Santé Canada Health Canada

Biologics and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Annual Report

Fiscal Year

2021-2022

April 1 2021 - March 31 2022

Canada

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OVERVIEW

The Biologics and Radiopharmaceutical Drugs Directorate (BRDD) Annual Drug Submission Performance Report reflects biologic and radiopharmaceutical 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 lists details of Priority Submissions and New Active Substances approved during the fiscal year 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- The Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was repealed and replaced on February 27, 2022 by the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations to allow sponsors to continue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, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report.

[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*. 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.

Biosimilar is a biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

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

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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 biologic 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
YBPR	-	Yearly Biologic Product Report

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.
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.

Fee Category	Fee Category Description
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.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS - Category discontinued.

For further information, please refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications.

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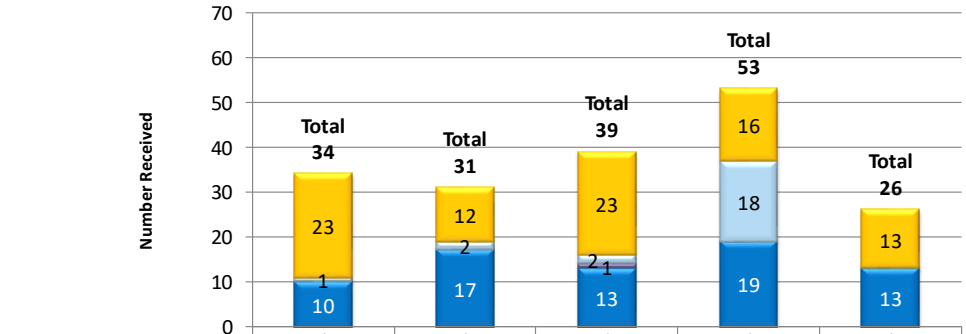
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

SUBMISSIONS RECEIVED [7]

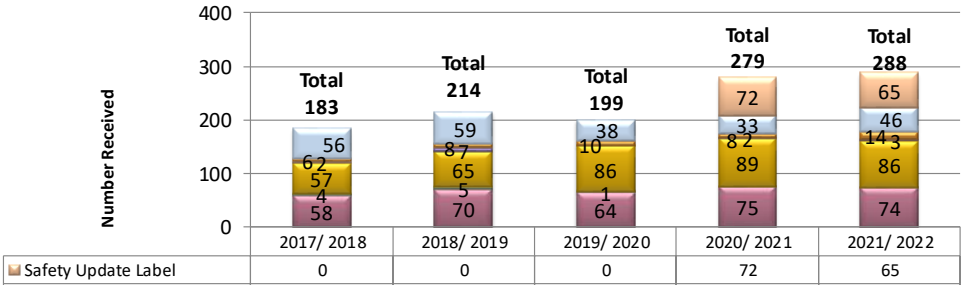
NDS: Received by Fee Category



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Clinical or Non-Clin and C&M	23	12	23	16	13
Labelling Only	1	2	2	18	0
Comparative Studies	0	0	1	0	0
New Active Substance	10	17	13	19	13
Total	34	31	39	53	26
Priority (subset)	5	5	3	4	4
NOC/c Class	2	1	1	3	2
Emergency Use NDS	1	0	1	0	0
Biosimilar	14	8	13	10	7

Fiscal Year

SNDS: Received by Fee Category



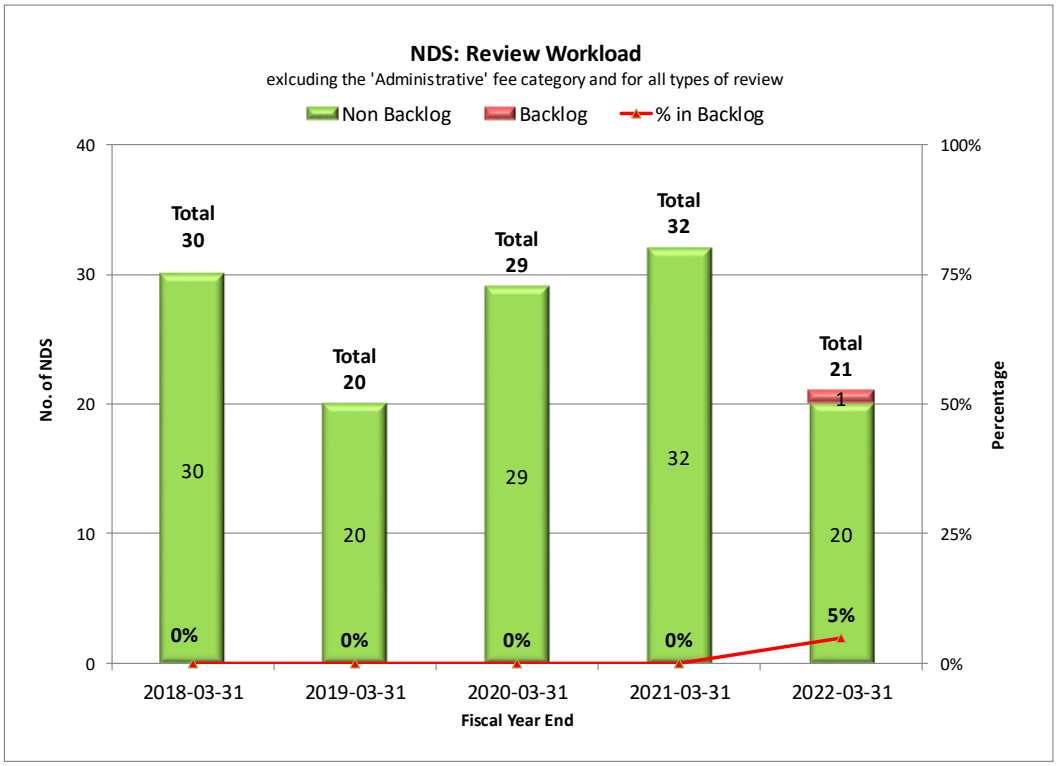
	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Safety Update Label	0	0	0	72	65
Labelling Only	56	59	38	33	46
Clinical or Non-Clin and C&M	6	8	10	8	14
Comparative Studies	2	7	0	2	3
Clinical or Non-Clin Only	57	65	86	89	86
Published Data Only	4	5	1	0	0
Chemistry & Manufacturing	58	70	64	75	74
Total	183	214	199	279	288
Priority (subset)	2	5	3	3	10
NOC/c Class	3	2	1	1	0
SNDS Confirmatory	5	5	9	6	6
Emergency Use SNDS	0	0	2	0	1
Biosimilar	11	13	21	23	17

Fiscal Year

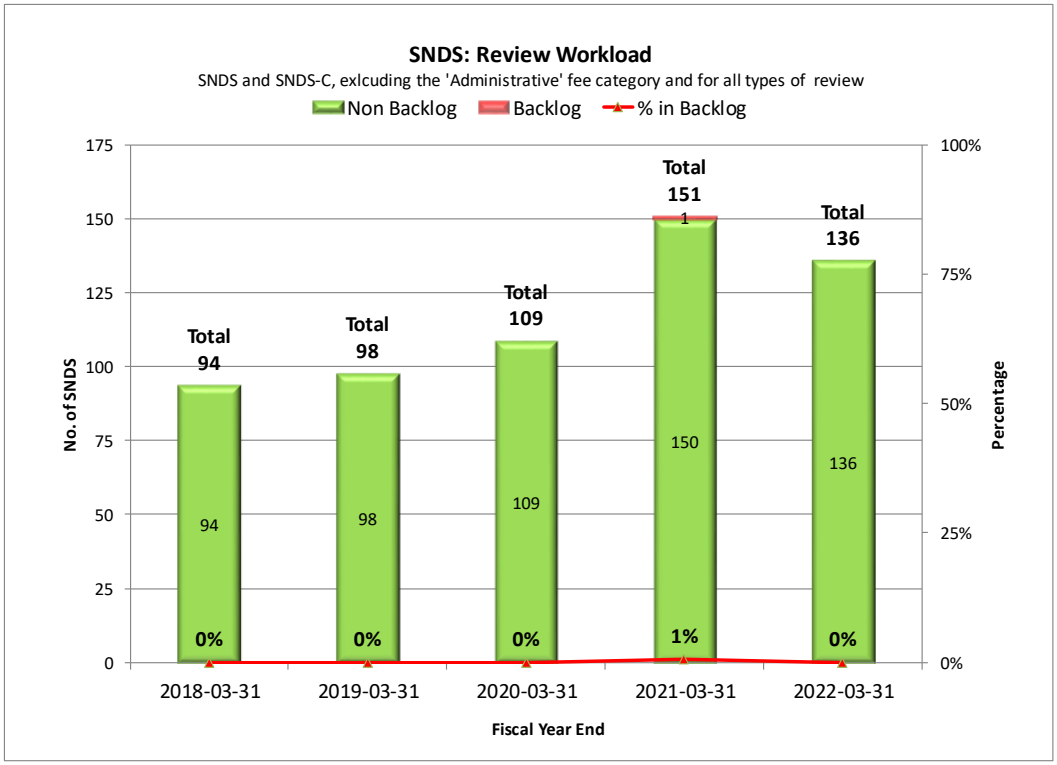
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

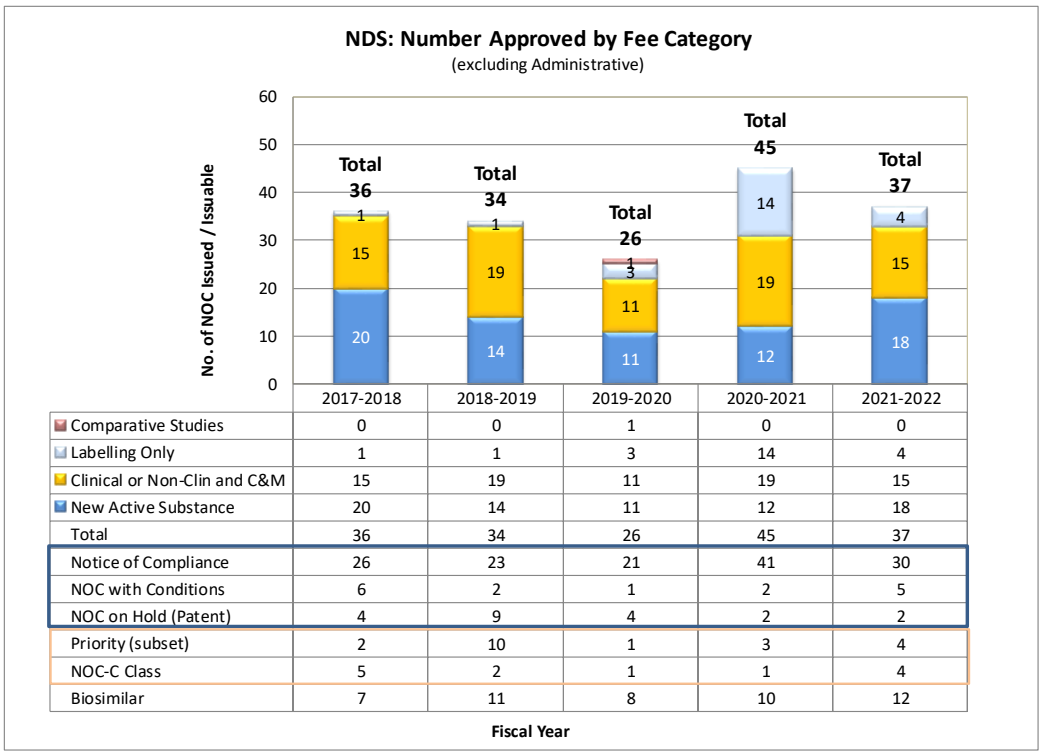
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Clinical or Non-Clin and C&M	21	10	18	14	10
Backlog	*0*	*0*	*0*	*0*	*1*
Labelling Only	0	0	0	4	0
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	9	10	11	14	11
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**30**	**20**	**29**	**32**	**21**
Non Backlog	**30**	**20**	**29**	**32**	**20**
Backlog	**0**	**0**	**0**	**0**	**1**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**5%**
Priority (subset)	5	0	2	3	3
Backlog	*0*	*0*	*0*	*0*	*1*

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
Comparative Studies	1	4	0	2	2
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	26	26	31	31	31
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	54	49	63	75	64
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	2	3	3	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	4	6	8	5	7
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	25	18
Backlog	*0*	*0*	*0*	*1*	*0*
Labelling Only	7	10	4	13	14
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**94**	**98**	**109**	**151**	**136**
Non Backlog	**94**	**98**	**109**	**150**	**136**
Backlog	**0**	**0**	**0**	**1**	**0**
% in Backlog	**0%**	**0%**	**0%**	**1%**	**0%**
Priority (subset)	2	4	0	2	6
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	5	5	6	5	5
Backlog	*0*	*0*	*0*	*0*	*0*

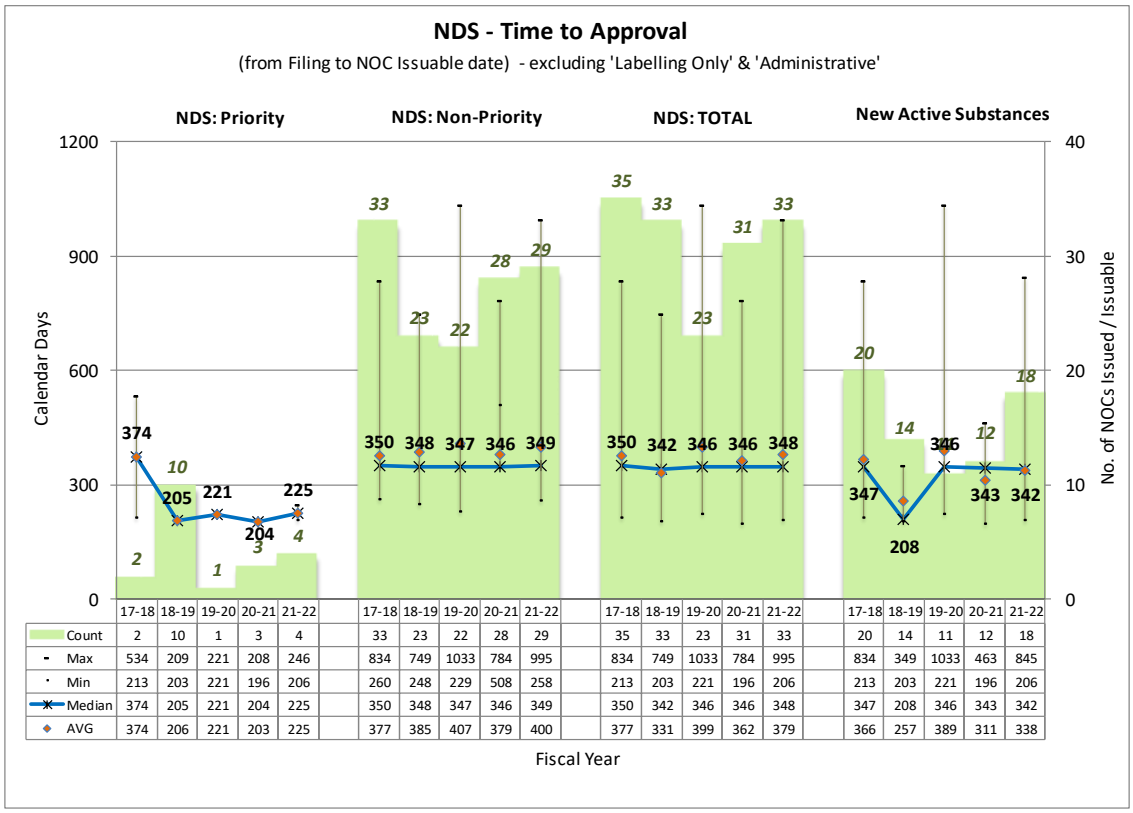
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Comparative Studies	0	0	1	0	0
Labelling Only	1	1	3	14	4
Clinical or Non-Clin and C&M	15	19	11	19	15
New Active Substance	20	14	11	12	18
Total	36	34	26	45	37
Notice of Compliance	26	23	21	41	30
NOC with Conditions	6	2	1	2	5
NOC on Hold (Patent)	4	9	4	2	2
Priority (subset)	2	10	1	3	4
NOC-C Class	5	2	1	1	4
Biosimilar	7	11	8	10	12

NDS Approval Times

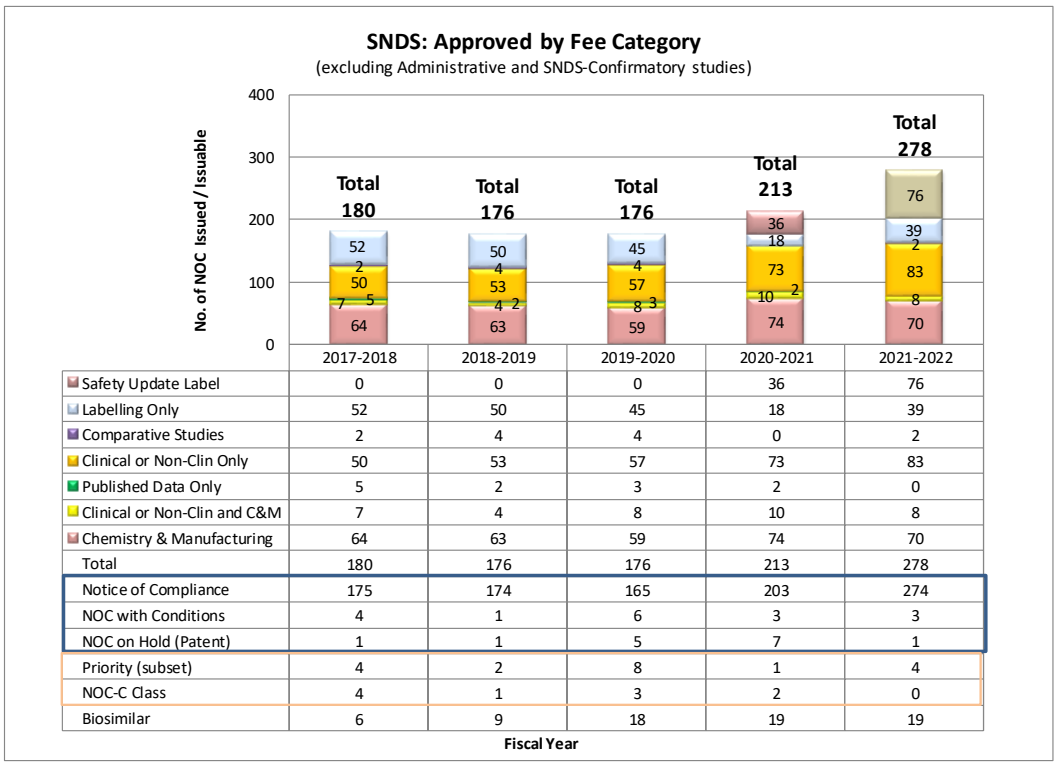


	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22	17-18	18-19	19-20	20-21	21-22
Count	2	10	1	3	4	33	23	22	28	29	35	33	23	31	33	20	14	11	12	18
Max	534	209	221	208	246	834	749	1033	784	995	834	749	1033	784	995	834	349	1033	463	845
Min	213	203	221	196	206	260	248	229	508	258	213	203	221	196	206	213	203	221	196	206
Median	374	205	221	204	225	350	348	347	346	349	350	342	346	346	348	347	208	346	343	342
AVG	374	206	221	203	225	377	385	407	379	400	377	331	399	362	379	366	257	389	311	338

Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

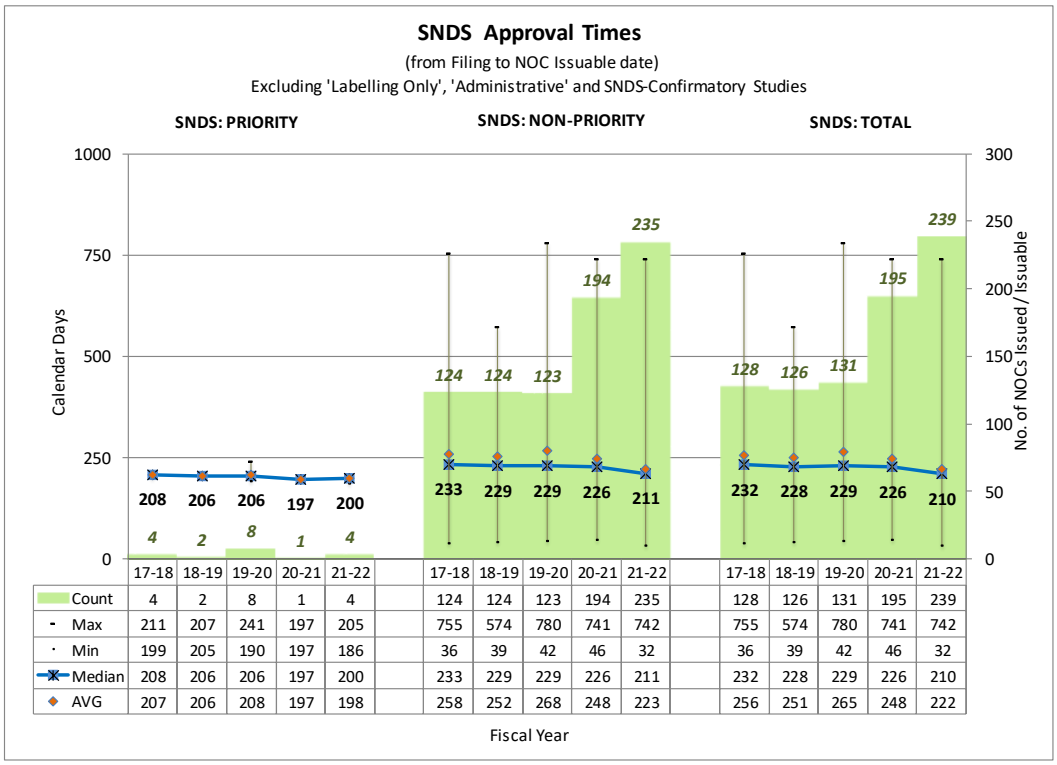
APPROVALS

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	36	76
Labelling Only	52	50	45	18	39
Comparative Studies	2	4	4	0	2
Clinical or Non-Clin Only	50	53	57	73	83
Published Data Only	5	2	3	2	0
Clinical or Non-Clin and C&M	7	4	8	10	8
Chemistry & Manufacturing	64	63	59	74	70
Total	180	176	176	213	278
Notice of Compliance	175	174	165	203	274
NOC with Conditions	4	1	6	3	3
NOC on Hold (Patent)	1	1	5	7	1
Priority (subset)	4	2	8	1	4
NOC-C Class	4	1	3	2	0
Biosimilar	6	9	18	19	19

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	4	2	8	1	4	124	124	123	194	235	128	126	131	195	239
Max	211	207	241	197	205	755	574	780	741	742	755	574	780	741	742
Min	199	205	190	197	186	36	39	42	46	32	36	39	42	46	32
Median	208	206	206	197	200	233	229	229	226	211	232	228	229	226	210
AVG	207	206	208	197	198	258	252	268	248	223	256	251	265	248	222

Approval Time is the total number of calendar days between the date a submission is filed (CR date) and the date it is approved (NOC Issuable). This includes time in processing, screening, review and any time taken by the company to respond to notices of deficiency or non-compliance.

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New Active Substance Approvals (NAS) - BRDD - Fiscal Year 2021-2022

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
ABECMA (Idecabtagene Vicleucel) - Abecma is used to treat adults with a type of cancer called multiple myeloma which is a cancer of the bone marrow. It is given when your cancer has not responded to at least three different treatments or has come back after these treatments. It is used as a treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and who are refractory to their last therapy.	PRIORITY-NAS	Celgene Inc.	22-09-2020	26-05-2021 NOC-C
ADTRALZA (Tralokinumab) - Adtralza (tralokinumab injection) is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adtralza can be used with or without topical corticosteroids. It is not known if Adtralza is safe and effective in children under 18 years old.	NAS	Leo Pharma Inc.	30-10-2020	13-10-2021
BIMZELX (Bimekizumab) - is used in adults to treat a moderate to severe form of a skin condition called “plaque psoriasis”, which causes pain, itching and scaling of the skin.	NAS	UCB Canada Inc.	18-01-2021	14-02-2022
COMIRNATY (Tozinameran) - COMIRNATY is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. COMIRNATY can be given to people from 5 years of age and older.	NAS	Biontech Manufacturing GMBH	10-06-2021	16-09-2021

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

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
COVIFENZ (Virus-Like Particles (VLP) of SARS-CoV-2 Spike Protein) - is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.	NAS	Medicago Inc.	09-08-2021	24-02-2022
ENHERTU (Trastuzumab Deruxtecan) - ENHERTU is used in adults who have: HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery and also received prior trastuzumab emtansine (T-DM1). ENHERTU (trastuzumab deruxtecan) is used in adults who have HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery and also received prior trastuzumab emtansine (T-DM1).	NOC-C NAS	Astrazeneca Canada Inc.	24-07-2020	15-04-2021 NOC-C
HYQVIA (Immunoglobulin (Human), Hyaluronidase (Human Recombinant) - is used to treat patients with primary immunodeficiency diseases (PI) and with secondary immunodeficiency diseases (SI).	NAS	Takeda Canada Inc.	18-12-2020	14-01-2022
ILUMYA (Tildrakizumab) - Ilumya is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body.	NAS	Sun Pharma Global FZE	25-01-2019	19-05-2021
JANSSEN COVID-19 VACCINE (AD26.COV2.S {Recombinant}) - Janssen COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. Janssen COVID-19 Vaccine can be given to protect people aged 18 years and older.	NAS	Janssen Inc.	14-06-2021	23-11-2021

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
JEMPERLI (Dostarlimab) - For the following indication(s), JEMPERLI has been approved with conditions (NOC/c). JEMPERLI is a prescription medicine used in adults to treat: a kind of cancer called endometrial cancer (cancer of the lining of the womb) in adults that is shown by a laboratory test to be mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) that has progressed on or following prior treatment with a platinum containing regimen.	NOC-C NAS	GlaxoSmithKline Inc.	26-03-2021	23-12-2021 NOC-C
MINJUVI (Tafasitamab) - For the following indication, Minjuvi has been approved with conditions (NOC/c). Minjuvi (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for autologous stem cell transplant (ASCT).	NOC-C NAS	Incyte Corporation	04-12-2020	19-08-2021 NOC-C
NETVISION (Gallium (68Ga) Oxodotreotide) - is indicated for use with positron emission tomography (PET), as an adjunct to other diagnostic tests, for the detection and localization of somatostatin receptor-positive neuroendocrine tumours (NETs).	NAS	Canadian Molecular Imaging Probe Consortium (Canprobe)	12-03-2021	24-02-2022
NEXVIAZYME (Avalglucosidase Alfa) - Nexviazyme is a medicine that is used to treat adults, children and adolescents who have a confirmed diagnosis of late-onset Pompe disease.	NAS	Sanofi-Aventis Canada Inc.	26-10-2020	12-11-2021
NGENLA (Somatrogon) - Ngenla is used for the long-term treatment of children who are not growing because of low growth hormone levels.	NAS	Pfizer Canada ULC	24-11-2020	26-10-2021
NUVAXOVID (SARS-CoV-2 Recombinant Spike Protein) - is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults aged 18 years and older.	NAS	Novarax Inc.	27-08-2021	17-02-2022

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
PADCEV (Enfortumab Vedotin) - Padcev is a medicine used to treat adults with bladder cancer and cancer of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. Padcev may be used if you have received chemotherapy that contains platinum and an immunotherapy medicine.	PRIORITY-NAS	Seagen Inc.	06-04-2021	29-10-2021
PALYNZIQ (Pegvaliase) - is a treatment for patients aged 16 years and older with phenylketonuria (PKU), a rare inherited disorder that causes phenylalanine from proteins in food to build up in the body. People who have PKU have high levels of phenylalanine and this can lead to serious health problems. Palynziq reduces the levels of phenylalanine in the blood of patients who have PKU whose blood phenylalanine levels cannot be kept below 600 micromol/l by other means such as by diet.	NAS	Biomarin International Limited	14-04-2021	30-03-2022
RYBREVANT (Amivantamab) - is used in adults with a type of cancer called 'non-small cell lung cancer'. It is used when the cancer has spread in your body and has gone through certain genetic changes (Exon 20 insertion mutations) in a gene called 'epidermal growth factor receptor' (EGFR).	NOC-C NAS	Janssen Inc.	05-07-2021	30-03-2022 NOC-C
SAPHNELO (Anifrolumab) - Saphnelo is used for the treatment of: active lupus (systemic lupus erythematosus, SLE) in adults whose disease is not well controlled by other standard therapies (oral corticosteroids and/or immunosuppressants and/or antimalarials) they are also receiving. You will be given Saphnelo as well as your standard therapy for lupus. Lupus is a disease in which the immune system (the system that fights infection) attacks your own cells and tissues, causing inflammation and organ damage.	NAS	Astrazeneca Canada Inc.	09-11-2020	30-11-2021

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
SPIKEVAX (Elasomeran {mRNA}) - SPIKEVAX is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to people aged 12 years and older.	NAS	Modernatx, Inc.	15-05-2021	16-09-2021
TECARTUS (Brexucabtagene Autoleucel) - Tecartus is a treatment for your mantle cell lymphoma – a form of white blood cell cancer. It is used when at least two other available medicines have stopped working for you.	PRIORITY-NAS	Gilead Sciences Canada Inc.	13-11-2020	08-06-2021
TRODELVY (Sacituzumab Govitecan) - Trodelvy is a prescription medicine used to treat adults 18 years or older with breast cancer that is: estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer), and that has spread to other parts of the body or cannot be removed by surgery (metastatic), and who previously received two or more prior therapies, at least one of them for metastatic disease.	PRIORITY-NAS	Gilead Sciences Canada Inc.	25-01-2021	24-09-2021
VAXNEUVANCE (Corynebacterium Diphtheriae CRM-197 Protein, Pneumococcal Polysaccharide Serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F) - VAXNEUVANCE is a vaccine for adults 18 years of age and older to help protect against invasive disease caused by 15 types of bacteria called pneumococcus. Invasive disease includes: an infection in the blood; an infection of the lungs (pneumonia) that comes with an infection in the blood; an infection of the coverings of the brain and spinal cord (meningitis). VAXNEUVANCE will not give you disease caused by pneumococcus. VAXNEUVANCE may not protect against diseases caused by types of pneumococcus that are not covered by the vaccine.	NAS	Merck Canada Inc.	14-12-2020	16-11-2021

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[8])**	**Approval Date**
VAXZEVRIA (Chadox1-S {Recombinant}) - VAXZEVRIA is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults 18 years of age and older.	NAS	Astrazenaca Canada Inc.	14-06-2021	19-11-2021

Priority Submission Approvals - BRDD: Fiscal Year 2021-2022

Priority Submission Approvals - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[9])**	**Approval Date**
ABECMA (Idecabtagene Vicleucel) - Abecma is used to treat adults with a type of cancer called multiple myeloma which is a cancer of the bone marrow. It is given when your cancer has not responded to at least three different treatments or has come back after these treatments. It is used as a treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and who are refractory to their last therapy.	PRIORITY-NAS	Celgene Inc.	22-09-2020	26-05-2021 NOC-C
CRYSVITA (Burosumab) - New Indication : Burosumab is indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with tumors that cannot be curatively resected or localized in adult patients.	PRIORITY-CLIN ONLY	Kyowa Kirin Limited	05-02-2021	26-08-2021
KEYTRUDA (Pembrolizumab) - New indication: Keytruda, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2 negative adenocarcinoma of the esophagogastric junction (tumour centre 1 to 5 centimetres above the gastric cardia).	PRIORITY-CLIN ONLY	Merck Canada Inc.	30-11-2020	04-06-2021

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

Priority Submission Approvals - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[9])**	**Approval Date**
LIBTAYO (Cemiplimab) - New indication: Cervical Cancer - is indicated for: the treatment of adult patients with cervical cancer who have progressed on or after prior platinum-based chemotherapy and who require additional systemic therapy to treat recurrent or metastatic disease.	PRIORITY-CLIN ONLY	Sanofi-Aventis Canada Inc.	30-08-2021	23-03-2022
PADCEV (Enfortumab Vedotin) - Padcev is a medicine used to treat adults with bladder cancer and cancer of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. Padcev may be used if you have received chemotherapy that contains platinum and an immunotherapy medicine.	PRIORITY-NAS	Seagen Inc.	06-04-2021	29-10-2021
TECARTUS (Brexucabtagene Autoleucel) - Tecartus is a treatment for your mantle cell lymphoma – a form of white blood cell cancer. It is used when at least two other available medicines have stopped working for you.	PRIORITY-NAS	Gilead Sciences Canada Inc.	13-11-2020	08-06-2021
TECENTRIQ (Atezolizumab) - Non-Small Cell Lung Cancer (NSCLC): TECENTRIQ as monotherapy, is indicated as adjuvant treatment following complete resection and no progression after platinum-based adjuvant chemotherapy for adult patients with Stage II to IIIA* NSCLC whose tumours have PD-L1 expression on $\geq$ 50% of tumour cells (TCs) (see Part II: 14 CLINICAL TRIALS). *According to American Joint Committee on Cancer [7th edition].	PRIORITY-CLIN ONLY	Hoffmann-La Roche Limited	30-06-2021	14-01-2022

Priority Submission Approvals - BRDD Fiscal Year 2021-2022 (April 1 2021 to March 31 2022)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[9])**	**Approval Date**
TRODELVY (Sacituzumab Govitecan) - Trodelvy is a prescription medicine used to treat adults 18 years or older with breast cancer that is: estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer), and that has spread to other parts of the body or cannot be removed by surgery (metastatic), and who previously received two or more prior therapies, at least one of them for metastatic disease.	PRIORITY-NAS	Gilead Sciences Canada Inc.	25-01-2021	24-09-2021

BIOSIMILARS: NDS & SNDS Market Authorizations

Biosimilars: Number of Market Authorization for NDS & SNDS by Fiscal Year

		Fiscal Year of Market Authorization				
Subm Type	**Class**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
NDS	CLIN/C&M	3	5	4	16	11
NDS Total		**3**	**5**	**4**	**16**	**11**
SNDS	C&M ONLY	1	3	5	8	7
	C&M/LABELLING	0	0	0	3	2
	CLIN ONLY	0	2	3	7	7
	CLIN/C&M	0	0	0	1	0
	COMP/C&M	0	1	0	0	0
	LABELLING ONLY	4	2	5	1	1
	SAFETY UPDATE LABEL	0	0	0	2	4
	PUBLISHED DATA ONLY	0	0	0	0	0
SNDS Total		**5**	**8**	**13**	**22**	**21**

Biosimilars: NDS Market Authorizations during Fiscal Year 2021-2022

Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2021-22	Notice of Compliance (NOC) Date
ABEVMY	CLIN/C&M	BGP PHARMA ULC	BEVACIZUMAB	Q3	2021-Nov-5
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
BAMBEVI	CLIN/C&M	APOTEX INC.	BEVACIZUMAB	Q2	2021-Sep-23
BYOOVIZ	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	RANIBIZUMAB	Q4	2022-Mar-8
IXIFI	CLIN/C&M	PFIZER CANADA ULC	INFLIXIMAB	Q3	2021-Dec-21
KIRSTY	CLIN/C&M	BGP PHARMA ULC	INSULIN ASPART	Q3	2021-Oct-12
NYPOZI	CLIN/C&M	TANVEX BIOPHARMA USA, INC	FILGRASTIM (R-METHUG-CSF)	Q3	2021-Oct-8
ONTRUZANT	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	TRASTUZUMAB	Q4	2022-Jan-28
SIMLANDI	CLIN/C&M	JAMP PHARMA CORPORATION	ADALIMUMAB	Q4	2022-Jan-5
YUFLYMA	CLIN/C&M	CELLTRION HEALTHCARE CO LTD	ADALIMUMAB	Q3	2021-Dec-24
New Drug Submission Total					**11**

Please note: Approved Biosimilars that remain on Intellectual Property Hold are not included.

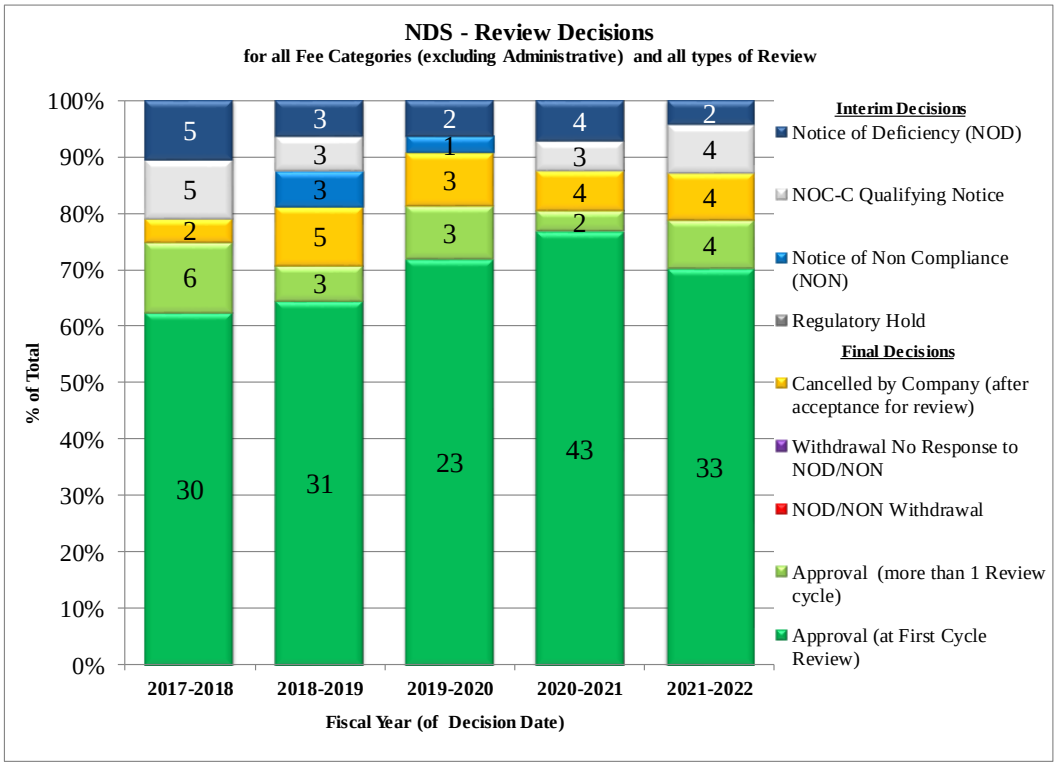
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

Biosimilars: SNDS Market Authorizations during Fiscal Year 2021-2022

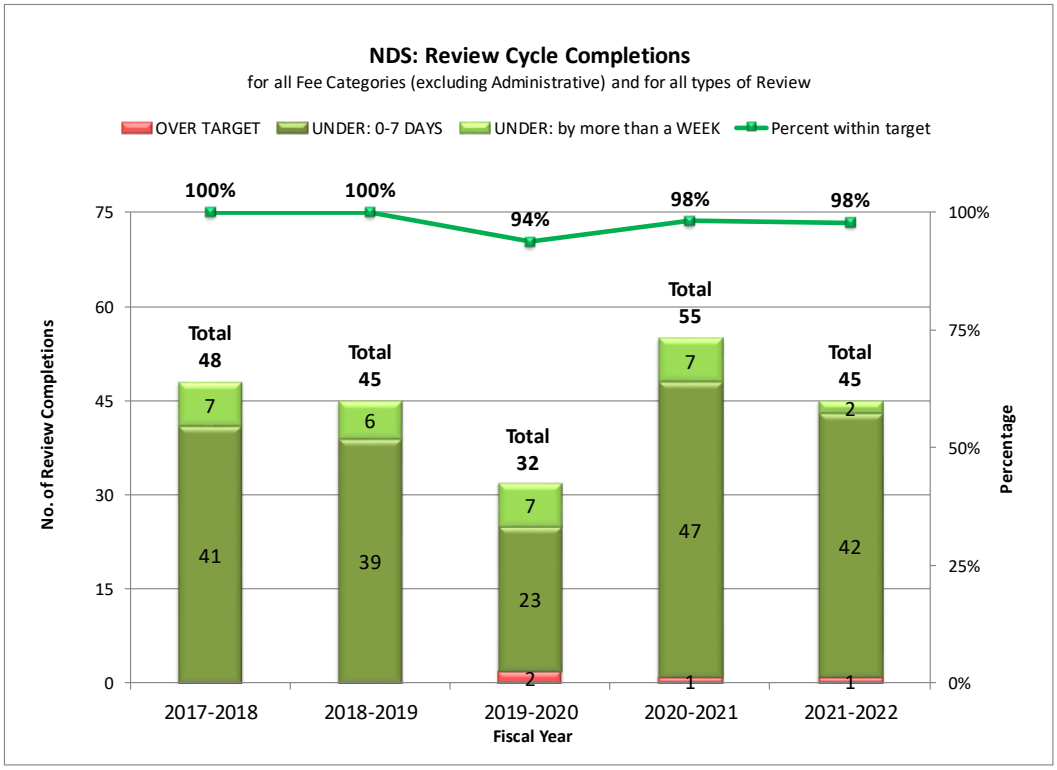
Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2021-22	Notice of Compliance (NOC) Date
AVSOLA	C&M ONLY	AMGEN CANADA INC	INFLIXIMAB	Q3	2021-Oct-27
BRENZYS	SAFETY UPDATE LABEL	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q4	2022-Mar-17
ERELZI	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q1	2021-Jun-24
GRASTOFIL	CLIN ONLY	APOTEX INC.	FILGRASTIM (R-METHUG-CSF)	Q2	2021-Sep-29
FILGRASTIM (R-METHUG-CSF)	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q2	2021-Aug-4
HERZUMA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	TRASTUZUMAB	Q1	2021-Apr-16
HULIO	C&M ONLY	BGP PHARMA ULC	ADALIMUMAB	Q1	2021-May-14
HYRIMOZ	CLIN ONLY	SANDOZ CANADA INCORPORATED	ADALIMUMAB	Q2	2021-Sep-10
KANJINTI	CLIN ONLY	AMGEN CANADA INC	TRASTUZUMAB	Q1	2021-Apr-14
KANJINTI	LABELLING ONLY	AMGEN CANADA INC	ABP 980	Q2	2021-Jul-20
KANJINTI	C&M/LABELLING	AMGEN CANADA INC	ABP 980, TRASTUZUMAB	Q2	2021-Aug-4
LAPELGA	C&M/LABELLING	APOTEX INC.	PEGFILGRASTIM	Q3	2021-Dec-24
NYVEPRIA	C&M ONLY	PFIZER CANADA ULC	PEGFILGRASTIM	Q3	2021-Nov-9
NYVEPRIA	SAFETY UPDATE LABEL	PFIZER CANADA ULC	PEGFILGRASTIM	Q4	2022-Feb-14
OGIVRI	CLIN ONLY	BGP PHARMA ULC	TRASTUZUMAB	Q3	2021-Dec-6
OMNITROPE	C&M ONLY	SANDOZ CANADA INCORPORATED	SOMATROPIN	Q2	2021-Aug-11
OSNUVO	SAFETY UPDATE LABEL	AVIR PHARMA INC.	TERIPARATIDE	Q4	2022-Mar-14
REDESCA, REDESCA HP	C&M ONLY	SHENZHEN TECHDOW PHARMACEUTICAL CO LTD	ENOXAPARIN SODIUM	Q4	2022-Feb-22
RITUXIMAB	CLIN ONLY	SANDOZ CANADA INCORPORATED	RITUXIMAB	Q1	2021-Jun-30
TRAZIMERA	CLIN ONLY	PFIZER CANADA ULC	TRASTUZUMAB	Q1	2021-Apr-14
TRAZIMERA	SAFETY UPDATE LABEL	PFIZER CANADA ULC	TRASTUZUMAB	Q1	2021-Jun-18
Supplemental New Drug Submission				**TOTAL**	**21**

REVIEW PERFORMANCE

NDS: Review Decisions by Type

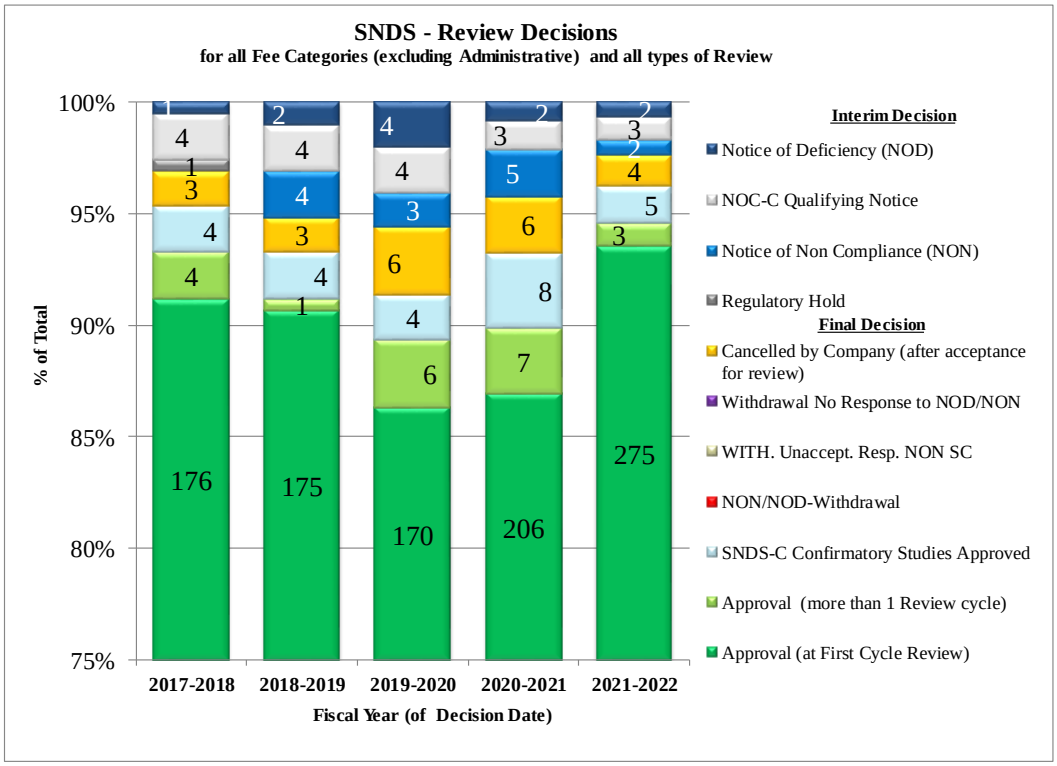


NDS: Review Cycle Completions

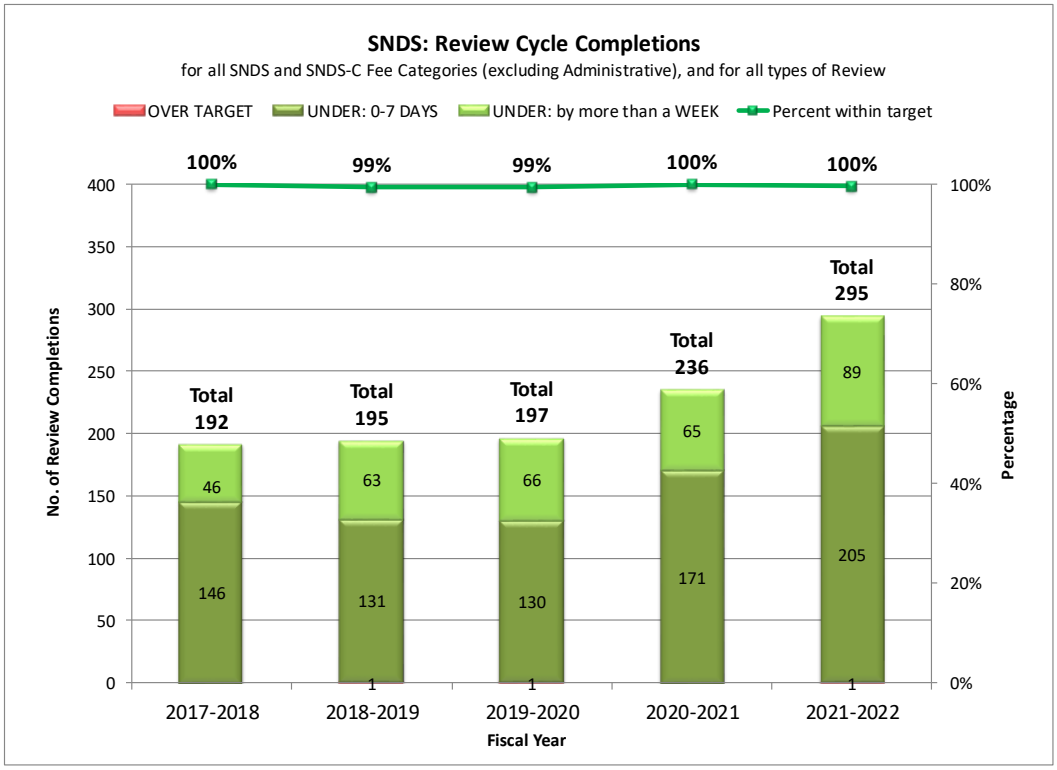


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

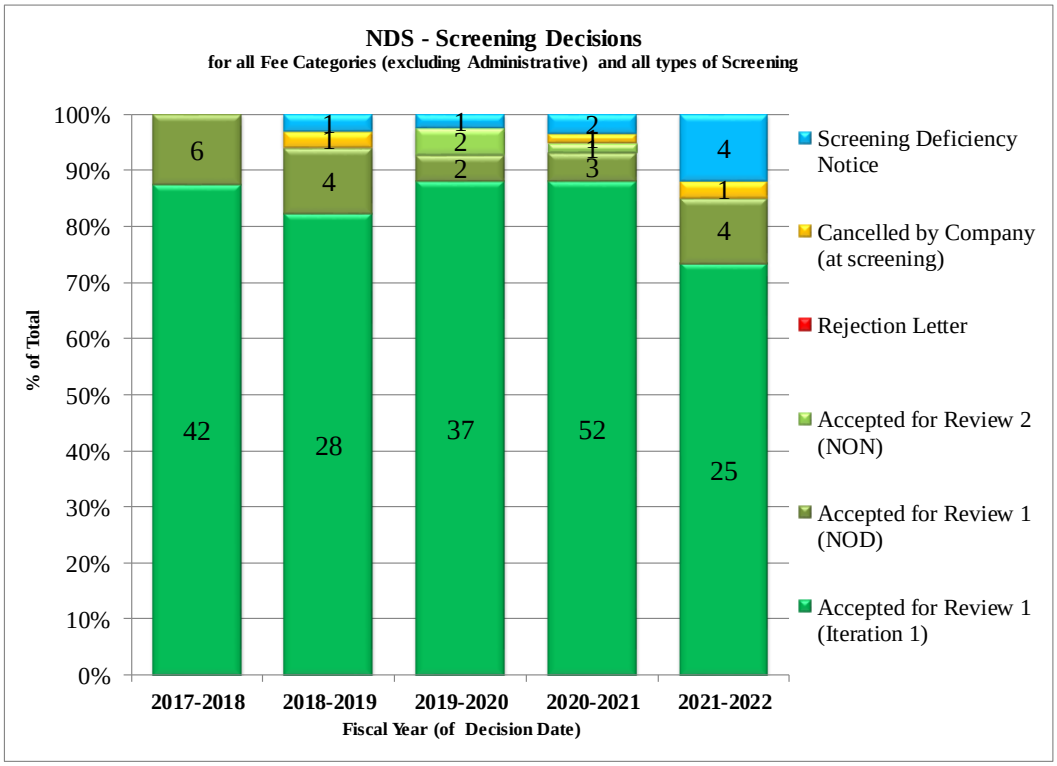


SNDS: Review Cycle Completions

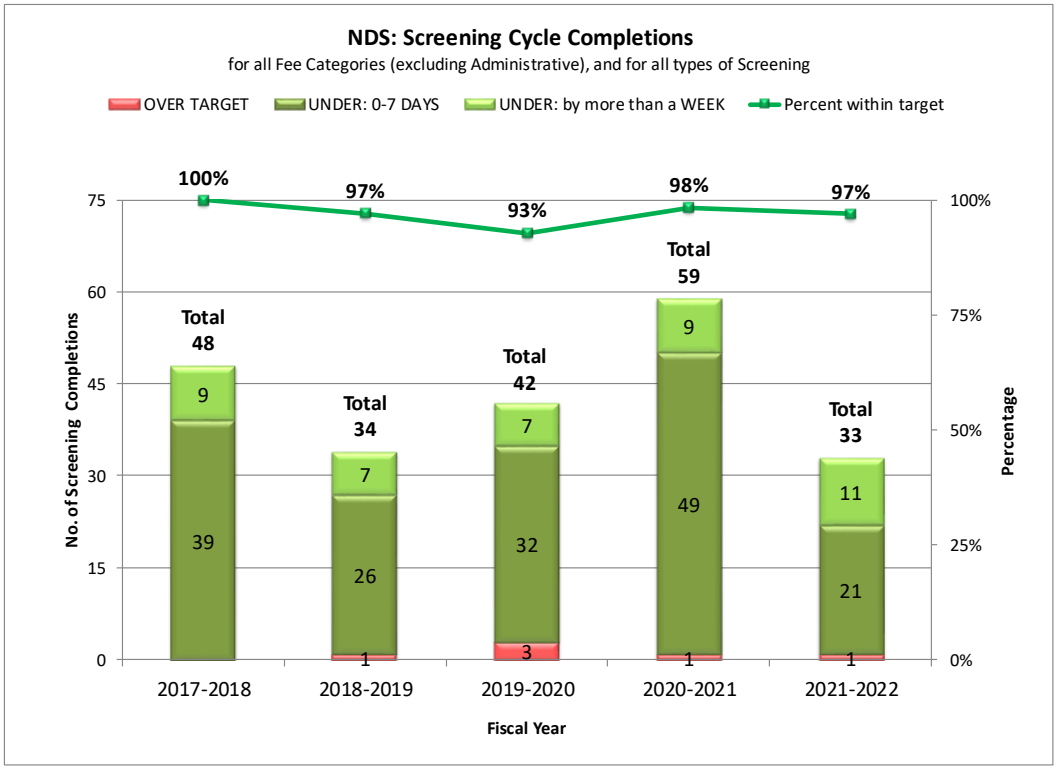


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

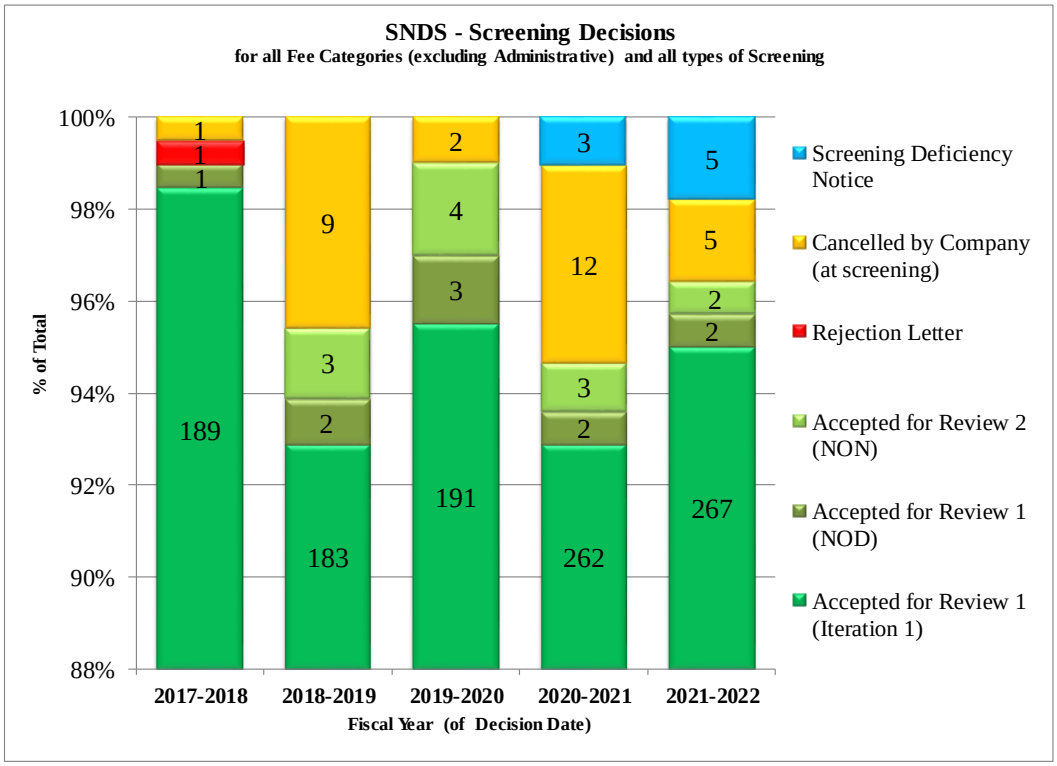


NDS: Screening Cycle Completions



SCREENING PERFORMANCE

SNDS: Screening Decisions by Type



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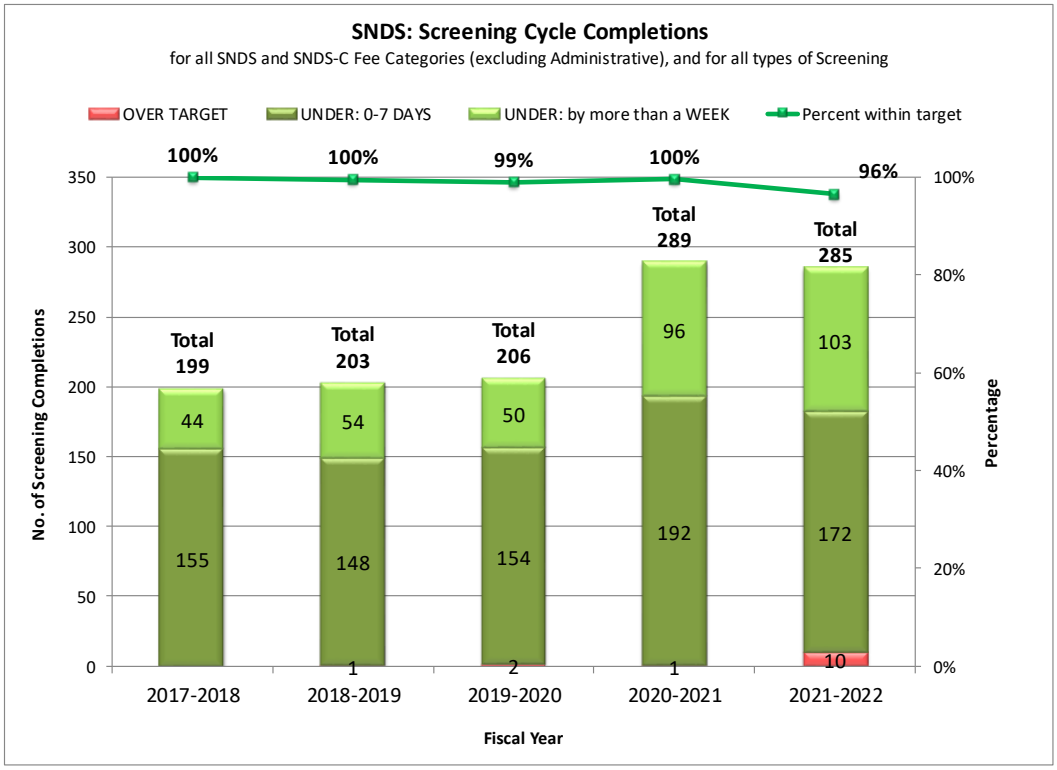

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions - NDS, SNDS & ANDS

Reconsideration of Final Decisions Requests Received NDS, SNDS & ANDS					
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

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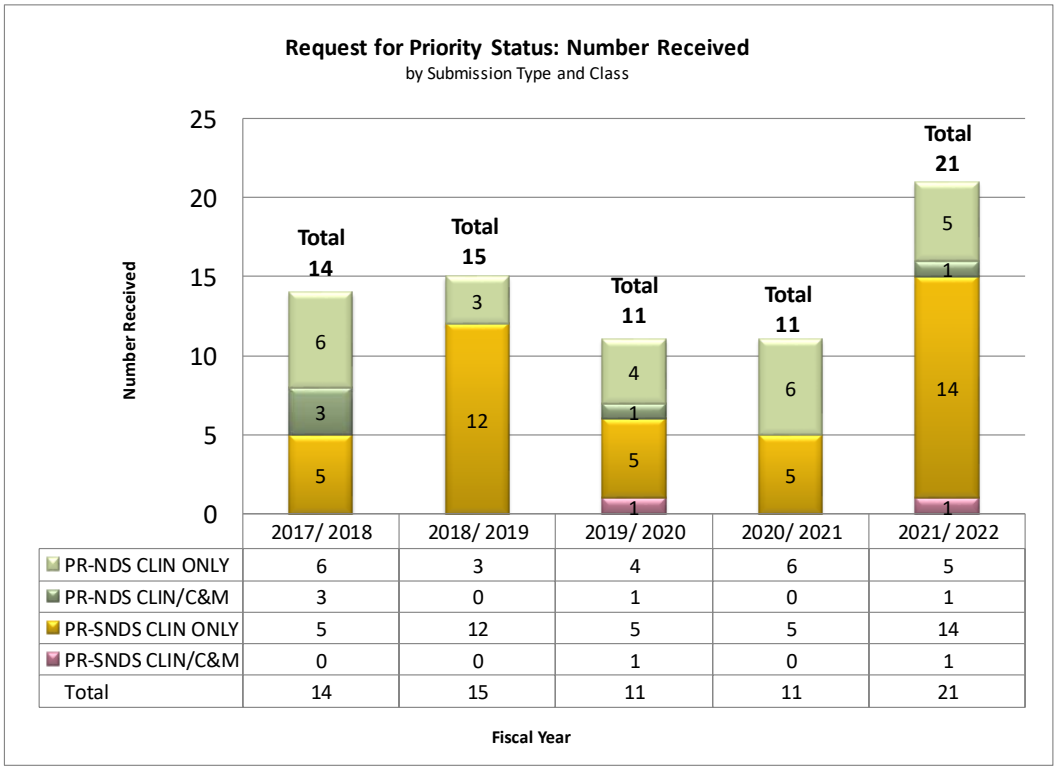
REQUEST FOR PRIORITY REVIEW STATUS RECEIVED

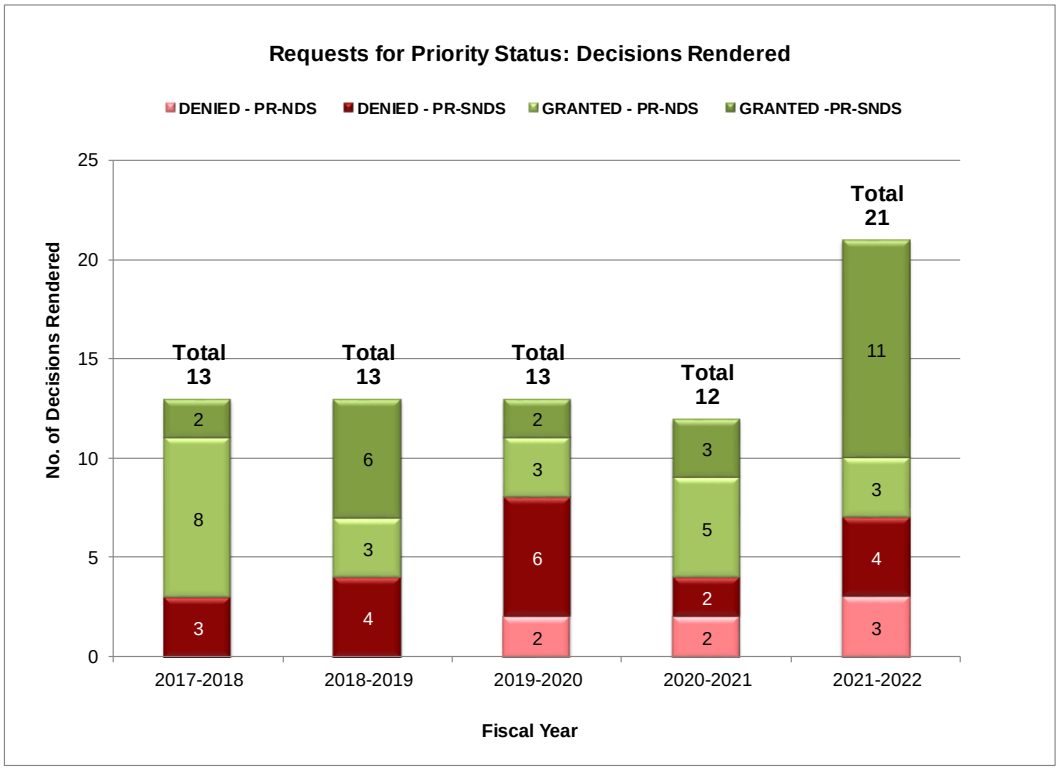
Request for Priority Review Status: Number Received



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
PR-NDS CLIN ONLY	6	3	4	6	5
PR-NDS CLIN/C&M	3	0	1	0	1
PR-SNDS CLIN ONLY	5	12	5	5	14
PR-SNDS CLIN/C&M	0	0	1	0	1
Total	14	15	11	11	21

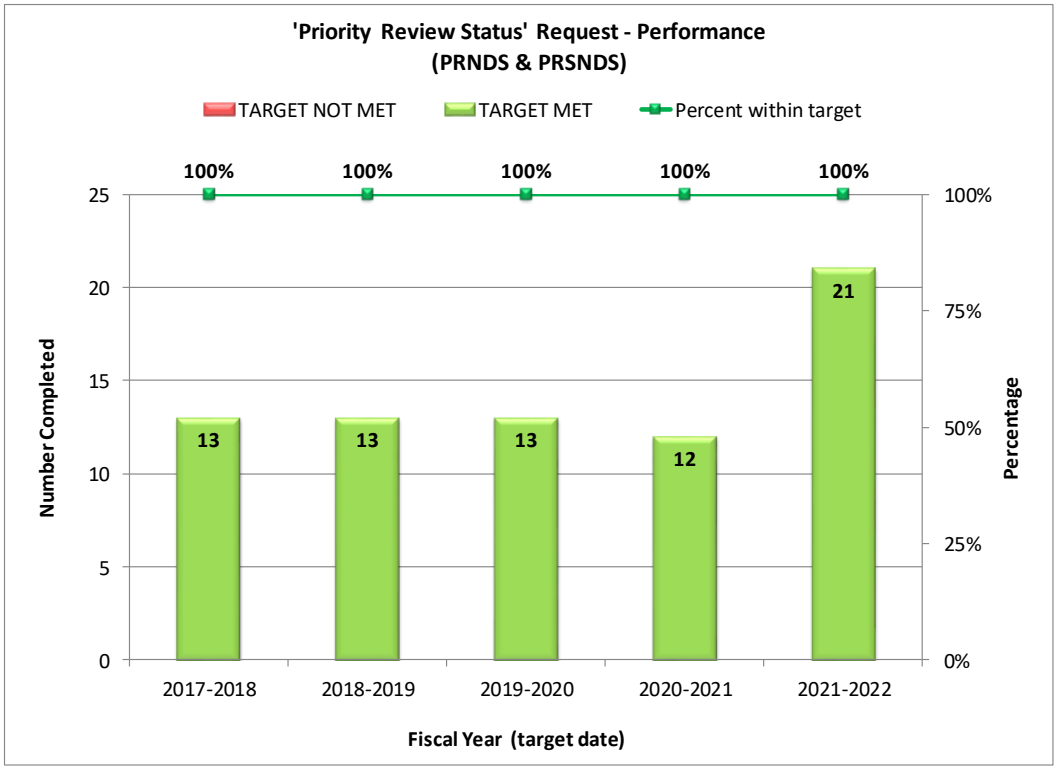
DECISIONS

Request for Priority Review Status: Decisions Rendered



REQUEST FOR PRIORITY REVIEW STATUS PERFORMANCE

Request for Priority Review Status: Performance



REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

Requests for Reconsideration of Final Decisions - Priority Review Requests

"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	0	1	0	0	0		
Total Denied	0	1	0	0	0	PR-SNDS: Priority Review Request Denied	Rejected

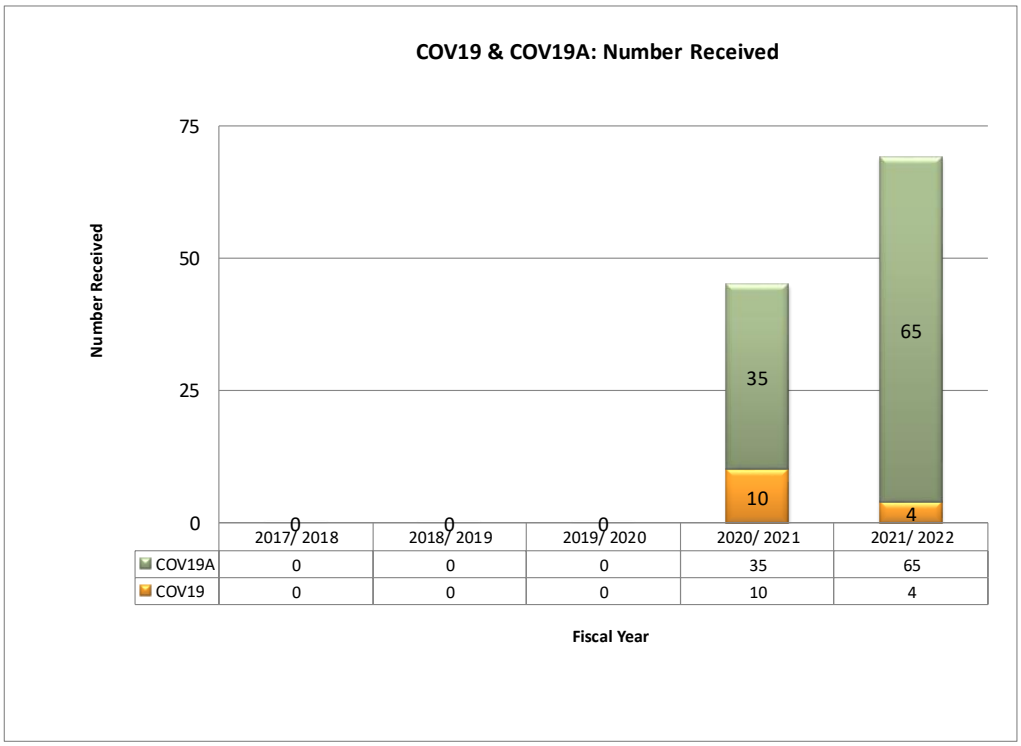
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

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)

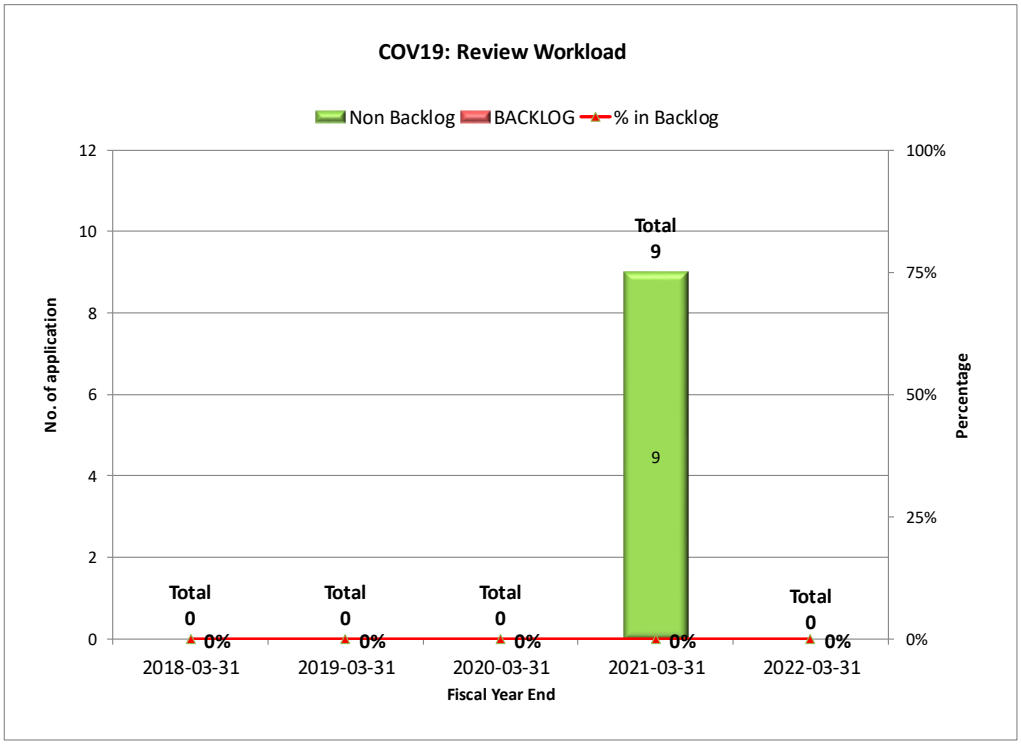
SUBMISSIONS RECEIVED

COV19 & COV19A: Number received



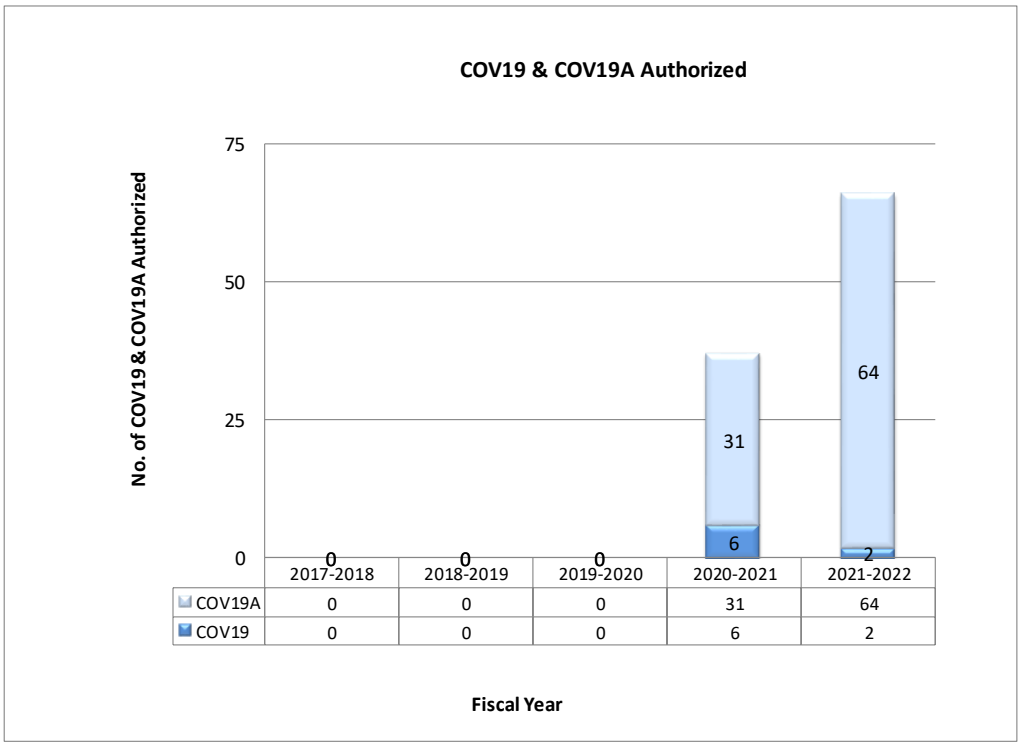
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized

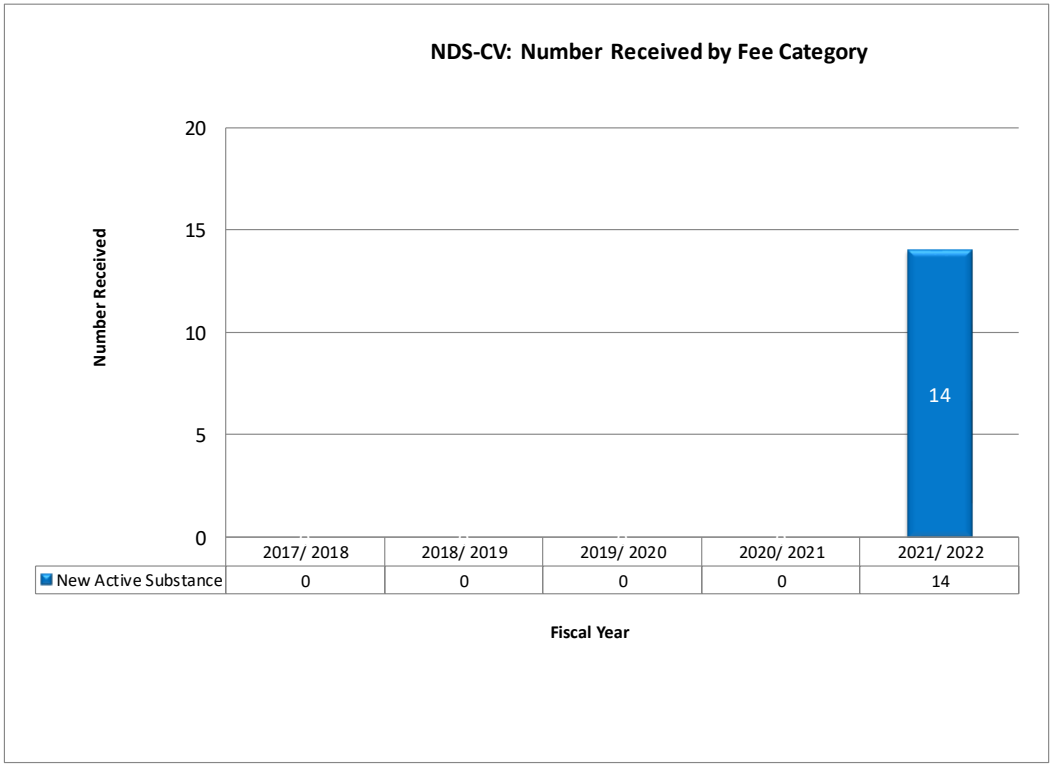


	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
COV19A	0	0	0	31	64
COV19	0	0	0	6	2

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

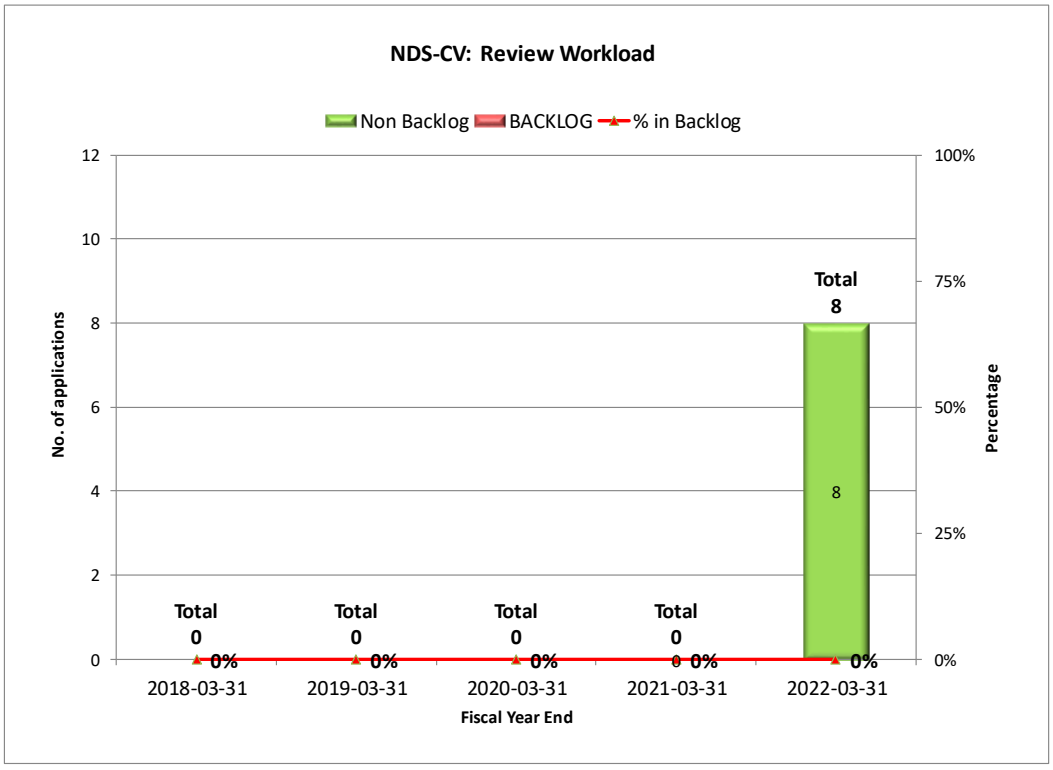
RECEIVED

NDS-CV: Number Received



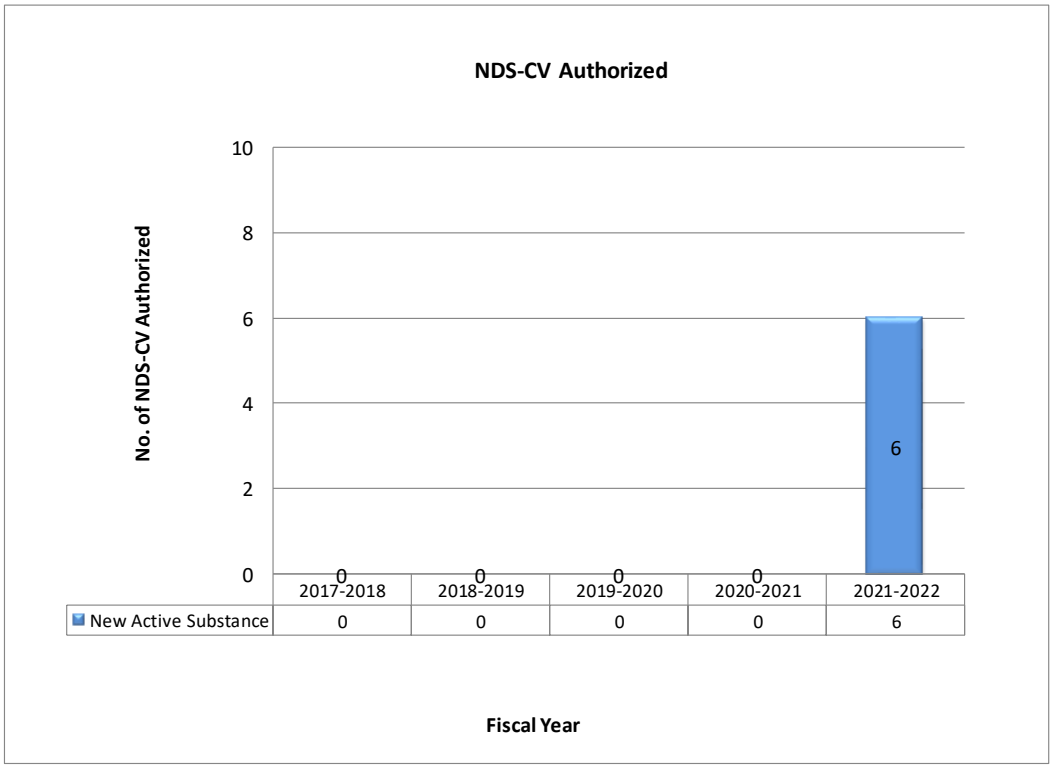
WORKLOAD

NDS-CV: Review Workload



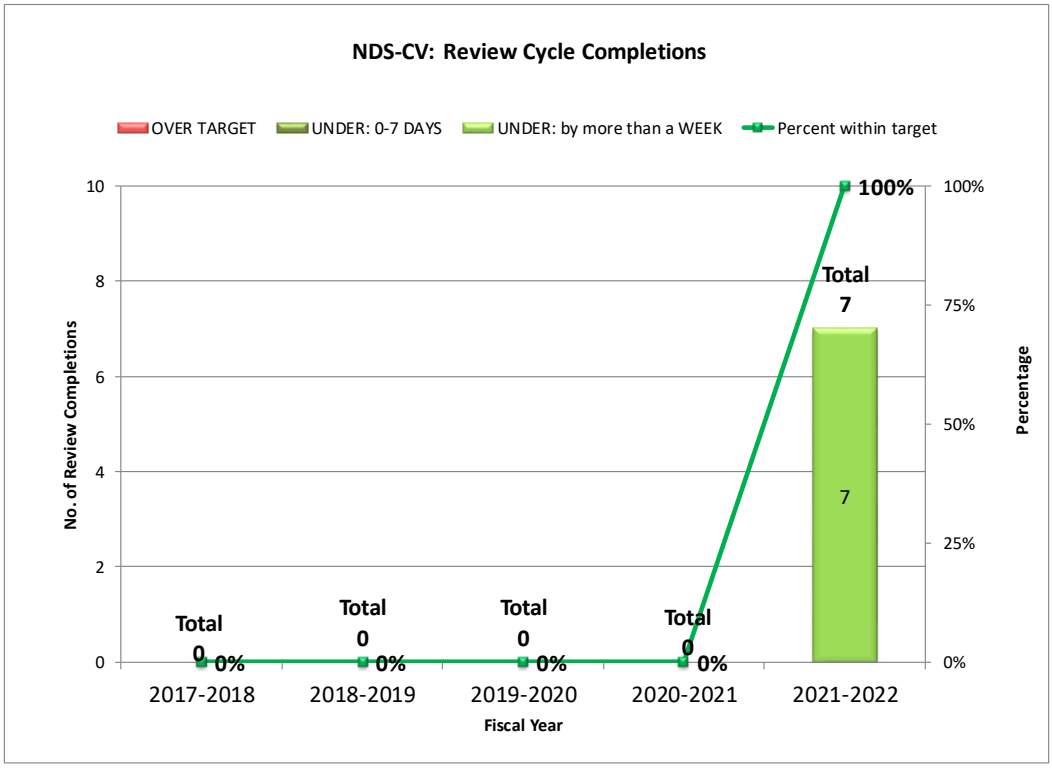
AUTHORIZATIONS

NDS-CV: Number Authorized

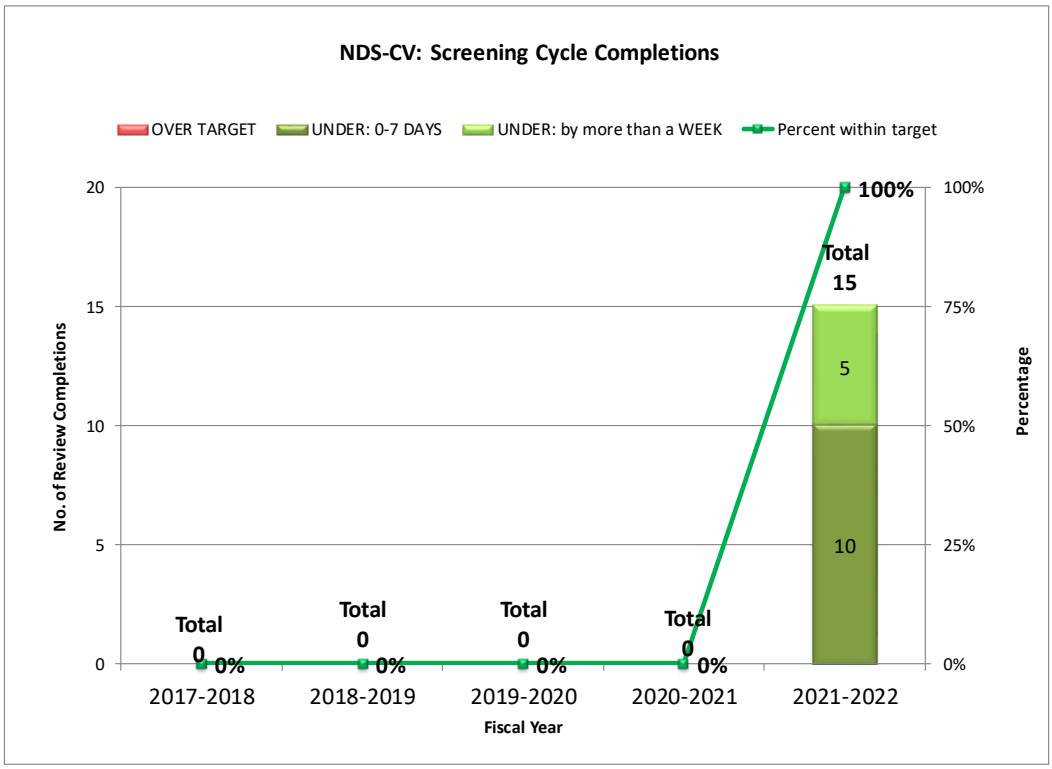


PERFORMANCE

NDS-CV: Review Cycle Completions



NDS-CV: Screening Cycle Completions

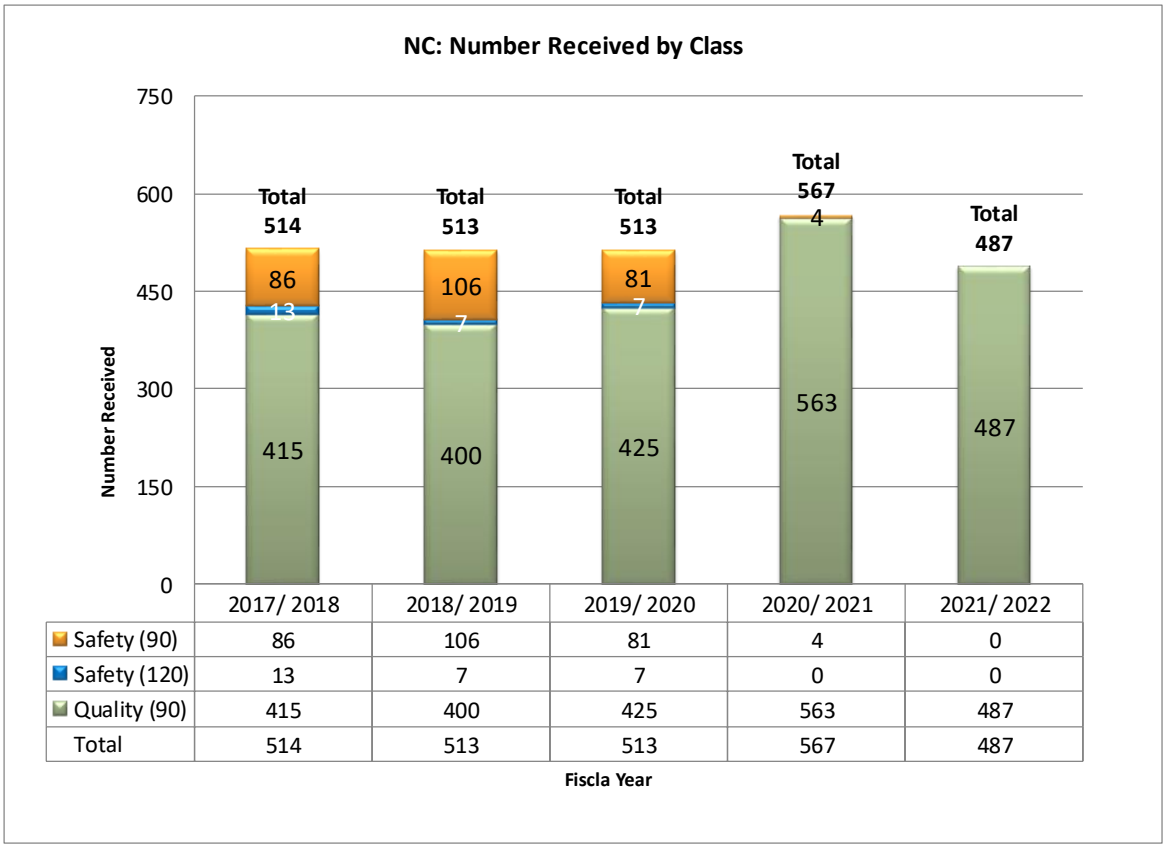


NC: NOTIFIABLE CHANGE

NC: NOTIFIABLE CHANGE

RECEIVED

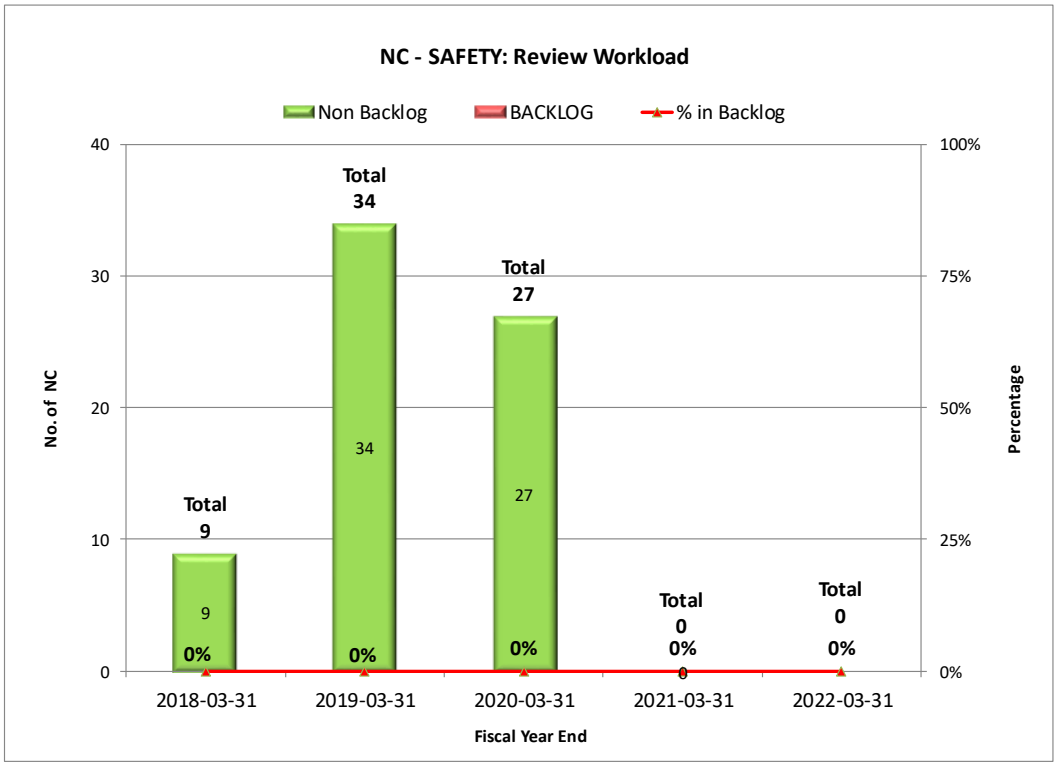
NC: Number Received by Class



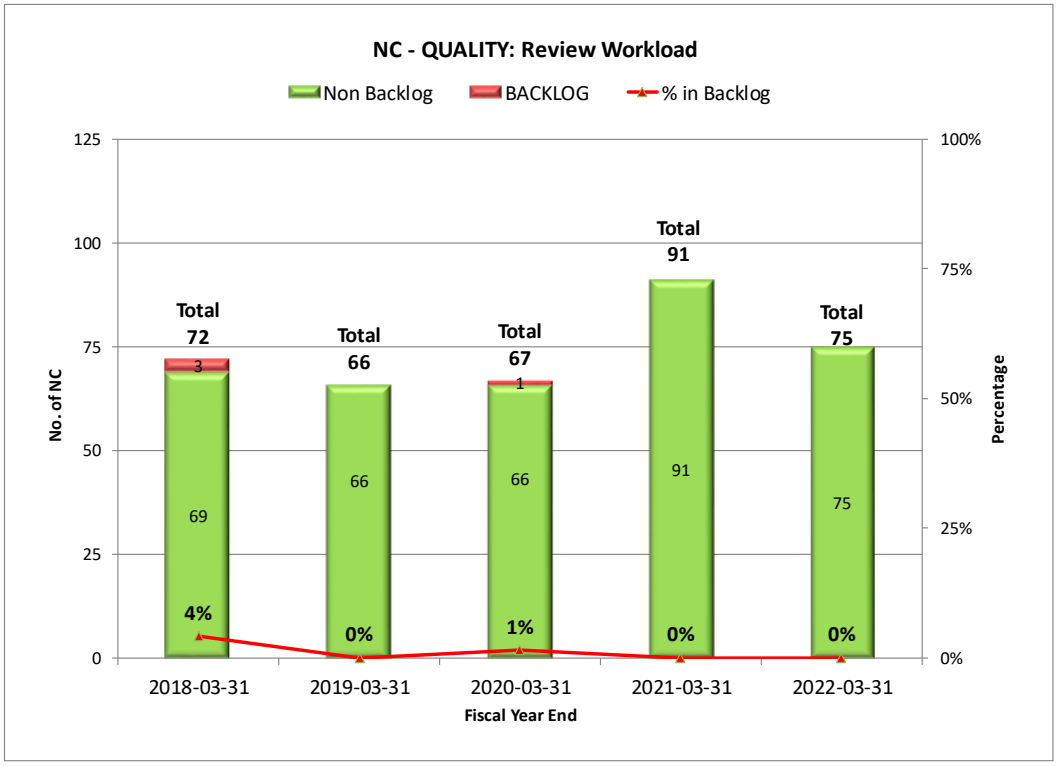
	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Safety (90)	86	106	81	4	0
Safety (120)	13	7	7	0	0
Quality (90)	415	400	425	563	487
Total	514	513	513	567	487

WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

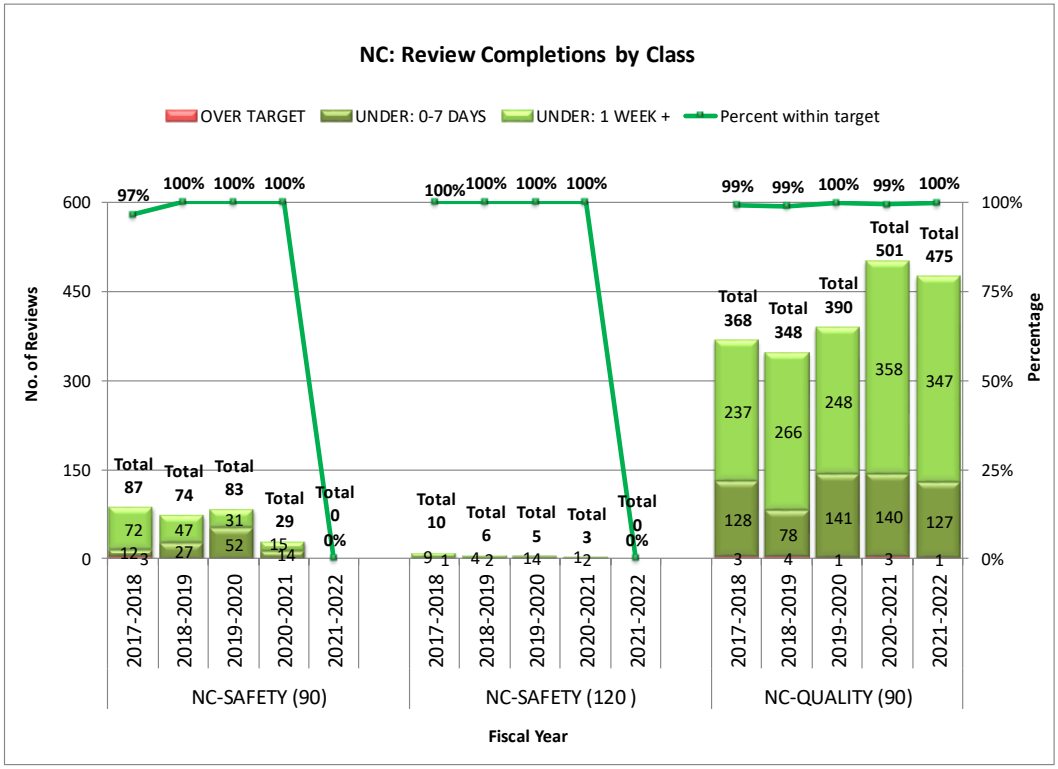
BRDD NC - SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
SAFETY - 90 day	8	34	24	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	1	0	3	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**9**	**34**	**27**	**0**	**0**
Non Backlog	**9**	**34**	**27**	**0**	**0**
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-QUALITY: Review Workload by Class

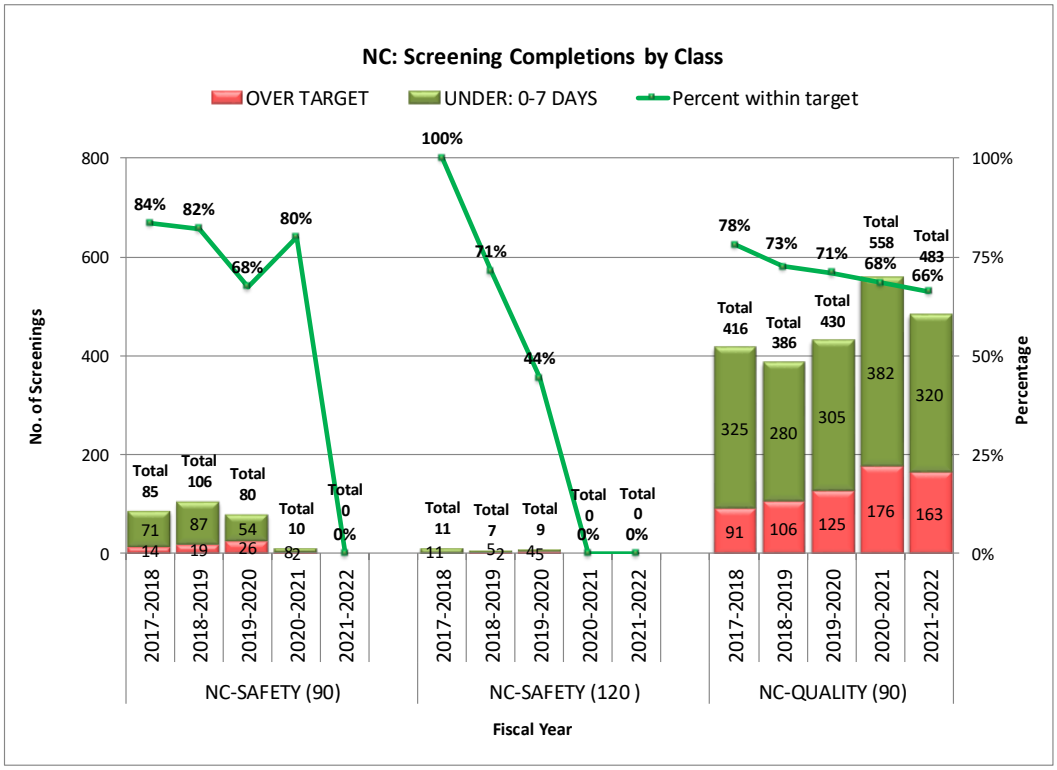
BRDD NC - QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**	**2022-03-31**
QUALITY - 90 day	**72**	**66**	**67**	**91**	**75**
Backlog	*3*	*0*	*1*	*0*	*0*
Total	**72**	**66**	**67**	**91**	**75**
Non Backlog	**69**	**66**	**66**	**91**	**75**
BACKLOG	3	0	1	0	0
% in Backlog	4%	0%	1%	0%	0%

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



DECISIONS

NC: Decision Documents by Class

DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NC - QUALITY (90)					
NO OBJECTION LETTER	381	358	415	516	463
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	12	16	1	1	14
CANCELLED BY COMPANY	8	16	15	23	22
SCREENING DEFICIENCY NOTICE	2	0	0	0	0
NC - HOLD (PATENT)	0	3	1	0	0
NC - SAFETY (90)					
NO OBJECTION LETTER	88	78	82	28	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	2	0
CANCELLED BY COMPANY	6	5	9	4	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0
NC - SAFETY (120)					
NO OBJECTION LETTER	12	6	5	3	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
CANCELLED BY COMPANY	2	2	1	0	0
NC - ADMINISTRATIVE					
NO OBJECTION LETTER	9	5	2	0	0

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

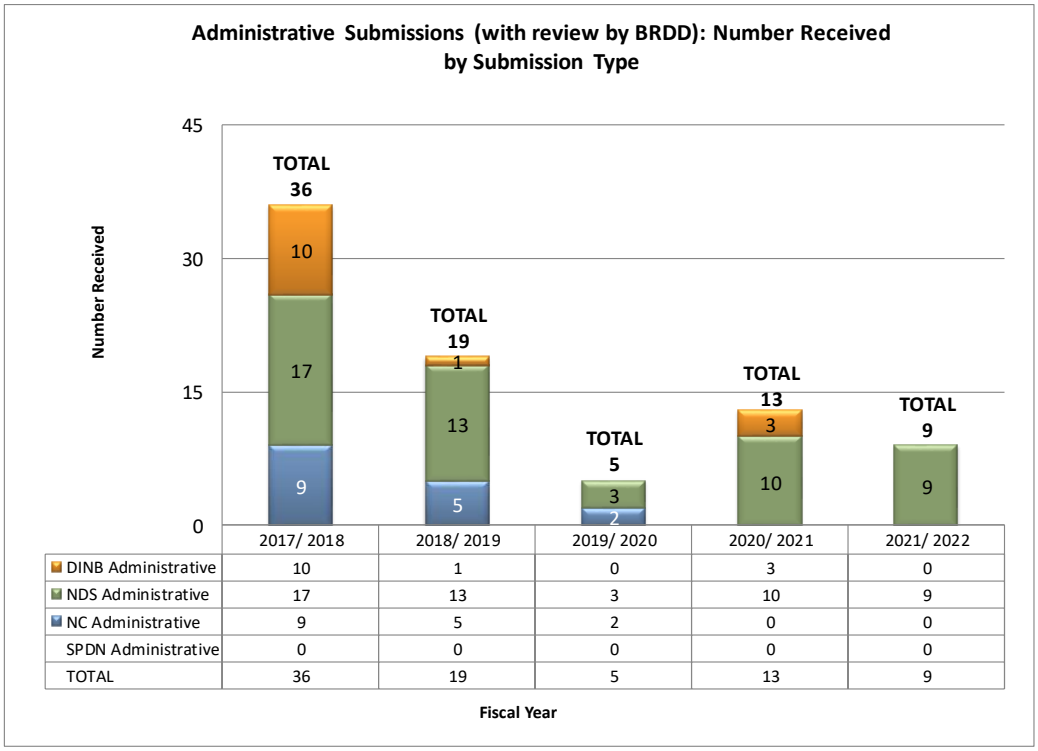
Requests for Reconsideration of Final Decisions - NC

NC - Requests for Reconsideration of Final Decisions					
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

ADMINISTRATIVE SUBMISSIONS (Processed by BRDD)

RECEIVED

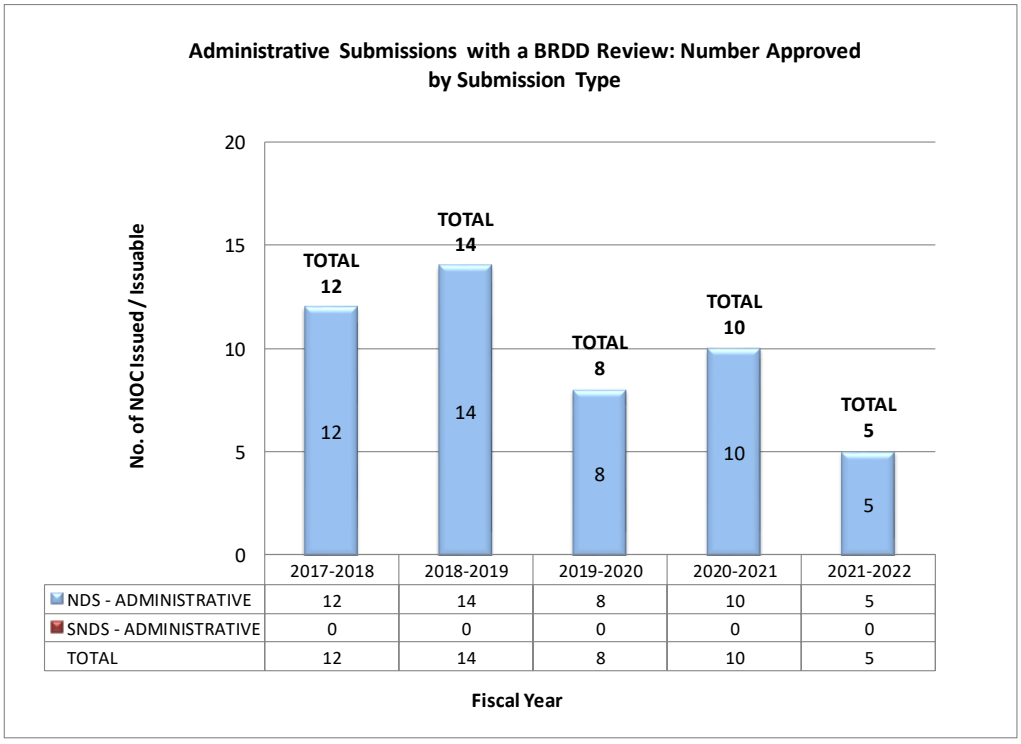
Administrative Submissions (with BRDD Review): Number Received



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
DINB Administrative	10	1	0	3	0
NDS Administrative	17	13	3	10	9
NC Administrative	9	5	2	0	0
SPDN Administrative	0	0	0	0	0
TOTAL	36	19	5	13	9

APPROVALS

Administrative Submissions (with BRDD Review): Number Approved



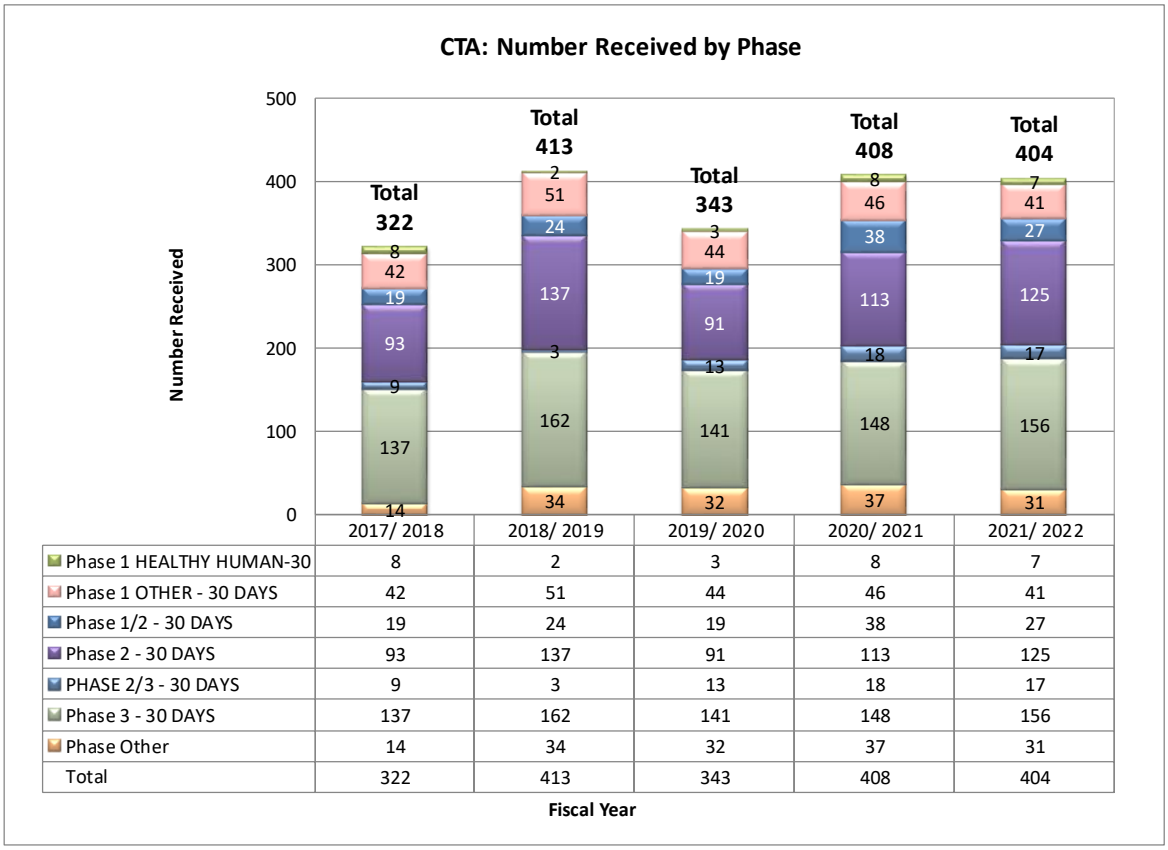
	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NDS - ADMINISTRATIVE	12	14	8	10	5
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	12	14	8	10	5

CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS (CTA) RECEIVED

CTA: Number Received by Phase



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 HEALTHY HUMAN-30	8	2	3	8	7
Phase 1 OTHER - 30 DAYS	42	51	44	46	41
Phase 1/2 - 30 DAYS	19	24	19	38	27
Phase 2 - 30 DAYS	93	137	91	113	125
PHASE 2/3 - 30 DAYS	9	3	13	18	17
Phase 3 - 30 DAYS	137	162	141	148	156
Phase Other	14	34	32	37	31
Total	322	413	343	408	404

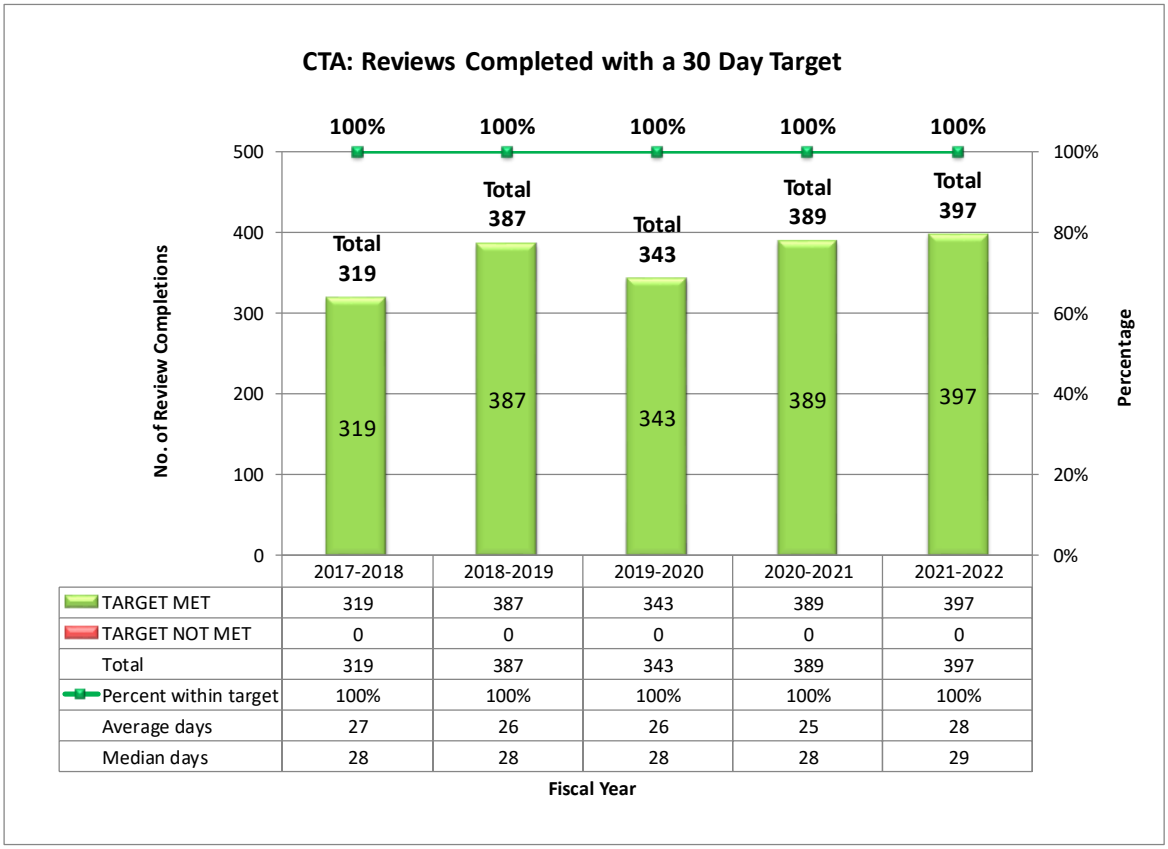
DECISIONS

CTA: Number of Decisions by Document Type

DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NO OBJECTION LETTER	307	380	326	353	385
NOTICE OF AUTHORIZATION	0	0	0	14	11
NOTICE OF AUTHORIZA/ TC	0	0	0	0	2
CANCELLED BY COMPANY DURING REVIEW	12	7	17	21	14
CANCELLED BY COMPANY AT PROCESSING	6	6	14	6	5
NOT SATISFACTORY NOTICE	0	1	0	0	0
REJECTION LETTER (SCR)	0	2	5	1	0

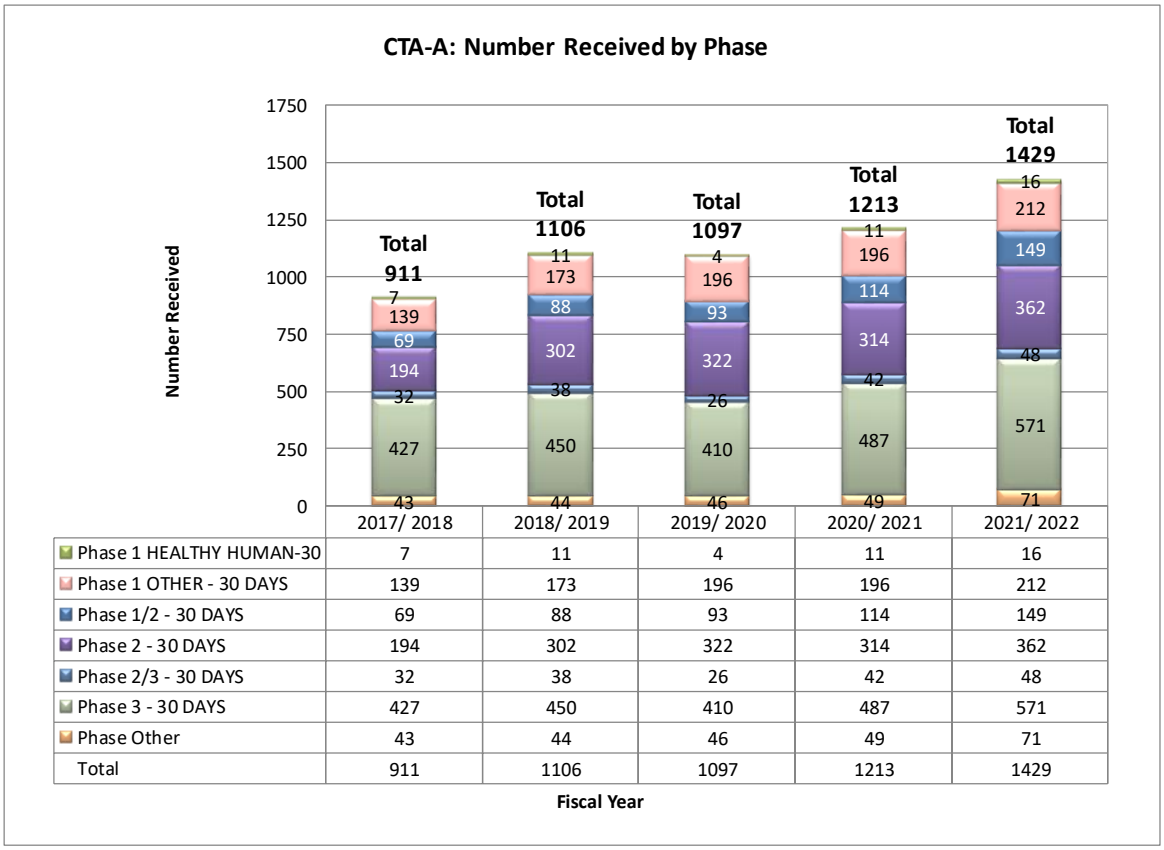
PERFORMANCE

CTA: Reviews Completed with a 30 Day Target



CLINICAL TRIAL APPLICATION-AMENDMENTS (CTA-A) RECEIVED

CTA-A: Number Received by Phase



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 HEALTHY HUMAN-30	7	11	4	11	16
Phase 1 OTHER - 30 DAYS	139	173	196	196	212
Phase 1/2 - 30 DAYS	69	88	93	114	149
Phase 2 - 30 DAYS	194	302	322	314	362
Phase 2/3 - 30 DAYS	32	38	26	42	48
Phase 3 - 30 DAYS	427	450	410	487	571
Phase Other	43	44	46	49	71
Total	911	1106	1097	1213	1429

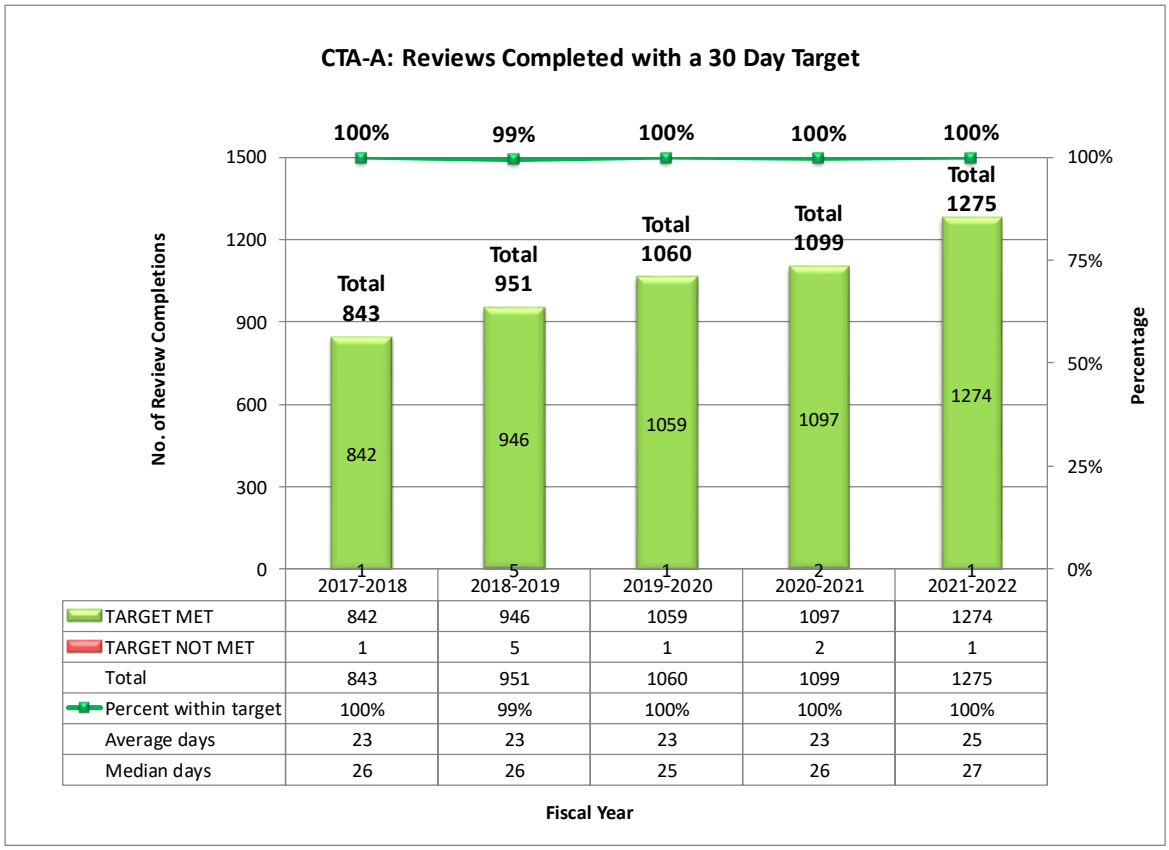
DECISIONS

CTA-A: Number of Decisions by Document Type

DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
NO OBJECTION LETTER	869	1048	1080	1115	1335
NOTICE OF AUTHORIZATION	0	0	0	14	43
NOTICE OF AUTHORIZ A/TC	0	0	0	0	1
NOTICE OF AUTHORIZA/ TC	0	0	0	0	1
CANCELLED BY COMPANY DURING REVIEW	15	4	9	12	13
CANCELLED BY COMPANY AT PROCESSING	9	9	10	9	8
REJECTION LETTER (SCR)	15	20	23	14	19

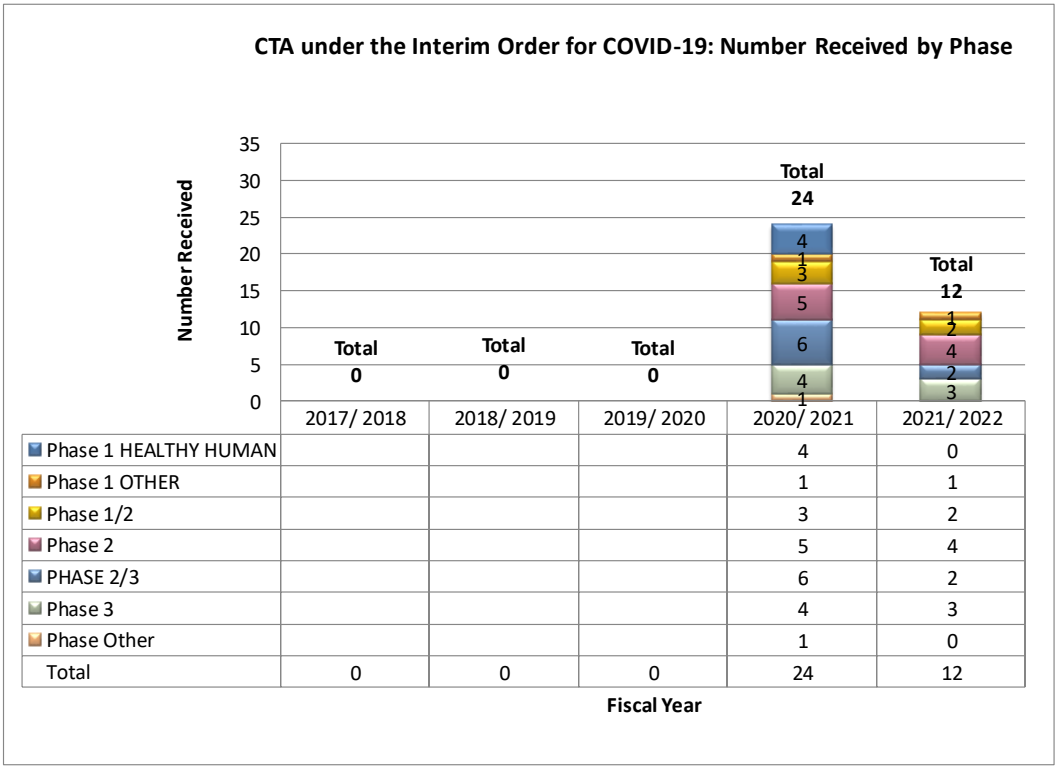
PERFORMANCE

CTA-A: Reviews Completed with a 30 Day Target



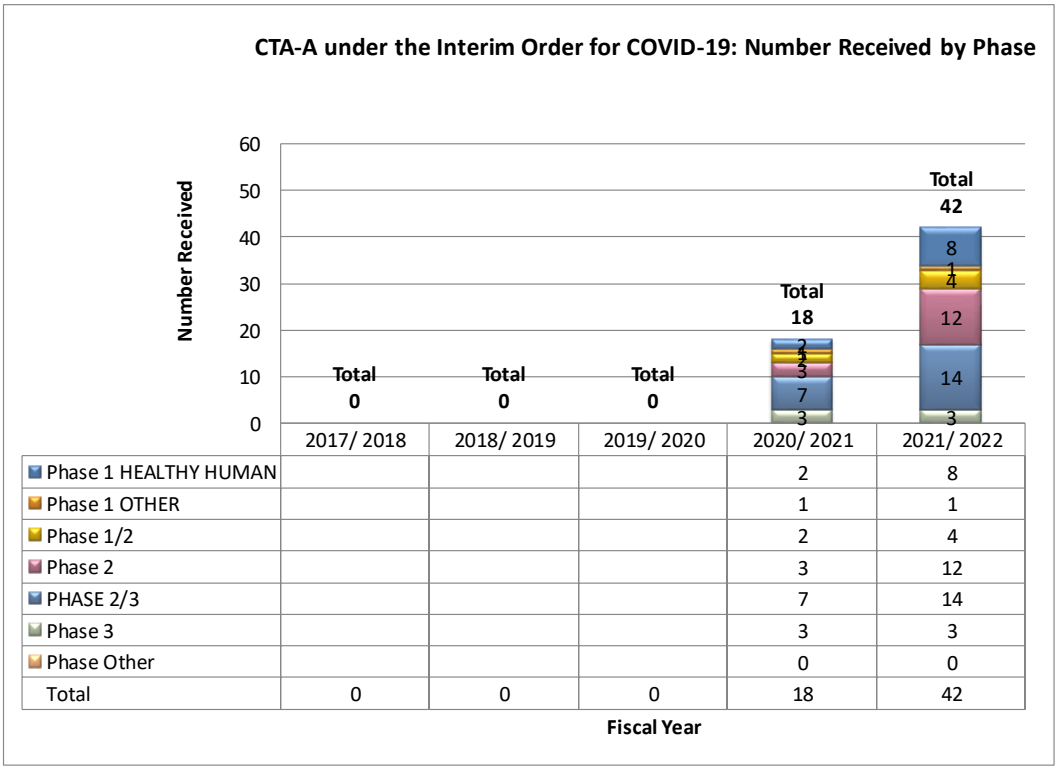
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19

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



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 HEALTHY HUMAN				4	0
Phase 1 OTHER				1	1
Phase 1/2				3	2
Phase 2				5	4
PHASE 2/3				6	2
Phase 3				4	3
Phase Other				1	0
Total	0	0	0	24	12

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



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Phase 1 HEALTHY HUMAN				2	8
Phase 1 OTHER				1	1
Phase 1/2				2	4
Phase 2				3	12
PHASE 2/3				7	14
Phase 3				3	3
Phase Other				0	0
Total	0	0	0	18	42

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

DINB

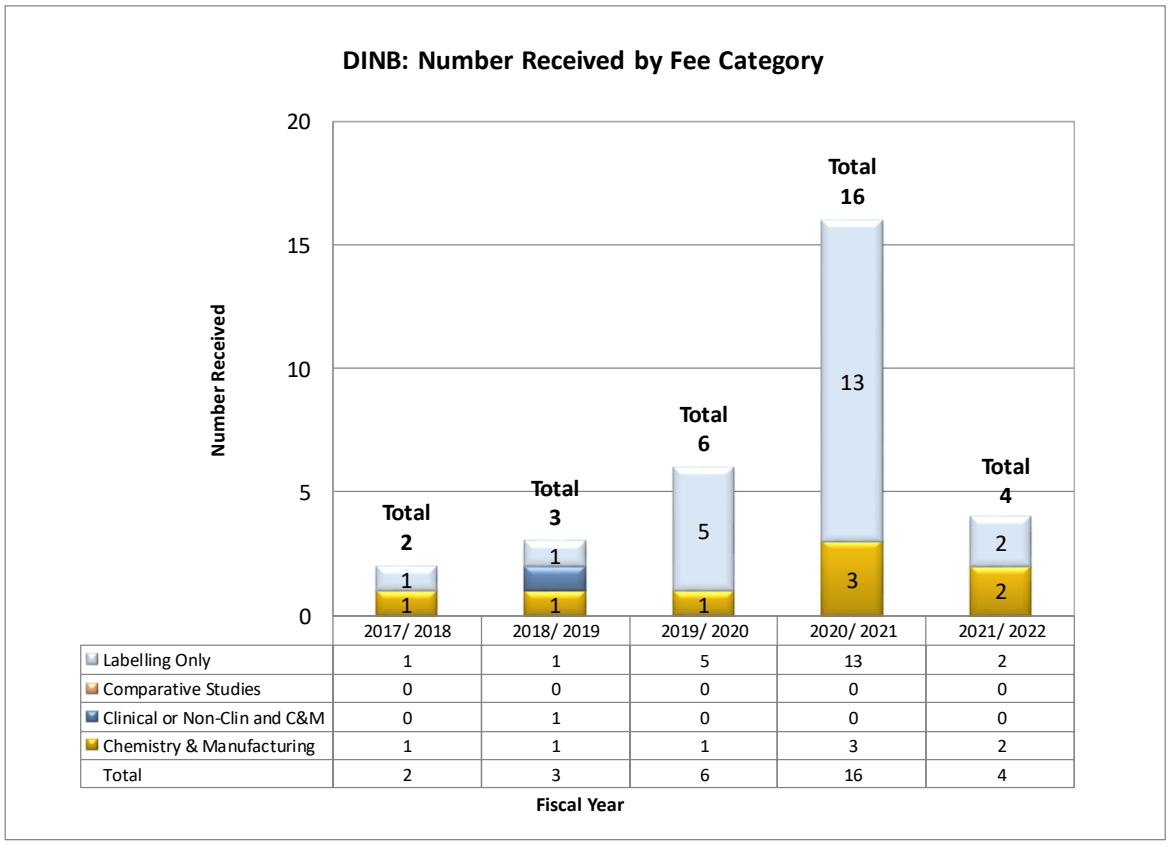
Application for a Drug Identification Number

Biological Product

DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

RECEIVED

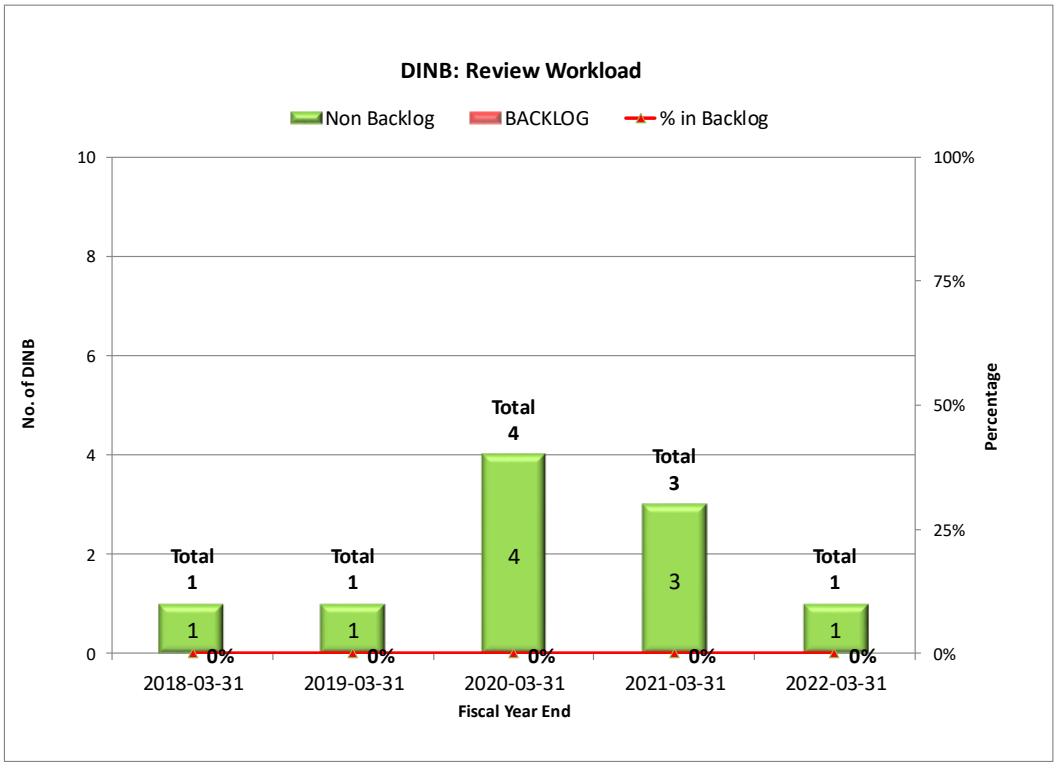
DINB: Number Received by Fee Category



	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Labelling Only	1	1	5	13	2
Comparative Studies	0	0	0	0	0
Clinical or Non-Clin and C&M	0	1	0	0	0
Chemistry & Manufacturing	1	1	1	3	2
Total	2	3	6	16	4

REVIEW WORKLOAD

DINB: Review Workload

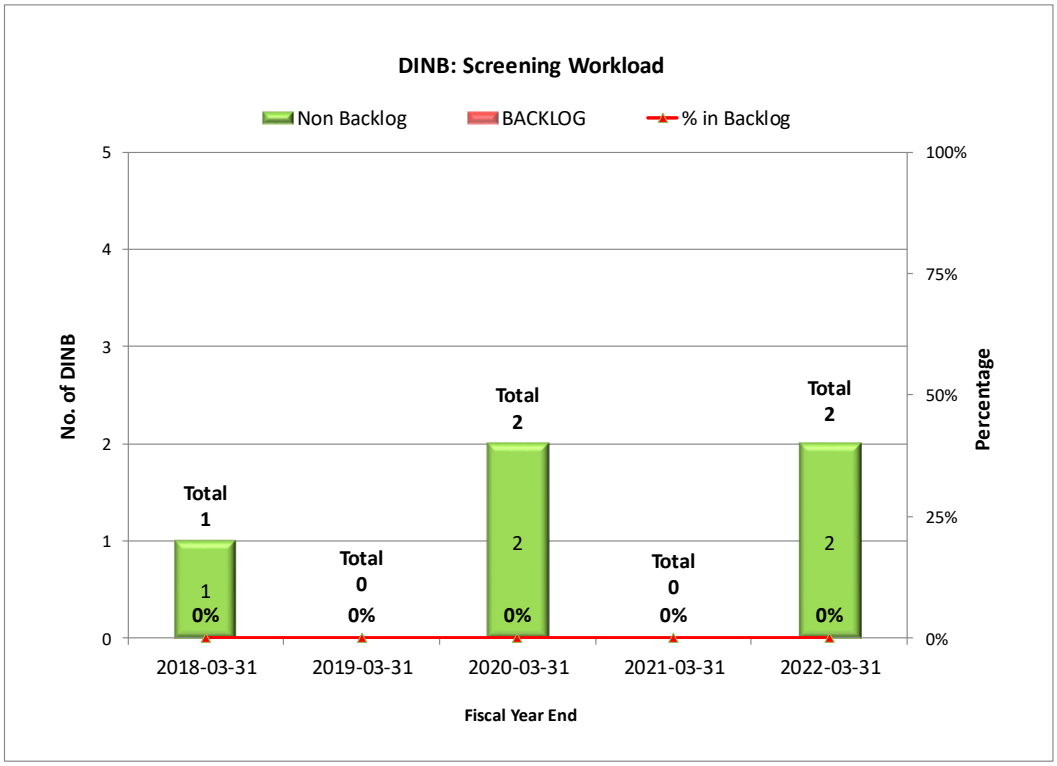


DINB: Review Workload by Fee Category

DINB: 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	1	0	3	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	1	1	2	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**1**	**4**	**3**	**1**
Non Backlog	**1**	**1**	**4**	**3**	**1**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

DINB: Screening Workload



DINB: Screening Workload by Fee Category

DINB: 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	0	0	2	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**0**	**2**	**0**	**2**
Non Backlog	**1**	**0**	**2**	**0**	**2**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINB: Number of Decisions by Fee Category

DOCUMENT TYPE	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
DINB - LABELLING ONLY					
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
DINB APPROVAL LETTER	0	0	0	15	3
NEW DRUG LETTER SCREEN	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	2	0
CANCELLED BY COMPANY	6	0	0	2	0
DINB - CHEMISTRY & MANUFACTURING					
NO OBJECTION LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
DINB APPROVAL LETTER	0	0	0	1	3
NOTIFICATION FORM DIN SUB	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0
DINB - CLIN/C&M					
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0
DINB - ADMINISTRATIVE					
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
DINB APPROVAL LETTER	0	0	0	3	0
CANCELLED BY COMPANY	1	0	0	0	0
DINB - COMPARATIVE STUDIES					
REJECTION LETTER (SCREENING)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

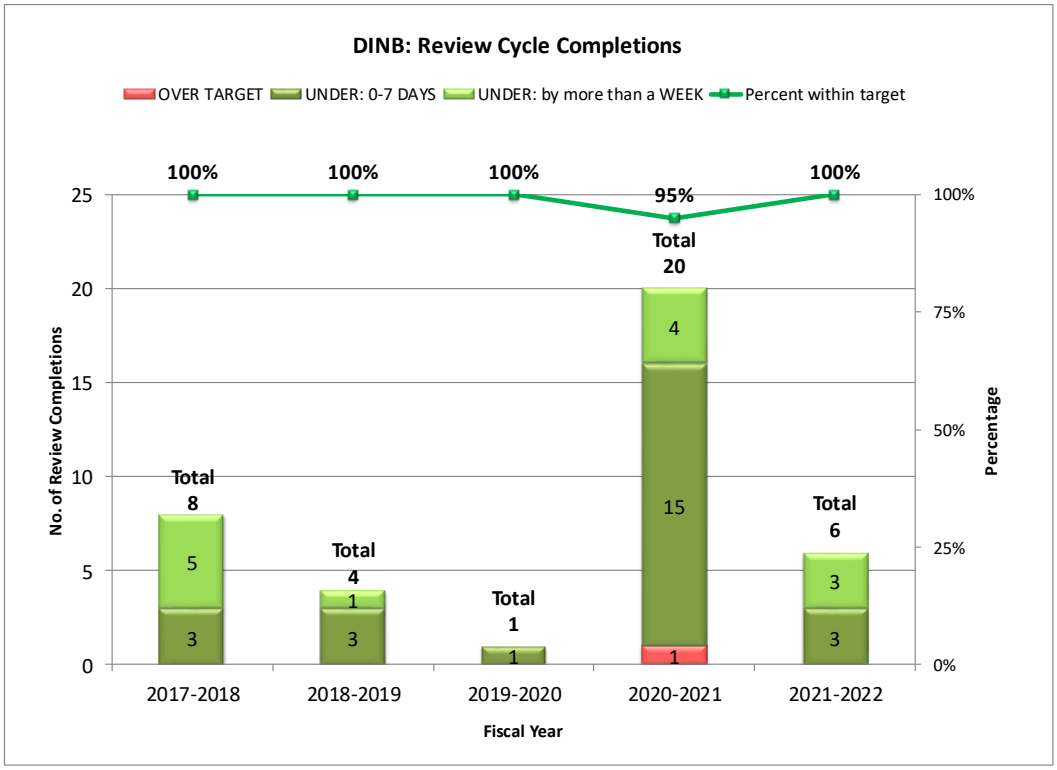
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

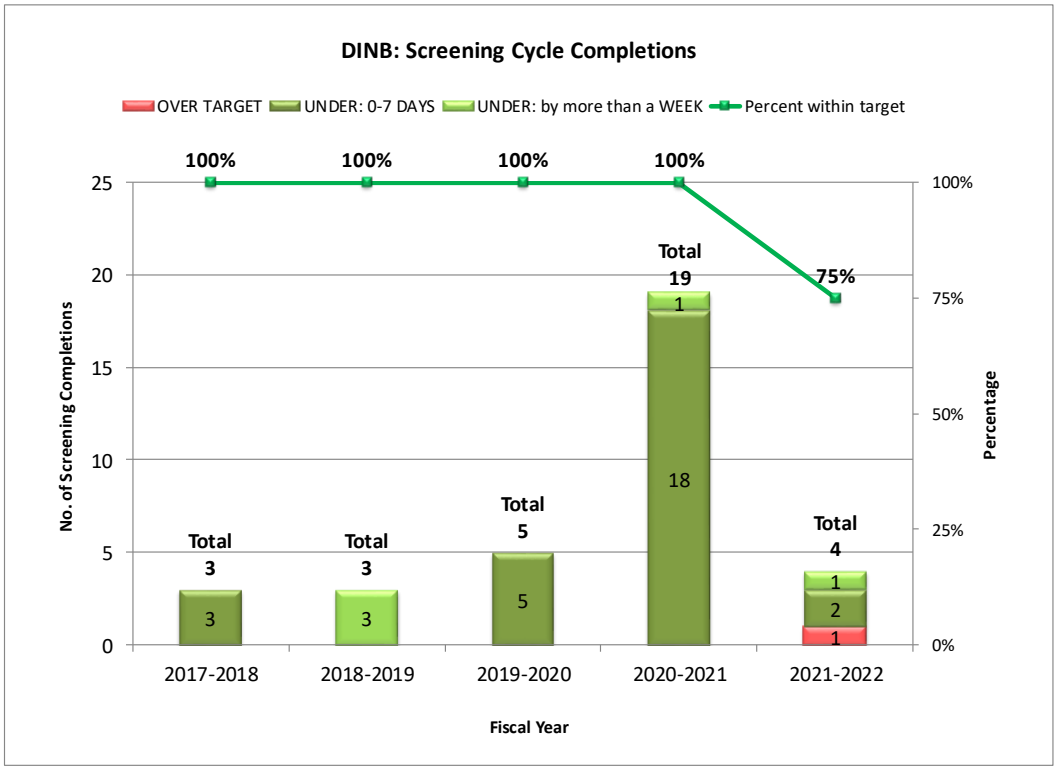
DINB - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
Total	*0*	*0*	*0*	*0*	*0*

PERFORMANCE

DINB: Review Cycle Completions



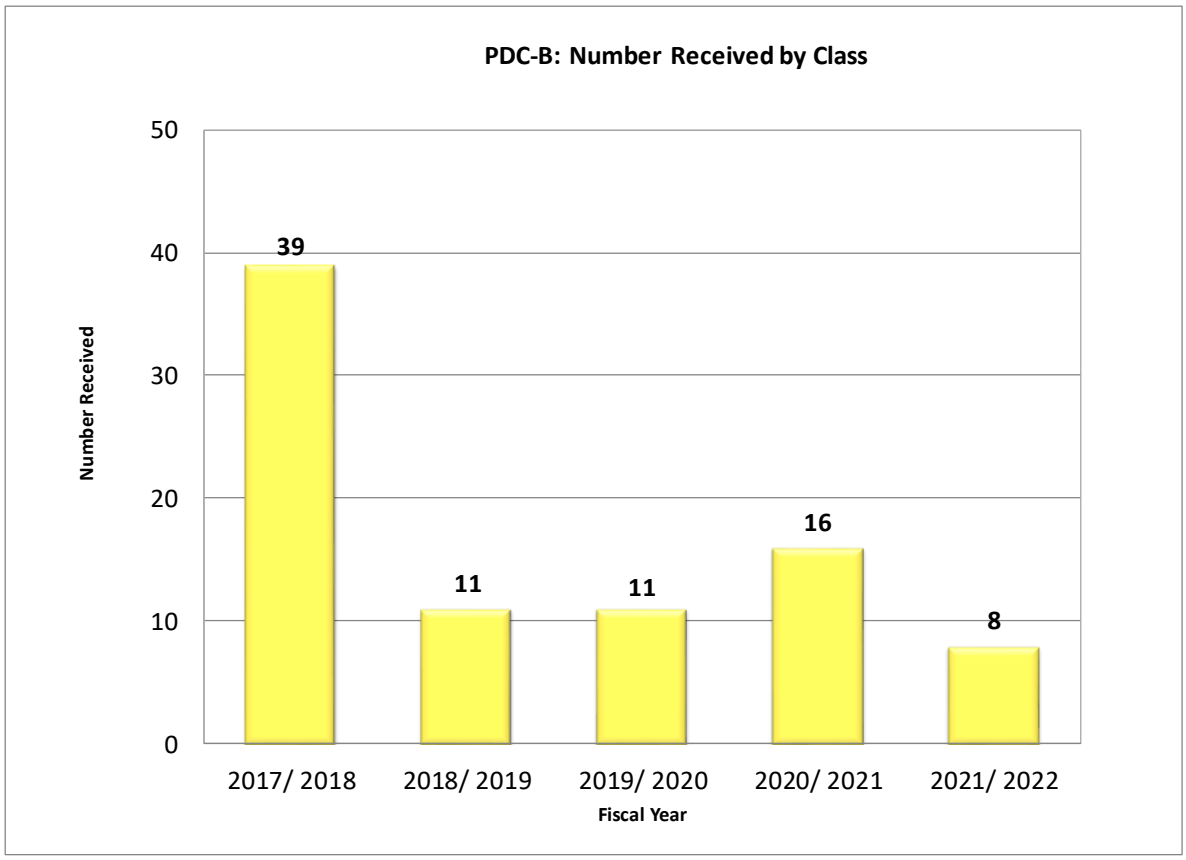
DINB: Screening Cycle Completions



PDC-B: POST AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT

RECEIVED

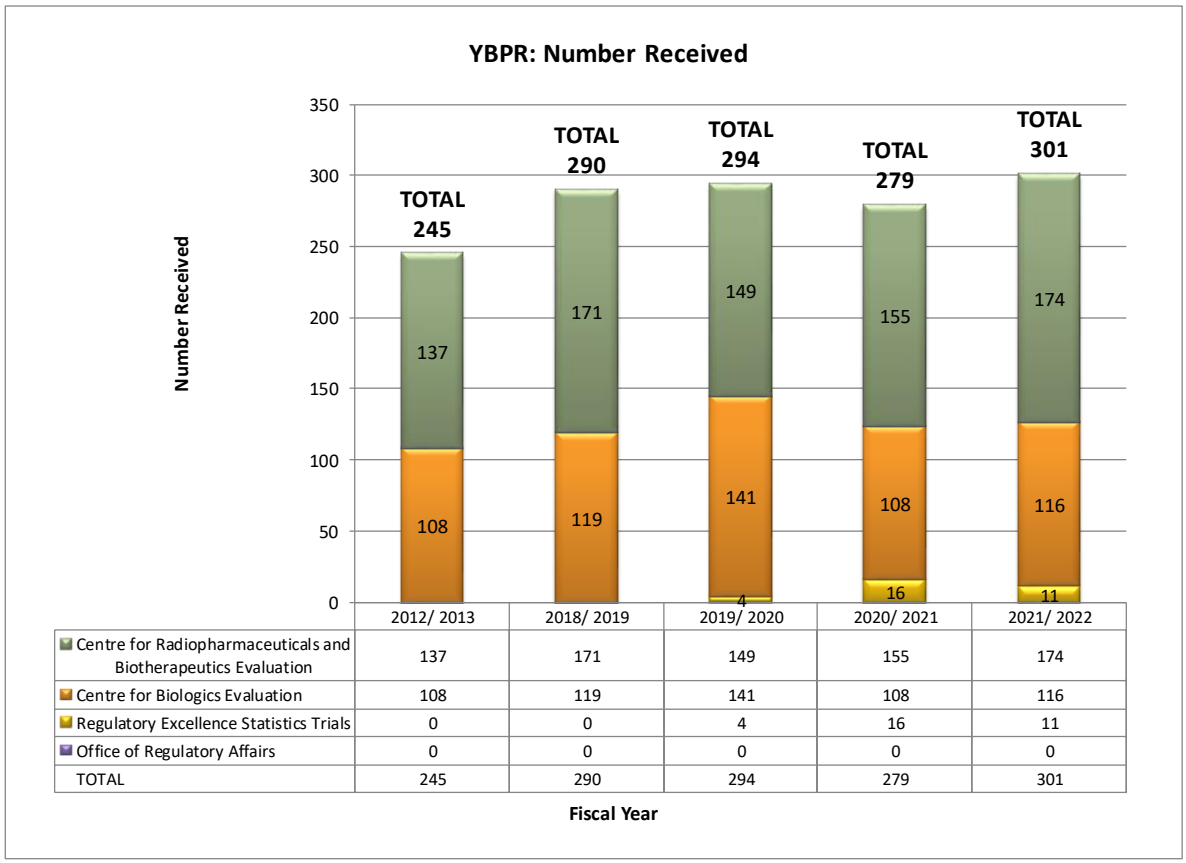
PDC-B: Number Received



YBPR: YEARLY BIOLOGIC PRODUCT REPORTS [10]

RECEIVED

YBPR: Number Received

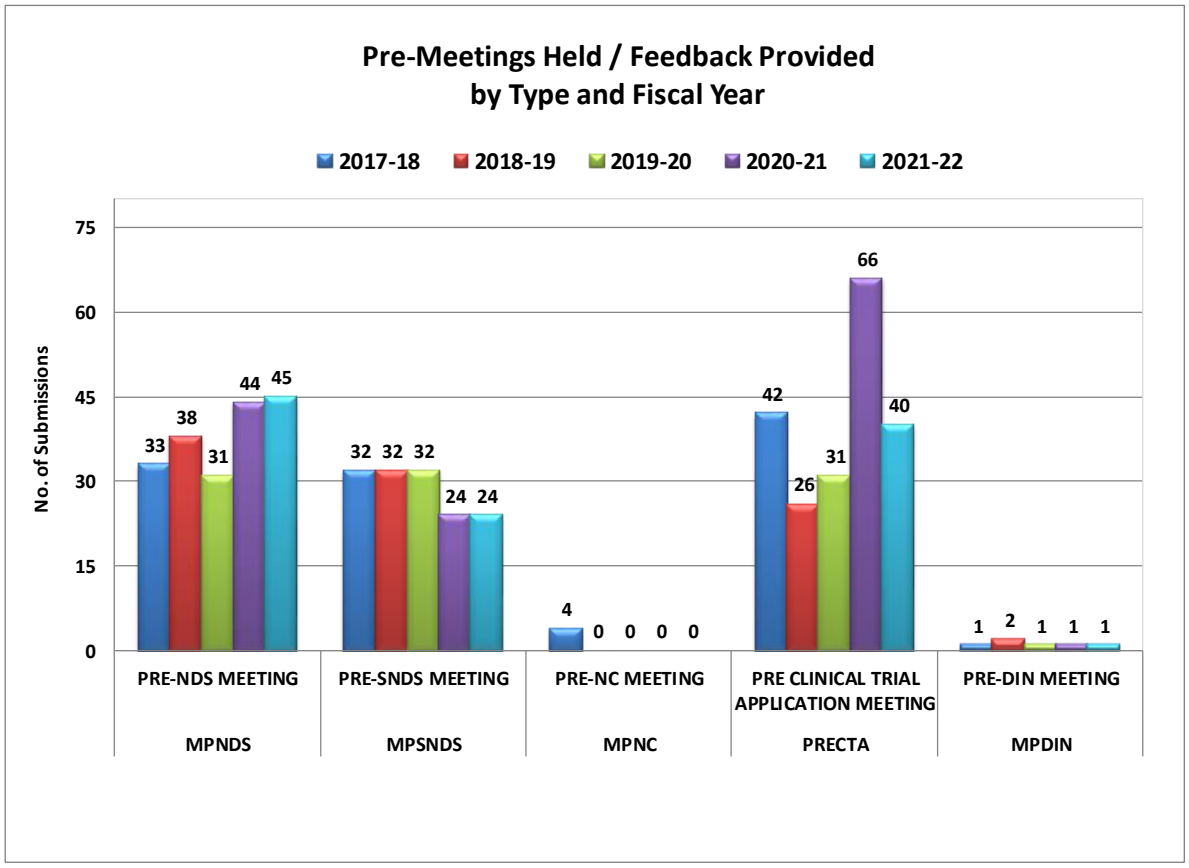


	2012/ 2013	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	137	171	149	155	174
Centre for Biologics Evaluation	108	119	141	108	116
Regulatory Excellence Statistics Trials	0	0	4	16	11
Office of Regulatory Affairs	0	0	0	0	0
TOTAL	245	290	294	279	301

[10] Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

APPENDIX A: PRE-SUBMISSION MEETINGS [11]

Pre-Submission Meetings Held / Feedback Provided



[11] Prior to filing a submission, the 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 and Applications

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