Santé Canada Health Canada

Biologics and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Annual Report

Fiscal Year

2020-2021

April 1 2020 - March 31 2021

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 2016-2017 to 2020-2021.

Statistics are provided by submission type and show the number received, the number in workload, the number of decisions, the number of approvals and approval times. The report lists details of Priority Submissions and New Active Substances approved during the fiscal year April 1 2020 to March 31 2021.

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

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

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

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

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

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

General Information

There are several steps involved in the drug submission review[1] and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on the last day of the quarter. **"Backlog"** is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

Approvals[2] are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

Authorization means an authorization issued under section 5 of the ISAD Interim Order.

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

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[1] For further clarification refer to the Guidance for Industry: Management of Drug Submissions and Applications.

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

[3] Review cycles include all types e.g. Review 1, Review 2, Review QN. The total number of "review decisions" may surpass the total number of review cycle completions as they include cancellations/withdrawals that occur while the submission is 'inactive'. For example, a withdrawal can be issued when a company fails to respond to a notice of non-compliance within the allotted time frame. A 'Cancelled by Company' is counted as a review decision when a company sends a cancellation letter after the submission's original materials have been accepted for review.

[4] Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the Guidance for Industry: Management of Drug Submissions and Applications. This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

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

Biosimilar designates 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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Resource Management and Operations Directorate
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Email: hc.osip-bppi.sc@canada.ca

[5] For further clarification refer to the Guidance for Industry: Management of Drug Submissions and Applications

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
COV19	-	Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
COV19A	-	Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINA	-	Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	-	Application for a Drug Identification Number for a biological product
DIND	-	Application for a Drug Identification Number for a disinfectant product
DINF	-	Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	-	Abbreviated Extraordinary Use New Drug Submission
EUNDS	-	Extraordinary Use New Drug Submission
EUSANDS	-	Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	-	Supplement to an Extraordinary Use New Drug Submission
MPNDS	-	Pre-Submission Meeting New Drug Submission
MPSNDS	-	Pre-Submission Meeting Supplement to a New Drug Submission
NC	-	Notifiable Change
NDS	-	New Drug Submission
NDS-D	-	New Drug Submission for disinfectant products
PDC	-	Post-Authorization Division 1 Change for a pharmaceutical product
PDC-B	-	Post-Authorization Division 1 Change for a 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 new active substance.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
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

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

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[7]	Submissions in support of a manufacturer or product name change.
Disinfectants[8]	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.

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

[7] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)
[8] The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

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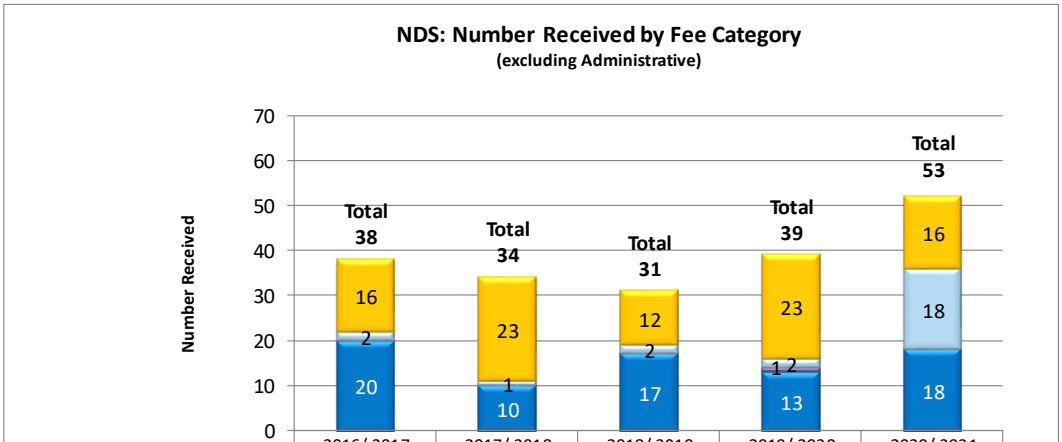
New Drug Submission (NDS)

&

Supplemental New Drug Submission (SNDS)

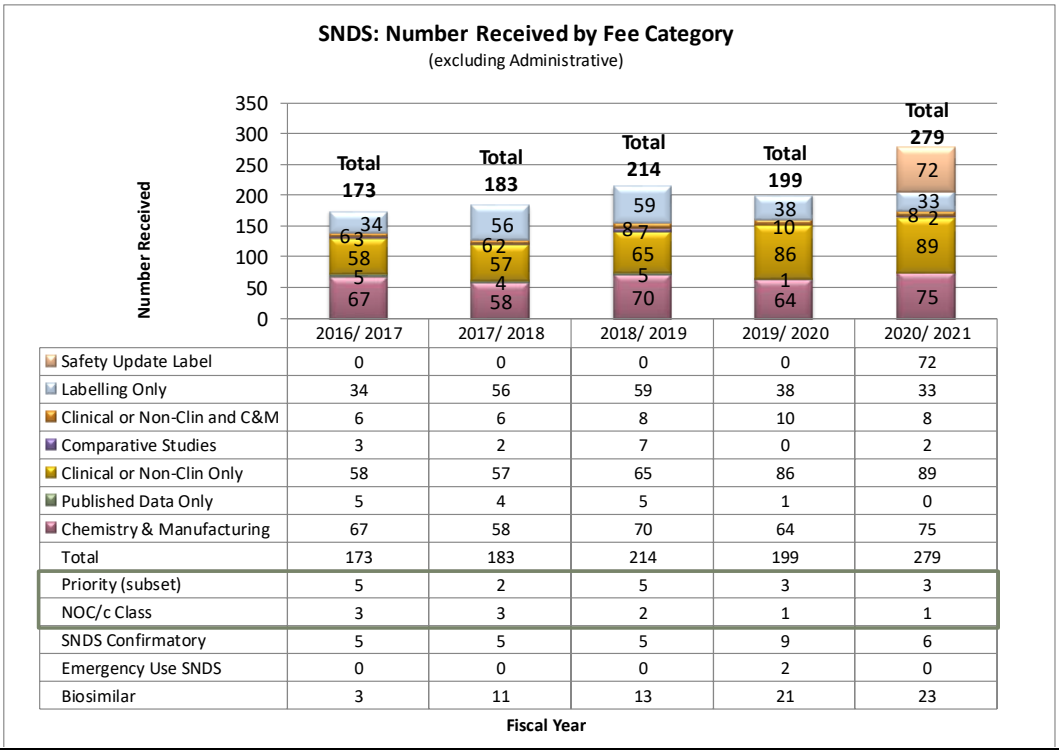
SUBMISSIONS RECEIVED [9]

NDS: Received by Fee Category



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Clinical or Non-Clin and C&M	16	23	12	23	16
Labelling Only	2	1	2	2	18
Comparative Studies	0	0	0	1	0
New Active Substance	20	10	17	13	18
Total	38	34	31	39	53
Priority (subset)	2	5	5	3	4
NOC/c Class	4	2	1	1	3
Emergency Use NDS	2	1	0	1	0
Biosimilar	7	14	8	13	10

SNDS: Received by Fee Category

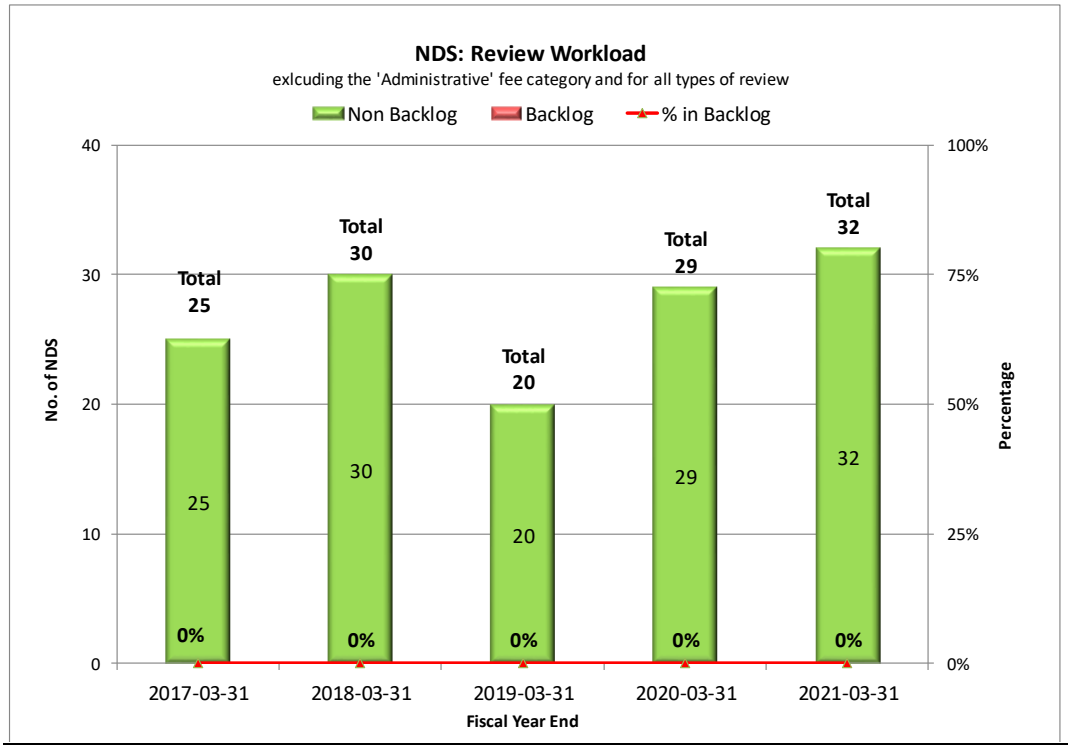


	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Safety Update Label	0	0	0	0	72
Labelling Only	34	56	59	38	33
Clinical or Non-Clin and C&M	6	6	8	10	8
Comparative Studies	3	2	7	0	2
Clinical or Non-Clin Only	58	57	65	86	89
Published Data Only	5	4	5	1	0
Chemistry & Manufacturing	67	58	70	64	75
Total	173	183	214	199	279
Priority (subset)	5	2	5	3	3
NOC/c Class	3	3	2	1	1
SNDS Confirmatory	5	5	5	9	6
Emergency Use SNDS	0	0	0	2	0
Biosimilar	3	11	13	21	23

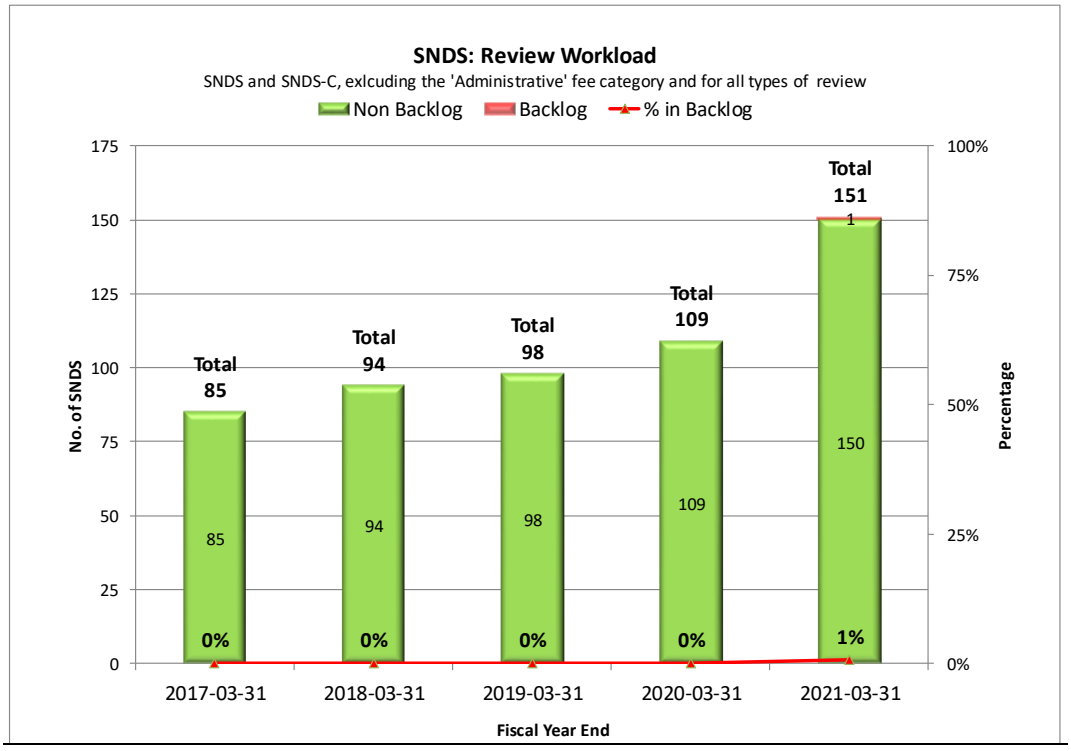
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

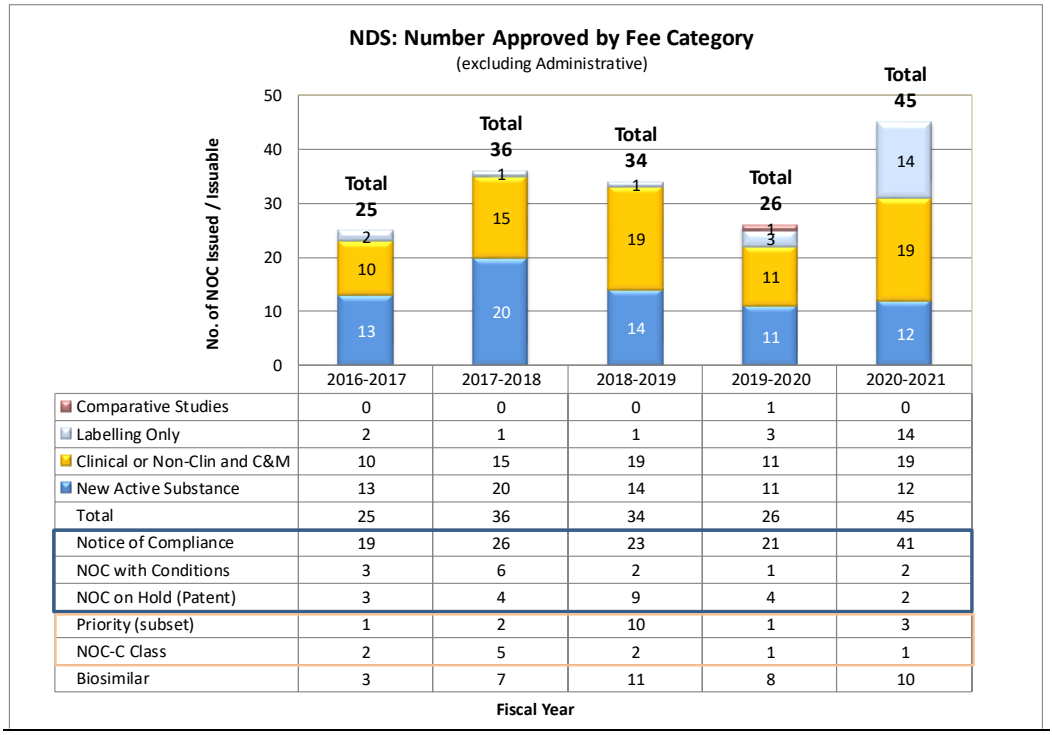
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Clinical or Non-Clin and C&M	11	21	10	18	14
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	0	0	4
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	14	9	10	11	14
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**25**	**30**	**20**	**29**	**32**
Non Backlog	25	30	20	29	32
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	1	5	0	2	3
Backlog	*0*	*0*	*0*	*0*	*0*

SNDS: Review Workload by Fee Category

SNDS REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Comparative Studies	1	1	4	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	28	26	26	31	31
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	44	54	49	63	75
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	3	2	3	3	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	4	4	6	8	5
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	25
Backlog	*0*	*0*	*0*	*0*	*1*
Labelling Only	5	7	10	4	13
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**85**	**94**	**98**	**109**	**151**
Non Backlog	85	94	98	109	150
Backlog	0	0	0	0	**1**
% in Backlog	0%	0%	0%	0%	**1%**
Priority (subset)	3	2	4	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	3	5	5	6	5
Backlog	*0*	*0*	*0*	*0*	*0*

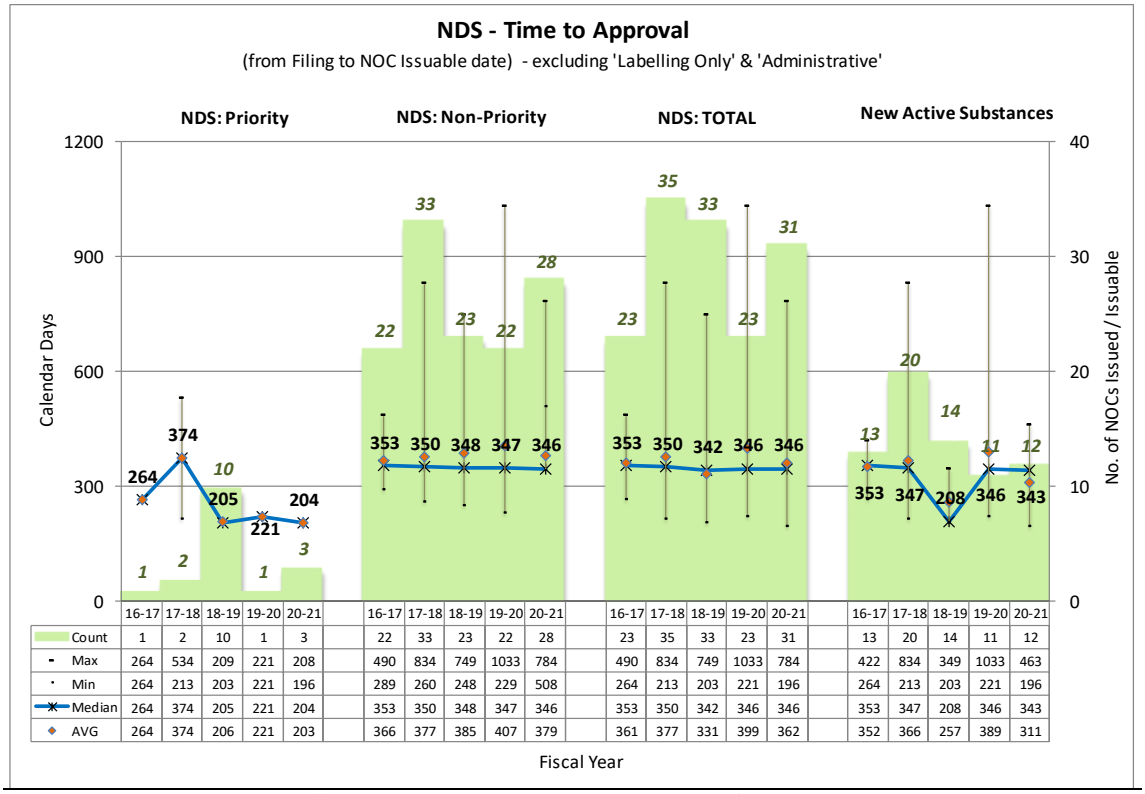
APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Comparative Studies	0	0	0	1	0
Labelling Only	2	1	1	3	14
Clinical or Non-Clin and C&M	10	15	19	11	19
New Active Substance	13	20	14	11	12
Total	25	36	34	26	45
Notice of Compliance	19	26	23	21	41
NOC with Conditions	3	6	2	1	2
NOC on Hold (Patent)	3	4	9	4	2
Priority (subset)	1	2	10	1	3
NOC-C Class	2	5	2	1	1
Biosimilar	3	7	11	8	10

NDS Approval Times

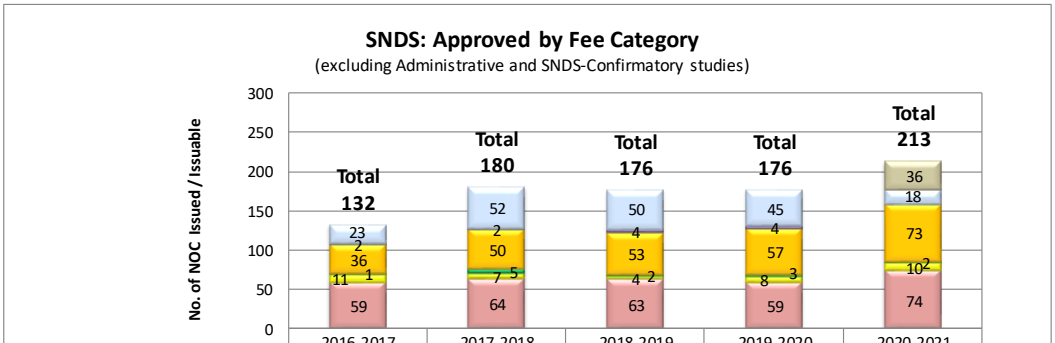


	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	1	2	10	1	3	22	33	23	22	28	23	35	33	23	31	13	20	14	11	12
Max	264	534	209	221	208	490	834	749	1033	784	490	834	749	1033	784	422	834	349	1033	463
Min	264	213	203	221	196	289	260	248	229	508	264	213	203	221	196	264	213	203	221	196
Median	264	374	205	221	204	353	350	348	347	346	353	350	342	346	346	353	347	208	346	343
AVG	264	374	206	221	203	366	377	385	407	379	361	377	331	399	362	352	366	257	389	311

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..

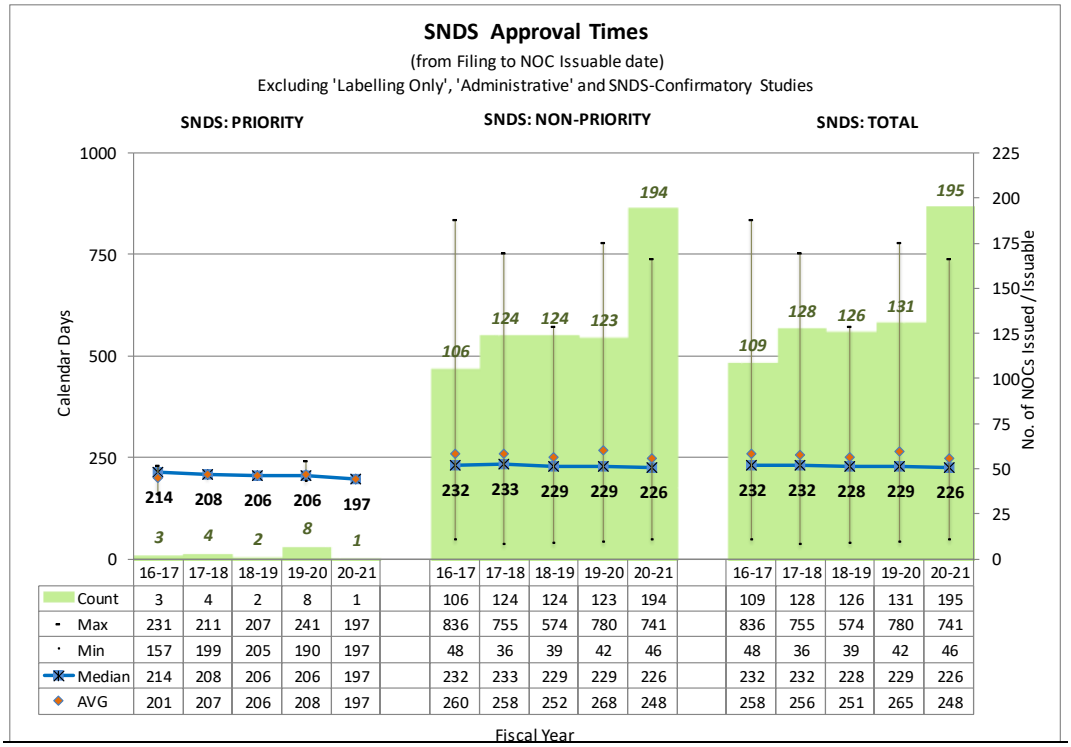
APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Safety Update Label	0	0	0	0	36
Labelling Only	23	52	50	45	18
Comparative Studies	2	2	4	4	0
Clinical or Non-Clin Only	36	50	53	57	73
Published Data Only	1	5	2	3	2
Clinical or Non-Clin and C&M	11	7	4	8	10
Chemistry & Manufacturing	59	64	63	59	74
Total	132	180	176	176	213
Notice of Compliance	127	175	174	165	203
NOC with Conditions	2	4	1	6	3
NOC on Hold (Patent)	3	1	1	5	7
Priority (subset)	3	4	2	8	1
NOC-C Class	2	4	1	3	2
Biosimilar	6	6	9	18	19

SNDS Approval Times



	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21	16-17	17-18	18-19	19-20	20-21
Count	3	4	2	8	1	106	124	124	123	194	109	128	126	131	195
Max	231	211	207	241	197	836	755	574	780	741	836	755	574	780	741
Min	157	199	205	190	197	48	36	39	42	46	48	36	39	42	46
Median	214	208	206	206	197	232	233	229	229	226	232	232	228	229	226
AVG	201	207	206	208	197	260	258	252	268	248	258	256	251	265	248

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 2020-2021

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2020-2021 (April 1 2020 to March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
AJOVY (FREMANEZUMAB) Ajovy is a prescription medicine used for the prevention of migraine in adults who have at least 4 migraine days per month.	NAS	Teva Canada Limited	1-May-19	9-Apr-20
ANTHIM (OBILTOXAXIMAB) Anthim is a prescription medicine used along with antibiotic medicines to treat people with inhalational anthrax. Anthim can also be used to prevent anthrax disease after exposure to anthrax spores when there are no other treatment options. • The effectiveness of Anthim has been studied only in animals with inhalational anthrax. There have been no studies in people who have inhalational anthrax. • The safety of Anthim was studied in healthy adults. There have been no studies of Anthim in children younger than 18 years. • Anthim is not used in prevention or treatment of anthrax meningitis.	NAS	Elusys Therapeutics Inc.	16-Aug-19	30-Jul-20
ENSPRYNG (SATRALIZUMAB) Enspryng is for treatment of 'neuromyelitis optica spectrum disorders' (NMOSD). It is used in adults and young people from 12 years of age. Enspryng reduces the risk of a relapse or attack of NMOSD.	PRIORITY-NAS	Hoffmann La Roche Limited	18-Nov-19	1-Jun-20

[10] 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 2020-2021 (April 1 2020 to March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
GALLIAPHARM (GALLIUM 68 Ga CHLORIDE) The eluate from the radionuclide generator (gallium (68Ga) chloride solution) is indicated for in vitro labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging. The gallium (68Ga) chloride eluate from the GalliaPharm generator is not intended for direct use in patients.	NAS	Eckert & Ziegler Radiopharma GMBH	15-May-19	19-Aug-20
INCRELEX (MECASERMIN) Increlex is used to treat children and adolescents from 2 to 18 years old who are very short for their age because their body does not make enough IGF-1. This condition is called primary IGF-1 deficiency. Increlex has not been studied in children younger than 2 years.	NAS	Ipsen Biopharmaceuticals Canada Inc.	9-Jan-20	17-Dec-20
LUXTURNA (VORETIGENE NEPARVOVEC) Luxturna is used for the treatment of adults and children with vision loss due to inherited retinal dystrophy caused by mutations in the RPE65 gene. These mutations prevent the body from producing a protein needed for vision which can lead to loss of sight and eventual blindness.	NAS	Novartis Pharmaceuticals Canada Inc.	31-Oct-19	13-Oct-20
POLIVY (POLATUZUMAB VEDOTINXX) Polivy is given to adults to treat “relapsed or refractory diffuse large B-cell lymphoma” that has come back or has not responded to at least one previous therapy and who cannot receive a stem cell transplant. Diffuse large B-cell lymphoma is a cancer that develops from “B-lymphocytes”; a type of blood cell in the lymphatic system. Polivy is given in combination with two other medicines for cancer called rituximab and bendamustine.	NOC-C NAS	Hoffmann La Roche Limited	7-Oct-19	9-Jul-20 NOC-C

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2020-2021 (April 1 2020 to March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
REBLOZYL (LUSPATERCEPT) Reblozyl is used to treat adults who have low red blood cell counts (anemia) and require red blood cell transfusions due to a blood disorder (β-thalassemia) that affects the production of hemoglobin (a protein in the red blood cells that transports oxygen throughout the body).	PRIORITY-NAS	Celgene Inc.	5-Mar-20	25-Sep-20
SARCLISA (ISATUXIMAB) Sarclisa is used in adults 18 years or older to treat a type of cancer called multiple myeloma. This is a cancer of your plasma cells which are found in your bone marrow.	NAS	Sanofi-Aventis Canada Inc.	28-Jun-19	29-Apr-20
SUPEMTEK (RECOMBINANT HAEMAGGLUTININ PROTEIN-STRAIN B (YAMAGATA), RECOMBINANT HAEMAGGLUTININ PROTEIN-STRAIN A(H1N1), RECOMBINANT HAEMAGGLUTININ PROTEIN-STRAIN A(H3N2), RECOMBINANT HAEMAGGLUTININ PROTEIN-STRAIN B (VICTORIA)) SupemtekTM vaccine is indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus lineages contained in the vaccine. Supemtek is approved for use in persons 18 years of age and older.	NAS	Sanofi Pasteur Limited	31-Jan-20	14-Jan-21
VYEPTI (EPTINEZUMAB) VYEPTI® (eptinezumab for injection) is indicated for the prevention of migraine in adults who have at least 4 migraine days per month.	NAS	Lundbeck Canada Inc.	3-Feb-20	11-Jan-21

New Active Substance Approvals (NAS) - BRDD Fiscal Year 2020-2021 (April 1 2020 to March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[10]) dd-mon-yy**	**Approval Date dd-mon-yy**
ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC) Zolgensma is a type of medicine called a 'gene therapy'. It contains the active ingredient onasemnogene abeparvovec, which contains human genetic material. Zolgensma is used to treat babies and young children who have a rare, serious inherited condition called 'spinal muscular atrophy' (SMA).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	21-May-20	15-Dec-20

Priority Submission Approvals – BRDD: Fiscal Year 2020-2021

Priority Submission Approvals - BRDD Fiscal Year 2020-2021 (April 1 2020 to March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	**Class**	**Company**	**Filing (CR Date[11]) dd-mon-yy**	**Approval Date dd-mon-yy**
BAVENCIO (AVELUMAB) Expansion of Indication: BAVENCIO is indicated for the maintenance treatment of patients with unresectable locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed following first-line platinum-based chemotherapy.	PRIORITY-CLIN ONLY	EMD Serono a Division of EMD Inc. Canada	27-May-20	10-Dec-20
ENSPRYNG (SATRALIZUMAB) Enspryng is for treatment of 'neuromyelitis optica spectrum disorders' (NMOSD). It is used in adults and young people from 12 years of age. Enspryng reduces the risk of a relapse or attack of NMOSD.	PRIORITY-NAS	Hoffmann La Roche Limited	18-Nov-19	1-Jun-20
REBLOZYL (LUSPATERCEPT) Reblozyl is used to treat adults who have low red blood cell counts (anemia) and require red blood cell transfusions due to a blood disorder (β-thalassemia) that affects the production of hemoglobin (a protein in the red blood cells that transports oxygen throughout the body).	PRIORITY-NAS	Celgene Inc.	5-Mar-20	25-Sep-20
ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC) Zolgensma is a type of medicine called a 'gene therapy'. It contains the active ingredient onasemnogene abeparvovec, which contains human genetic material. Zolgensma is used to treat babies and young children who have a rare, serious inherited condition called 'spinal muscular atrophy' (SMA).	PRIORITY-NAS	Novartis Pharmaceuticals Canada Inc.	21-May-20	15-Dec-20

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

BIOSIMILARS: MARKET AUTHORIZATIONS

Biosimilars: Number of Market Authorization by Fiscal Year

		Fiscal Year of Market Authorization				
Subm Type	**Class**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NDS	CLIN/C&M	1	3	5	4	16
NDS Total		**1**	**3**	**5**	**4**	**16**
SNDS	C&M ONLY	2	1	3	5	8
	C&M/LABELLING	1	0	0	0	3
	CLIN ONLY	0	0	2	3	7
	CLIN/C&M	2	0	0	0	1
	COMP/C&M	1	0	1	0	0
	LABELLING ONLY	0	4	2	5	1
	SAFETY UPDATE LABEL	0	0	0	0	2
	PUBLISHED DATA ONLY	0	0	0	0	0
SNDS Total		**6**	**5**	**8**	**13**	**22**

Biosimilars: NDS Market Authorizations during Fiscal Year 2020-2021

Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2020-21	Notice of Compliance (NOC) Date
ADALIMUMAB INJECTIO	CLIN/C&M	PFIZER CANADA ULC	ADALIMUMAB	Q4	2021-Jan-14
AMGEVITA	CLIN/C&M	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
HULIO	CLIN/C&M	BGP PHARMA ULC	ADALIMUMAB	Q3	2020-Nov-24
HYRIMOZ	CLIN/C&M	SANDOZ CANADA INCORPORATED	ADALIMUMAB	Q3	2020-Nov-04
IDACIO	CLIN/C&M	FRESENIUS KABI CANADA LTD.	ADALIMUMAB	Q3	2020-Oct-30
INCLUNOX, INCLUNOX HP	CLIN/C&M	SANDOZ CANADA INCORPORATED	ENOXAPARIN SODIUM	Q3	2020-Nov-05
NIVESTYM	CLIN/C&M	PFIZER CANADA ULC	FILGRASTIM (R-METHUG-CSF)	Q1	2020-Apr-16
NOROMBY, NOROMBY HP	CLIN/C&M	JUNO PHARMACEUTICALS CORP.	ENOXAPARIN SODIUM	Q3	2020-Oct-14
NYVEPRIA	CLIN/C&M	PFIZER CANADA ULC	PEGFILGRASTIM	Q3	2020-Oct-28
REDESCA / REDESCA HP	CLIN/C&M	SHENZHEN TECHDOW PHARMACEUTICAL CO. LTD.	ENOXAPARIN SODIUM	Q3	2020-Dec-07
RIABNI	CLIN/C&M	AMGEN CANADA INC.	RITUXIMAB	Q4	2021-Mar-11
RIXIMYO	CLIN/C&M	SANDOZ CANADA INCORPORATED	RITUXIMAB	Q1	2020-Apr-28
RUXIENCE	CLIN/C&M	PFIZER CANADA ULC	RITUXIMAB	Q1	2020-May-04
TRURAPI	CLIN/C&M	SANOFI-AVENTIS CANADA INC	INSULIN ASPART	Q3	2020-Oct-15
ZIEXTENZO	CLIN/C&M	SANDOZ CANADA INCORPORATED	PEGFILGRASTIM	Q1	2020-Apr-21
ZIRABEV	CLIN/C&M	PFIZER CANADA ULC	BEVACIZUMAB	Q4	2021-Jan-05
New Drug Submission Total					**16**

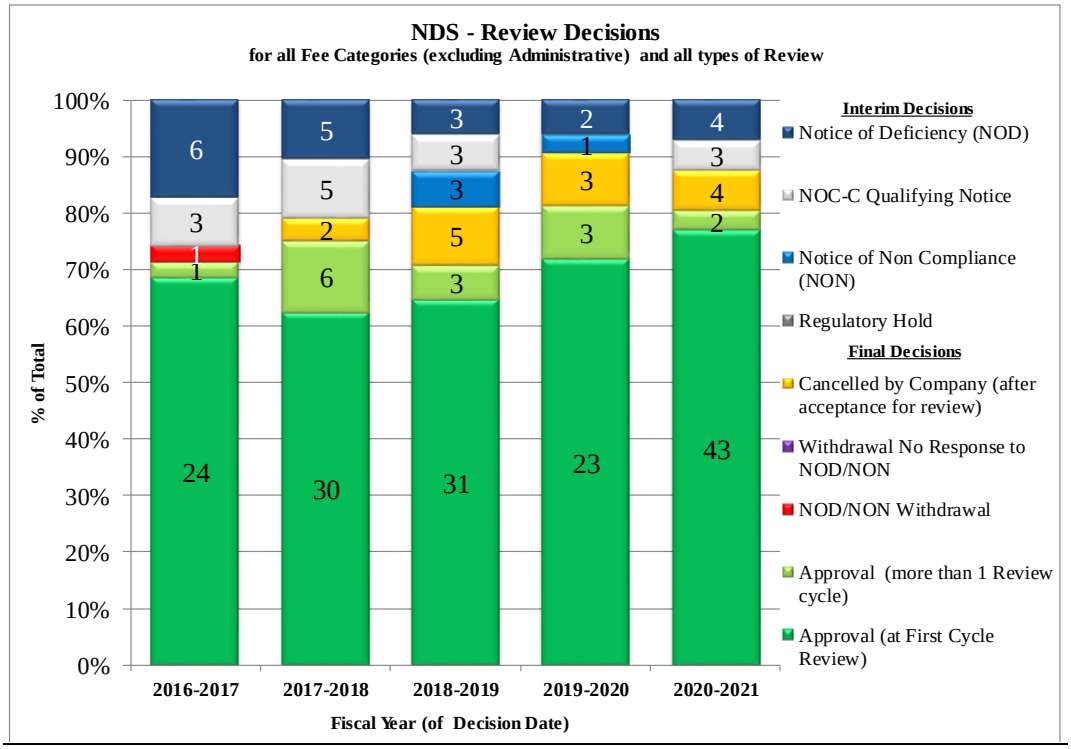
Please note: Approved Biosimilars that remain on Intellectual Property HOLD are not included.

Biosimilars: SNDS Market Authorizations during Fiscal Year 2020-2021

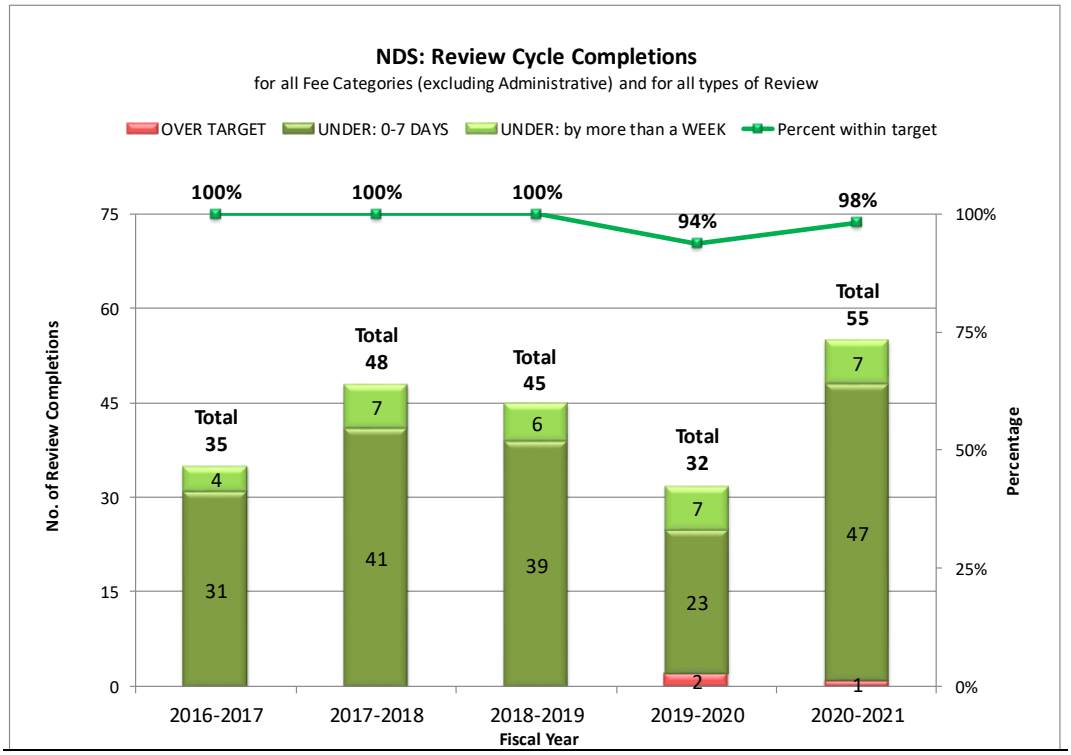
Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2020-21	Notice of Compliance (NOC) Date
AMGEVITA	C&M ONLY	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
AMGEVITA	C&M ONLY	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
AMGEVITA	CLIN ONLY	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
AMGEVITA	CLIN ONLY	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
AMGEVITA	LABELLING ONLY	AMGEN CANADA INC.	ADALIMUMAB	Q3	2020-Nov-04
BASAGLAR	C&M ONLY	ELI LILLY CANADA INC.	INSULIN GLARGINE	Q4	2021-Jan-20
BASAGLAR	SAFETY UPDATE LABEL	ELI LILLY CANADA INC.	INSULIN GLARGINE	Q4	2021-Mar-26
BRENZYS (PFS), BRENZYS (AUTOINJECTOR)	CLIN ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q2	2020-Aug-19
ERELZI (PEN), ERELZI (SYRINGE)	CLIN ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q1	2020-Jun-09
FULPHILA	C&M ONLY	BGP PHARMA ULC	PEGFILGRASTIM	Q1	2020-May-15
HADLIMA, HADLIMA PUSH TOUCH	C&M/LABELLING	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q2	2020-Jul-15
HADLIMA, HADLIMA PUSHTOUCH	CLIN ONLY	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q3	2020-Nov-26
HERZUMA	C&M LABELLING	CELLTRION HEALTHCARE CO. LTD.	TRASTUZUMAB	Q3	2020-Oct-21
HYRIMOZ	C&M LABELLING	SANDOZ CANADA INCORPORATED	ADALIMUMAB	Q3	2020-Nov-04
INFLECTRA	C&M ONLY	CELLTRION HEALTHCARE CO LTD.	INFLIXIMAB	Q4	2021-Feb-19
KANJINTI	C&M ONLY	AMGEN CANADA INC.	TRASTUZUMAB	Q3	2020-Nov-17
LAPELGA	SAFETY UPDATE LABEL	APOTEX INC.	PEGFILGRASTIM	Q3	2020-Dec-17
MVASI	CLIN ONLY	AMGEN CANADA INC.	BEVACIZUMAB	Q4	2021-Jan-05
REMSIMA SC, REMSIMA/REMSIMA SC	CLIN/C&M	CELLTRION HEALTHCARE CO LTD.	INFLIXIMAB	Q4	2021-Jan-28
TRAZIMERA	C&M ONLY	PFIZER CANADA ULC	TRAZIMERA	Q4	2021-Mar-12
TRUXIMA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	RITUXIMAB	Q1	2020-May-22
ZIEXTENZO	C&M ONLY	SANDOZ CANADA INCORPORATED	PEGFILGRASTIM	Q4	2021-Mar-22
Supplemental New Drug Submission Total					**22**

REVIEW PERFORMANCE

NDS: Review Decisions by Type

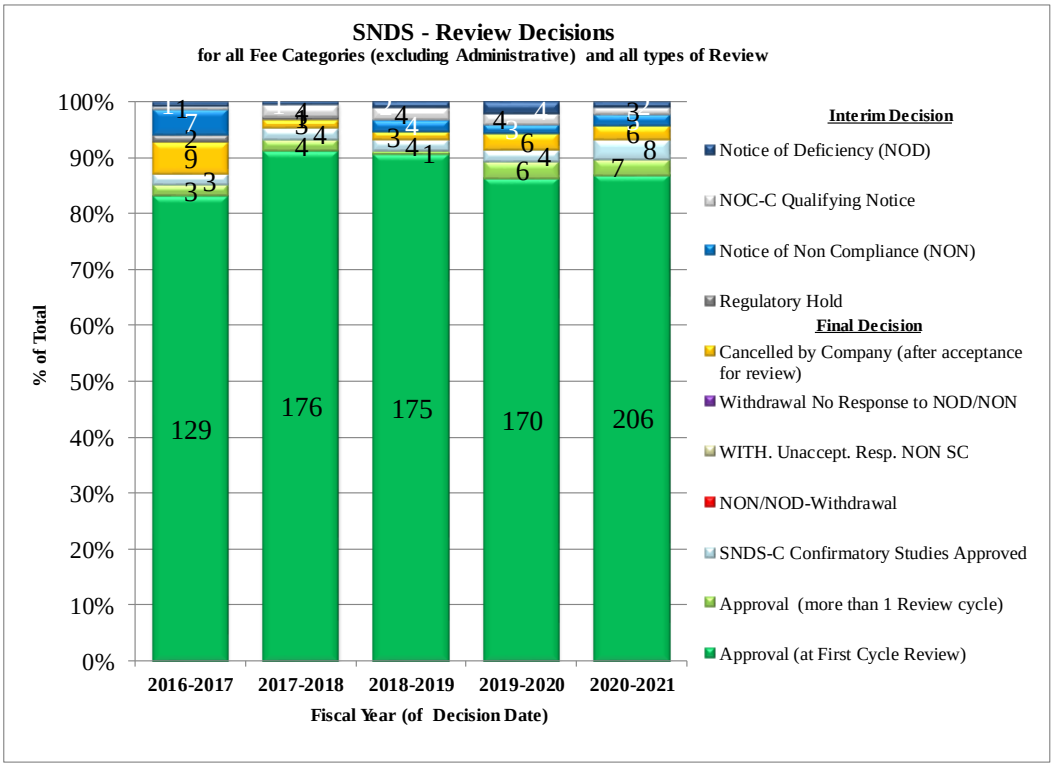


NDS: Review Cycle Completions

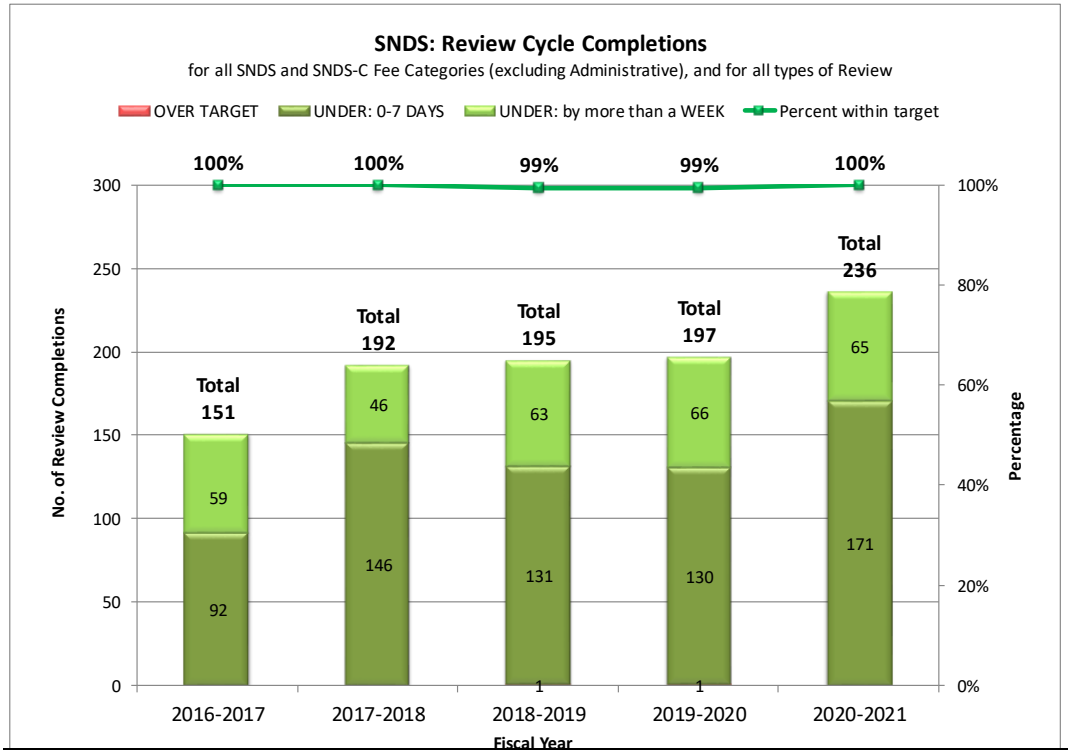


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

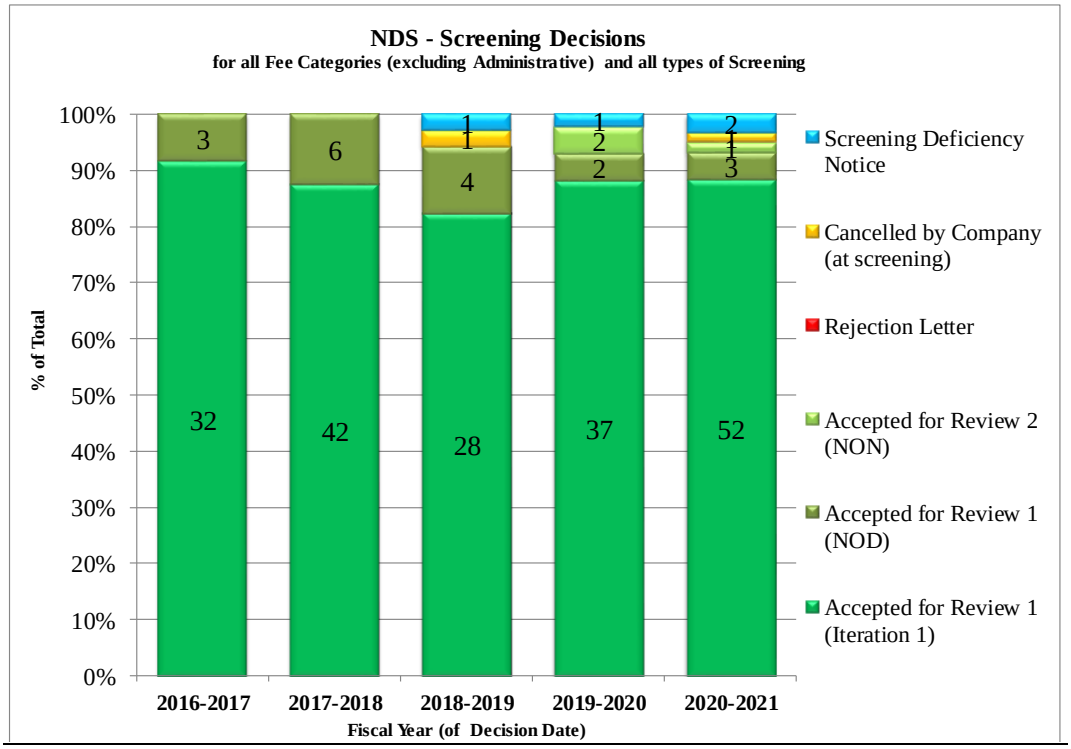


SNDS: Review Cycle Completions

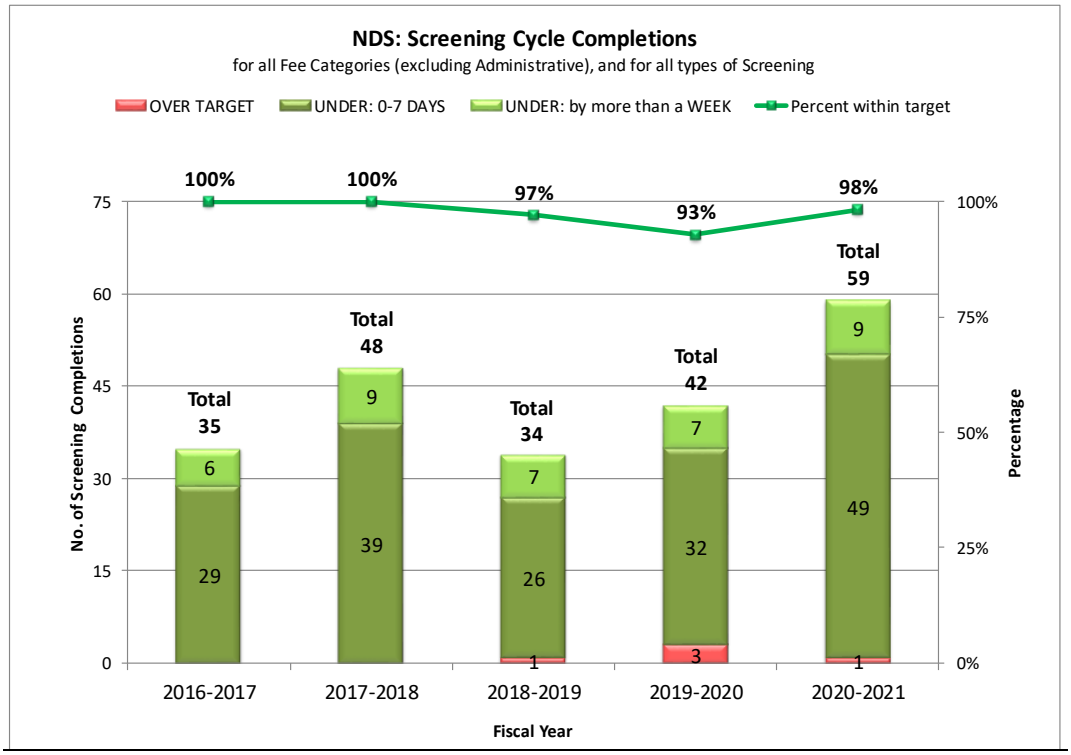


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

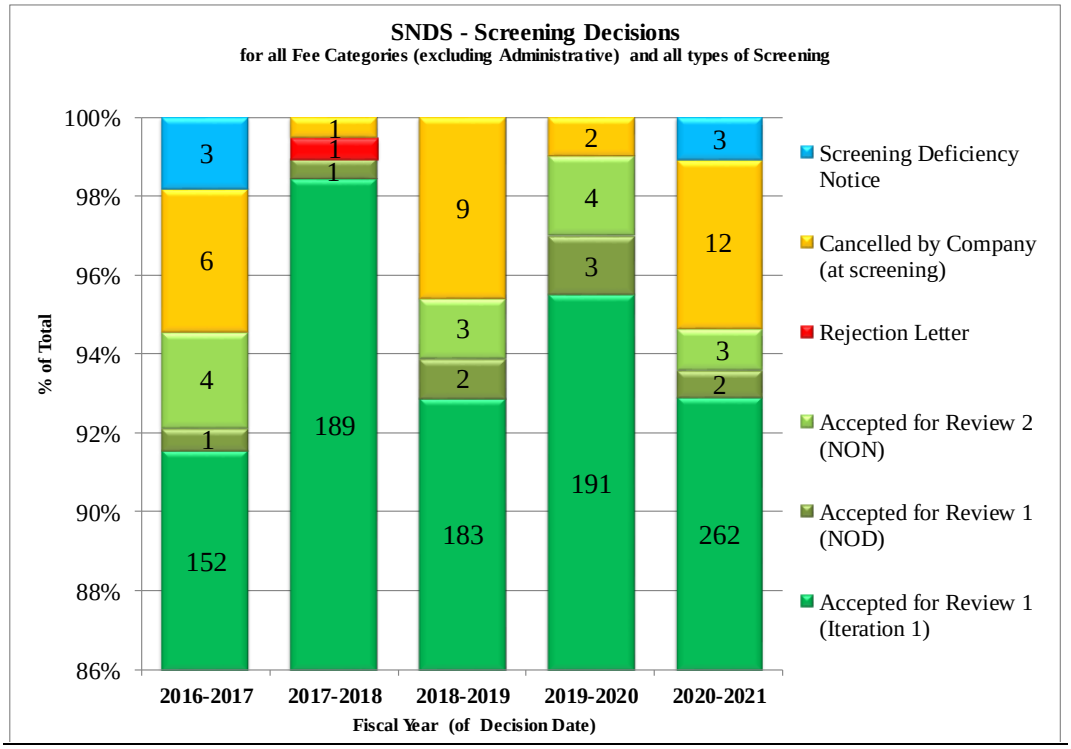


NDS: Screening Cycle Completions

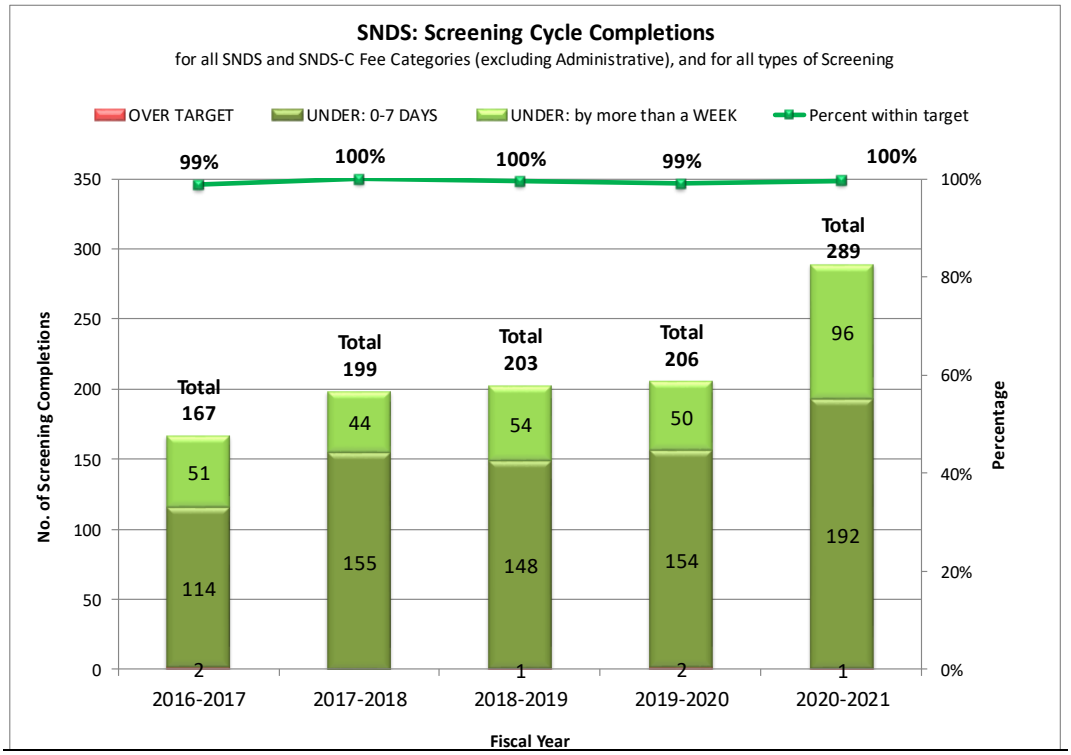


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



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

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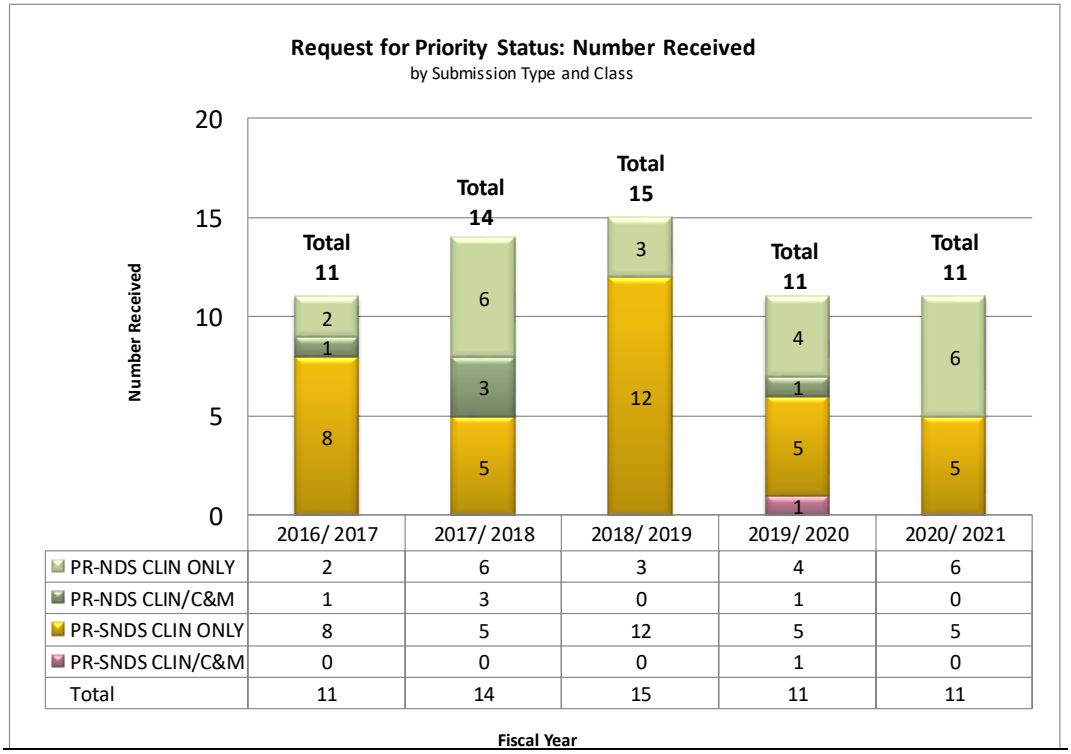
REQUEST FOR PRIORITY REVIEW STATUS RECEIVED

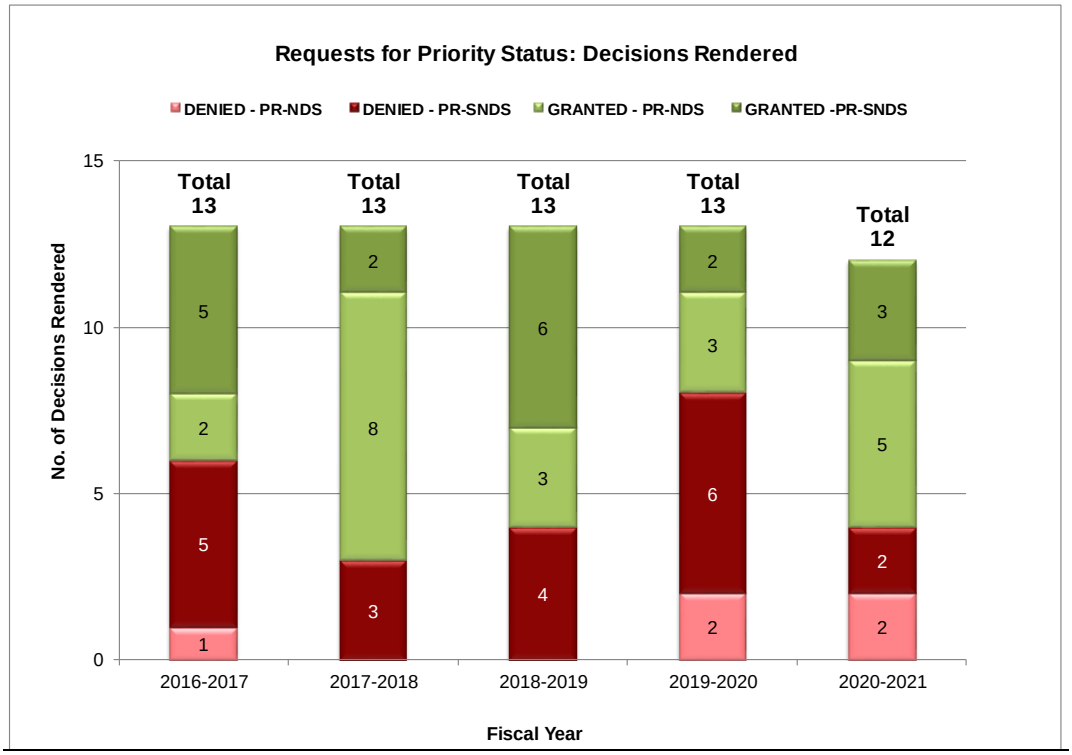
Request for Priority Review Status: Number Received



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
PR-NDS CLIN ONLY	2	6	3	4	6
PR-NDS CLIN/C&M	1	3	0	1	0
PR-SNDS CLIN ONLY	8	5	12	5	5
PR-SNDS CLIN/C&M	0	0	0	1	0
Total	11	14	15	11	11

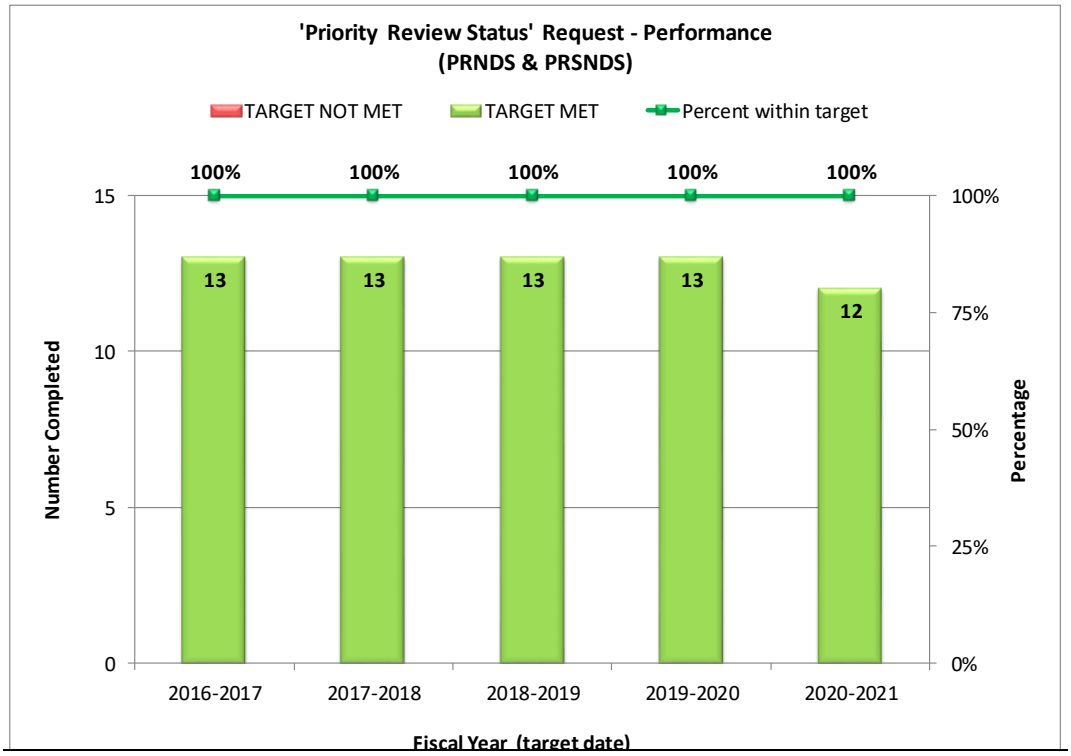
DECISIONS

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

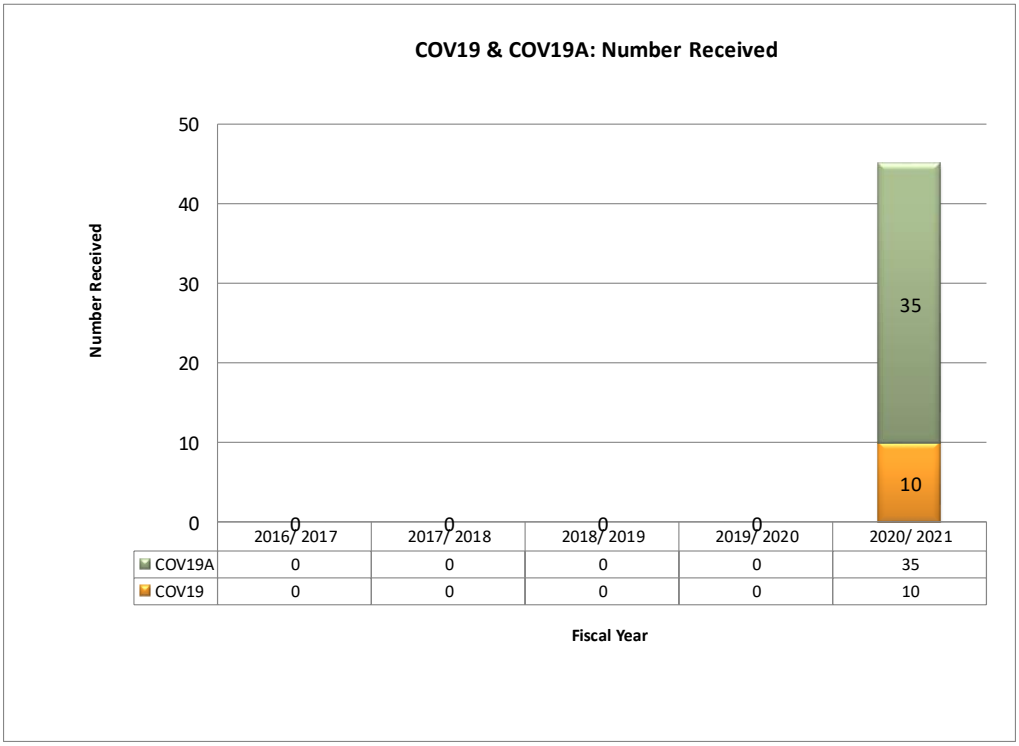
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

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

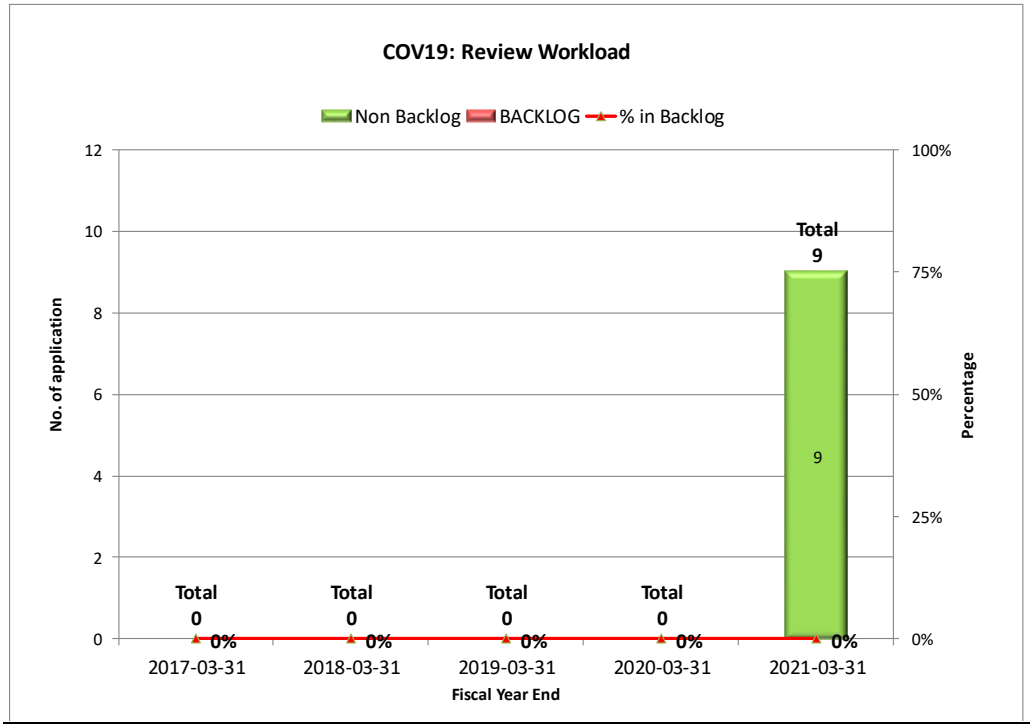
COV19 & COV19A: Number received



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
COV19A	0	0	0	0	35
COV19	0	0	0	0	10

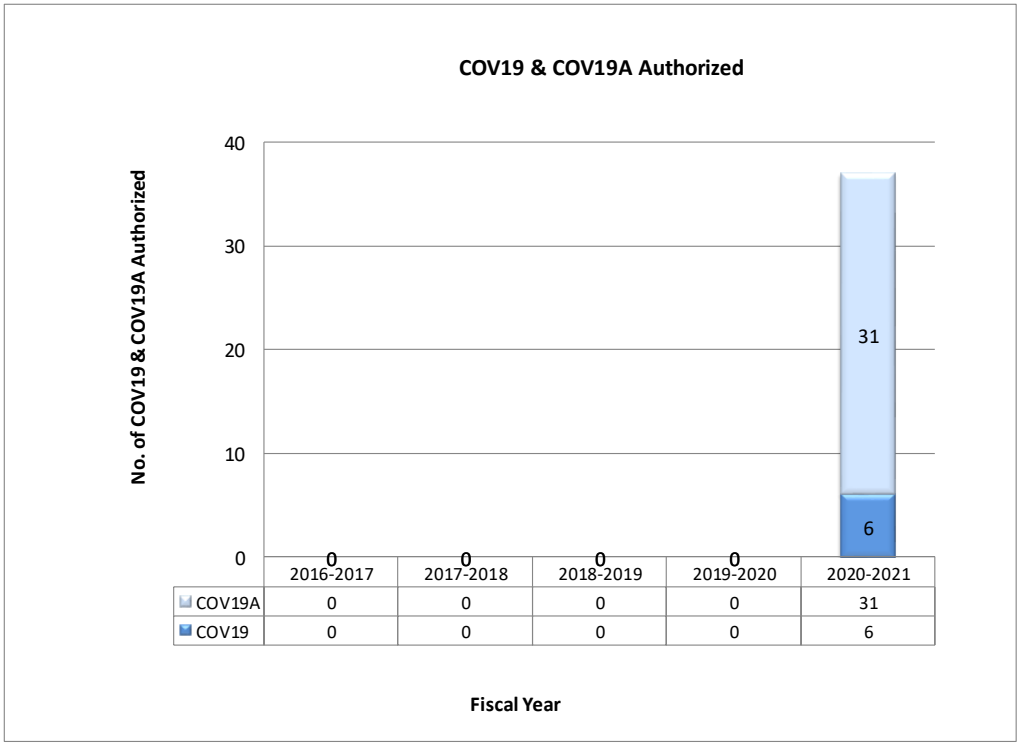
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



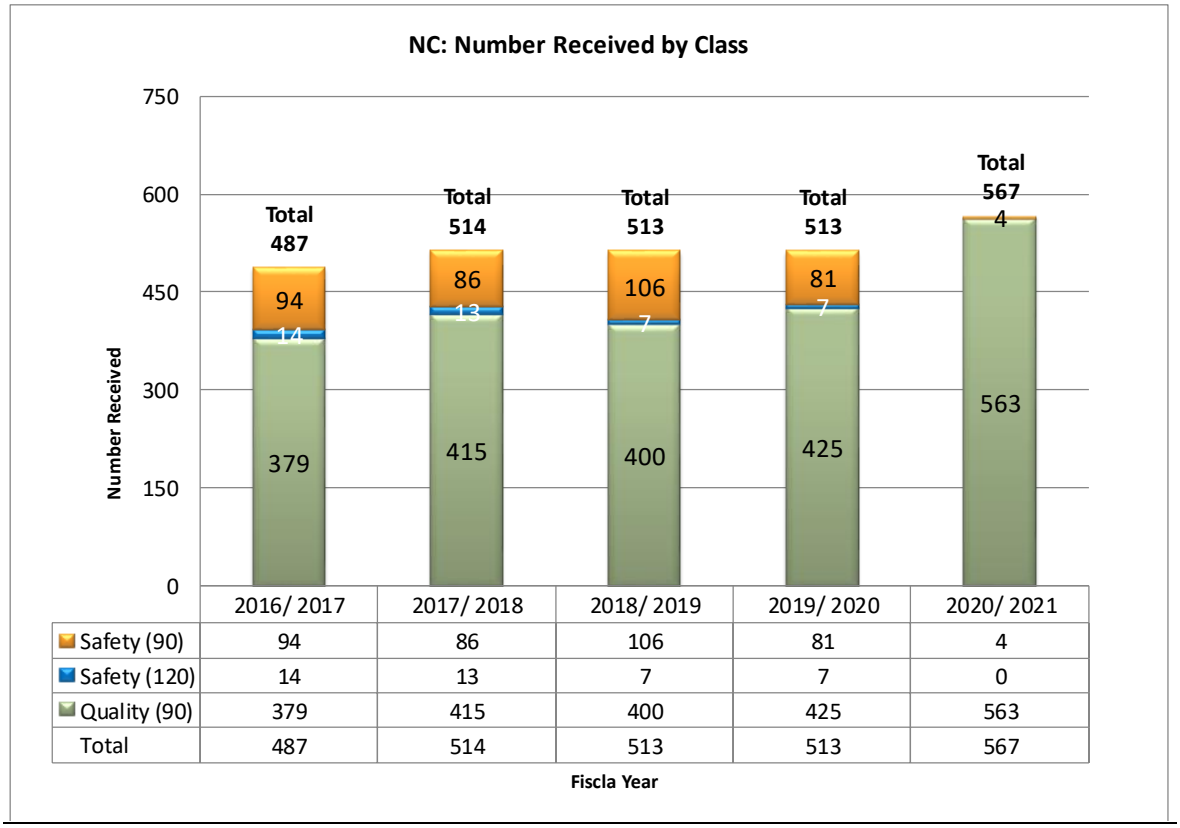
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
COV19A	0	0	0	0	31
COV19	0	0	0	0	6

NC: NOTIFIABLE CHANGES

NC: NOTIFIABLE CHANGE

RECEIVED

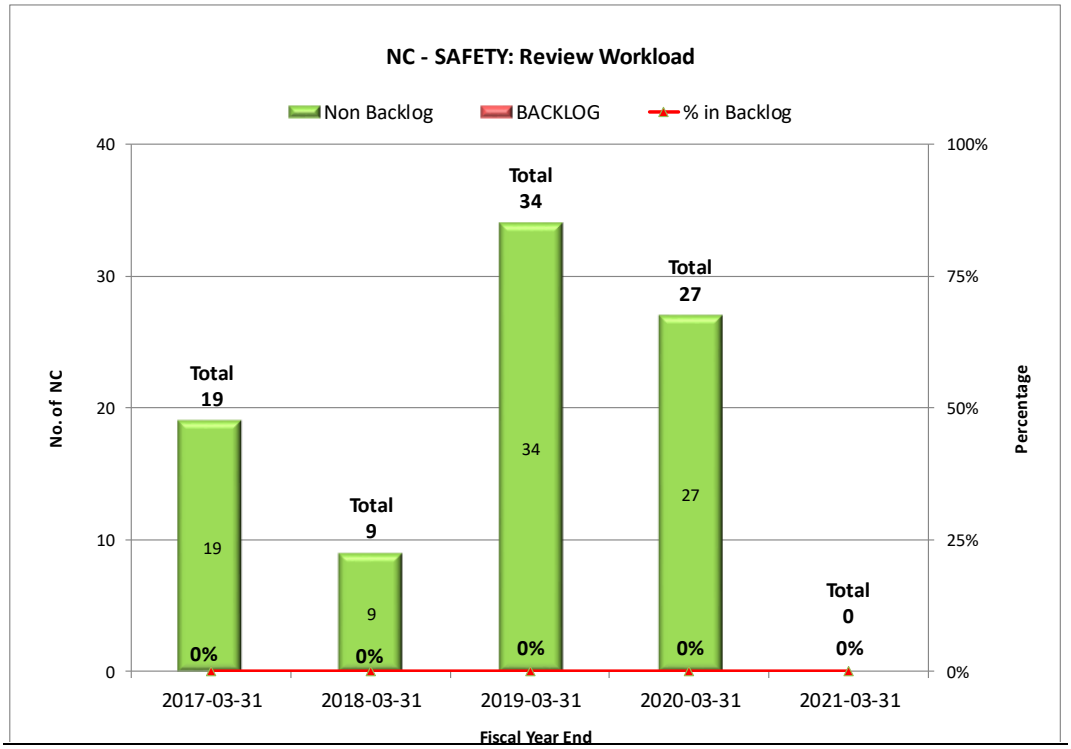
NC: Number Received by Class



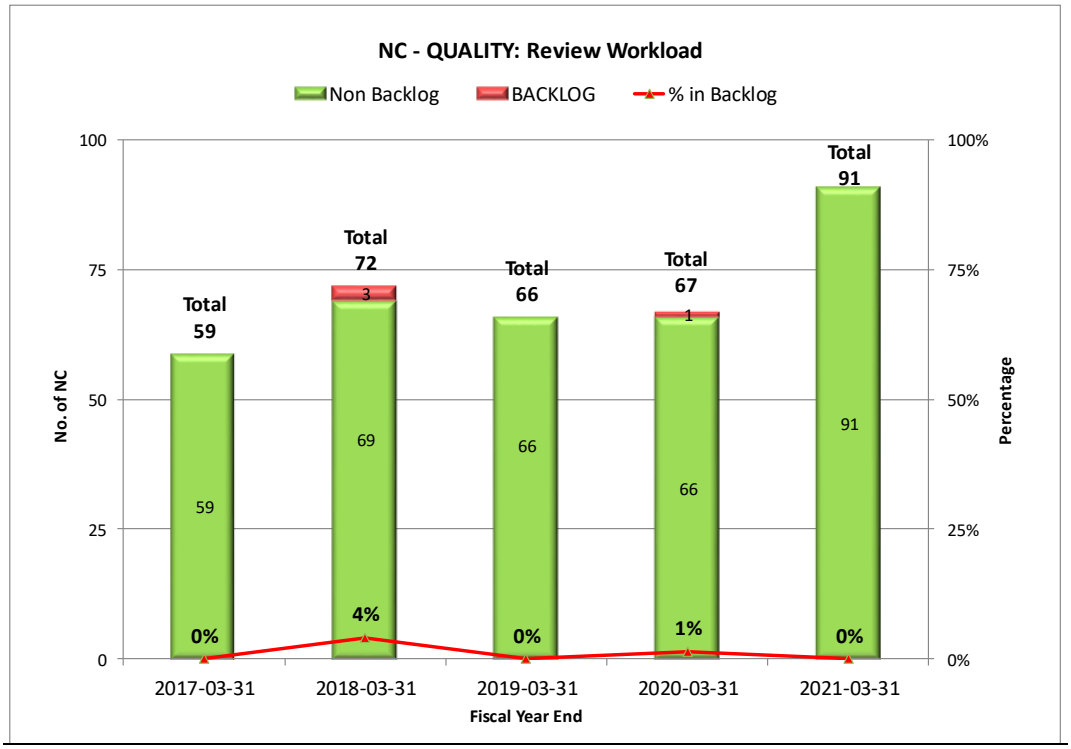
	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Safety (90)	94	86	106	81	4
Safety (120)	14	13	7	7	0
Quality (90)	379	415	400	425	563
Total	487	514	513	513	567

WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

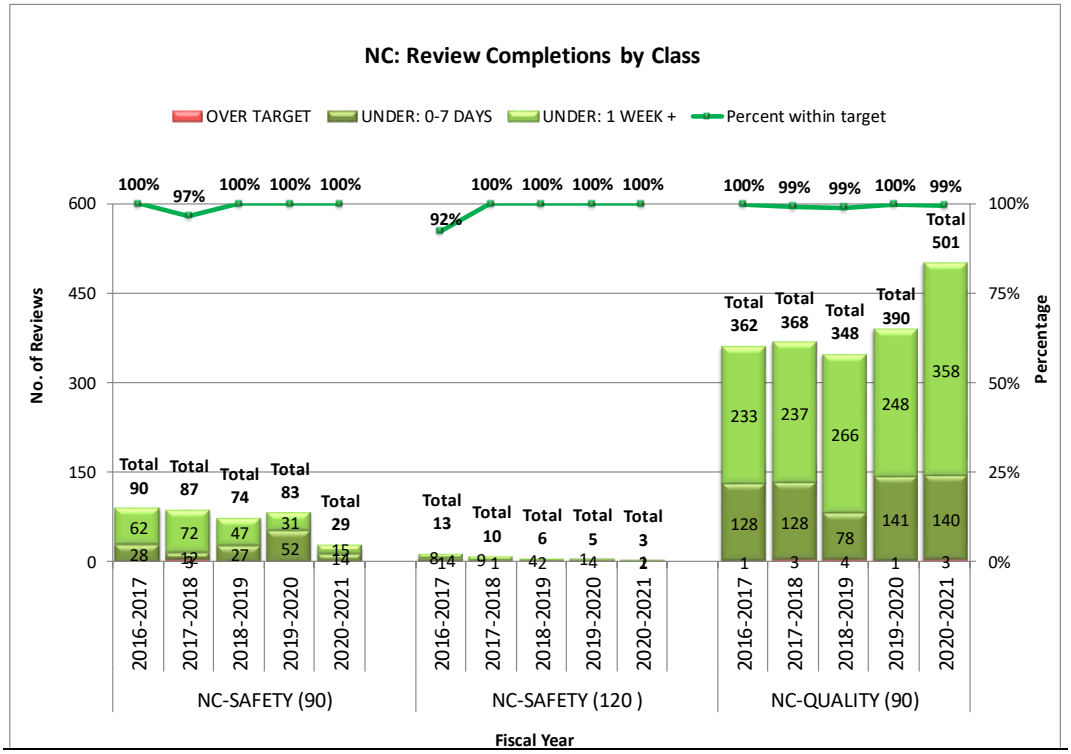
BRDD NC - SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
SAFETY - 90 day	15	8	34	24	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	4	1	0	3	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**19**	**9**	**34**	**27**	**0**
Non Backlog	**19**	**9**	**34**	**27**	**0**
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-QUALITY: Review Workload by Class

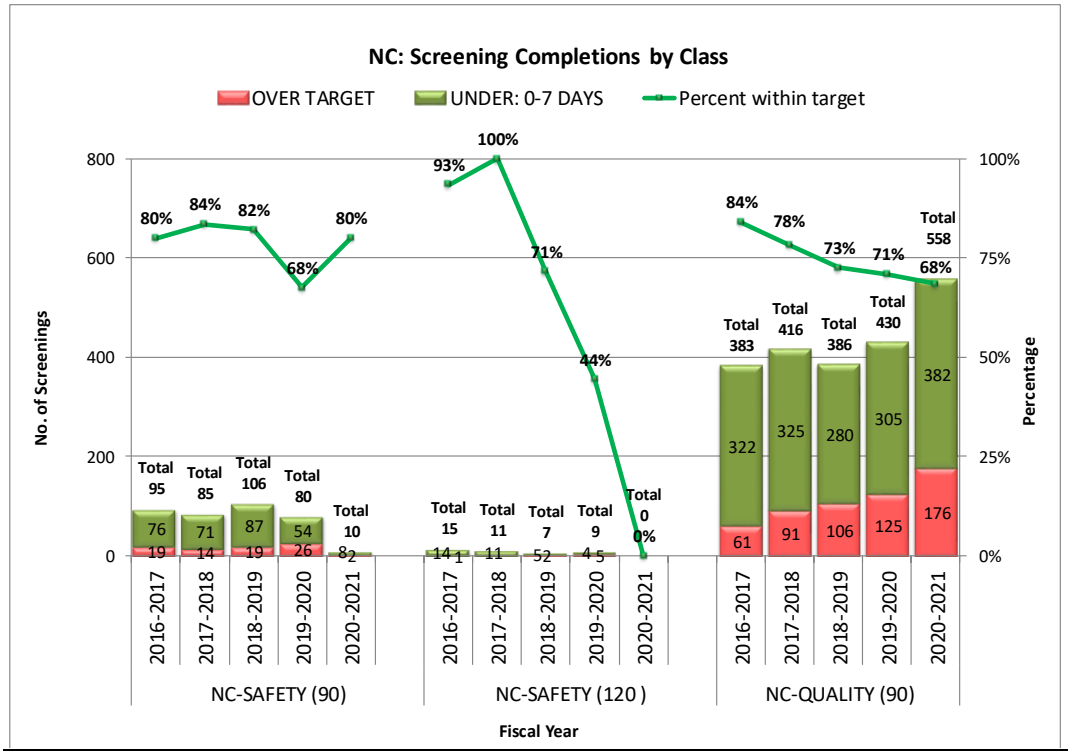
BRDD NC - QUALITY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
QUALITY - 90 day	**59**	**72**	**66**	**67**	**91**
Backlog	*0*	*3*	*0*	*1*	*0*
Total	**59**	**72**	**66**	**67**	**91**
Non Backlog	**59**	**69**	**66**	**66**	**91**
BACKLOG	0	3	0	1	0
% in Backlog	0%	4%	0%	1%	0%

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



DECISIONS

NC: Decision Documents by Class

DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NC - QUALITY (90)					
NO OBJECTION LETTER	363	381	358	415	516
NOT SATISFACTORY NOTICE	1	0	0	0	0
REJECTION LETTER (SCR)	7	12	16	1	1
CANCELLED BY COMPANY	13	8	16	15	23
SCREENING DEFICIENCY NOTICE	5	2	0	0	0
NC - HOLD (PATENT)	0	0	3	1	0
NC - SAFETY (90)					
NO OBJECTION LETTER	97	88	78	82	28
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	2
CANCELLED BY COMPANY	3	6	5	9	4
SCREENING DEFICIENCY NOTICE	1	1	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0
NC - SAFETY (120)					
NO OBJECTION LETTER	12	12	6	5	3
NOT SATISFACTORY NOTICE	1	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	0	0	0
CANCELLED BY COMPANY	1	2	2	1	0
NC - ADMINISTRATIVE					
NO OBJECTION LETTER	22	9	5	2	0

REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

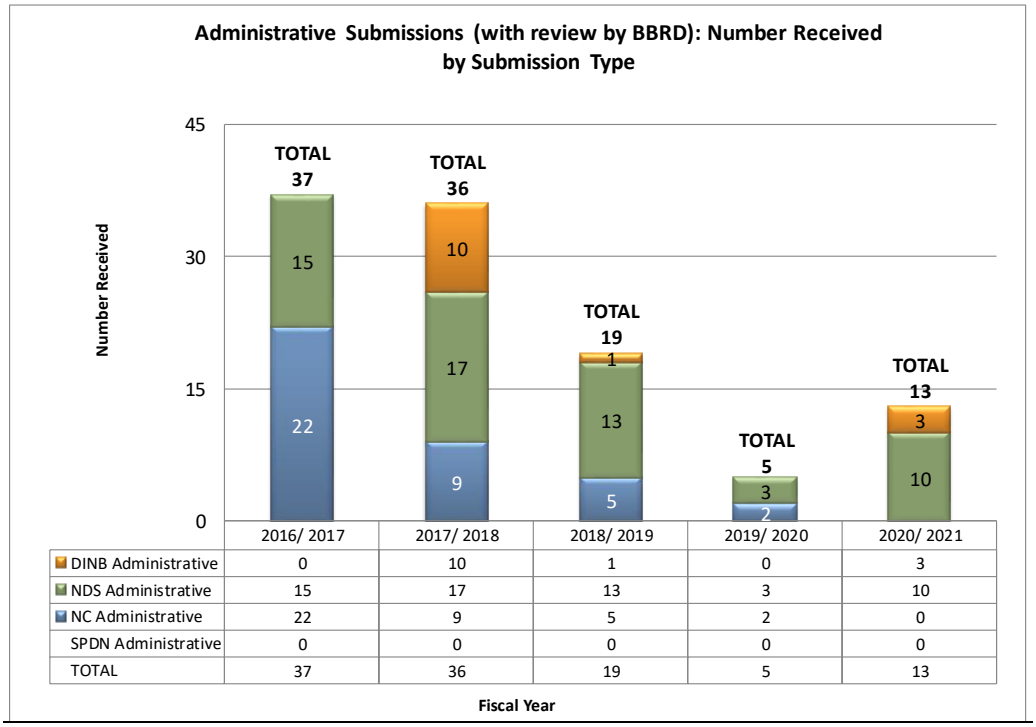
Requests for Reconsideration of Final Decisions- NC

NC - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Total Received	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS (processed by BRDD)

RECEIVED

Administrative Submissions: Number Received

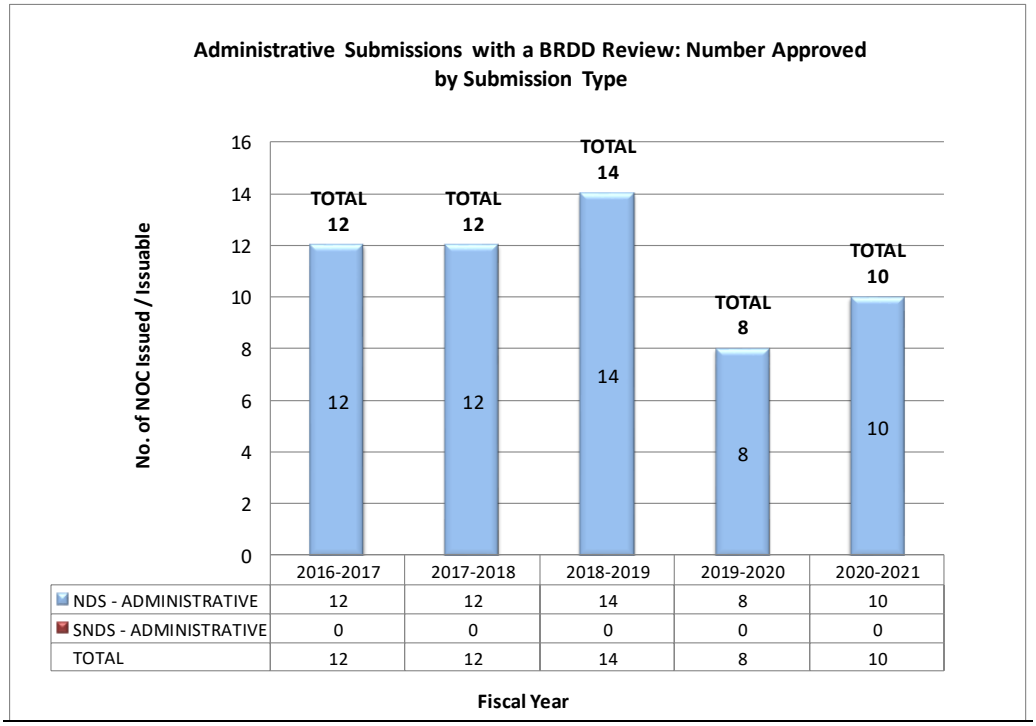


	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
DINB Administrative	0	10	1	0	3
NDS Administrative	15	17	13	3	10
NC Administrative	22	9	5	2	0
SPDN Administrative	0	0	0	0	0
TOTAL	37	36	19	5	13

Fiscal Year

APPROVALS

Administrative Submission (with BRDD Review): Number Approved



	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NDS - ADMINISTRATIVE	12	12	14	8	10
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	12	12	14	8	10

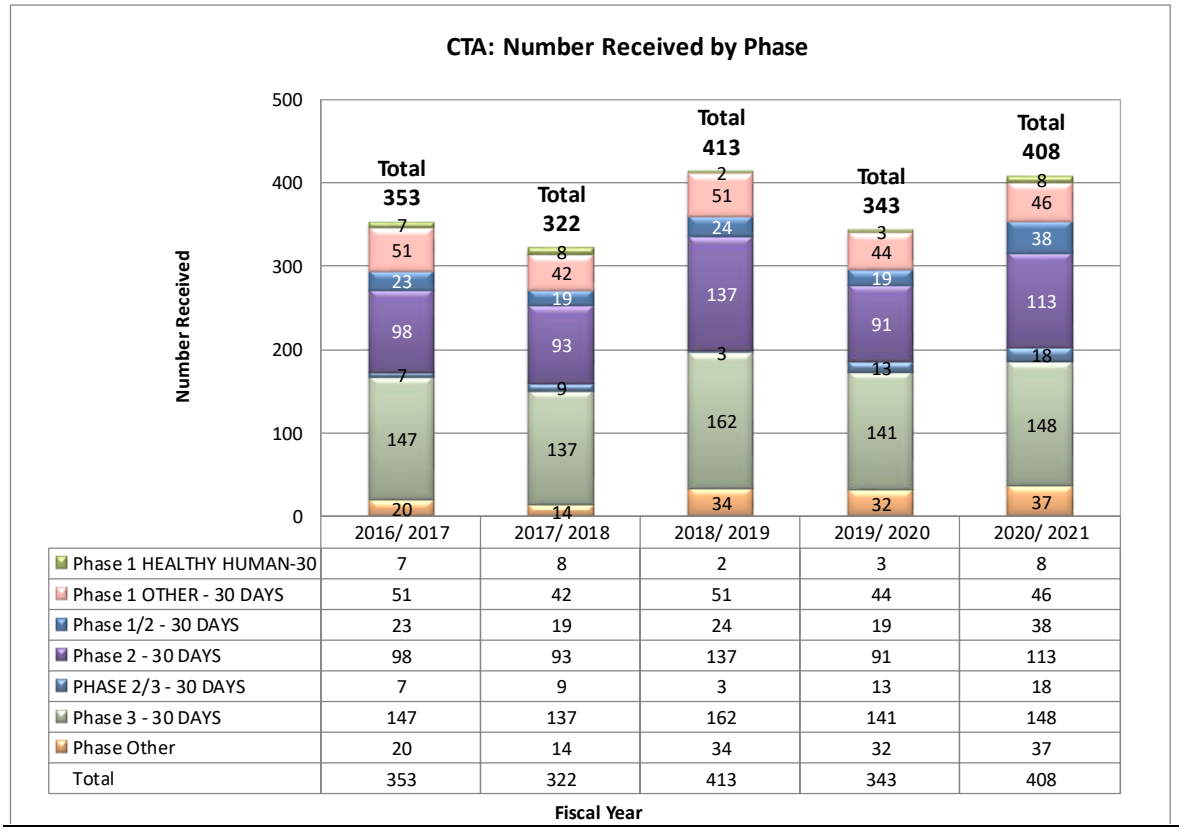
Fiscal Year

CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

CTA: Number Received by Phase



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 HEALTHY HUMAN-30	7	8	2	3	8
Phase 1 OTHER - 30 DAYS	51	42	51	44	46
Phase 1/2 - 30 DAYS	23	19	24	19	38
Phase 2 - 30 DAYS	98	93	137	91	113
PHASE 2/3 - 30 DAYS	7	9	3	13	18
Phase 3 - 30 DAYS	147	137	162	141	148
Phase Other	20	14	34	32	37
Total	353	322	413	343	408

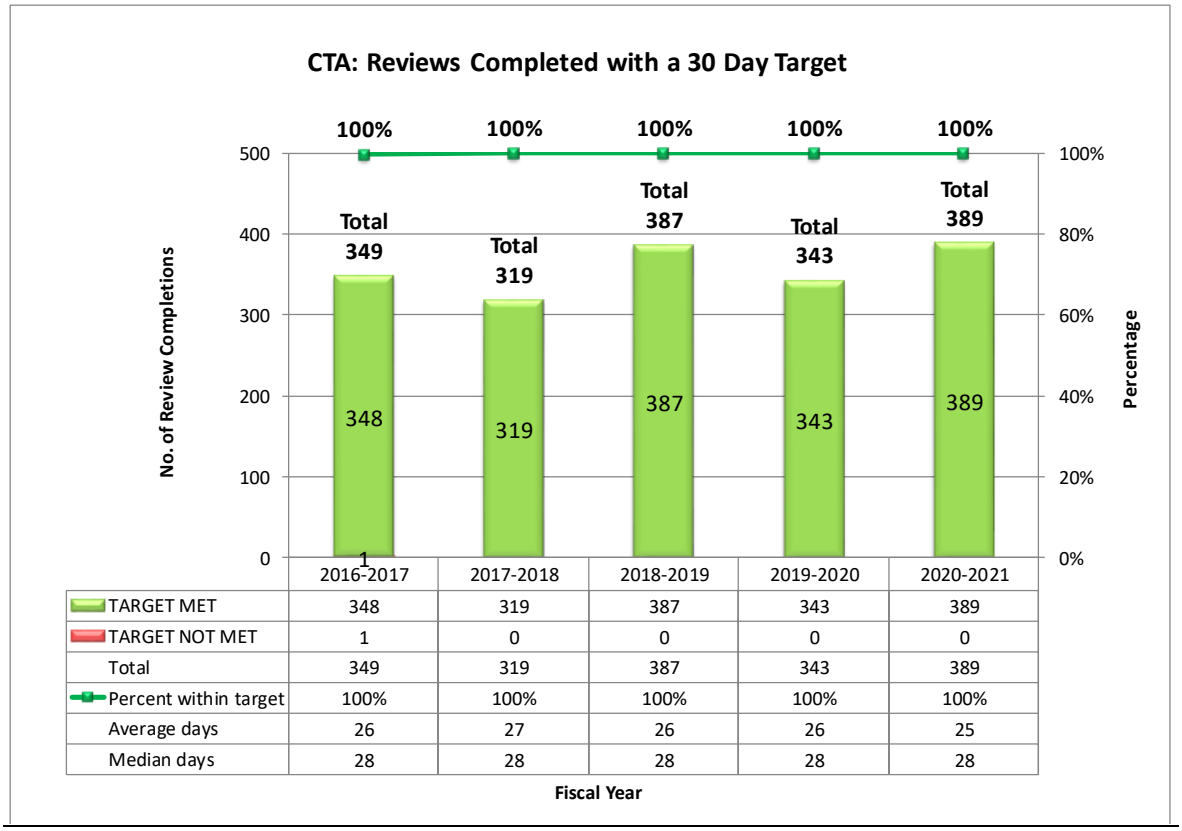
DECISIONS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	328	307	380	326	353
NOTICE OF AUTHORIZATION	0	0	0	0	14
CANCELLED BY COMPANY DURING REVIEW	21	12	7	17	21
CANCELLED BY COMPANY AT PROCESSING	10	6	6	14	6
NOT SATISFACTORY NOTICE	0	0	1	0	0
REFUSAL LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	1	0	2	5	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

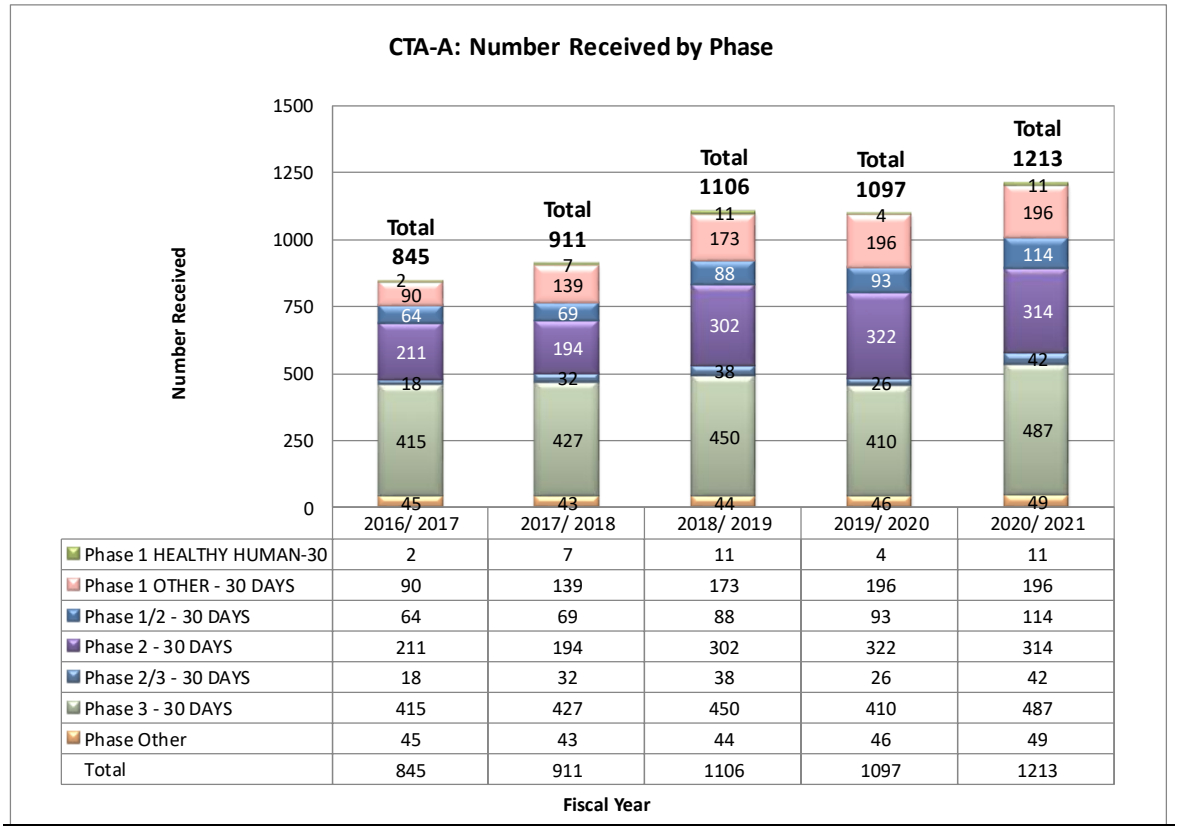
PERFORMANCE

CTA: Reviews Completed with a 30 Day Target



CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 HEALTHY HUMAN-30	2	7	11	4	11
Phase 1 OTHER - 30 DAYS	90	139	173	196	196
Phase 1/2 - 30 DAYS	64	69	88	93	114
Phase 2 - 30 DAYS	211	194	302	322	314
Phase 2/3 - 30 DAYS	18	32	38	26	42
Phase 3 - 30 DAYS	415	427	450	410	487
Phase Other	45	43	44	46	49
Total	845	911	1106	1097	1213

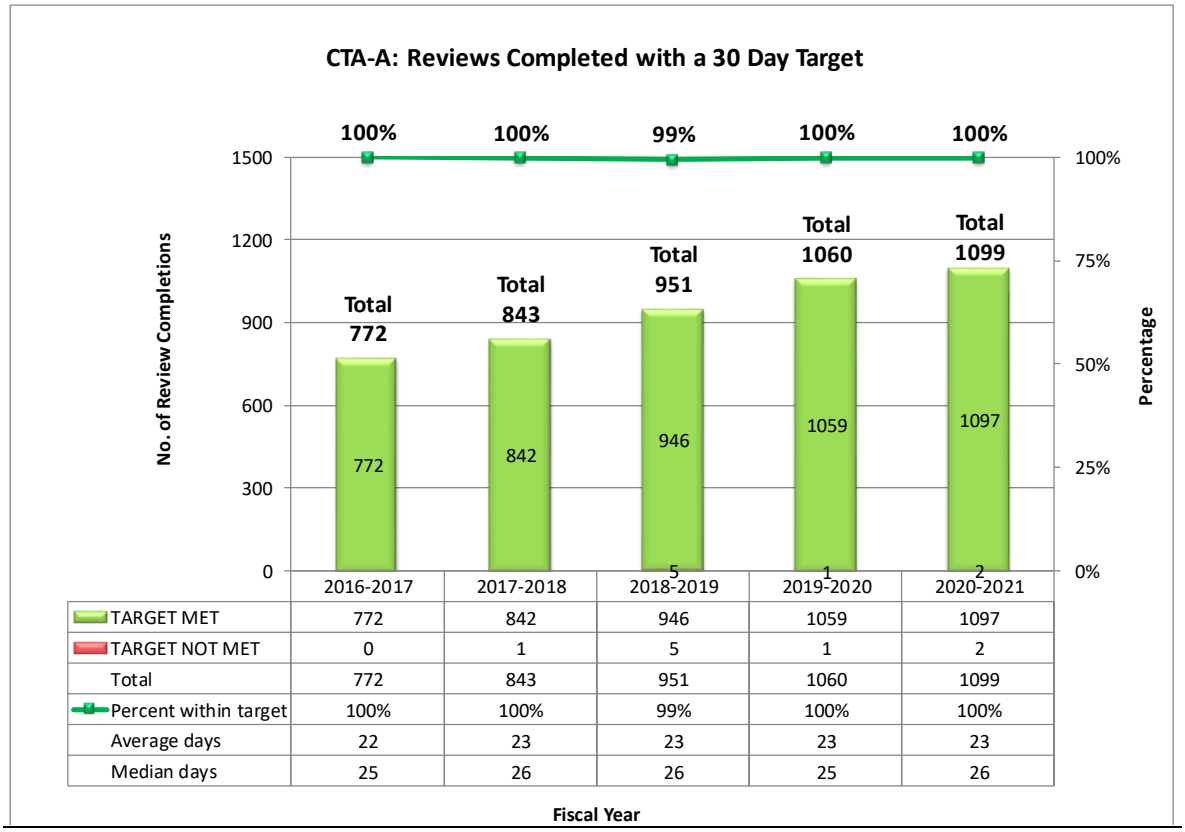
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A					
DOCUMENT TYPE	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**
NO OBJECTION LETTER	794	869	1048	1080	1115
NOTICE OF AUTHORIZATION	0	0	0	0	14
CANCELLED BY COMPANY DURING REVIEW	7	15	4	9	12
CANCELLED BY COMPANY AT PROCESSING	10	9	9	10	9
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	15	15	20	23	14

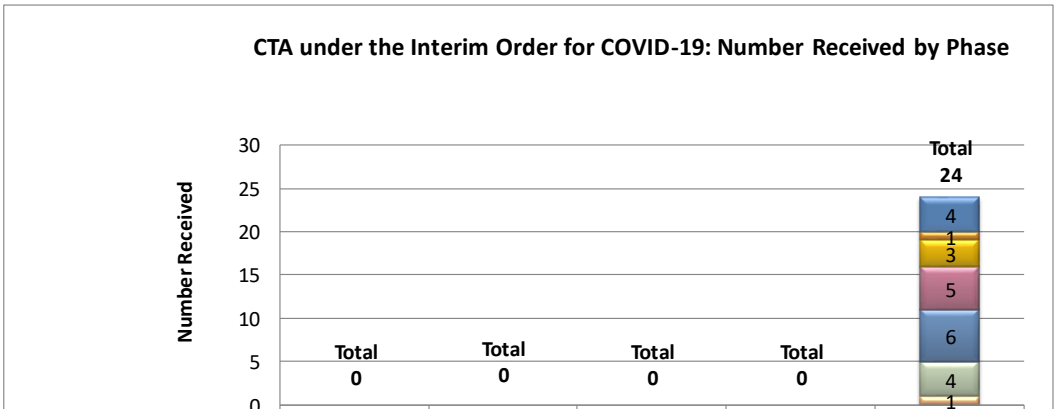
PERFORMANCE

CTA-A: Reviews Completed with a 30 Day Target



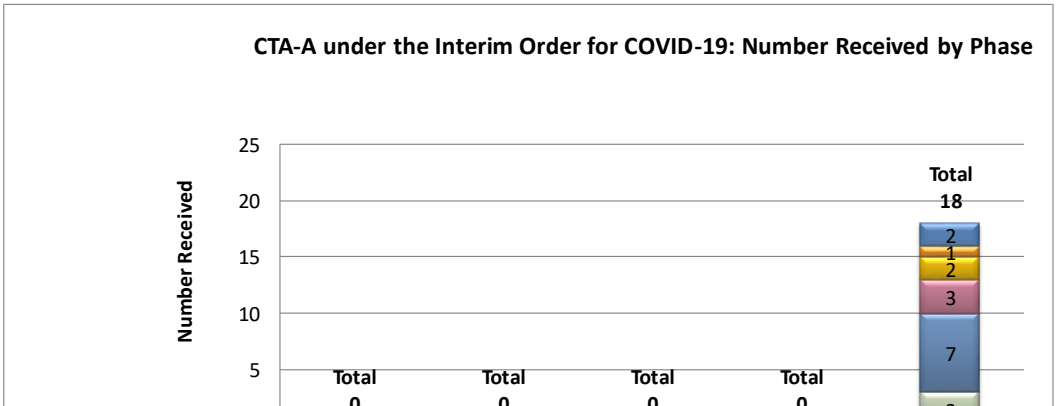
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19

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



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 HEALTHY HUMAN					4
Phase 1 OTHER					1
Phase 1/2					3
Phase 2					5
PHASE 2/3					6
Phase 3					4
Phase Other					1
Total	0	0	0	0	24

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



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Phase 1 HEALTHY HUMAN					2
Phase 1 OTHER					1
Phase 1/2					2
Phase 2					3
PHASE 2/3					7
Phase 3					3
Phase Other					0
Total	0	0	0	0	18

DINB

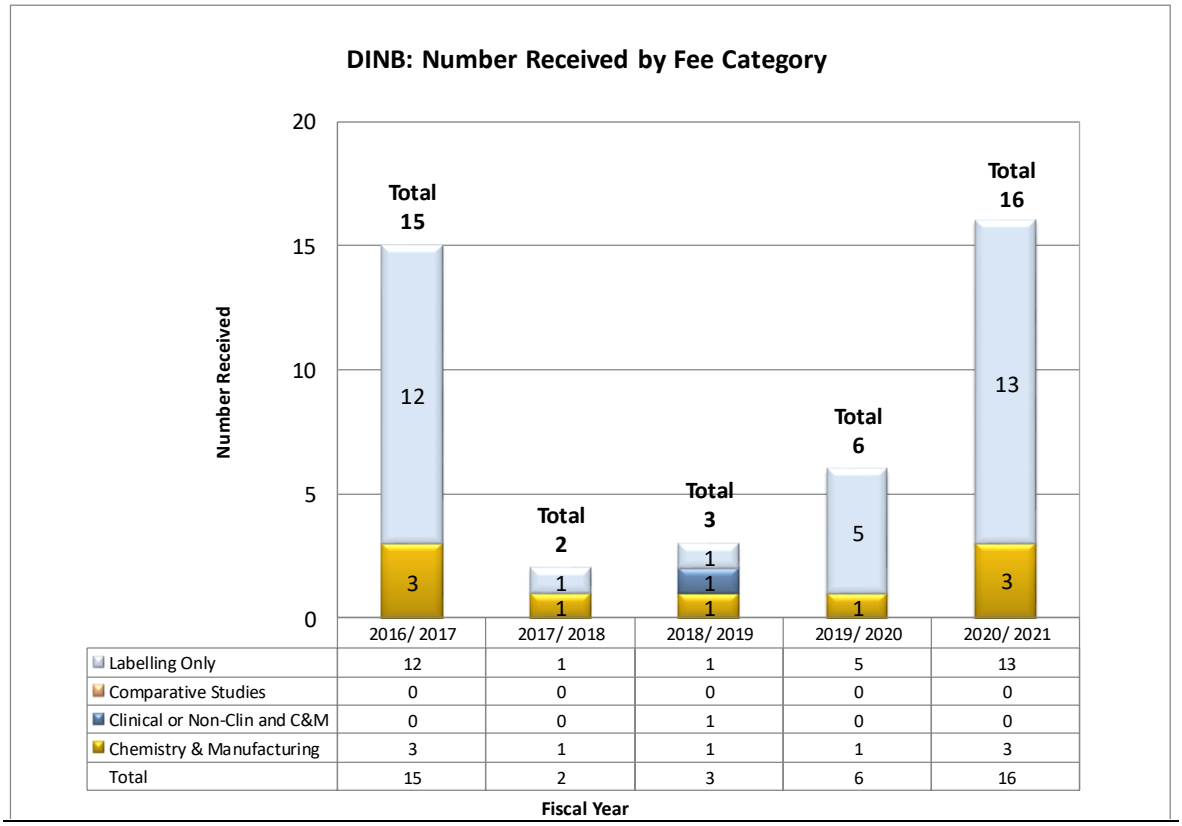
Application for a Drug Identification Number

Biological Products

DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

RECEIVED

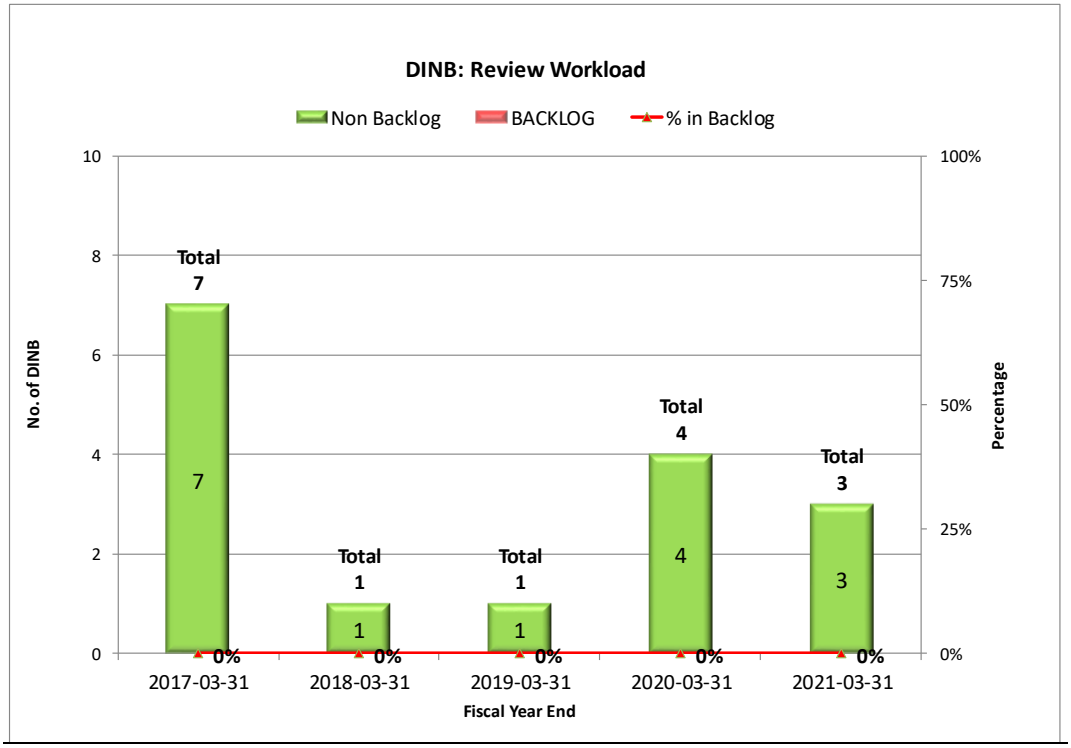
DINB: Number Received by Fee Category



	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Labelling Only	12	1	1	5	13
Comparative Studies	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	1	0	0
Chemistry & Manufacturing	3	1	1	1	3
Total	15	2	3	6	16

REVIEW WORKLOAD

DINB: Review Workload

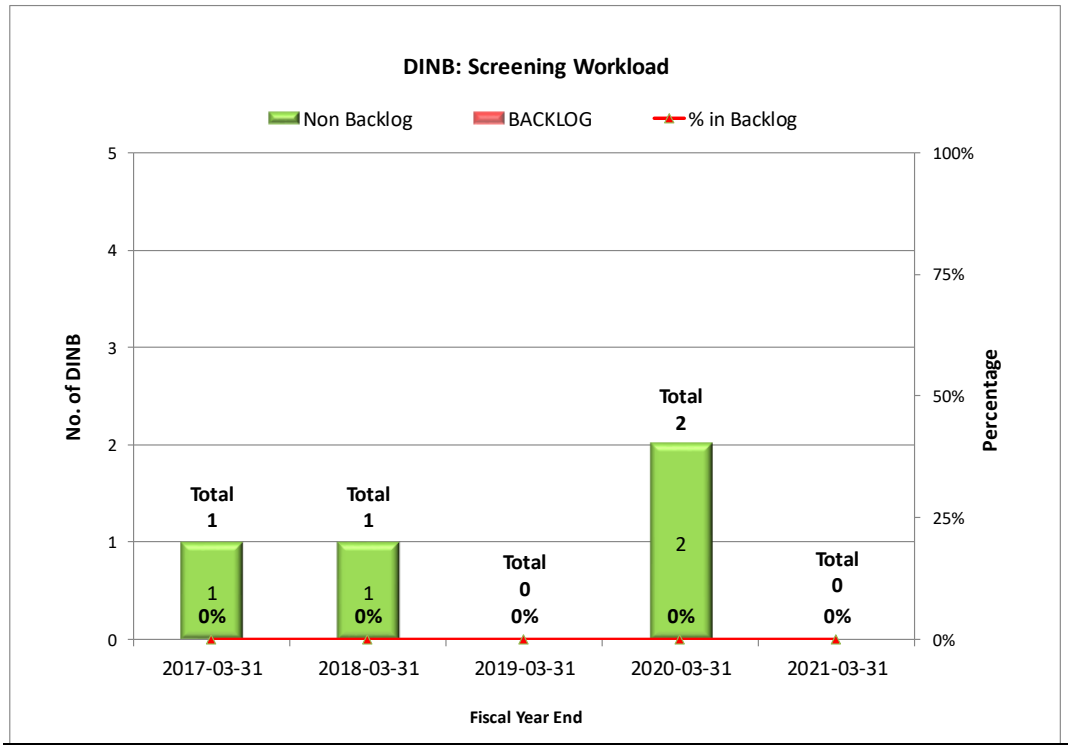


DINB: Review Workload by Fee Category

DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Only	6	1	0	3	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	0	1	1	2
Backlog	*0*	*0*	*0*	*0*	*0*
Total	7	1	1	4	3
Non Backlog	7	1	1	4	3
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	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Only	0	0	0	2	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	1	1	0	2	0
Non Backlog	1	1	0	2	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

DINB: Number of Decisions by Fee Category

DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
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	0	15
NEW DRUG LETTER SCREEN	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	2
CANCELLED BY COMPANY	6	6	0	0	2
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	0	1
NOTIFICATION FORM DIN SUB	0	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	1	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	0	3
CANCELLED BY COMPANY	0	1	0	0	0
DINB - COMPARATIVE STUDIES					
REJECTION LETTER (SCREENING)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0

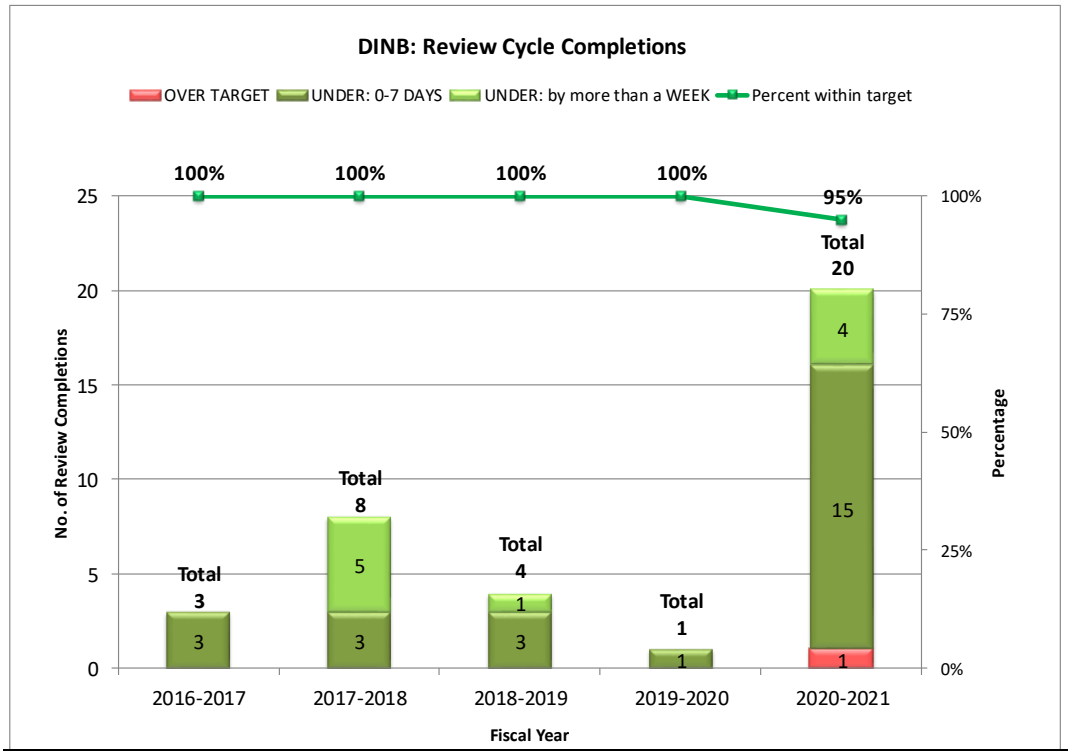
REQUESTS FOR RECONSIDERATION OF FINAL DECISIONS

DINB: Requests for Reconsideration of Final Decisions

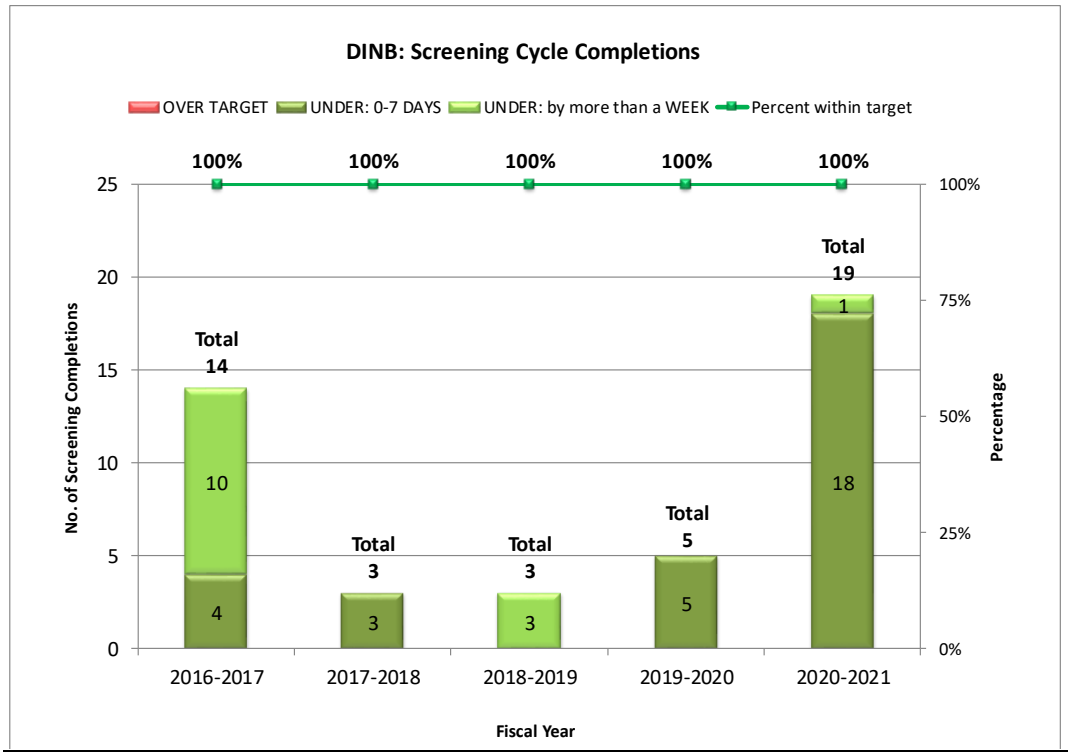
DINB - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Total	0	0	0	0	0

PERFORMANCE

DINB: Review Cycle Completions



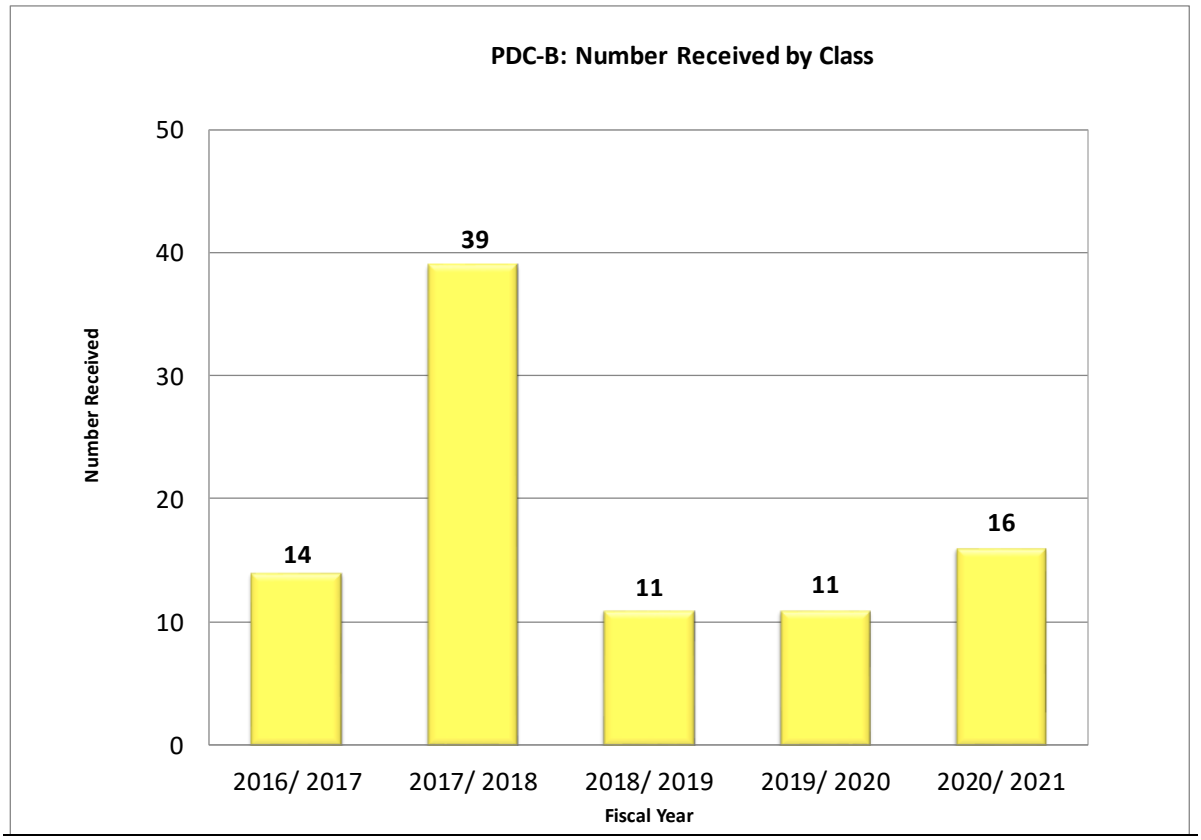
DINB: Screening Cycle Completions



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

RECEIVED

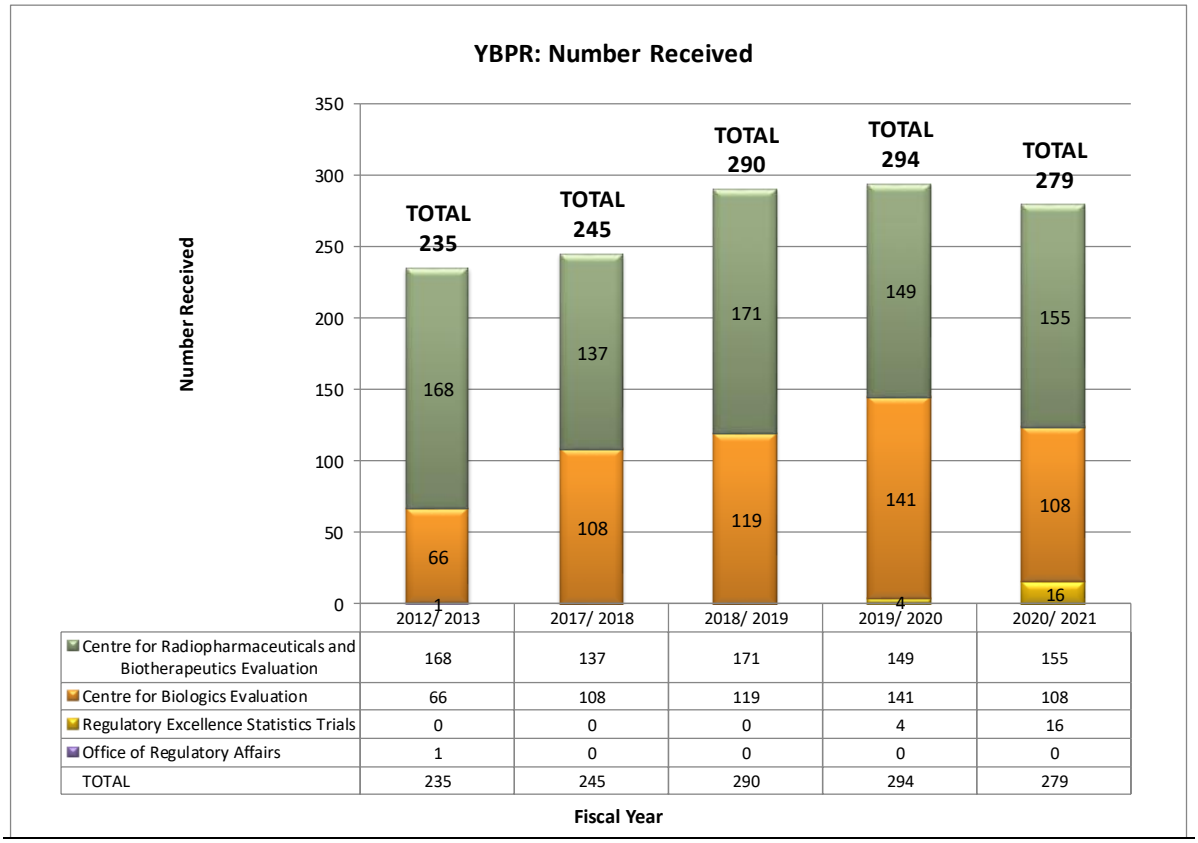
PDC-B: Number Received



YBPR: YEARLY BIOLOGIC PRODUCT REPORTS [12]

RECEIVED

YBPR: Number Received

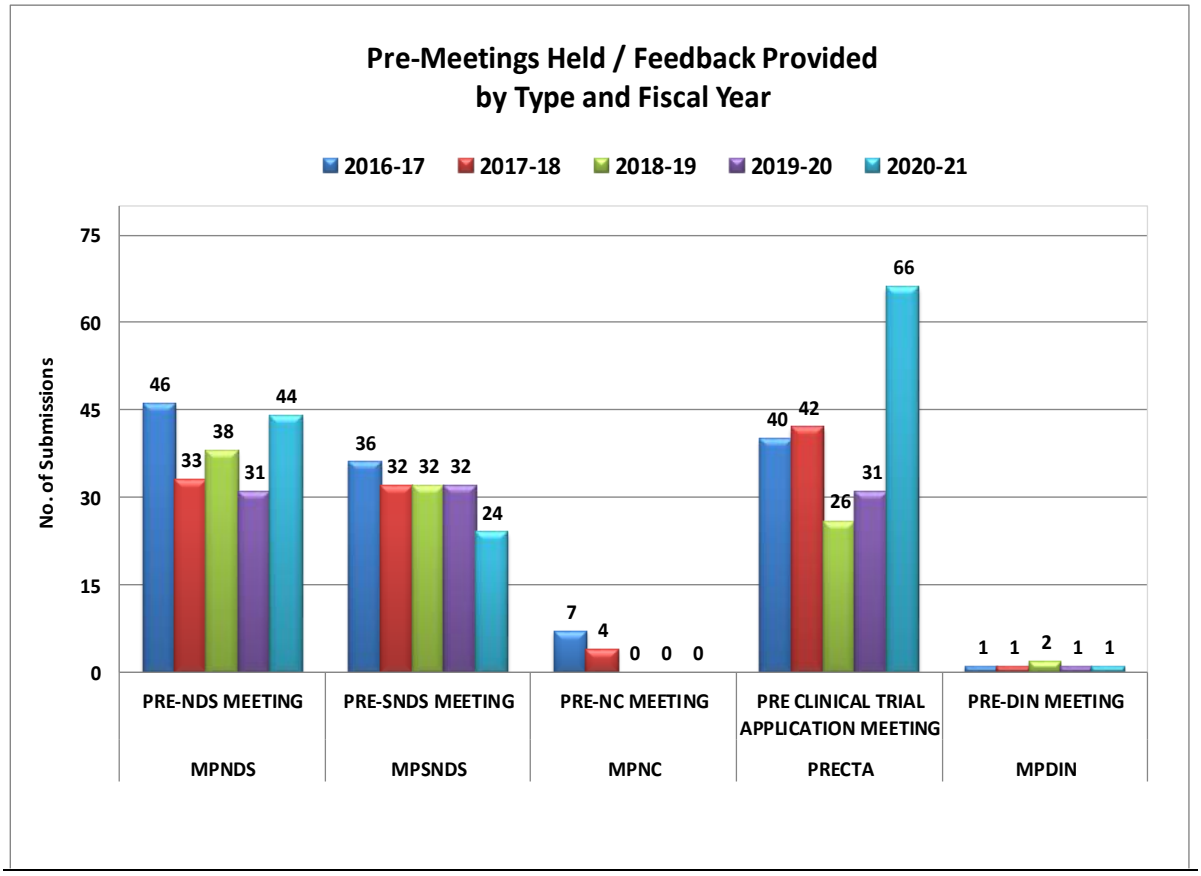


	2012/ 2013	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	168	137	171	149	155
Centre for Biologics Evaluation	66	108	119	141	108
Regulatory Excellence Statistics Trials	0	0	0	4	16
Office of Regulatory Affairs	1	0	0	0	0
TOTAL	235	245	290	294	279

[12] 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 [13]

Pre-Submission Meetings Held / Feedback Provided



[13] 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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