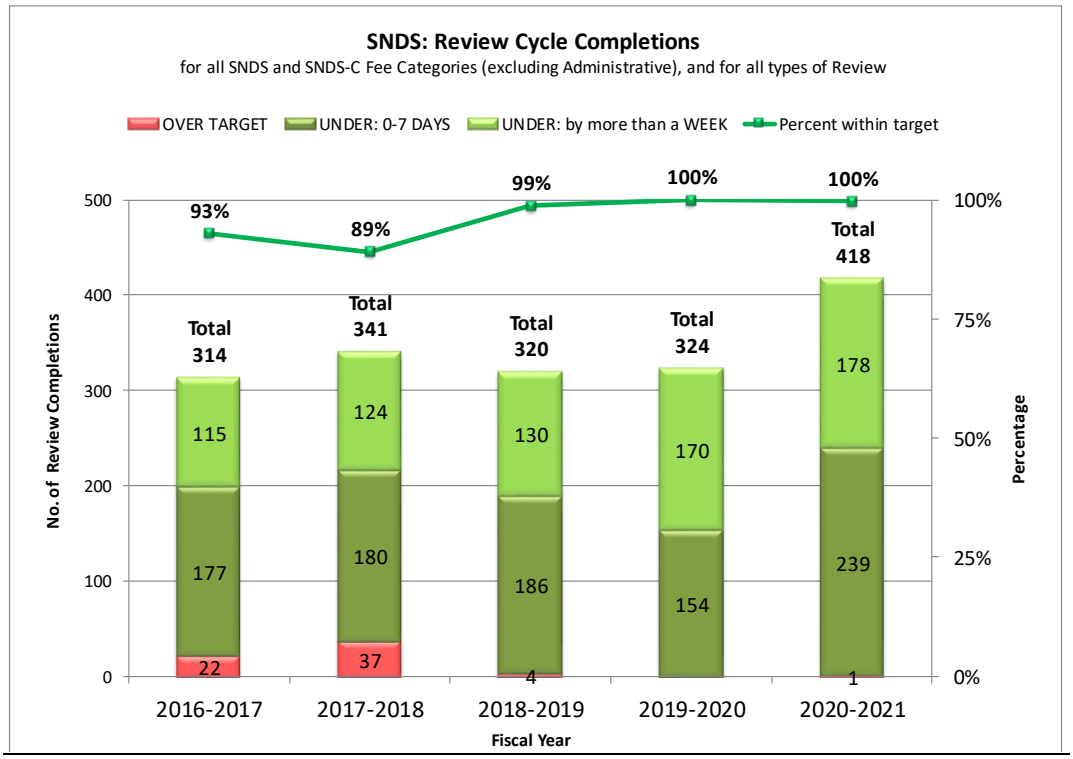


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

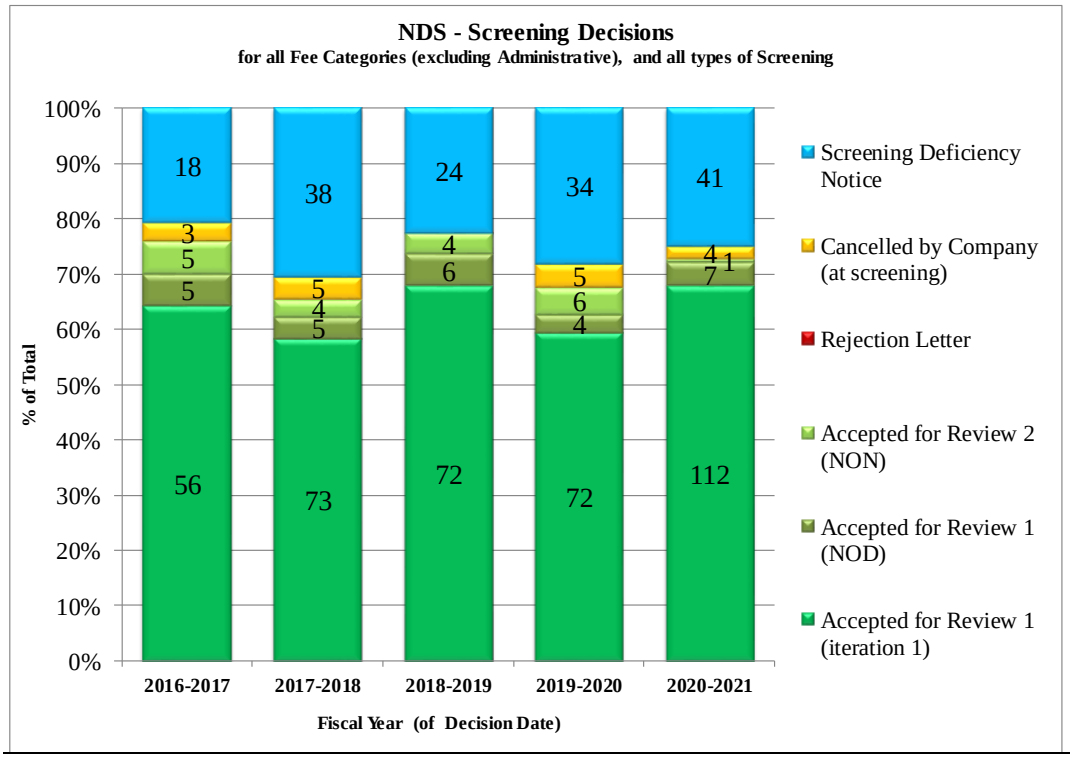


SNDS: Review Cycle Completions

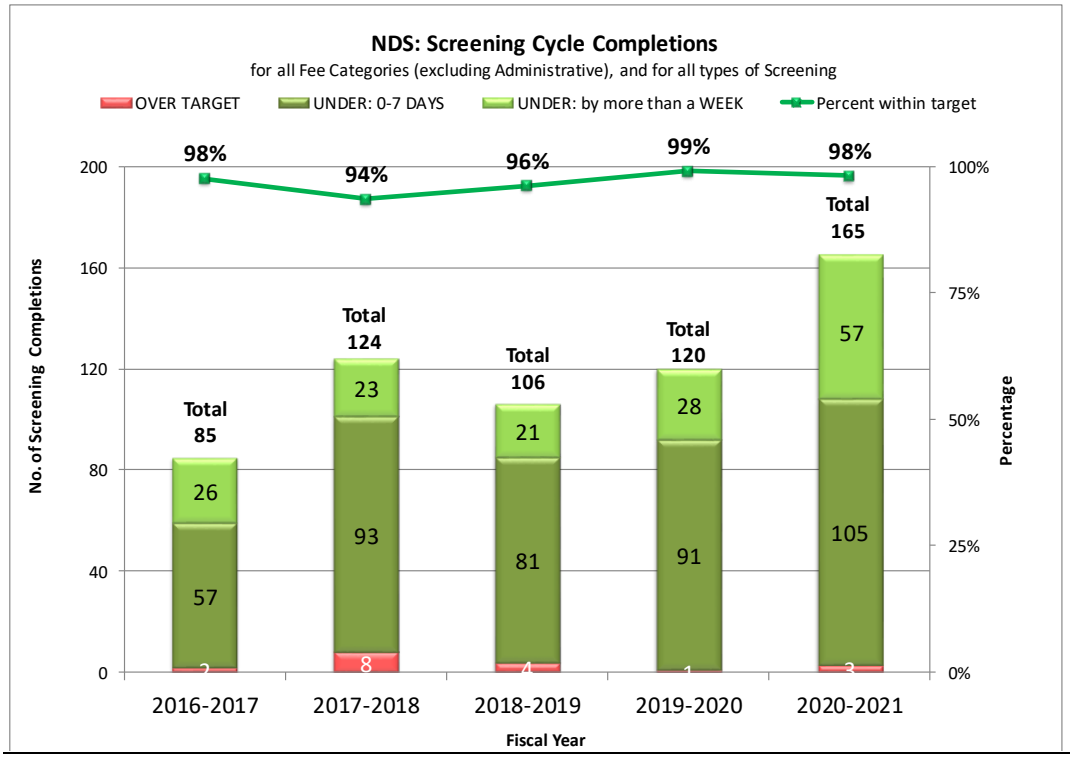


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

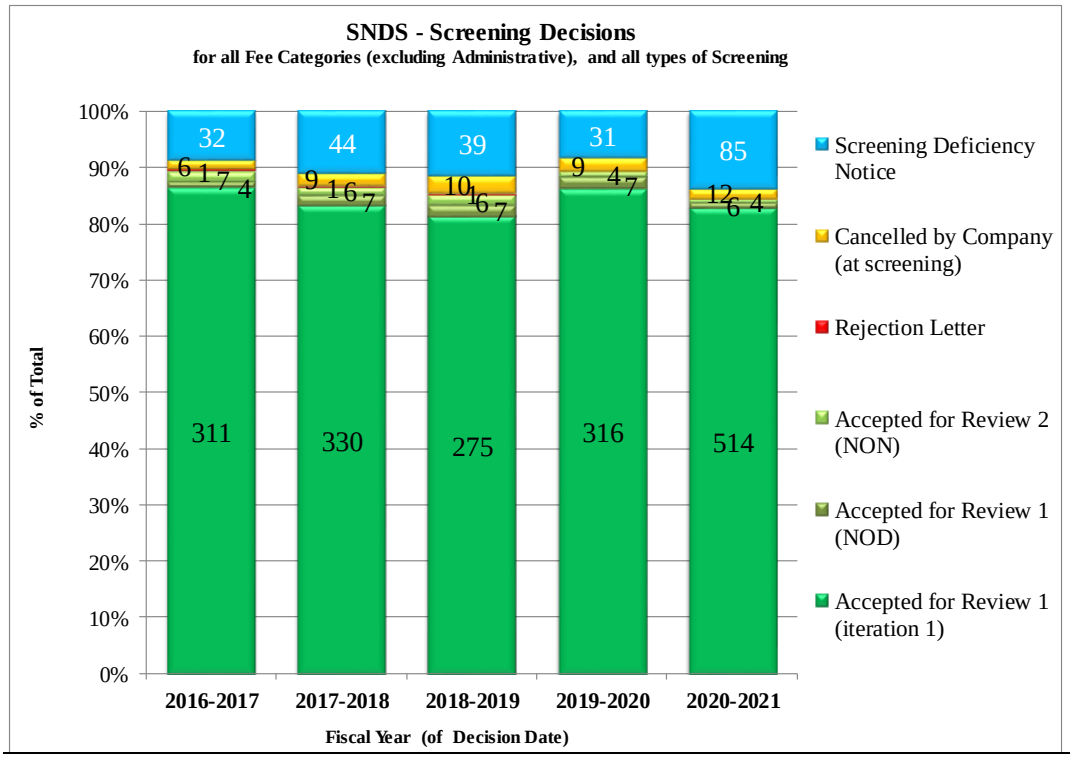


NDS: Screening Cycle Completions

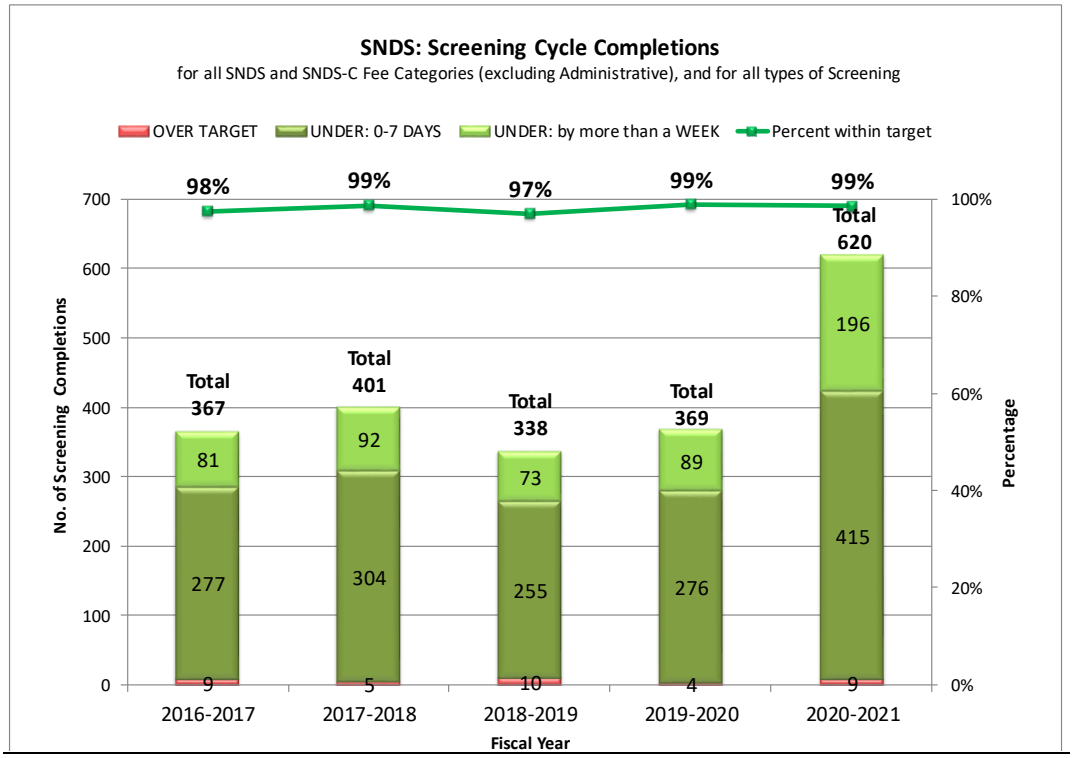


SCREENING PERFORMANCE

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	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	NDS Status (as of June 2021)
Total Received	1	0	1	0	0		
Total Pending	*0*	*0*	*0*	*0*	*0*		
PENDING						NOD-Withdrawal	Under Reconsideration
Total Granted	*0*	*0*	*0*	*0*	*0*		
GRANTED	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Total Denied	*1*	*0*	*1*	*0*	*0*		
DENIED	1	0	0	0	0	NOD-Withdrawal	Withdrawn
DENIED	0	0	1	0	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	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	SNDS Status (as of June 2021)
Total Received	0	0	0	0	0		
Total Denied	0	0	0	0	0	NOD-Withdrawal	Withdrawn

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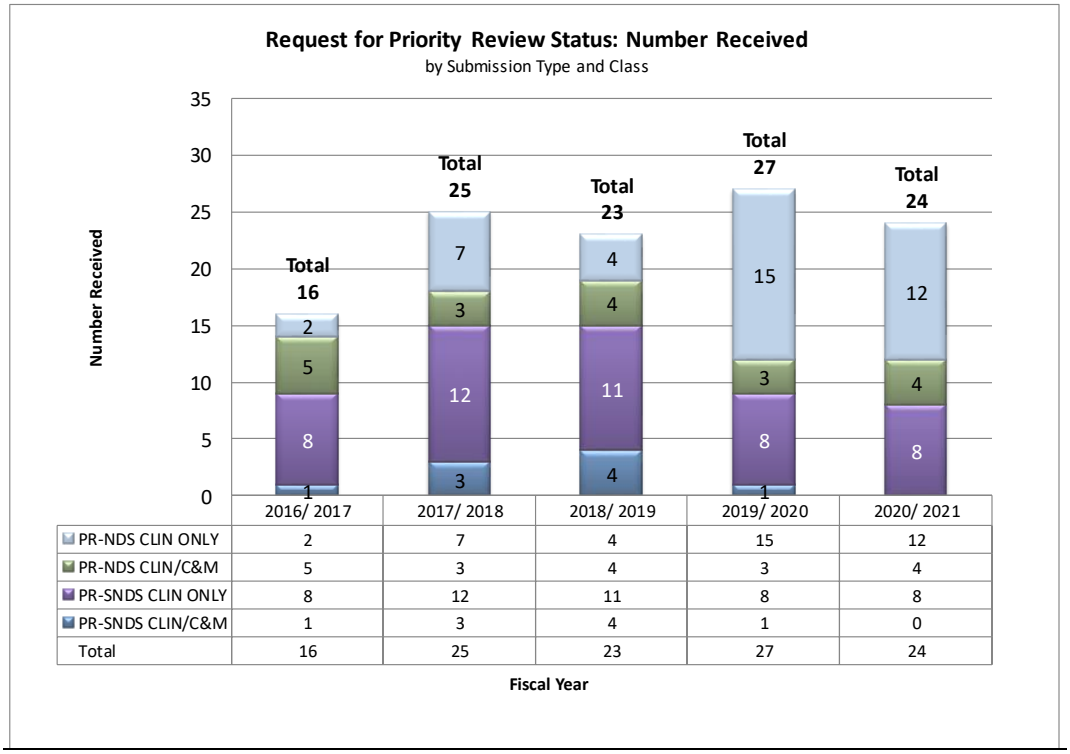
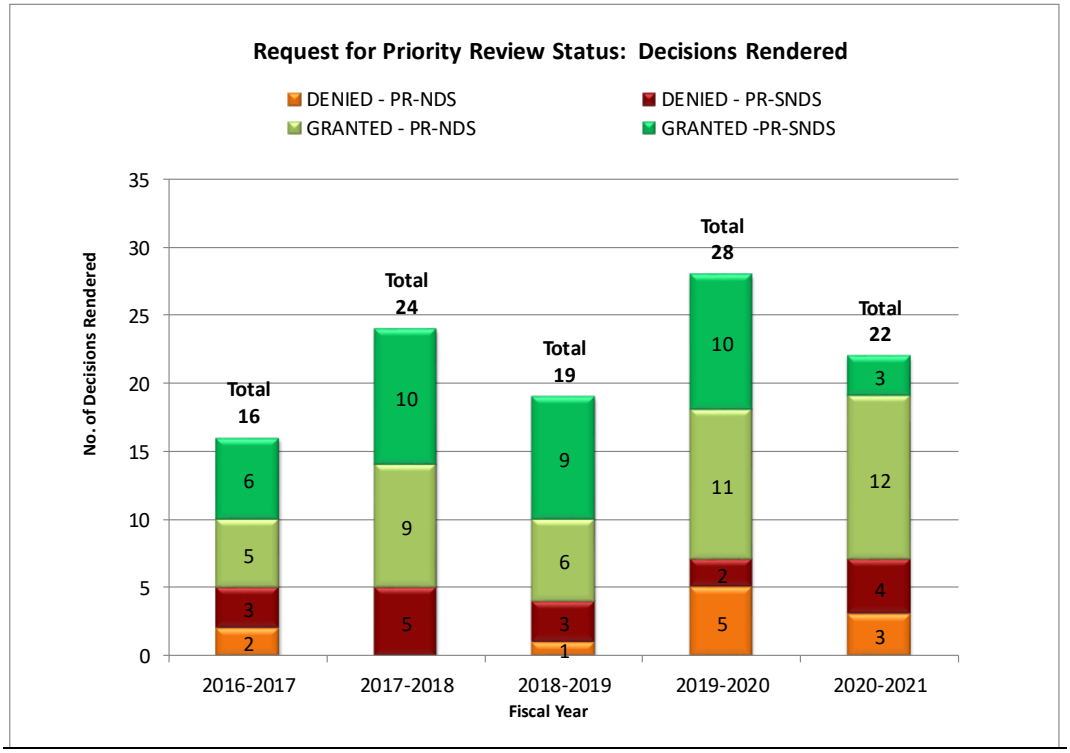
REQUEST FOR PRIORITY REVIEW STATUS

Request for Priority Review Status: Number Received



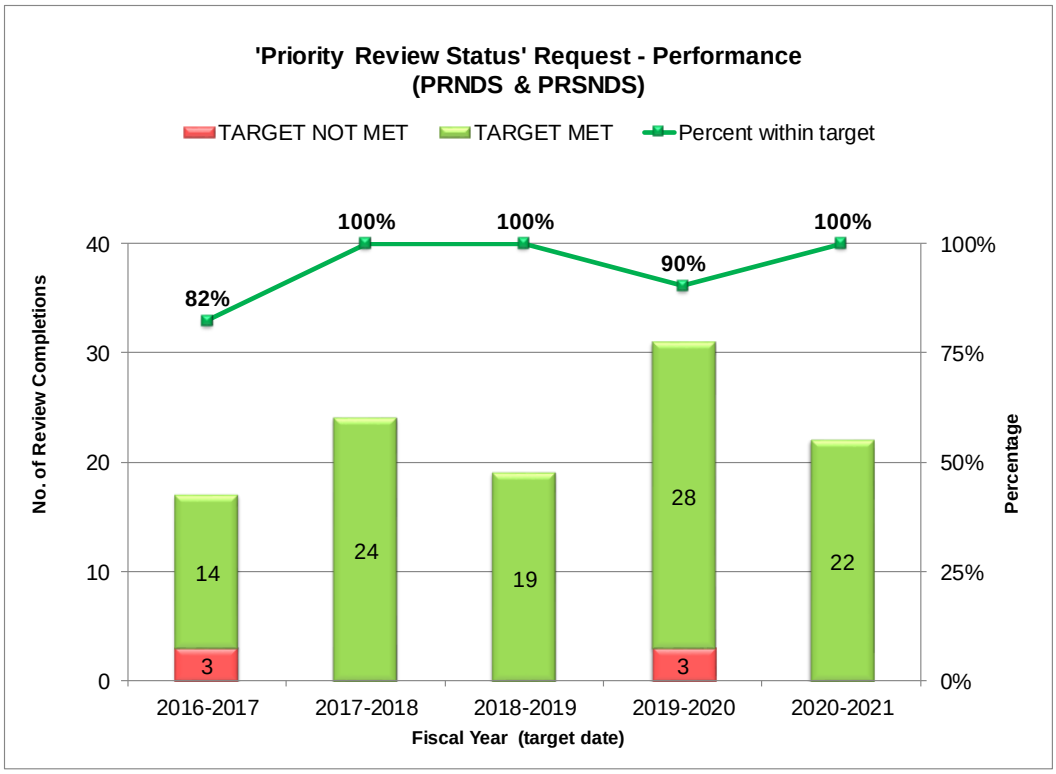
	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
PR-NDS CLIN ONLY	2	7	4	15	12
PR-NDS CLIN/C&M	5	3	4	3	4
PR-SNDS CLIN ONLY	8	12	11	8	8
PR-SNDS CLIN/C&M	1	3	4	1	0
Total	16	25	23	27	24

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	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	Submission Status (as of June 2021)
Total Received	0	1	1	0	0		
Total Granted	*0*	*1*	*0*	*0*	*0*	Priority Review Request (for SNDS) Denied	Cleared

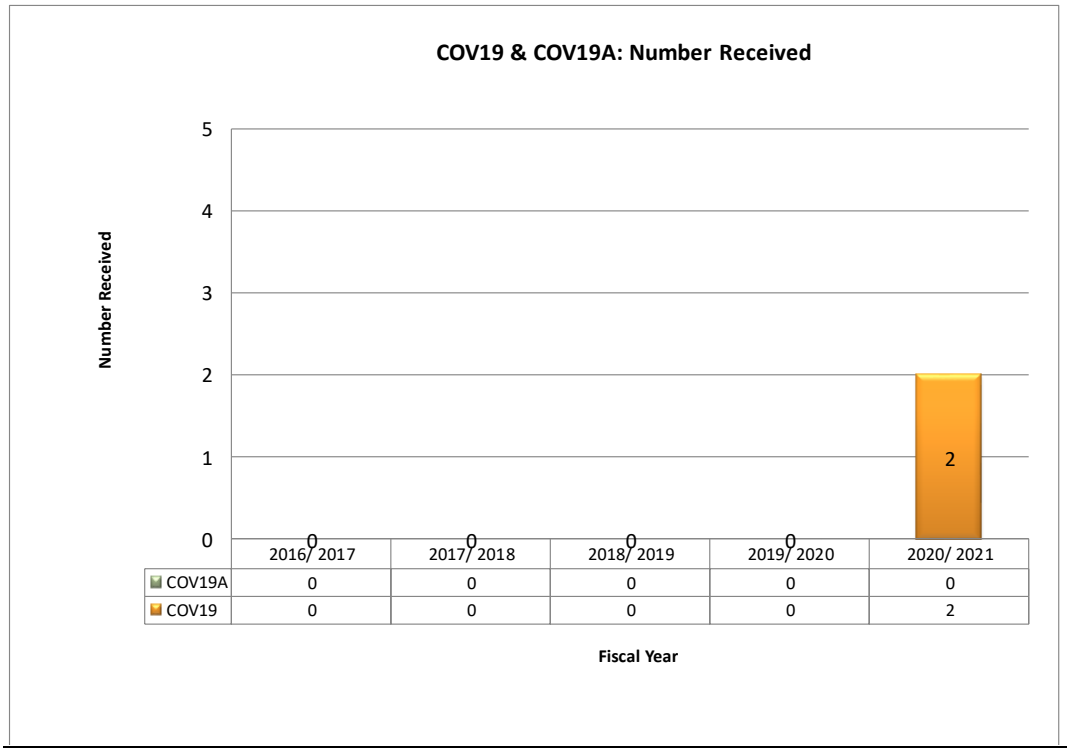
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19A)

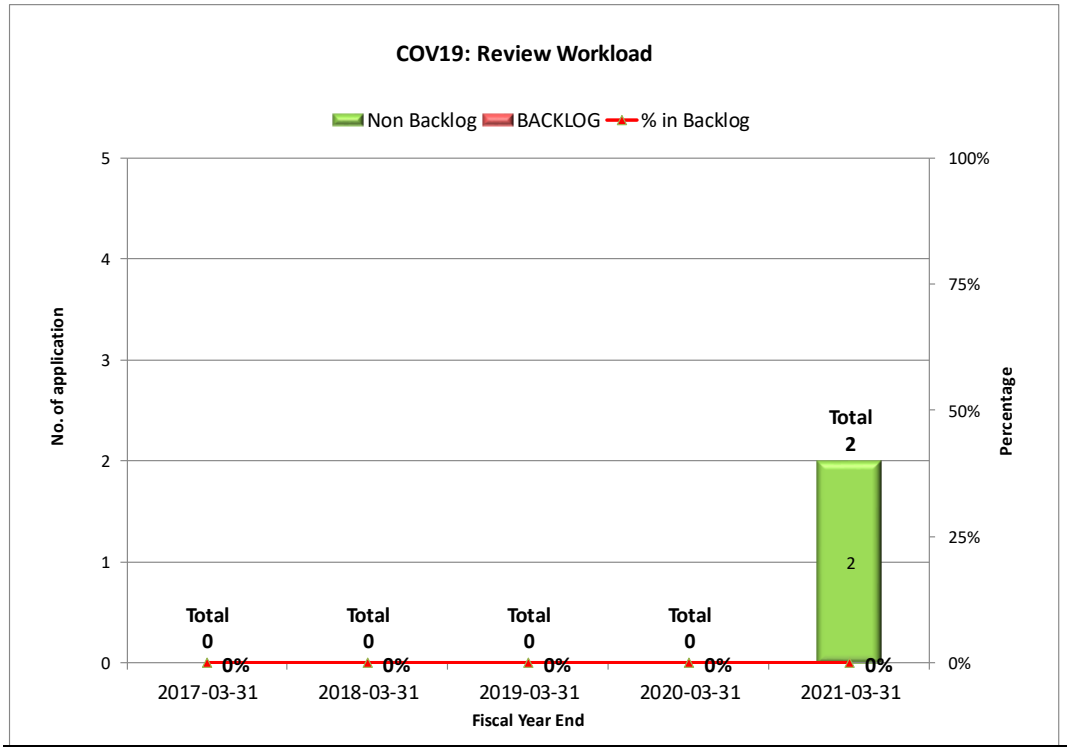
SUBMISSION RECEIVED

COV19 & COV19A: Number Received



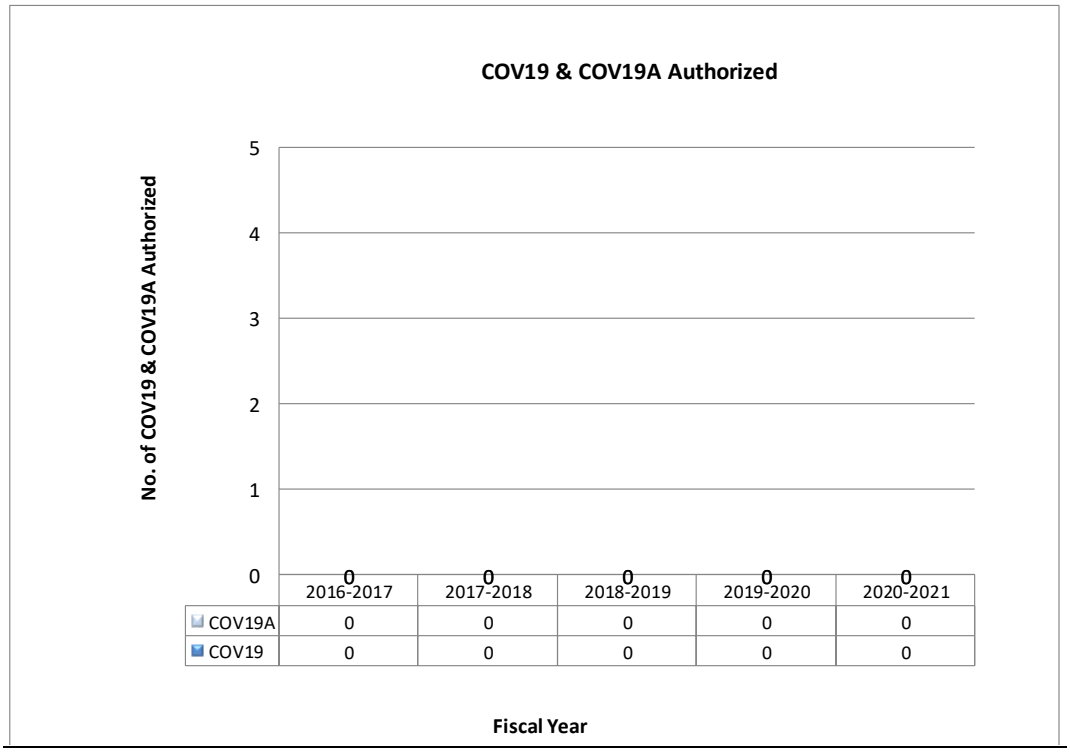
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
COV19A	0	0	0	0	0
COV19	0	0	0	0	0

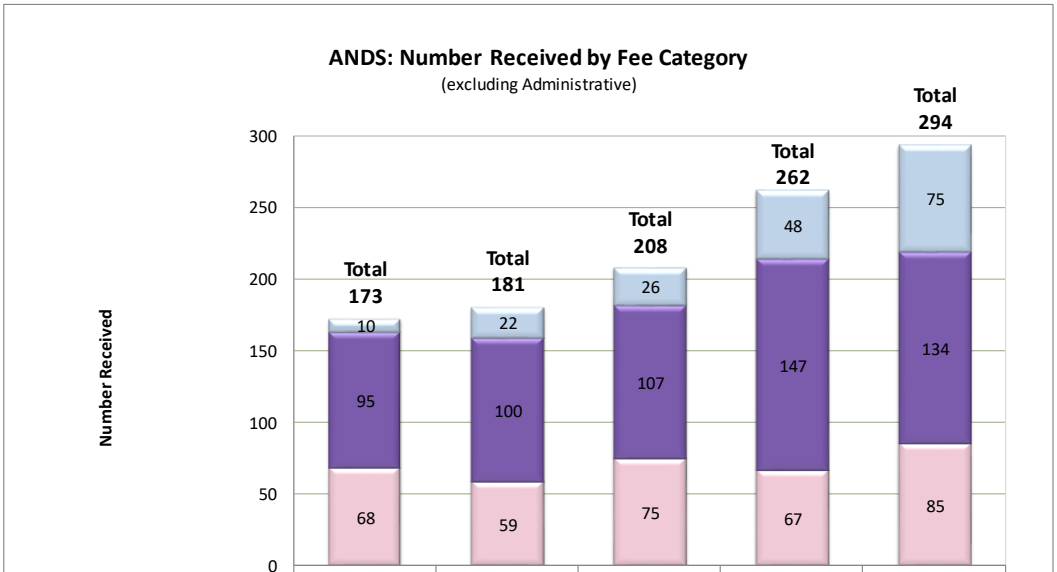
ABBREVIATED NEW DRUG SUBMISSIONS (ANDS)

&

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSIONS (SANDS)

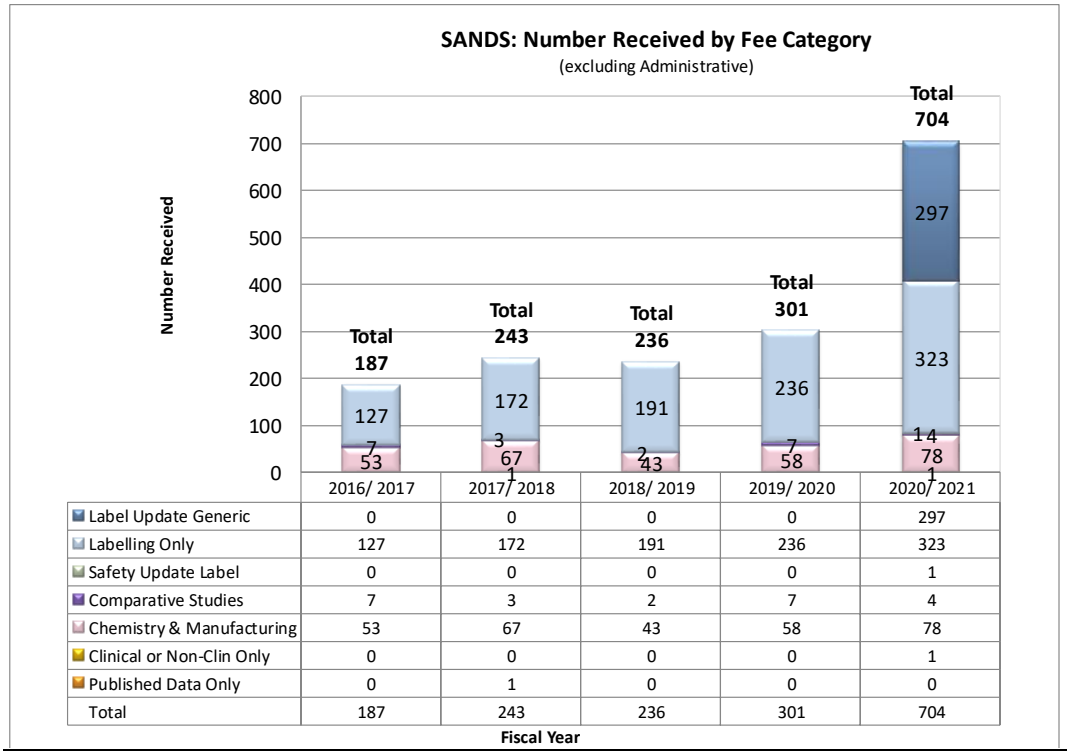
SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Labelling Only	10	22	26	48	75
Comparative Studies	95	100	107	147	134
Chemistry & Manufacturing	68	59	75	67	85
Total	173	181	208	262	294

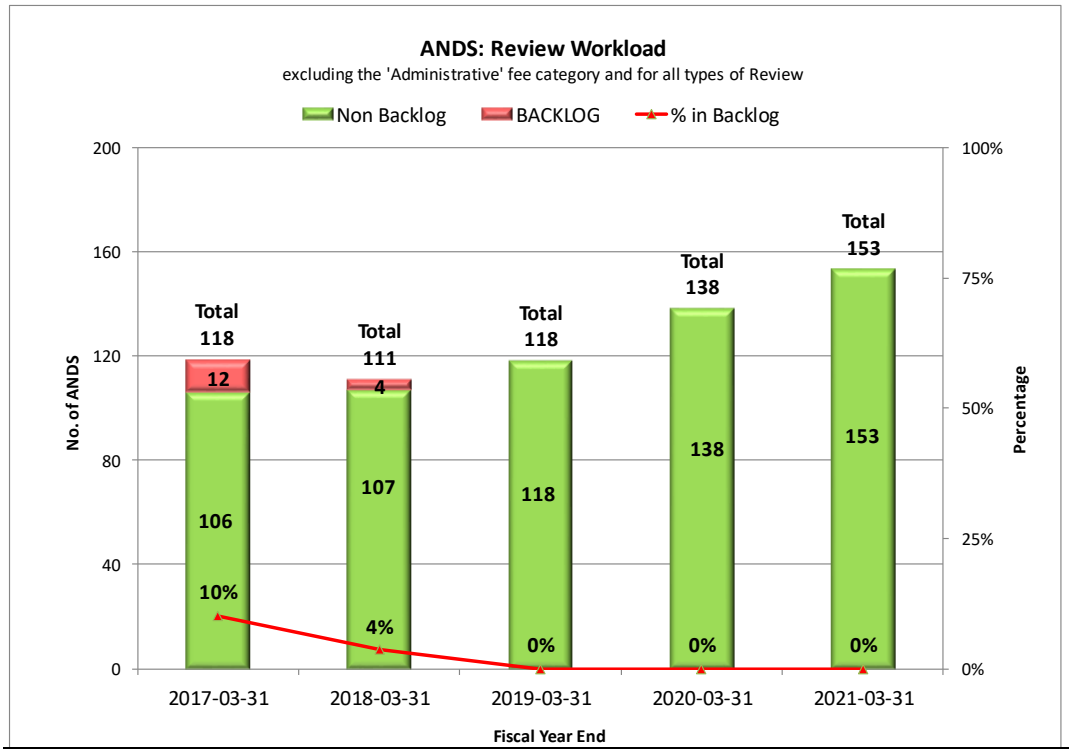
SANDS: Number Received by Fee Category



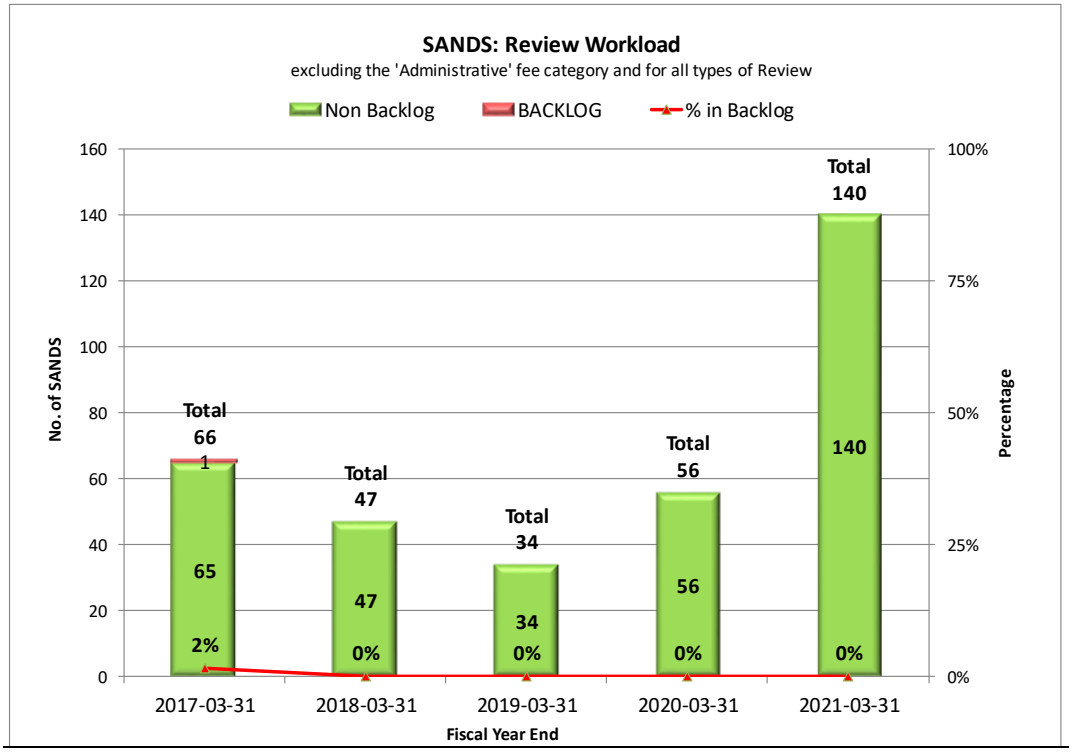
	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Label Update Generic	0	0	0	0	297
Labelling Only	127	172	191	236	323
Safety Update Label	0	0	0	0	1
Comparative Studies	7	3	2	7	4
Chemistry & Manufacturing	53	67	43	58	78
Clinical or Non-Clin Only	0	0	0	0	1
Published Data Only	0	1	0	0	0
Total	187	243	236	301	704

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

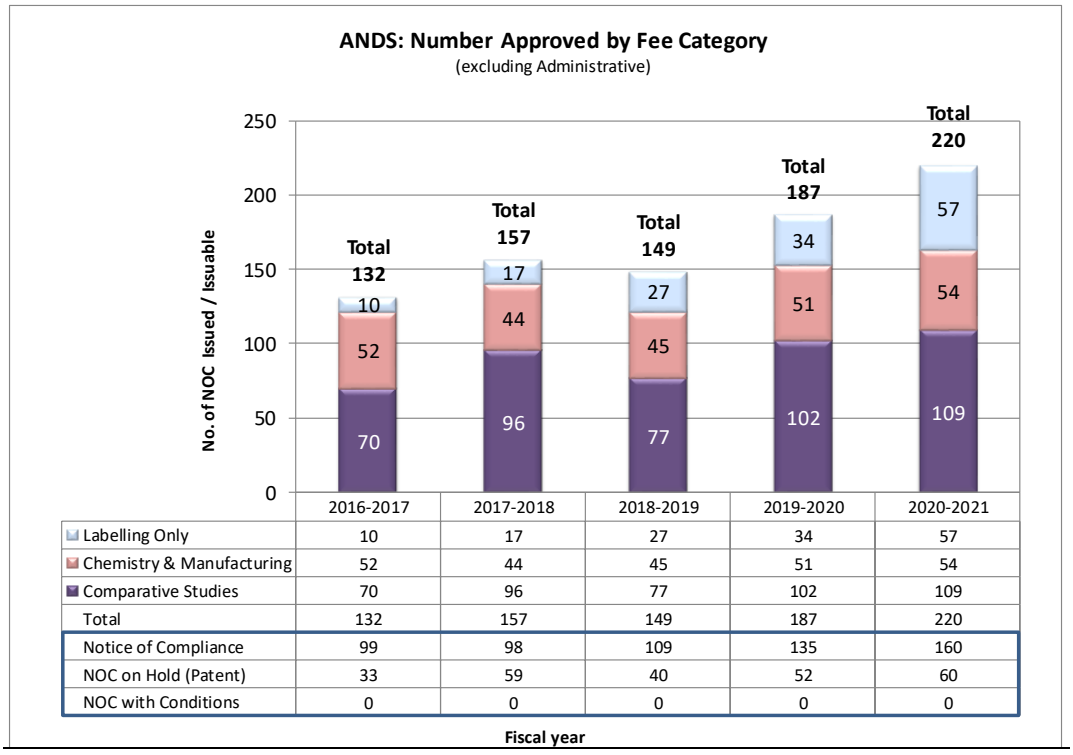
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Chemistry & Manufacturing	46	43	38	42	53
Backlog	*5*	*2*	*0*	*0*	*0*
Comparative Studies	71	65	77	88	89
Backlog	*7*	*2*	*0*	*0*	*0*
Labelling Only	1	3	3	8	11
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**118**	**111**	**118**	**138**	**153**
Non Backlog	**106**	**107**	**118**	**138**	**153**
BACKLOG	**12**	**4**	**0**	**0**	**0**
% in Backlog	**10%**	**4%**	**0%**	**0%**	**0%**

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Chemistry & Manufacturing	32	26	22	24	30
Backlog	*1*	*0*	*0*	*0*	*0*
Comparative Studies	4	2	2	3	1
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	30	19	10	29	91
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	0	18
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**66**	**47**	**34**	**56**	**140**
Non Backlog	**65**	**47**	**34**	**56**	**140**
BACKLOG	**1**	**0**	**0**	**0**	**0**
% in Backlog	**2%**	**0%**	**0%**	**0%**	**0%**

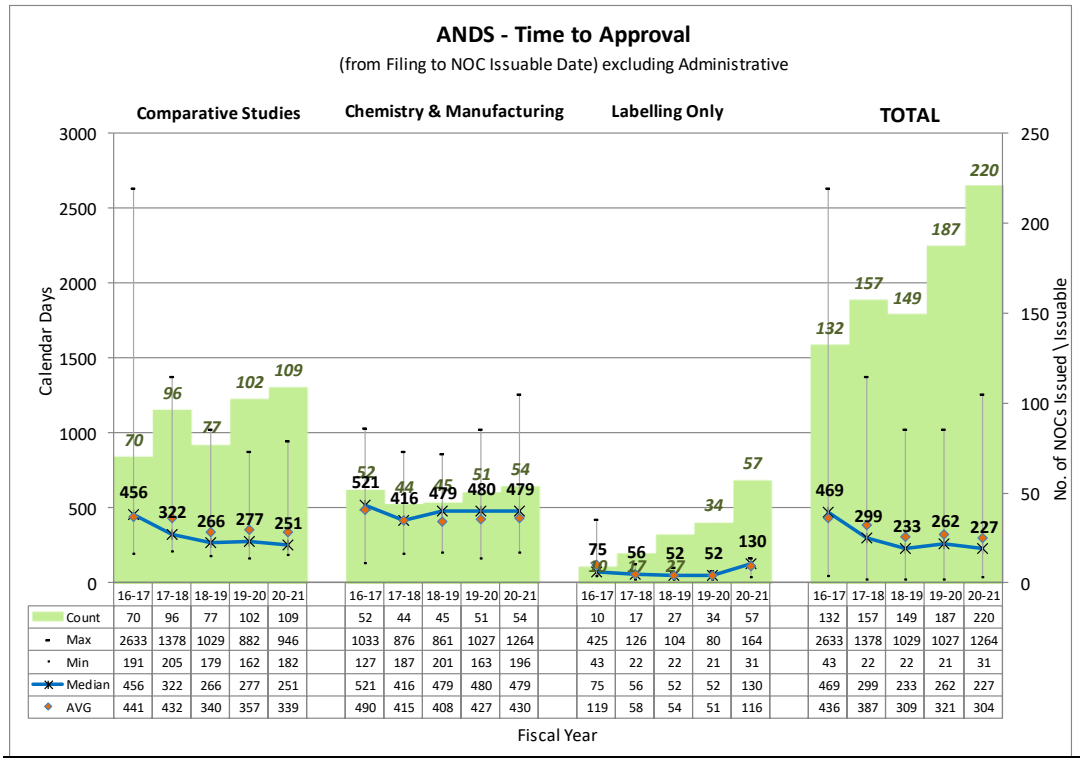
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Labelling Only	10	17	27	34	57
Chemistry & Manufacturing	52	44	45	51	54
Comparative Studies	70	96	77	102	109
Total	132	157	149	187	220
Notice of Compliance	99	98	109	135	160
NOC on Hold (Patent)	33	59	40	52	60
NOC with Conditions	0	0	0	0	0

ANDS Approval Times

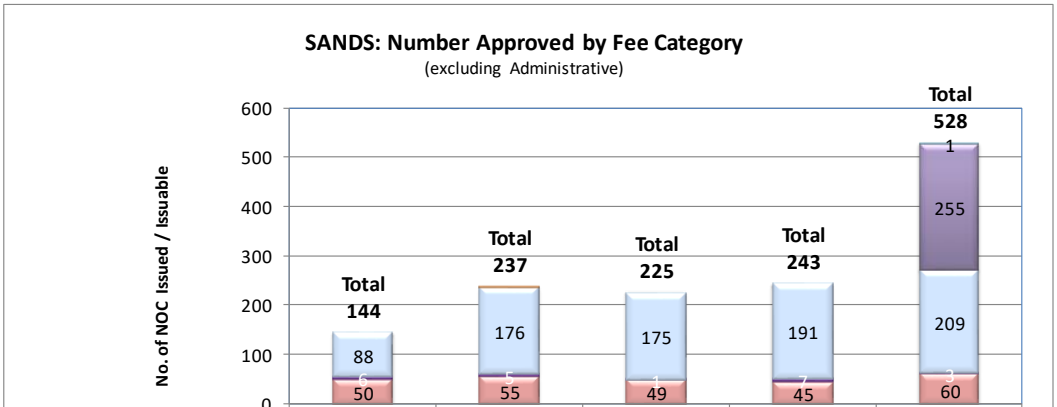


	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	70	96	77	102	109	52	44	45	51	54	10	17	27	34	57	132	157	149	187	220
Max	2633	1378	1029	882	946	1033	876	861	1027	1264	425	126	104	80	164	2633	1378	1029	1027	1264
Min	191	205	179	162	182	127	187	201	163	196	43	22	22	21	31	43	22	22	21	31
Median	456	322	266	277	251	521	416	479	480	479	75	56	52	52	130	469	299	233	262	227
AVG	441	432	340	357	339	490	415	408	427	430	119	58	54	51	116	436	387	309	321	304

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

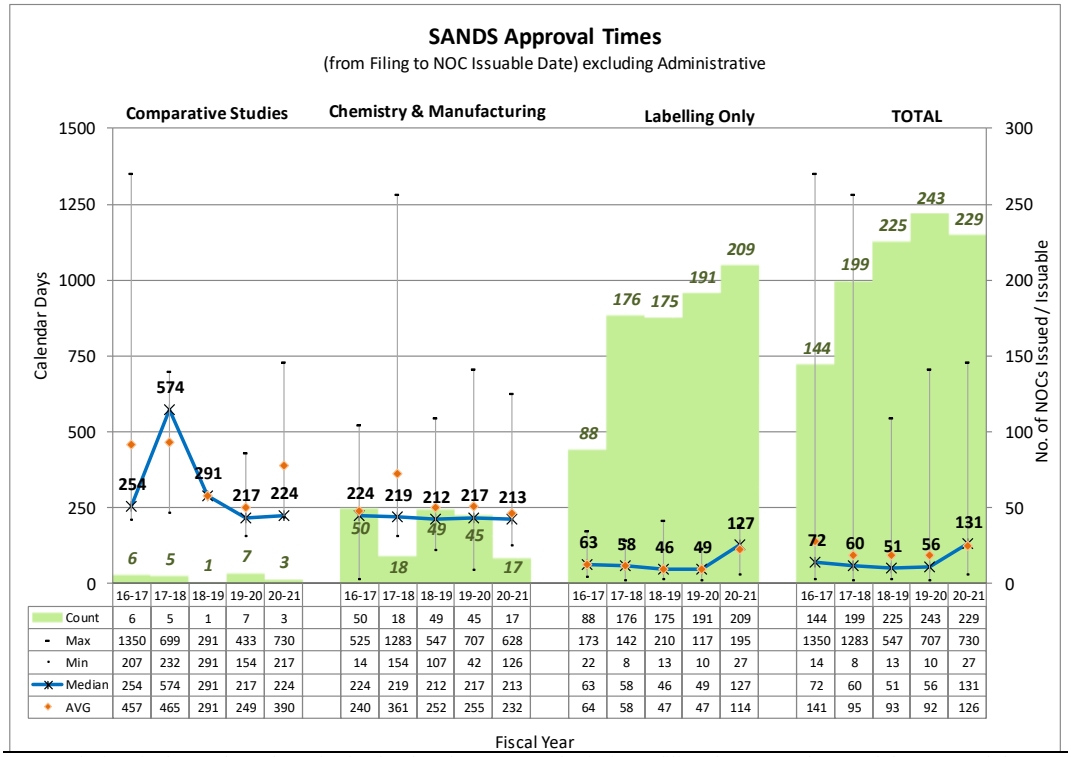
SANDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Safety Update Label	0	0	0	0	1
Label Update Generic	0	0	0	0	255
Published Data Only	0	1	0	0	0
Labelling Only	88	176	175	191	209
Comparative Studies	6	5	1	7	3
Chemistry & Manufacturing	50	55	49	45	60
Total	144	237	225	243	528
Notice of Compliance	133	217	206	224	491
NOC on Hold (Patent)	11	20	19	19	37

Fiscal Year

SANDS Approval Times



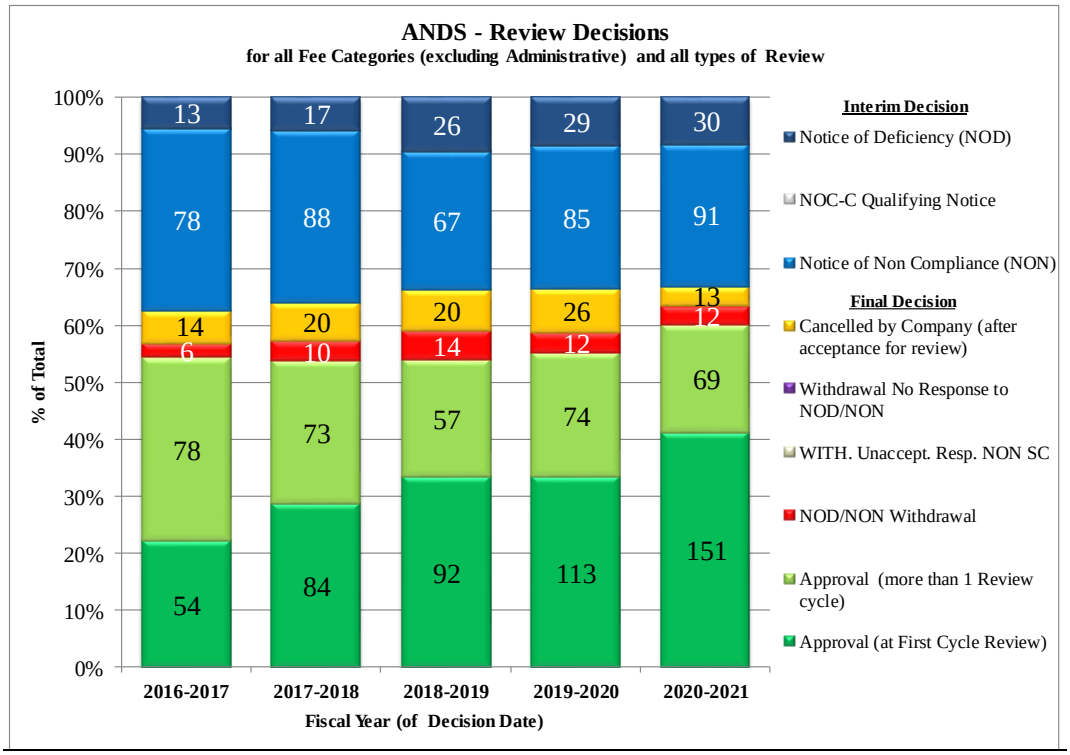
	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	6	5	1	7	3	50	18	49	45	17	88	176	175	191	209	144	199	225	243	229
Max	1350	699	291	433	730	525	1283	547	707	628	173	142	210	117	195	1350	1283	547	707	730
Min	207	232	291	154	217	14	154	107	42	126	22	8	13	10	27	14	8	13	10	27
Median	254	574	291	217	224	224	219	212	217	213	63	58	46	49	127	72	60	51	56	131
AVG	457	465	291	249	390	240	361	252	255	232	64	58	47	47	114	141	95	93	92	126

Fiscal Year

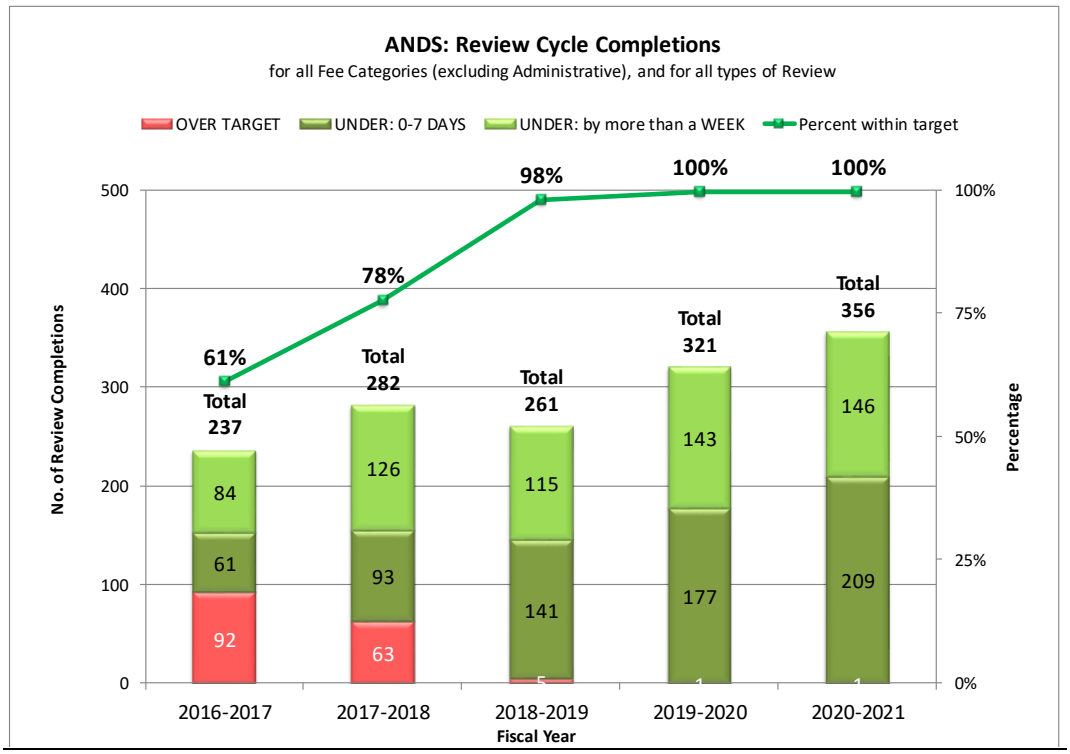
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW PERFORMANCE

ANDS: Review Decisions by Type

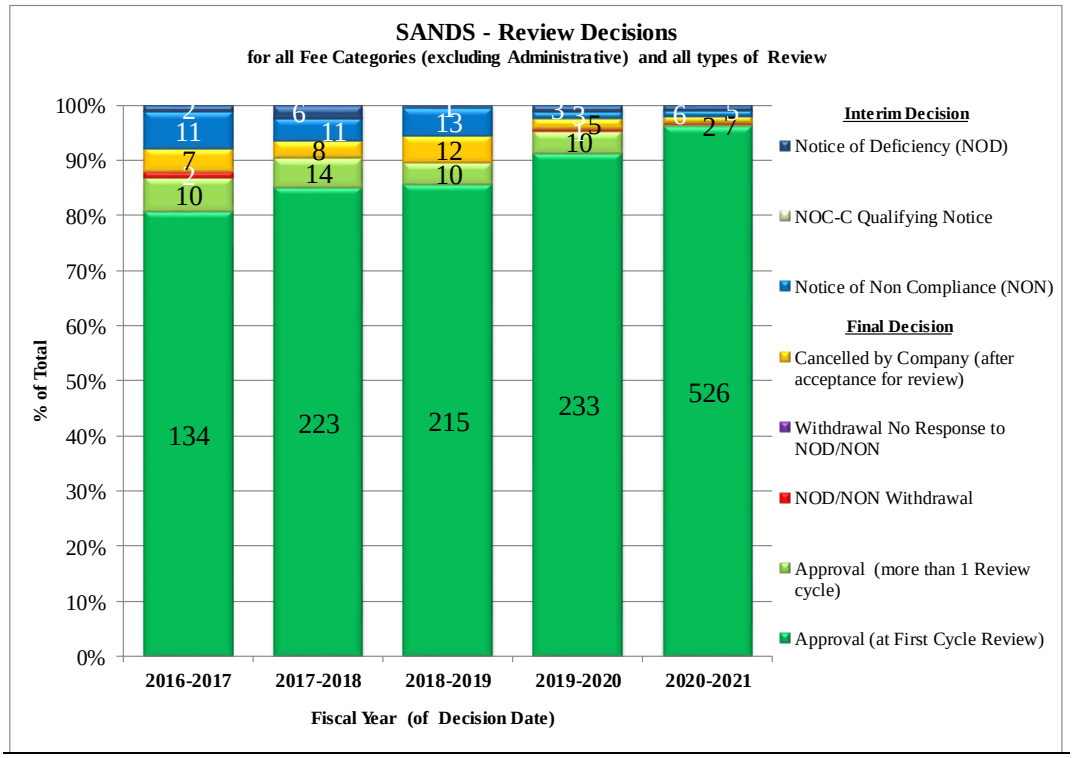


ANDS: Review Cycle Completions

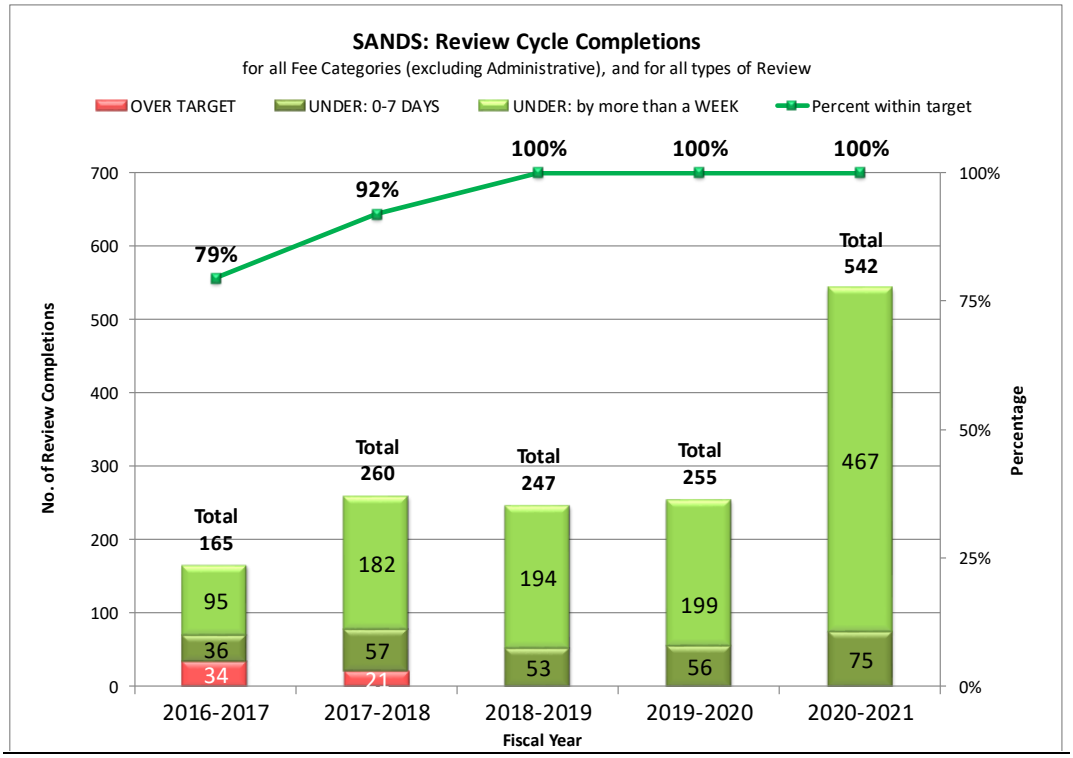


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

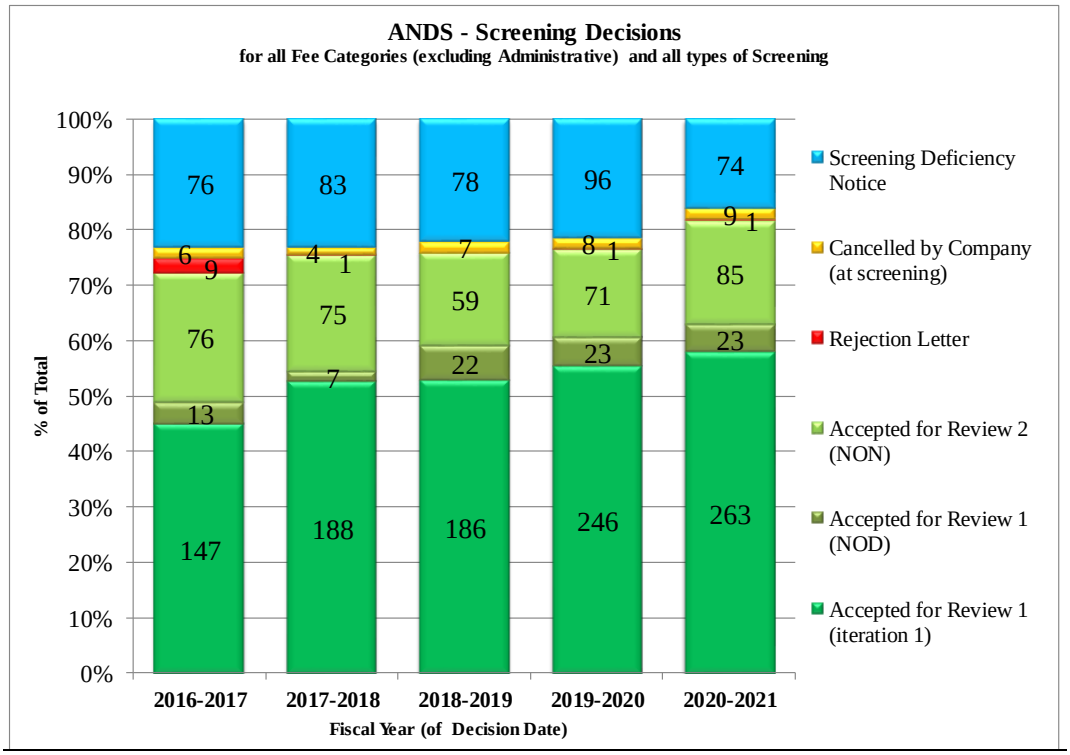


SANDS: Review Cycle Completions

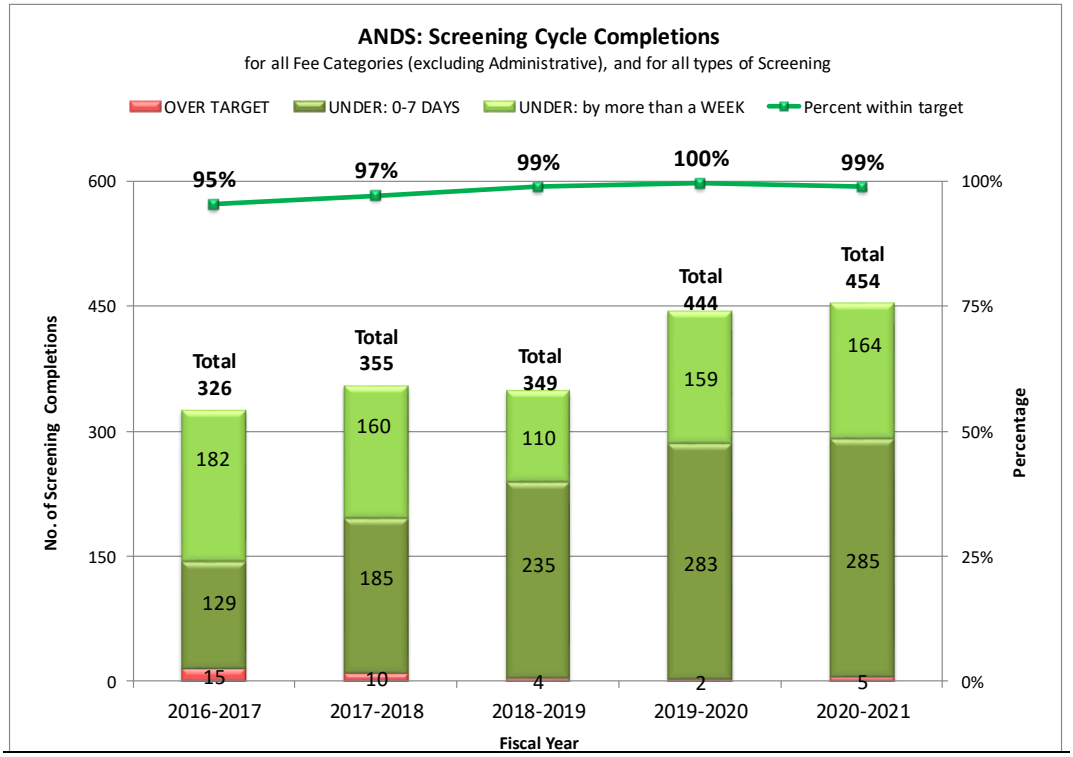


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

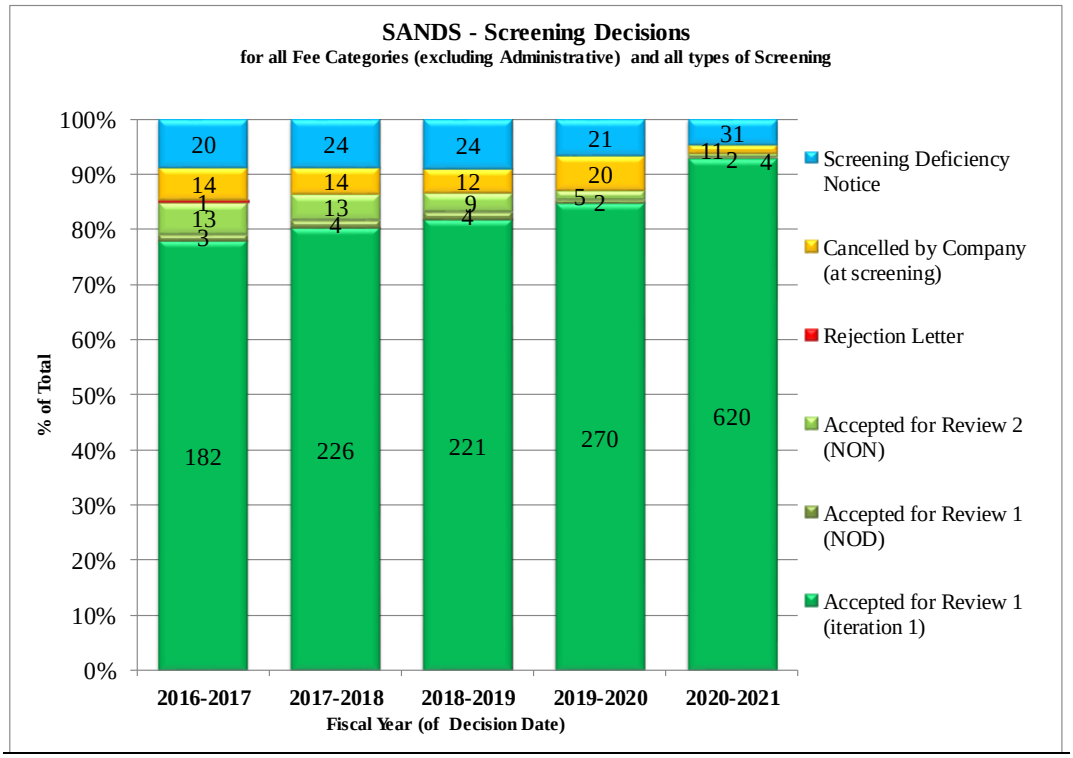


ANDS: Screening Cycle Completions

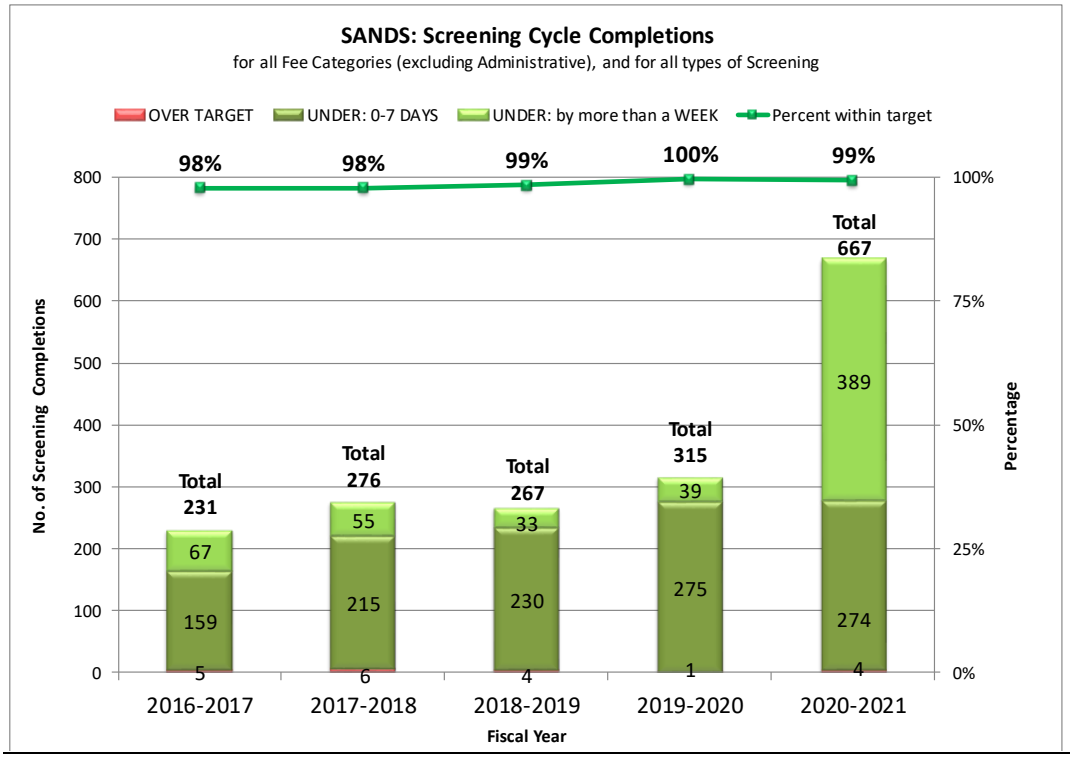


SCREENING PERFORMANCE

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	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	ANDS Status (as of June 2021)
TOTAL Received	**2**	**0**	**3**	**2**	**0**		
Total Pending	*0*	*0*	*1*	*0*	*0*		
Pending	0	0	1	0	0	NON-Withdrawal	Under Reconsideration
Total Granted	*1*	*0*	*2*	*0*	*0*		
Granted	0	0	0	0	0	NOD-Withdrawal	Cleared
Granted	0	0	2	0	0	NON-Withdrawal	Cleared
Granted	1	0	0	0	0	Rejection at Screening	Cleared
Total Denied	*0*	*0*	*0*	*0*	*0*		
Denied	0	0	0	0	0	Rejection at Screening	Rejected
Denied	0	0	0	0	0	Rejection at Screening	Cancelled by Company
Denied	0	0	0	0	0	NOD-Withdrawal	Withdrawn
Denied	0	0	0	0	0	NON-Withdrawal	Withdrawn
Total Cancelled	*1*	*0*	*0*	*2*	*0*		
Cancelled by Health Canada	0	0	0	0	0	NOD-Withdrawal	Cleared
Cancelled by Health Canada	0	0	0	0	0	NOD-Withdrawal	Withdrawn
Cancelled by Health Canada	0	0	0	0	0	NON-Withdrawal	Cleared
Cancelled by Health Canada	0	0	0	0	0	NON-Withdrawal	Withdrawn
Cancelled by Health Canada	0	0	0	0	0	Rejection at Screening	Cleared
Cancelled by Company	1	0	0	2	0	NOD-Withdrawal	Withdrawn

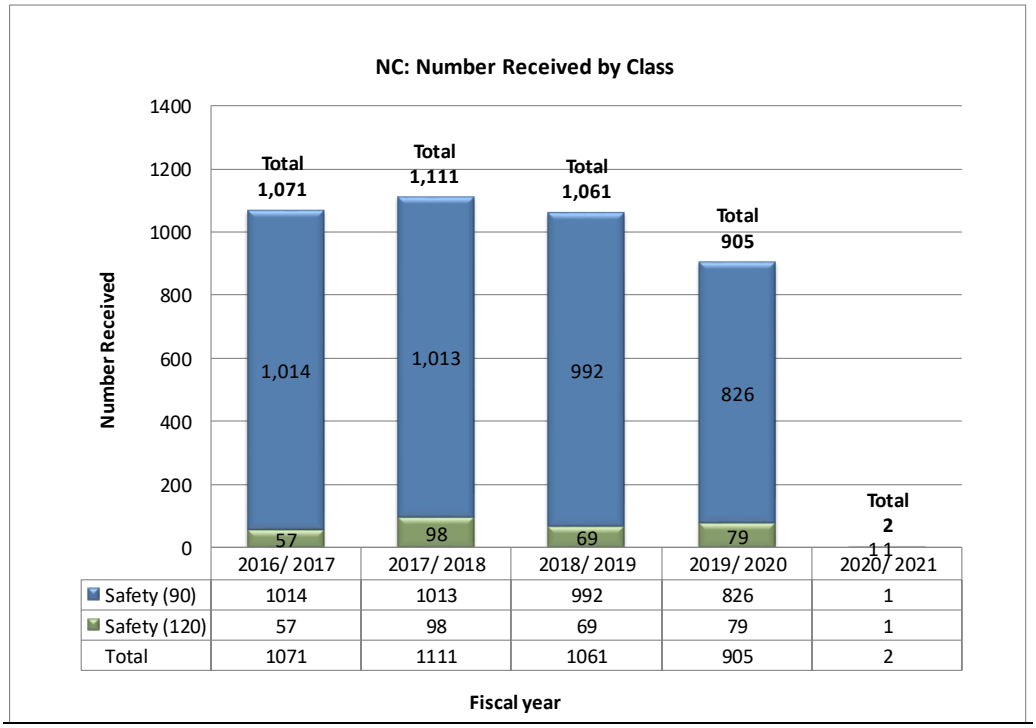
SANDS: Request for Reconsideration of Final Decisions

SANDS - Reconsideration of Final Decisions Requests Received Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	SANDS Status (as of June 2021)
Total Received	**1**	**0**	**0**	**0**	**0**		
Total Granted	*0*	*0*	*0*	*0*	*0*		
Granted	0	0	0	0	0	NOD-Withdrawal	Cleared
Total Cancelled	*1*	*0*	*0*	*0*	*0*		
Cancelled by Health Canada	1	0	0	0	0	NOD-Withdrawal	Withdrawn

NC: NOTIFIABLE CHANGE

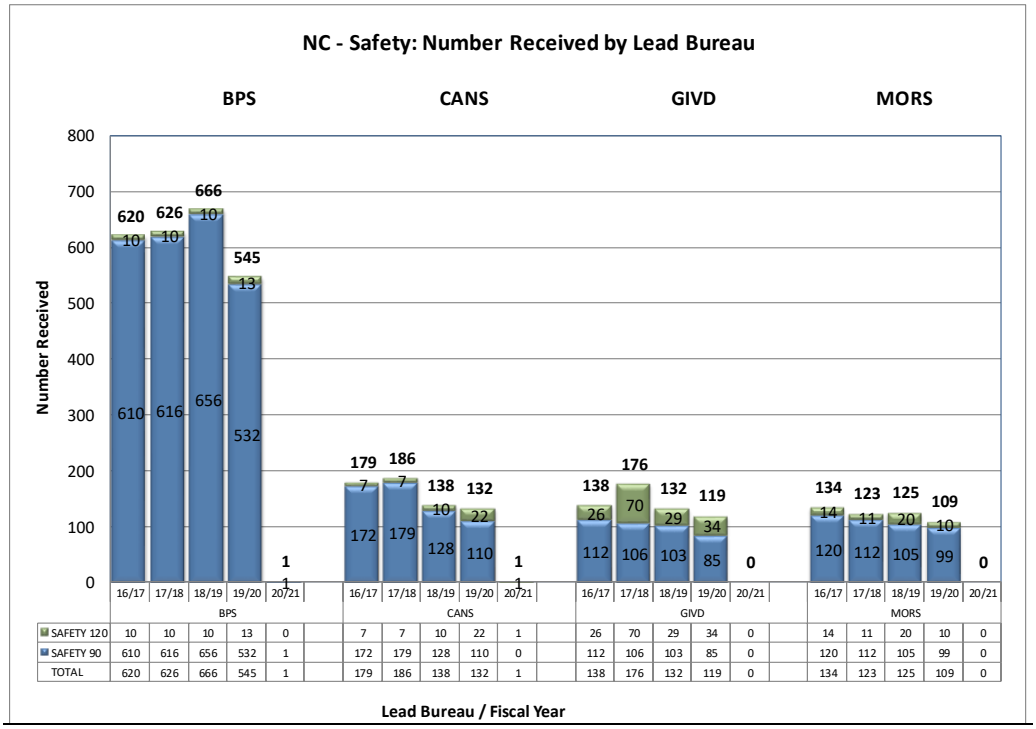
NOTIFIABLE CHANGES RECEIVED

NC: Number Received by Class



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Safety (90)	1014	1013	992	826	1
Safety (120)	57	98	69	79	1
Total	1071	1111	1061	905	2

NC-SAFETY: Number Received by Lead Bureau

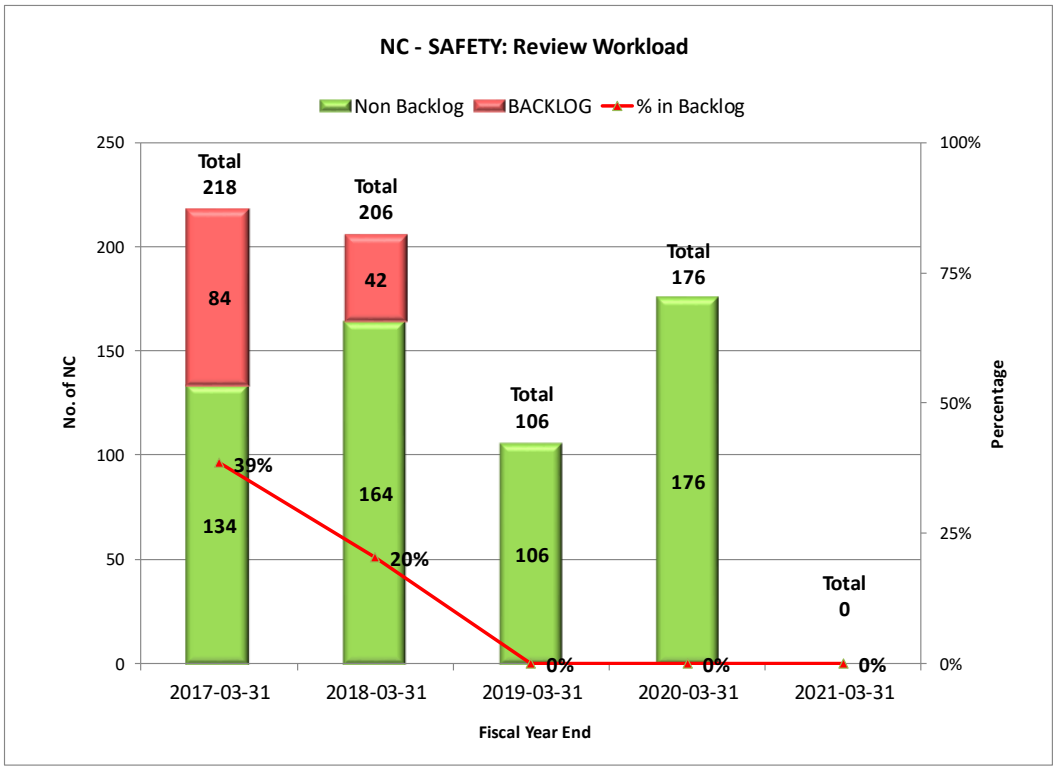


	BPS 16/17	BPS 17/18	BPS 18/19	BPS 19/20	BPS 20/21	CANS 16/17	CANS 17/18	CANS 18/19	CANS 19/20	CANS 20/21	GIVD 16/17	GIVD 17/18	GIVD 18/19	GIVD 19/20	GIVD 20/21	MORS 16/17	MORS 17/18	MORS 18/19	MORS 19/20	MORS 20/21
SAFETY 120	10	10	10	13	0	7	7	10	22	1	26	70	29	34	0	14	11	20	10	0
SAFETY 90	610	616	656	532	1	172	179	128	110	0	112	106	103	85	0	120	112	105	99	0
TOTAL	620	626	666	545	1	179	186	138	132	1	138	176	132	119	0	134	123	125	109	0

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

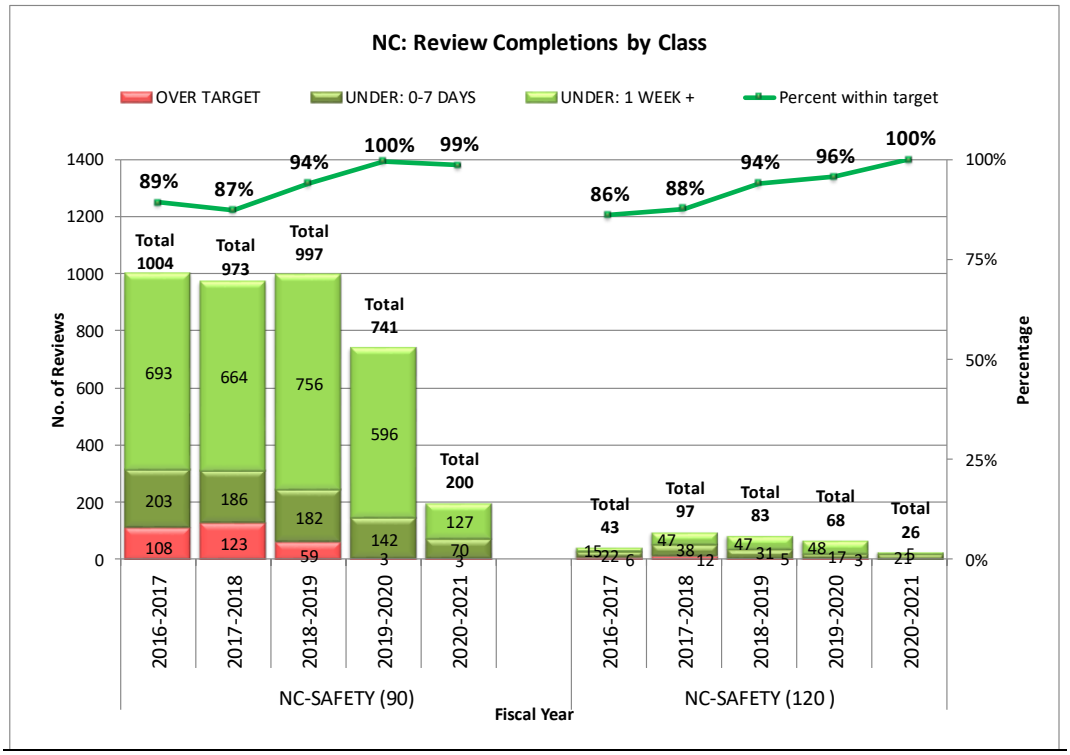


NC-SAFETY: Review Workload by Class

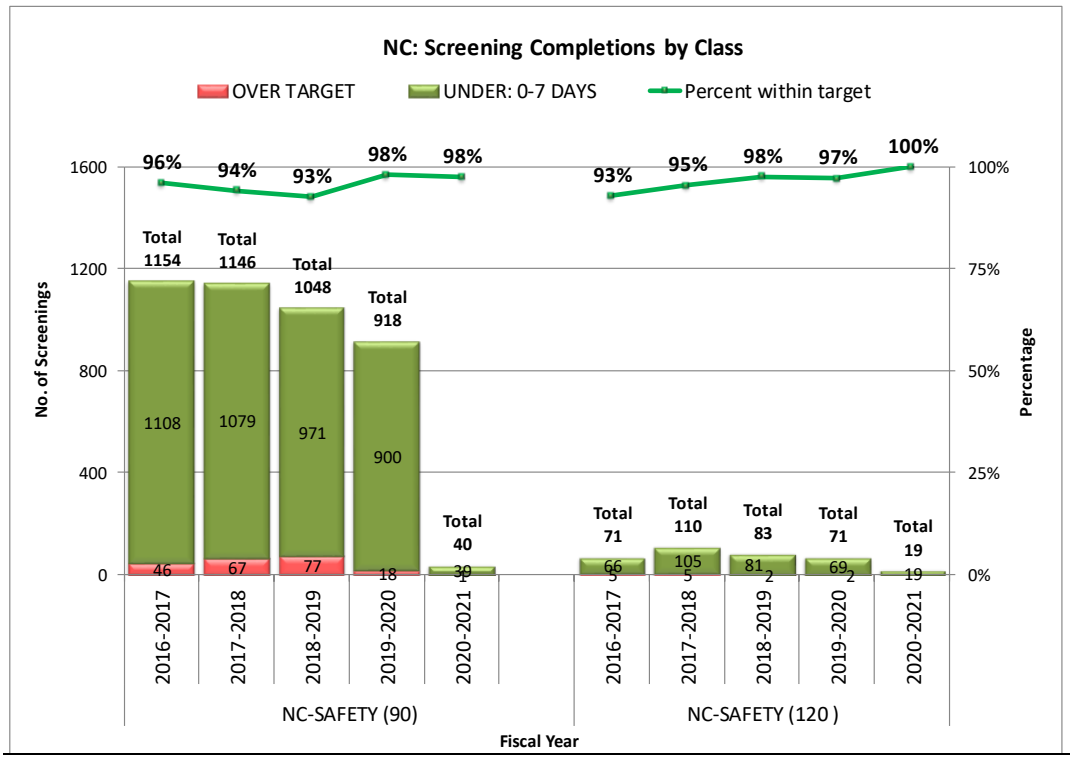
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
SAFETY - 90 day	188	184	95	166	0
Backlog	*78*	*39*	*0*	*0*	*0*
SAFETY - 120 day	30	22	11	10	0
Backlog	*6*	*3*	*0*	*0*	*0*
Total	**218**	**206**	**106**	**176**	**0**
Non Backlog	**134**	**164**	**106**	**176**	**0**
BACKLOG	84	42	0	0	0
% in Backlog	**39%**	**20%**	**0%**	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	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	954	990	977	736	201
CANCELLED BY COMPANY	65	66	63	43	6
NC - HOLD (PATENT)	69	46	35	23	1
SCREEN. DEFICIENCY NOTICE	136	161	115	90	5
REJECTION LETTER (SCR)	2	3	2	1	0
NOT SATISFACTORY NOTICE	2	0	1	0	0
NC - SAFETY (120)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	43	90	81	62	26
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	11	20	11	4	2
CANCELLED BY COMPANY	4	8	2	7	1
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	1	2	0

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)				
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Total Received	0	0	0	0	0

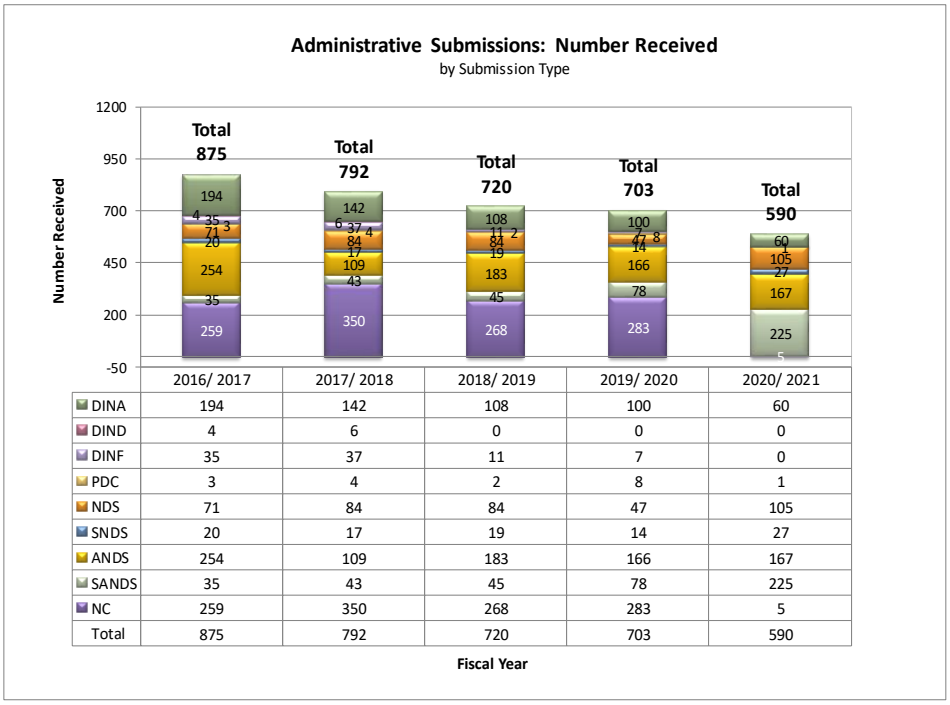
ADMINISTRATIVE SUBMISSIONS

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS[11]

RECEIVED

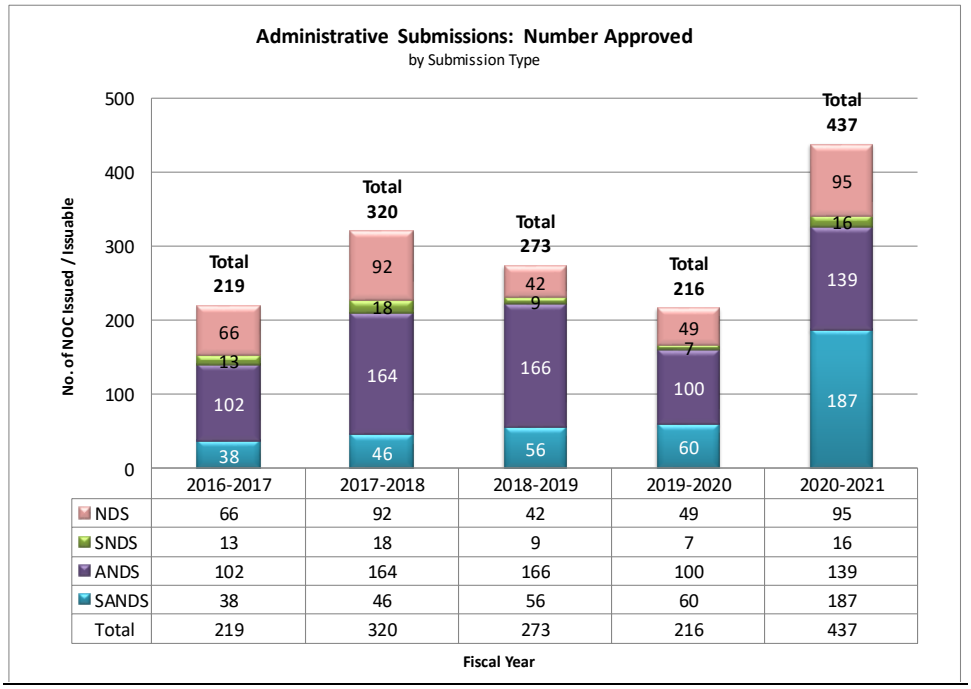
Administrative Submissions: Number Received by Submission Type



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
DINA	194	142	108	100	60
DIND	4	6	0	0	0
DINF	35	37	11	7	0
PDC	3	4	2	8	1
NDS	71	84	84	47	105
SNDS	20	17	19	14	27
ANDS	254	109	183	166	167
SANDS	35	43	45	78	225
NC	259	350	268	283	5
Total	875	792	720	703	590

APPROVALS

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



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NDS	66	92	42	49	95
SNDS	13	18	9	7	16
ANDS	102	164	166	100	139
SANDS	38	46	56	60	187
Total	219	320	273	216	437

[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	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NDS - Administrative					
NOTICE OF COMPLIANCE	65	92	42	49	95
NOC ON IP HOLD	1	0	0	0	0
NOC WITH CONDITIONS	0	0	0	0	0
SCREEN. DEFICIENCY NOTICE	6	5	0	0	2
CANCELLATION LETTER	1	3	4	6	3
PROCESSING HOLD LETTER	58	46	12	22	16
SNDS - Administrative					
NOTICE OF COMPLIANCE	12	18	9	7	16
NOC ON IP HOLD	1	0	0	0	0
CANCELLATION LETTER	2	1	7	1	2
SCREEN. DEFICIENCY NOTICE	0	0	0	0	1
PROCESSING HOLD LETTER	4	4	5	1	3
ANDS - Administrative					
NOTICE OF COMPLIANCE	77	157	165	99	137
NOC ON IP HOLD	25	3	1	1	2
SCREEN. DEFICIENCY NOTICE	10	1	5	0	3
CANCELLATION LETTER	3	8	6	23	14
PROCESSING HOLD LETTER	79	88	44	34	23
SANDS - Administrative					
NOTICE OF COMPLIANCE	36	46	56	60	187
NOC ON IP HOLD	2	0	0	0	0
SCREEN. DEFICIENCY NOTICE	2	0	2	0	0
CANCELLATION LETTER	1	2	9	10	12
PROCESSING HOLD LETTER	20	27	20	16	20
NC - Administrative					
NO OBJECTION LETTER	298	271	265	196	2
NC - HOLD (PATENT)	29	0	1	0	0
SCREEN. DEFICIENCY NOTICE	0	1	0	0	1
CANCELLATION LETTER	13	13	21	32	4
PROCESSING HOLD LETTER	6	2	16	12	2

DECISIONS

Administrative Applications (Division 1): Number of Decisions

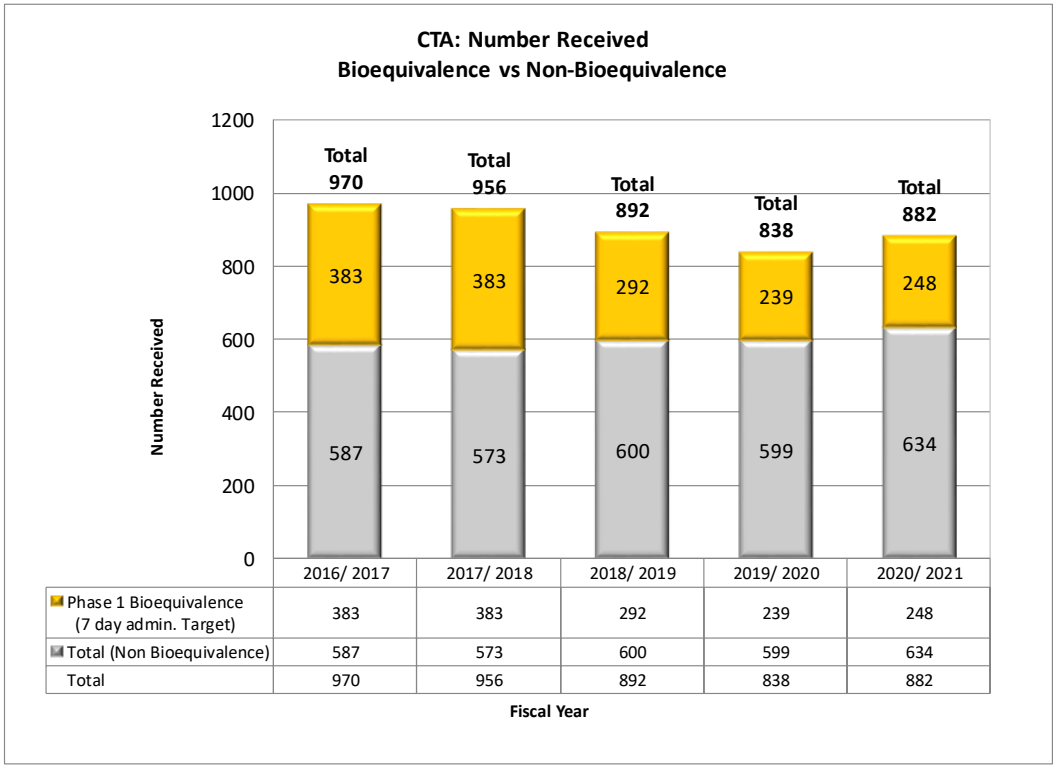
SUBMISSION TYPE - DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
DINA - Administrative					
NOTIFICATION FORM/DIN ISSUED	104	124	84	37	46
NO OBJECTION LETTER	0	0	2	1	1
SCREEN. DEFICIENCY NOTICE	63	11	8	0	0
CANCELLATION LETTER	4	8	11	20	11
PROCESSING HOLD LETTER	76	54	27	30	4
DIND - Administrative					
NOTIFICATION FORM/ DIN ISSUED	2	0	0	0	0
CANCELLATION LETTER	4	0	0	0	0
PROCESSING HOLD LETTER	9	0	0	0	0
DINF - Administrative					
NOTIFICATION FORM/ DIN ISSUED	29	9	0	7	0
NO OBJECTION LETTER	0	1	0	0	0
SCREEN. DEFICIENCY NOTICE	1	0	0	0	0
CANCELLATION LETTER	1	1	0	0	0
PROCESSING HOLD LETTER	24	16	7	0	0
PDC - Administrative					
NO OBJECTION LETTER	3	1	5	3	0
CANCELLATION LETTER	3	0	3	1	1
PROCESSING HOLD LETTER	1	0	2	0	0

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

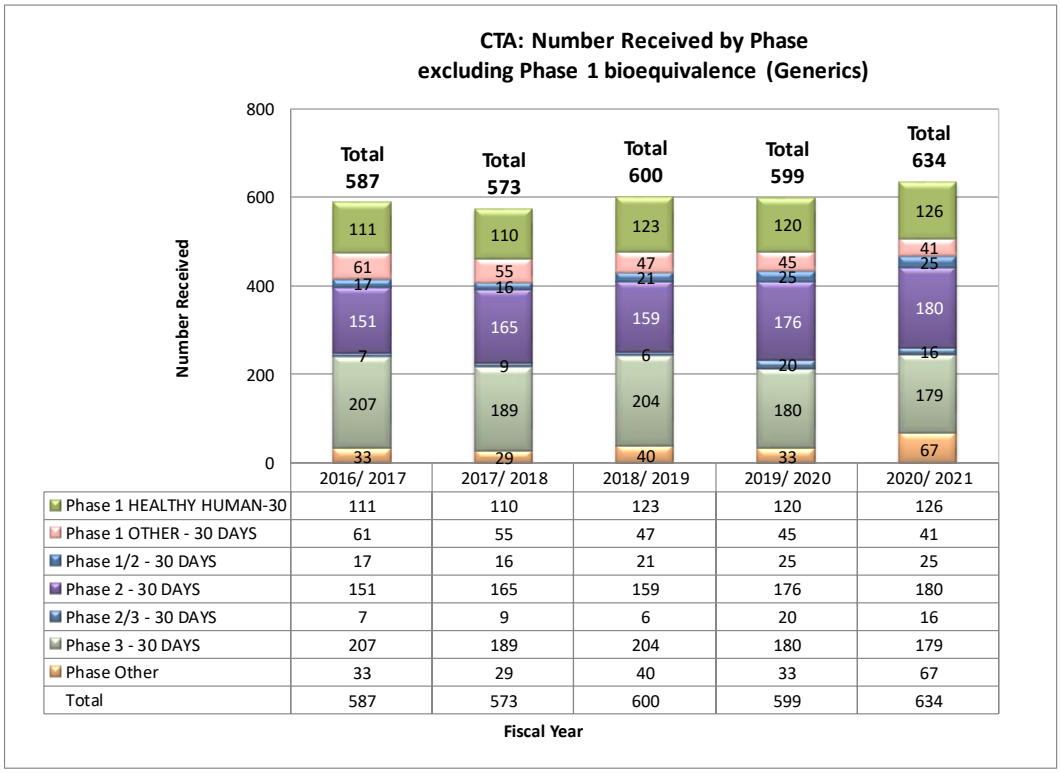
CTA: Number Received



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 Bioequivalence (7 day admin. Target)	383	383	292	239	248
Total (Non Bioequivalence)	587	573	600	599	634
Total	970	956	892	838	882

Fiscal Year

CTA: Number Received by Phase excluding Bioequivalence (Generics)



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 HEALTHY HUMAN-30	111	110	123	120	126
Phase 1 OTHER - 30 DAYS	61	55	47	45	41
Phase 1/2 - 30 DAYS	17	16	21	25	25
Phase 2 - 30 DAYS	151	165	159	176	180
Phase 2/3 - 30 DAYS	7	9	6	20	16
Phase 3 - 30 DAYS	207	189	204	180	179
Phase Other	33	29	40	33	67
Total	587	573	600	599	634

Fiscal Year

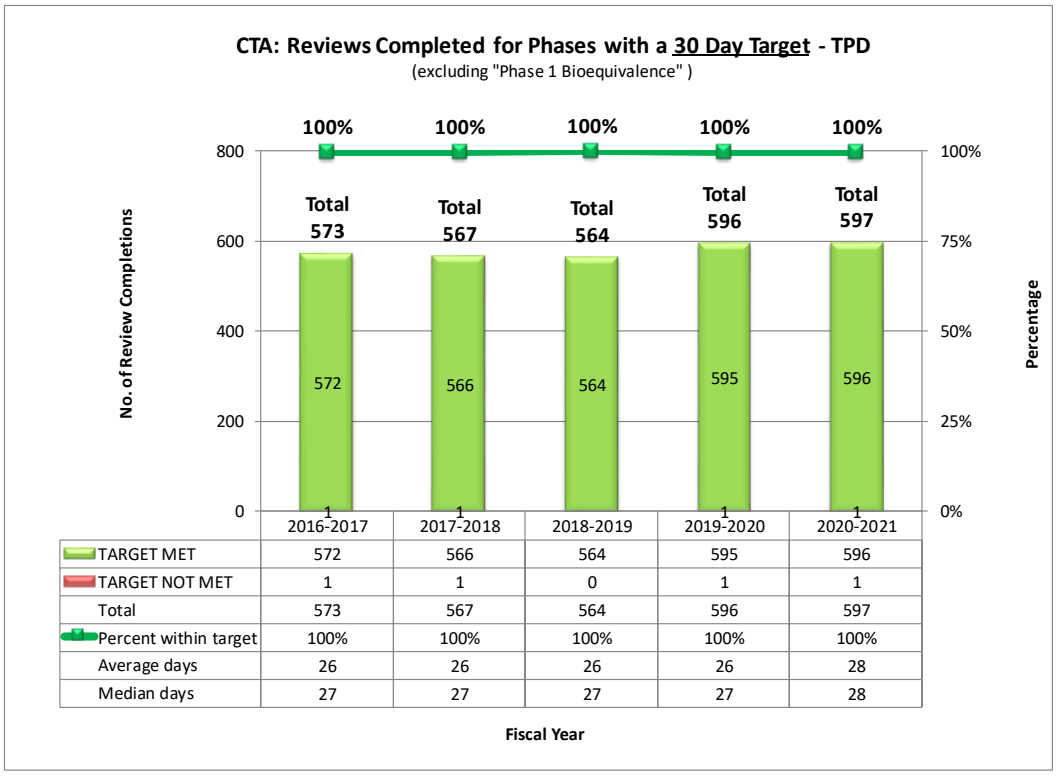
DECISION DOCUMENTS

CTA: Number of Decisions by Type

CTA (Total)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	926	898	821	775	803
NOTICE OF AUTHORIZATION	0	0	0	0	9
CANCELLED BY COMPANY DURING REVIEW	36	53	37	60	47
CANCELLED BY COMPANY AT PROCESSING	4	11	11	15	12
CTA Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	386	379	286	229	240
CANCELLED BY COMPANY DURING REVIEW	3	3	5	8	5
CANCELLED BY COMPANY AT PROCESSING	0	1	2	2	2
CTA (30 day target)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	540	519	535	546	563
CANCELLED BY COMPANY DURING REVIEW	33	50	32	52	42
CANCELLED BY COMPANY AT PROCESSING	4	10	9	13	10
NOT SATISFACTORY NOTICE	0	0	1	0	0

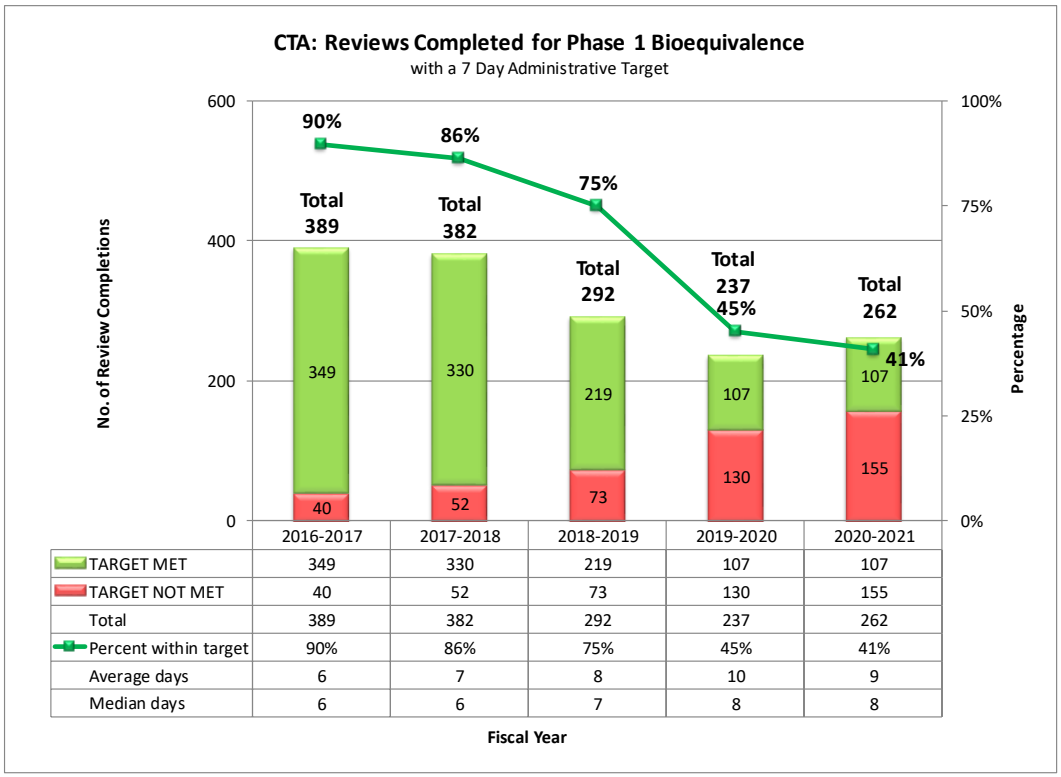
PERFORMANCE

CTA: Reviews Completed for Phases with a 30 Day Target



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
TARGET MET	572	566	564	595	596
TARGET NOT MET	1	1	0	1	1
Total	573	567	564	596	597
Percent within target	100%	100%	100%	100%	100%
Average days	26	26	26	26	28
Median days	27	27	27	27	28

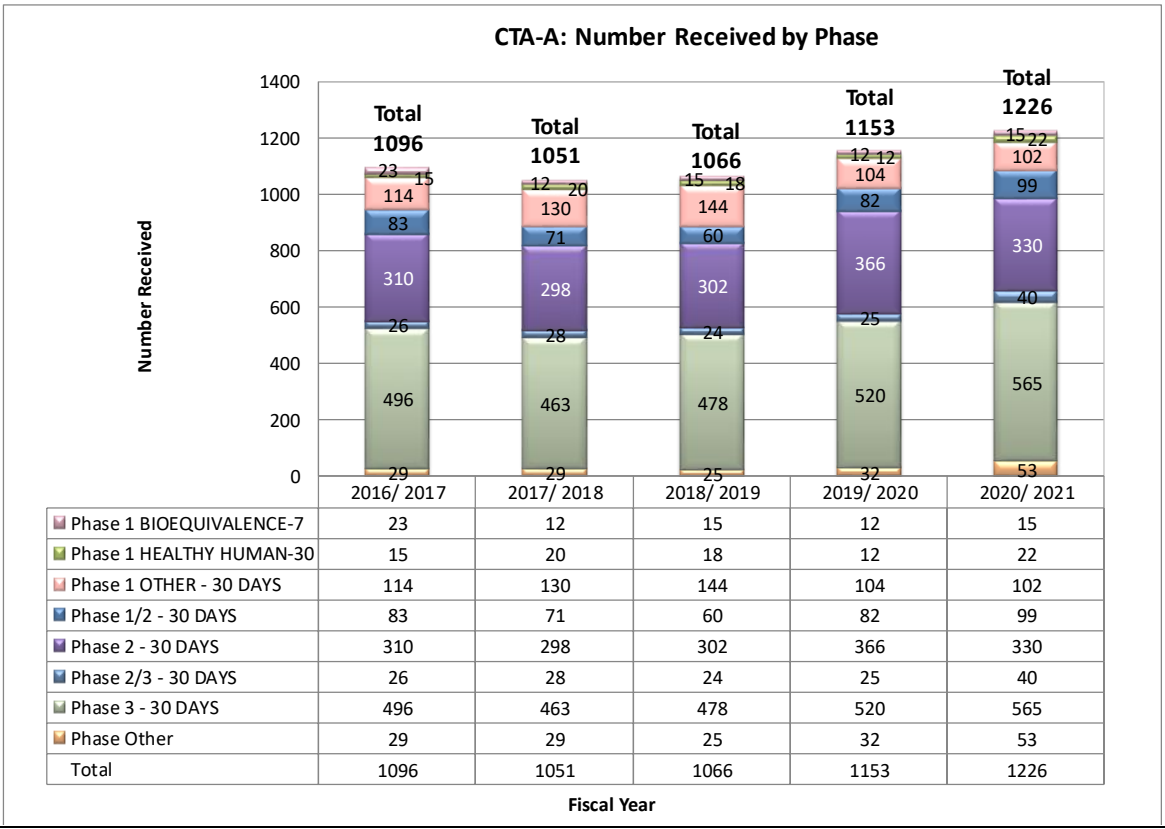
CTA: Reviews Completed for Phases with a 7 Day Administrative Target



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
TARGET MET	349	330	219	107	107
TARGET NOT MET	40	52	73	130	155
Total	389	382	292	237	262
Percent within target	90%	86%	75%	45%	41%
Average days	6	7	8	10	9
Median days	6	6	7	8	8

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 BIOEQUIVALENCE-7	23	12	15	12	15
Phase 1 HEALTHY HUMAN-30	15	20	18	12	22
Phase 1 OTHER - 30 DAYS	114	130	144	104	102
Phase 1/2 - 30 DAYS	83	71	60	82	99
Phase 2 - 30 DAYS	310	298	302	366	330
Phase 2/3 - 30 DAYS	26	28	24	25	40
Phase 3 - 30 DAYS	496	463	478	520	565
Phase Other	29	29	25	32	53
Total	1096	1051	1066	1153	1226

DECISIONS

CTA-A: Number of Decisions by Type

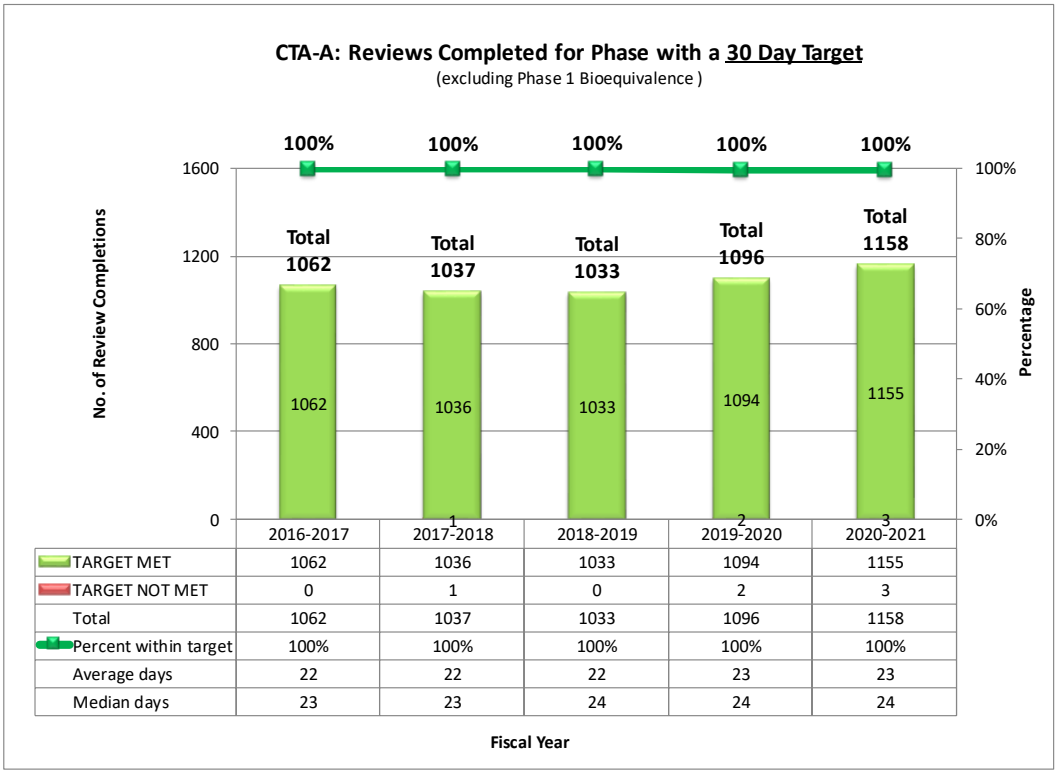
CTA-A (Total)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	1070	1037	1032	1079	1160
NOTICE OF AUTHORIZATION	0	0	0	0	10
CANCELLED BY COMPANY DURING REVIEW	15	11	15	30	16
CANCELLED BY COMPANY AT PROCESSING	0	1	3	33	50

CTA-A Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	23	12	12	13	15
CANCELLED BY COMPANY DURING REVIEW	0	0	2	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0

CTA-A (30 day target)					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	1047	1025	1020	1066	1145
CANCELLED BY COMPANY DURING REVIEW	15	11	13	30	16
CANCELLED BY COMPANY AT PROCESSING	0	1	3	33	50
NOT SATISFACTORY NOTICE	0	0	0	1	0
REJECTION LETTER (SCR)	0	0	0	1	0

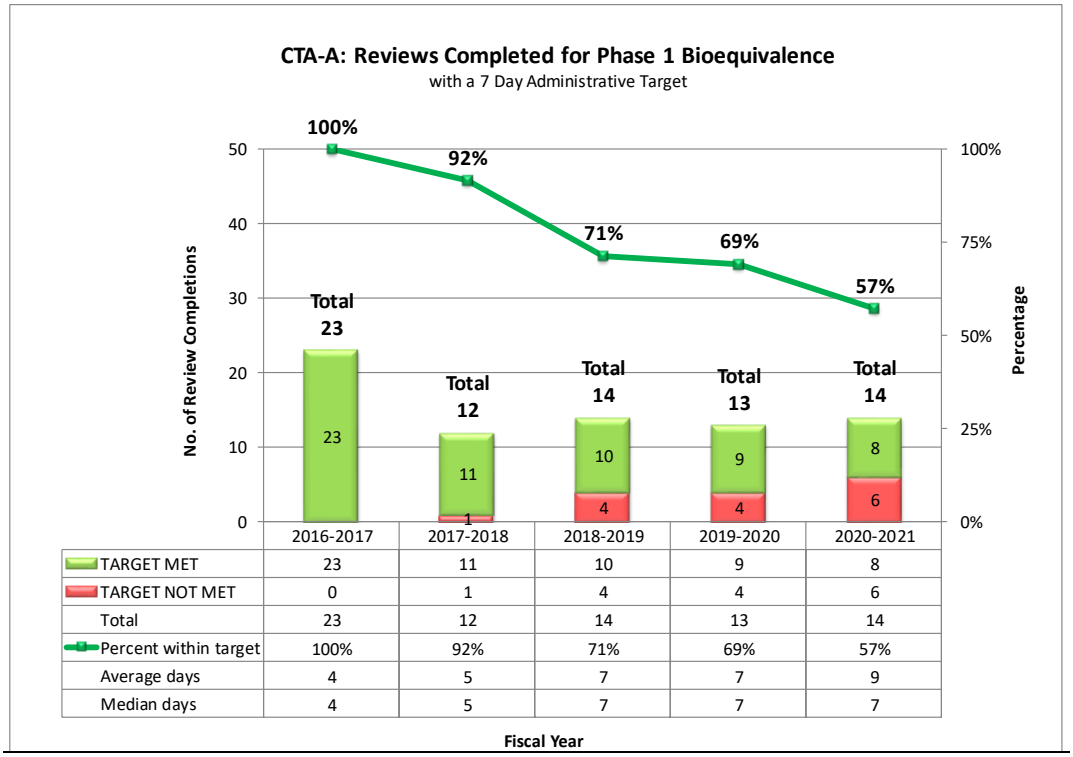
PERFORMANCE

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



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
TARGET MET	1062	1036	1033	1094	1155
TARGET NOT MET	0	1	0	2	3
Total	1062	1037	1033	1096	1158
Percent within target	100%	100%	100%	100%	100%
Average days	22	22	22	23	23
Median days	23	23	24	24	24

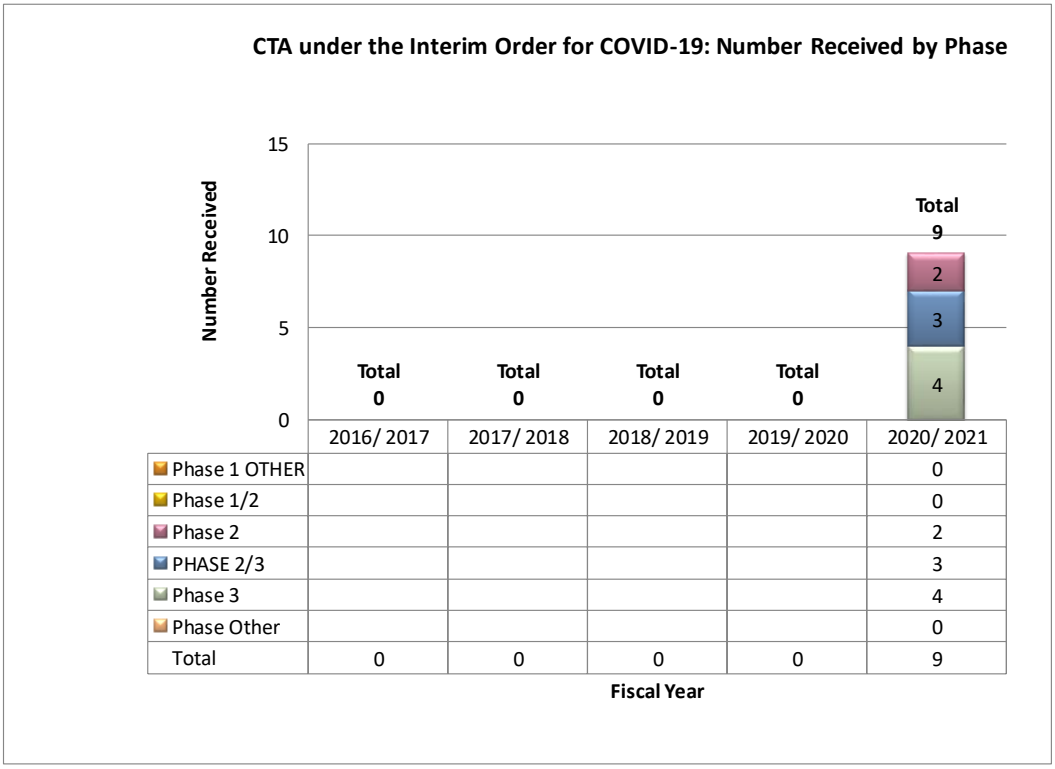
CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target



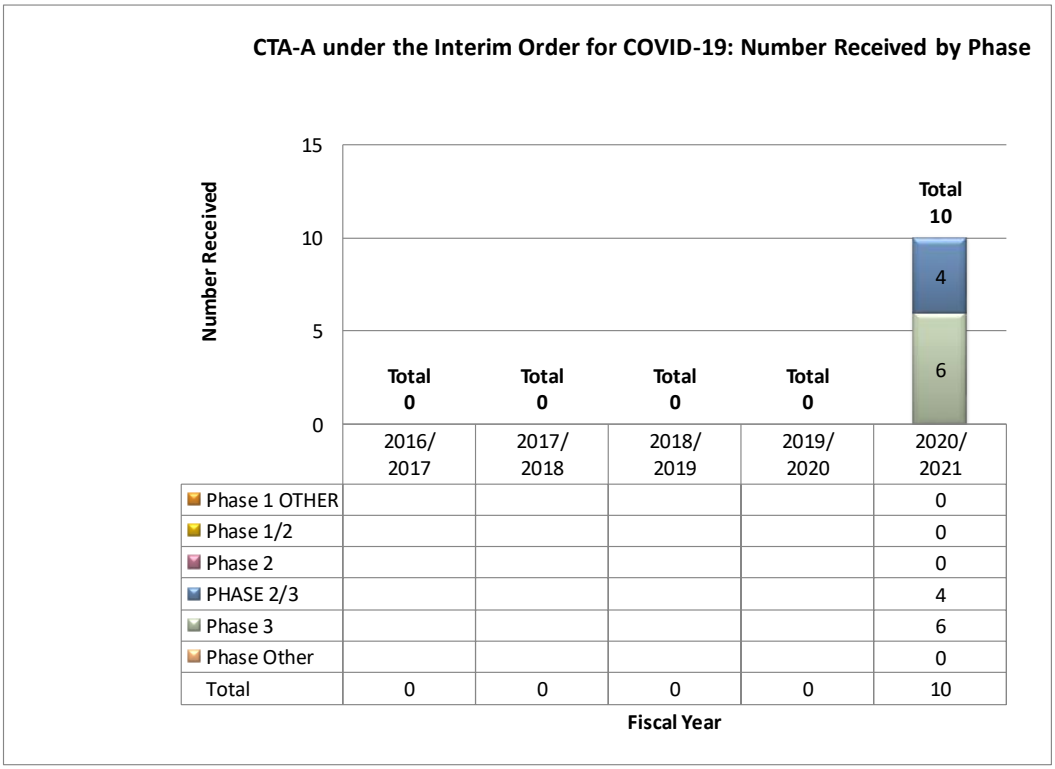
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
TARGET MET	23	11	10	9	8
TARGET NOT MET	0	1	4	4	6
Total	23	12	14	13	14
Percent within target	100%	92%	71%	69%	57%
Average days	4	5	7	7	9
Median days	4	5	7	7	7

CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

CTA: Number Received under the Interim Order Covid-19 by phase



CTA-A: Number Received under the Interim Order Covid-19 by phase



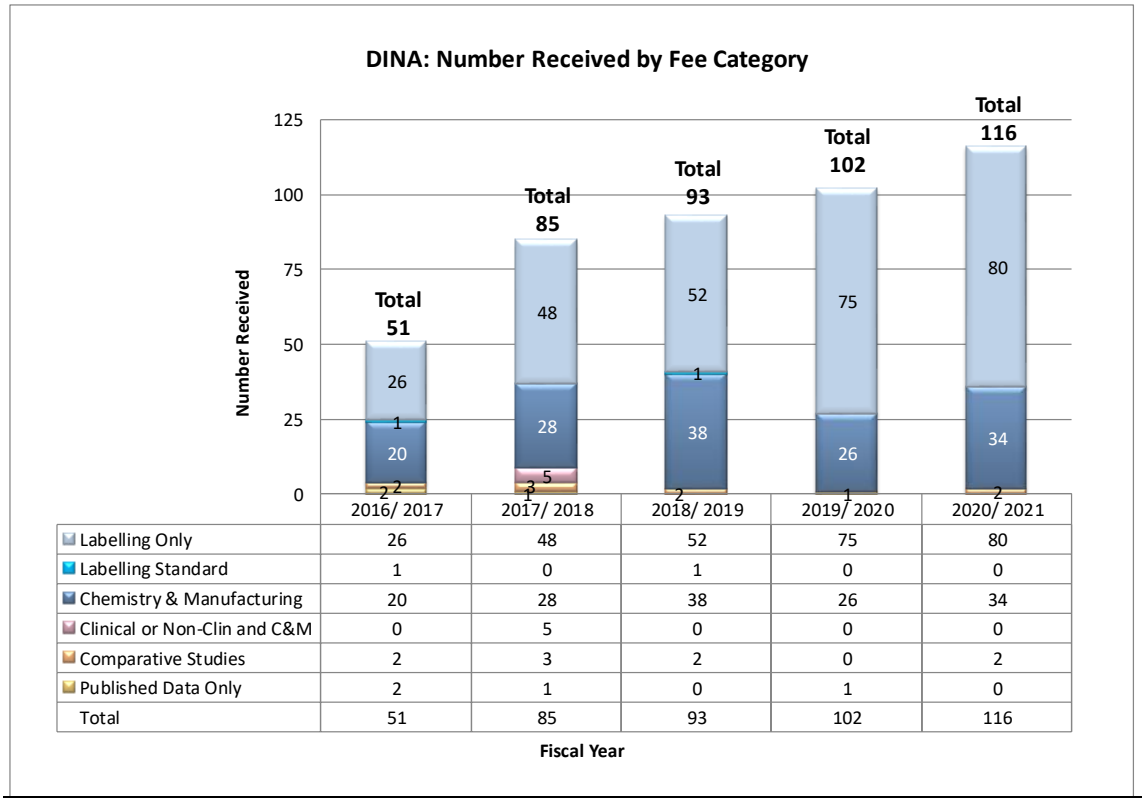
DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

RECEIVED

DINA: Number Received by Fee Category

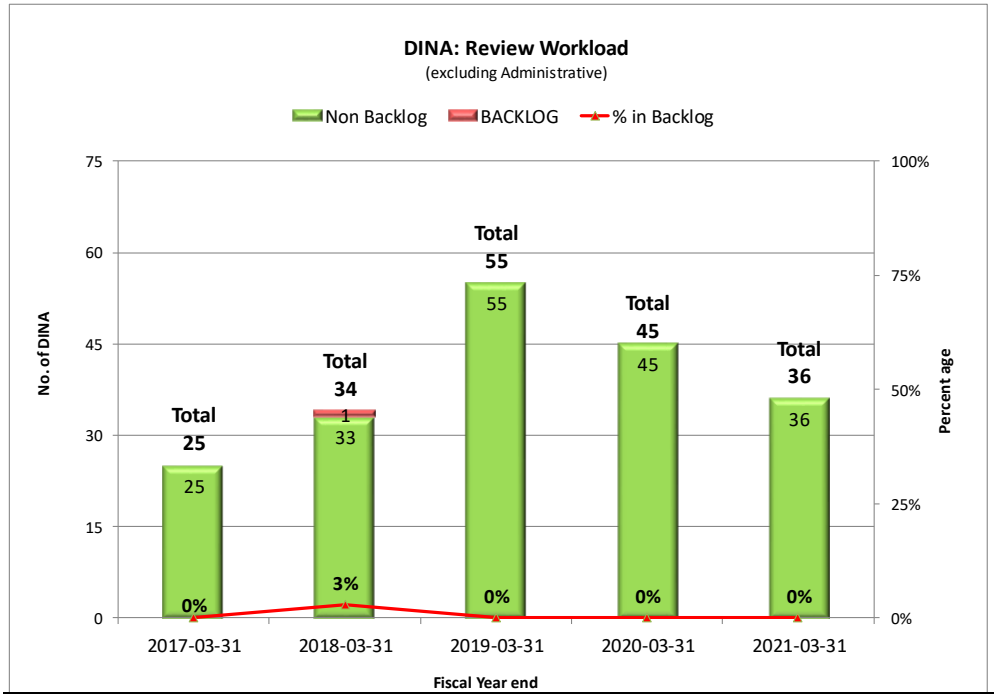


	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Labelling Only	26	48	52	75	80
Labelling Standard	1	0	1	0	0
Chemistry & Manufacturing	20	28	38	26	34
Clinical or Non-Clin and C&M	0	5	0	0	0
Comparative Studies	2	3	2	0	2
Published Data Only	2	1	0	1	0
Total	51	85	93	102	116

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

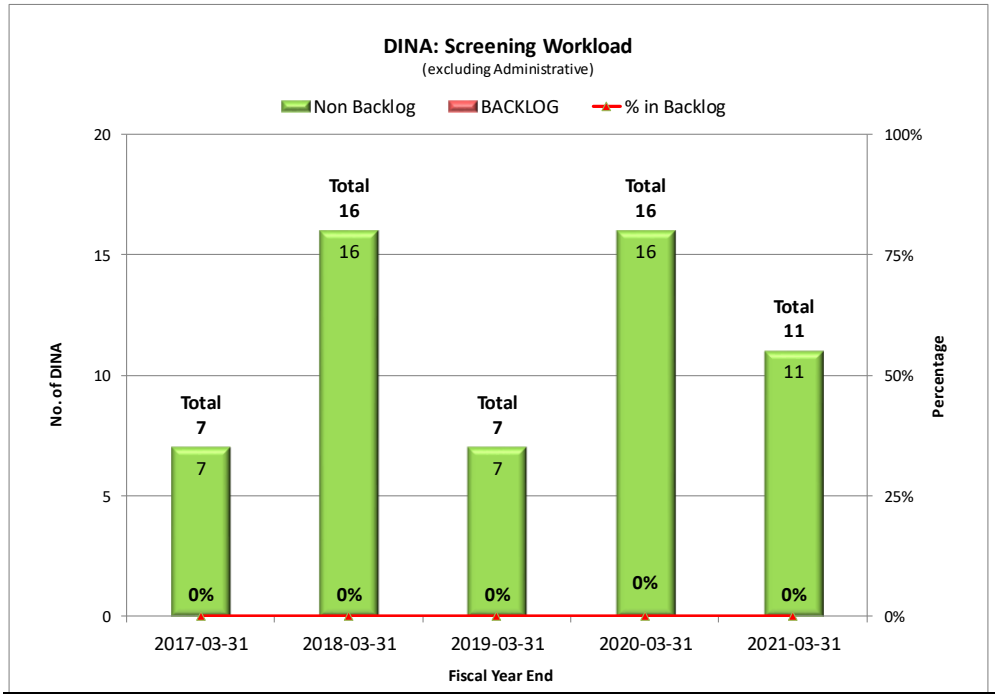


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Labelling Only	13	13	27	29	16
Backlog	*0*	*1*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	0	0	1	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	12	19	26	15	19
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	1	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**25**	**34**	**55**	**45**	**36**
Non Backlog	**25**	**33**	**55**	**45**	**36**
BACKLOG	**0**	**1**	**0**	**0**	**0**
% in Backlog	**0%**	**3%**	**0%**	**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	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
Labelling Only	4	8	3	10	7
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	0	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	2	4	3	6	4
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	2	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	2	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**7**	**16**	**7**	**16**	**11**
Non Backlog	**7**	**16**	**7**	**16**	**11**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINA: Number of Decisions by Fee Category

CATEGORY / DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
DINA - LABELLING ONLY					
NOTIFICATION FORM/DIN ISSUED	3	12	9	2	19
NO OBJECTION LETTER	4	25	29	59	71
CANCELLED BY COMPANY	6	3	7	2	6
NOTICE OF DEFICIENCY	1	-	-	-	1
NOTICE OF NON-COMPLIANCE	1	-	2	-	-
REJECTION LETTER (SCREENING)	-	1	-	-	-
SCREENING DEFICIENCY NOTICE	9	8	6	4	3
DINA - PUBLISHED DATA ONLY					
NO OBJECTION LETTER	2	-	1	-	-
SCREENING DEFICIENCY NOTICE	-	1	-	-	-
CANCELLED BY COMPANY	1	-	-	1	-
NOTICE OF NON-COMPLIANCE	1	-	-	-	-
NOT SATISFACTORY NOTICE	1	-	-	-	-
DINA - CHEMISTRY & MANUFACTURING					
NOTIFICATION FORM/DIN ISSUED	6	13	12	15	13
NOTICE OF DEFICIENCY	1	2	3	-	-
REJECTION LETTER (SCREENING)	3	-	-	-	-
SCREENING DEFICIENCY NOTICE	17	9	7	8	20
CANCELLED BY COMPANY	4	3	7	2	1
NO OBJECTION LETTER	5	3	11	20	17
NEW DRUG LETTER REVIEW	-	1	-	-	-
NOTICE OF NON-COMPLIANCE	8	6	7	6	2
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	-	1
NOTIFICATION FORM/DIN ISSUED	-	-	1	1	-
DINA - COMPARATIVE STUDIES					
NOTIFICATION FORM/DIN ISSUED	2	1	2	1	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	-	-

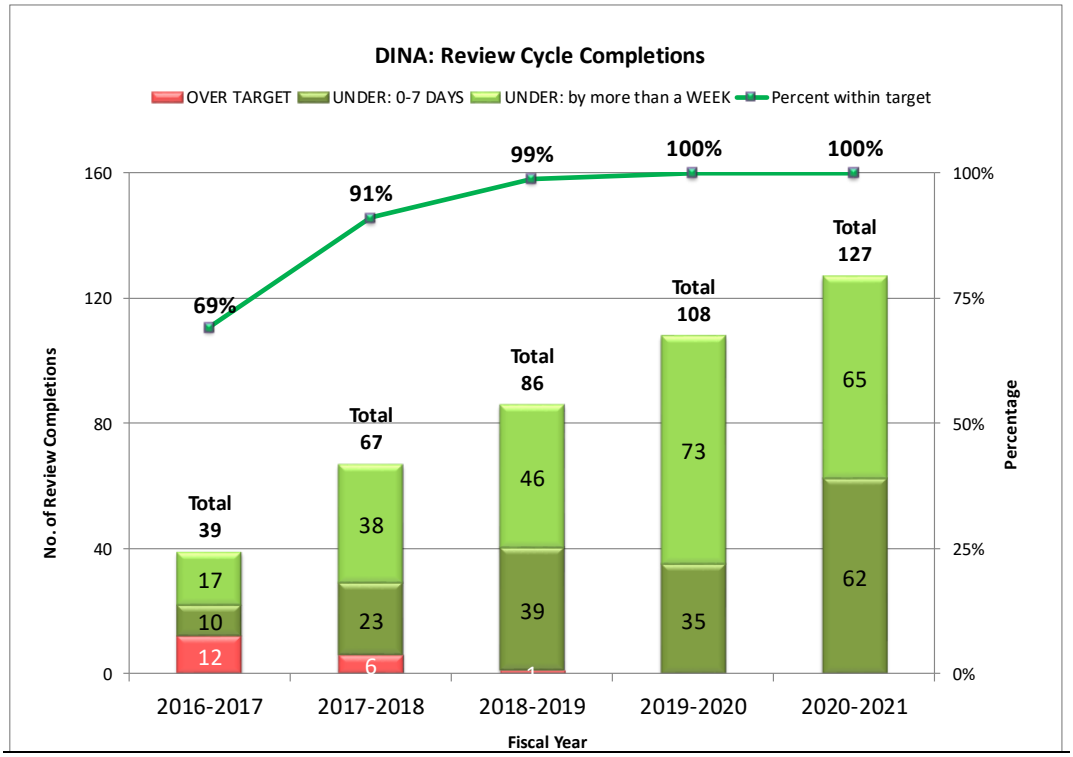
REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Request for Reconsideration of Final Decisions

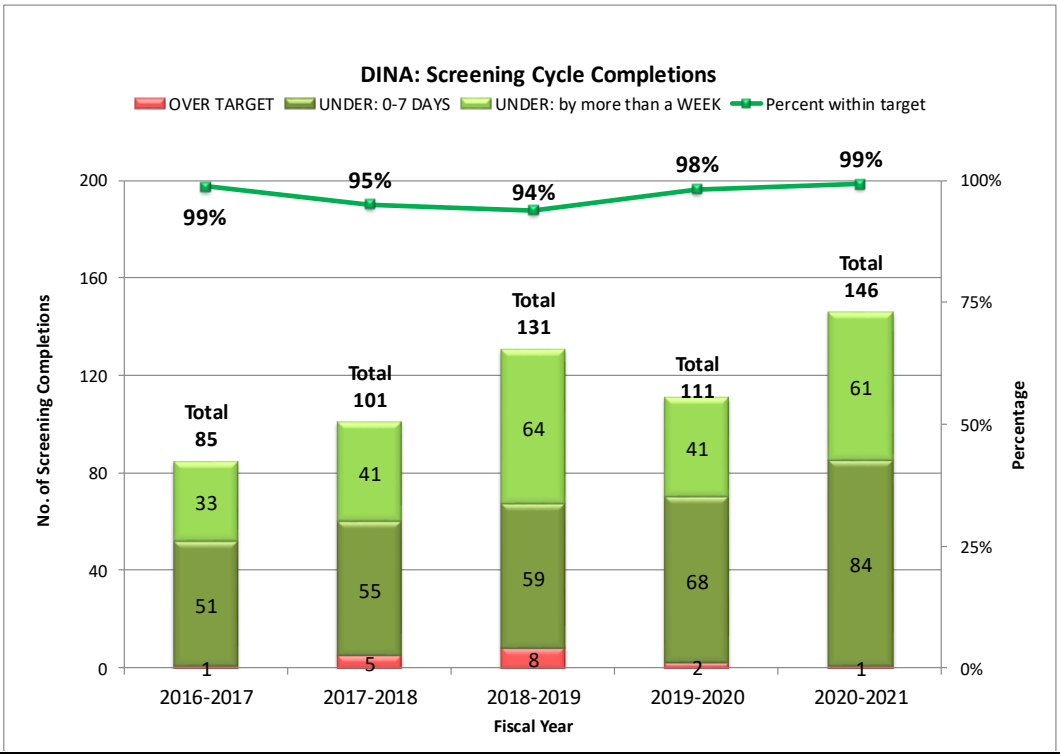
DINA - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	Submission Status (as of June 2021)
Total Received	1	1	0	0	0		
Total Granted	*1*	*1*	*0*	*0*	*0*		
Granted	0	1	0	0	0	New Drug Letter	Cancelled by Company
Granted	1	0	0	0	0	NON-Withdrawal	Cleared
Total Denied	*0*	*0*	*0*	*0*	*0*		

PERFORMANCE

DINA: Review Cycle Completions



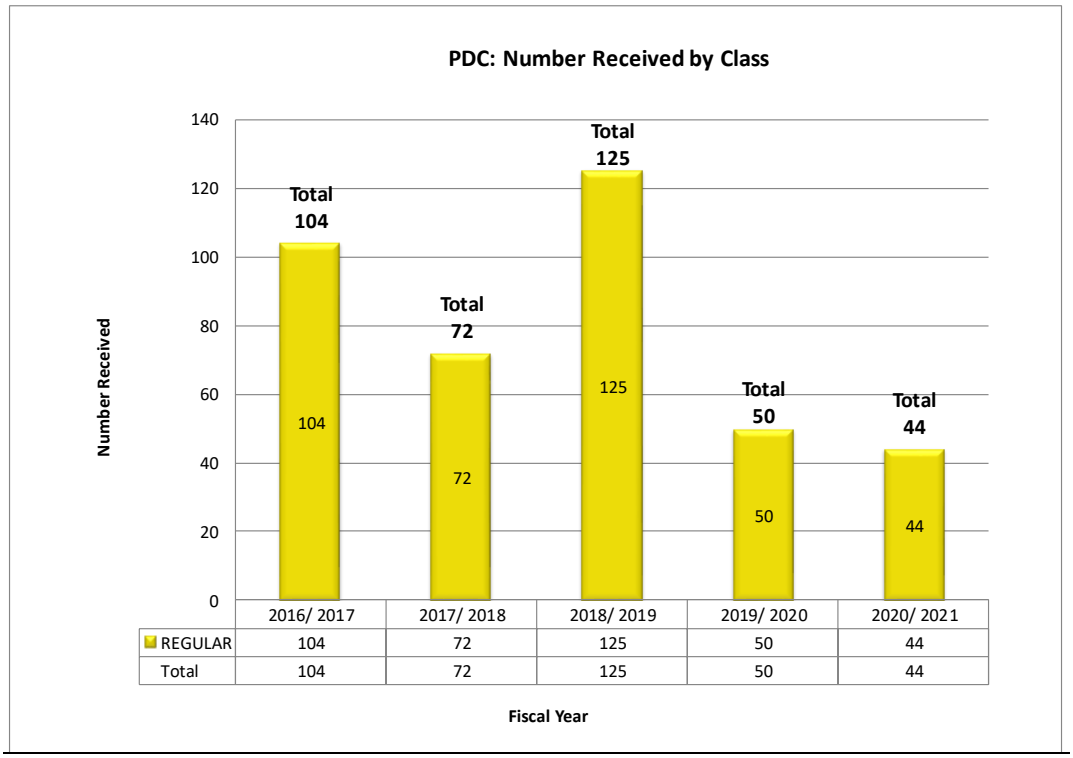
DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

RECEIVED

PDC: Number Received



DECISIONS

PDC: Number of Decision by Type

PDC- Regular					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
CANCELLED BY COMPANY	18	15	20	18	17
NO OBJECTION LETTER	80	35	131	39	31
NOT SATISFACTORY NOTICE	1	0	0	0	1
REJECTION LETTER (SCREENING)	0	0	0	0	0

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

PDC: Request for Reconsideration of Final Decisions

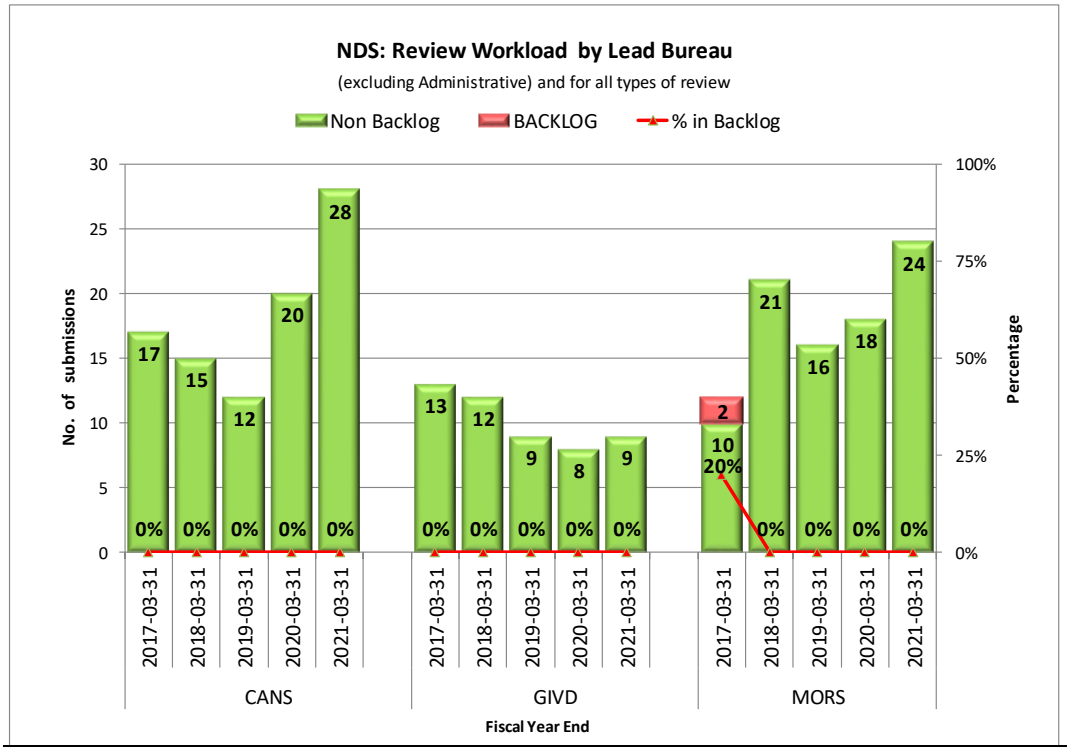
PDC - Reconsideration of Final Decisions by Year Requested Fiscal Year of Request (April 1 - March 31)					
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Total Received	0	0	0	0	0

APPENDIX A - Lead Bureau Summaries

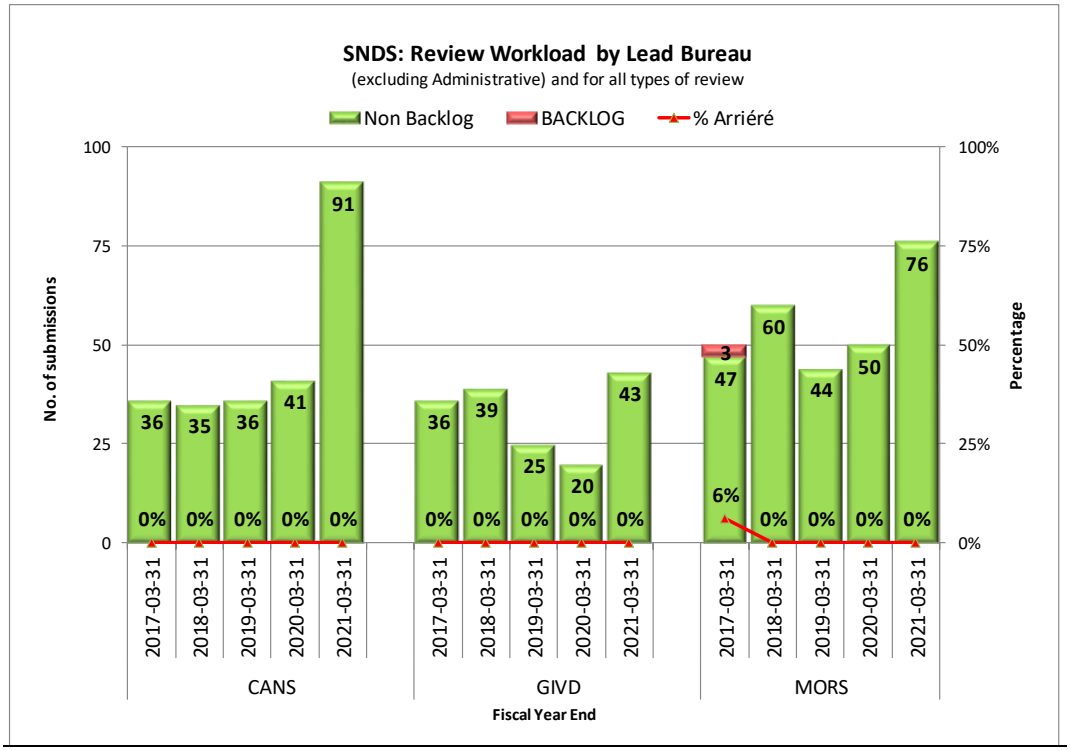
NDS & SNDS

WORKLOAD by Lead Bureau

NDS: Review Workload by Lead Bureau

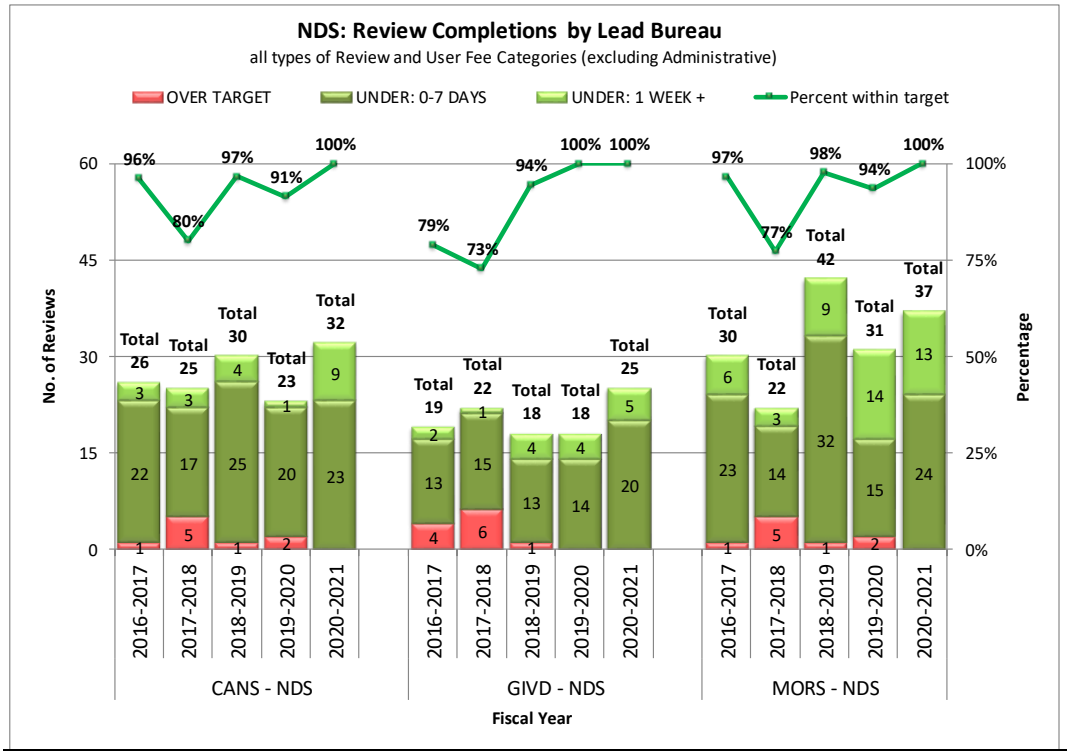


SNDS: Review Workload by Lead Bureau

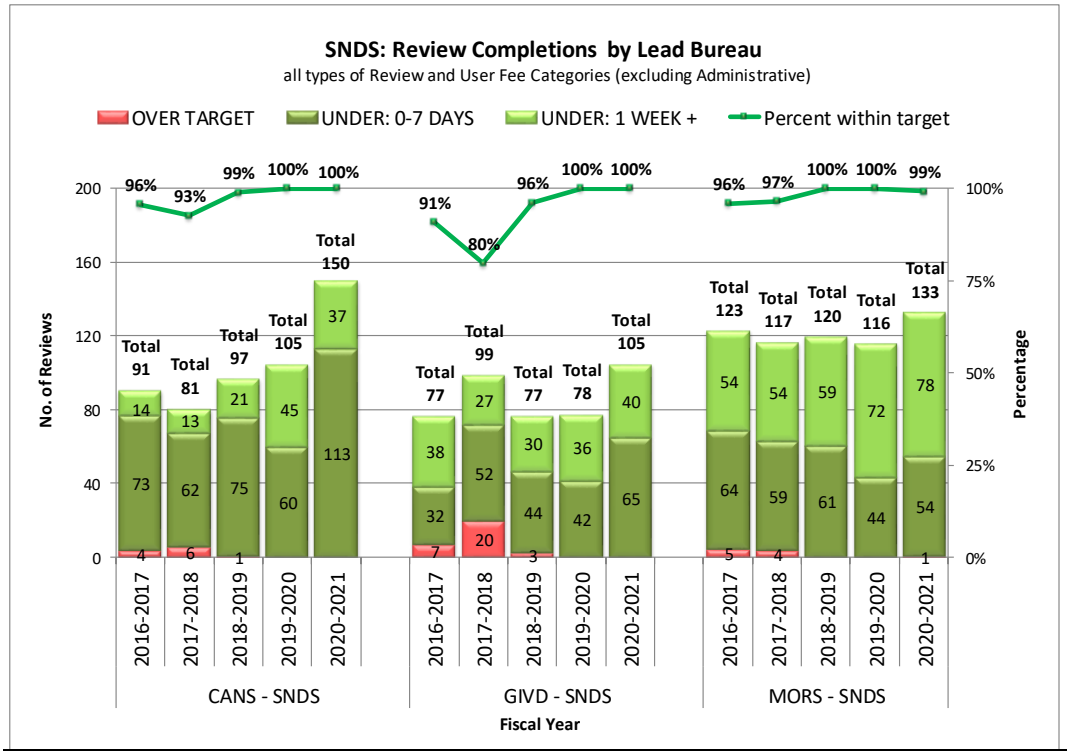


PERFORMANCE by Lead Bureau

NDS: Review Performance by Lead Bureau

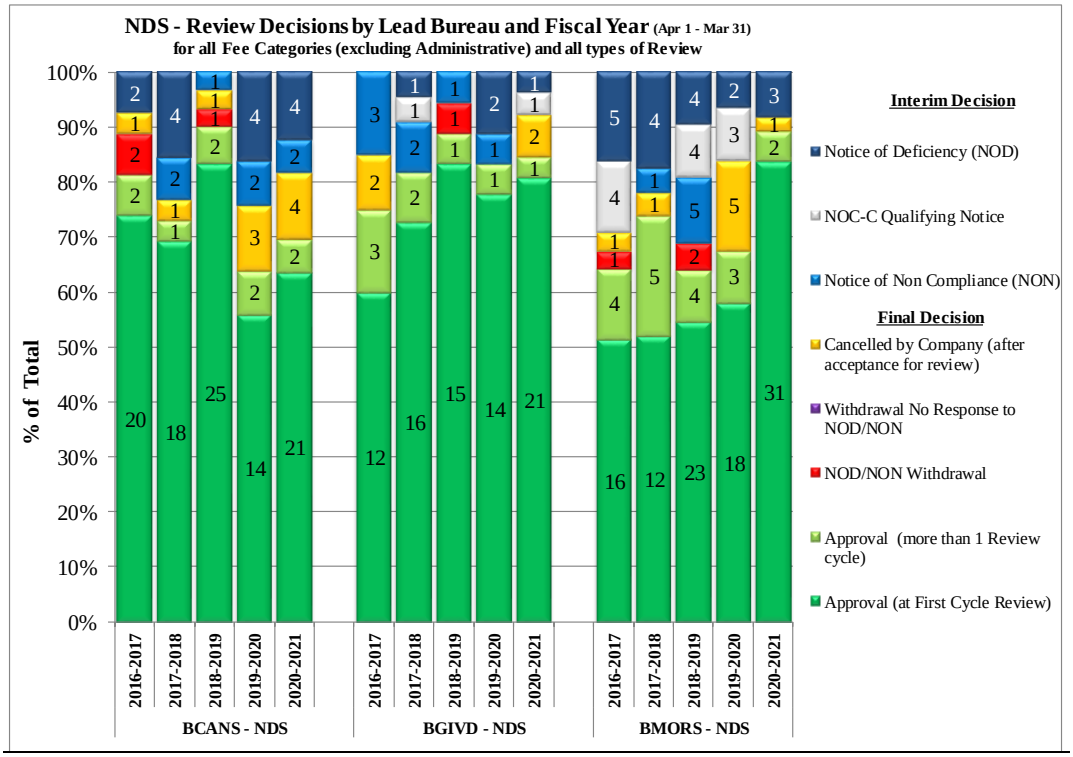


SNDS: Review Performance by Lead Bureau

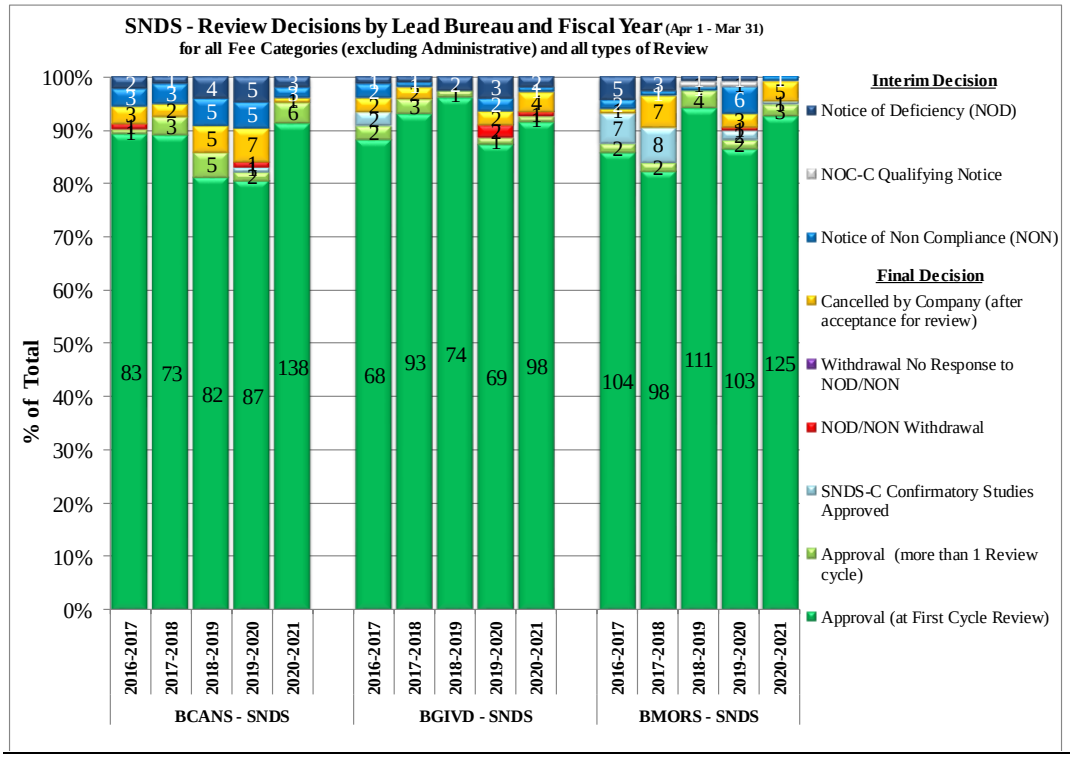


REVIEW DECISIONS by Lead Bureau

NDS: Review Decisions by Lead Bureau

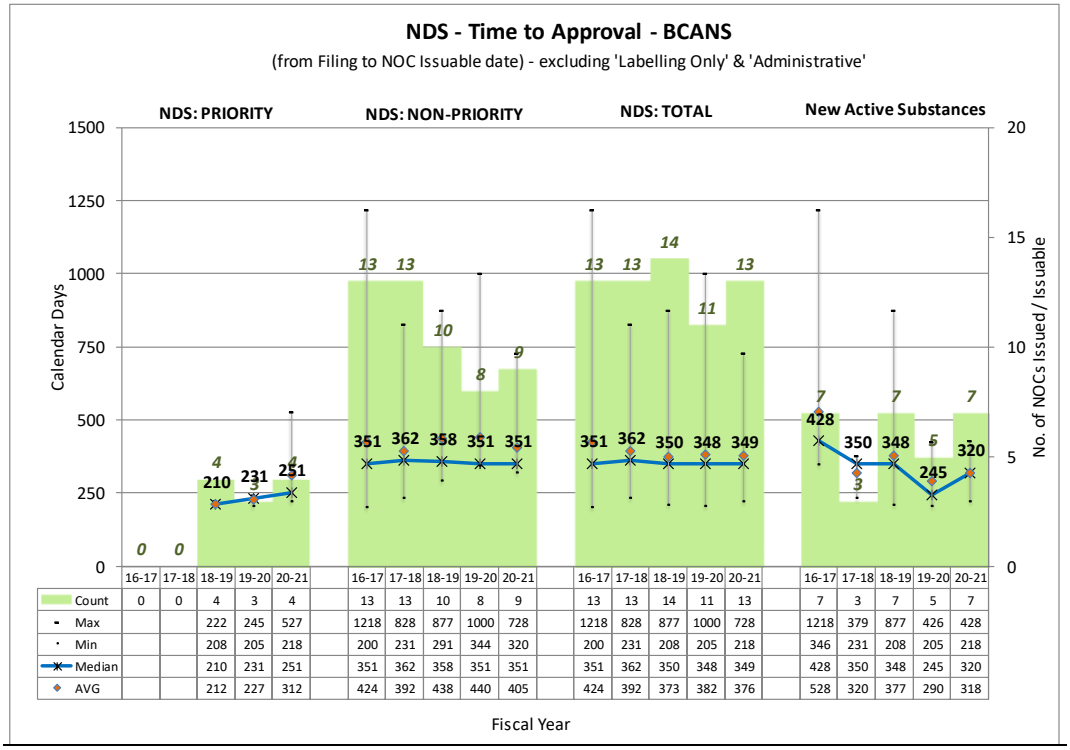


SNDS: Review Decisions by Lead Bureau



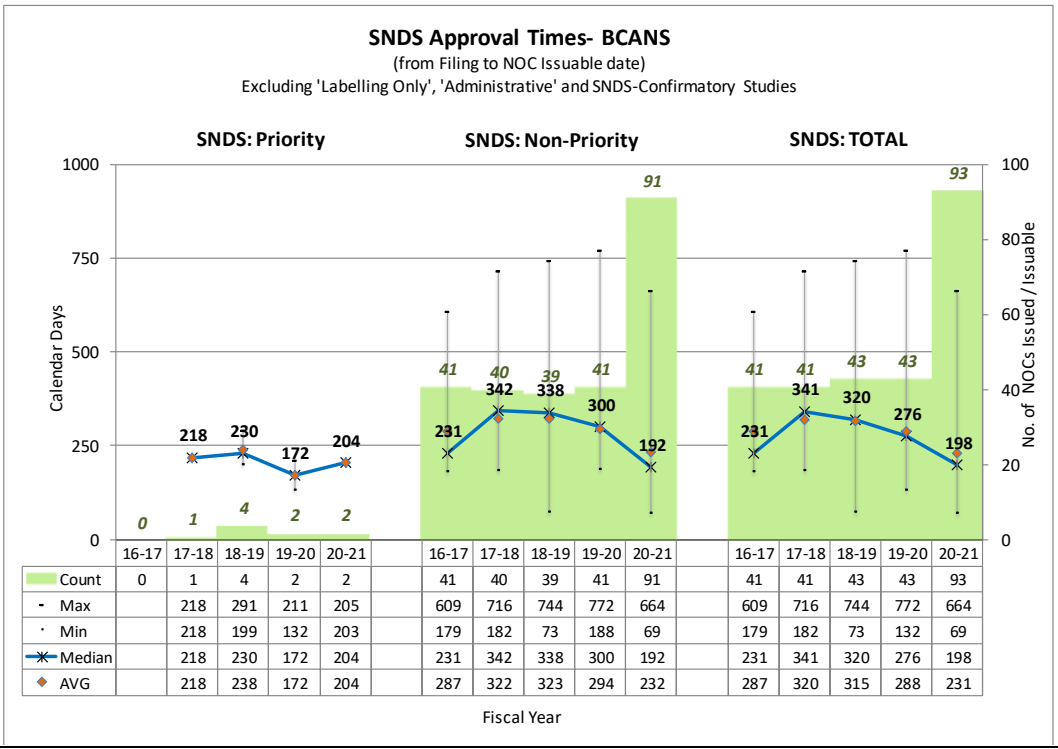
APPROVALS: Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)

NDS Time to Approval: BCANS



	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	0	0	4	3	4	13	13	10	8	9	13	13	14	11	13	7	3	7	5	7
Max			222	245	527	1218	828	877	1000	728	1218	828	877	1000	728	1218	379	877	426	428
Min			208	205	218	200	231	291	344	320	200	231	208	205	218	346	231	208	205	218
Median			210	231	251	351	362	358	351	351	351	362	350	348	349	428	350	348	245	320
AVG			212	227	312	424	392	438	440	405	424	392	373	382	376	528	320	377	290	318

SNDS Time to Approval: BCANS

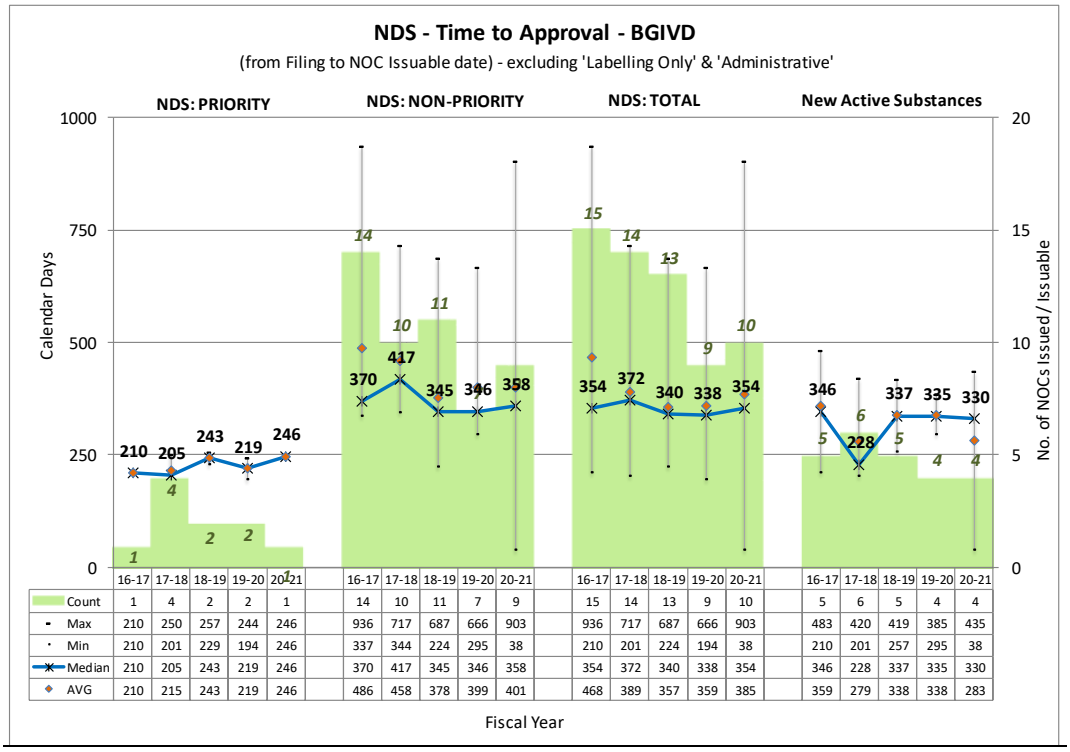


	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	0	1	4	2	2	41	40	39	41	91	41	41	43	43	93
Max		218	291	211	205	609	716	744	772	664	609	716	744	772	664
Min		218	199	132	203	179	182	73	188	69	179	182	73	132	69
Median		218	230	172	204	231	342	338	300	192	231	341	320	276	198
AVG		218	238	172	204	287	322	323	294	232	287	320	315	288	231

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.

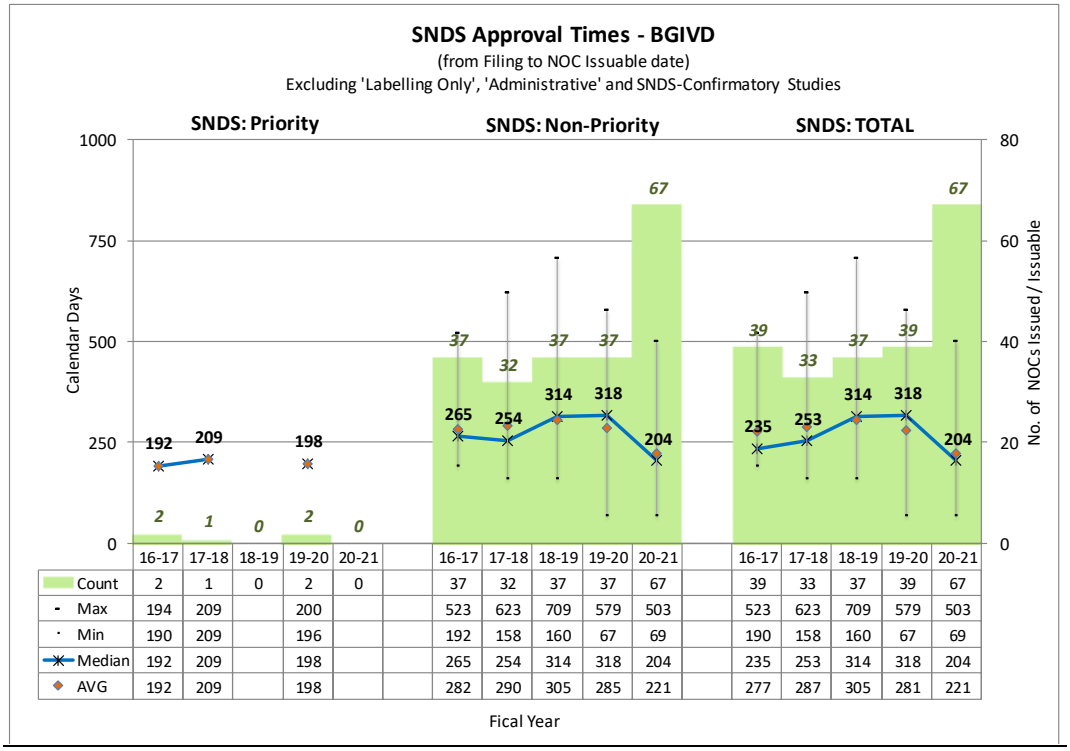
APPROVALS: Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)

NDS Time to Approval: BGIVD



	NDS: PRIORITY					NDS: NON-PRIORITY					NDS: TOTAL					New Active Substances				
	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	1	4	2	2	1	14	10	11	7	9	15	14	13	9	10	5	6	5	4	4
Max	210	250	257	244	246	936	717	687	666	903	936	717	687	666	903	483	420	419	385	435
Min	210	201	229	194	246	337	344	224	295	38	210	201	224	194	38	210	201	257	295	38
Median	210	205	243	219	246	370	417	345	346	358	354	372	340	338	354	346	228	337	335	330
AVG	210	215	243	219	246	486	458	378	399	401	468	389	357	359	385	359	279	338	338	283

SNDS Time to Approval: BGIVD

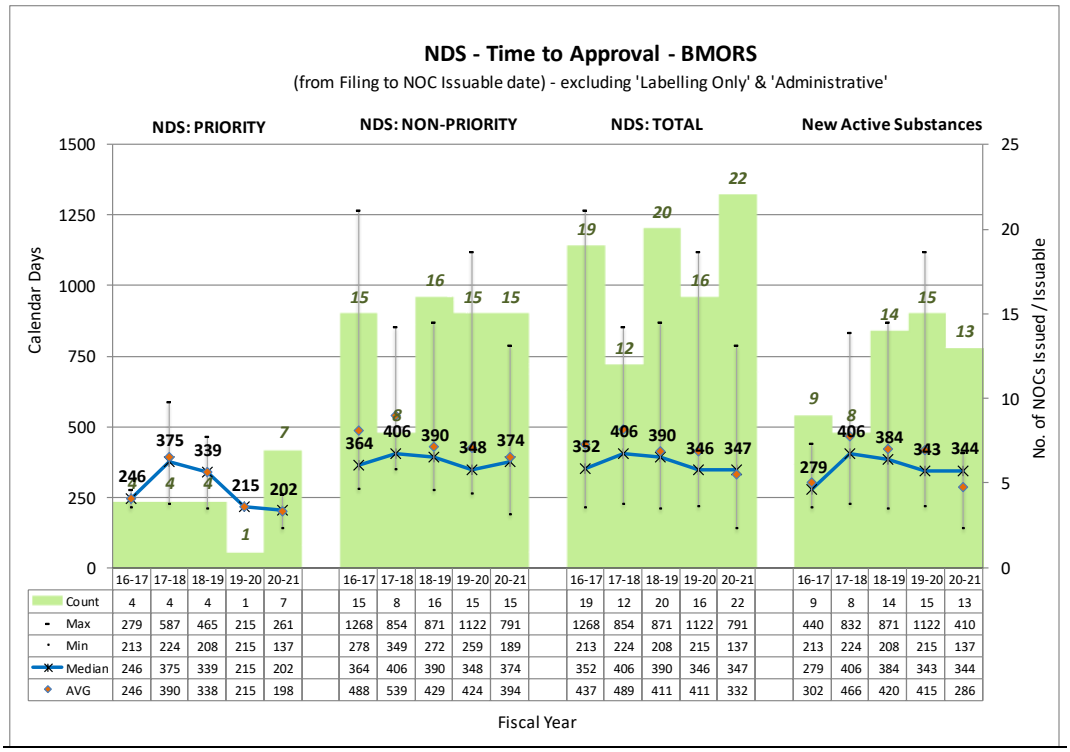


	SNDS: Priority					SNDS: Non-Priority					SNDS: TOTAL				
	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	2	1	0	2	0	37	32	37	37	67	39	33	37	39	67
Max	194	209		200		523	623	709	579	503	523	623	709	579	503
Min	190	209		196		192	158	160	67	69	190	158	160	67	69
Median	192	209		198		265	254	314	318	204	235	253	314	318	204
AVG	192	209		198		282	290	305	285	221	277	287	305	281	221

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.

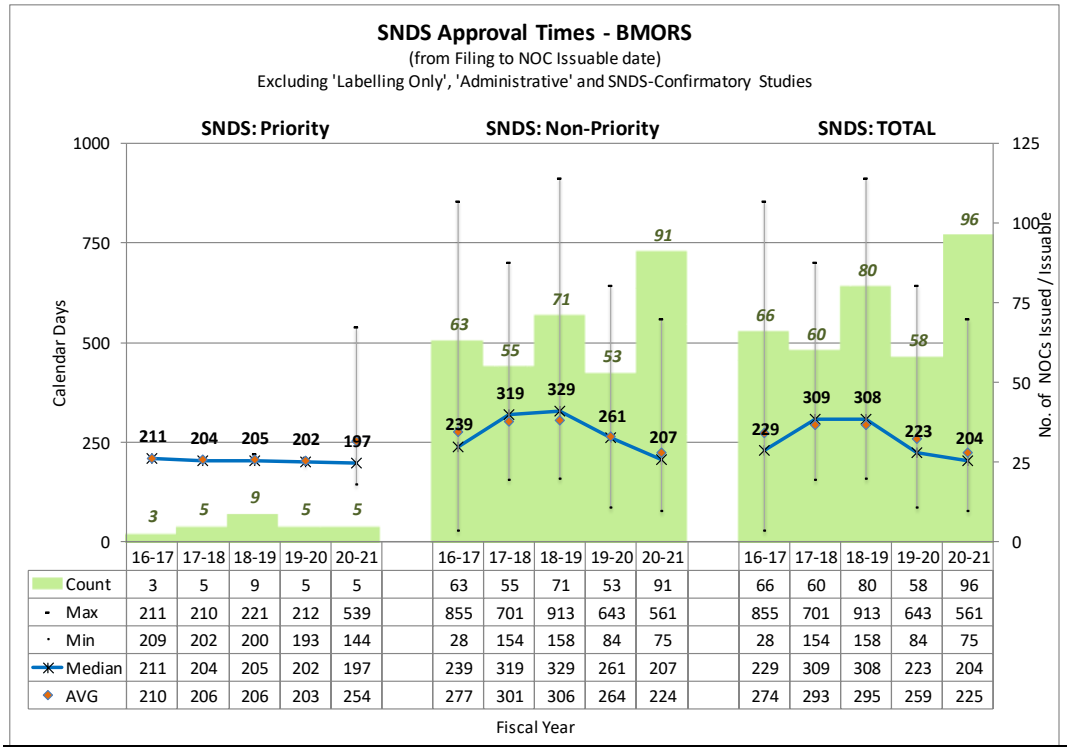
APPROVALS - Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)

NDS Time to Approval: BMORS



	16-17	17-18	18-19	19-20	20-21		16-17	17-18	18-19	19-20	20-21		16-17	17-18	18-19	19-20	20-21		16-17	17-18	18-19	19-20	20-21
Count	4	4	4	1	7		15	8	16	15	15		19	12	20	16	22		9	8	14	15	13
Max	279	587	465	215	261		1268	854	871	1122	791		1268	854	871	1122	791		440	832	871	1122	410
Min	213	224	208	215	137		278	349	272	259	189		213	224	208	215	137		213	224	208	215	137
Median	246	375	339	215	202		364	406	390	348	374		352	406	390	346	347		279	406	384	343	344
AVG	246	390	338	215	198		488	539	429	424	394		437	489	411	411	332		302	466	420	415	286

SNDS Time to Approval: BMORS



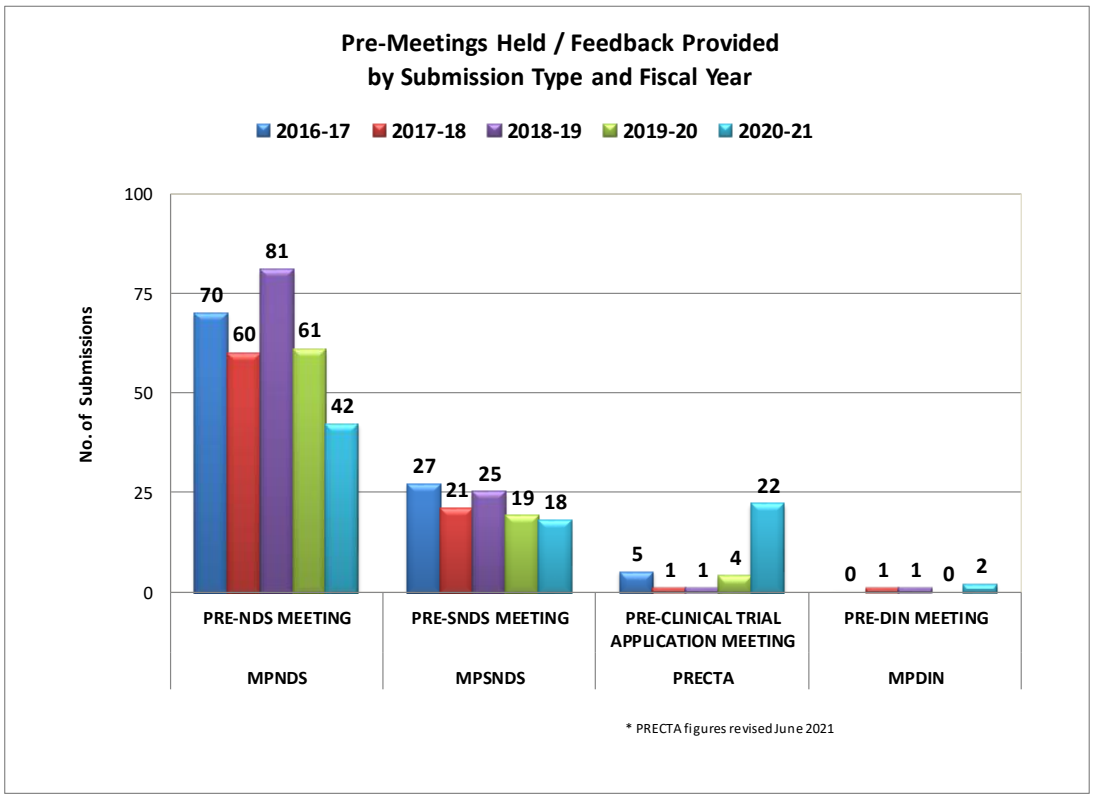
	16-17	17-18	18-19	19-20	20-21		16-17	17-18	18-19	19-20	20-21		16-17	17-18	18-19	19-20	20-21
Count	3	5	9	5	5		63	55	71	53	91		66	60	80	58	96
Max	211	210	221	212	539		855	701	913	643	561		855	701	913	643	561
Min	209	202	200	193	144		28	154	158	84	75		28	154	158	84	75
Median	211	204	205	202	197		239	319	329	261	207		229	309	308	223	204
AVG	210	206	206	203	254		277	301	306	264	224		274	293	295	259	225

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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