Health Canada Santé Canada

Pharmaceutical Drugs Directorate

Drug Submission Performance Annual Report

Fiscal Year 2021-2022

April 1 2021 – March 31 2022

Canada

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Publication date: July 2022

Cat H166-6E-PDF
ISSN 2816-7325
Pub 220239

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OVERVIEW

On May 2nd 2022, the Therapeutic Products Directorate (TPD) changed its name to the Pharmaceutical Drugs Directorate (PDD). The PDD's Annual Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2017-2018 to 2021-2022.

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 2021-2022 fiscal year (from April 1 2021 to March 31 2022).

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.

- The Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was repealed and replaced on February 27, 2022 by the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations to allow sponsors to continue conducting clinical trials authorized under the interim order and ensure all authorizations, suspensions and exemptions for clinical trials issued under the interim order will remain in effect. The number of CTA and CTA-As received under the interim order and transition regulations 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 and the number of applications and amendments in review under the ISAD Interim Order are included in this report. As the ISAD Interim Order expired on September 16th 2021, the Covid-19 Authorizations section of this report has been removed as zero authorizations have been issued and no new authorizations are possible.

[1] The Regulatory Enrolment Process (REP) and the Common Electronic Submissions Gateway (CESG)

- Decisions made in 2020-2021 included submissions filed under both the pre-2020 and post-2020 cost recovery framework.

- The *Food and Drug Regulations* have been amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through a new drug submission (NDS). The amendments maintain some of the mechanisms introduced through the Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19 (ISAD IO), thus continuing to provide Canadians with quick access to safe and effective COVID-19 drugs. The "NDS CV" submission type has been created for NDSs that use any of the provisions in subsections C.08.002(2.1), C.08.002(2.2) or C.08.002(2.3) of the *Regulations*. The number of applications filed, in review and completed under the amended regulations are included in this report. Additional information can be found at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html.

General Information

There are several steps involved in the drug submission review[2] 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[3] 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 ISAD Interim Order.

A **review cycle completion**[4] 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 to complete a cycle (excluding any pause days[5]) is compared to a set performance standard which is based on the type of submission, class and cycle (status).

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

[2] For further clarification, refer to the Guidance for Industry: Management of Drug Submissions.

[3] 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).

[4] Review cycles include all types e.g. Review 1, Review 2, Review QN, Review Post Jr. 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.

[5] In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance (effective date: April 1, 2020).

"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"[6] submissions.

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

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Ottawa, Ontario, K1A 0K9

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

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

[6] For further clarification, refer to the Guidance for Industry: Management of Drug Submissions.

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-CV	-	New Drug Submission – for Designated COVID-19 Drugs
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 NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS - **Category discontinued**.
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 - **Category discontinued**.
Labelling Only	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.

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	Submissions in support of a manufacturer or product name change.
Disinfectants	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.

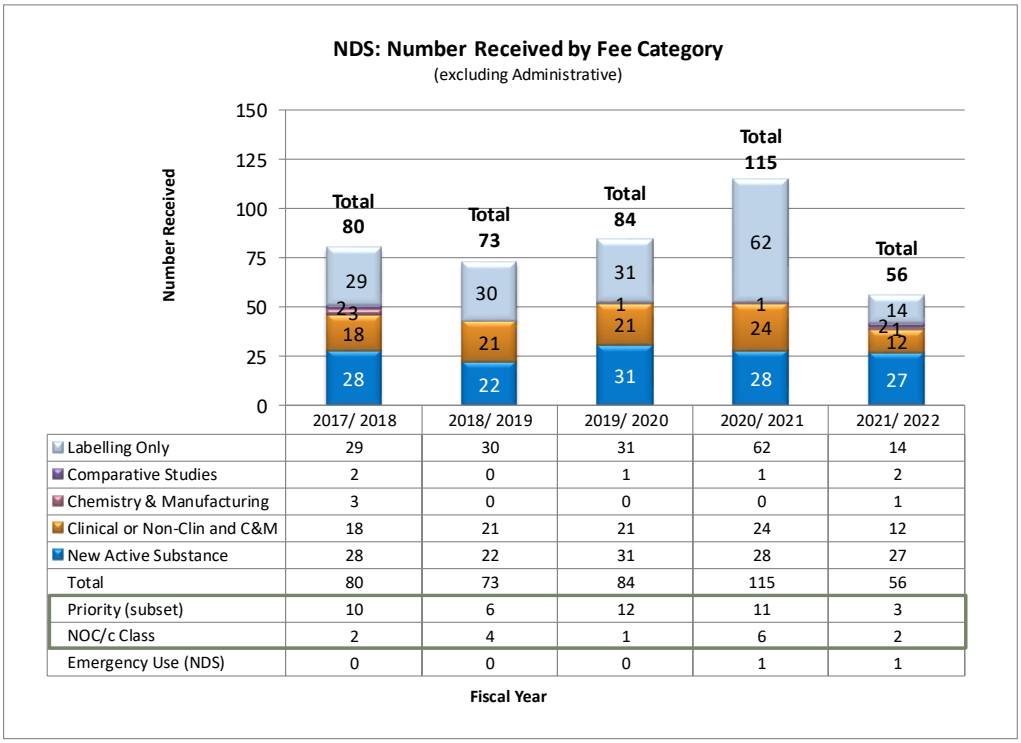
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENTAL NEW DRUG SUBMISSION (SNDS)

SUBMISSIONS RECEIVED [7]

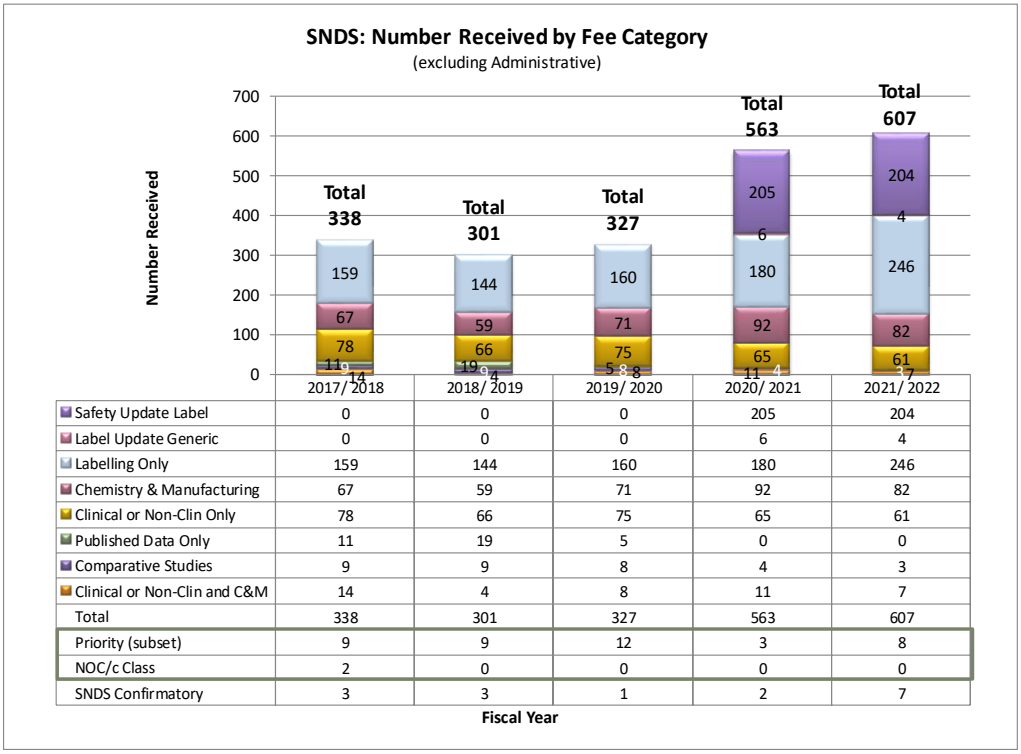
NDS: Number Received by Fee Category



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Labelling Only	29	30	31	62	14
Comparative Studies	2	0	1	1	2
Chemistry & Manufacturing	3	0	0	0	1
Clinical or Non-Clin and C&M	18	21	21	24	12
New Active Substance	28	22	31	28	27
Total	80	73	84	115	56
Priority (subset)	10	6	12	11	3
NOC/c Class	2	4	1	6	2
Emergency Use (NDS)	0	0	0	1	1

Fiscal Year

SNDS: Number Received by Fee Category



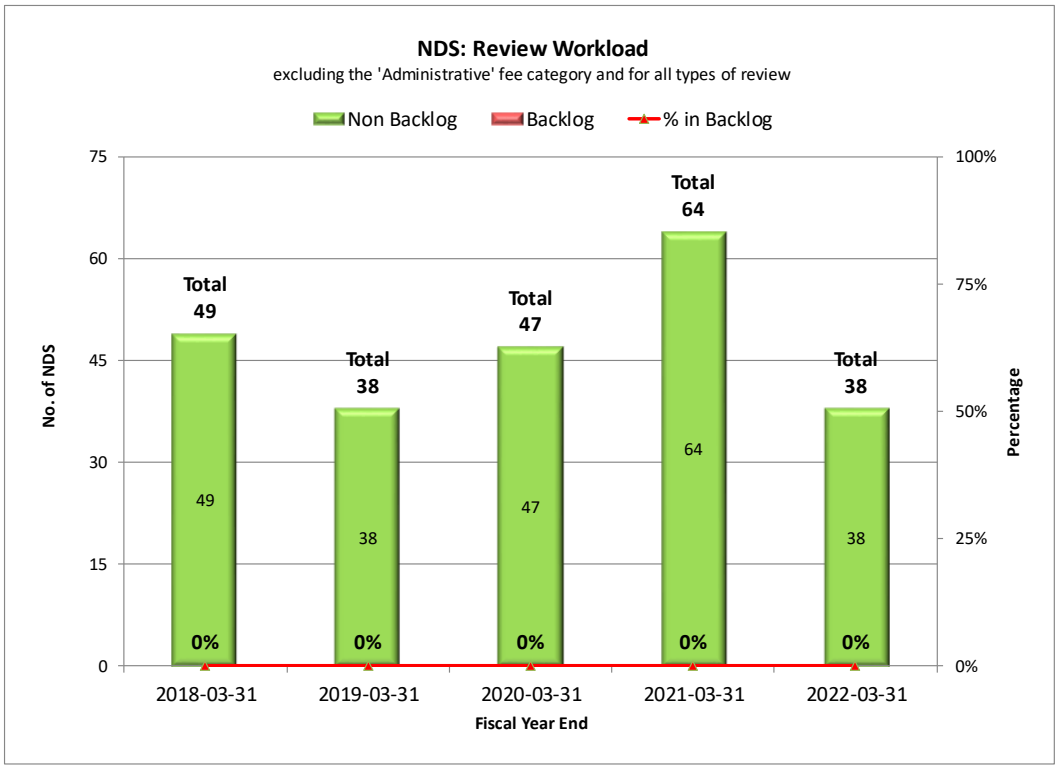
	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Safety Update Label	0	0	0	205	204
Label Update Generic	0	0	0	6	4
Labelling Only	159	144	160	180	246
Chemistry & Manufacturing	67	59	71	92	82
Clinical or Non-Clin Only	78	66	75	65	61
Published Data Only	11	19	5	0	0
Comparative Studies	9	9	8	4	3
Clinical or Non-Clin and C&M	14	4	8	11	7
Total	338	301	327	563	607
Priority (subset)	9	9	12	3	8
NOC/c Class	2	0	0	0	0
SNDS Confirmatory	3	3	1	2	7

Fiscal Year

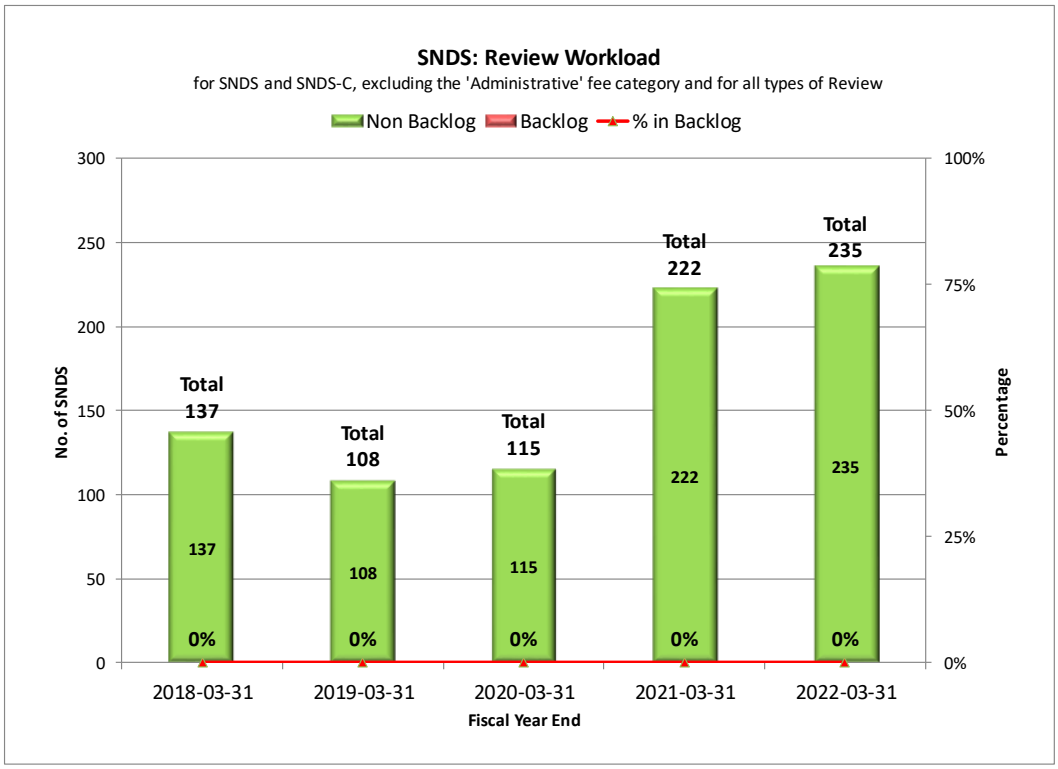
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions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

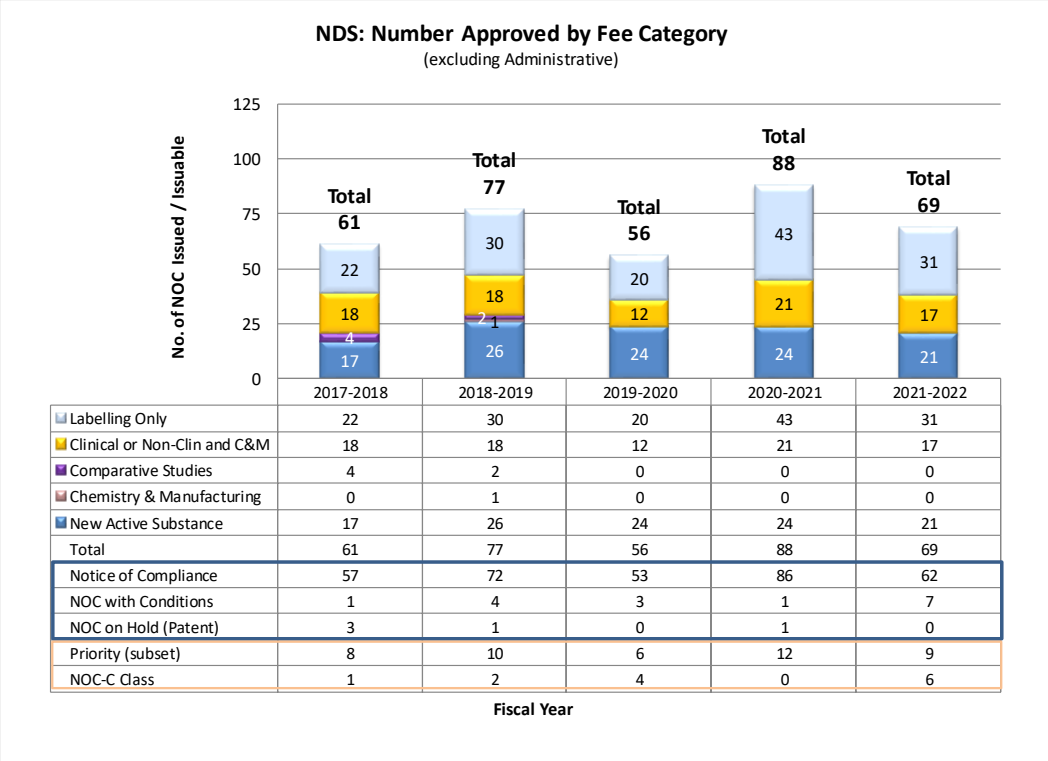
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Labelling Only	4	4	4	17	2
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	18	15	24	22	9
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	25	19	19	25	27
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**49**	**38**	**47**	**64**	**38**
Non Backlog	**49**	**38**	**47**	**64**	**38**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	6	3	8	6	2
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	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Labelling Only	19	10	24	49	69
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	4	7	5	1	2
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	30	29	26	47	37
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	63	53	49	53	49
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	11	1	8	9	5
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	10	8	3	0	0
Backlog	0	0	0	0	0
Label Update Generic	0	0	0	2	0
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	61	73
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**137**	**108**	**115**	**222**	**235**
Non Backlog	**137**	**108**	**115**	**222**	**235**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	7	4	5	2	4
Backlog	0	0	0	0	0
*SNDS-C (Confirmatory)	3	2	1	1	7
Backlog	0	0	0	0	0

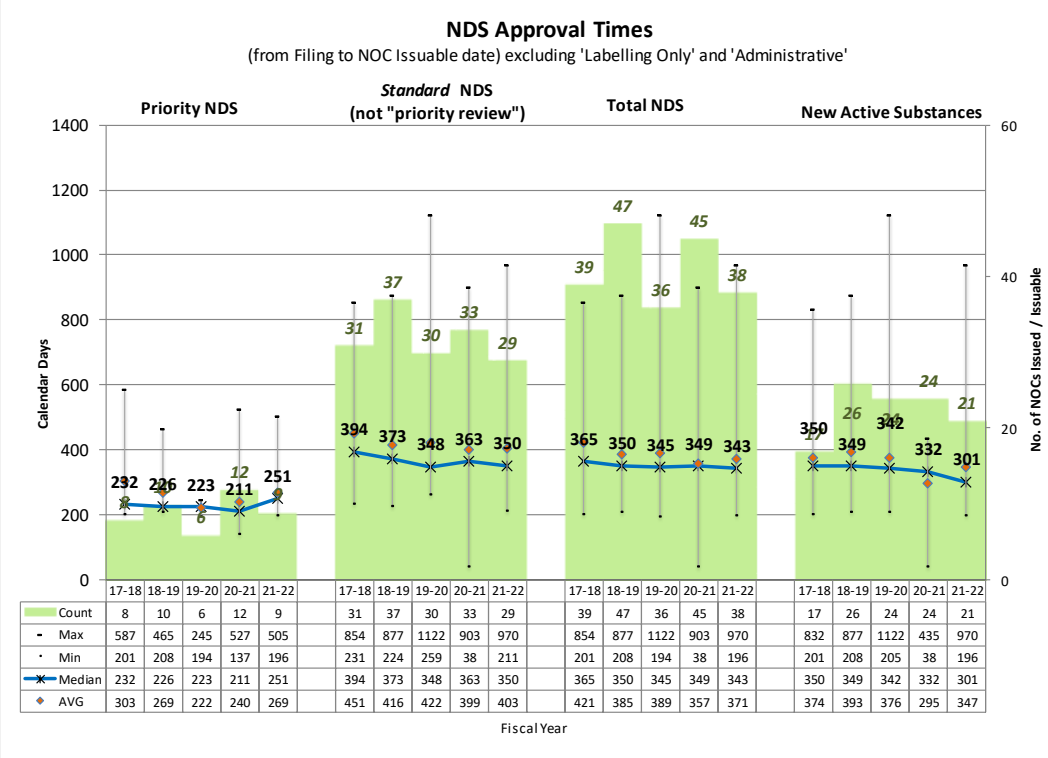
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Labelling Only	22	30	20	43	31
Clinical or Non-Clin and C&M	18	18	12	21	17
Comparative Studies	4	2	0	0	0
Chemistry & Manufacturing	0	1	0	0	0
New Active Substance	17	26	24	24	21
Total	61	77	56	88	69
Notice of Compliance	57	72	53	86	62
NOC with Conditions	1	4	3	1	7
NOC on Hold (Patent)	3	1	0	1	0
Priority (subset)	8	10	6	12	9
NOC-C Class	1	2	4	0	6

NDS Approval Times

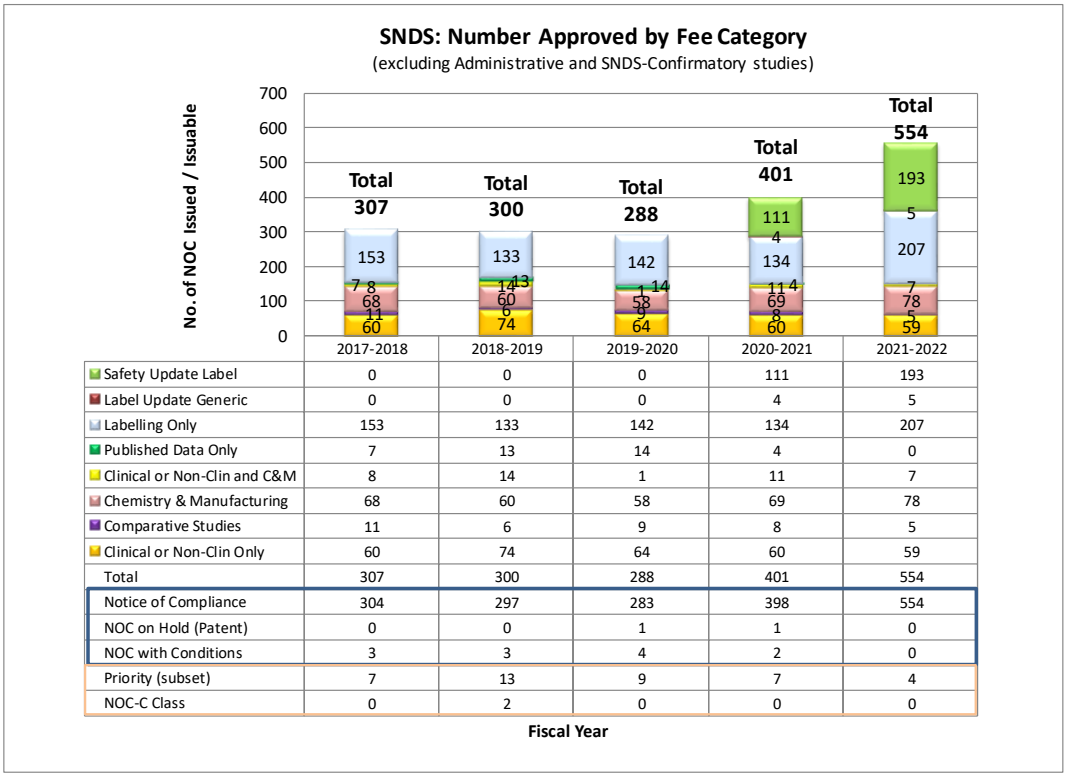


	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	8	10	6	12	9	31	37	30	33	29	39	47	36	45	38	17	26	24	24	21
Max	587	465	245	527	505	854	877	1122	903	970	854	877	1122	903	970	832	877	1122	435	970
Min	201	208	194	137	196	231	224	259	38	211	201	208	194	38	196	201	208	205	38	196
Median	232	226	223	211	251	394	373	348	363	350	365	350	345	349	343	350	349	342	332	301
AVG	303	269	222	240	269	451	416	422	399	403	421	385	389	357	371	374	393	376	295	347

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 .

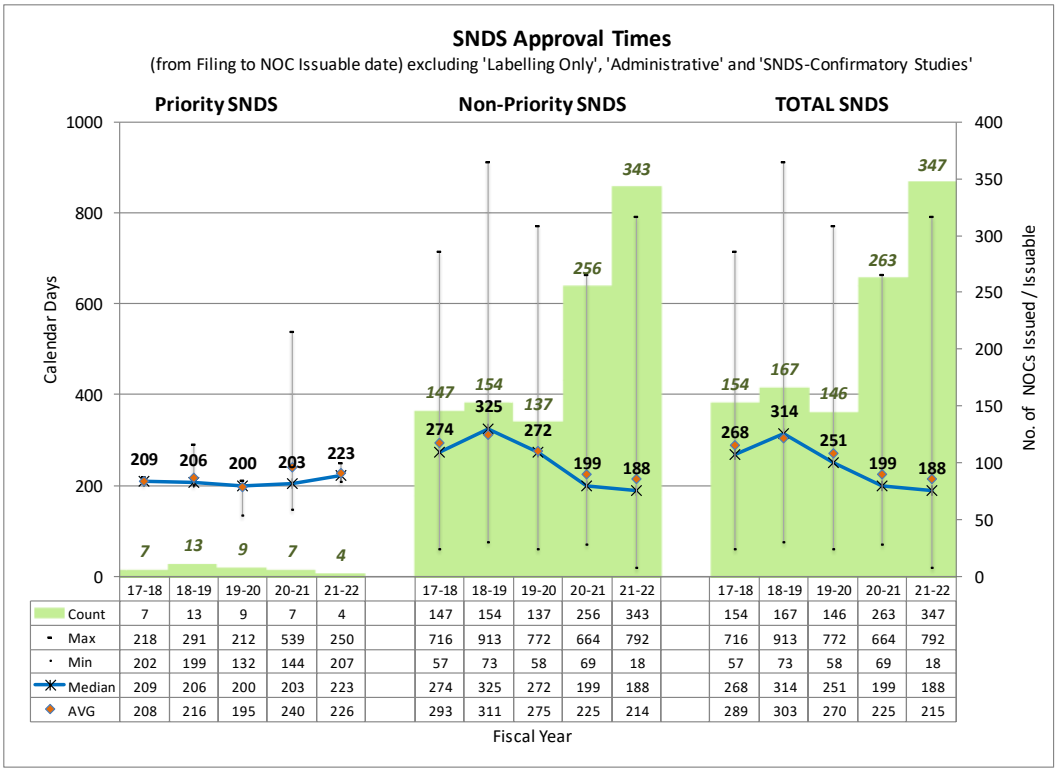
APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Safety Update Label	0	0	0	111	193
Label Update Generic	0	0	0	4	5
Labelling Only	153	133	142	134	207
Published Data Only	7	13	14	4	0
Clinical or Non-Clin and C&M	8	14	1	11	7
Chemistry & Manufacturing	68	60	58	69	78
Comparative Studies	11	6	9	8	5
Clinical or Non-Clin Only	60	74	64	60	59
Total	307	300	288	401	554
Notice of Compliance	304	297	283	398	554
NOC on Hold (Patent)	0	0	1	1	0
NOC with Conditions	3	3	4	2	0
Priority (subset)	7	13	9	7	4
NOC-C Class	0	2	0	0	0

SNDS Approval Times



	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	7	13	9	7	4	147	154	137	256	343	154	167	146	263	347
Max	218	291	212	539	250	716	913	772	664	792	716	913	772	664	792
Min	202	199	132	144	207	57	73	58	69	18	57	73	58	69	18
Median	209	206	200	203	223	274	325	272	199	188	268	314	251	199	188
AVG	208	216	195	240	226	293	311	275	225	214	289	303	270	225	215

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 - PDD - Fiscal Year 2021-2022

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
EVRYSDI (Risdiplam) - Evrysdi is a medicine used to treat spinal muscular atrophy (SMA), which is a condition that affects the nervous system. Evrysdi is for use in children 2 months of age and older and in adults.	PRIORITY-NAS	Hoffmann-La Roche Limited	31-07-2020	14-04-2021
GAVRETO (Pralsetinib) - For the following indication Gavreto has been approved with conditions (NOC/c). Gavreto is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). The non-small cell lung cancer: is caused by abnormal Rearranged During Transfection (RET) gene(s) and cannot be removed by surgery or has spread to other parts of the body. A test will be done to determine if the non-small cell lung cancer is caused by RET genes.	NOC-C NAS	Hoffmann-La Roche Limited	10-09-2020	30-06-2021 NOC-C
LEQVIO (Inclisiran Sodium) - Leqvio is used in adults to further lower the LDL cholesterol levels. It is for patients who are currently taking a statin (a medicine used to treat high cholesterol. Leqvio is used in addition to lifestyle changes, including diet in patients who have: Heterozygous familial hypercholesterolemia (HeFH) (an inherited genetic disorder that causes extremely high cholesterol levels), or Non-familial hypercholesterolemia (a condition that affects the body processes cholesterol) with atherosclerotic cardiovascular disease (a hardening of the arteries). The effect of Leqvio on heart problems such as heart attacks, stroke or death is not known.	NAS	Novartis Pharmaceuticals Canada Inc.	31-08-2020	26-07-2021

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

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
LUMAKRAS (Sotorasib) - For the following indication Lumakras has been approved with conditions (NOC/c). Lumakras is used to treat adults with non-small cell lung cancer (NSCLC) with an abnormal gene called KRAS G12C. This cancer cannot be removed by surgery or other treatment, or has spread to other parts of the body, and has been treated with at least one type of cancer treatment before. Lumakras is not approved for use in children and adolescents under 18 years of age.	NOC-C NAS	Amgen Canada Inc.	14-01-2021	10-09-2021 NOC-C
OSPHENA (Ospemifene) - Osphena is used in postmenopausal (after menopause) women to treat some symptoms of Genitourinary Syndrome of Menopause (GSM). Osphena is used to treat moderate to severe symptoms such as: pain during sex due to changes in and around the vagina; dryness due to changes in and around the vagina.	NAS	Duchesnay Inc.	19-11-2018	16-07-2021
OXLUMO (Lumasiran Sodium) - is used to treat primary hyperoxaluria type 1 (PH1) in adults and children.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-07-2021	07-03-2022
PAXLOVID (Ritonavir, Nirmatrelvir) - is used in adults to treat mild to moderate coronavirus disease 2019 (COVID-19) in patients who: have a positive result from a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral test and who have a high risk of getting severe COVID-19, including hospitalization or death.	NAS	Pfizer Canada ULC	01-12-2021	17-01-2022

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
PEMAZYRE (Pemigatinib) - For the following indication, Pemazyre has been approved with conditions (NOC/c). Pemazyre is used to treat adults with a type of cancer called cholangiocarcinoma (bile duct cancer) when it: has a type of abnormality in a specific gene called Fibroblast Growth Factor Receptor 2 (FGFR2); and has been treated previously cannot be removed with surgery; and is at an advanced stage or has spread to other parts of the body (called metastatic). A test will be done to find out if the cancer has an FGFR2 gene abnormality.	NAS	Incyte Corporation	10-09-2020	17-09-2021 NOC-C
PONVORY (Ponesimod) - Ponvory is used to treat adults with relapsing remitting Multiple Sclerosis (RRMS).	NAS	Janssen Inc.	15-05-2020	28-04-2021
RETEVMO (Selpercatinib) - For the following indications, Retevmo has been approved with conditions (NOC/c). Retevmo is used to treat certain cancers caused by abnormal RET genes in: adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when your cancer has spread to other parts of your body. Adults and children 12 to 17 years old with medullary thyroid cancer. It is used when: your cancer is advanced or has spread to other parts of your body, and your cancer cannot be removed using surgery. Adults with differentiated thyroid cancer. It is used when: your cancer is advanced or has spread to other parts of your body, your cancer cannot be removed using surgery, radioactive iodine therapy did not work, is no longer working or is not appropriate, and you have tried treatment with sorafenib and/or lenvatinib.	NOC-C NAS	Loxo Oncology Inc.	10-09-2020	15-06-2021 NOC-C

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
RHOLISTIQ (Belumosudil Mesylate) - is used to treat patients, 12 years of age and older, with chronic graft-versus-host disease (GVHD) after two or more prior treatments that did not work.	PRIORITY-NAS	Kadmon Pharmaceuticals LLC	03-11-2020	23-03-2022
RUKOBIA (Fostemsavir Tromethamine) - RUKOBIA is used to treat HIV (human immunodeficiency virus) infection in adults who have had difficulty in controlling their HIV with many other antiretroviral medicines. It is used in patients who have HIV that is resistant to many antiretroviral medicines. RUKOBIA is used in combination with other antiretroviral medicines.	PRIORITY-NAS	Viiv Healthcare Ulc	05-03-2021	01-10-2021
SOHONOS (Palovarotene) - is used to reduce the formation of heterotopic ossification. This is a condition where bone forms in soft tissues outside the skeleton. It is used in adults and children (females 8 years and older, males 10 years and older) who have the genetic disorder fibrodysplasia (myositis) ossificans progressiva, also called FOP.	PRIORITY-NAS	Ipsen Biopharmaceuticals Canada Inc.	23-04-2021	21-01-2022
SUNOSI (Solriamfetol Hydrochloride) - Sunosi helps you feel less sleepy during the day. It is used for adults with: narcolepsy – a condition that causes you to suddenly and unexpectedly feel very sleepy at any time, as well as Obstructive Sleep Apnea (OSA) – a condition where your breathing stops for brief periods of time when you sleep.	NAS	Jazz Pharmaceuticals Ireland Limited	30-03-2020	13-05-2021

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
TEPMETKO (Tepotinib Hydrochloride) - Tepmetko is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in adults: whose cancer has spread to other parts of the body or is advanced and cannot be removed by surgery, and whose tumors have a specific change (abnormality) in the mesenchymal epithelial transition (MET) gene.	NOC-C NAS	EMD Serono, a Division of EMD Inc., Canada	31-07-2020	27-05-2021 NOC-C
TPOXX (Tecovirimat Monohydrate) - TPOXX is used to treat smallpox disease. It can be given to people weighing at least 13 kg.	NAS	Siga Technologies, Inc.	22-12-2020	29-11-2021
TRIFERIC AVNU (Ferric Pyrophosphate Citrate) - Triferic Avnu is used to maintain iron levels in adults with chronic kidney disease who are undergoing hemodialysis.	NAS	Rockwell Medical Inc.	25-05-2020	22-04-2021
TRIKAFTA (Ivacaftor, Elexacaftor, Tezacaftor) - Trikafta is used for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. It is not known if Trikafta is safe and effective in children under 12 years of age.	PRIORITY-NAS	Vertex Pharmaceuticals (Canada) Incorporated	04-12-2020	18-06-2021

New Active Substance Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
TRUSELTIQ (Infigratinib Phosphate) - For the following indication Truseltiq has been approved with conditions (NOC/c). Truseltiq is used to treat adult patients with a type of cancer called cholangiocarcinoma (bile duct cancer) when it: has a type of abnormality in a specific gene called Fibroblast Growth Factor Receptor 2 (FGFR2); and has been treated previously, it cannot be removed with surgery, and is at an advanced stage or has spread to other parts of the body (called metastatic). A test will be done to find out if the cancer has an FGFR2 abnormality.	NOC-C NAS	QED Therapeutics, Inc.	30-11-2020	27-09-2021 NOC-C
WAKIX (Pitolisant Hydrochloride) - Wakix is used in adults with narcolepsy (a type of sleep disorder) to reduce: excessive sleepiness during the day; and cataplexy (sudden weak or paralyzed muscles).	NAS	Endo Ventures Ltd	06-04-2020	25-05-2021
WAYMADE-TRIENTINE (Trientine Hydrochloride) - Waymade-Trientine is used for the treatment of Wilson's disease in those who cannot take the drug penicillamine.	NAS	Waymade PLC	20-03-2020	20-04-2021
ZEPZELCA (Lurbinectedin) - For the following indication(s) Zepzelca has been approved with conditions (NOC/c). Zepzelca is used to treat a type of cancer called Stage III or metastatic small cell lung cancer (SCLC). It is used in adults who have received treatment with chemotherapy that contains platinum and it did not work or is no longer working.	NOC-C NAS	Jazz Pharmaceuticals Ireland Limited	16-12-2020	29-09-2021 NOC-C

Priority Submission Approvals - PDD - Fiscal Year 2021-2022

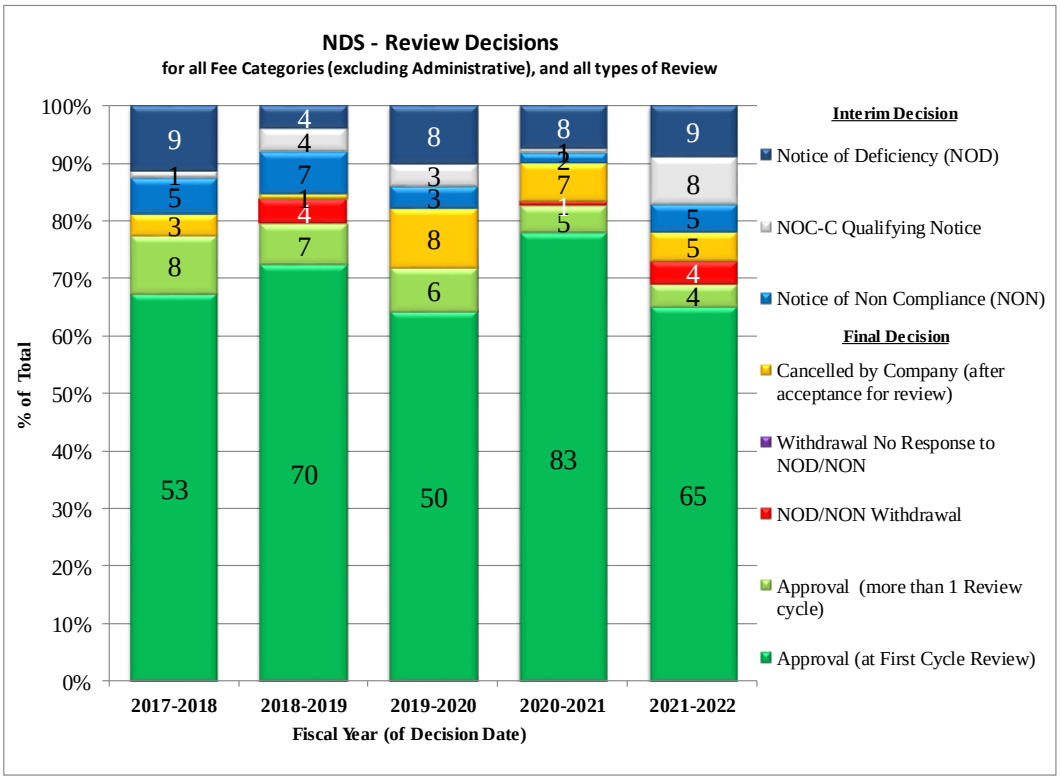
Priority Submission Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
BRUKINSA (Zanubrutinib) - new indication: BRUKINSA is used to treat cancers such as: Marginal Zone Lymphoma (MZL). BRUKINSA is used in patients who have received at least one previous antibody (anti-CD20) therapy against their cancer.	PRIORITY-CLIN ONLY	Beigene Switzerland GMBH	09-07-2021	18-02-2022
EVRYSDI (Risdiplam) - Evrysdi is a medicine used to treat spinal muscular atrophy (SMA), which is a condition that affects the nervous system. Evrysdi is for use in children 2 months of age and older and in adults.	PRIORITY-NAS	Hoffmann-La Roche Limited	31-07-2020	14-04-2021
FORXIGA (Dapagliflozin Propanediol) - New Indication to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular and renal death in adults with chronic kidney disease (CKD).	PRIORITY-CLIN ONLY	AstraZeneca Canada Inc.	15-01-2021	10-08-2021
KALYDECO (Ivacaftor) - Addition of new 25 mg strength and to expand the indication to include the treatment of children with cystic fibrosis (CF) aged 4 months to < 12 months and weighing 5 kg and more who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.	PRIORITY-CLIN/C&M	Vertex Pharmaceuticals (Canada) Incorporated	18-12-2020	25-08-2021

Priority Submission Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
KALYDECO (Ivacaftor) - Expanded indication to include the treatment of children with cystic fibrosis (CF) aged 4 months and weighing at least 5 kg to less than 18 years of age who have an R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	PRIORITY-CLIN ONLY	Vertex Pharmaceuticals (Canada) Incorporated	13-08-2021	23-03-2022
MYINFLA (Colchicine) - Myinfla is used to reduce cardiovascular risks in patients with plaque build-up in the arteries, which narrows the arteries and restricts the blood supply to the heart.	PRIORITY-CLIN/C&M	Pendopharm Division of Pharmascience Inc.	15-01-2021	23-08-2021
OXLUMO (Lumasiran Sodium) - is used to treat primary hyperoxaluria type 1 (PH1) in adults and children.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-07-2021	07-03-2022
RHOLISTIQ (Belumosudil Mesylate) - is used to treat patients, 12 years of age and older, with chronic graft-versus-host disease (GVHD) after two or more prior treatments that did not work.	PRIORITY-NAS	Kadmon Pharmaceuticals LLC	03-11-2020	23-03-2022
RUKOBIA (Fostemsavir Tromethamine) - RUKOBIA is used to treat HIV (human immunodeficiency virus) infection in adults who have had difficulty in controlling their HIV with many other antiretroviral medicines. It is used in patients who have HIV that is resistant to many antiretroviral medicines. RUKOBIA is used in combination with other antiretroviral medicines.	PRIORITY-NAS	Viiv Healthcare Ulc	05-03-2021	01-10-2021

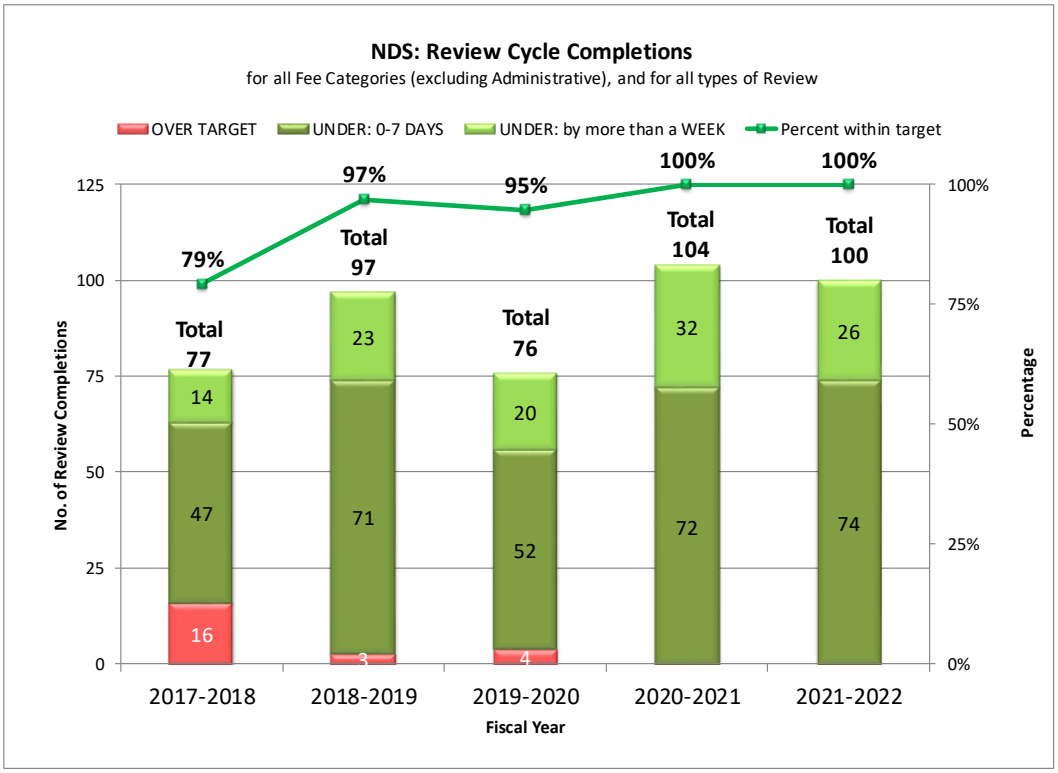
Priority Submission Approvals - PDD Fiscal Year 2021-2022 (April 1 2021 - March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date) dd-mon-yy**	**Approval Date dd-mon-yy**
SOHONOS (Palovarotene) - is used to reduce the formation of heterotopic ossification. This is a condition where bone forms in soft tissues outside the skeleton. It is used in adults and children (females 8 years and older, males 10 years and older) who have the genetic disorder fibrodysplasia (myositis) ossificans progressiva, also called FOP.	PRIORITY-NAS	Ipsen Biopharmaceuticals Canada Inc.	23-04-2021	21-01-2022
TRECONDYV (Treosulfan) - Trecondyv is used together with fludarabine to prepare patients for a blood stem cell transplant from a donor: in adults with the blood cancers Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) who are not able to tolerate the standard preparation therapies, in children and adolescents older than one year of age with AML or MDS.	PRIORITY-CLIN C&M	Medexus Inc.	21-09-2020	25-06-2021
TRIKAFTA (Ivacaftor, Elexacaftor, Tezacaftor) - Trikafta is used for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. It is not known if Trikafta is safe and effective in children under 12 years of age.	PRIORITY-NAS	Vertex Pharmaceuticals (Canada) Incorporated	04-12-2020	18-06-2021
VYXEOS (Cytarabine, Daunorubicin) - Vyxeos is used to treat adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).	PRIORITY-CLIN/C&M	Jazz Pharmaceuticals Ireland Limited	21-08-2020	29-04-2021

REVIEW PERFORMANCE

NDS: Review Decisions by Type

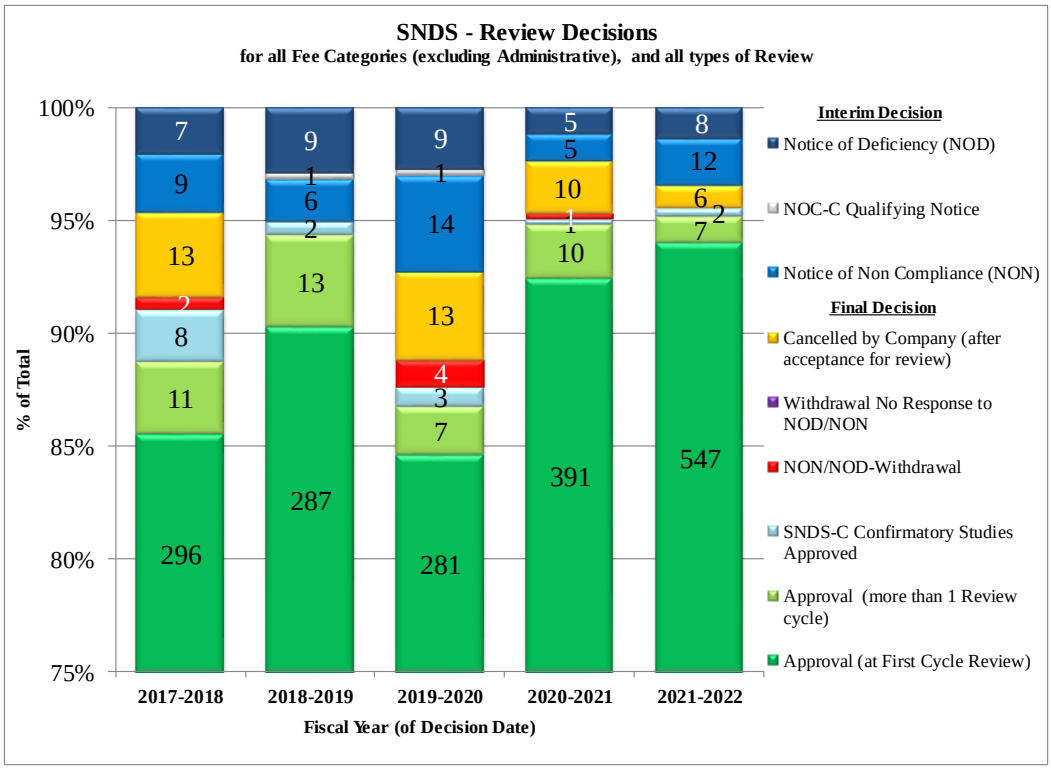


NDS: Review Cycle Completions

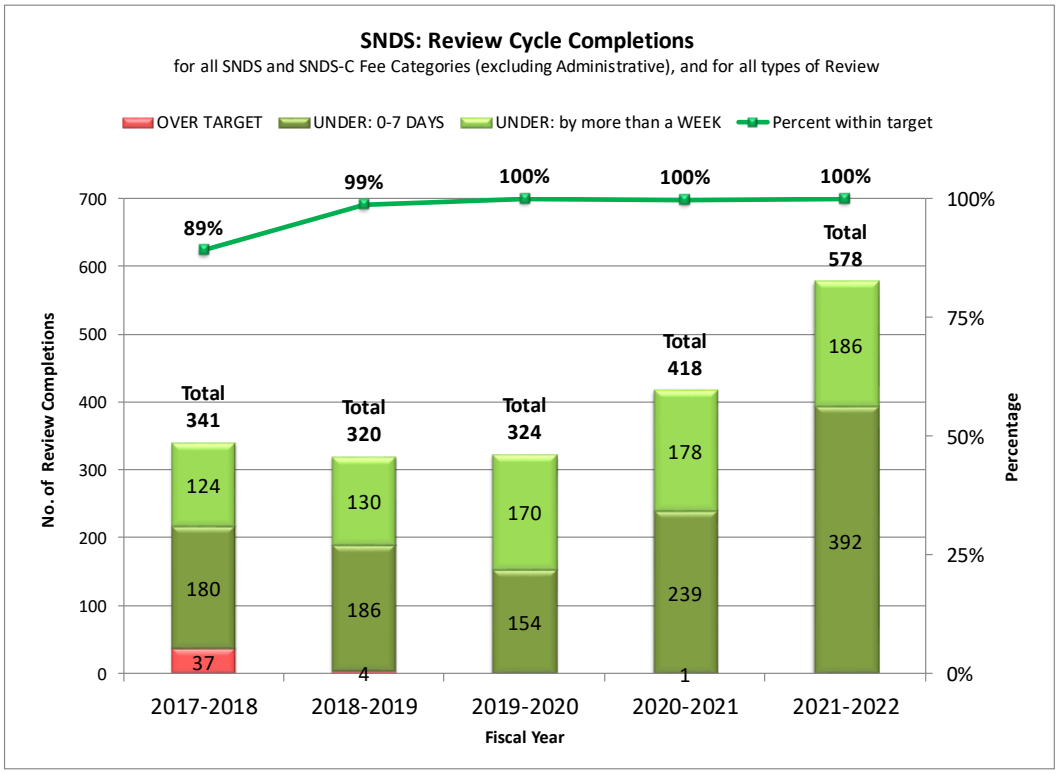


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

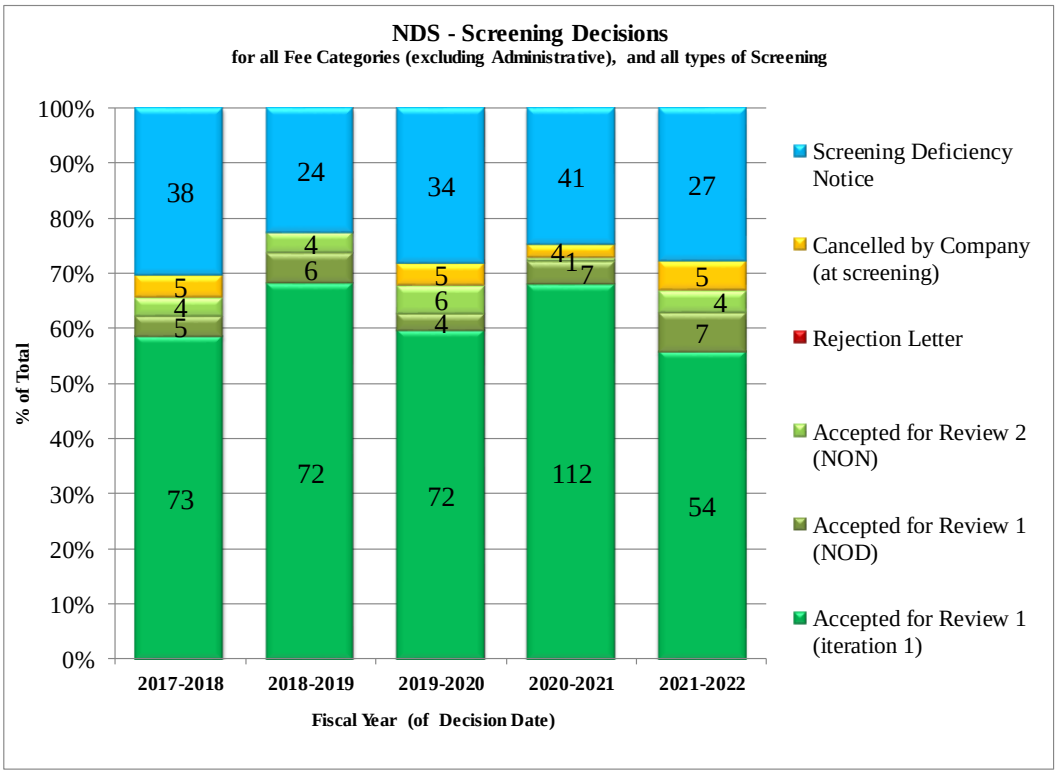


SNDS: Review Cycle Completions

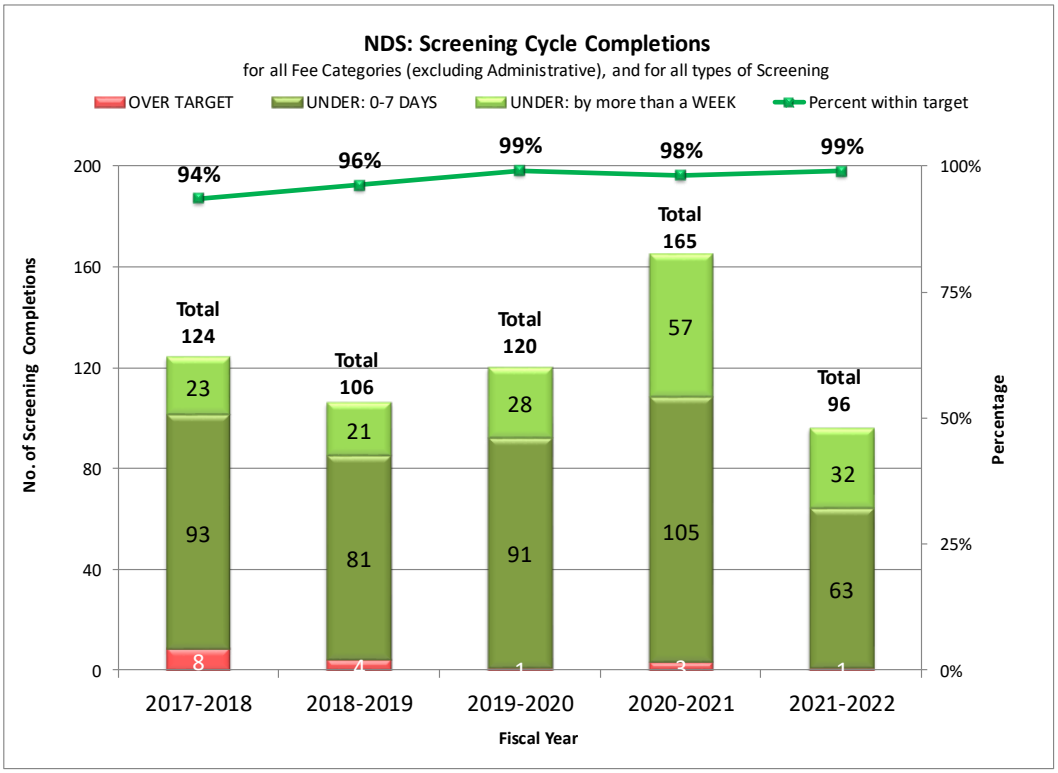


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

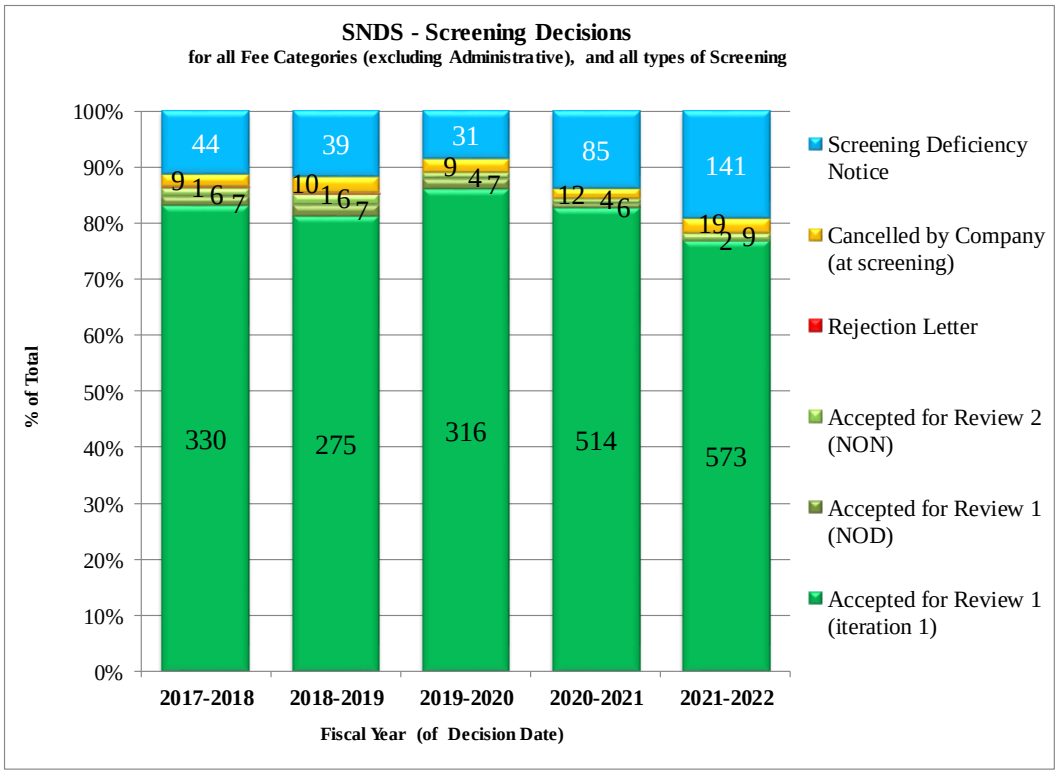


NDS: Screening Cycle Completions

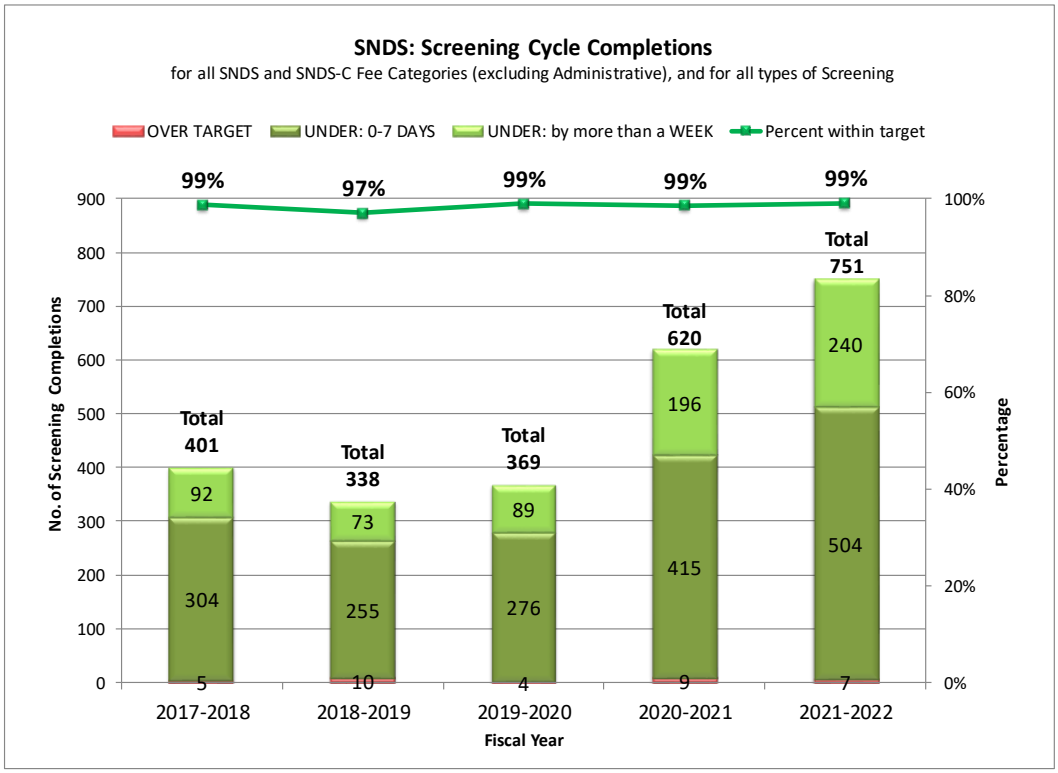


SCREENING PERFORMANCE

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	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	NDS Status (as of June 2022)
Total Received	0	1	0	0	1		
Total Pending	*0*	*0*	*0*	*0*	*0*		
PENDING	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Under Reconsideration
Total Granted	*0*	*0*	*0*	*0*	*0*		
GRANTED	0	0	0	0	0	NOD-Withdrawal	Cleared
Total Denied	*0*	*1*	*0*	*0*	*1*		
DENIED	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn
DENIED	*0*	*1*	*0*	*0*	*1*	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	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	SNDS Status (as of June 2022)
Total Received	0	0	0	0	0		
Total Denied	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn
Total Granted	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn

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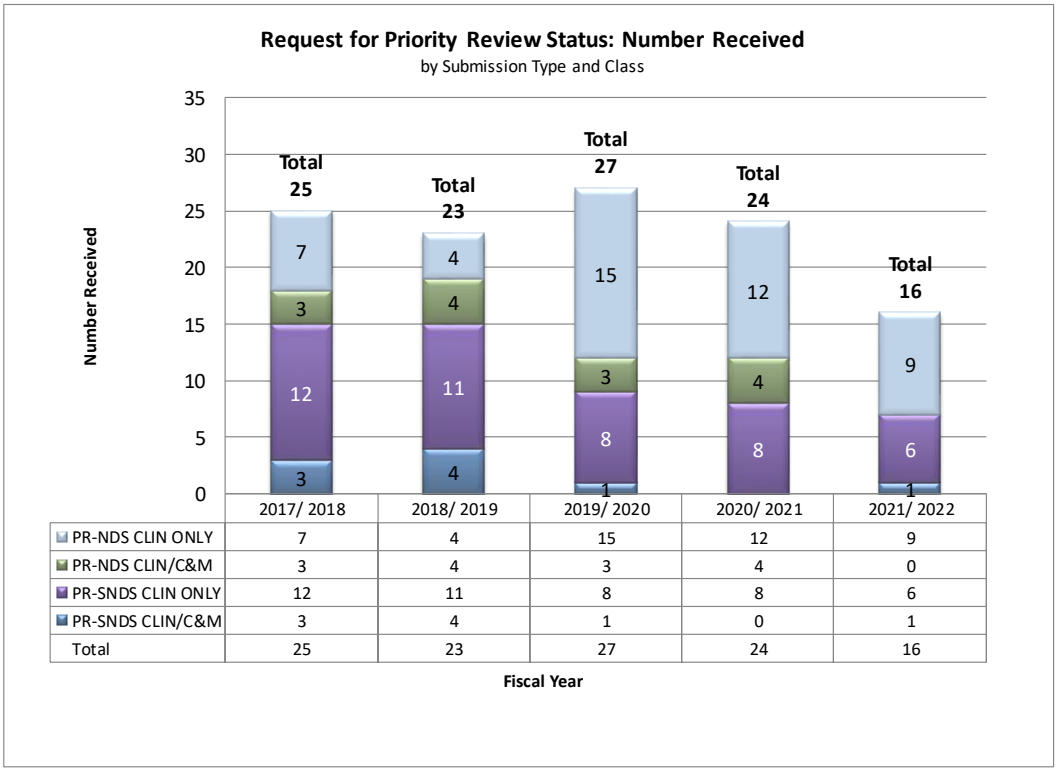
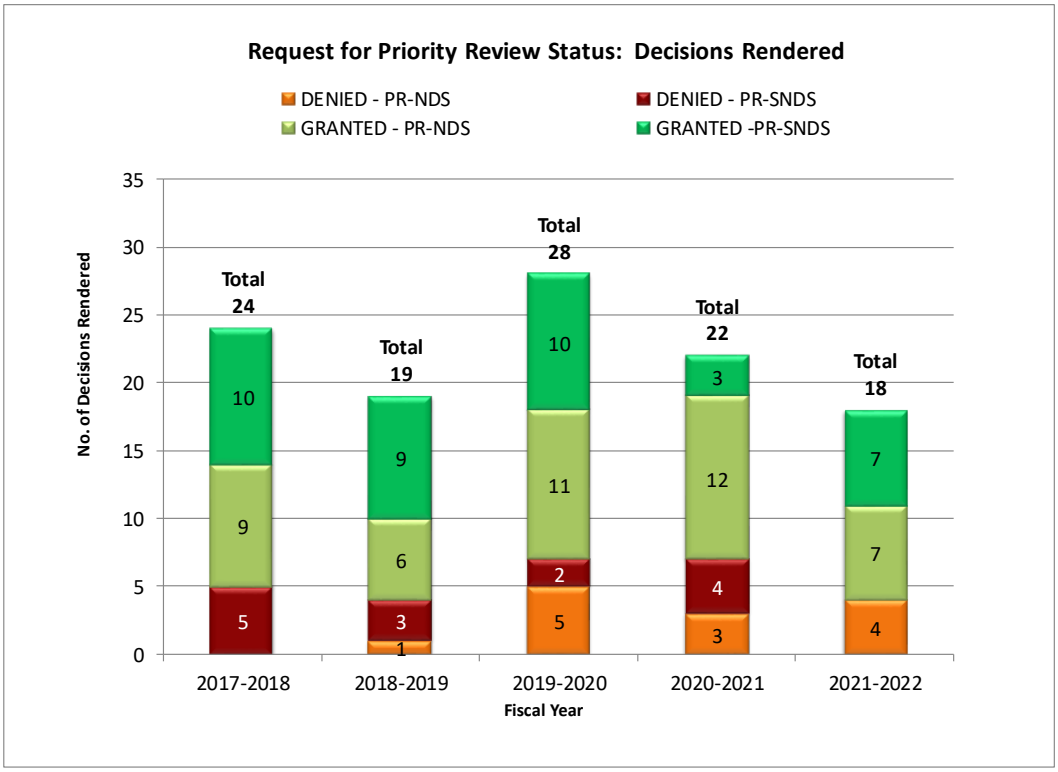
REQUEST FOR PRIORITY REVIEW STATUS

Request for Priority Review Status: Number Received



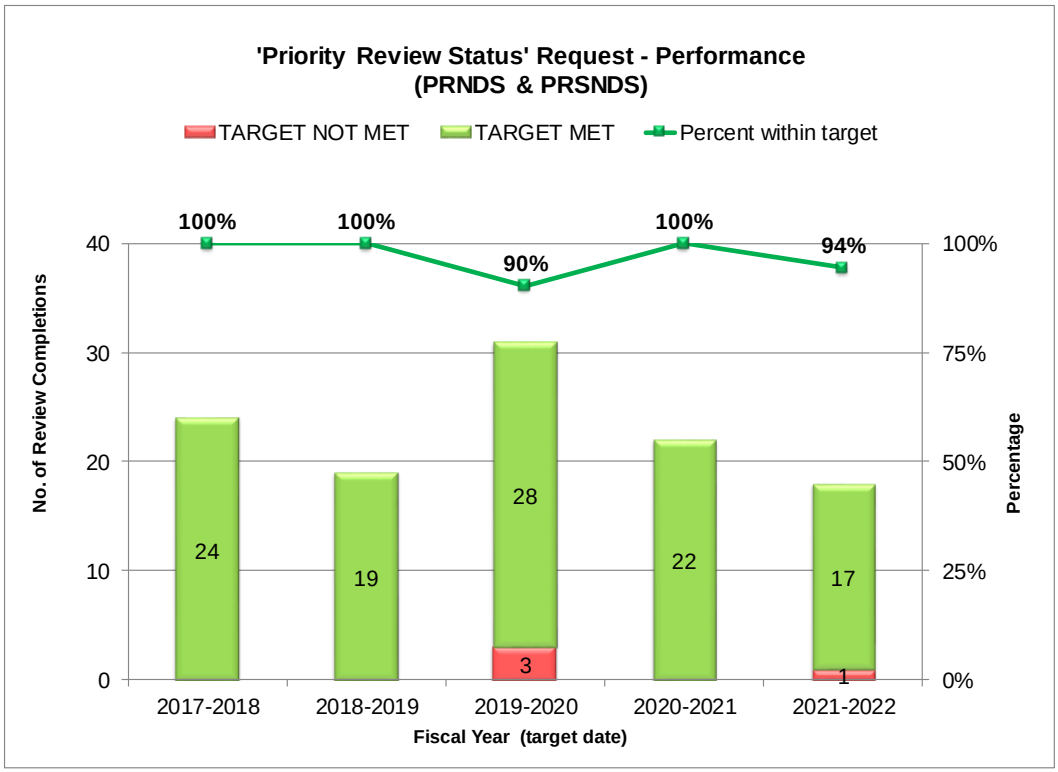
	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
PR-NDS CLIN ONLY	7	4	15	12	9
PR-NDS CLIN/C&M	3	4	3	4	0
PR-SNDS CLIN ONLY	12	11	8	8	6
PR-SNDS CLIN/C&M	3	4	1	0	1
Total	25	23	27	24	16

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	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	Submission Status (as of June 2022)
Total Received	1	0	0	0	0		
Total Granted	1	0	0	0	0	Priority Review Request (for SNDS) Denied	Cleared

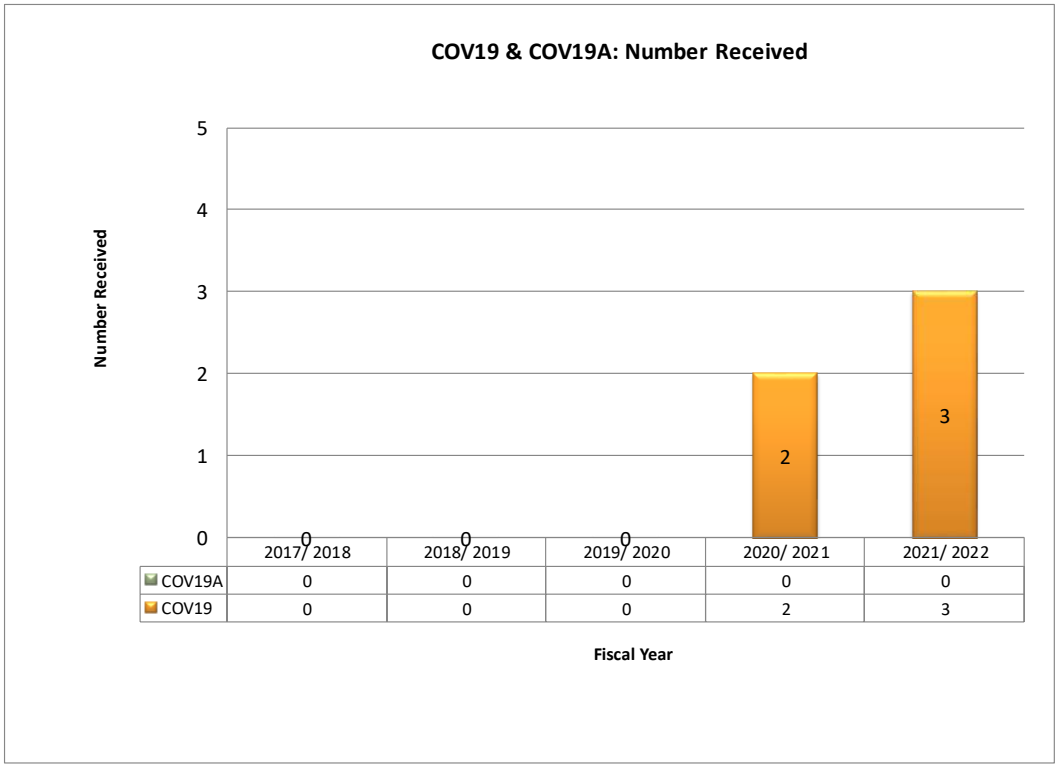
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

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)

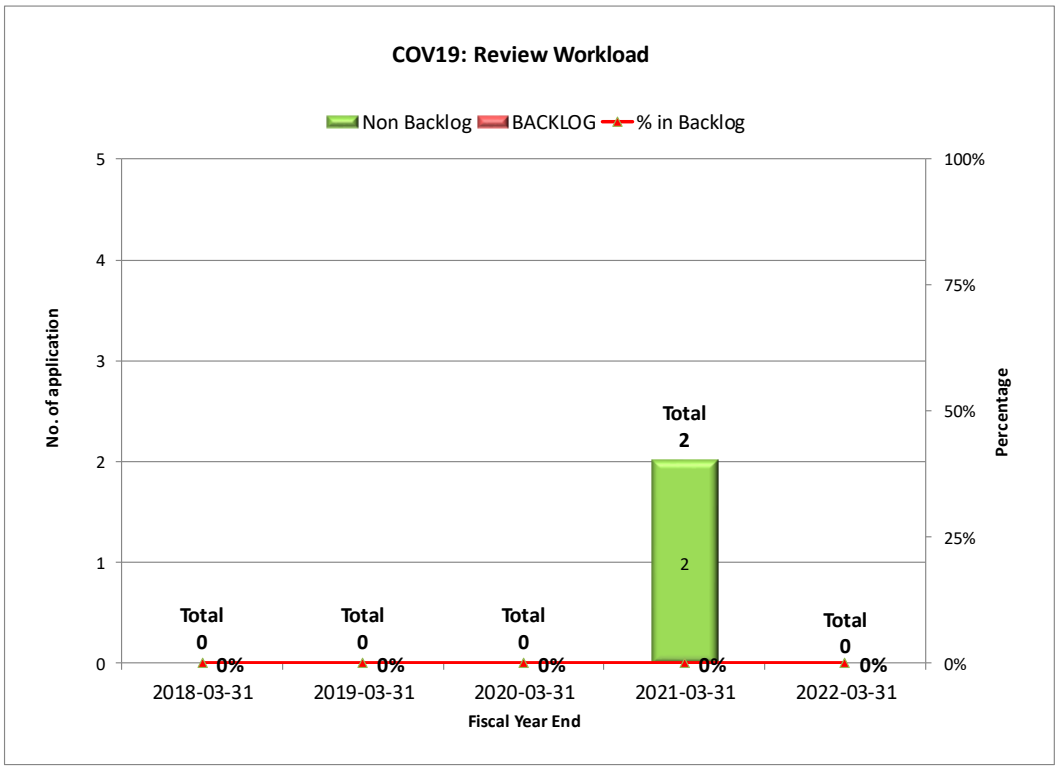
SUBMISSION RECEIVED

COV19 & COV19A: Number Received



WORKLOAD

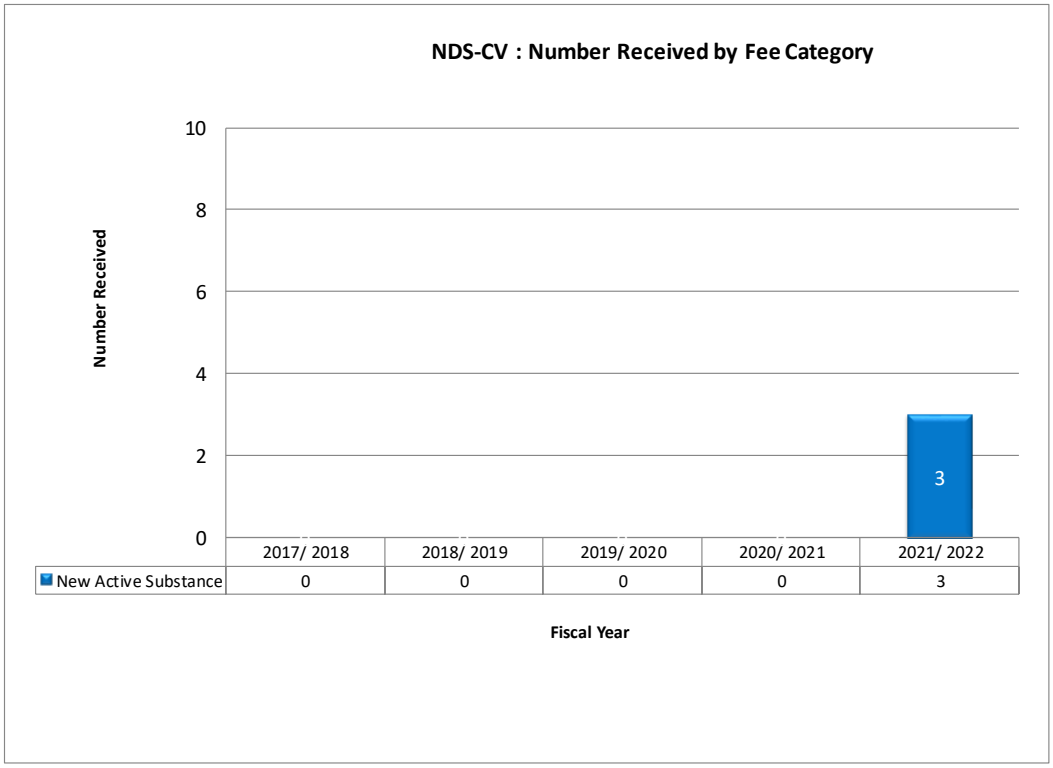
COV19: Review Workload



New Drug Submissions for Designated COVID-19 Drugs
(NDS-CV)

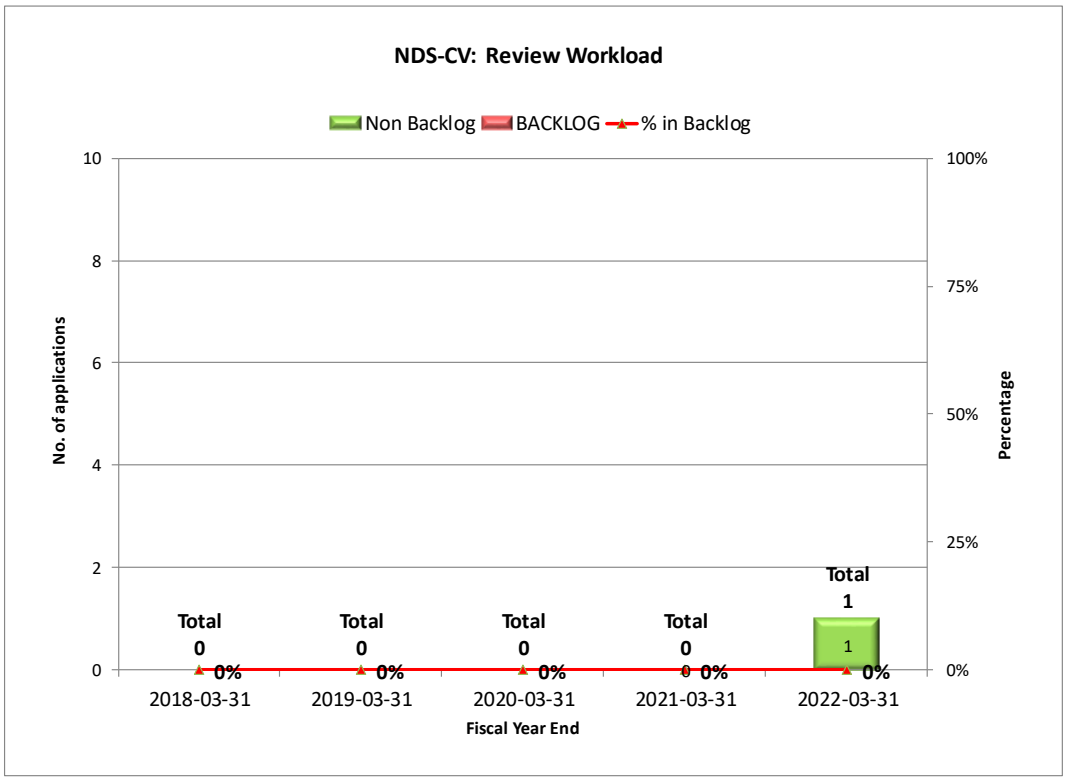
RECEIVED

NDS-CV: Number Received



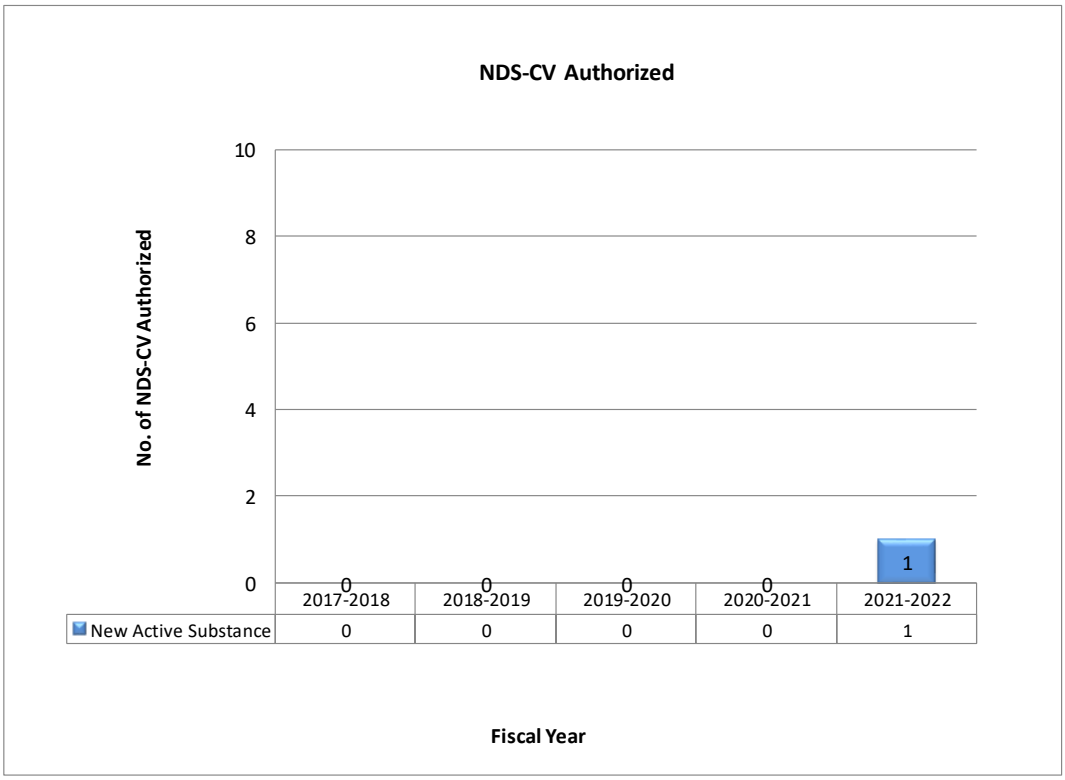
WORKLOAD

NDS-CV: Review Workload



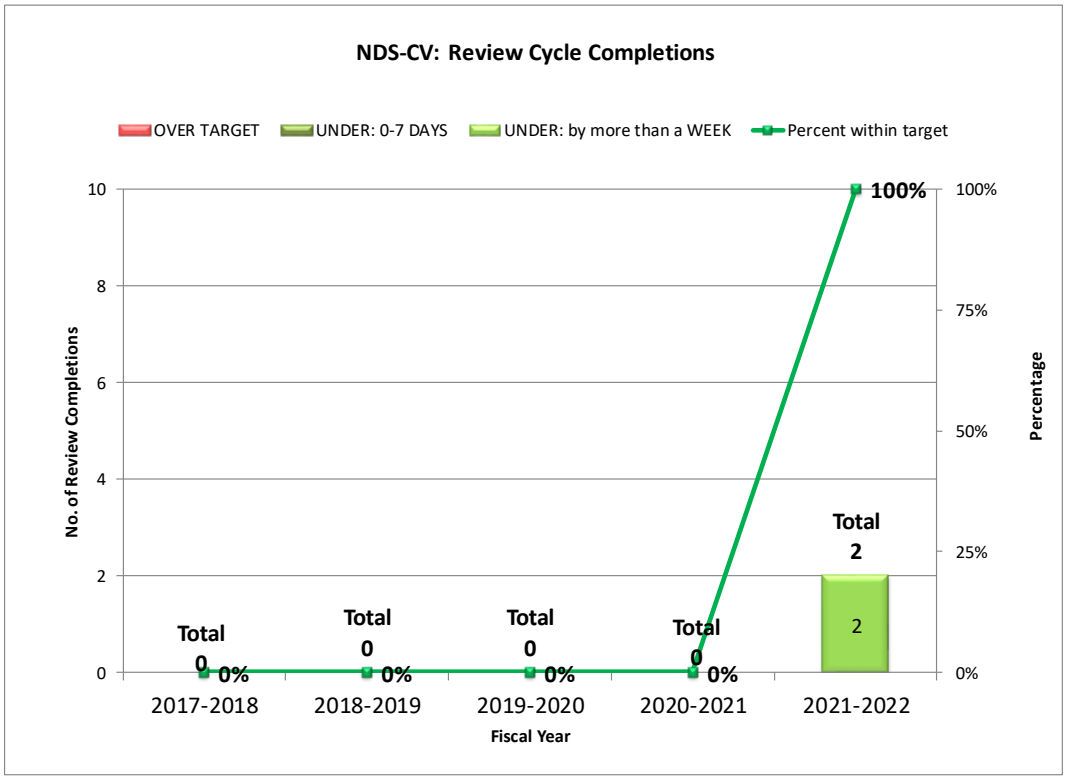
AUTHORIZATIONS

NDS-CV: Number Authorized

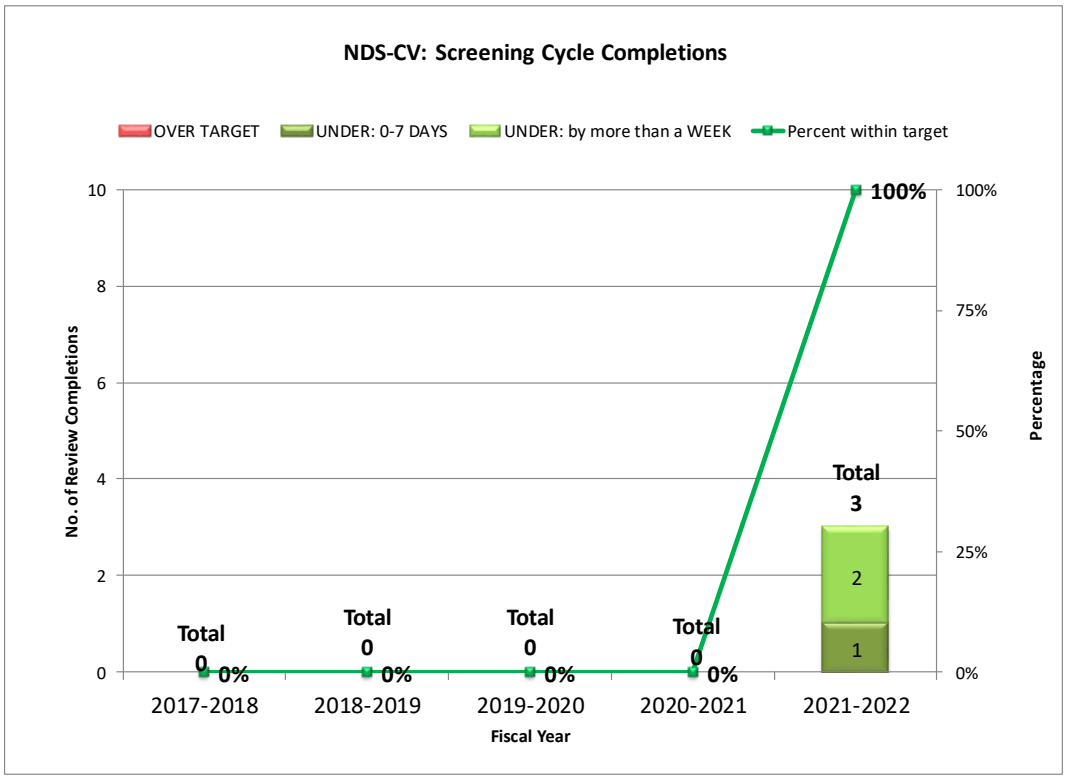


PERFORMANCE

NDS-CV: Review Cycle Completions



NDS-CV: Screening Cycle Completions



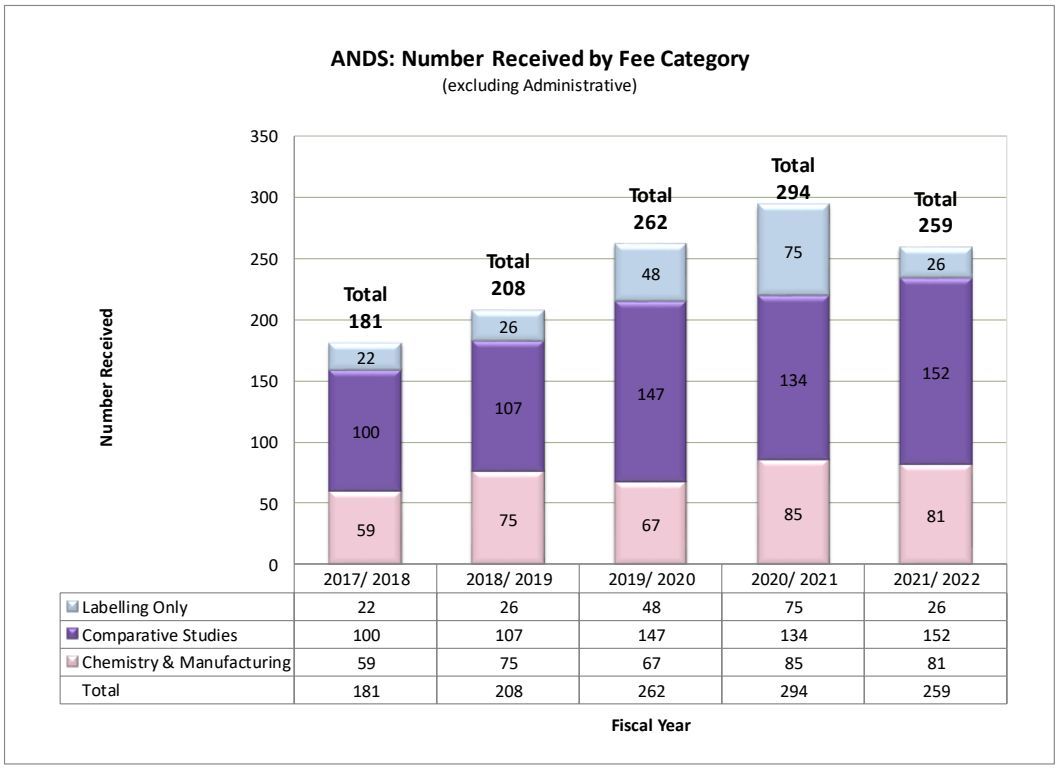
ABBREVIATED NEW DRUG SUBMISSIONS (ANDS)

&

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSIONS (SANDS)

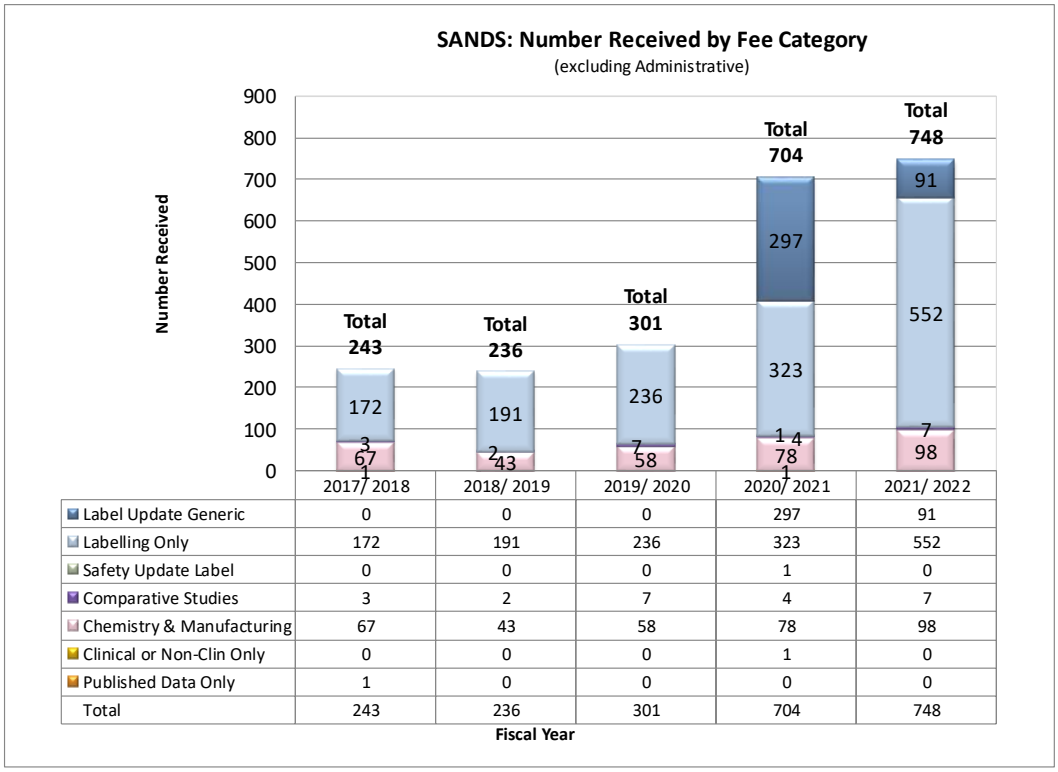
SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Labelling Only	22	26	48	75	26
Comparative Studies	100	107	147	134	152
Chemistry & Manufacturing	59	75	67	85	81
Total	181	208	262	294	259

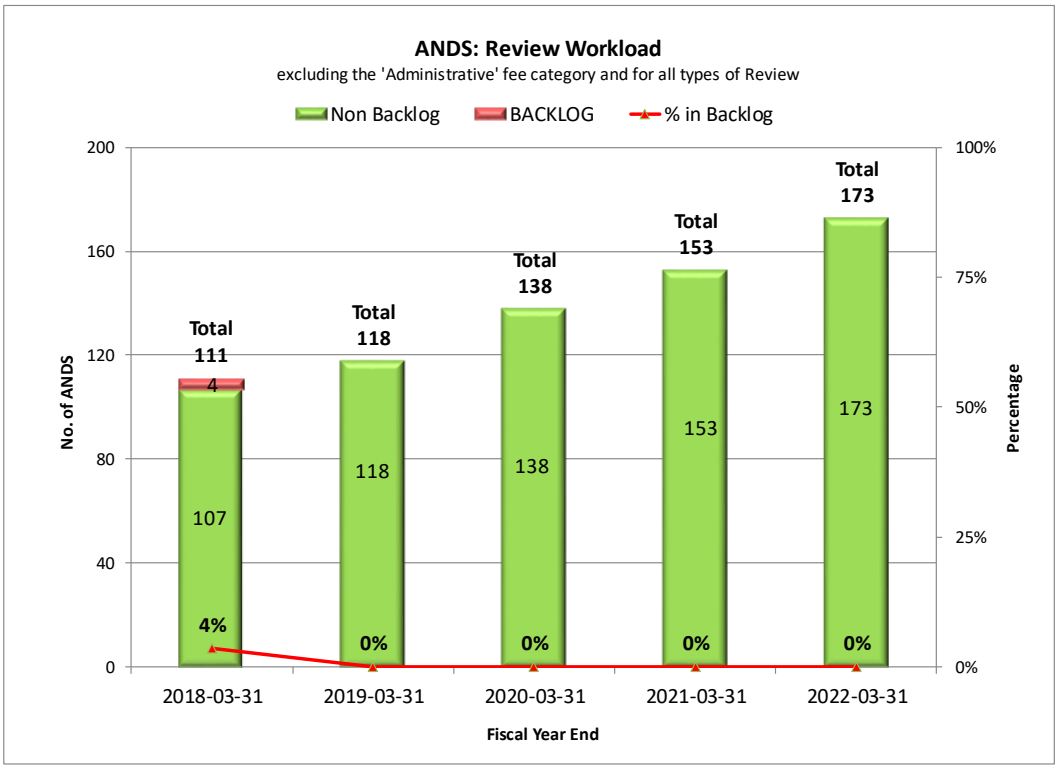
SANDS: Number Received by Fee Category



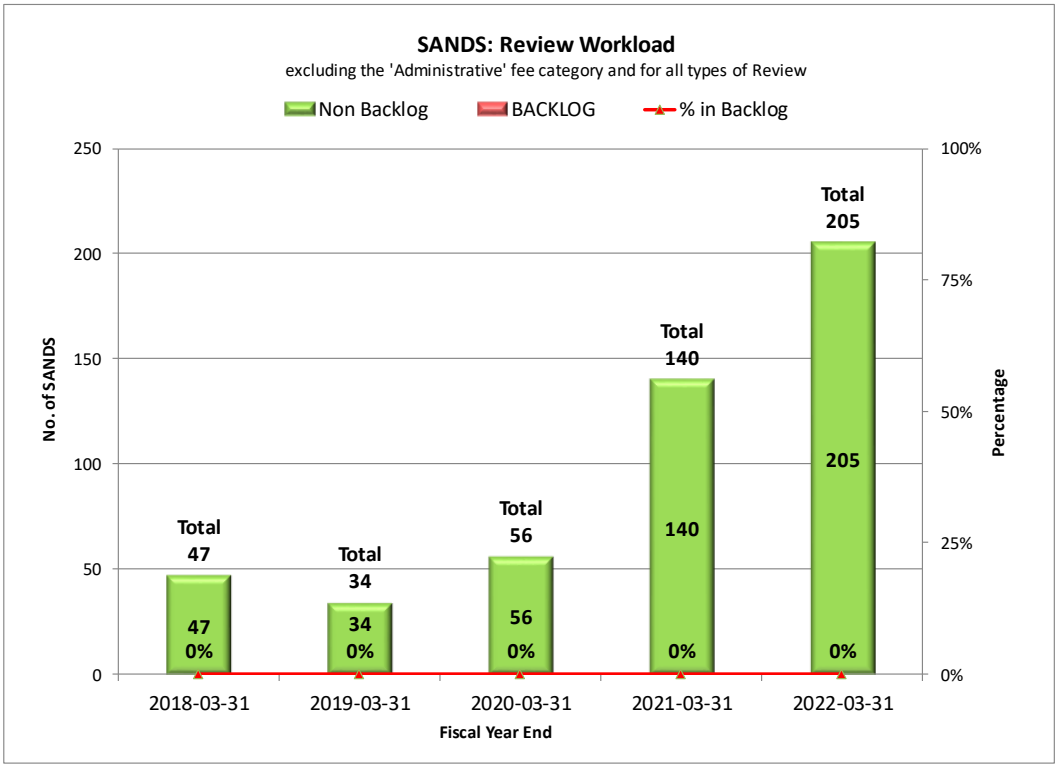
	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Label Update Generic	0	0	0	297	91
Labelling Only	172	191	236	323	552
Safety Update Label	0	0	0	1	0
Comparative Studies	3	2	7	4	7
Chemistry & Manufacturing	67	43	58	78	98
Clinical or Non-Clin Only	0	0	0	1	0
Published Data Only	1	0	0	0	0
Total	243	236	301	704	748

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

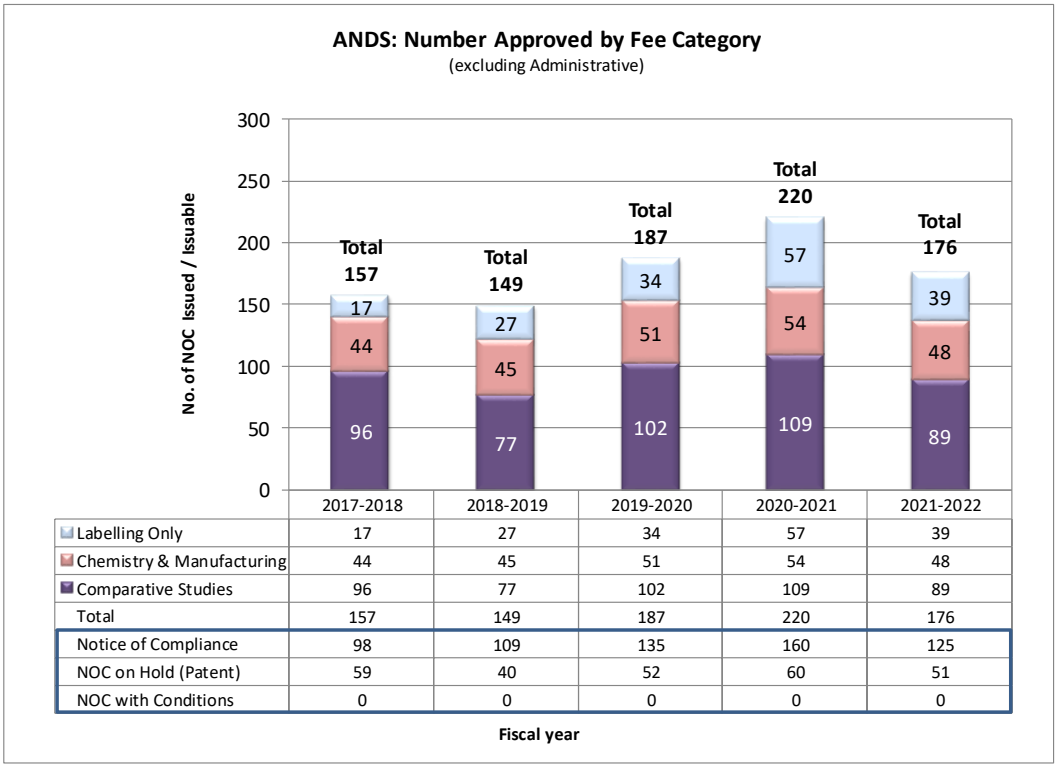
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Chemistry & Manufacturing	43	38	42	53	68
Backlog	*2*	*0*	*0*	*0*	*0*
Comparative Studies	65	77	88	89	96
Backlog	*2*	*0*	*0*	*0*	*0*
Labelling Only	3	3	8	11	9
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**111**	**118**	**138**	**153**	**173**
Non Backlog	**107**	**118**	**138**	**153**	**173**
BACKLOG	**4**	**0**	**0**	**0**	**0**
% in Backlog	**4%**	**0%**	**0%**	**0%**	**0%**

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Chemistry & Manufacturing	26	22	24	30	36
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	2	3	1	4
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	19	10	29	91	165
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	18	0
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**47**	**34**	**56**	**140**	**205**
Non Backlog	**47**	**34**	**56**	**140**	**205**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

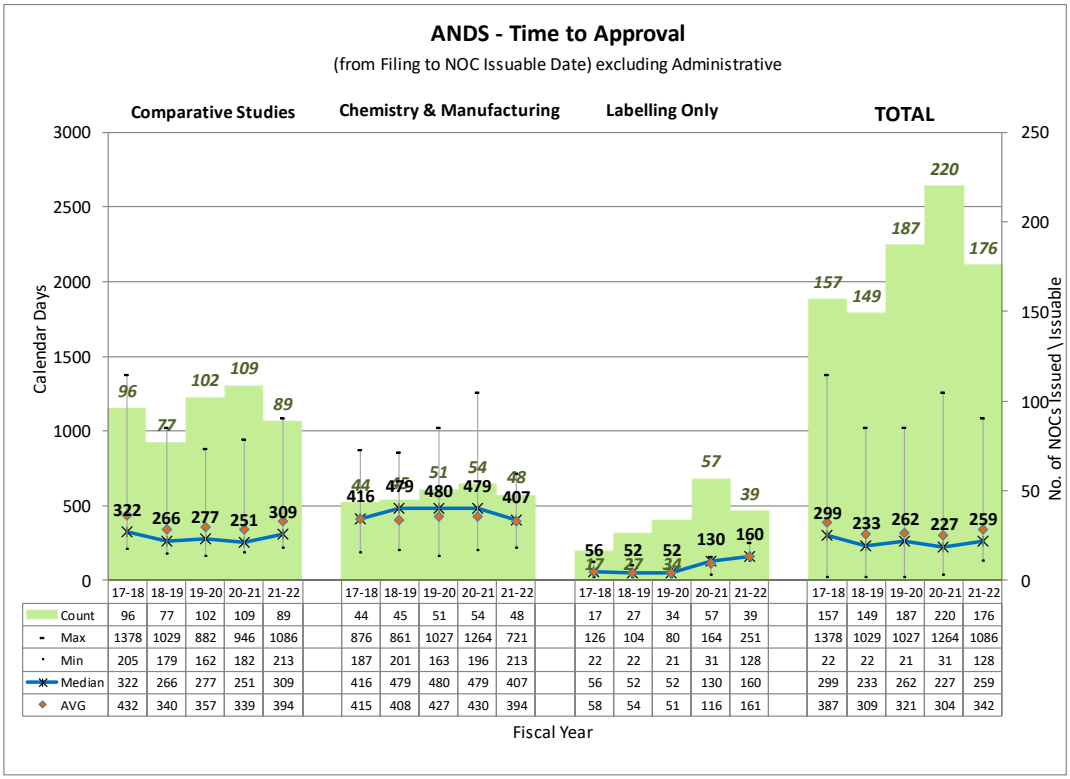
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Labelling Only	17	27	34	57	39
Chemistry & Manufacturing	44	45	51	54	48
Comparative Studies	96	77	102	109	89
Total	157	149	187	220	176
Notice of Compliance	98	109	135	160	125
NOC on Hold (Patent)	59	40	52	60	51
NOC with Conditions	0	0	0	0	0

ANDS Approval Times

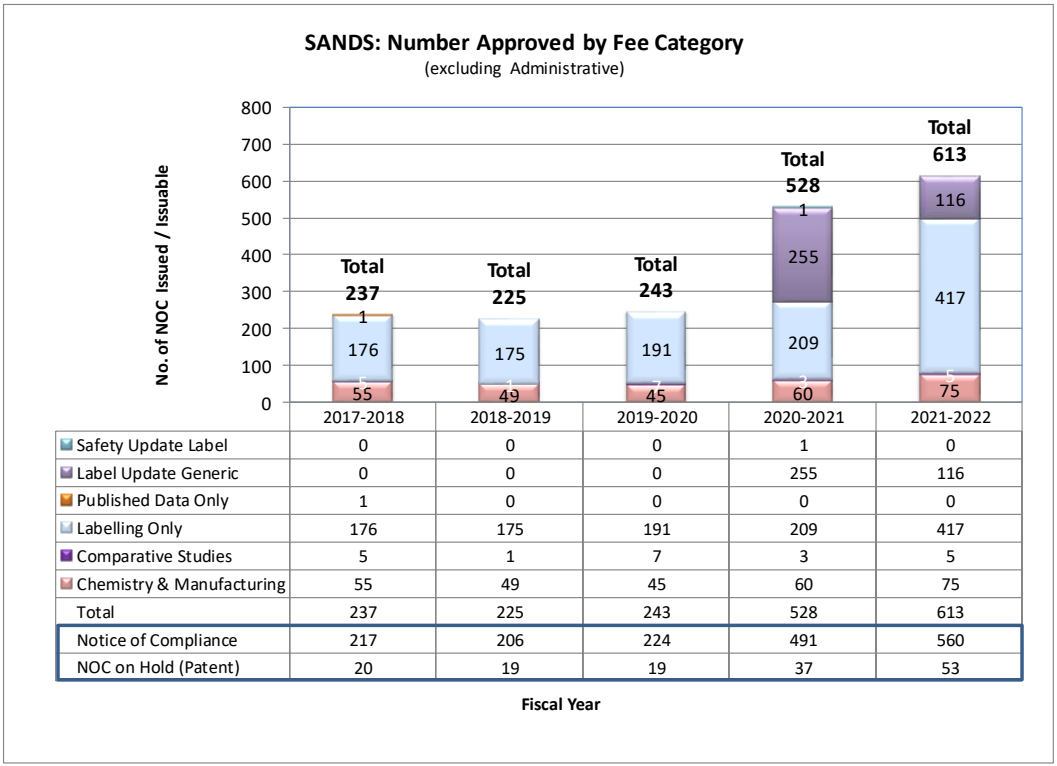


	Comparative Studies					Chemistry & Manufacturing					Labelling Only					TOTAL				
	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	96	77	102	109	89	44	45	51	54	48	17	27	34	57	39	157	149	187	220	176
Max	1378	1029	882	946	1086	876	861	1027	1264	721	126	104	80	164	251	1378	1029	1027	1264	1086
Min	205	179	162	182	213	187	201	163	196	213	22	22	21	31	128	22	22	21	31	128
Median	322	266	277	251	309	416	479	480	479	407	56	52	52	130	160	299	233	262	227	259
AVG	432	340	357	339	394	415	408	427	430	394	58	54	51	116	161	387	309	321	304	342

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.

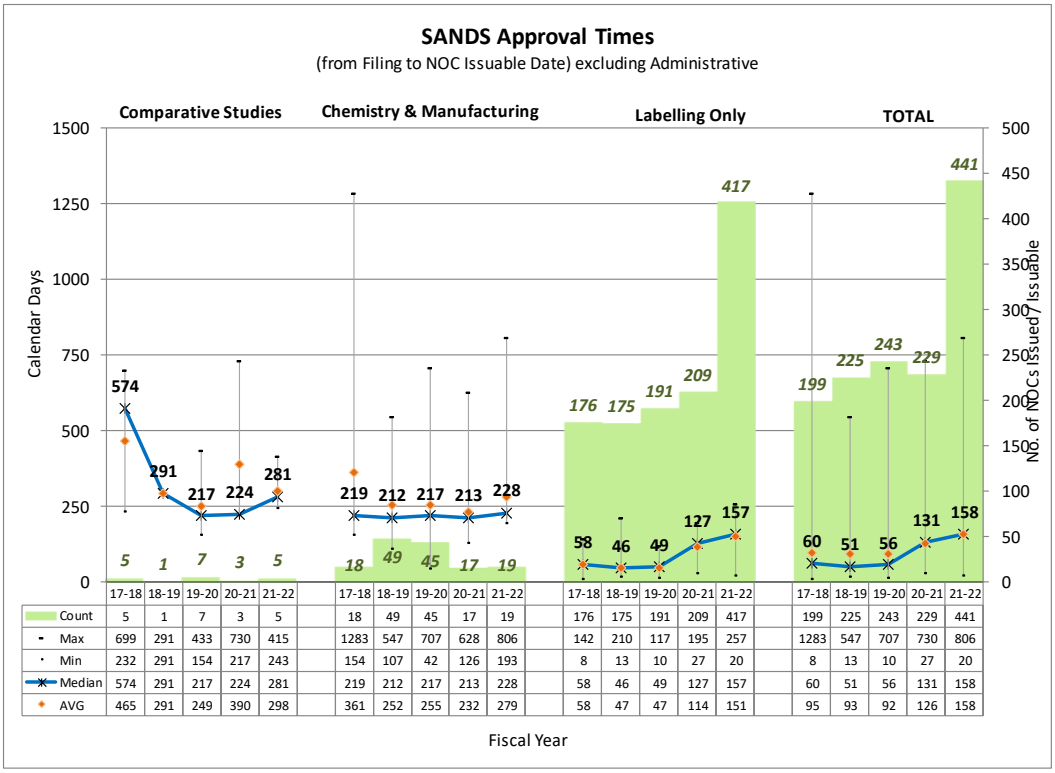
APPROVALS

SANDS: Number Approved by Fee Category and by NOC Type



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Safety Update Label	0	0	0	1	0
Label Update Generic	0	0	0	255	116
Published Data Only	1	0	0	0	0
Labelling Only	176	175	191	209	417
Comparative Studies	5	1	7	3	5
Chemistry & Manufacturing	55	49	45	60	75
Total	237	225	243	528	613
Notice of Compliance	217	206	224	491	560
NOC on Hold (Patent)	20	19	19	37	53

SANDS Approval Times

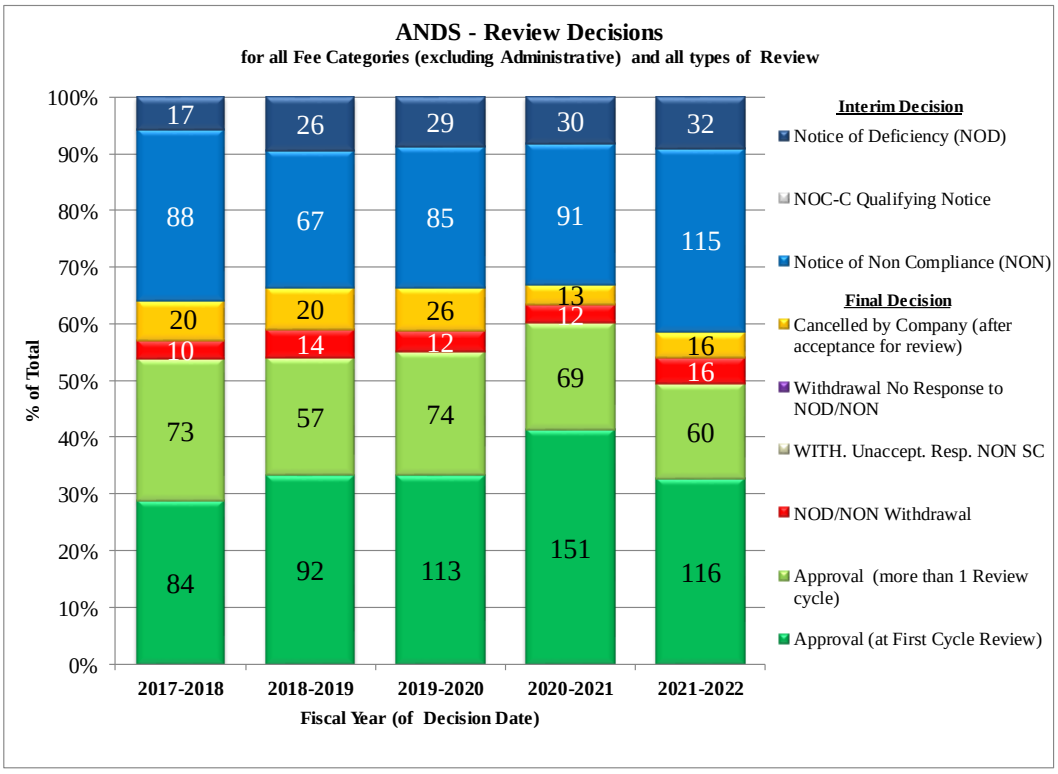


	Comparative Studies					Chemistry & Manufacturing					Labelling Only					TOTAL				
	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	5	1	7	3	5	18	49	45	17	19	176	175	191	209	417	199	225	243	229	441
Max	699	291	433	730	415	1283	547	707	628	806	142	210	117	195	257	1283	547	707	730	806
Min	232	291	154	217	243	154	107	42	126	193	8	13	10	27	20	8	13	10	27	20
Median	574	291	217	224	281	219	212	217	213	228	58	46	49	127	157	60	51	56	131	158
AVG	465	291	249	390	298	361	252	255	232	279	58	47	47	114	151	95	93	92	126	158

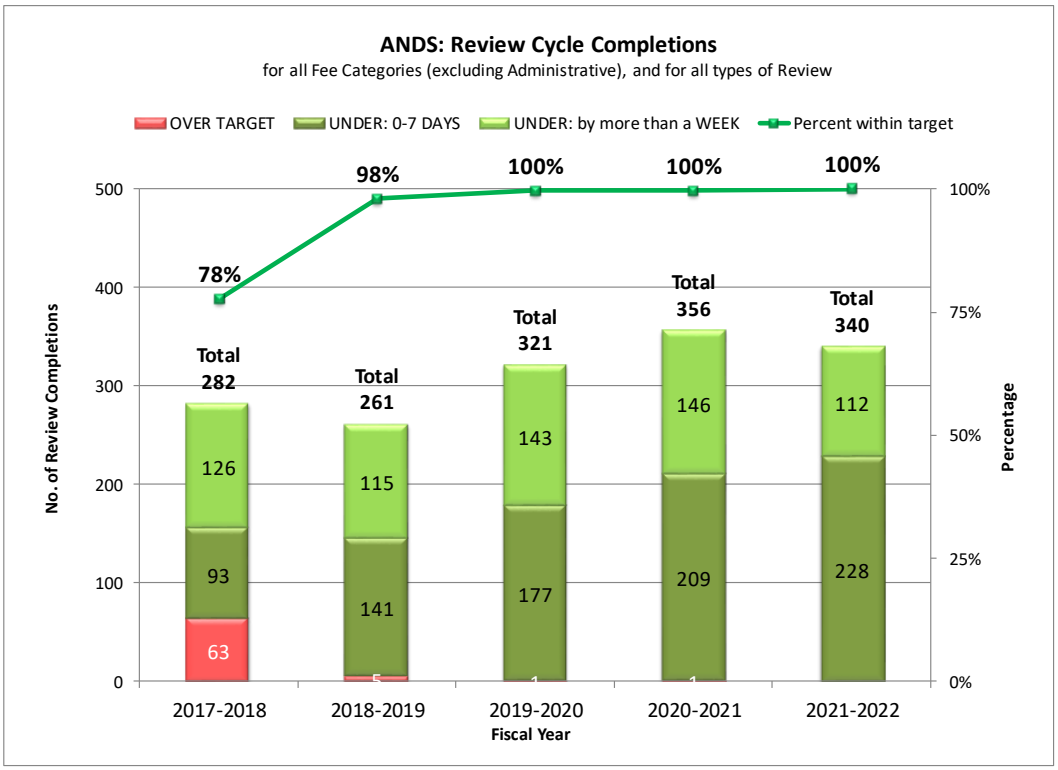
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW PERFORMANCE

ANDS: Review Decisions by Type

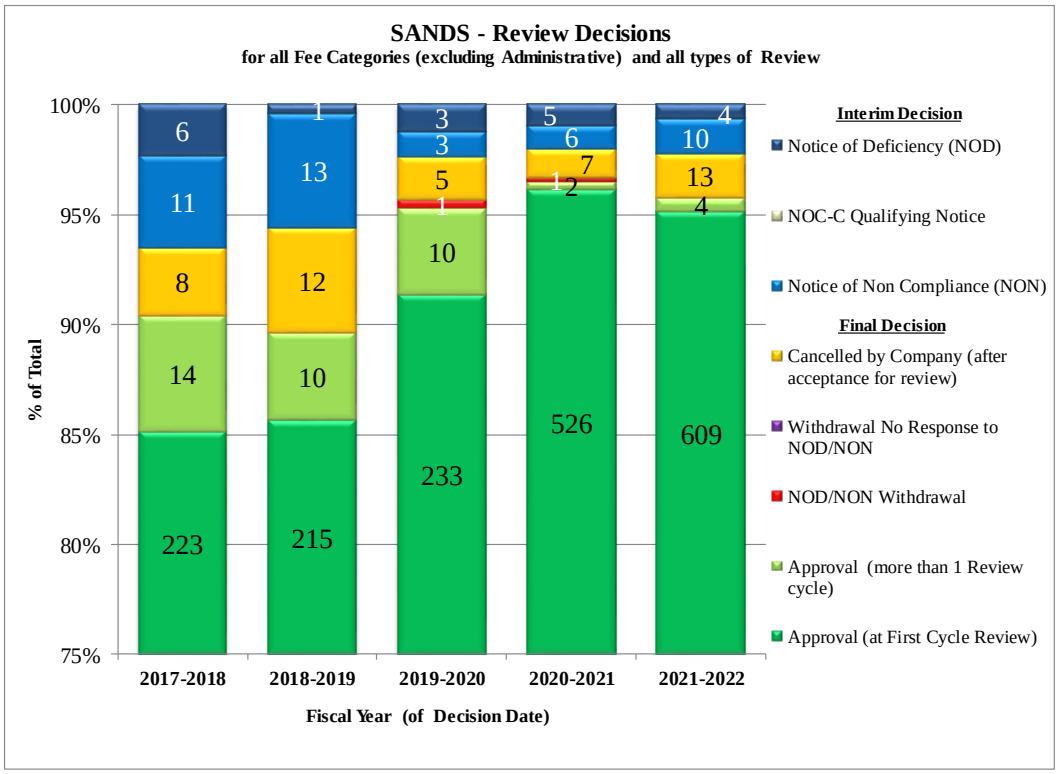


ANDS: Review Cycle Completions

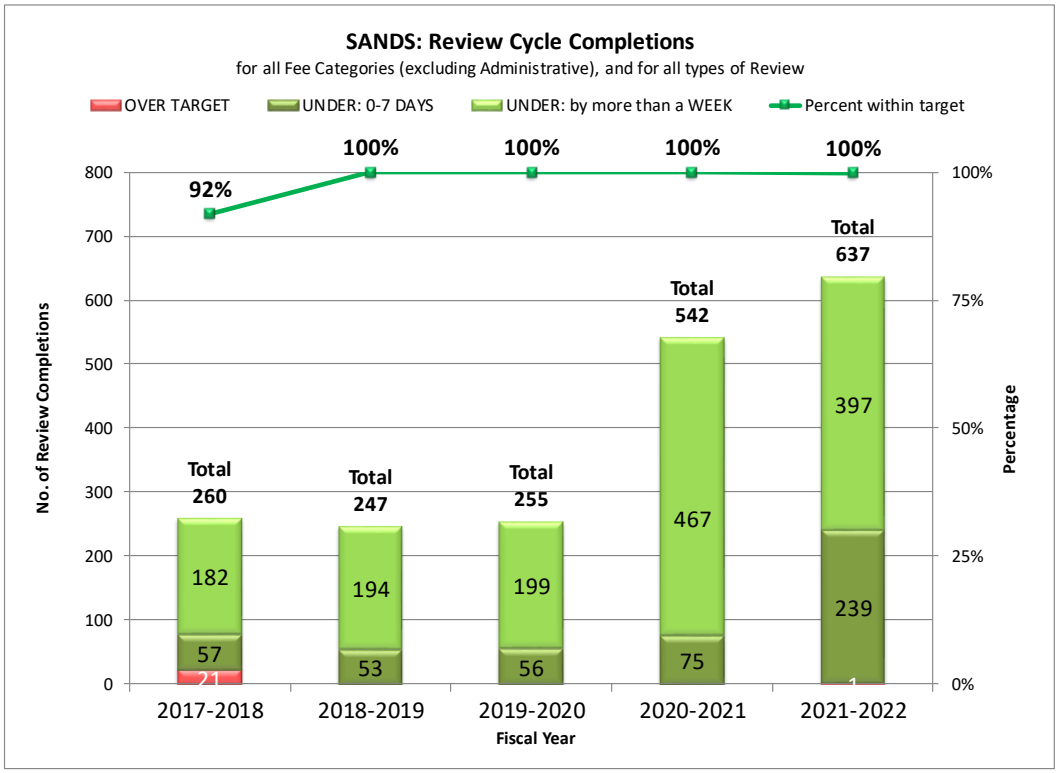


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

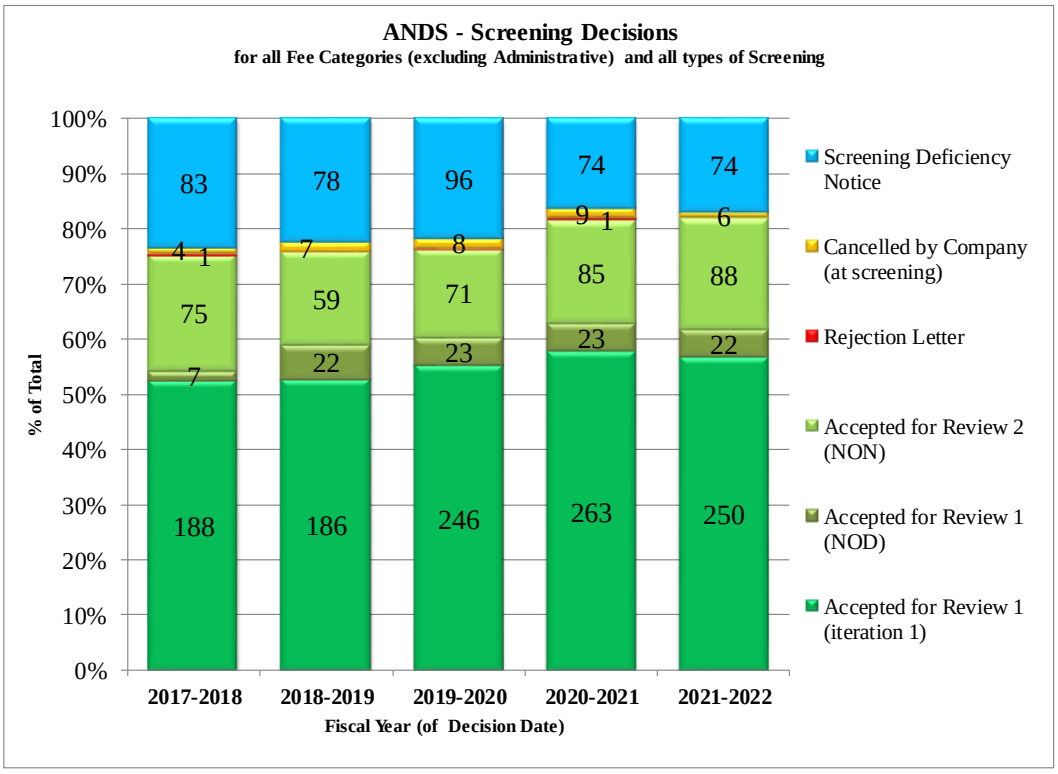


SANDS: Review Cycle Completions

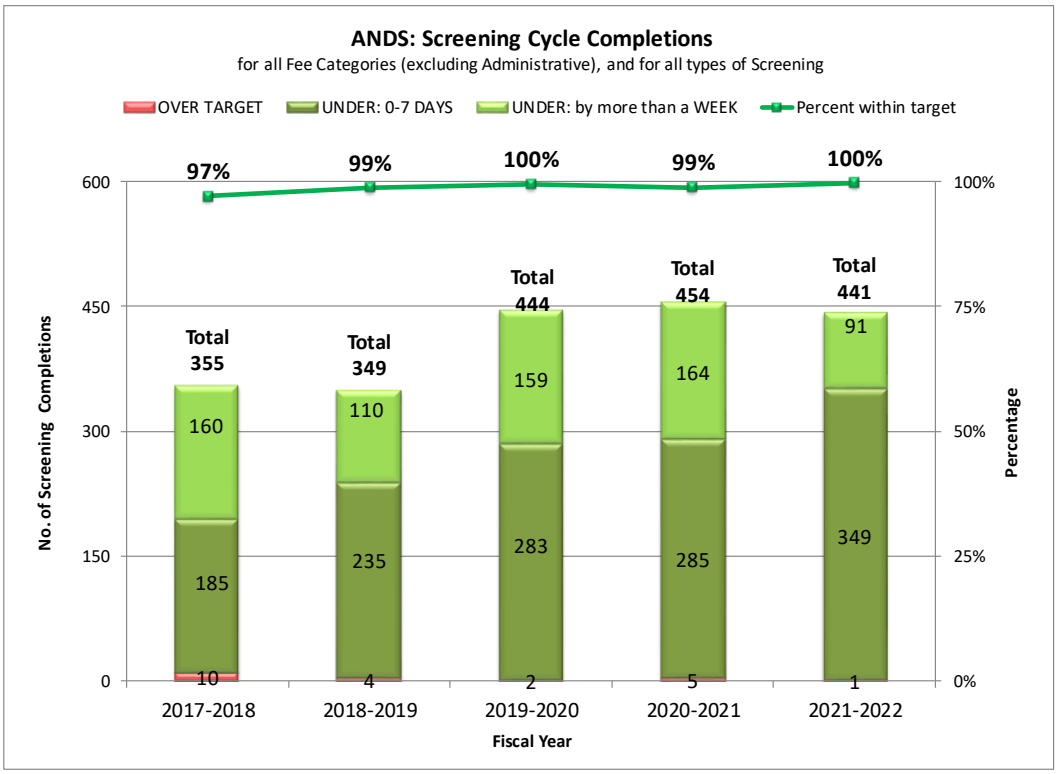


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

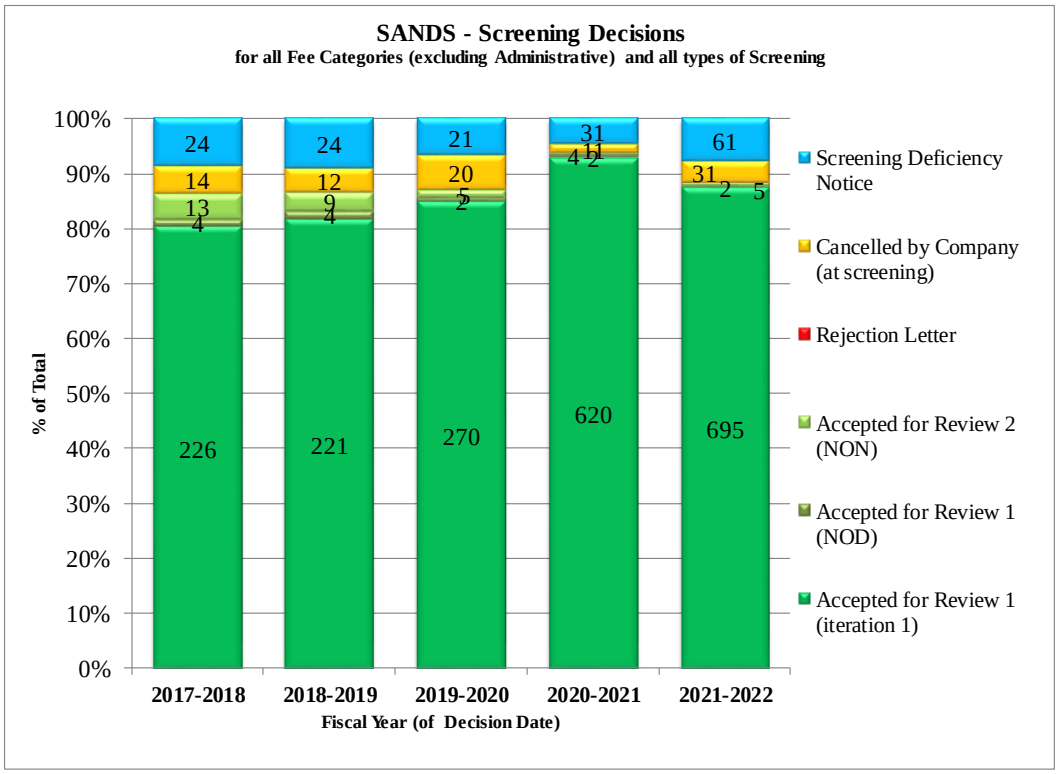


ANDS: Screening Cycle Completions

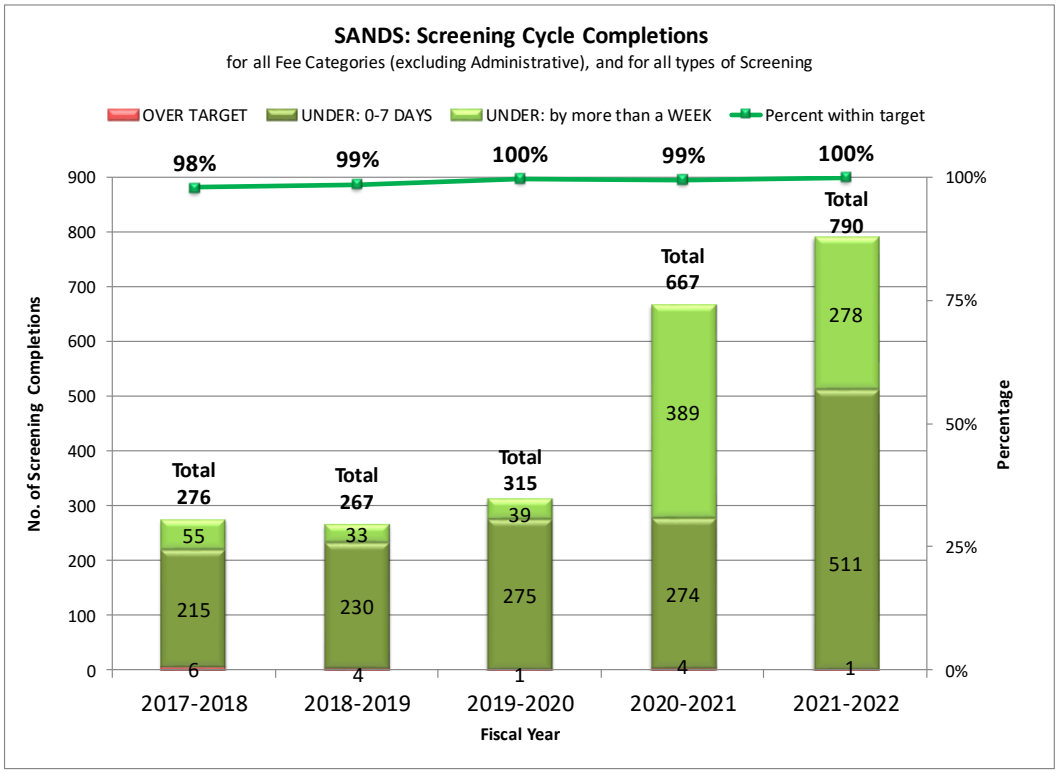


SCREENING PERFORMANCE

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	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	ANDS Status (as of June 2022)
TOTAL Received	**0**	**3**	**2**	**0**	**6**		
Total Pending	*0*	*1*	*0*	*0*	*0*		
Pending	*0*	*1*	*0*	*0*	*0*	NON-Withdrawal	Under Reconsideration
Total Granted	*0*	*2*	*0*	*0*	*0*		
Granted	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Granted	*0*	*2*	*0*	*0*	*0*	NON-Withdrawal	Cleared
Granted	*0*	*0*	*0*	*0*	*0*	Rejection at Screening	Cleared
Total Denied	*0*	*0*	*0*	*0*	*1*		
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*	*1*	NON-Withdrawal	Withdrawn
Total Cancelled	*0*	*0*	*2*	*0*	*5*		
Cancelled by Health Canada	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Cancelled by Health Canada	*0*	*0*	*0*	*0*	*5*	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	*0*	*0*	*2*	*0*	*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	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	SANDS Status (as of June 2022)
Total Received	**0**	**0**	**0**	**0**	**0**		
Total Granted	*0*	*0*	*0*	*0*	*0*		
Granted	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Cleared
Total Cancelled	*0*	*0*	*0*	*0*	*0*		
Cancelled by Health Canada	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn

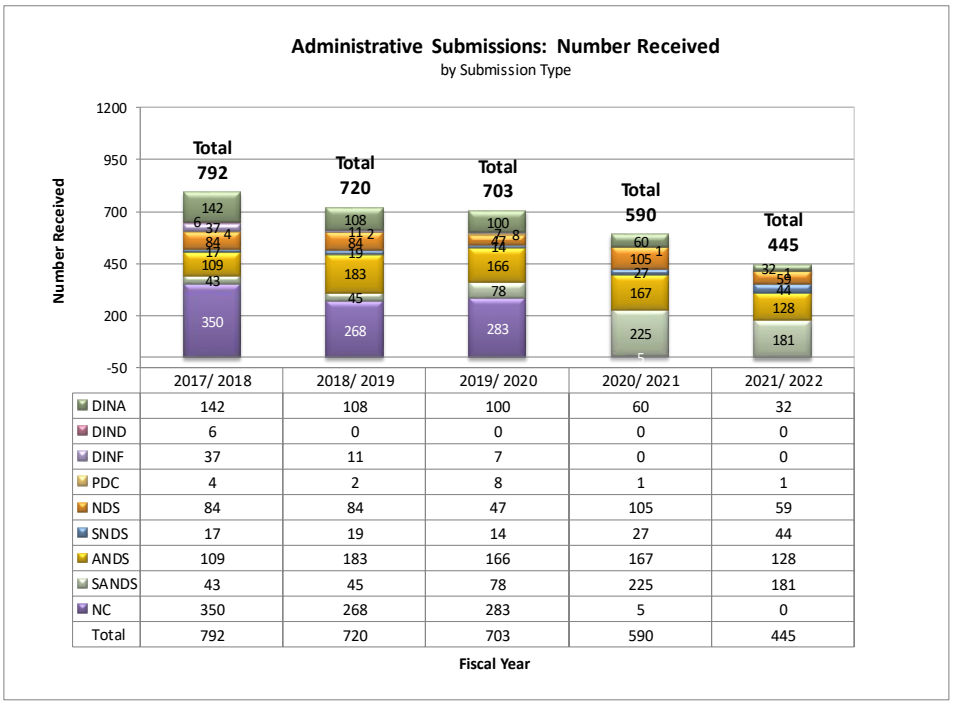
ADMINISTRATIVE SUBMISSIONS

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS[9]

RECEIVED

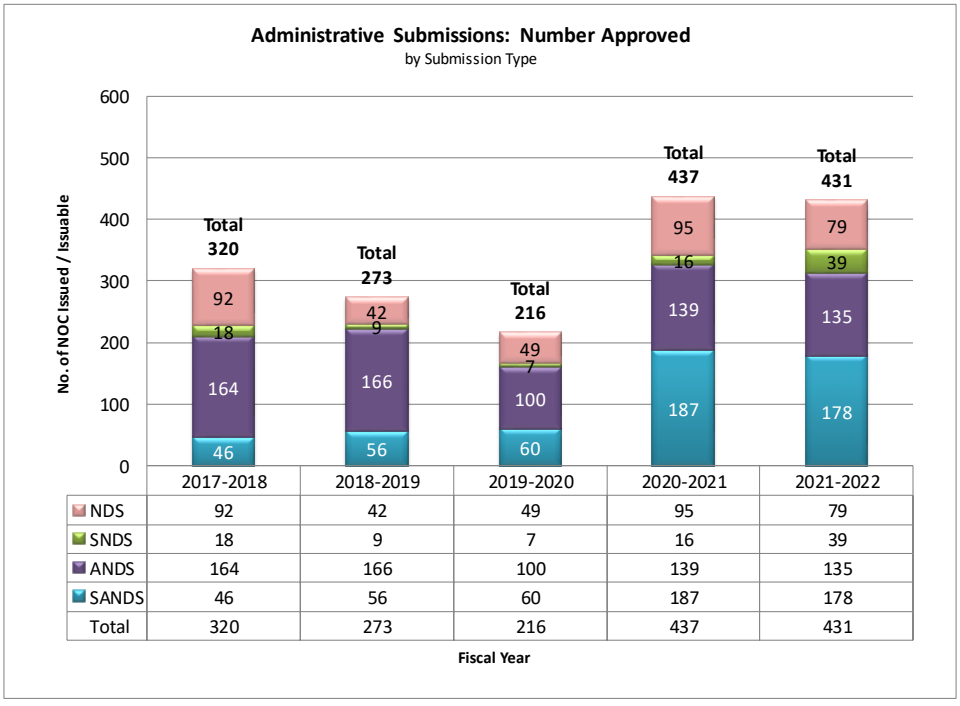
Administrative Submissions: Number Received by Submission Type



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
DINA	142	108	100	60	32
DIND	6	0	0	0	0
DINF	37	11	7	0	0
PDC	4	2	8	1	1
NDS	84	84	47	105	59
SNDS	17	19	14	27	44
ANDS	109	183	166	167	128
SANDS	43	45	78	225	181
NC	350	268	283	5	0
Total	792	720	703	590	445

APPROVALS

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



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NDS	92	42	49	95	79
SNDS	18	9	7	16	39
ANDS	164	166	100	139	135
SANDS	46	56	60	187	178
Total	320	273	216	437	431

[9] 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 PDD in December 2018 and to the NNHPD for non-prescription products.

DECISIONS

Administrative Submissions (Division 8): Number of Decisions

SUBMISSION TYPE - DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NDS - Administrative					
NOTICE OF COMPLIANCE	92	42	49	95	79
NOC ON IP HOLD	0	0	0	0	0
NOC WITH CONDITIONS	0	0	0	0	0
SCREEN. DEFICIENCY NOTICE	5	0	0	2	2
CANCELLATION LETTER	3	4	6	3	7
PROCESSING HOLD LETTER	46	12	22	16	3
SNDS - Administrative					
NOTICE OF COMPLIANCE	18	9	7	16	39
NOC ON IP HOLD	0	0	0	0	0
CANCELLATION LETTER	1	7	1	2	11
SCREEN. DEFICIENCY NOTICE	0	0	0	1	1
PROCESSING HOLD LETTER	4	5	1	3	0
ANDS - Administrative					
NOTICE OF COMPLIANCE	157	165	99	137	133
NOC ON IP HOLD	3	1	1	2	2
SCREEN. DEFICIENCY NOTICE	1	5	0	3	2
CANCELLATION LETTER	8	6	23	14	5
PROCESSING HOLD LETTER	88	44	34	23	4
SANDS - Administrative					
NOTICE OF COMPLIANCE	46	56	60	187	178
NOC ON IP HOLD	0	0	0	0	0
SCREEN. DEFICIENCY NOTICE	0	2	0	0	1
CANCELLATION LETTER	2	9	10	12	8
PROCESSING HOLD LETTER	27	20	16	20	9

DECISIONS

Administrative Applications (Division 1): Number of Decisions

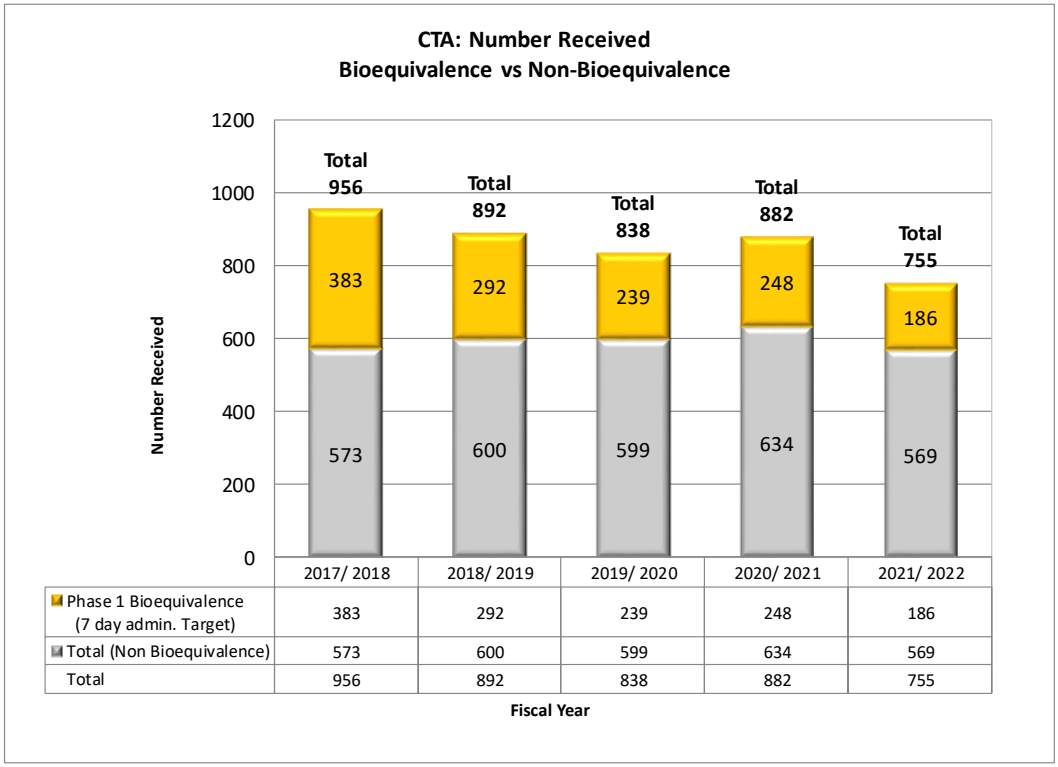
SUBMISSION TYPE - DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
DINA - Administrative					
NOTIFICATION FORM/DIN ISSUED	124	84	37	46	22
NO OBJECTION LETTER	0	2	1	1	3
SCREEN. DEFICIENCY NOTICE	11	8	0	0	8
CANCELLATION LETTER	8	11	20	11	2
PROCESSING HOLD LETTER	54	27	30	4	8
PDC - Administrative					
NO OBJECTION LETTER	1	5	3	0	0
CANCELLATION LETTER	0	3	1	1	0
PROCESSING HOLD LETTER	0	2	0	0	1

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

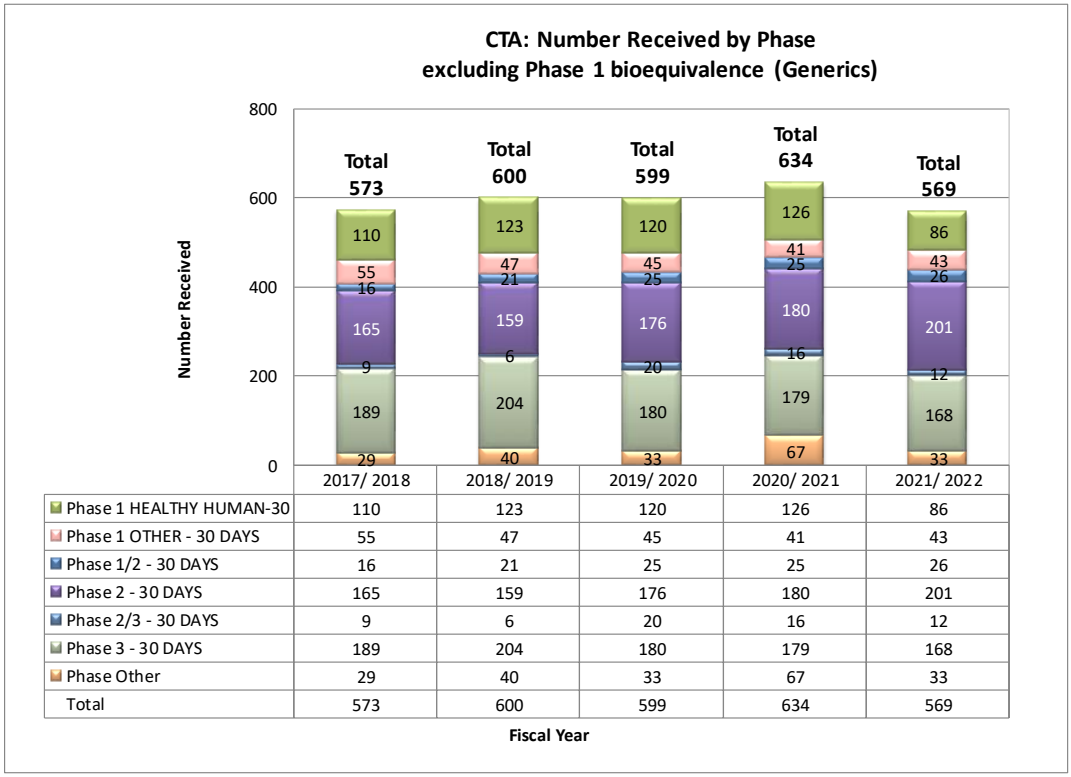
CTA: Number Received



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 Bioequivalence (7 day admin. Target)	383	292	239	248	186
Total (Non Bioequivalence)	573	600	599	634	569
Total	956	892	838	882	755

Fiscal Year

CTA: Number Received by Phase excluding Bioequivalence (Generics)



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 HEALTHY HUMAN-30	110	123	120	126	86
Phase 1 OTHER - 30 DAYS	55	47	45	41	43
Phase 1/2 - 30 DAYS	16	21	25	25	26
Phase 2 - 30 DAYS	165	159	176	180	201
Phase 2/3 - 30 DAYS	9	6	20	16	12
Phase 3 - 30 DAYS	189	204	180	179	168
Phase Other	29	40	33	67	33
Total	573	600	599	634	569

Fiscal Year

DECISION DOCUMENTS

CTA: Number of Decisions by Type

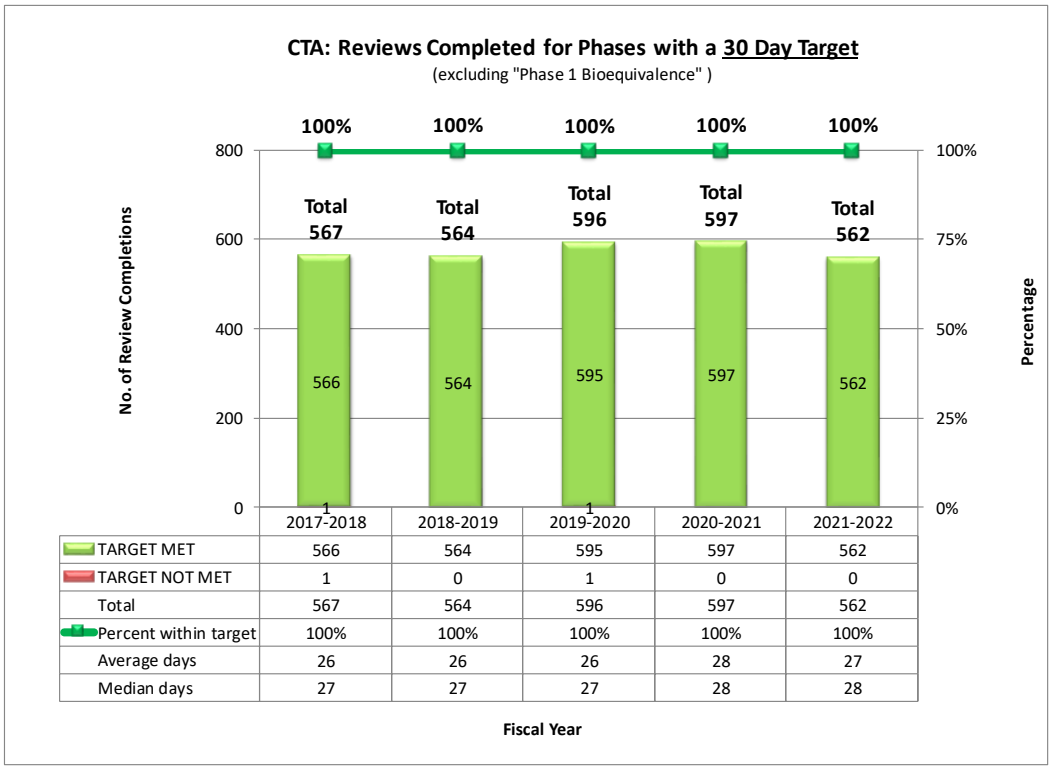
CTA (Total)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	898	821	775	803	624
NOTICE OF AUTHORIZATION	0	0	0	9	1
NOL W/COMMITMENTS	0	0	0	0	104
REJECTION LETTER (SCR)	0	0	0	0	4
CANCELLED BY COMPANY DURING REVIEW	53	37	60	47	26
CANCELLED BY COMPANY AT PROCESSING	11	11	15	12	22

CTA Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	379	286	229	240	182
NOL W/COMMITMENTS	0	0	0	0	1
CANCELLED BY COMPANY DURING REVIEW	3	5	8	5	4
CANCELLED BY COMPANY AT PROCESSING	1	2	2	2	0

CTA (30 day target)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	519	535	546	563	442
NOL W/COMMITMENTS	0	0	0	0	103
NOTICE OF AUTHORIZATION	0	0	0	0	1
REJECTION LETTER (SCR)	0	0	0	0	4
CANCELLED BY COMPANY DURING REVIEW	50	32	52	42	22
CANCELLED BY COMPANY AT PROCESSING	10	9	13	10	22
NOT SATISFACTORY NOTICE	0	1	0	0	0

PERFORMANCE

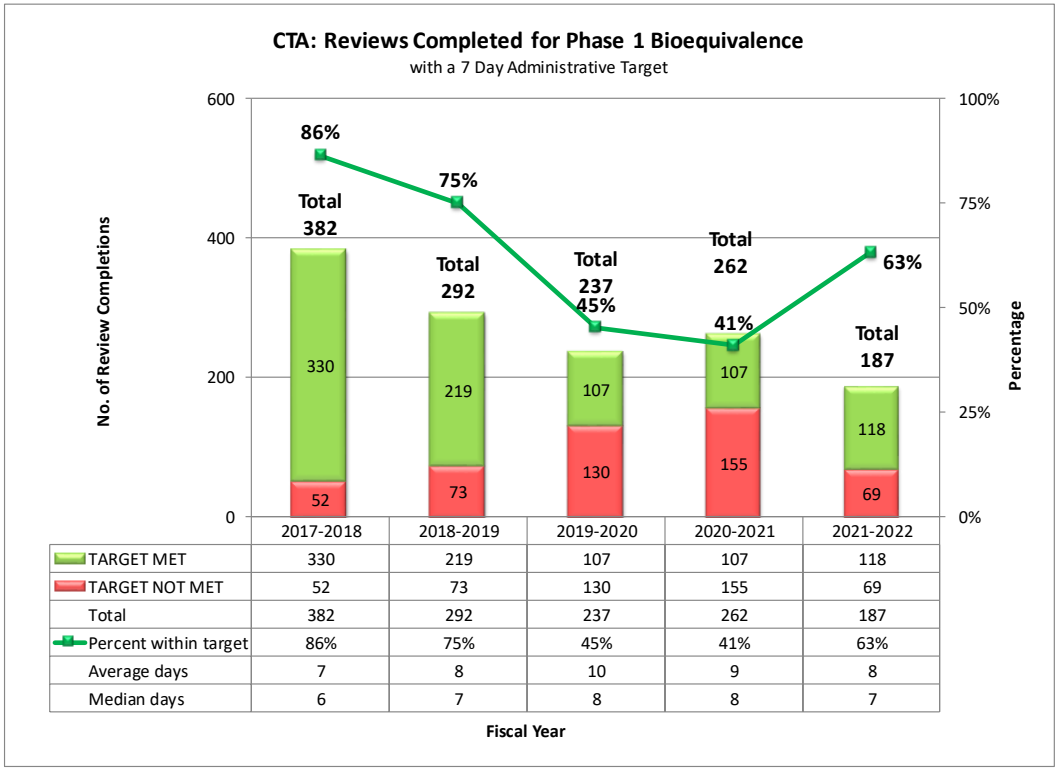
CTA: Reviews Completed for Phases with a 30 Day Target



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
TARGET MET	566	564	595	597	562
TARGET NOT MET	1	0	1	0	0
Total	567	564	596	597	562
Percent within target	100%	100%	100%	100%	100%
Average days	26	26	26	28	27
Median days	27	27	27	28	28

Fiscal Year

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

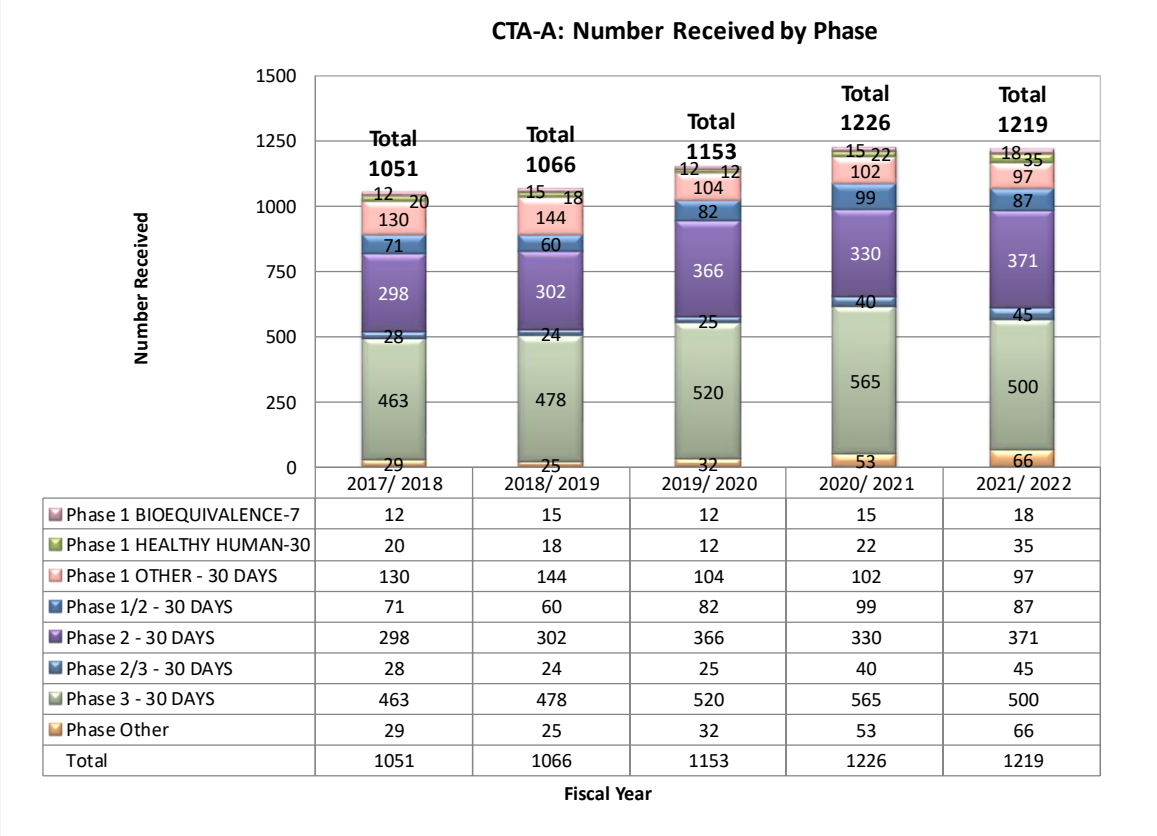


	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
TARGET MET	330	219	107	107	118
TARGET NOT MET	52	73	130	155	69
Total	382	292	237	262	187
Percent within target	86%	75%	45%	41%	63%
Average days	7	8	10	9	8
Median days	6	7	8	8	7

Fiscal Year

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 BIOEQUIVALENCE-7	12	15	12	15	18
Phase 1 HEALTHY HUMAN-30	20	18	12	22	35
Phase 1 OTHER - 30 DAYS	130	144	104	102	97
Phase 1/2 - 30 DAYS	71	60	82	99	87
Phase 2 - 30 DAYS	298	302	366	330	371
Phase 2/3 - 30 DAYS	28	24	25	40	45
Phase 3 - 30 DAYS	463	478	520	565	500
Phase Other	29	25	32	53	66
Total	1051	1066	1153	1226	1219

DECISIONS

CTA-A: Number of Decisions by Type

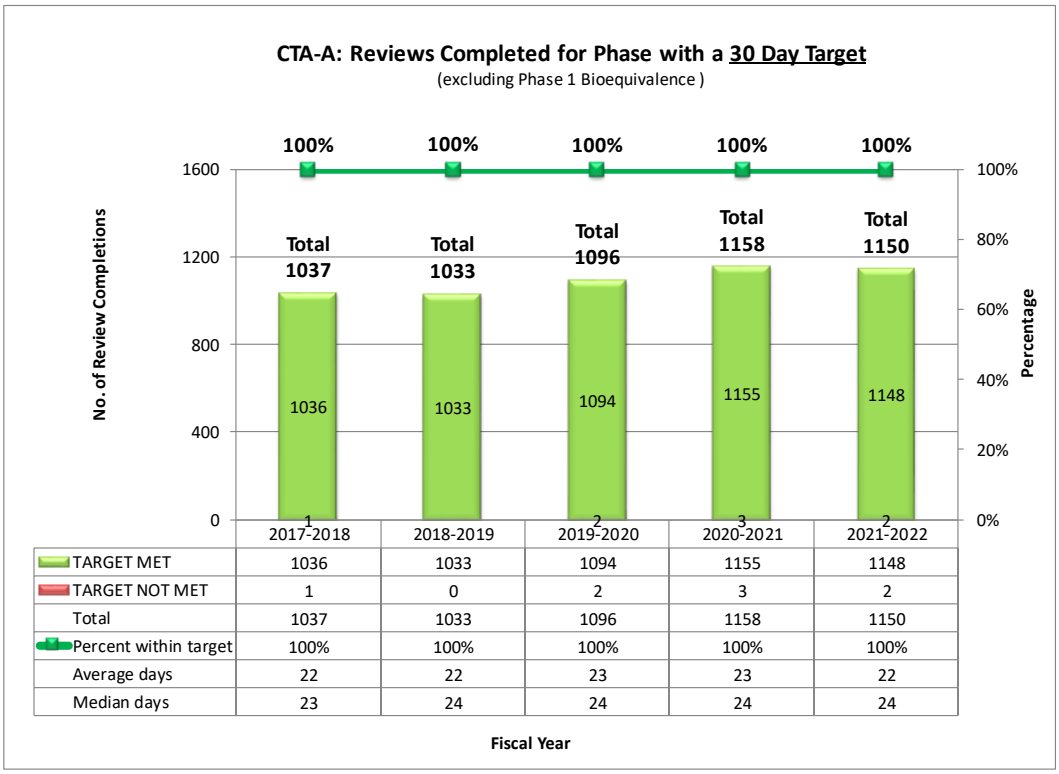
CTA-A (Total)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	1037	1032	1079	1160	1111
NOTICE OF AUTHORIZATION	0	0	0	10	5
NOTICE OF AUTHORIZA AMEND	0	0	0	0	3
NOL W/COMMITMENTS	0	0	0	0	51
CANCELLED BY COMPANY DURING REVIEW	11	15	30	16	7
CANCELLED BY COMPANY AT PROCESSING	1	3	33	50	35

CTA-A Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	12	12	13	15	17
CANCELLED BY COMPANY DURING REVIEW	0	2	0	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	2

CTA-A (30 day target)					
DOCUMENT TYPE	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NO OBJECTION LETTER	1025	1020	1066	1145	1094
NOL W/COMMITMENTS	0	0	0	0	51
NOTICE OF AUTHORIZA AMEND	0	0	0	0	3
NOTICE OF AUTHORIZATION	0	0	0	0	5
CANCELLED BY COMPANY DURING REVIEW	11	13	30	16	7
CANCELLED BY COMPANY AT PROCESSING	1	3	33	50	33
NOT SATISFACTORY NOTICE	0	0	1	0	0
REJECTION LETTER (SCR)	0	0	1	0	0

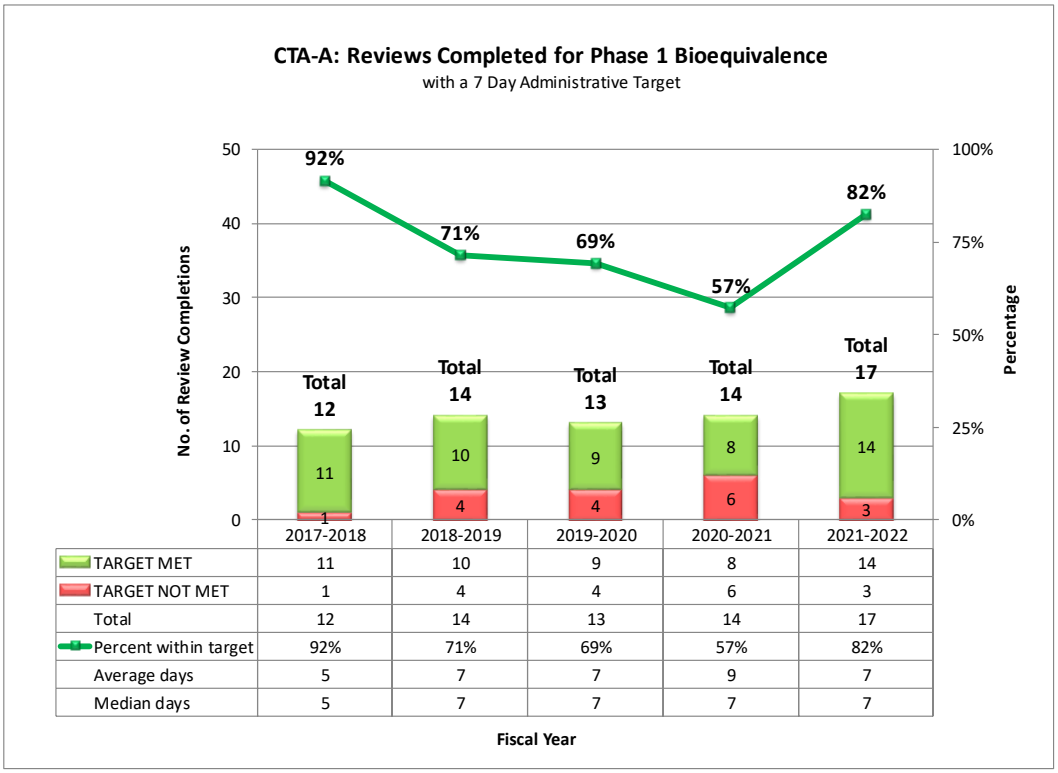
PERFORMANCE

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



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
TARGET MET	1036	1033	1094	1155	1148
TARGET NOT MET	1	0	2	3	2
Total	1037	1033	1096	1158	1150
Percent within target	100%	100%	100%	100%	100%
Average days	22	22	23	23	22
Median days	23	24	24	24	24

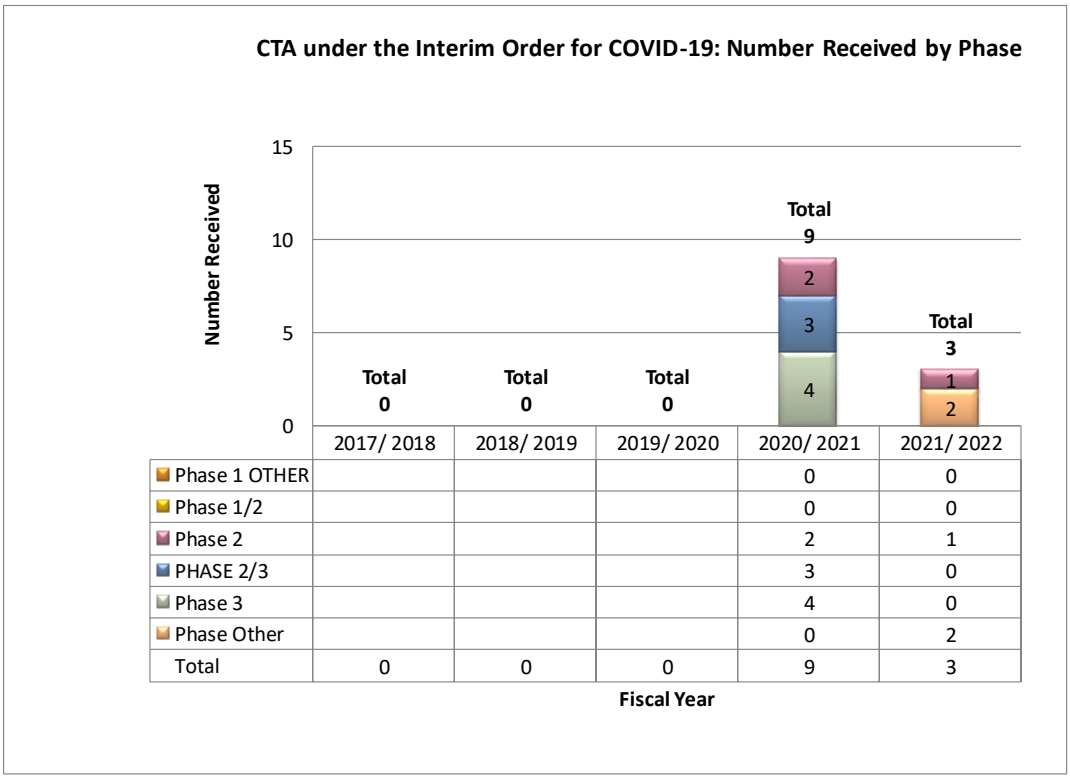
CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
TARGET MET	11	10	9	8	14
TARGET NOT MET	1	4	4	6	3
Total	12	14	13	14	17
Percent within target	92%	71%	69%	57%	82%
Average days	5	7	7	9	7
Median days	5	7	7	7	7

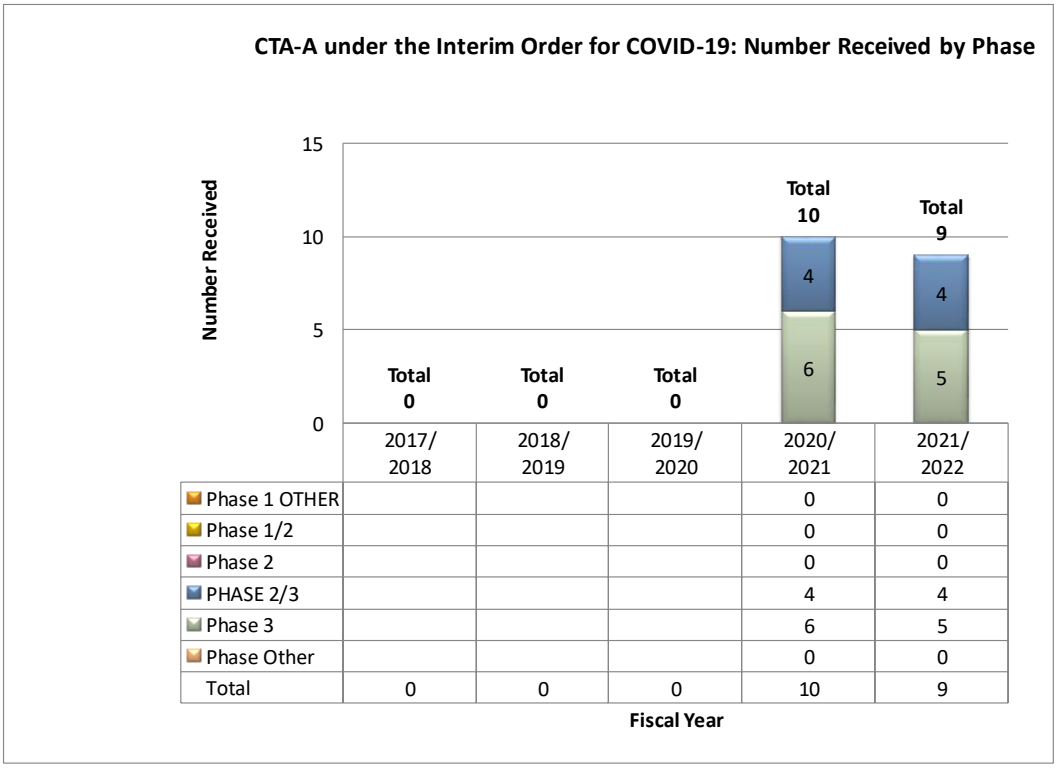
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

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



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 OTHER				0	0
Phase 1/2				0	0
Phase 2				2	1
PHASE 2/3				3	0
Phase 3				4	0
Phase Other				0	2
Total	0	0	0	9	3

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



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 OTHER				0	0
Phase 1/2				0	0
Phase 2				0	0
PHASE 2/3				4	4
Phase 3				6	5
Phase Other				0	0
Total	0	0	0	10	9

These figures are a subset of the total CTA and CTA-A received.

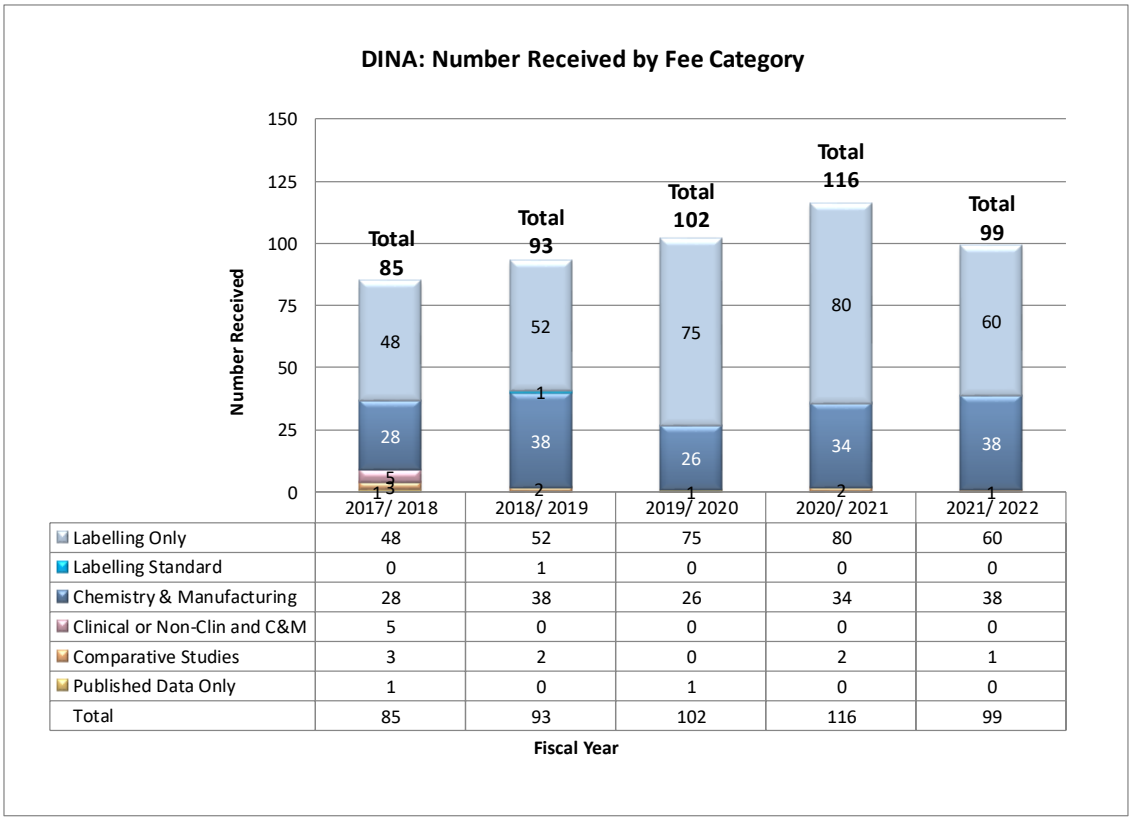
DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

RECEIVED

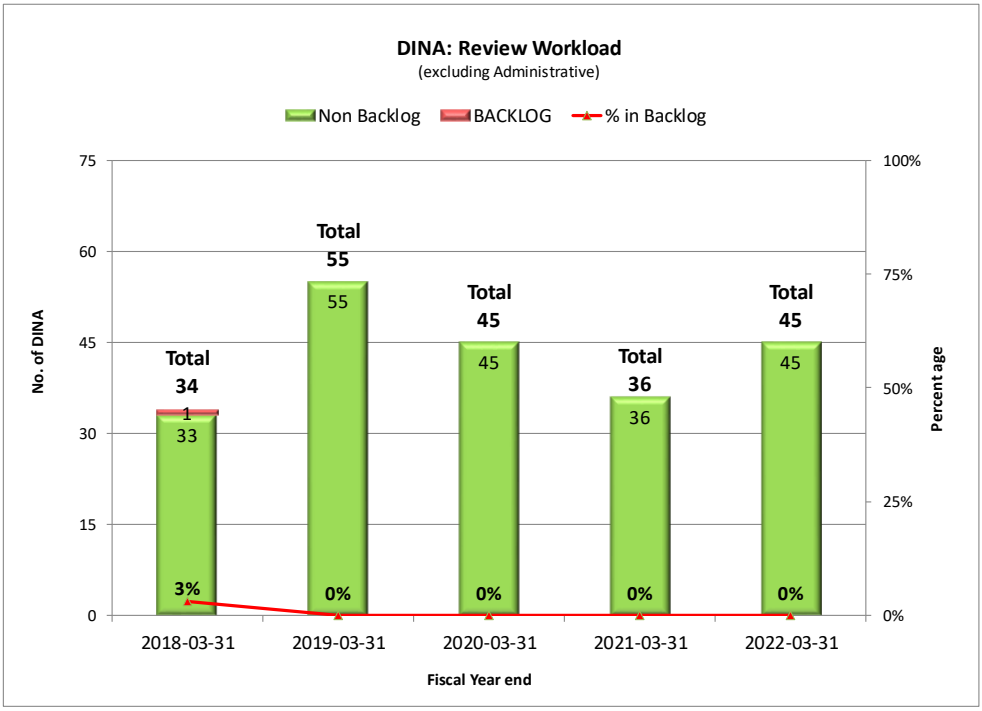
DINA: Number Received by Fee Category



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Labelling Only	48	52	75	80	60
Labelling Standard	0	1	0	0	0
Chemistry & Manufacturing	28	38	26	34	38
Clinical or Non-Clin and C&M	5	0	0	0	0
Comparative Studies	3	2	0	2	1
Published Data Only	1	0	1	0	0
Total	85	93	102	116	99

REVIEW WORKLOAD

DINA: Review Workload

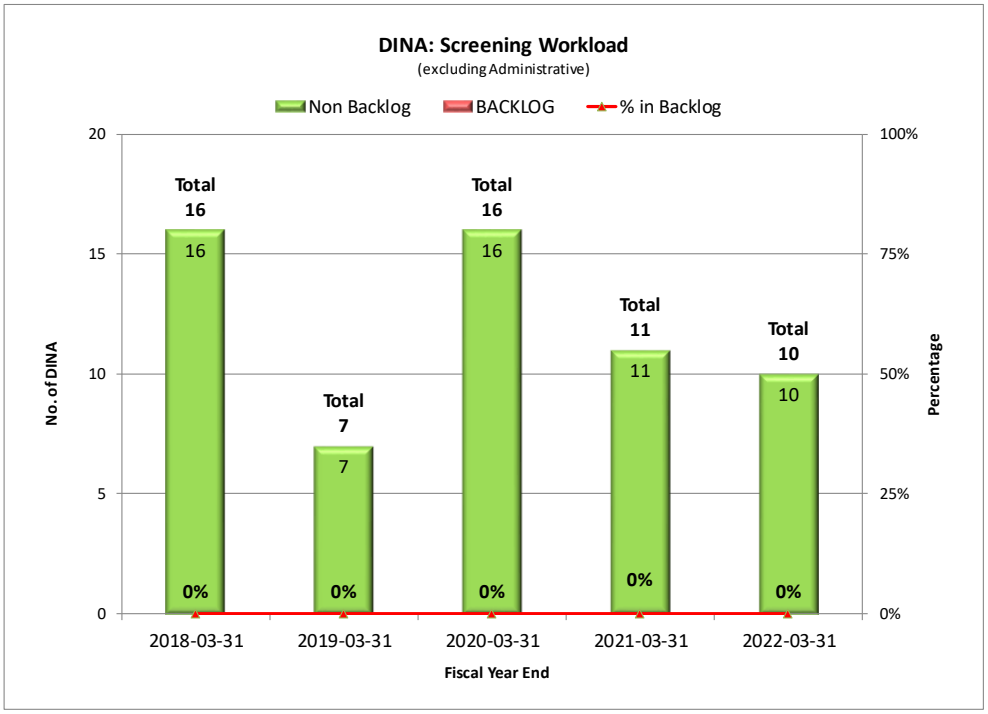


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Labelling Only	13	27	29	16	18
Backlog	*1*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	0	1	1	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	19	26	15	19	27
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**34**	**55**	**45**	**36**	**45**
Non Backlog	**33**	**55**	**45**	**36**	**45**
BACKLOG	**1**	**0**	**0**	**0**	**0**
% in Backlog	**3%**	**0%**	**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	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
Labelling Only	8	3	10	7	7
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	4	3	6	4	3
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	2	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	2	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**16**	**7**	**16**	**11**	**10**
Non Backlog	**16**	**7**	**16**	**11**	**10**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINA: Number of Decisions by Fee Category

CATEGORY / DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
DINA - LABELLING ONLY					
NOTIFICATION FORM/DIN ISSUED	12	9	2	19	10
NO OBJECTION LETTER	25	29	59	71	46
CANCELLED BY COMPANY	3	7	2	6	5
NOTICE OF DEFICIENCY	-	-	-	1	-
NOTICE OF NON-COMPLIANCE	-	2	-	-	-
REJECTION LETTER (SCREENING)	1	-	-	-	-
SCREENING DEFICIENCY NOTICE	8	6	4	3	9
DINA - PUBLISHED DATA ONLY					
NO OBJECTION LETTER	-	1	-	-	-
SCREENING DEFICIENCY NOTICE	1	-	-	-	-
CANCELLED BY COMPANY	-	-	1	-	-
NOTICE OF NON-COMPLIANCE	-	-	-	-	-
NOT SATISFACTORY NOTICE	-	-	-	-	-
DINA - CHEMISTRY & MANUFACTURING					
NOTIFICATION FORM/DIN ISSUED	13	12	15	13	13
NOTICE OF DEFICIENCY	2	3	-	-	5
REJECTION LETTER (SCREENING)	-	-	-	-	-
SCREENING DEFICIENCY NOTICE	9	7	8	20	12
CANCELLED BY COMPANY	3	7	2	1	4
NO OBJECTION LETTER	3	11	20	17	12
NEW DRUG LETTER REVIEW	1	-	-	-	-
NOTICE OF NON-COMPLIANCE	6	7	6	2	9
NON WITHDRAWAL LETTER	2	2	-	-	1
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	-	-
NON WITHDRAWAL LETTER	-	-	-	-	1
DINA - COMPARATIVE STUDIES					
NOTIFICATION FORM/DIN ISSUED	1	2	1	1	2
NO OBJECTION LETTER	-	-	-	-	-
NOTICE OF DEFICIENCY	-	-	-	1	-
NOTICE OF NON-COMPLIANCE	1	1	-	-	-
SCREENING DEFICIENCY NOTICE	3	2	-	-	-
NON WITHDRAWAL LETTER	-	1	-	-	-
CANCELLED BY COMPANY	-	1	-	-	-

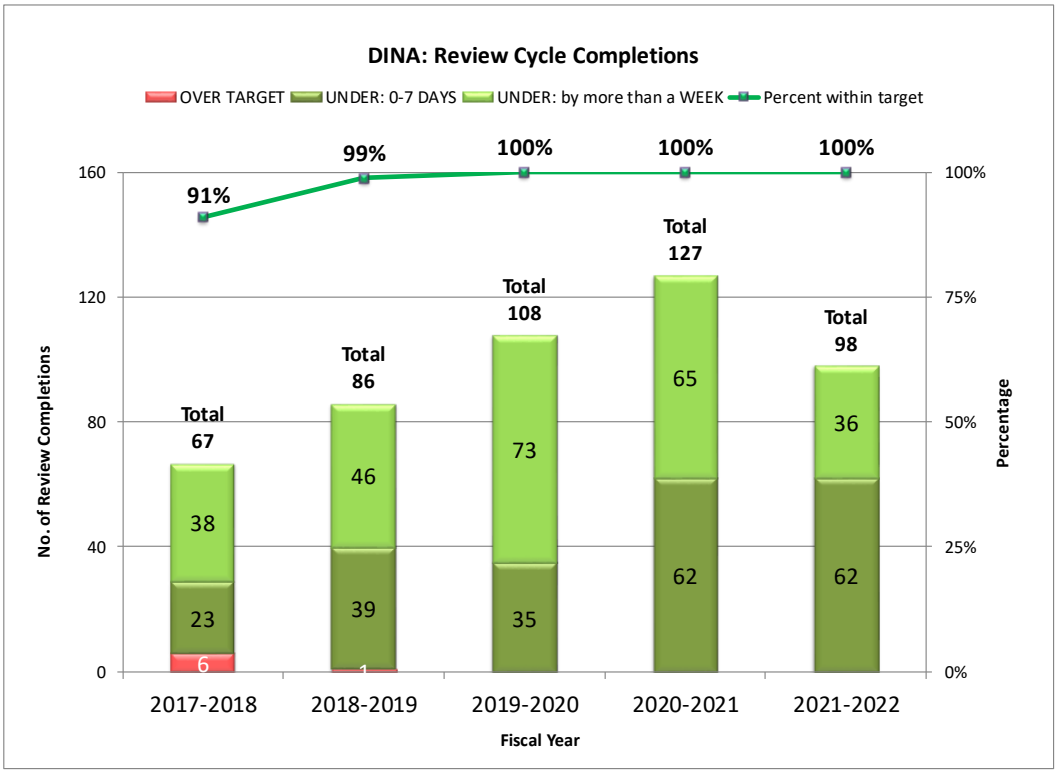
REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

DINA: Request for Reconsideration of Final Decisions

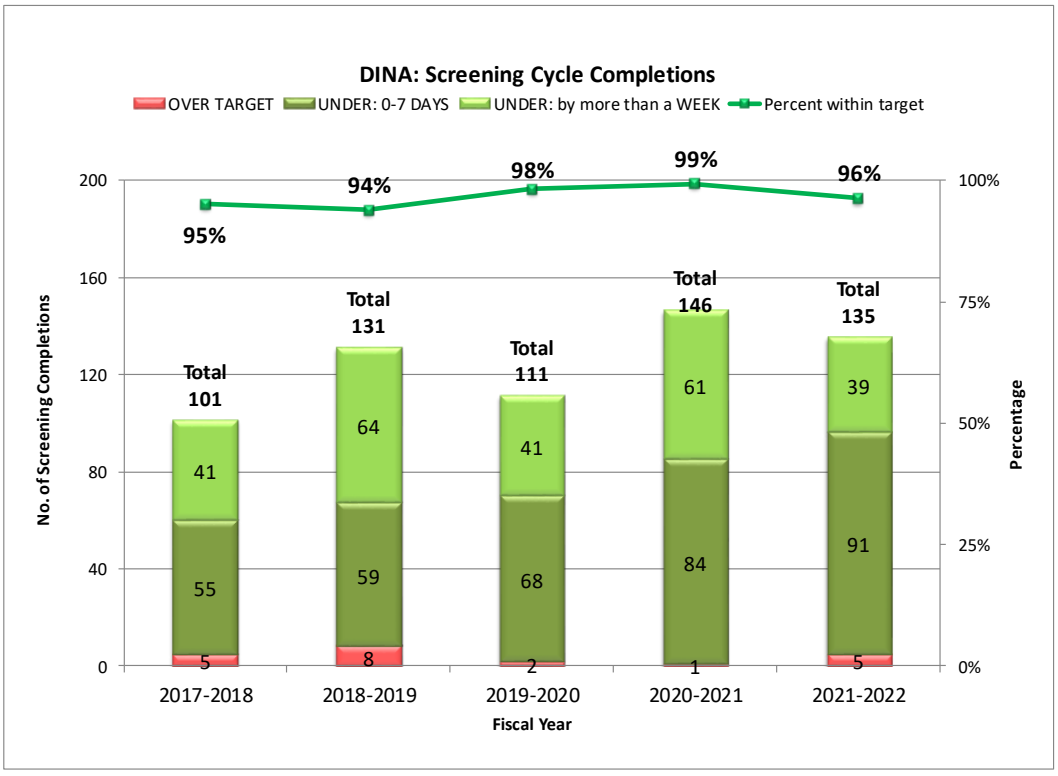
DINA - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Final Decision in Dispute	Submission Status (as of June 2022)
Total Received	1	0	0	0	0		
Total Granted	*1*	*0*	*0*	*0*	*0*		
Granted	*1*	*0*	*0*	*0*	*0*	New Drug Letter	Cancelled by Company
Granted	*0*	*0*	*0*	*0*	*0*	NON-Withdrawal	Cleared
Total Denied	*0*	*0*	*0*	*0*	*0*		
Denied	*0*	*0*	*0*	*0*	*0*	New Drug Letter	Rejected
Denied	*0*	*0*	*0*	*0*	*0*	NOD-Withdrawal	Withdrawn
Total Cancelled	***0***	***0***	***0***	***0***	***0***		

PERFORMANCE

DINA: Review Cycle Completions



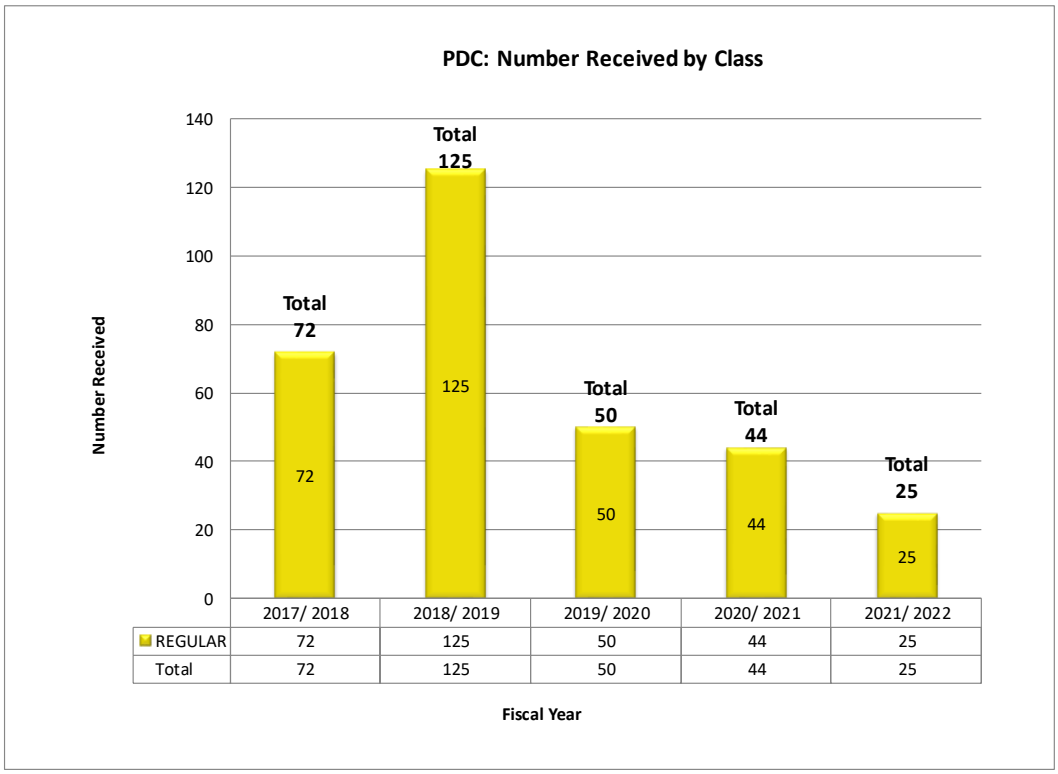
DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

RECEIVED

PDC: Number Received



DECISIONS

PDC: Number of Decision by Type

PDC- Regular					
DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
CANCELLED BY COMPANY	15	20	18	17	19
NO OBJECTION LETTER	35	131	39	31	7
NOT SATISFACTORY NOTICE	0	0	0	1	0
REJECTION LETTER (SCREENING)	0	0	0	0	0

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

PDC: Request for Reconsideration of Final Decisions

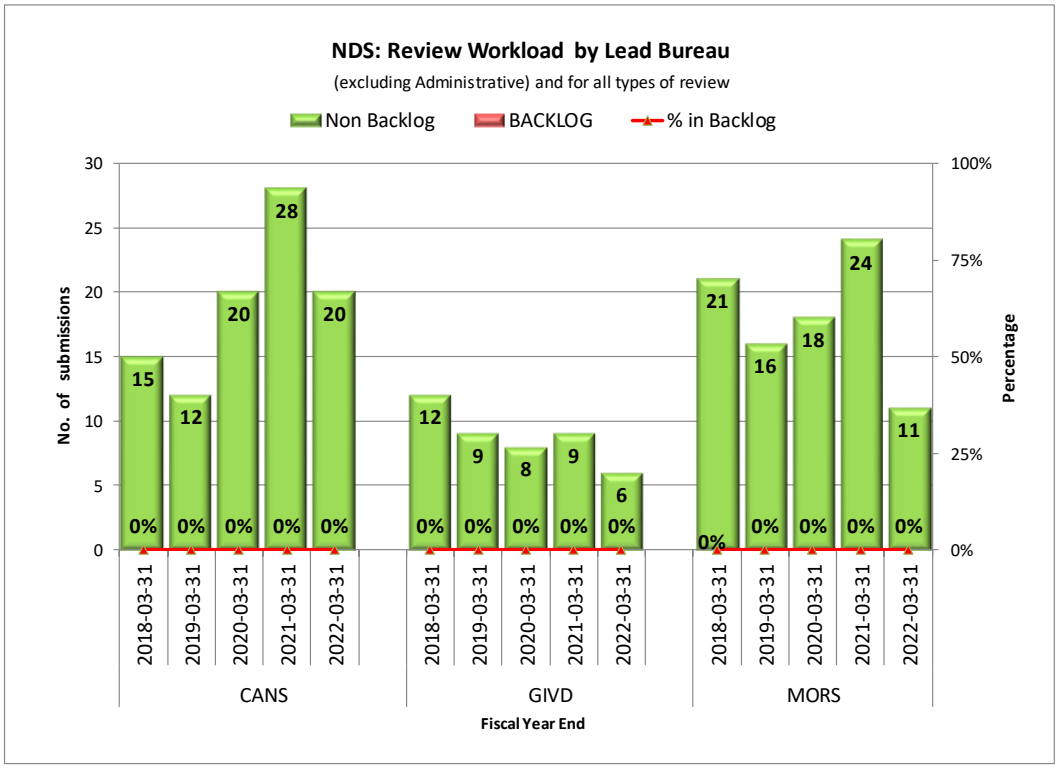
PDC - Reconsideration of Final Decisions by Year Requested					
	Fiscal Year of Request (April 1 - March 31)				
	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Total Received	0	0	0	0	0

APPENDIX A - Lead Bureau Summaries

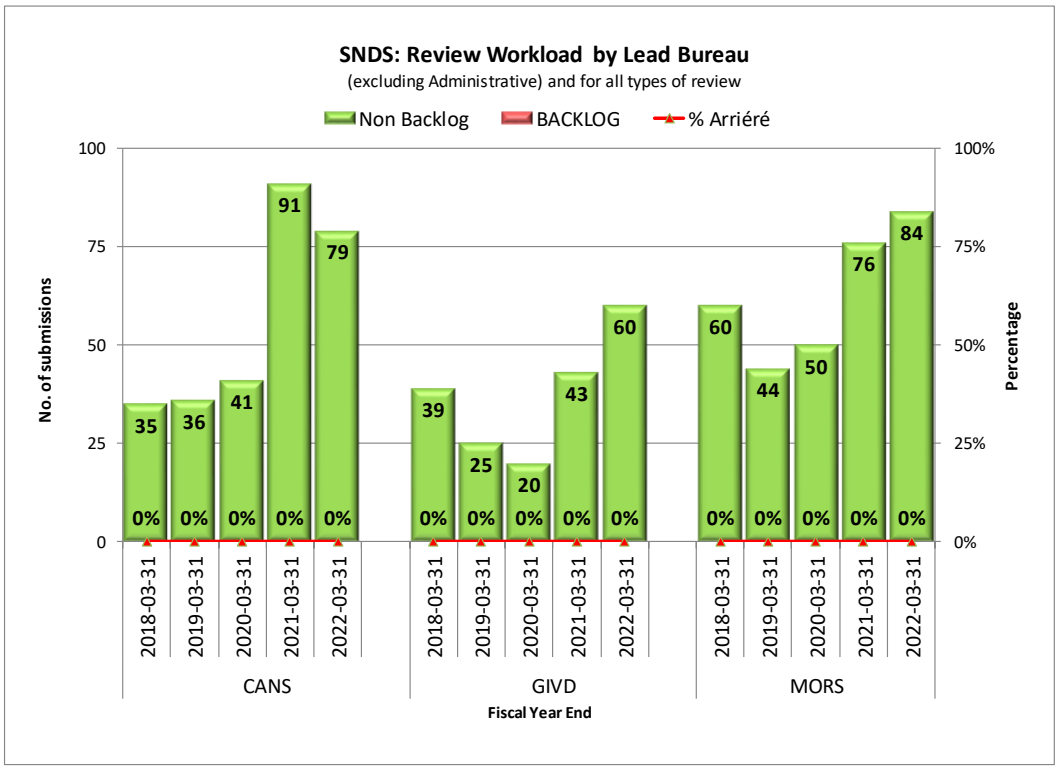
NDS & SNDS

WORKLOAD by Lead Bureau

NDS: Review Workload by Lead Bureau

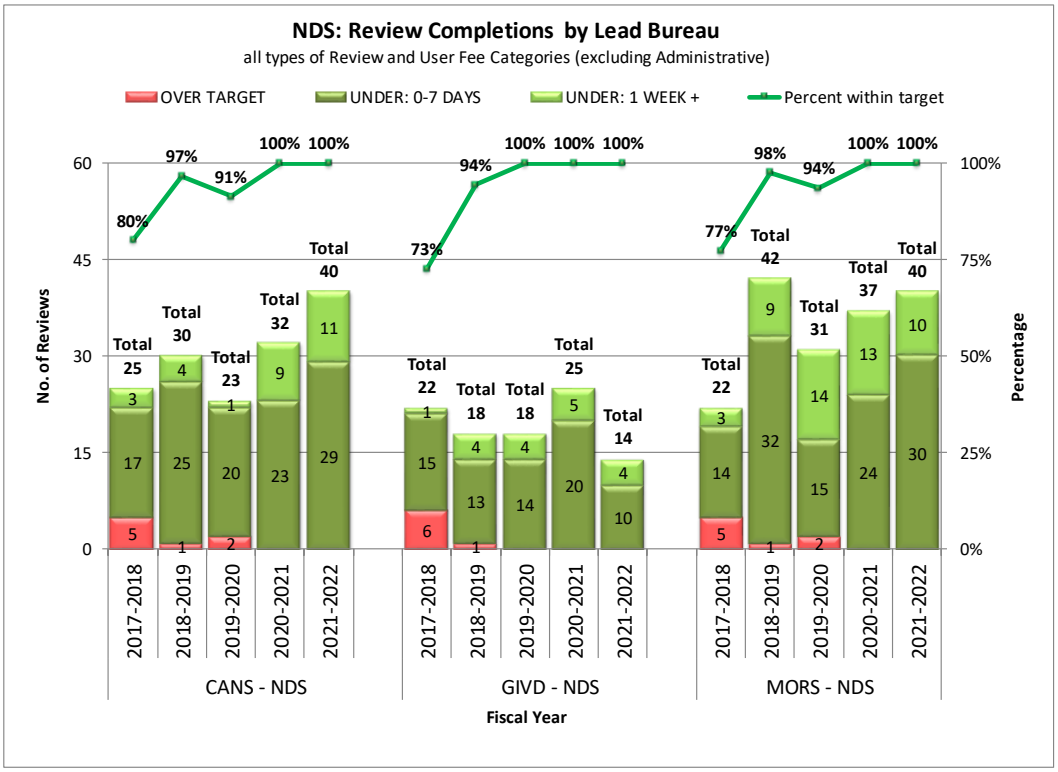


SNDS: Review Workload by Lead Bureau

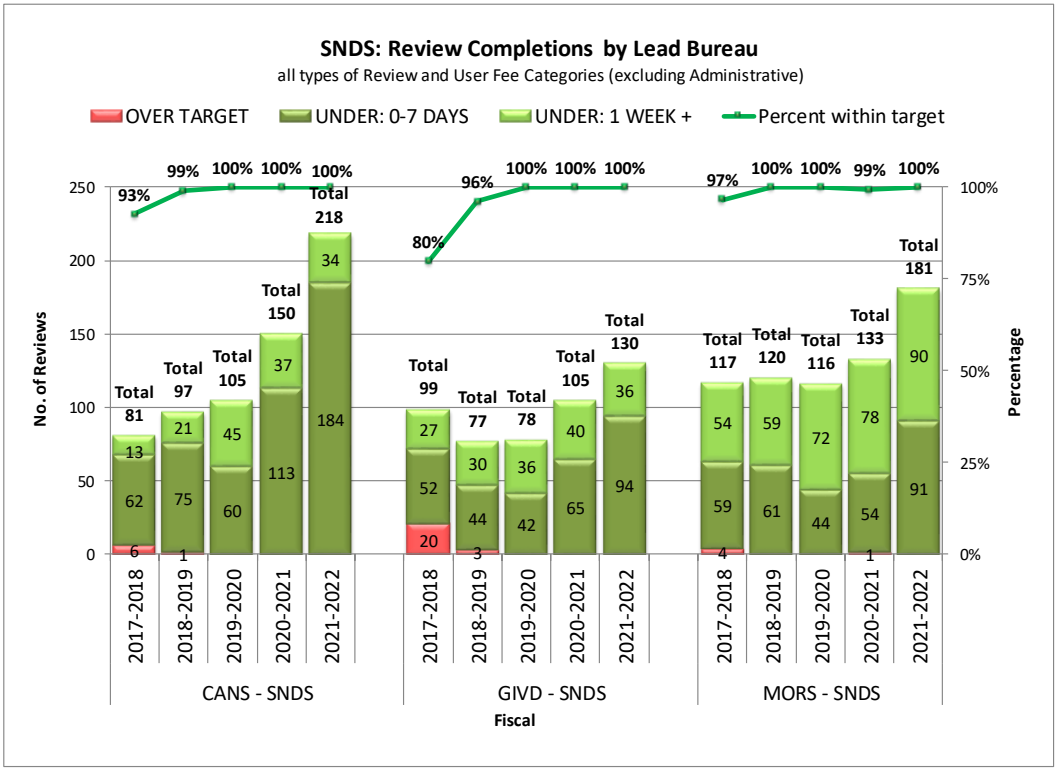


PERFORMANCE by Lead Bureau

NDS: Review Performance by Lead Bureau

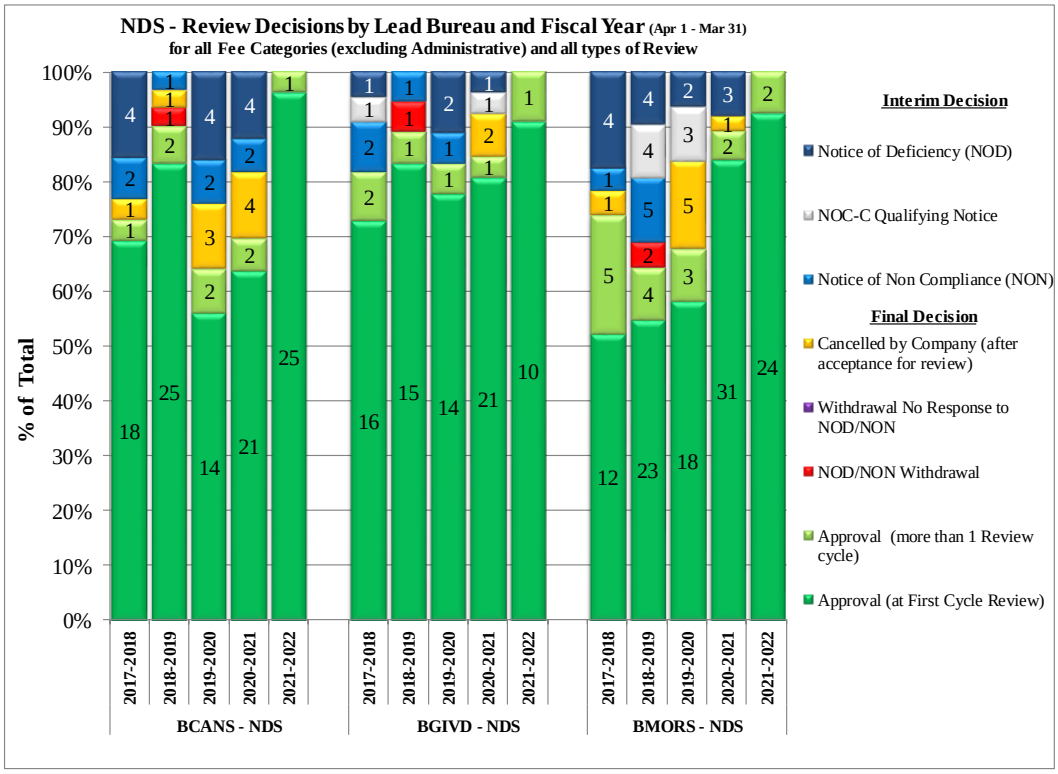


SNDS: Review Performance by Lead Bureau

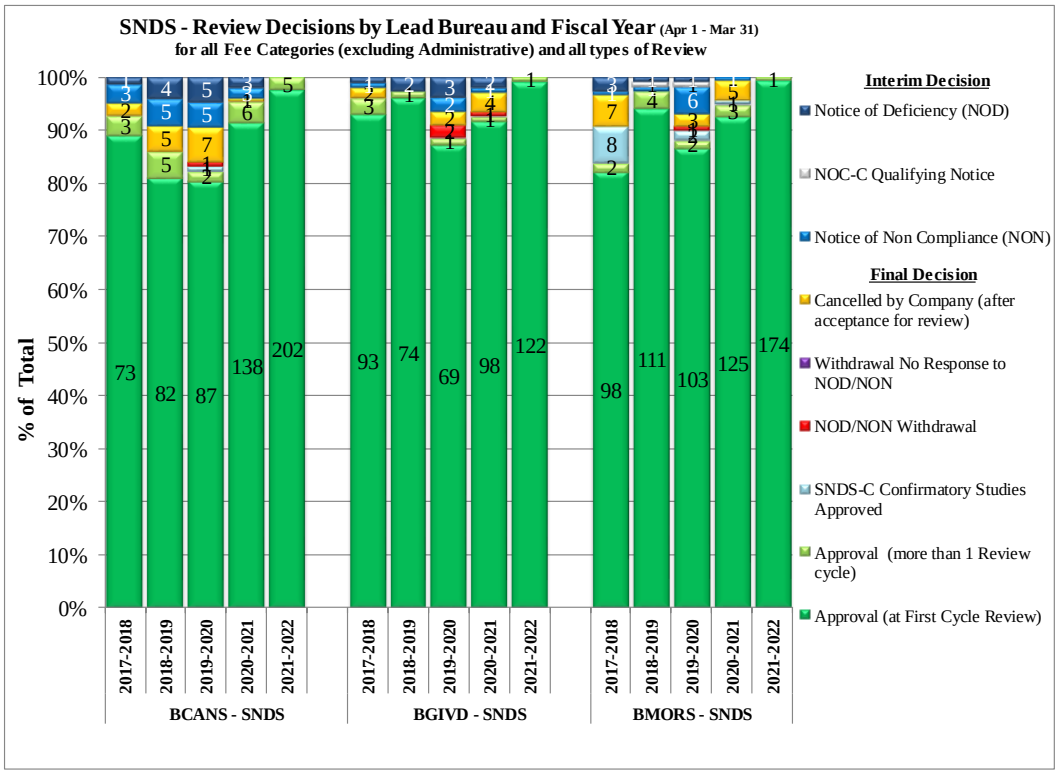


REVIEW DECISIONS by Lead Bureau

NDS: Review Decisions by Lead Bureau

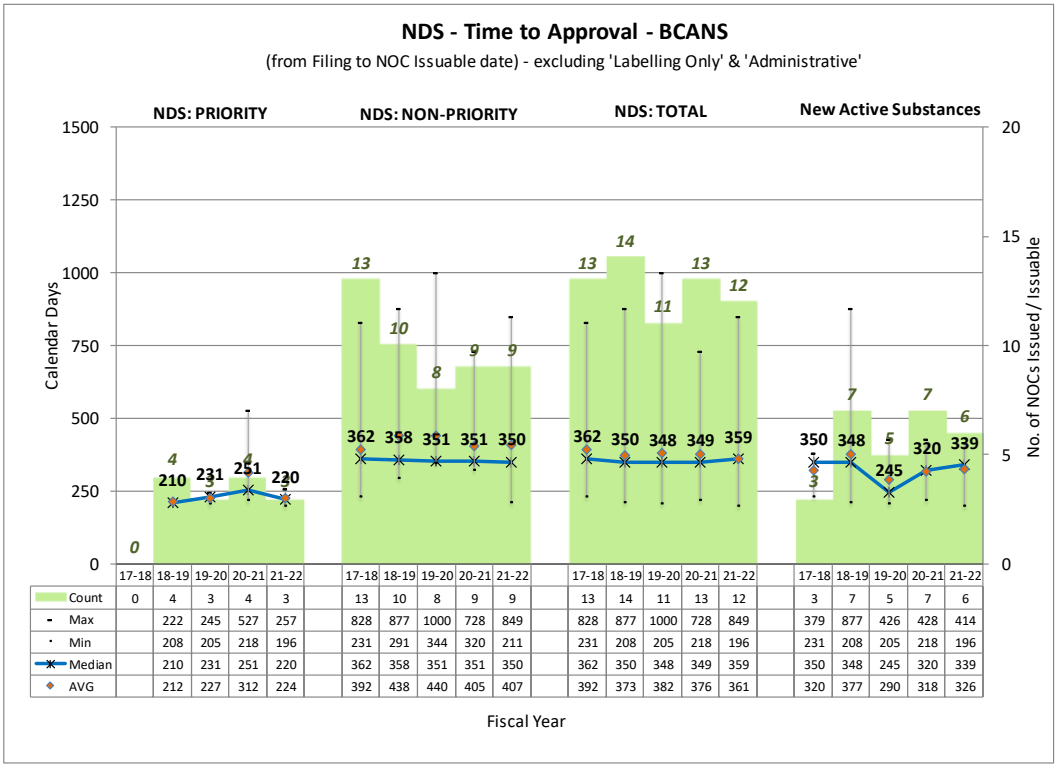


SNDS: Review Decisions by Lead Bureau



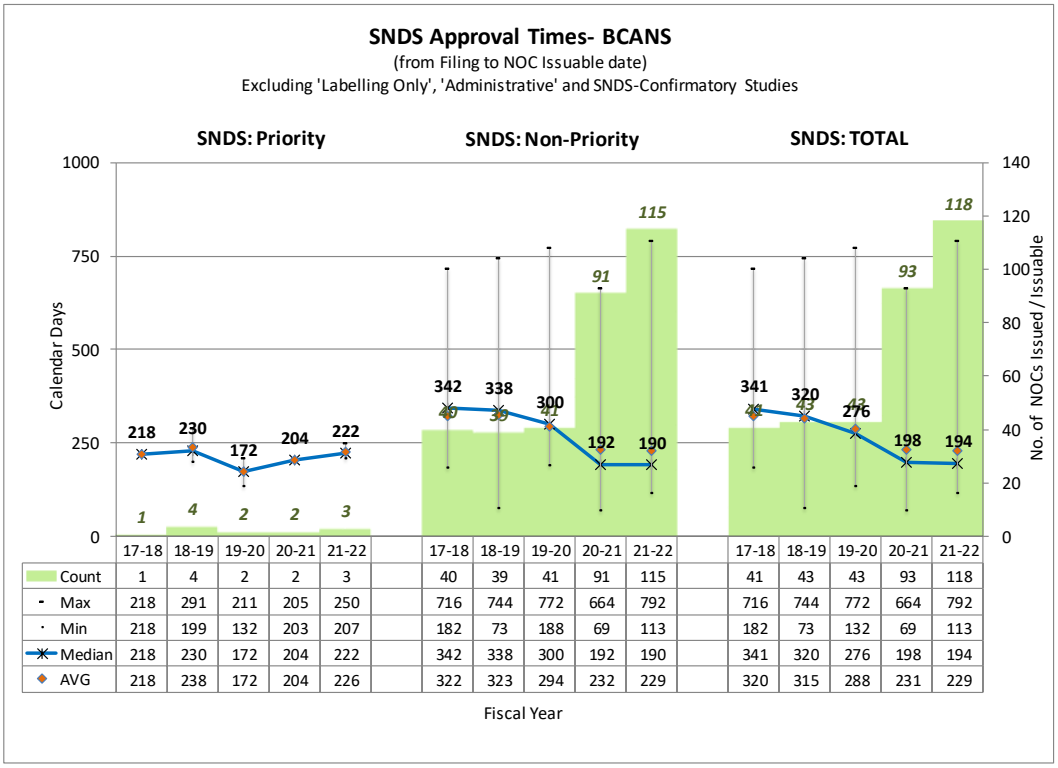
APPROVALS: Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)

NDS Time to Approval: BCANS



	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	0	4	3	4	3	13	10	8	9	9	13	14	11	13	12	3	7	5	7	6
Max		222	245	527	257	828	877	1000	728	849	828	877	1000	728	849	379	877	426	428	414
Min		208	205	218	196	231	291	344	320	211	231	208	205	218	196	231	208	205	218	196
Median		210	231	251	220	362	358	351	351	350	362	350	348	349	359	350	348	245	320	339
AVG		212	227	312	224	392	438	440	405	407	392	373	382	376	361	320	377	290	318	326

SNDS Time to Approval: BCANS

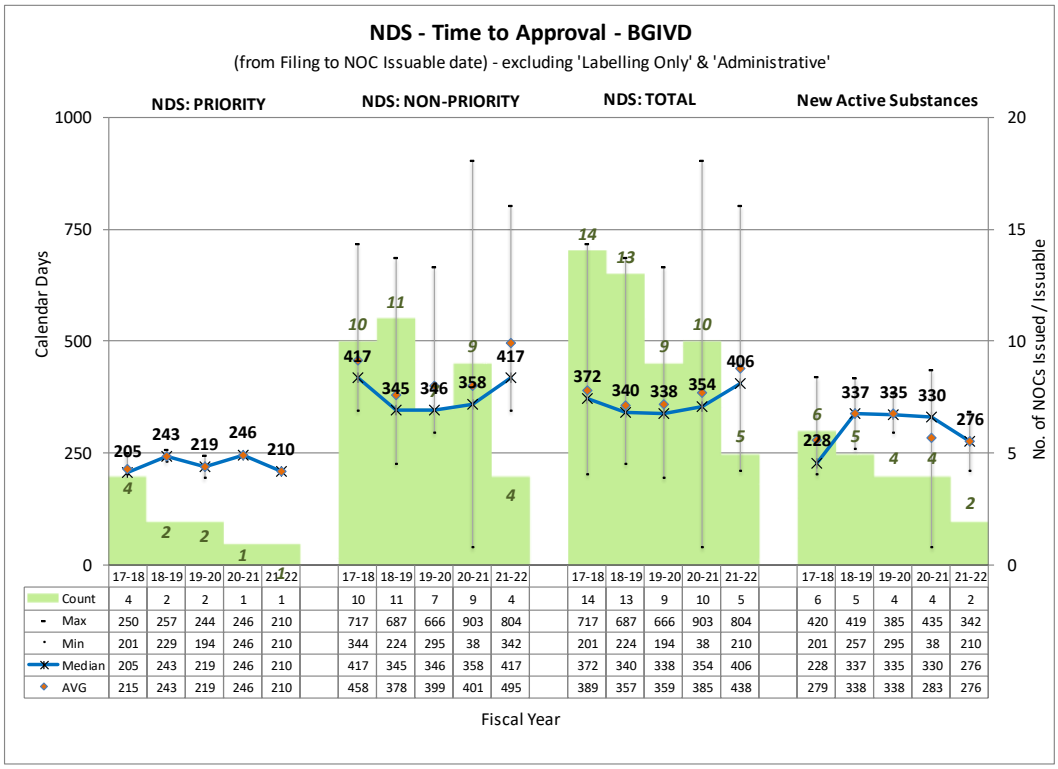


	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	1	4	2	2	3	40	39	41	91	115	41	43	43	93	118
Max	218	291	211	205	250	716	744	772	664	792	716	744	772	664	792
Min	218	199	132	203	207	182	73	188	69	113	182	73	132	69	113
Median	218	230	172	204	222	342	338	300	192	190	341	320	276	198	194
AVG	218	238	172	204	226	322	323	294	232	229	320	315	288	231	229

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.

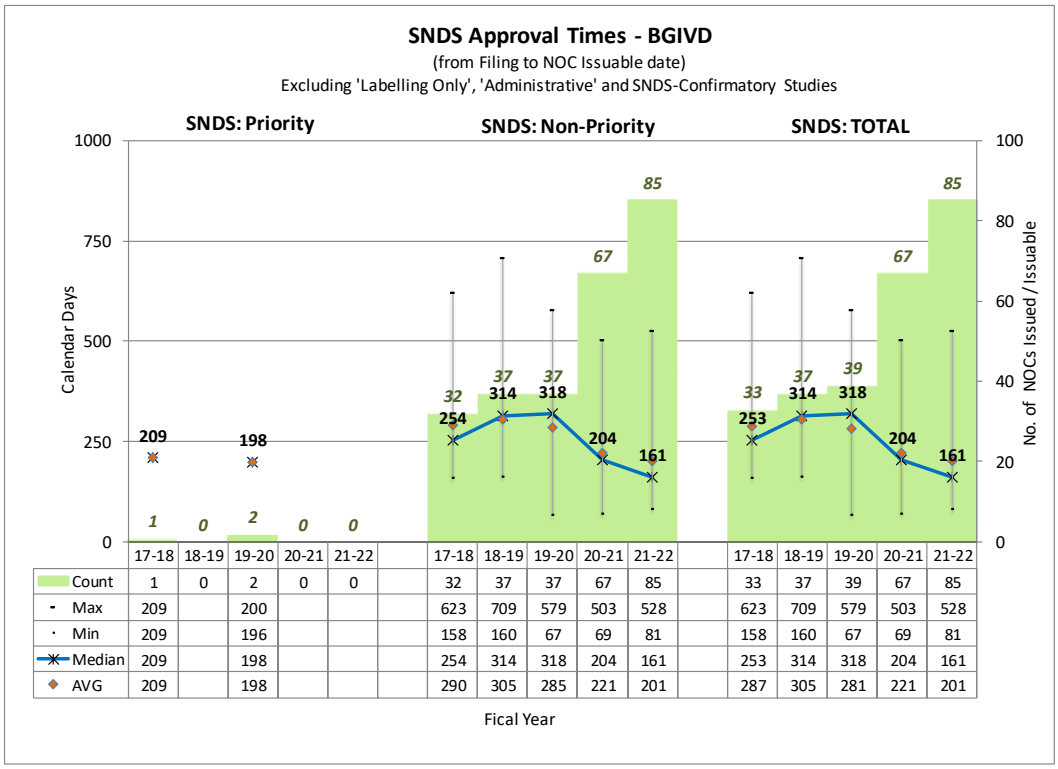
APPROVALS: Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)

NDS Time to Approval: BGIVD



	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	4	2	2	1	1	10	11	7	9	4	14	13	9	10	5	6	5	4	4	2
Max	250	257	244	246	210	717	687	666	903	804	717	687	666	903	804	420	419	385	435	342
Min	201	229	194	246	210	344	224	295	38	342	201	224	194	38	210	201	257	295	38	210
Median	205	243	219	246	210	417	345	346	358	417	372	340	338	354	406	228	337	335	330	276
AVG	215	243	219	246	210	458	378	399	401	495	389	357	359	385	438	279	338	338	283	276

SNDS Time to Approval: BGIVD

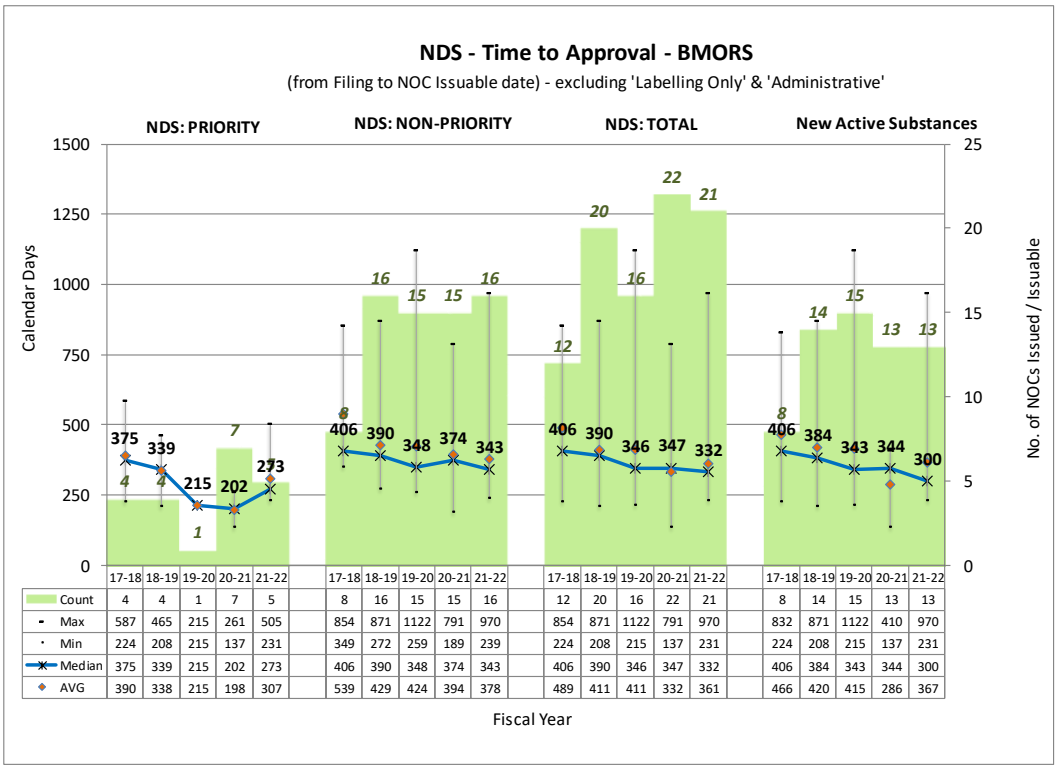


	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	1	0	2	0	0	32	37	37	67	85	33	37	39	67	85
Max	209		200			623	709	579	503	528	623	709	579	503	528
Min	209		196			158	160	67	69	81	158	160	67	69	81
Median	209		198			254	314	318	204	161	253	314	318	204	161
AVG	209		198			290	305	285	221	201	287	305	281	221	201

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.

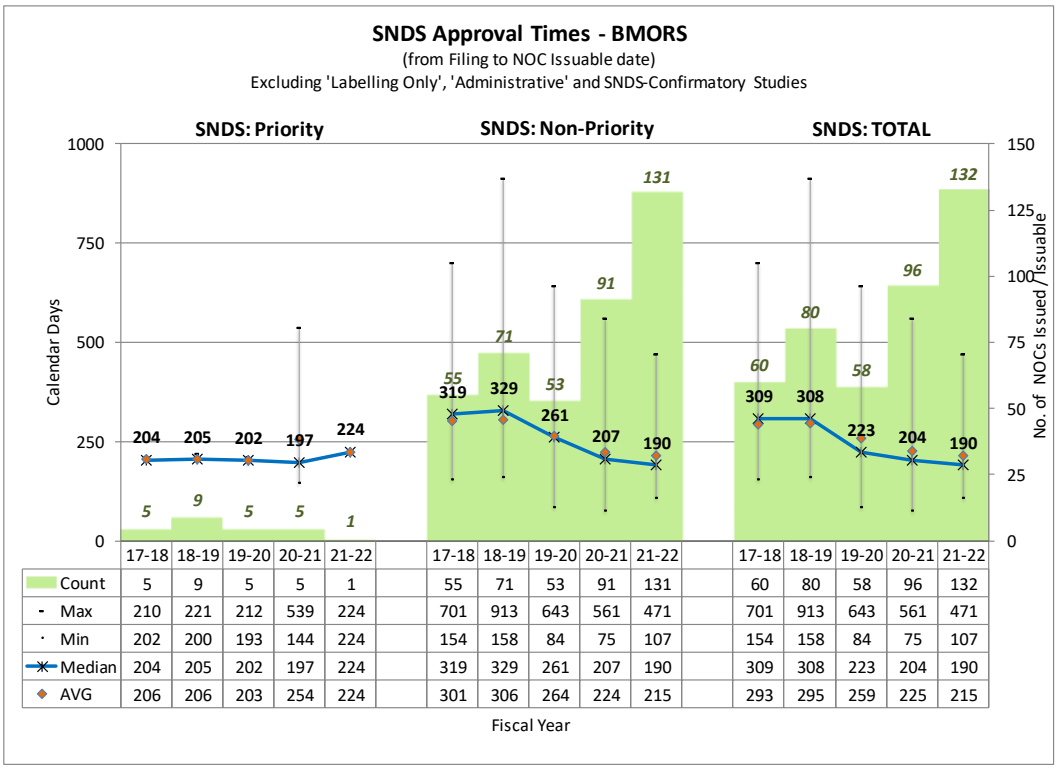
APPROVALS - Bureau of Metabolism, Oncology & Reproductive Sciences (BMORS)

NDS Time to Approval: BMORS



	NDS: PRIORITY					NDS: NON-PRIORITY					NDS: TOTAL					New Active Substances				
	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	4	4	1	7	5	8	16	15	15	16	12	20	16	22	21	8	14	15	13	13
Max	587	465	215	261	505	854	871	1122	791	970	854	871	1122	791	970	832	871	1122	410	970
Min	224	208	215	137	231	349	272	259	189	239	224	208	215	137	231	224	208	215	137	231
Median	375	339	215	202	273	406	390	348	374	343	406	390	346	347	332	406	384	343	344	300
AVG	390	338	215	198	307	539	429	424	394	378	489	411	411	332	361	466	420	415	286	367

SNDS Time to Approval: BMORS



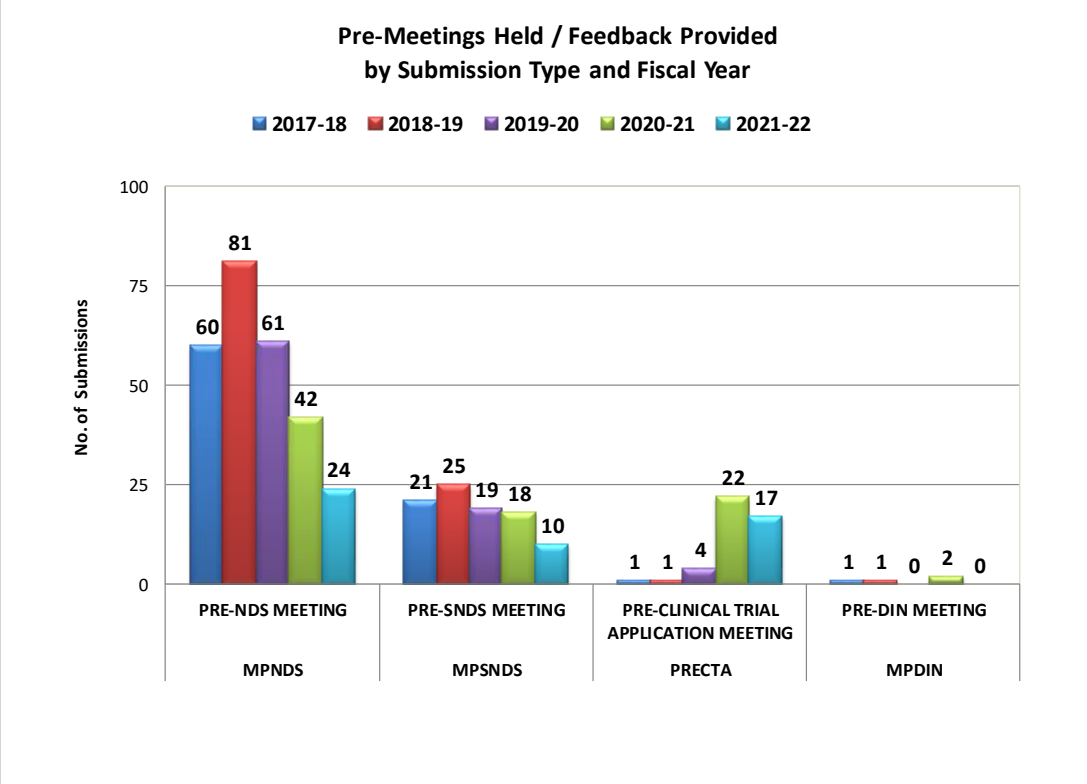
	SNDS: Priority					SNDS: Non-Priority					SNDS: TOTAL				
	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	5	9	5	5	1	55	71	53	91	131	60	80	58	96	132
Max	210	221	212	539	224	701	913	643	561	471	701	913	643	561	471
Min	202	200	193	144	224	154	158	84	75	107	154	158	84	75	107
Median	204	205	202	197	224	319	329	261	207	190	309	308	223	204	190
AVG	206	206	203	254	224	301	306	264	224	215	293	295	259	225	215

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

10

Pre-Submission Meetings Held / Feedback Provided



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[10] 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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