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Therapeutic Products Directorate

Drug Submission Performance
Annual Report

Fiscal Year 2020-2021

April 1 2020 - March 31 2021



Canada 

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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OVERVIEW

The Therapeutic Products Directorate's (TPD) Annual Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2016-2017 to 2020-2021.

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

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

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately, in 2019, HPFB had implemented [new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format](#).¹ This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.
- An [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was approved and on August 13, 2020 the Minister of Health approved an [order to temporarily extend the default period to review clinical trial applications and amendments](#) from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. The number of CTA and CTAs 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 review¹ 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.

Approvals² are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission’s NOC is placed “on hold” awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

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

¹ For further clarification refer to the [Management of Drug Submissions and Applications Guidance document](#).

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

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

[Performance for all submissions or applications filed after April 1, 2020 is tracked individually.](#)

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

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

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

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

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

⁵ For further clarification refer to the [Management of Drug Submissions and Applications Guidance document](#).

ACRONYMS

Submission Types

ANDS	- Abbreviated New Drug Submission
COV19	- Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
COV19A	- Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
CTA	- Clinical Trial Application
CTA-A	- Clinical Trial Application - Amendment
DINA	- Application for a Drug Identification Number for a pharmaceutical product. including non-prescription products attesting to a Labelling Standard
DINB	- Application for a Drug Identification Number for a biological product
DIND	- Application for a Drug Identification Number for a disinfectant product
DINF	- Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	- Abbreviated Extraordinary Use New Drug Submission
EUNDS	- Extraordinary Use New Drug Submission
EUSANDS	- Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	- Supplement to an Extraordinary Use New Drug Submission
MPNDS	- Pre-Submission Meeting New Drug Submission
MPSNDS	- Pre-Submission Meeting Supplement to a New Drug Submission
NC	- Notifiable Change
NDS	- New Drug Submission
NDS-D	- New Drug Submission for Disinfectant products
PDC	- Post-authorization Division 1 Change for a pharmaceutical product
PDC-B	- Post-authorization Division 1 Change for a biological drug product
PRNDS	- Request for Priority Review Status: New Drug Submission
PRSNDS	- Request for Priority Review Status: Supplemental New Drug Submission

- SANDS - Supplement to an Abbreviated New Drug Submission
- SANDS-C - Supplement to an Abbreviated New Drug Submission - Confirmatory
- SNDS - Supplement to a New Drug Submission
- SNDS-C - Supplement to a New Drug Submission - Confirmatory
- SNDS-D - Supplement to a New Drug Submission for Disinfectant products

Documents

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

Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a biosimilar biologic drug or an SNDS in support of changes to the manufacturing process of biologics.
Clinical or Non-Clinical Data and Chemistry and Manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only⁶	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.

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

Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment.
Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug.
Administrative Submission⁷	Submissions in support of a manufacturer or product name change.
Disinfectants⁸	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

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

⁷ For additional information, please consult the ["Changes in Manufacturer and/or Product Name Policy" \(2015\)](#).

⁸ The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

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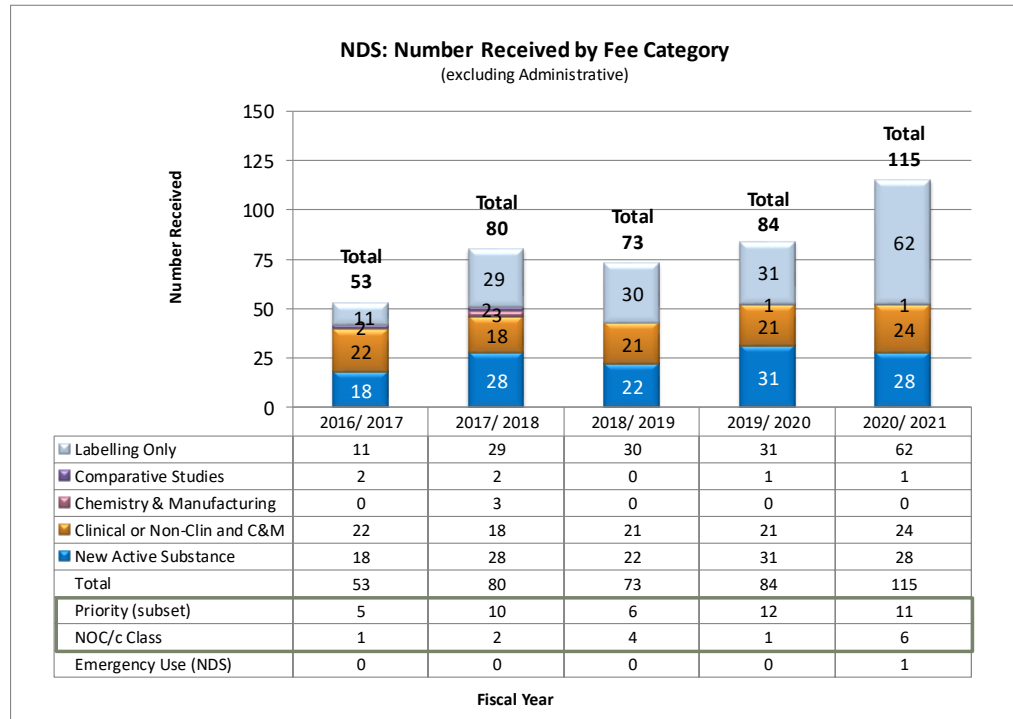
**NEW DRUG SUBMISSION
(NDS)**

&

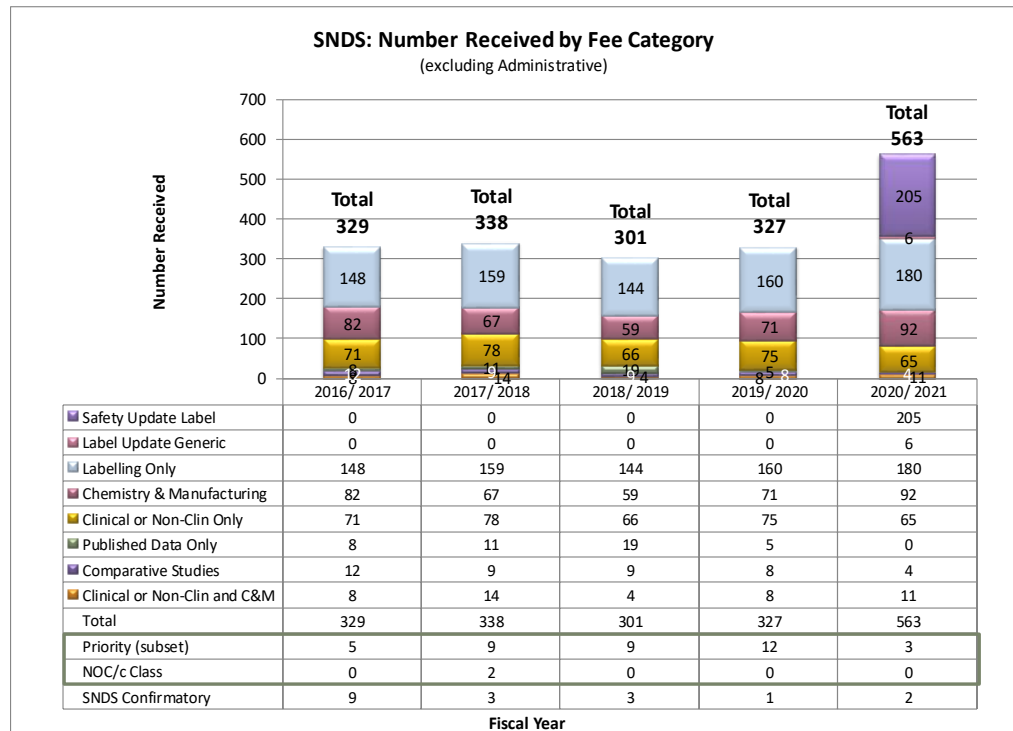
**SUPPLEMENTAL NEW DRUG SUBMISSION
(SNDS)**

SUBMISSIONS RECEIVED⁹

NDS: Number Received by Fee Category



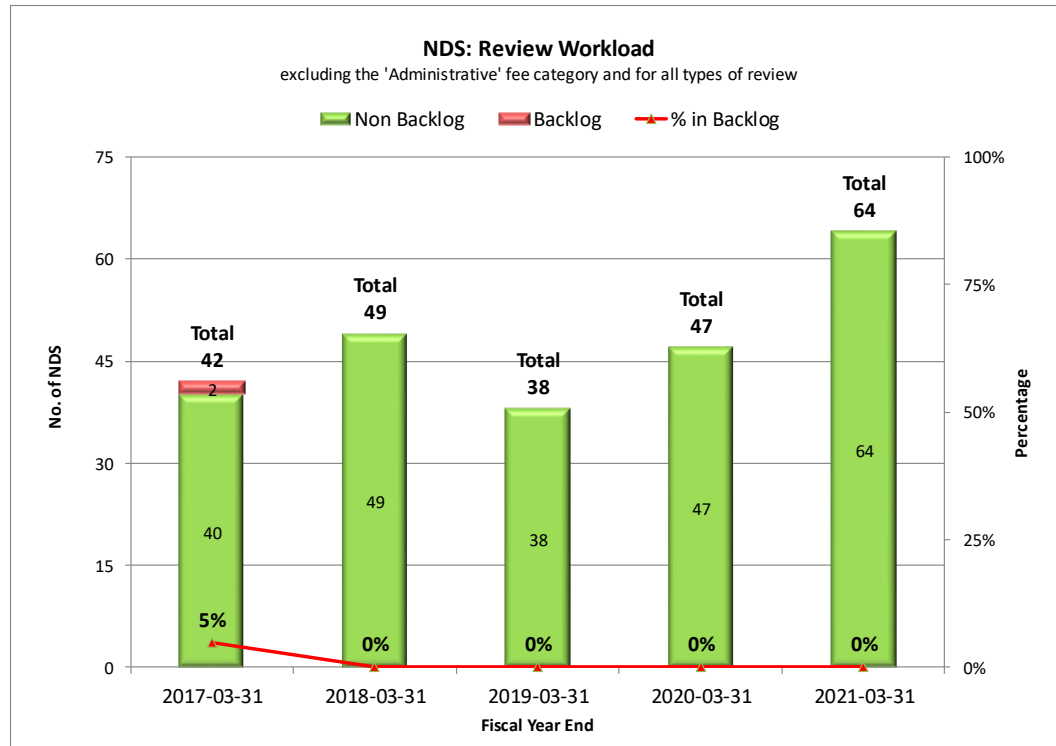
SNDS: Number Received by Fee Category



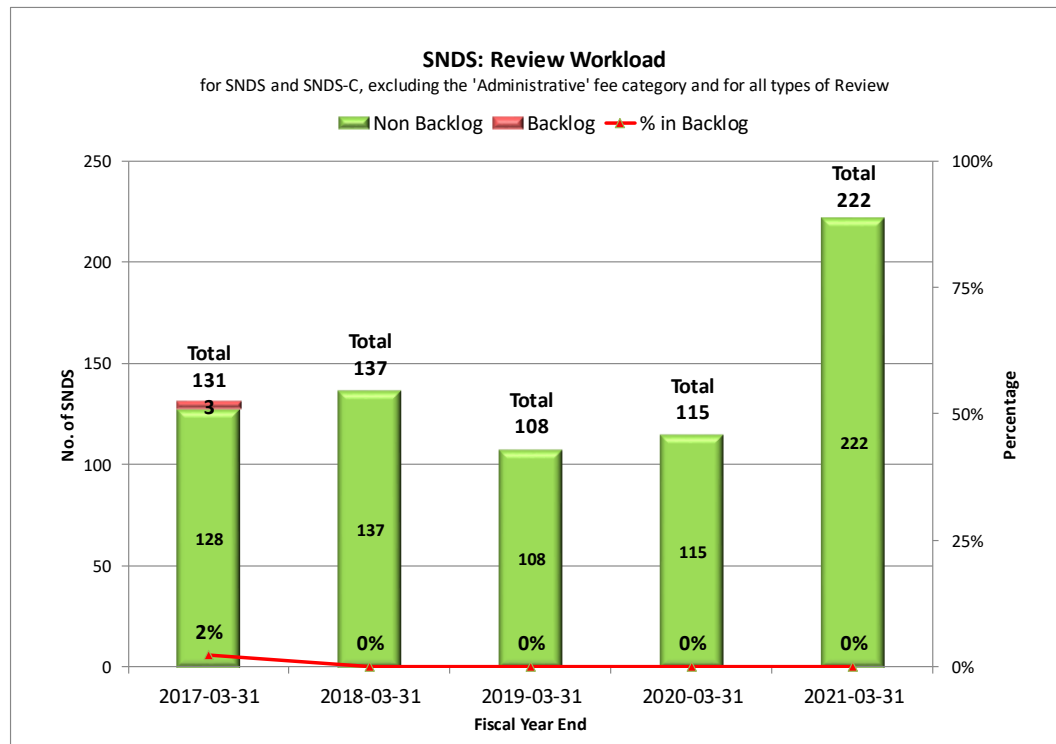
⁹ Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with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

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

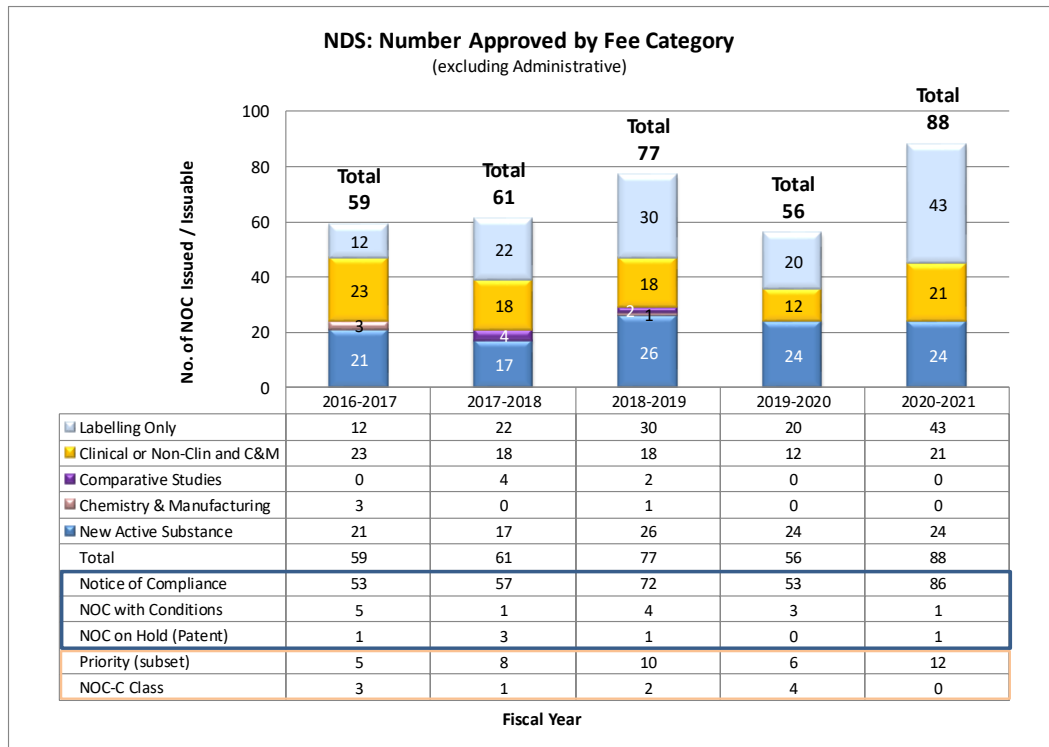
NDS: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Only	1	4	4	4	17
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	3	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin and C&M	19	18	15	24	22
<i>Backlog</i>	1	0	0	0	0
New Active Substance	19	25	19	19	25
<i>Backlog</i>	1	0	0	0	0
Total	42	49	38	47	64
Non Backlog	40	49	38	47	64
Backlog	2	0	0	0	0
% in Backlog	5%	0%	0%	0%	0%
Priority (subset)	6	6	3	8	6
<i>Backlog</i>	0	0	0	0	0

SNDS: Review Workload by Fee Category

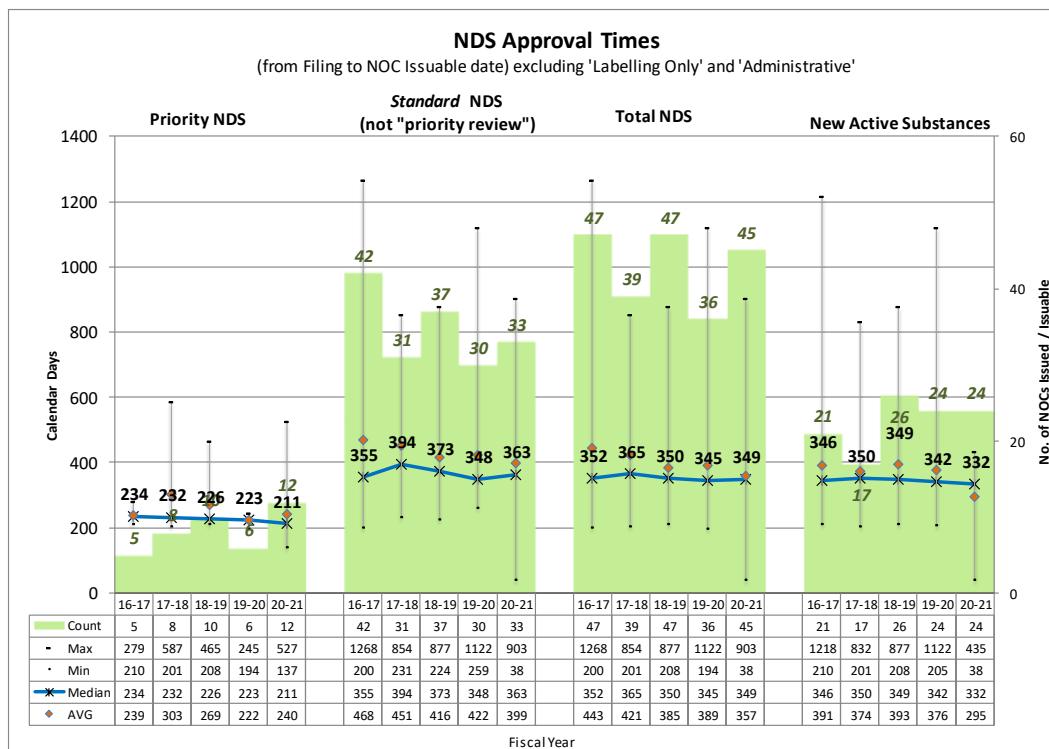
SNDS: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Only	22	19	10	24	49
<i>Backlog</i>	1	0	0	0	0
Comparative Studies	7	4	7	5	1
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	34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

APPROVALS

NDS: Number Approved by Fee Category and by NOC Type



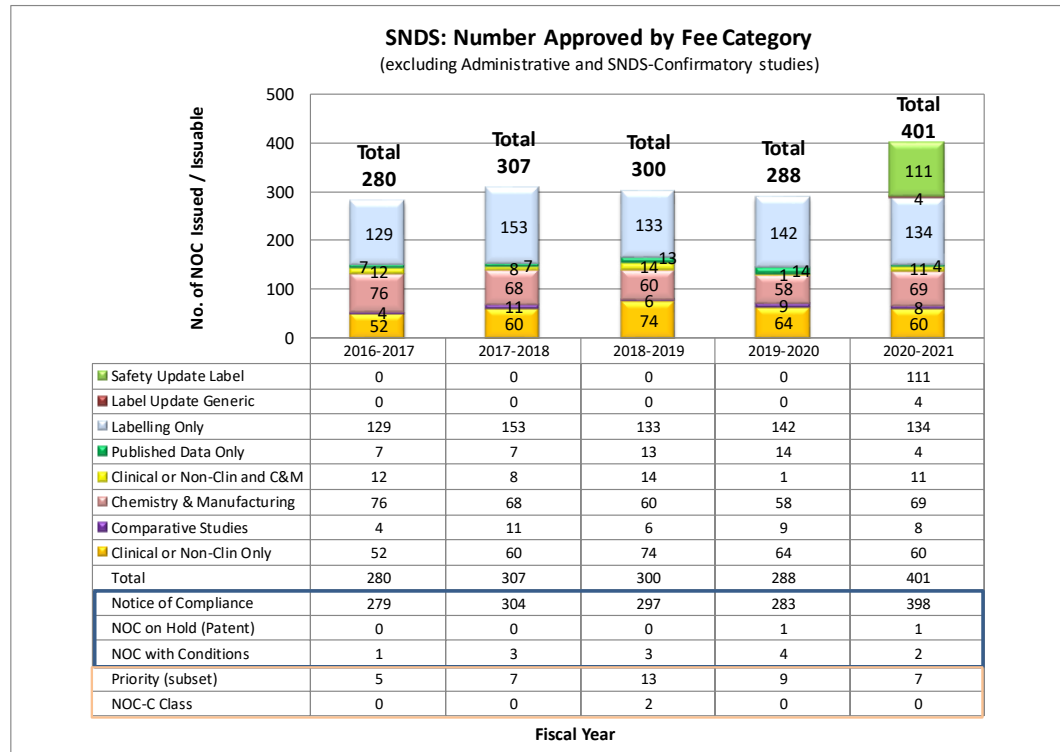
NDS Approval Times



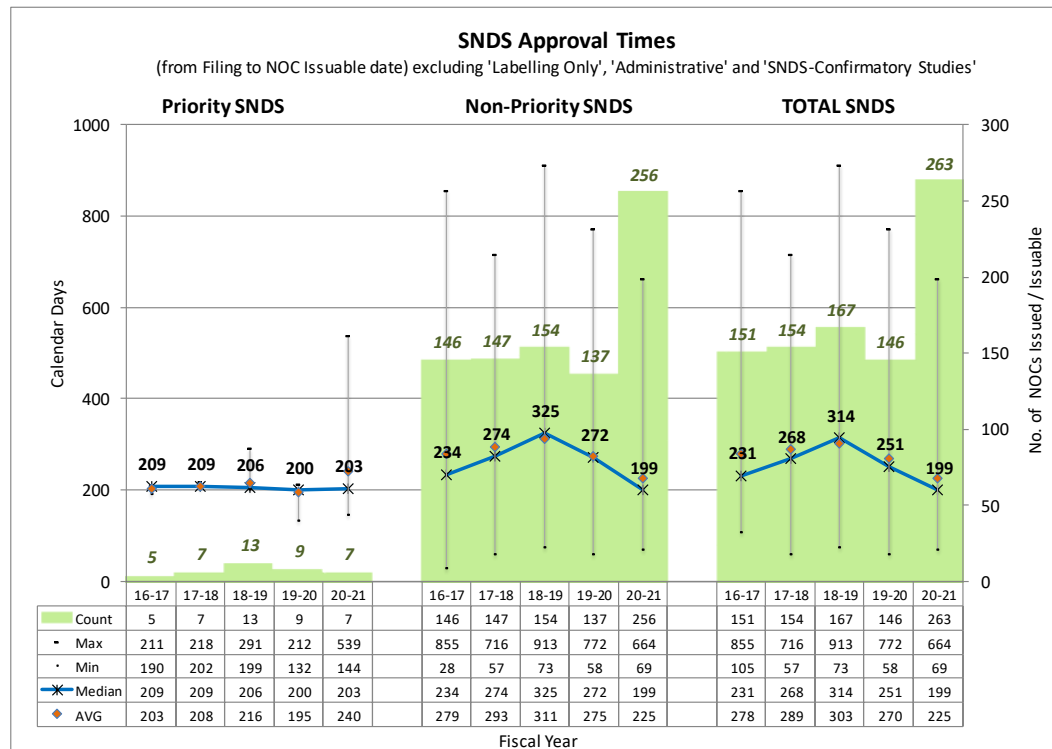
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor. Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice of Compliance with conditions \(NOC/c\) Guidance](#) and the [Management of Drug Submissions Guidance](#).

APPROVALS

SNDS: Number Approved by Fee Category and by NOC Type



SNDS Approval Times



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

NAS Approvals - TPD - Fiscal Year 2020-2021

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date ¹⁰) dd-mon-yy	Approval Date dd-mon-yy
BRAFTOVI (ENCORAFENIB) BRAFTOVI is used with a drug called binimetinib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body, or cannot be removed by surgery. BRAFTOVI is also used with a drug called cetuximab to treat adults with a type of large intestine cancer called metastatic colorectal cancer (mCRC). This type of intestine cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body and has already been treated with other cancer drugs	NAS	Pfizer Canada ULC	20-Mar-20	2-Mar-21
BRUKINSA (ZANUBRUTINIB) BRUKINSA is used in adults to treat patients with a kind of cancer called Waldenström's Macroglobulinemia (WM).	PRIORITY-NAS	Beigene Switzerland GmbH	12-Aug-20	1-Mar-21
CORZYNA (RANOLAZINE) Corzyna is a medicine used to treat chest pain (stable angina) in adults. It is used along with other medicines in patients who cannot tolerate other antianginal therapies or for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers).	PRIORITY-NAS	KYE Pharmaceuticals Inc.	27-May-20	31-Dec-20

¹⁰ The CR date is the date the submission is received and considered administratively complete by Health Canada.

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date¹⁰) dd-mon-yy	Approval Date dd-mon-yy
DAURISMO (GLASDEGIB as Glasdegib Maleate) Daurismo is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed and previously untreated acute myeloid leukemia (AML) in adult patients who are age ≥ 75 years or who are not eligible to receive intensive induction chemotherapy.	NAS	Pfizer Canada ULC	15-Mar-19	28-Apr-20
DAYVIGO (LEMBOREXANT) Dayvigo is used in adults who have trouble falling asleep and/or staying asleep (insomnia). Dayvigo is not for use in children under the age of 18 years.	NAS	Eisai Limited	3-Sep-19	4-Nov-20
DOJOLVI (TRiheptanoIn) Dojolvi is indicated as a source of calories and fatty acids for the treatment of adult and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).	PRIORITY-NAS	Ultragenyx Pharmaceutical Inc.	28-Jul-20	15-Feb-21
FIRDAPSE (AMIFAMPRIDINE (as Amifampridine Phosphate)) Firdapse is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	PRIORITY-NAS	KYE Pharmaceuticals Inc.	6-Nov-19	31-Jul-20
GIVLAARI (GIVOSIRAN as Givosiran Sodium) Givlaari is used to treat acute hepatic porphyria in adults.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-Mar-20	9-Oct-20
IBSRELA (TENAPANOR as Tenapanor Hydrochloride) Ibsrela is used in adults (18 years of age and older) to treat a condition called irritable bowel syndrome with constipation (IBS-C).	NAS	Knight Therapeutics Inc.	26-Feb-19	15-Apr-20

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date¹⁰) dd-mon-yy	Approval Date dd-mon-yy
INQOVI (CEDAZURIDINE, DECITABINE) Inqovi is used to treat adults with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). In MDS and CMML, the bone marrow does not make enough healthy mature blood cells. MDS and CMML are types of cancer.	NAS	Otsuka Pharmaceutical Co. Ltd.	31-Dec-19	7-Jul-20
INREBIC (FEDRATINIB as Fedratinib Hydrochloride) Inrebic is a prescription medicine. It is used to treat adults with an enlarged spleen and/or the associated symptoms caused by certain types of myelofibrosis. Myelofibrosis is a rare form of blood cancer.	NAS	Celgene Inc.	19-Jul-19	27-Jul-20
MAR-TRIENTINE (TRIENTINE HYDROCHLORIDE) MAR-Trientine is used for the treatment of Wilson's disease. It is used in patients who cannot take the drug penicillamine.	NAS	Marcan Pharmaceuticals Inc.	7-Aug-19	14-Sep-20
MEKTOVI (BINIMETINIB) MEKTOVI is used with a drug called encorafenib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have: · a change (mutation) in the BRAF gene, and · spread to other parts of the body, or cannot be removed by surgery.	NAS	Pfizer Canada ULC	20-Mar-20	2-Mar-21
NEXTSTELLIS (DROSPIRENONE, ESTETROL MONOHYDRATE) Nextstellis is indicated to prevent pregnancy.	NAS	Searchlight Pharma Inc.	18-Feb-20	5-Mar-21

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date¹⁰) dd-mon-yy	Approval Date dd-mon-yy
ODOMZO (SONIDEGIB (as Sonidegib Phosphate)) Odomzo is used to treat adults with a type of skin cancer, called basal cell carcinoma. It is used when the cancer has spread to surrounding areas (called “locally advanced” basal cell carcinoma (BCC)) and it cannot be treated with surgery or radiation.	NAS	Sun Pharma Global FZE	4-Jul-19	12-Jun-20
QINLOCK (RIPRETINIB) Qinlock is used to treat adults with gastrointestinal stromal tumor (GIST), which is a type of soft tissue cancer (sarcoma). The cancer must have been treated before with other cancer drugs for GIST including imatinib, sunitinib, and regorafenib.	PRIORITY-NAS	Deciphera Pharmaceuticals. LLC	23-Dec-19	19-Jun-20
RUZURGI (AMIFAMPRIDINE) Ruzurgi is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older. It is not known if Ruzurgi works or is safe in children less than 6 years old.	PRIORITY-NAS	Medunik Canada	20-Dec-19	10-Aug-20
TAVALISSE (FOSTAMATINIB (as Fostamatinib Disodium)) Tavalisse is used to treat adults with a bleeding disorder known as chronic immune thrombocytopenia when other treatments have not worked well enough.	NAS	Rigel Pharmaceuticals Inc.	30-Sep-19	19-Nov-20
TISSUEBLUE (BRILLIANT BLUE G) TISSUEBLUE is used as an aid in eye surgery. It is used to stain a part of your eye called the internal limiting membrane (ILM).	NAS	Dutch Ophthalmic Research Center International BV	7-Nov-19	15-Jan-21

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date¹⁰) dd-mon-yy	Approval Date dd-mon-yy
TOMVI (ETOMIDATE) Tomvi is an anesthetic that is used in adults: <ul style="list-style-type: none"> • to help make you asleep (unconscious) for a surgery or other medical procedure. • with other anesthetics to help keep you asleep for a short surgery. 	NAS	Sterimax Inc.	30-Aug-19	15-Jul-20
TUKYSA (TUCATINIB) Tukysa is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that: <ul style="list-style-type: none"> • is positive for human epidermal growth factor receptor 2 (HER2 positive), • cannot be removed by surgery, • has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and • has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine. 	PRIORITY-NAS	Seattle Genetics Inc.	20-Jan-20	5-Jun-20
VEKLURY (REMDESIVIR) Veklury is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen.	NAS	Gilead Sciences Canada Inc.	19-Jun-20	27-Jul-20 NOC-C

New Active Substance Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date¹⁰) dd-mon-yy	Approval Date dd-mon-yy
XENLETA (LEFAMULIN as Lefamulin Acetate) Xenleta is used: <ul style="list-style-type: none"> • In adults • To treat an infection of the lungs called Community-acquired pneumonia (CAP) • CAP develops in adults with limited or no contact with hospitals or healthcare centers • Adults with CAP get infected in a community setting • Antibacterial drugs like Xenleta treat only bacterial infections. They do not treat viral infections. 	PRIORITY-NAS	Sunovion Pharmaceuticals Canada Inc.	7-Nov-19	10-Jul-20
ZEPOSIA (OZANIMOD as Ozanimod Hydrochloride) Zeposia is used to treat adult patients with the relapsing and remitting form of multiple sclerosis (RRMS). Zeposia is not authorized for use in children.	NAS	Celgene Inc.	25-Oct-19	2-Oct-20

Priority Submission Approvals - TPD - Fiscal Year 2020-2021

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

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
DOJOLVI (TRiheptanoin) Dojolvi is indicated as a source of calories and fatty acids for the treatment of adult and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).	PRIORITY-NAS	Ultragenyx Pharmaceutical Inc.	28-Jul-20	15-Feb-21
FIRDAPSE (Amifampridine (as Amifampridine Phosphate)) Firdapse is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	PRIORITY-NAS	KYE Pharmaceuticals Inc.	6-Nov-19	31-Jul-20
FORXIGA (Dapagliflozin (as Dapagliflozin Propanediol Monohydrate)) Heart Failure FORXIGA can be used in adults along with other heart failure medicines when your heart is unable to pump blood as well as normal to: <ul style="list-style-type: none"> • reduce your risk of cardiovascular death, • reduce your risk of hospitalization or urgent visits for heart failure. 	PRIORITY-CLIN ONLY	Astrazeneca Canada Inc.	10-Dec-19	30-Jun-20
GIVLAARI (Givosiran (as Givosiran Sodium)) Givlaari is used to treat acute hepatic porphyria in adults.	PRIORITY-NAS	Alnylam Netherlands B.V.	19-Mar-20	9-Oct-20
GLEOLAN (Aminolevulinic Acid Hydrochloride) Gleolan is used to help visualize certain brain tumours (called malignant glioma) during tumour surgery.	PRIORITY-CLIN/C&M	Medexus Inc.	23-Dec-19	9-Sep-20

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
LYNPARZA (OLAPARIB) NEW INDICATION: <u>Prostate Cancer</u> Lynparza is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA or ATM mutated metastatic castrationresistant Prostate Cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent. BRCA or ATM mutations must be confirmed before LYNPARZA treatment is initiated.	PRIORITY-CLIN ONLY	Astrazeneca Canada Inc.	31-Jan-20	21-Aug-20
OFEV (NINTEDANIB as Nintedanib Esilate) Use OFEV to treat adults with: <ul style="list-style-type: none"> • Interstitial Lung Diseases (ILDs) where lung fibrosis continues to worsen (progress). May also be know as progressive fibrosing ILD (PF-ILD). 	PRIORITY-CLIN ONLY	Boehringer Ingelheim (Canada) Ltd Ltee	28-Oct-19	20-May-20
ONUREG (AZACITIDINE) Onureg is a nucleoside metabolic inhibitor indicated for: <ul style="list-style-type: none"> • maintenance therapy in adult patients with acute myeloid leukemia (AML) who achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy with or without consolidation treatment, and who are not eligible for hematopoietic stem cell transplantation (HSCT). 	PRIORITY-CLIN/C&M	Celgene Inc.	15-Jun-20	5-Jan-21

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

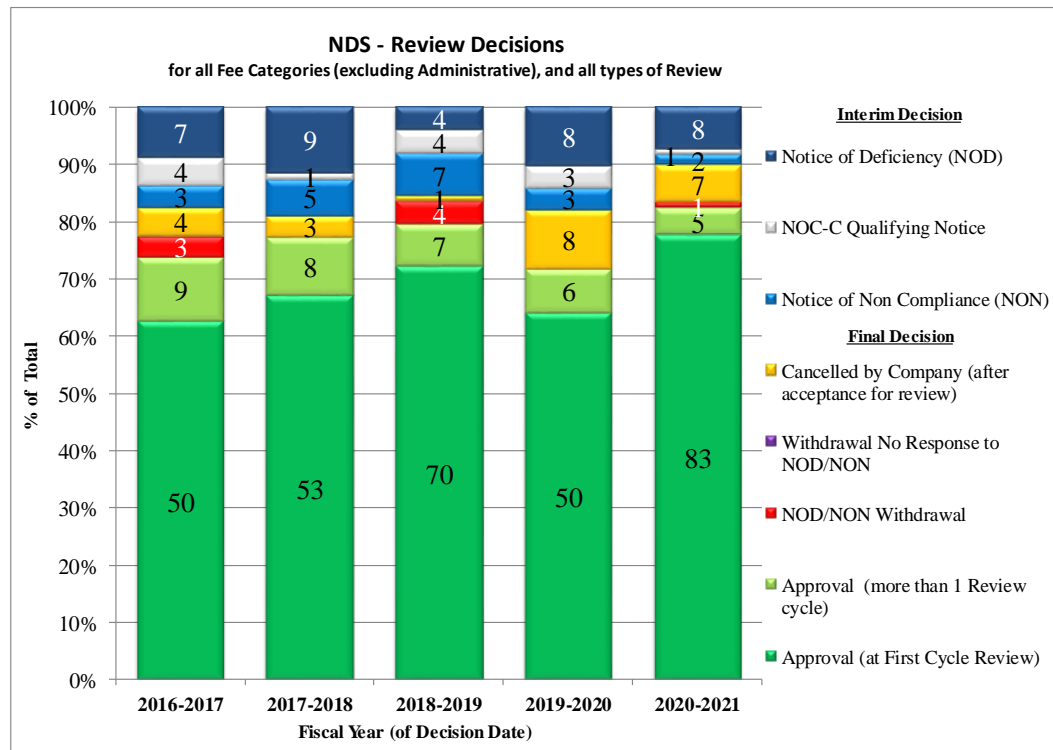
Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
<p>SPRAVATO (ESKETAMINE as Esketamine Hydrochloride) Spravato is a nasal spray used to treat adults with major depressive disorder that:</p> <ul style="list-style-type: none"> • is moderate to severe in intensity and • has not responded to two or more separate courses of treatment in the current episode of depression. <p>Separate courses refers to previous treatment with different antidepressants, each given at adequate doses for an adequate amount of time. Spravato nasal spray is used together with an antidepressant taken by mouth that is either:</p> <ul style="list-style-type: none"> • a selective serotonin reuptake inhibitor (SSRI) or • a serotonin and norepinephrine reuptake inhibitor (SNRI) <p>Spravato is not for use in children or adolescents. If you are 65 years or older, talk to your doctor before starting Spravato. Spravato may not be an effective treatment for you and you may be more sensitive to experiencing side effects.</p>	<p>PRIORITY-CLIN/C&M</p>	<p>Janssen Inc.</p>	<p>10-Dec-18</p>	<p>20-May-20</p>
<p>TAGRISSO (OSIMERTINIB as Osimertinib Mesylate) is indicated as adjuvant therapy after tumour resection in patients with stage IB-IIIa non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.</p>	<p>PRIORITY-CLIN/C&M</p>	<p>Astrazeneca Canada Inc.</p>	<p>27-Aug-20</p>	<p>18-Jan-21</p>

Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
TUKYSA (TUCATINIB) Tukysa is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that: <ul style="list-style-type: none"> • is positive for human epidermal growth factor receptor 2 (HER2 positive), • cannot be removed by surgery, • has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and • has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine. 	PRIORITY-NAS	Seattle Genetics Inc.	20-Jan-20	5-Jun-20
XENLETA (LEFAMULIN as Lefamulin Acetate) Xenleta is used: <ul style="list-style-type: none"> • In adults • To treat an infection of the lungs called Community-acquired pneumonia (CAP) • CAP develops in adults with limited or no contact with hospitals or healthcare centers • Adults with CAP get infected in a community setting • Antibacterial drugs like Xenleta treat only bacterial infections. They do not treat viral infections. 	PRIORITY-NAS	Sunovion Pharmaceuticals Canada Inc.	7-Nov-19	10-Jul-20
XTANDI (ENZALUTAMIDE) NEW INDICATION: Xtandi is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).	PRIORITY-CLIN ONLY	Astellas Pharma Canada Inc.	18-Nov-19	2-Jun-20

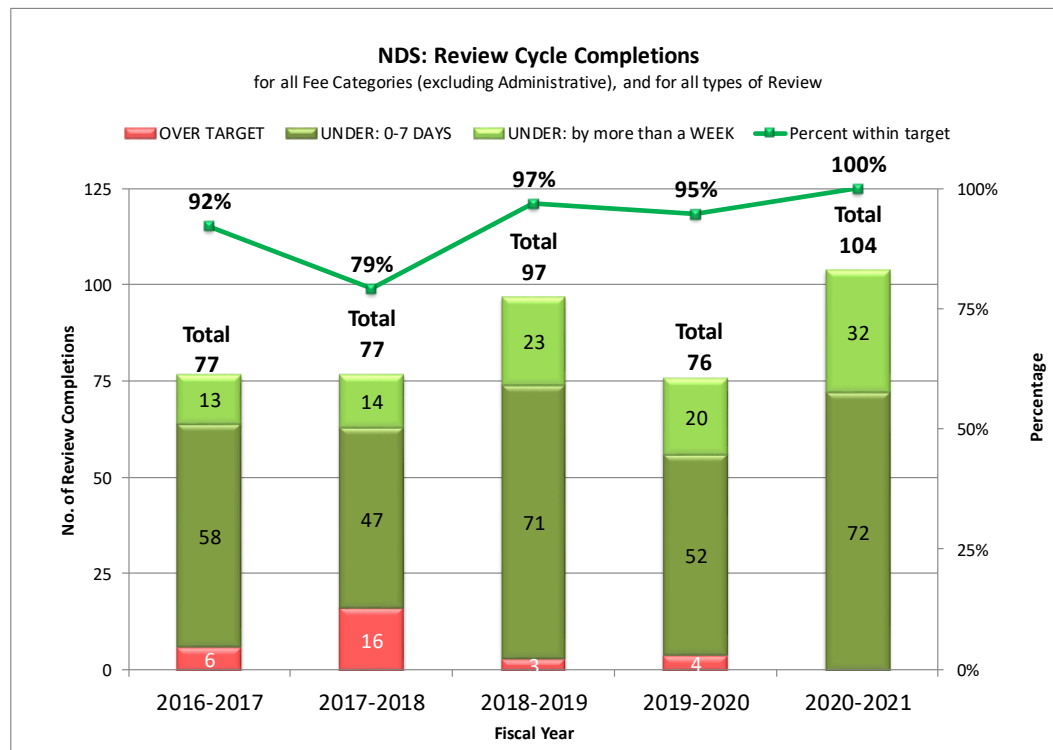
Priority Submission Approvals - TPD Fiscal Year 2020-2021 (April 1 2020 - March 31 2021)				
Brand Name (Active Ingredient(s)) - Indication(s)	Class	Company	Filing (CR Date) dd-mon-yy	Approval Date dd-mon-yy
ZEJULA (NIRAPARIB as Niraparib Tosylate) ZEJULA is used in adult women for the maintenance treatment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

REVIEW PERFORMANCE

NDS: Review Decisions by Type

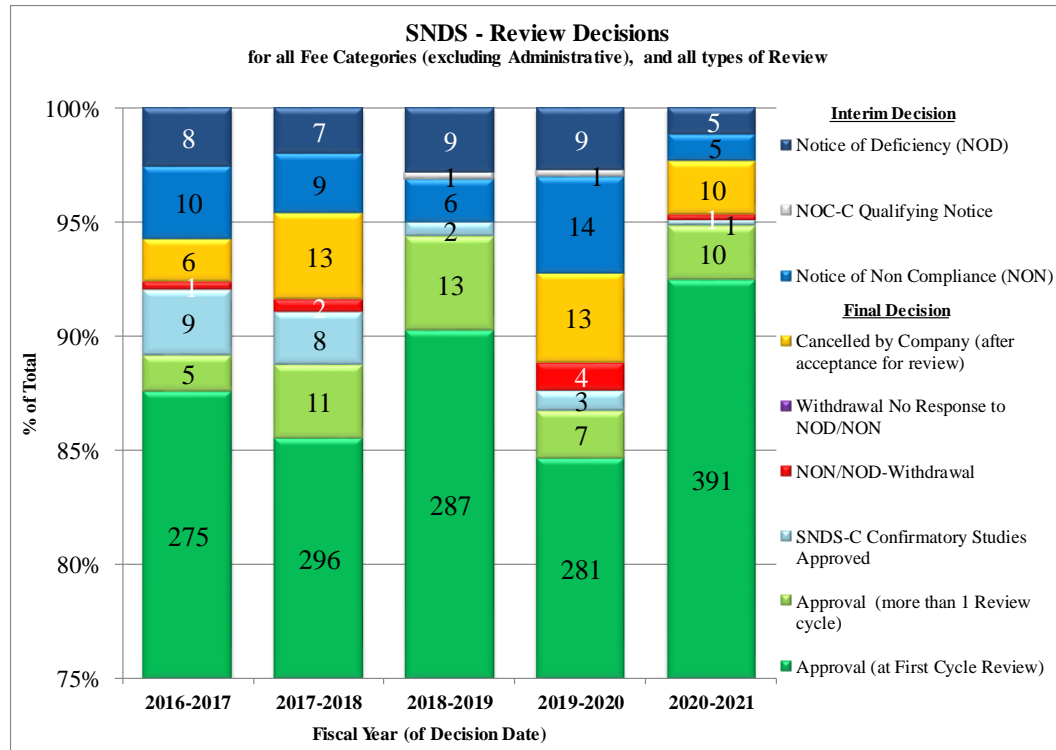


NDS: Review Cycle Completions

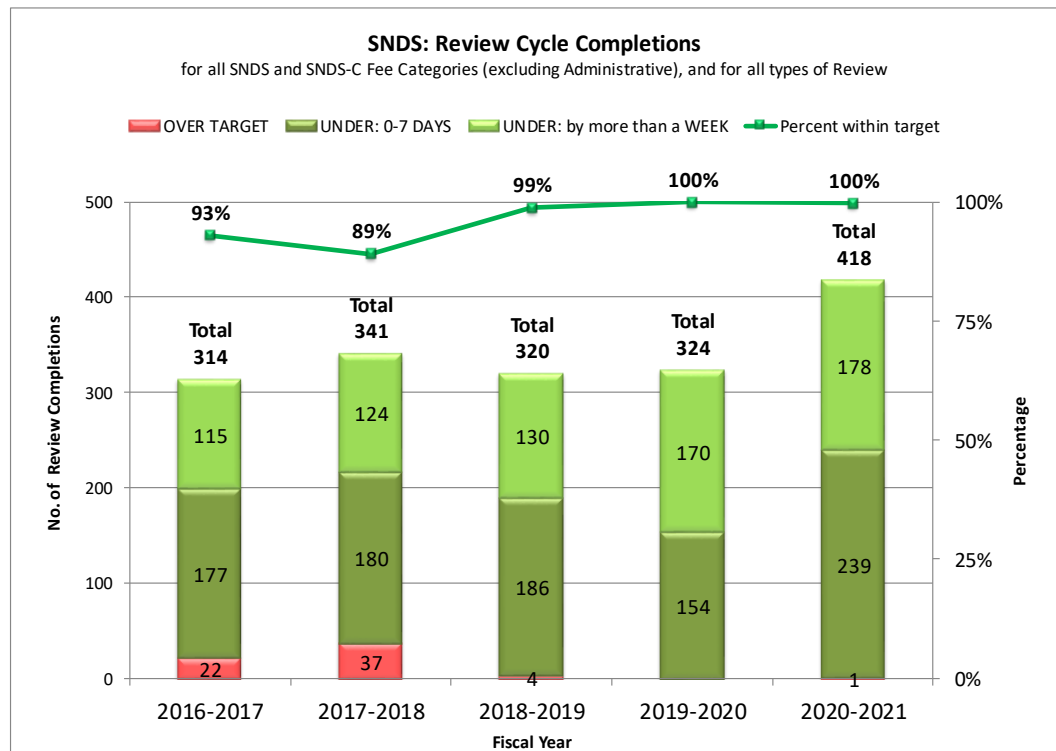


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

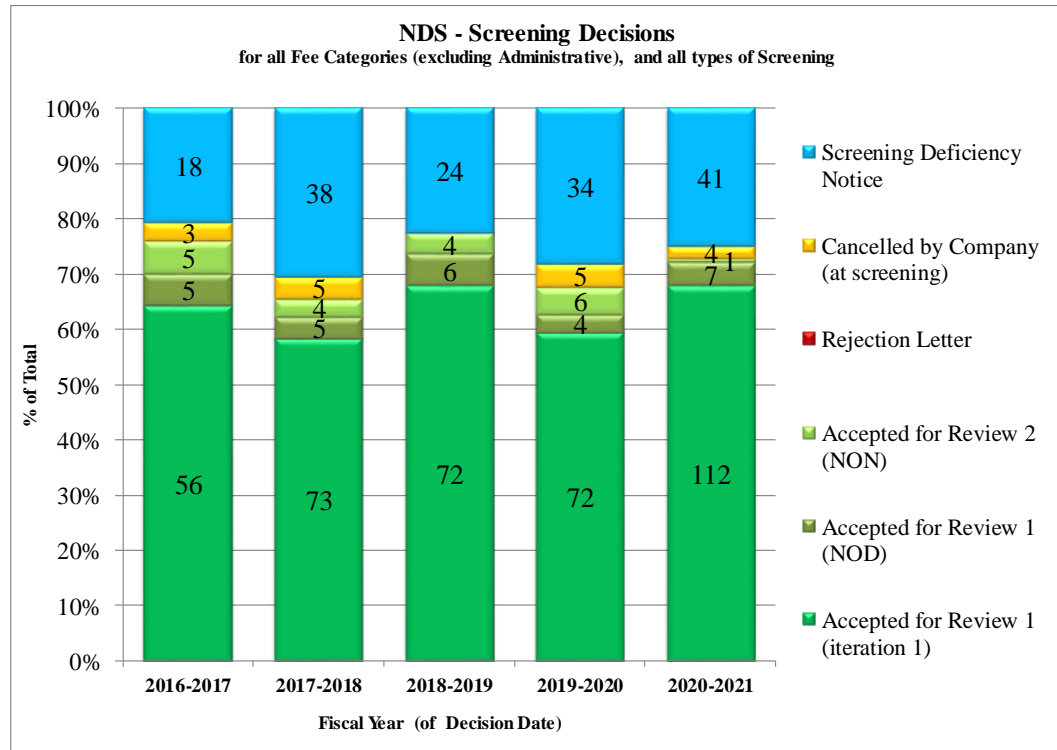


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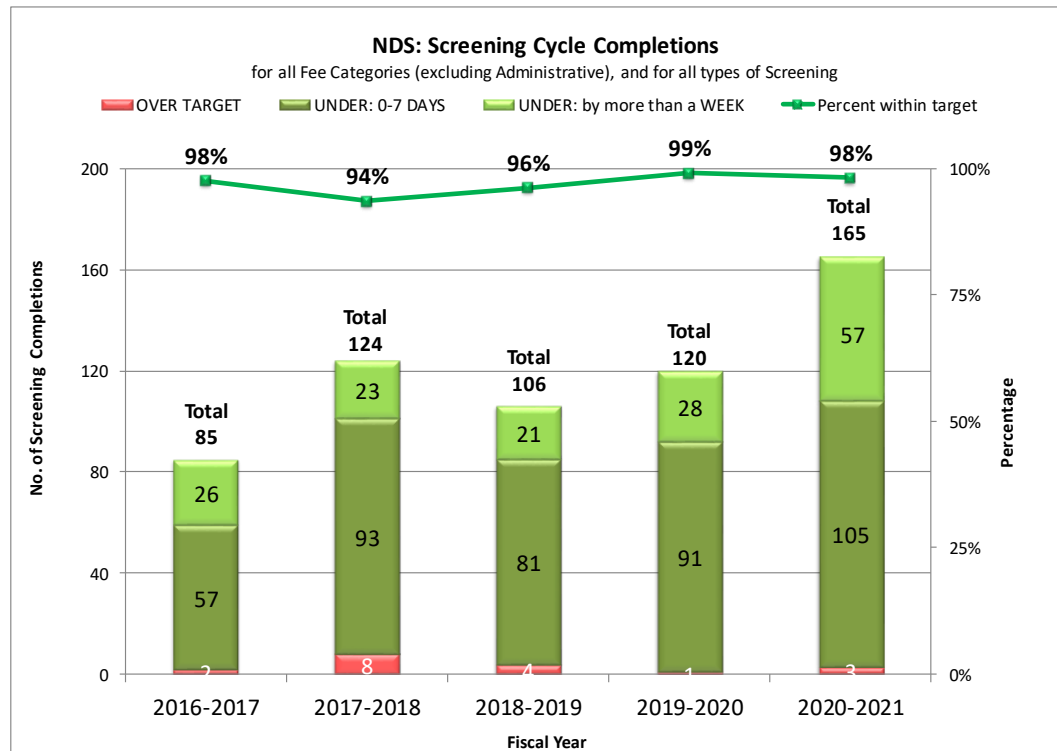


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

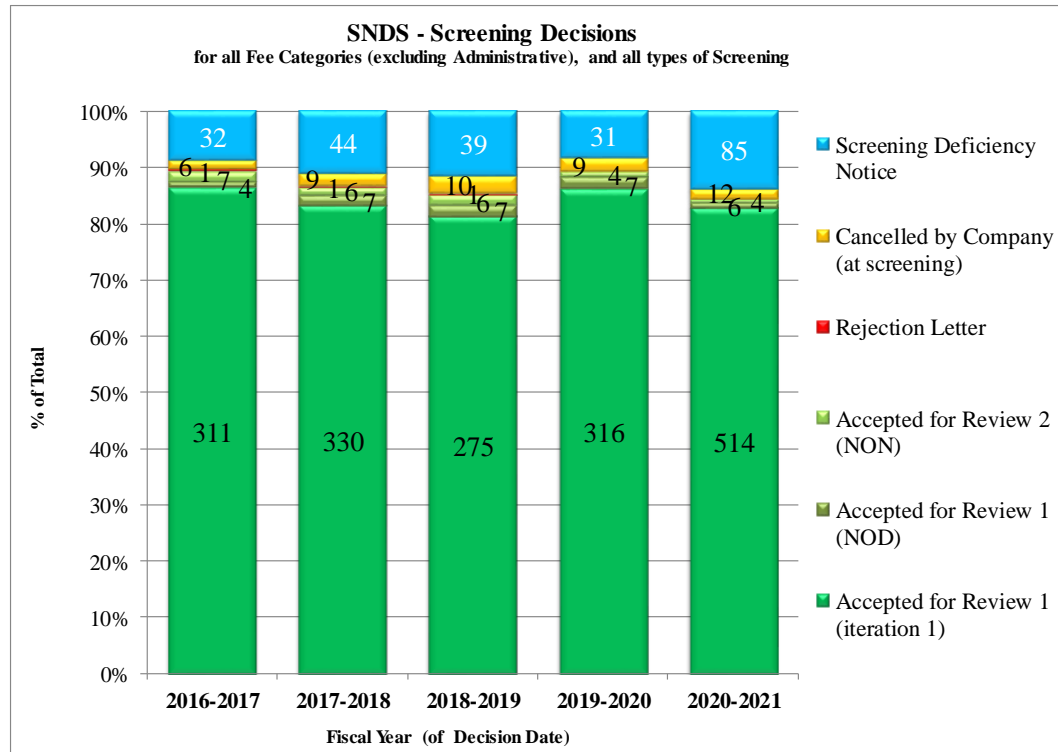


NDS: Screening Cycle Completions

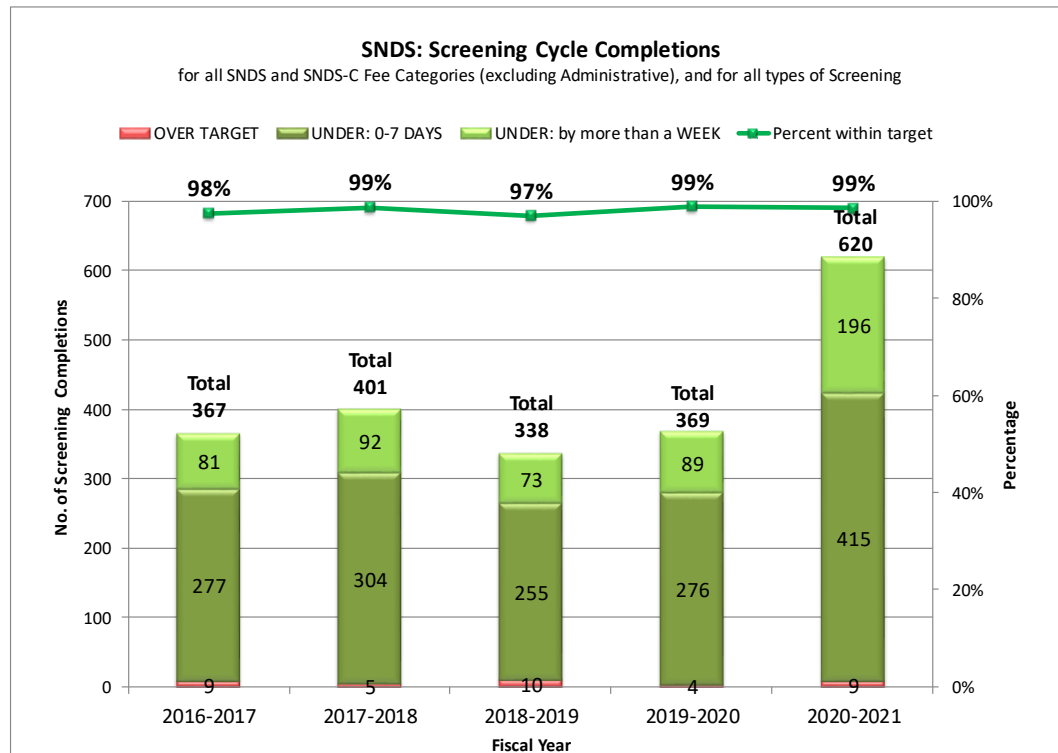


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

NDS: Request for Reconsideration of Final Decisions

NDS - Reconsideration of Final Decisions Requests Received							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	NDS Status (as of June 2021)
Total Received	1	0	1	0	0		
<i>Total Pending</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>		
PENDING						NOD-Withdrawal	Under Reconsideration
<i>Total Granted</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>		
GRANTED	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	NOD-Withdrawal	Cleared
<i>Total Denied</i>	<i>1</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>		
DENIED	1	0	0	0	0	NOD-Withdrawal	Withdrawn
DENIED	0	0	1	0	0	NON-Withdrawal	Withdrawn

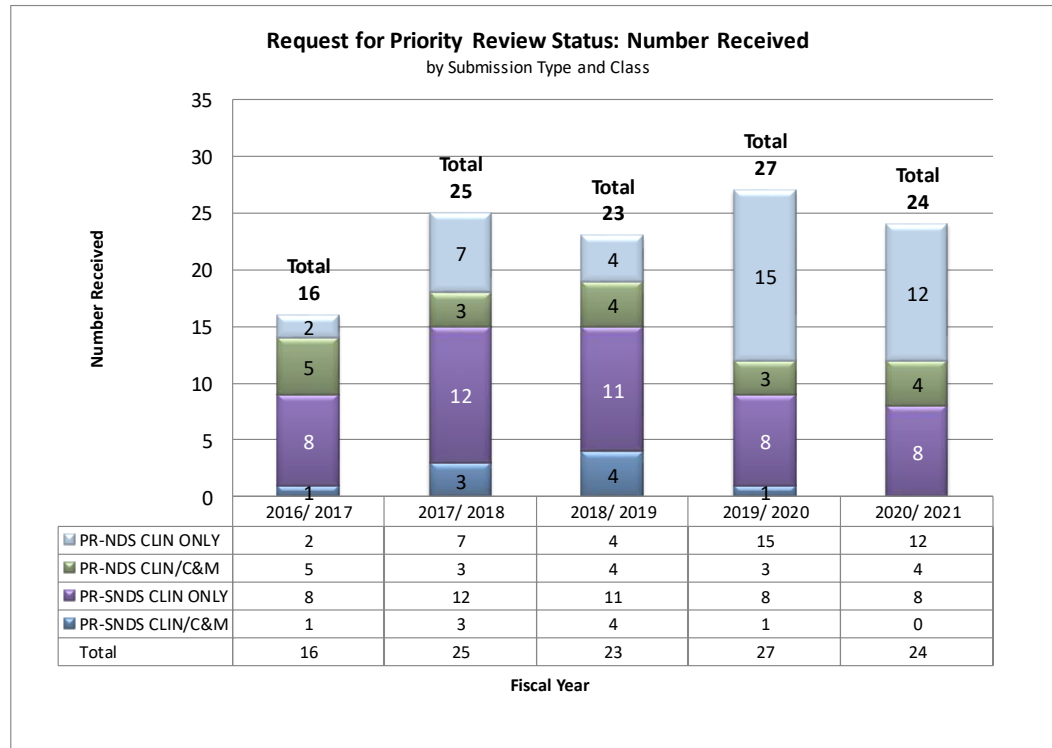
SNDS: Request for Reconsideration of Final Decisions

SNDS - Reconsideration of Final Decisions Requests Received							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	SNDS Status (as of June 2021)
Total Received	0	0	0	0	0		
Total Denied	0	0	0	0	0	NOD-Withdrawal	Withdrawn

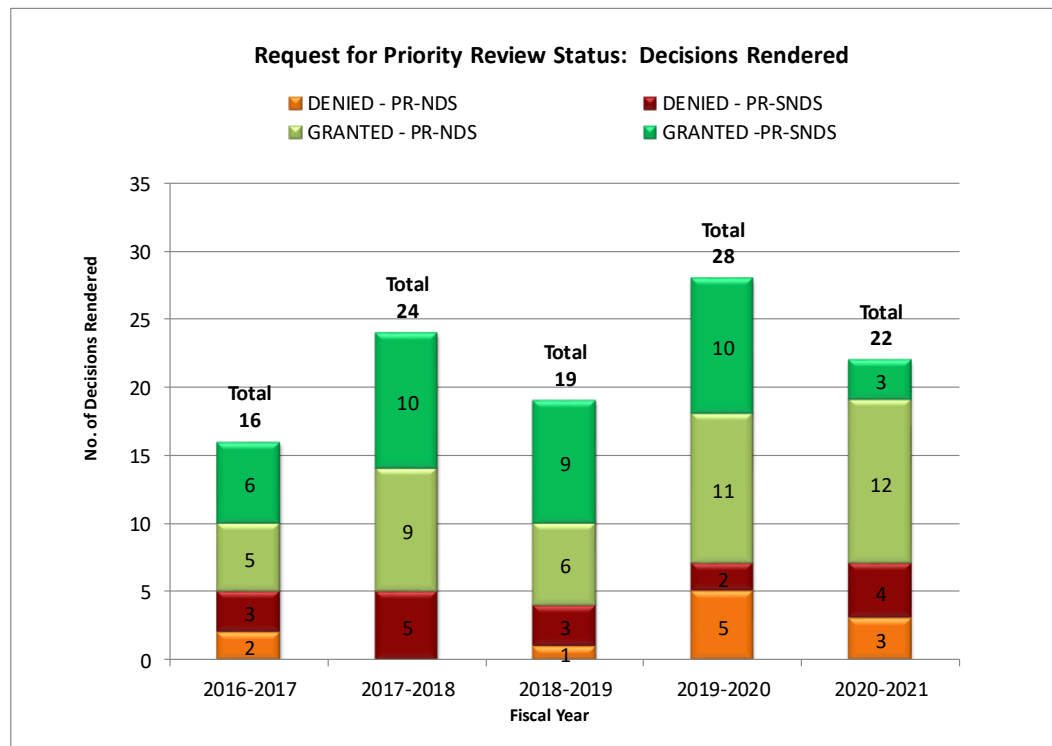
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REQUEST FOR PRIORITY REVIEW STATUS

Request for Priority Review Status: Number Received

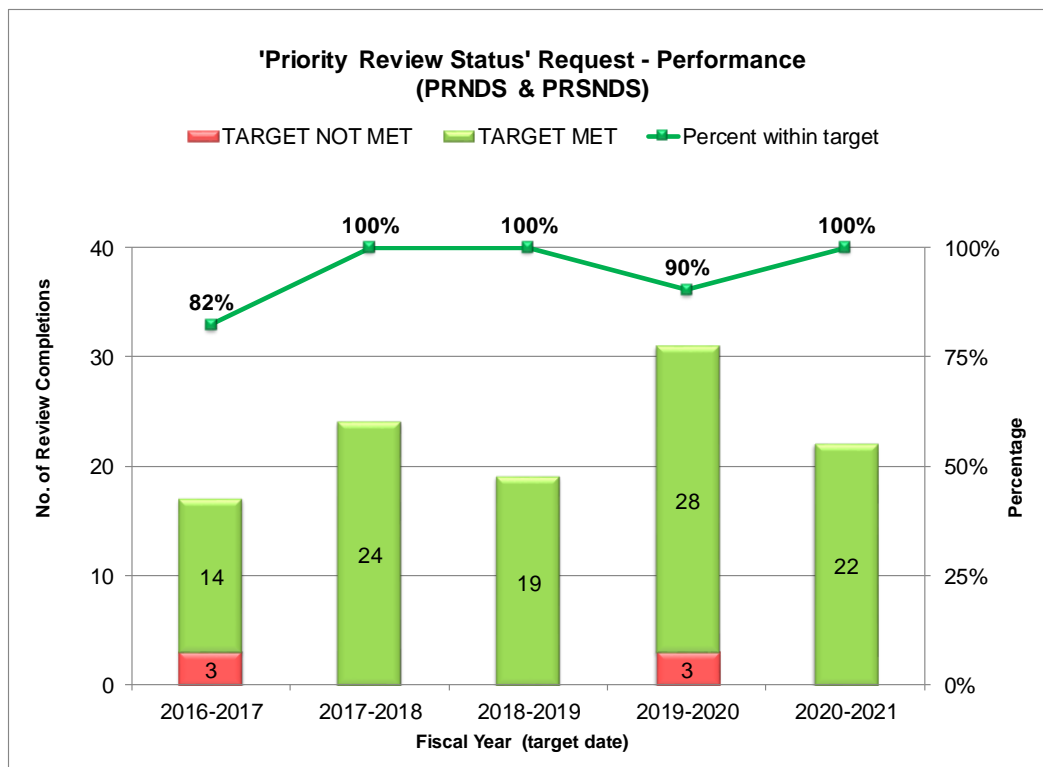


Request for Priority Review Status: Decisions Rendered



REQUEST FOR PRIORITY REVIEW STATUS

Request for Priority Review Status: Performance



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

Priority Review Requests: Request for Reconsideration of Final Decisions

"Priority Review Request" - Requests for Reconsideration of Final Decisions							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	Submission Status (as of June 2021)
Total Received	0	1	1	0	0		
Total Granted	0	1	0	0	0	Priority Review Request (for SNDS) Denied	Cleared

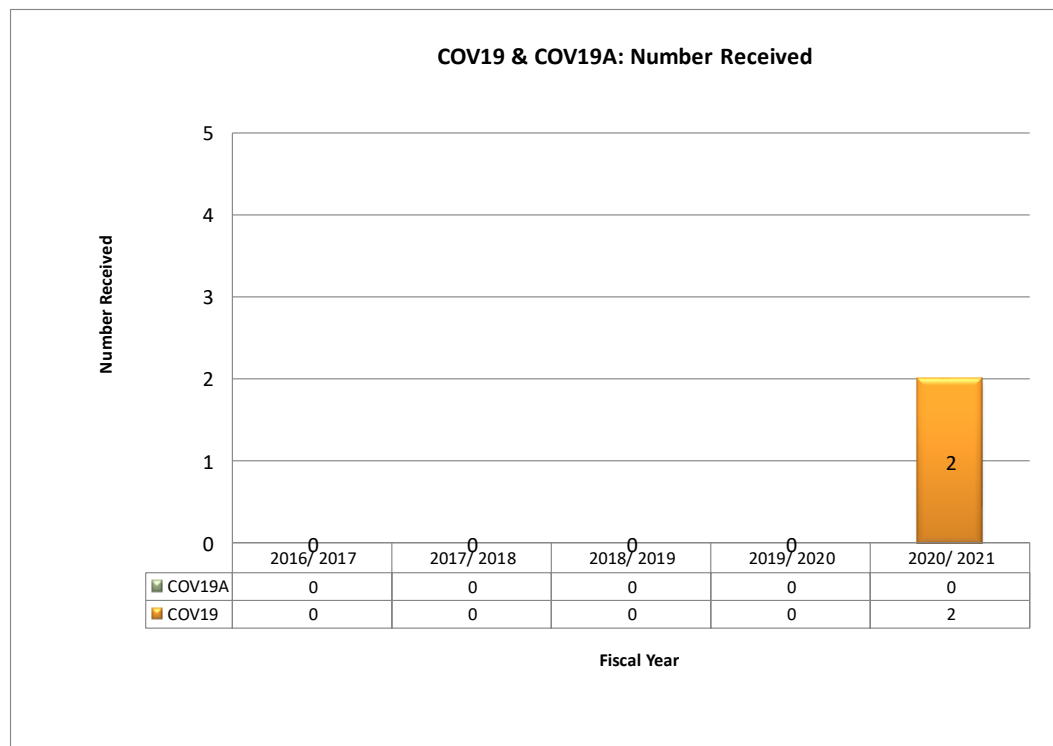
**Application under the Interim Order Respecting the
Importation, Sale and Advertising of Drugs for Use in
Relation to COVID-19
(COV19)**

&

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

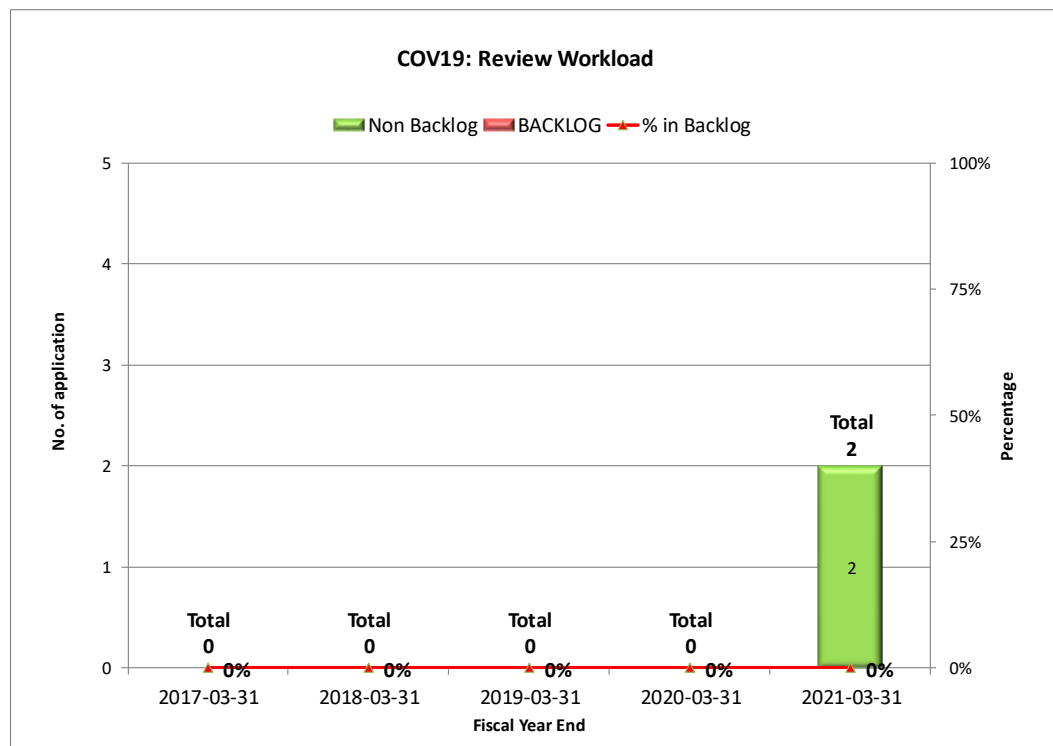
SUBMISSION RECEIVED

COV19 & COV19A: Number Received



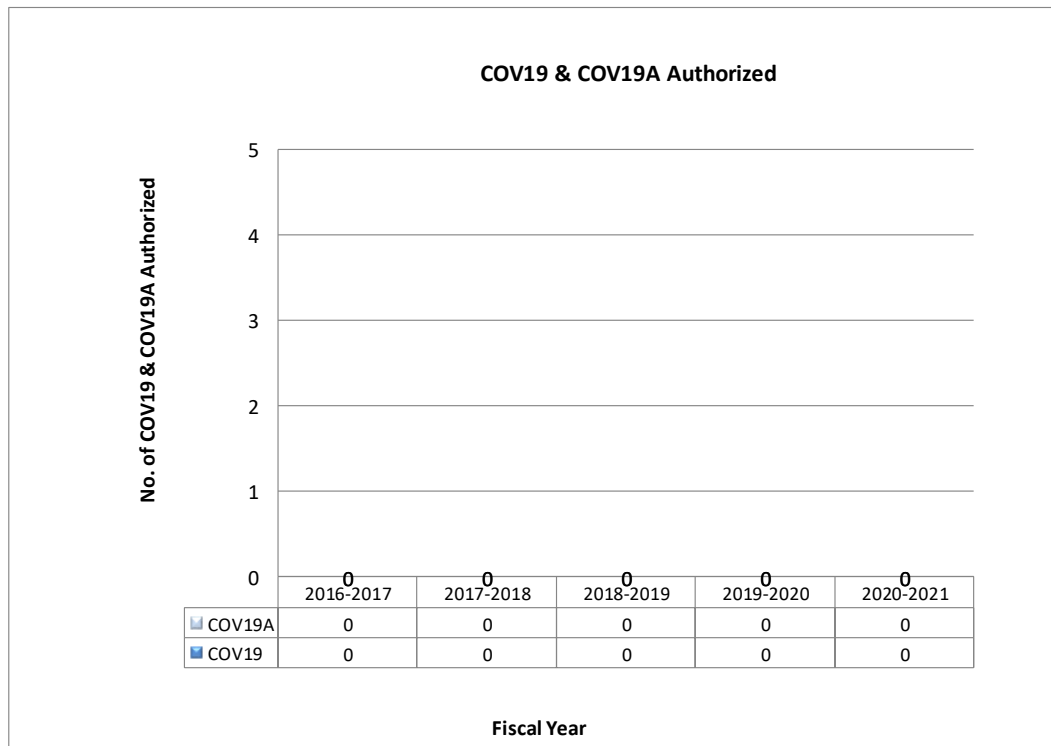
WORKLOAD

COV19: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



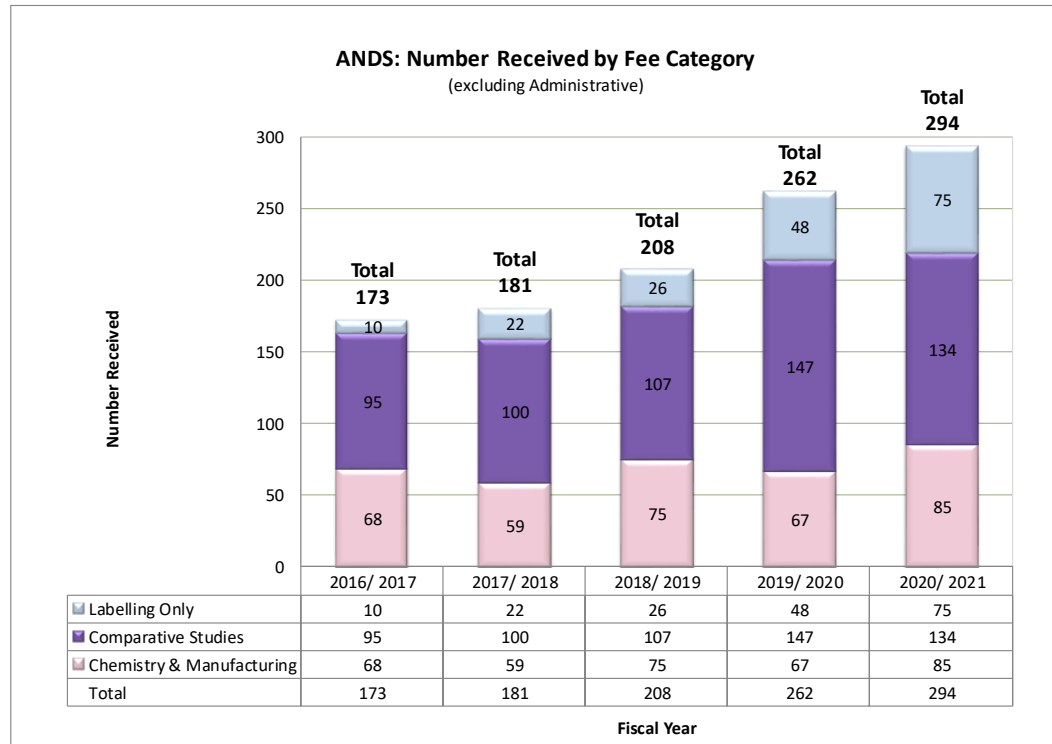
**ABBREVIATED NEW DRUG SUBMISSIONS
(ANDS)**

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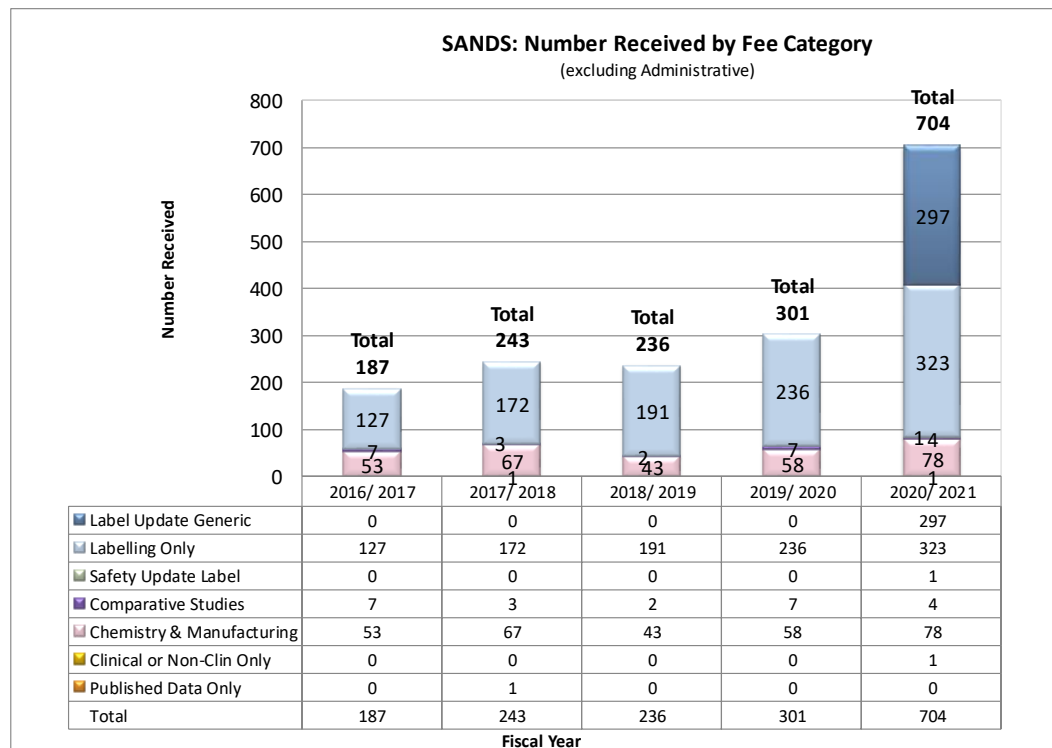
**SUPPLEMENTAL ABBREVIATED NEW DRUG
SUBMISSIONS
(SANDS)**

SUBMISSIONS RECEIVED

ANDS: Number Received by Fee Category

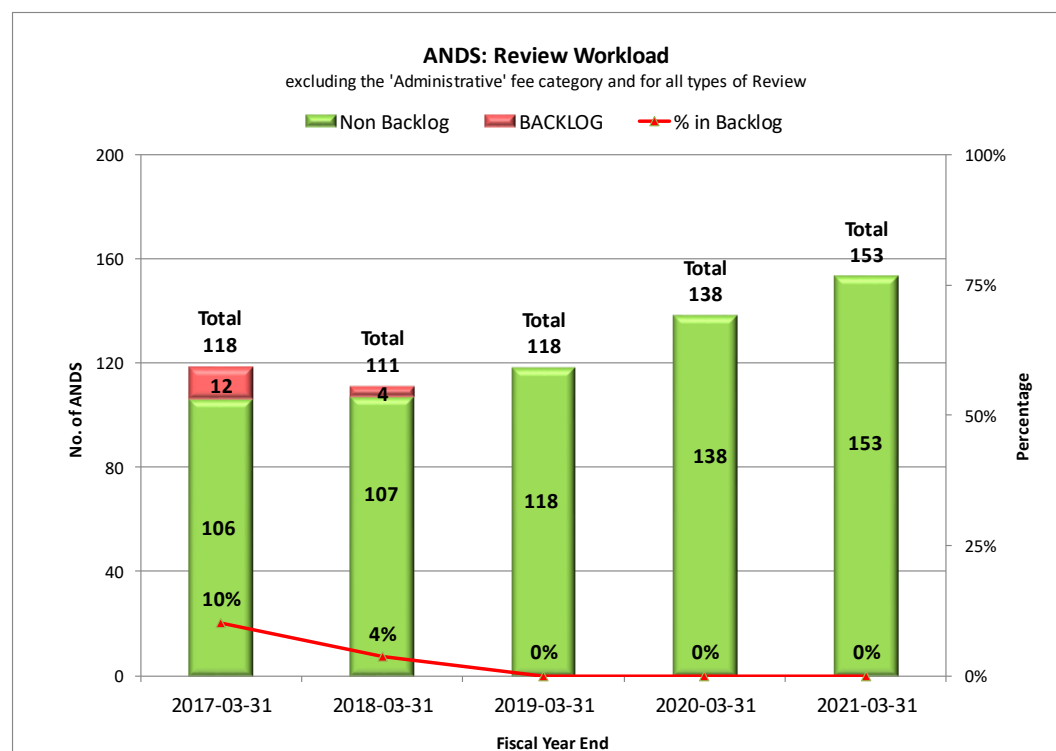


SANDS: Number Received by Fee Category

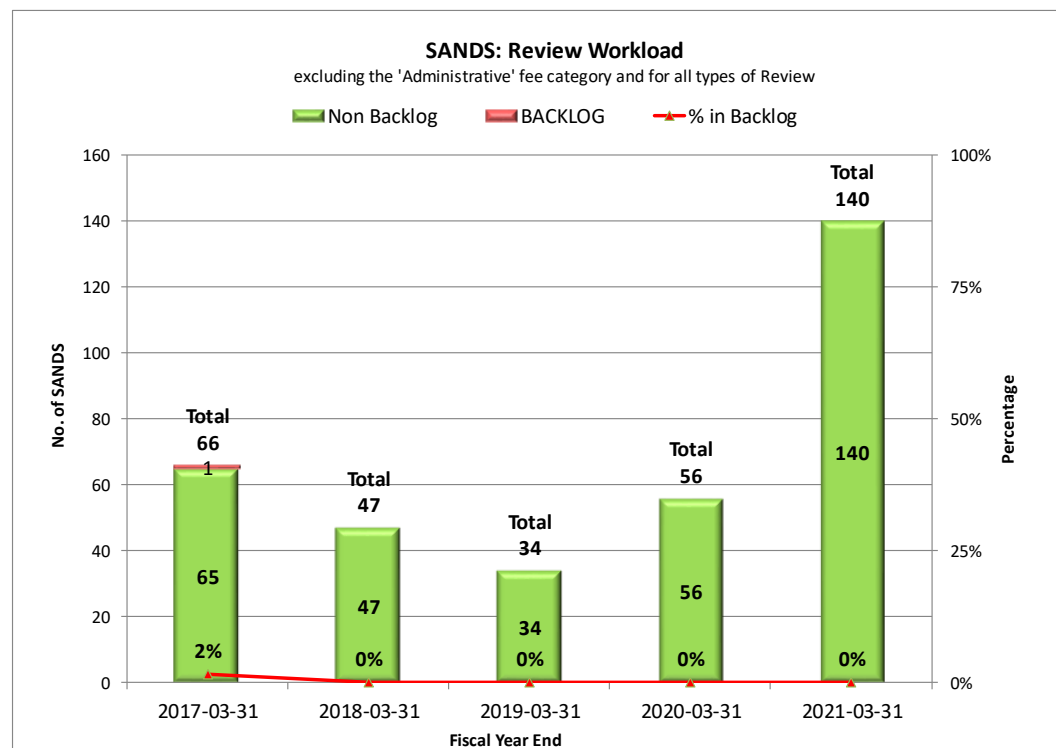


WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

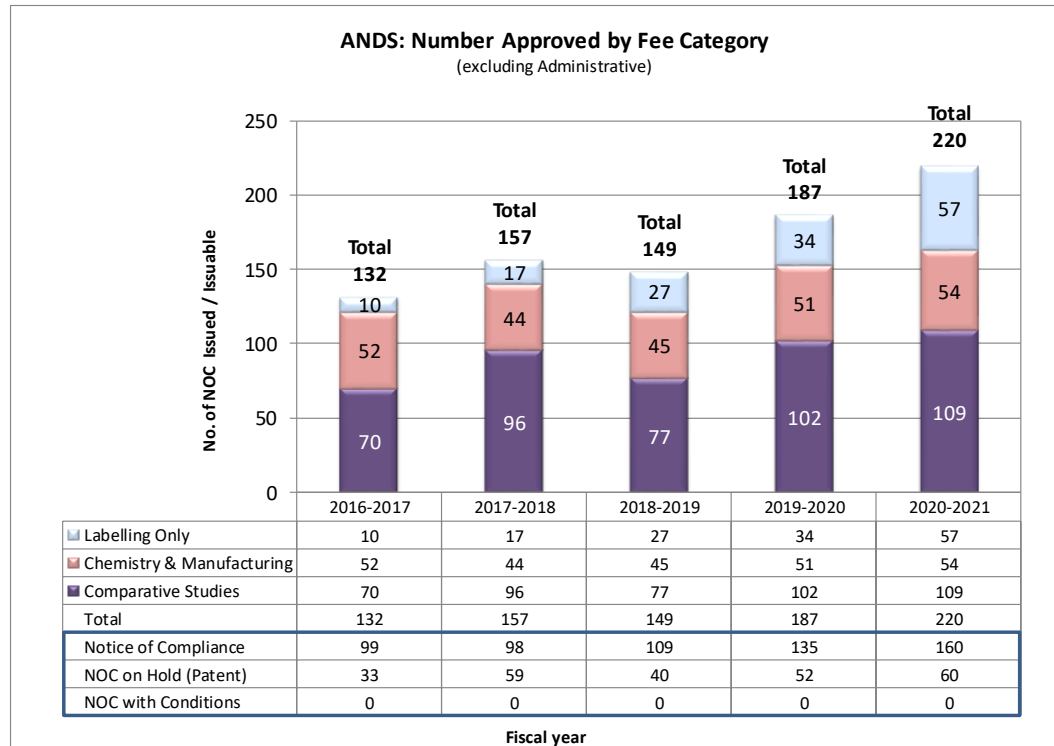
ANDS: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Chemistry & Manufacturing	46	43	38	42	53
<i>Backlog</i>	5	2	0	0	0
Comparative Studies	71	65	77	88	89
<i>Backlog</i>	7	2	0	0	0
Labelling Only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

SANDS: Review Workload by Fee Category

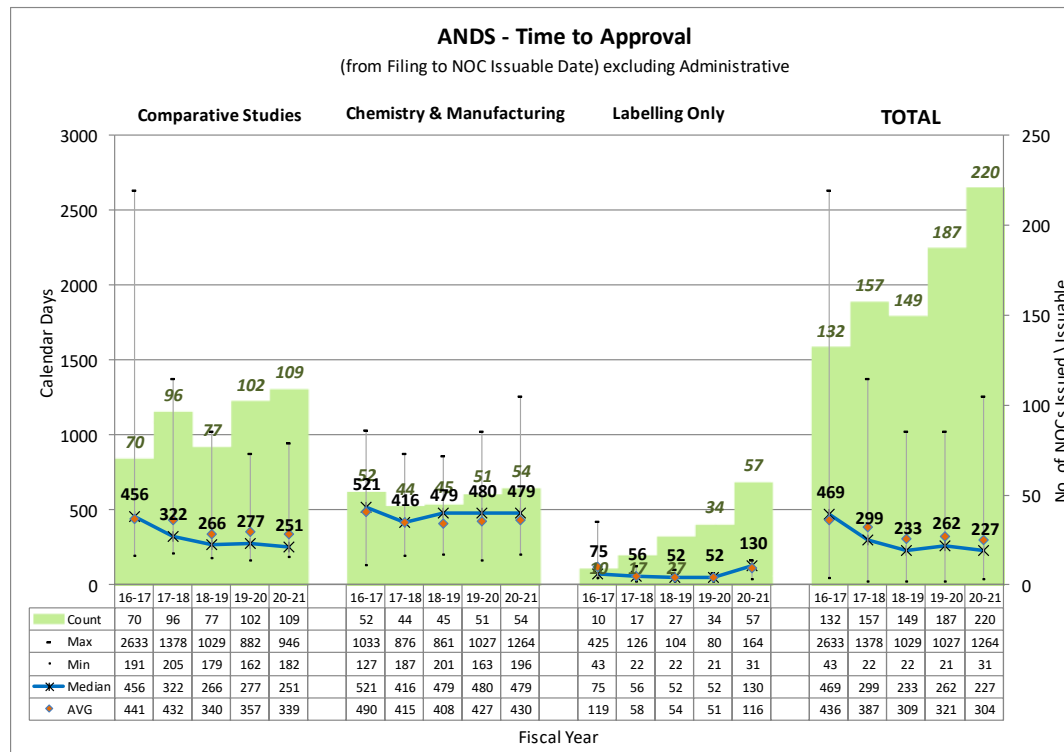
SANDS: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Chemistry & Manufacturing	32	26	22	24	30
<i>Backlog</i>	1	0	0	0	0
Comparative Studies	4	2	2	3	1
<i>Backlog</i>	0	0	0	0	0
Labelling Only	30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

APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



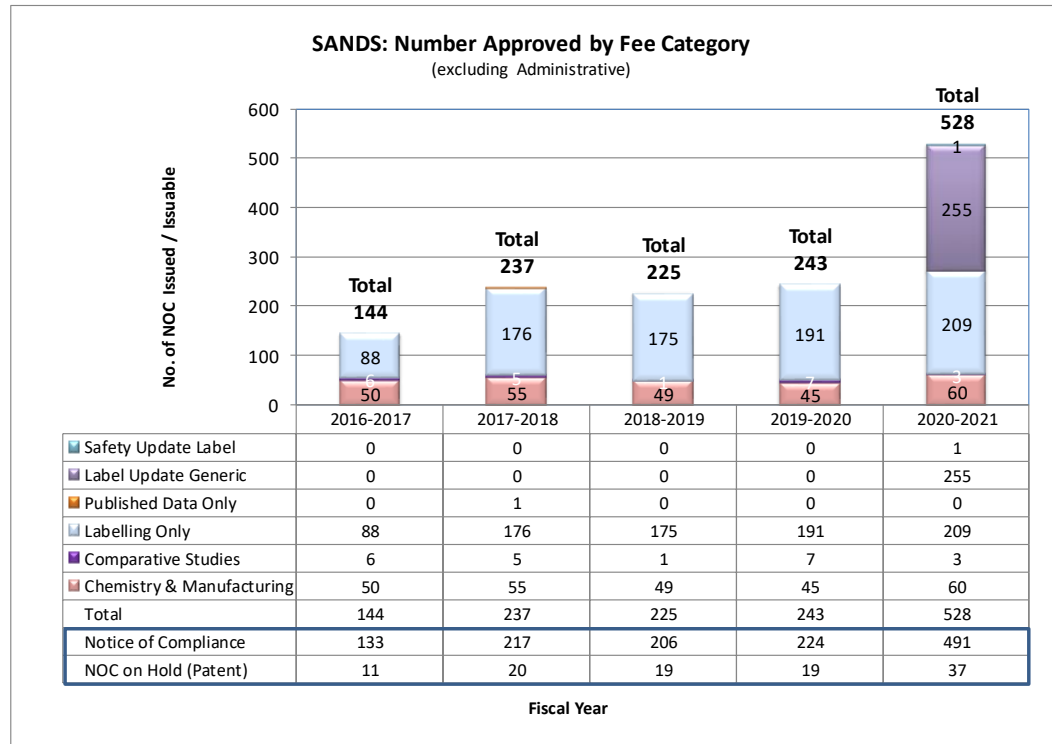
ANDS Approval Times



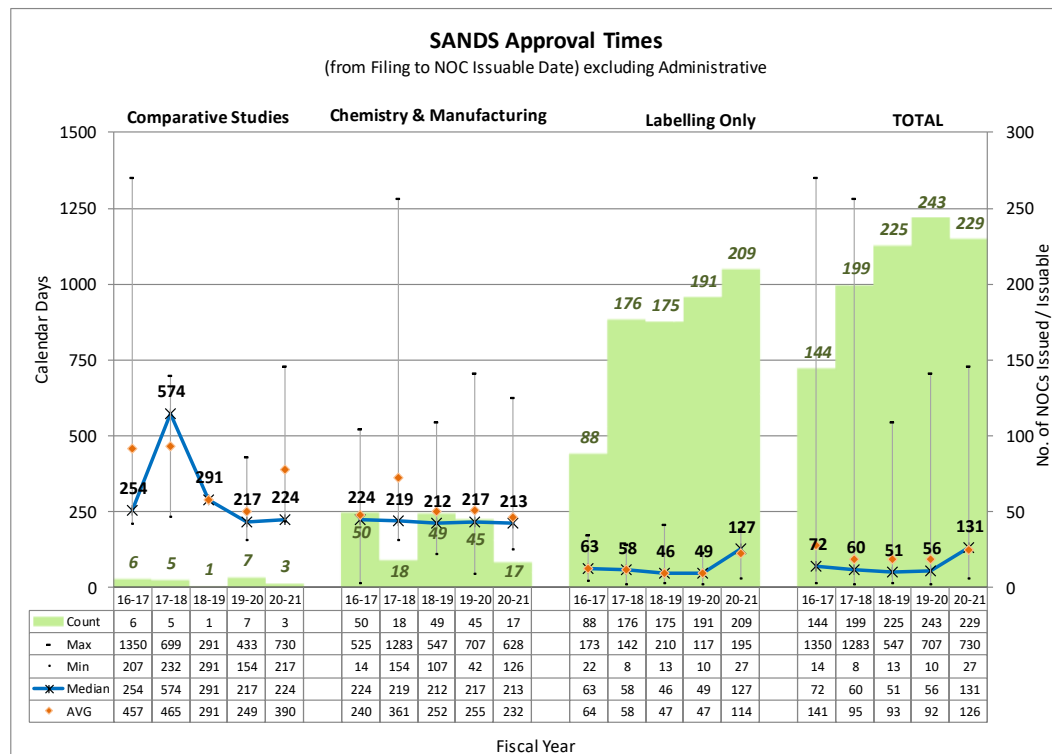
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

APPROVALS

SANDS: Number Approved by Fee Category and by NOC Type



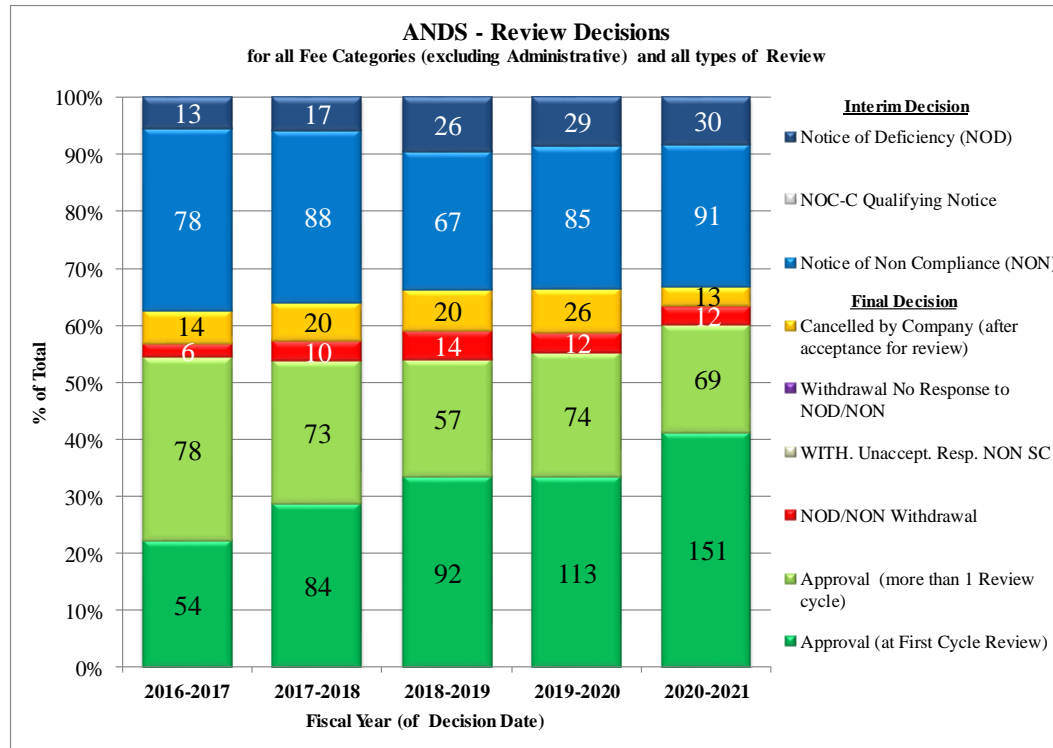
SANDS Approval Times



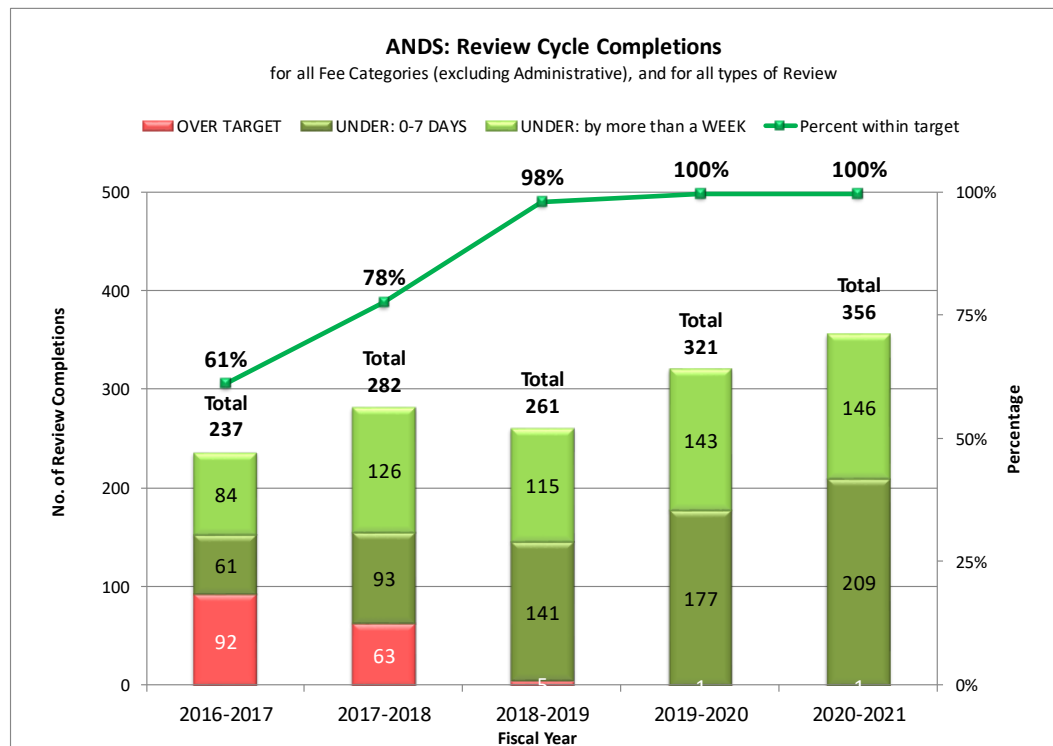
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

REVIEW PERFORMANCE

ANDS: Review Decisions by Type

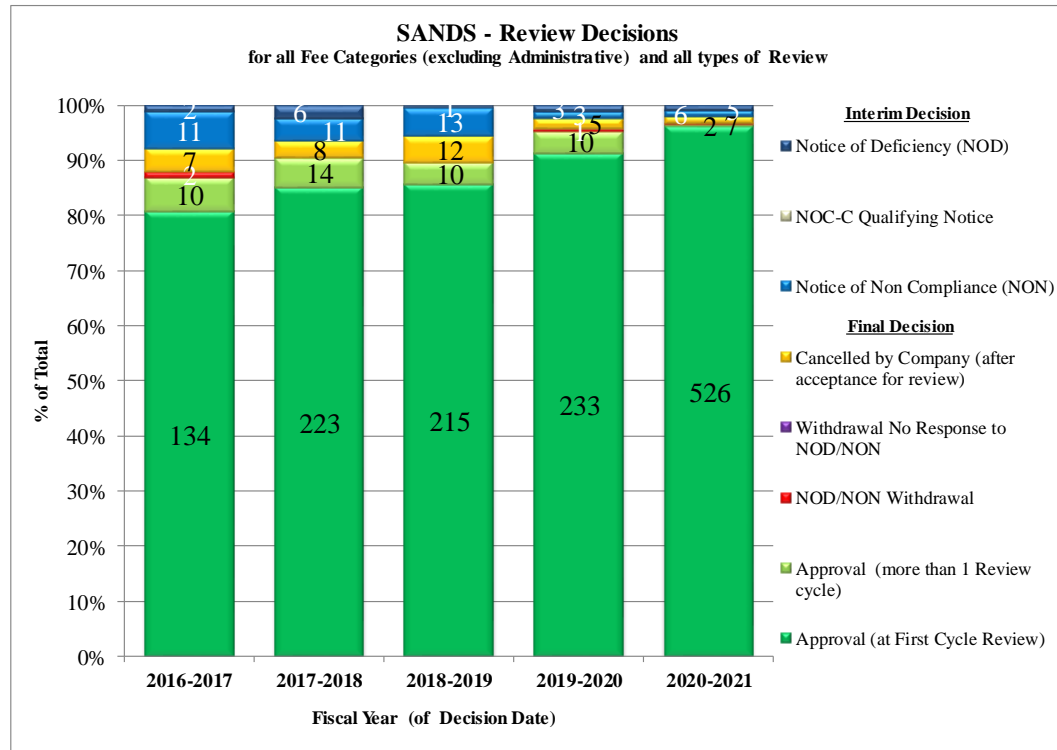


ANDS: Review Cycle Completions

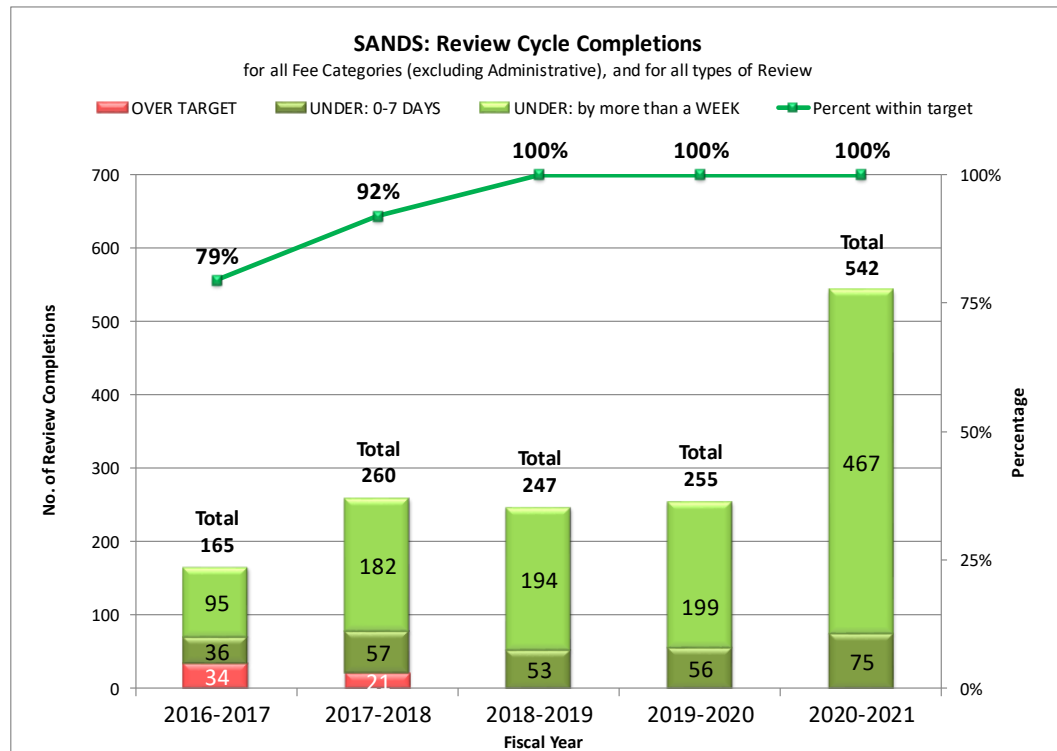


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

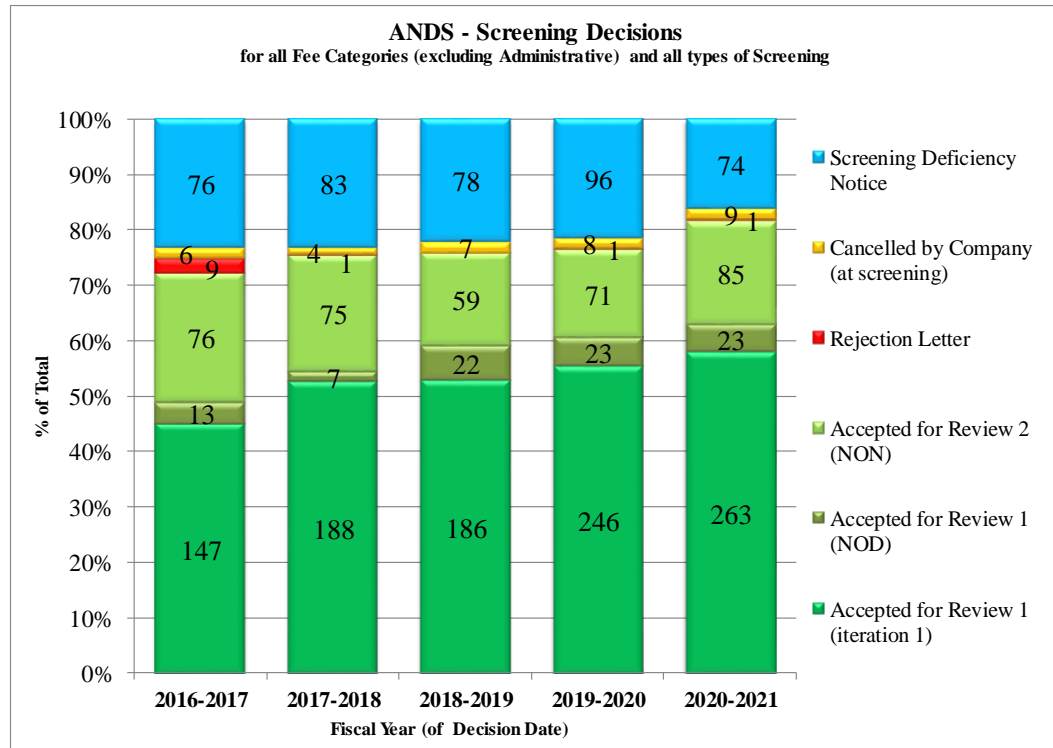


SANDS: Review Cycle Completions

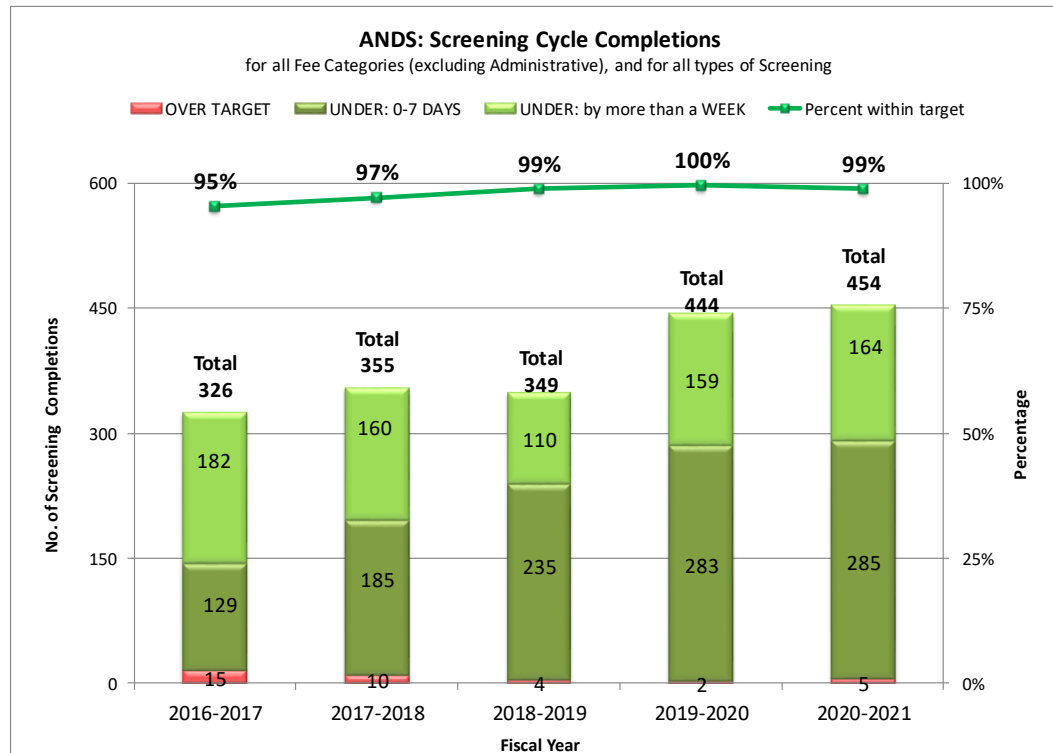


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

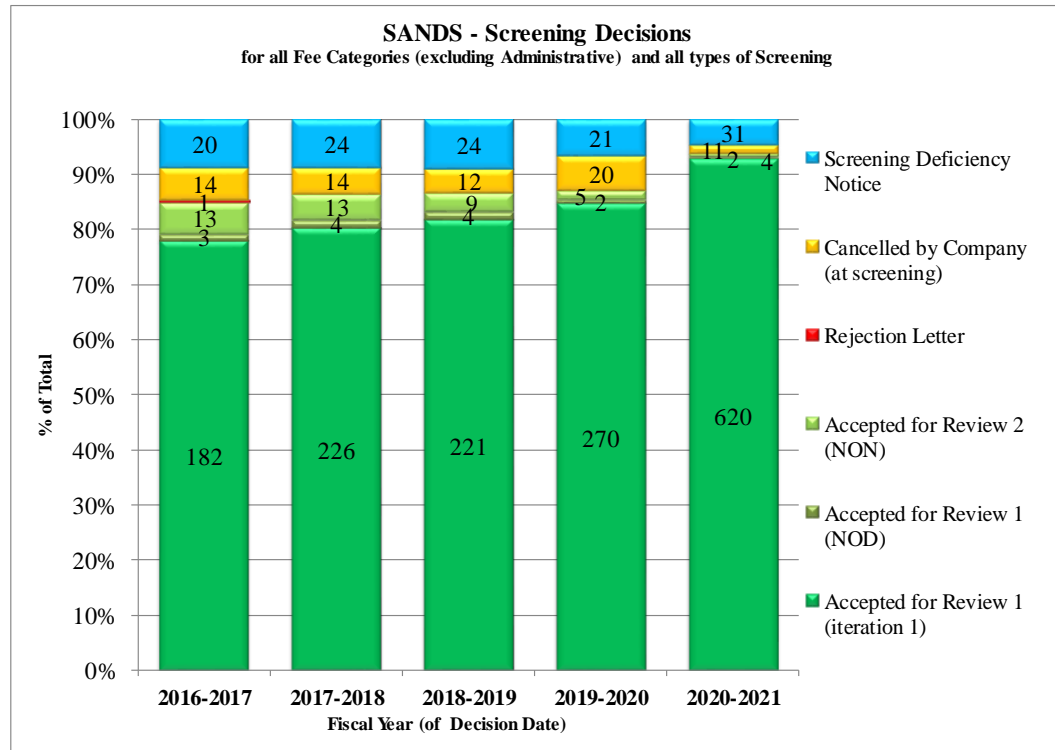


ANDS: Screening Cycle Completions

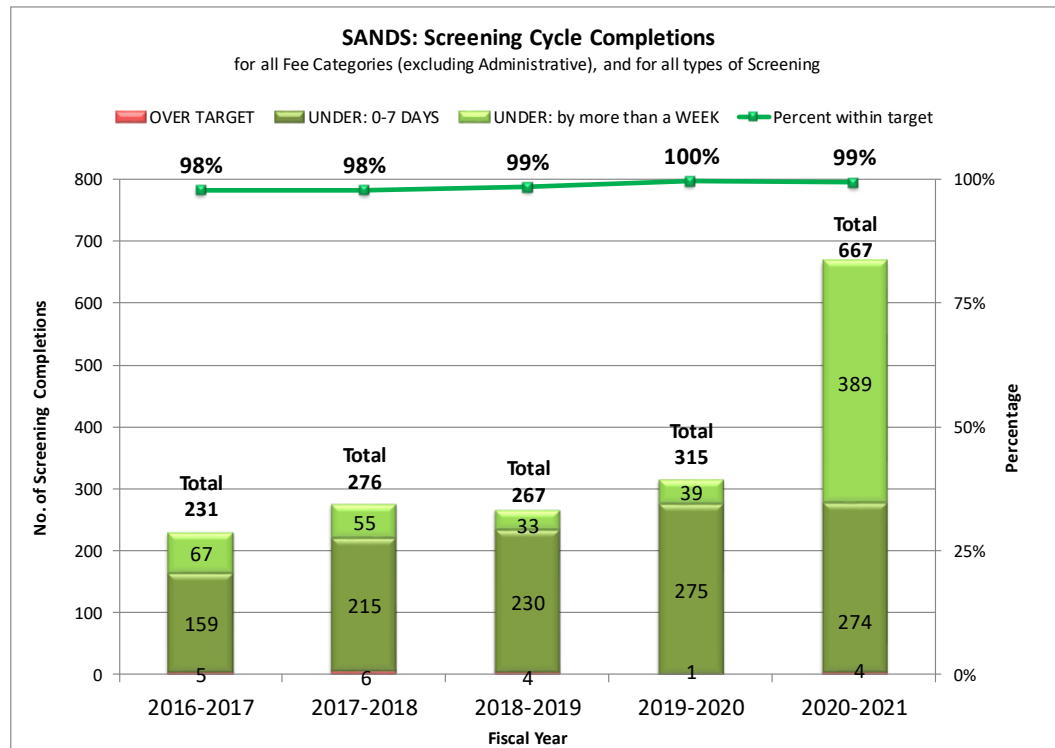


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type



SANDS: Screening Cycle Completions



REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

ANDS: Request for Reconsideration of Final Decisions

ANDS - Reconsideration of Final Decisions Requests Received							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	ANDS Status (as of June 2021)
TOTAL Received	2	0	3	2	0		
<i>Total Pending</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>		
Pending	0	0	1	0	0	NON-Withdrawal	Under Reconsideration
<i>Total Granted</i>	<i>1</i>	<i>0</i>	<i>2</i>	<i>0</i>	<i>0</i>		
Granted	0	0	0	0	0	NOD-Withdrawal	Cleared
Granted	0	0	2	0	0	NON-Withdrawal	Cleared
Granted	1	0	0	0	0	Rejection at Screening	Cleared
<i>Total Denied</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>		
Denied	0	0	0	0	0	Rejection at Screening	Rejected
Denied	0	0	0	0	0	Rejection at Screening	Cancelled by Company
Denied	0	0	0	0	0	NOD-Withdrawal	Withdrawn
Denied	0	0	0	0	0	NON-Withdrawal	Withdrawn
<i>Total Cancelled</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>2</i>	<i>0</i>		
Cancelled by Health Canada	0	0	0	0	0	NOD-Withdrawal	Cleared
Cancelled by Health Canada	0	0	0	0	0	NOD-Withdrawal	Withdrawn
Cancelled by Health Canada	0	0	0	0	0	NON-Withdrawal	Cleared
Cancelled by Health Canada	0	0	0	0	0	NON-Withdrawal	Withdrawn
Cancelled by Health Canada	0	0	0	0	0	Rejection at Screening	Cleared
Cancelled by Company	1	0	0	2	0	NOD-Withdrawal	Withdrawn

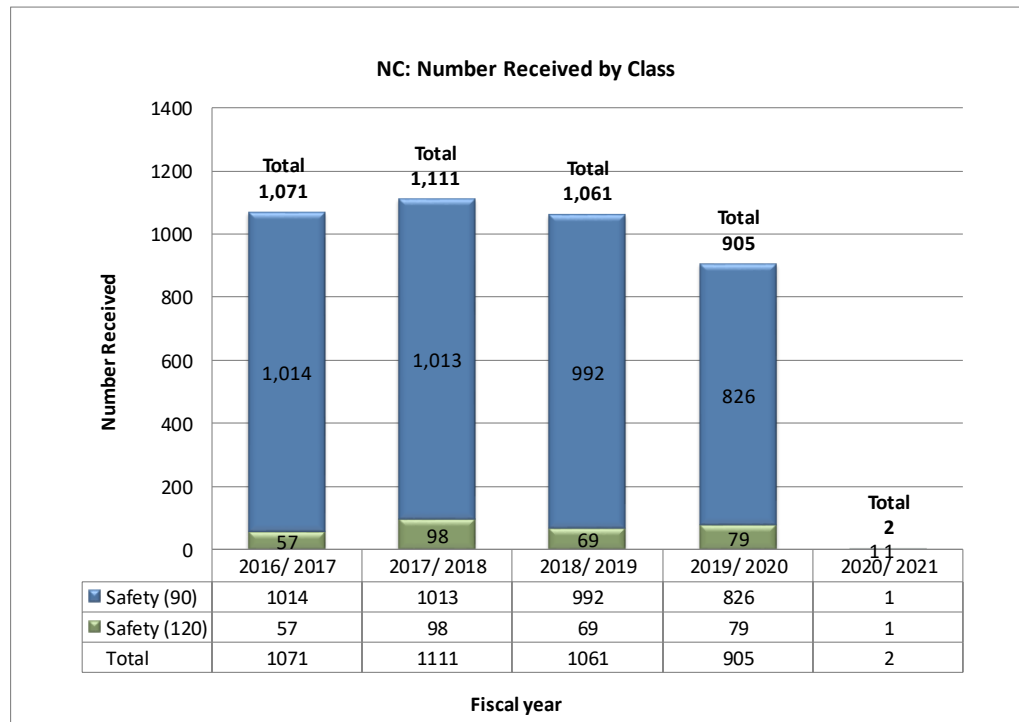
SANDS: Request for Reconsideration of Final Decisions

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

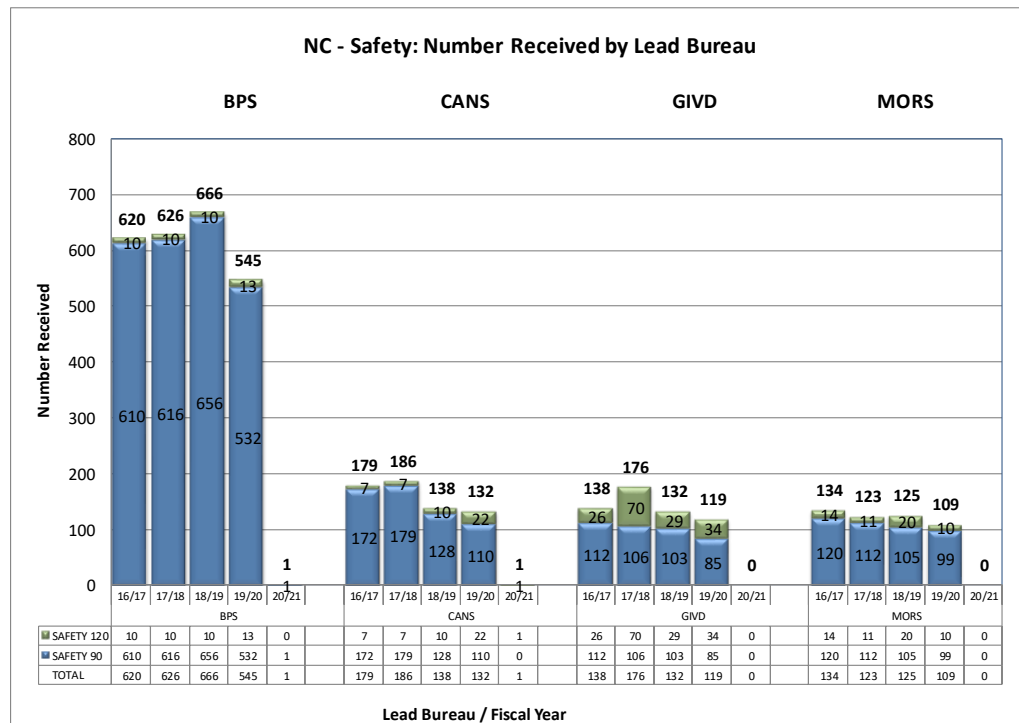
NC: NOTIFIABLE CHANGE

NOTIFIABLE CHANGES RECEIVED

NC: Number Received by Class



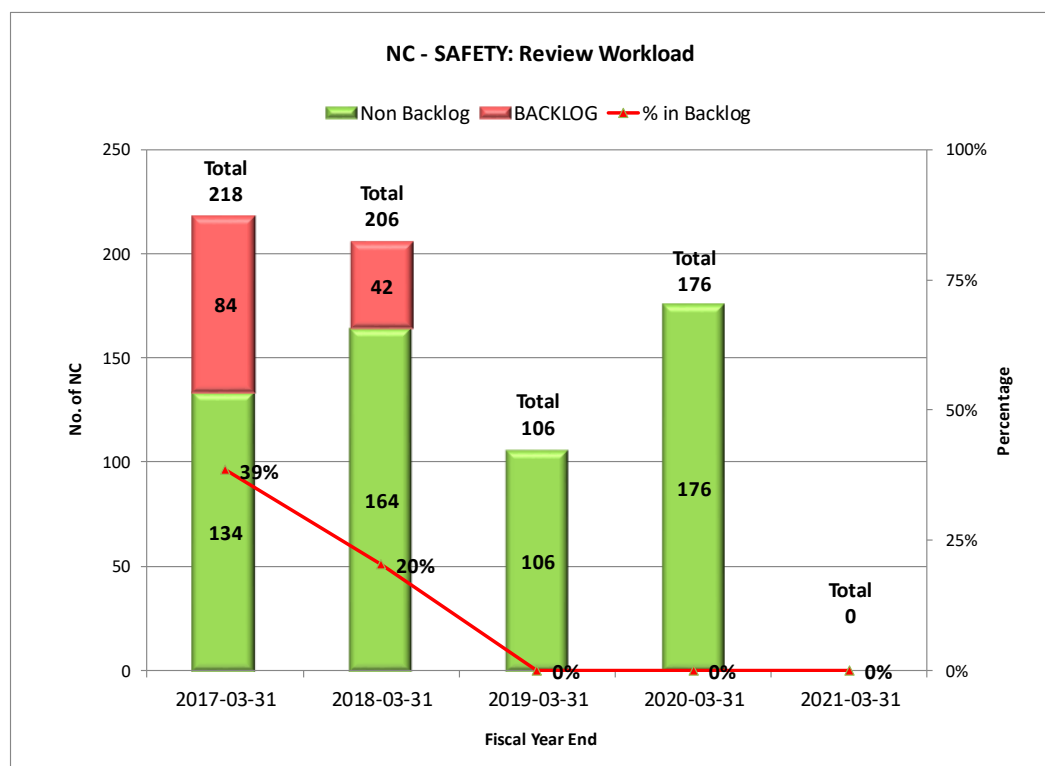
NC-SAFETY: Number Received by Lead Bureau



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

WORKLOAD

NC-SAFETY: Review Workload

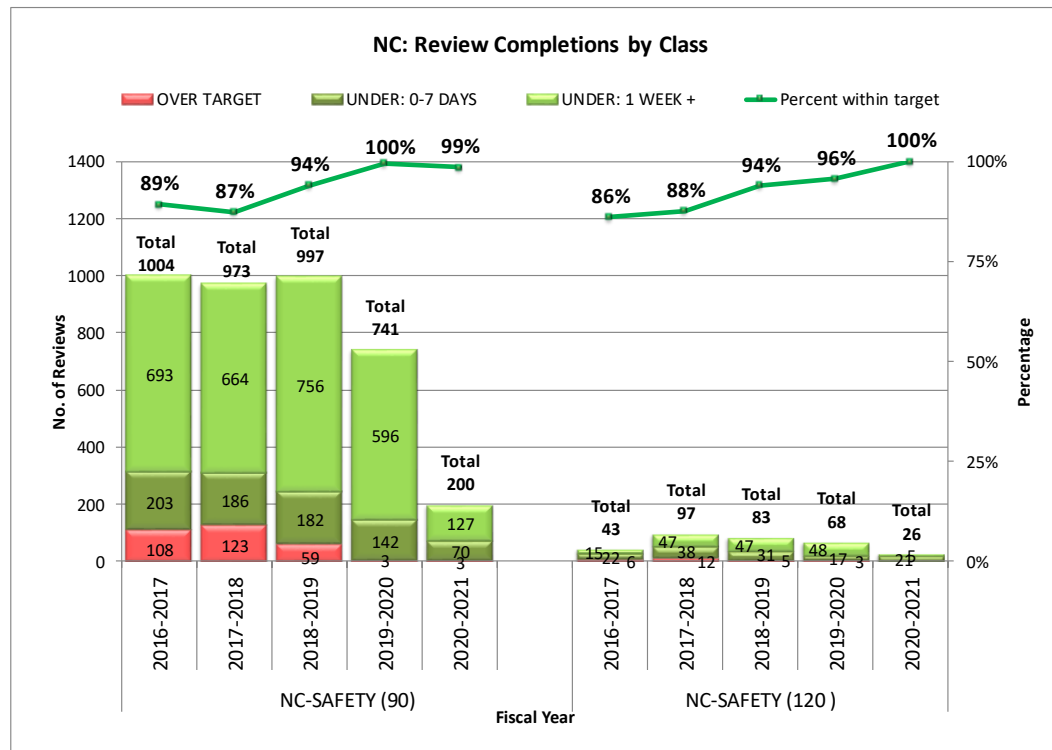


NC-SAFETY: Review Workload by Class

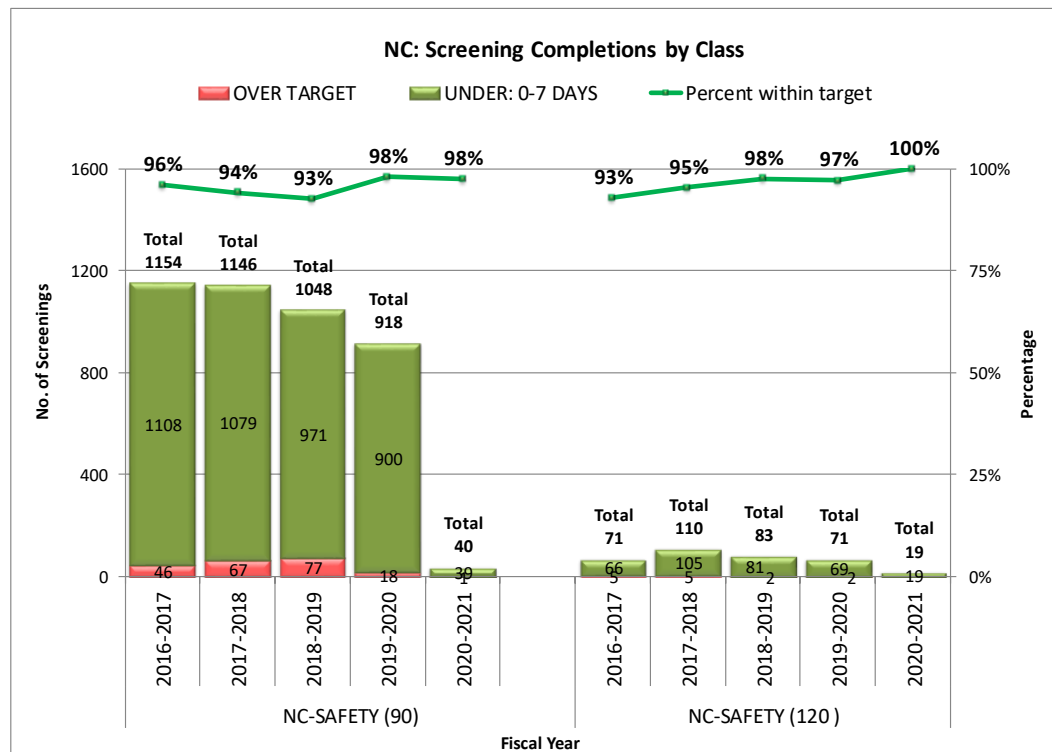
TPD NC- SAFETY: REVIEW WORKLOAD AT FISCAL YEAR END					
CLASS	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
SAFETY - 90 day	188	184	95	166	0
Backlog	78	39	0	0	0
SAFETY - 120 day	30	22	11	10	0
Backlog	6	3	0	0	0
Total	218	206	106	176	0
Non Backlog	134	164	106	176	0
BACKLOG	84	42	0	0	0
% in Backlog	39%	20%	0%	0%	0%

PERFORMANCE

NC-SAFETY: Review Completions by Class



NC-SAFETY: Screening Completions by Class



DECISIONS**NC-SAFETY: Number of Decisions by Class**

NC - SAFETY (90)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	954	990	977	736	201
CANCELLED BY COMPANY	65	66	63	43	6
NC - HOLD (PATENT)	69	46	35	23	1
SCREEN. DEFICIENCY NOTICE	136	161	115	90	5
REJECTION LETTER (SCR)	2	3	2	1	0
NOT SATISFACTORY NOTICE	2	0	1	0	0
NC - SAFETY (120)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	43	90	81	62	26
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	11	20	11	4	2
CANCELLED BY COMPANY	4	8	2	7	1
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	1	2	0

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS**NC: Request for Reconsideration of Final Decisions**

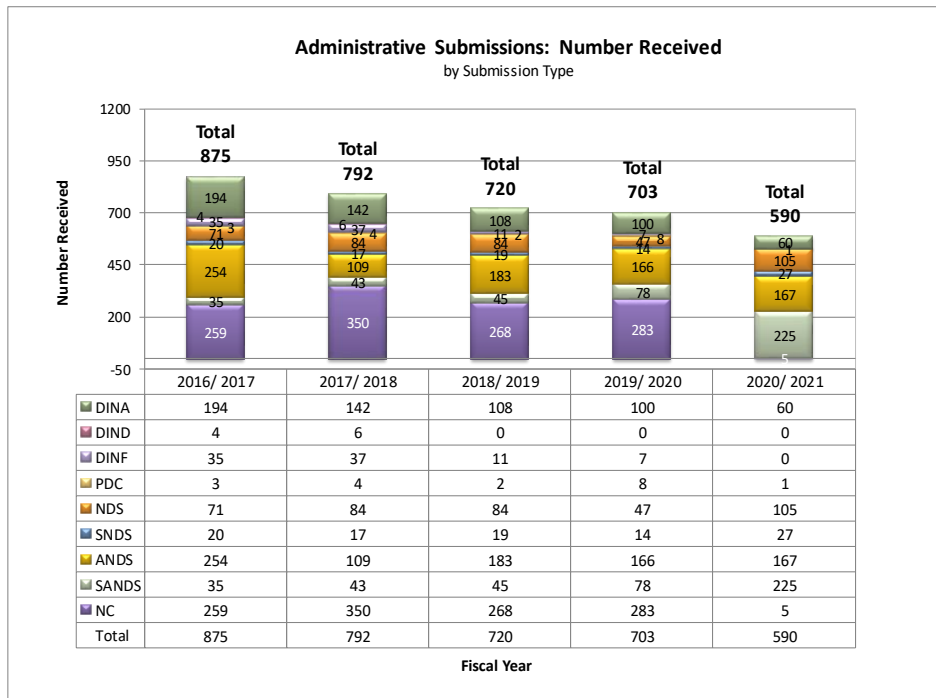
NC - Requests for Reconsideration of Final Decisions					
Fiscal Year of Request (April 1 - March 31)					
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Total Received	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS

Submissions in support of a manufacturer or product name change.

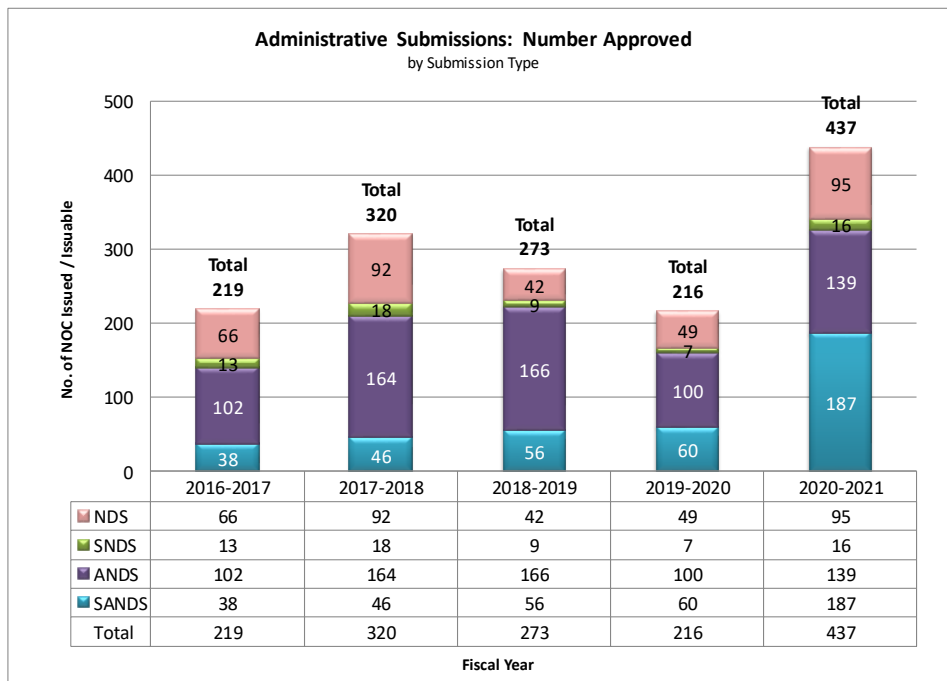
ADMINISTRATIVE SUBMISSIONS¹¹ RECEIVED

Administrative Submissions: Number Received by Submission Type



APPROVALS

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



¹¹ The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling areas of the Bureau of Gastroenterology, Infection and Viral Disease (BGIVD) at TPD in December 2018 and to the NNHPD for non-prescription products.

DECISIONS

Administrative Submissions (Division 8): Number of Decisions

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

DECISIONS

Administrative Applications (Division 1): Number of Decisions

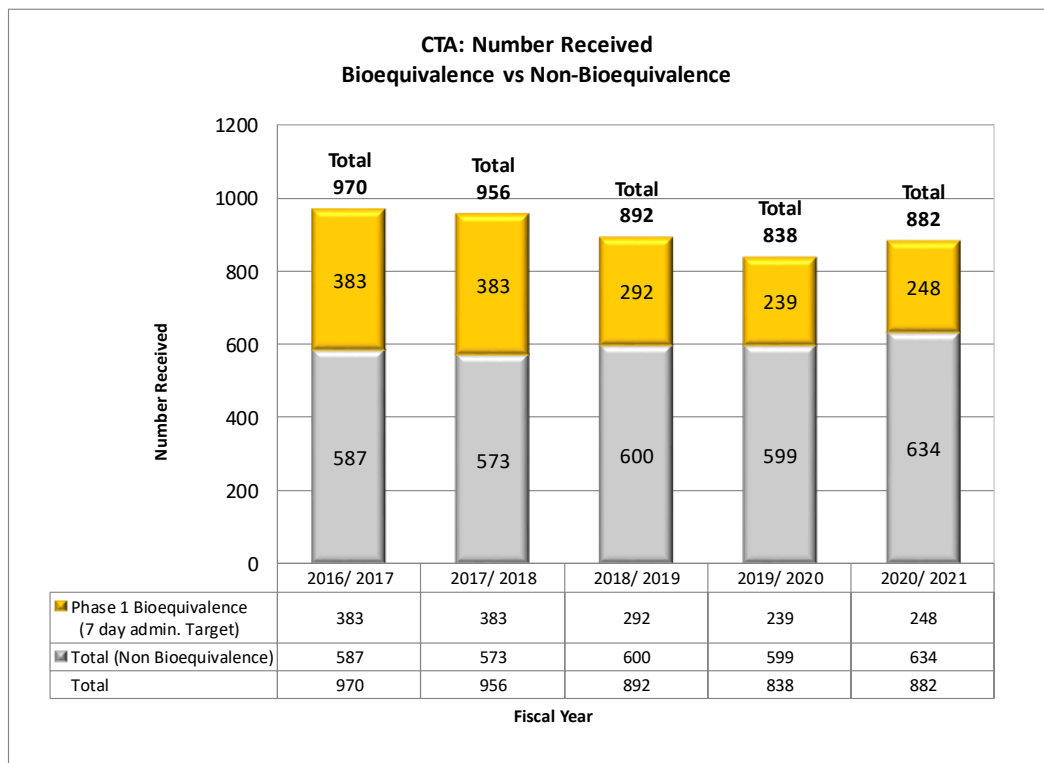
SUBMISSION TYPE - DOCUMENT TYPE	2016- 2017	2017- 2018	2018- 2019	2019- 2020	2020- 2021
DINA - Administrative					
NOTIFICATION FORM/DIN ISSUED	104	124	84	37	46
NO OBJECTION LETTER	0	0	2	1	1
SCREEN. DEFICIENCY NOTICE	63	11	8	0	0
CANCELLATION LETTER	4	8	11	20	11
PROCESSING HOLD LETTER	76	54	27	30	4
DIND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

Clinical Trial Applications and Amendments

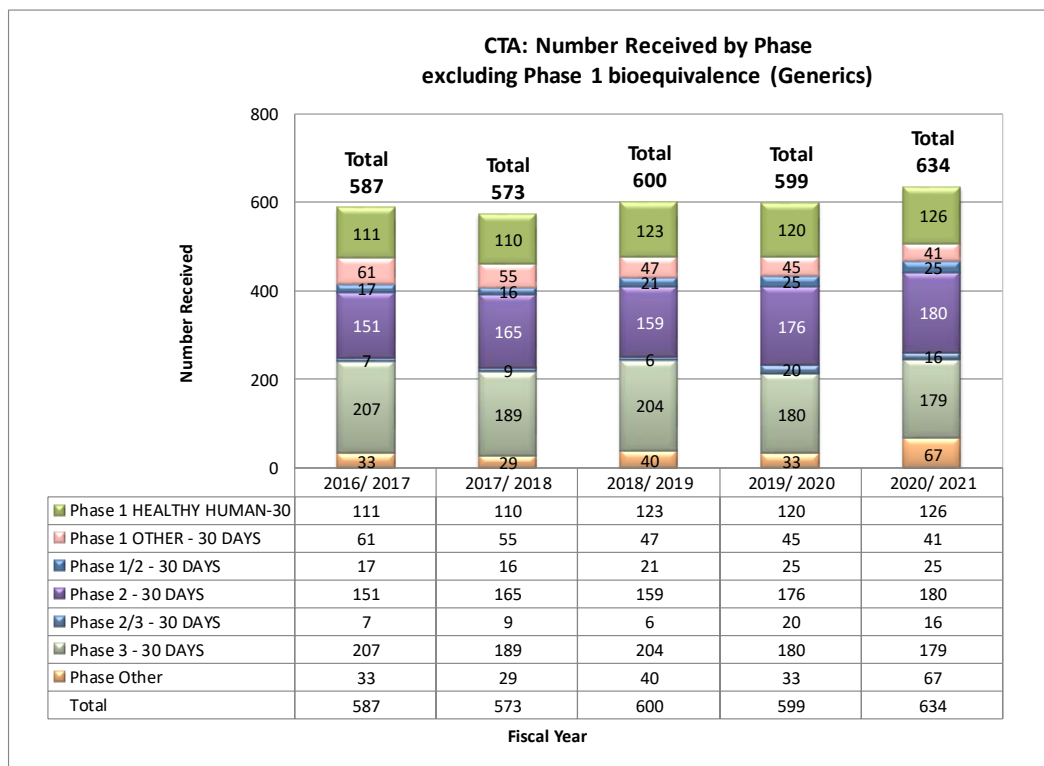
(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS RECEIVED

CTA: Number Received



CTA: Number Received by Phase excluding Bioequivalence (Generics)



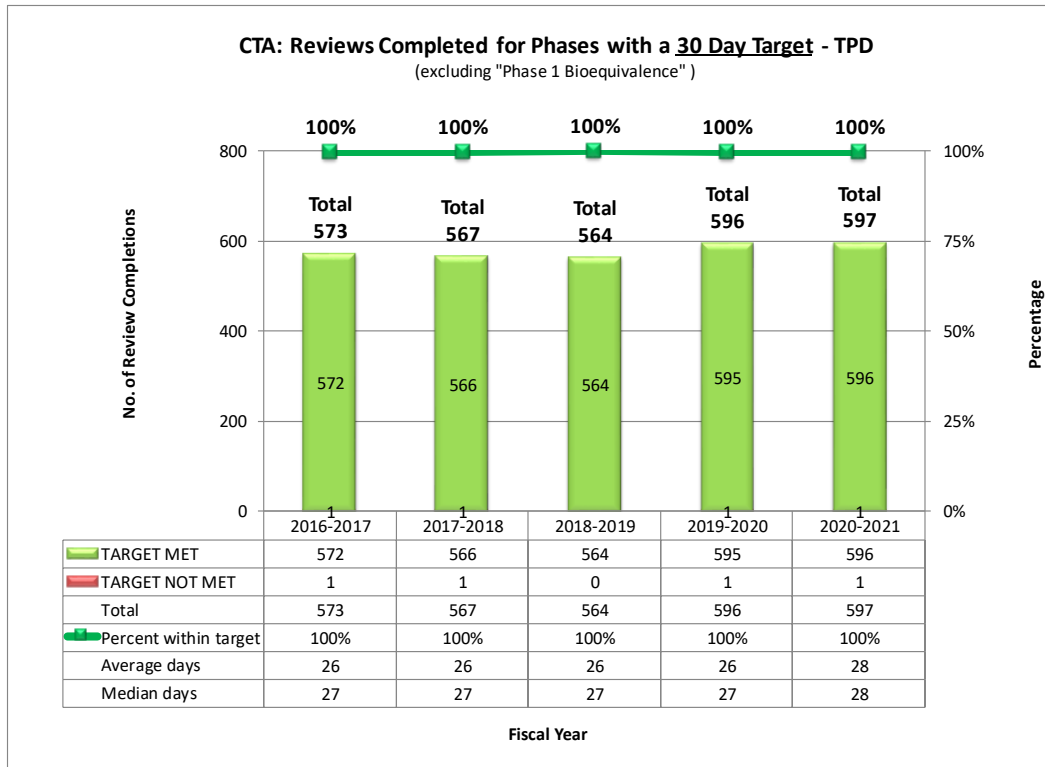
DECISION DOCUMENTS

CTA: Number of Decisions by Type

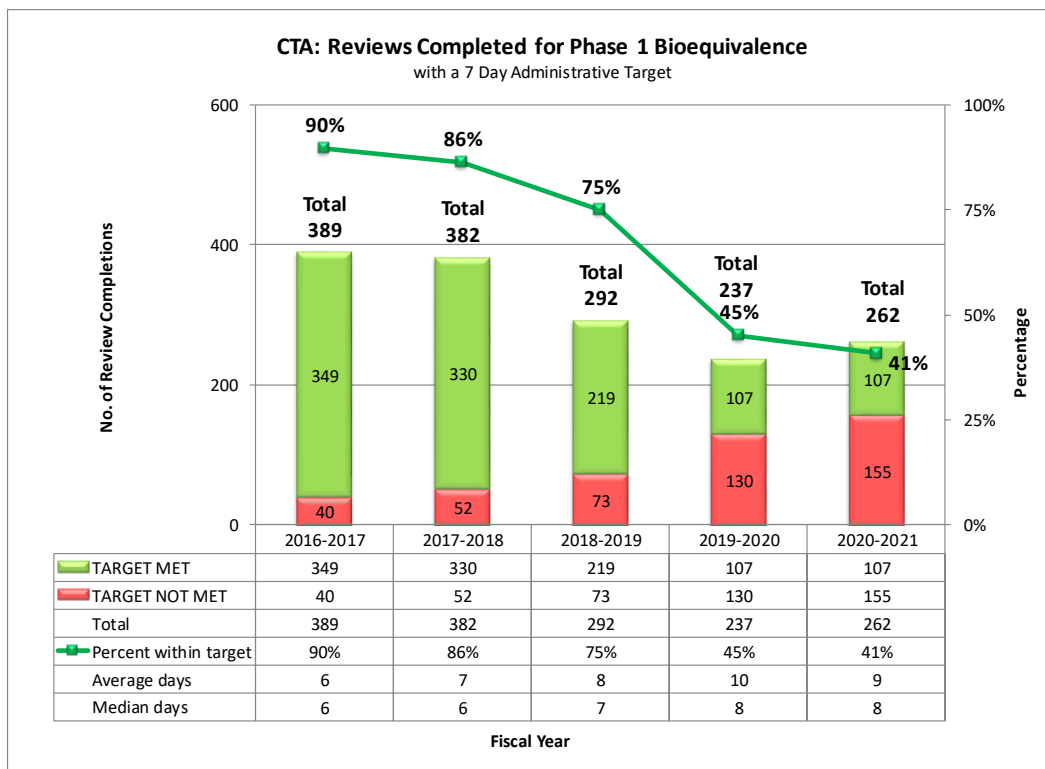
CTA (Total)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	926	898	821	775	803
NOTICE OF AUTHORIZATION	0	0	0	0	9
CANCELLED BY COMPANY DURING REVIEW	36	53	37	60	47
CANCELLED BY COMPANY AT PROCESSING	4	11	11	15	12
CTA Phase 1 Bioequivalence (7 day administrative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

PERFORMANCE

CTA: Reviews Completed for Phases with a 30 Day Target

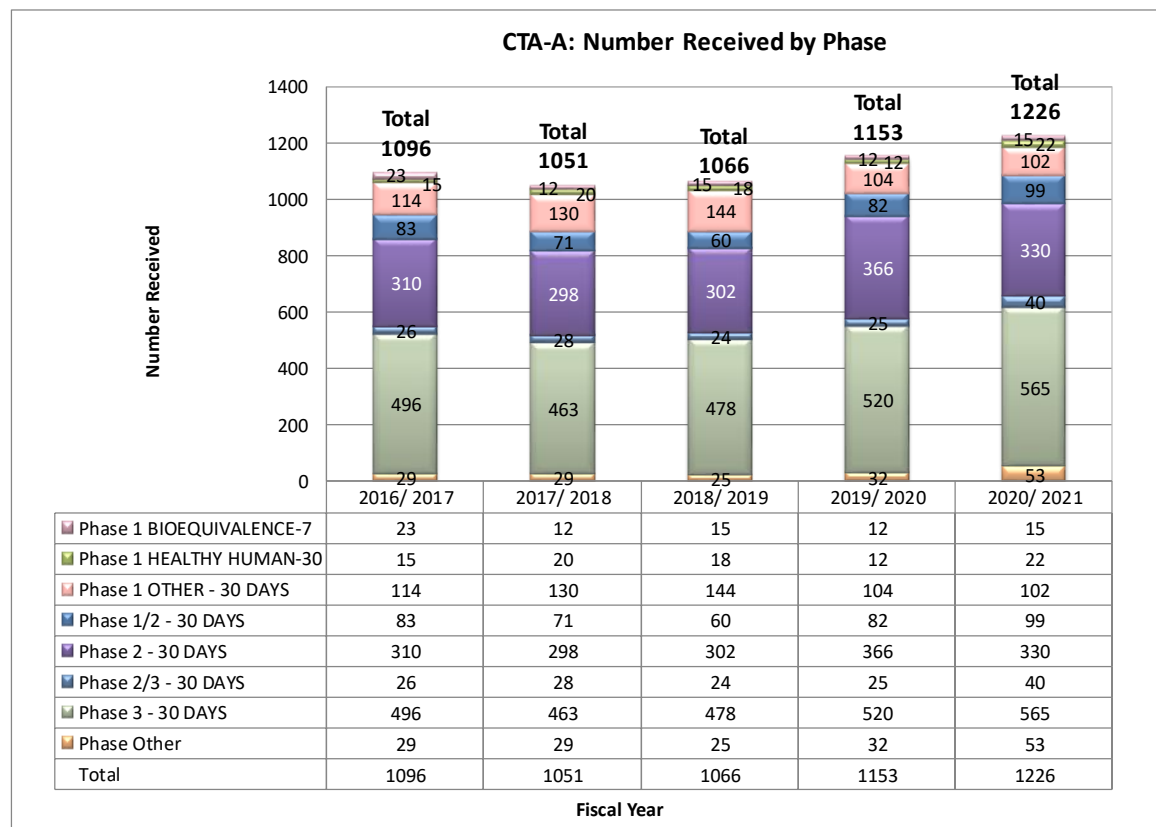


CTA: Reviews Completed for Phases with a 7 Day Administrative Target



CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS RECEIVED

CTA-A: Number Received by Phase



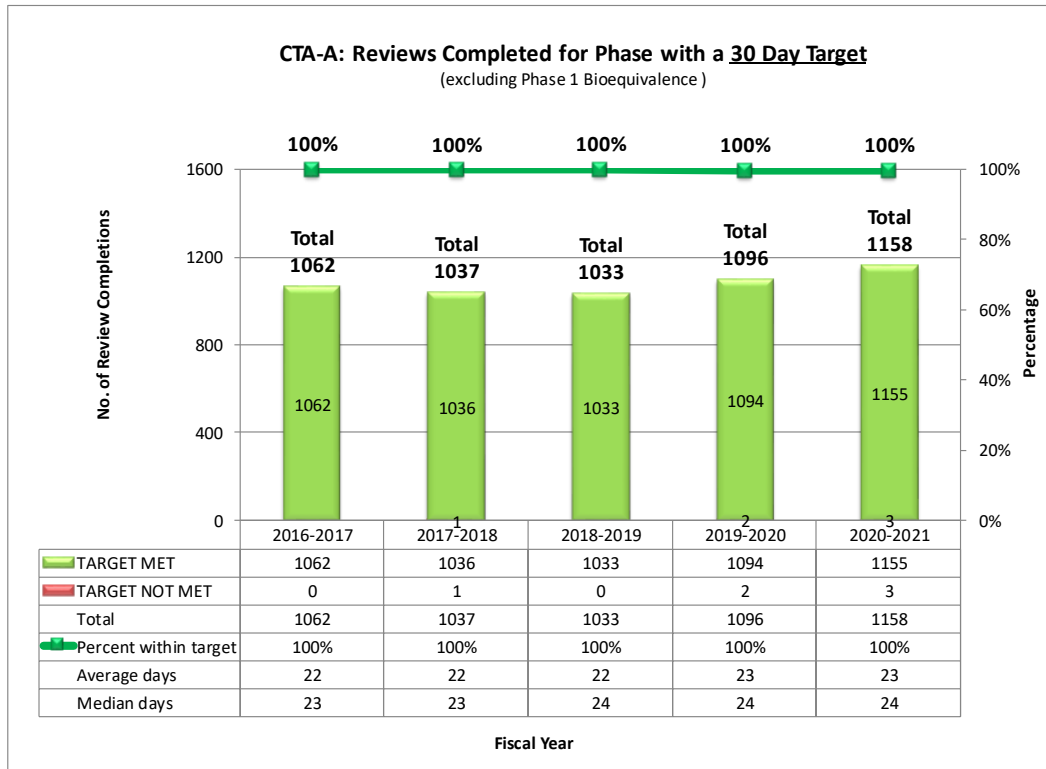
DECISIONS

CTA-A: Number of Decisions by Type

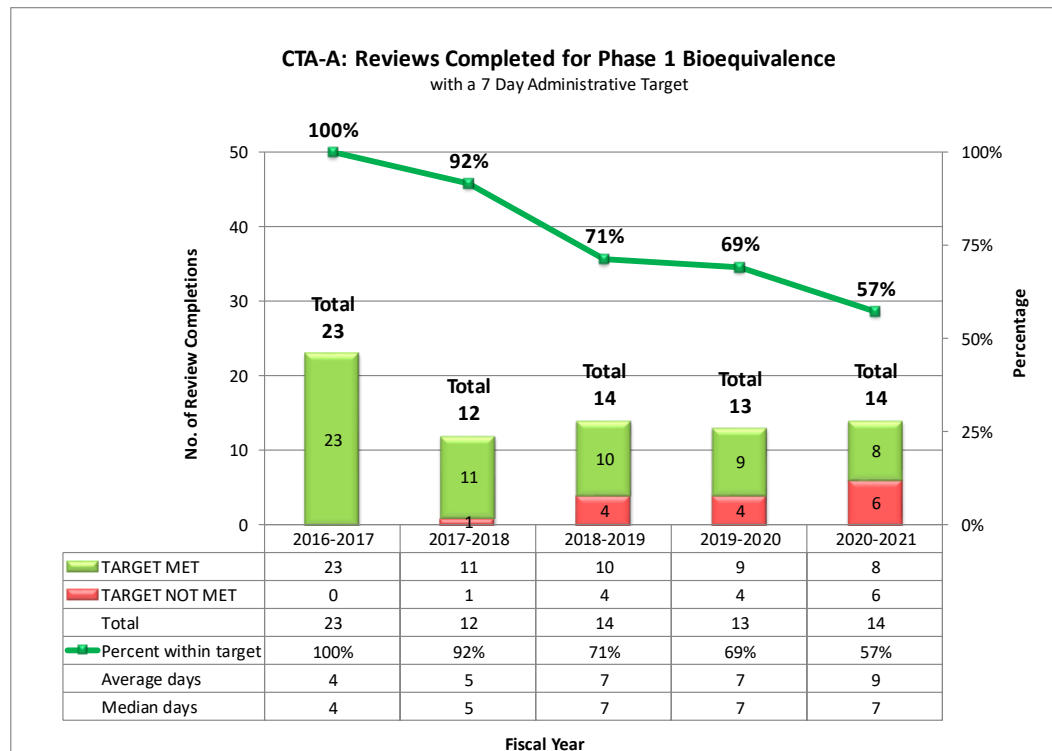
CTA-A (Total)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	1070	1037	1032	1079	1160
NOTICE OF AUTHORIZATION	0	0	0	0	10
CANCELLED BY COMPANY DURING REVIEW	15	11	15	30	16
CANCELLED BY COMPANY AT PROCESSING	0	1	3	33	50
CTA-A Phase 1 Bioequivalence (7 day administrative target)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	23	12	12	13	15
CANCELLED BY COMPANY DURING REVIEW	0	0	2	0	0
CANCELLED BY COMPANY AT PROCESSING	0	0	0	0	0
CTA-A (30 day target)					
DOCUMENT TYPE	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
NO OBJECTION LETTER	1047	1025	1020	1066	1145
CANCELLED BY COMPANY DURING REVIEW	15	11	13	30	16
CANCELLED BY COMPANY AT PROCESSING	0	1	3	33	50
NOT SATISFACTORY NOTICE	0	0	0	1	0
REJECTION LETTER (SCR)	0	0	0	1	0

PERFORMANCE

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

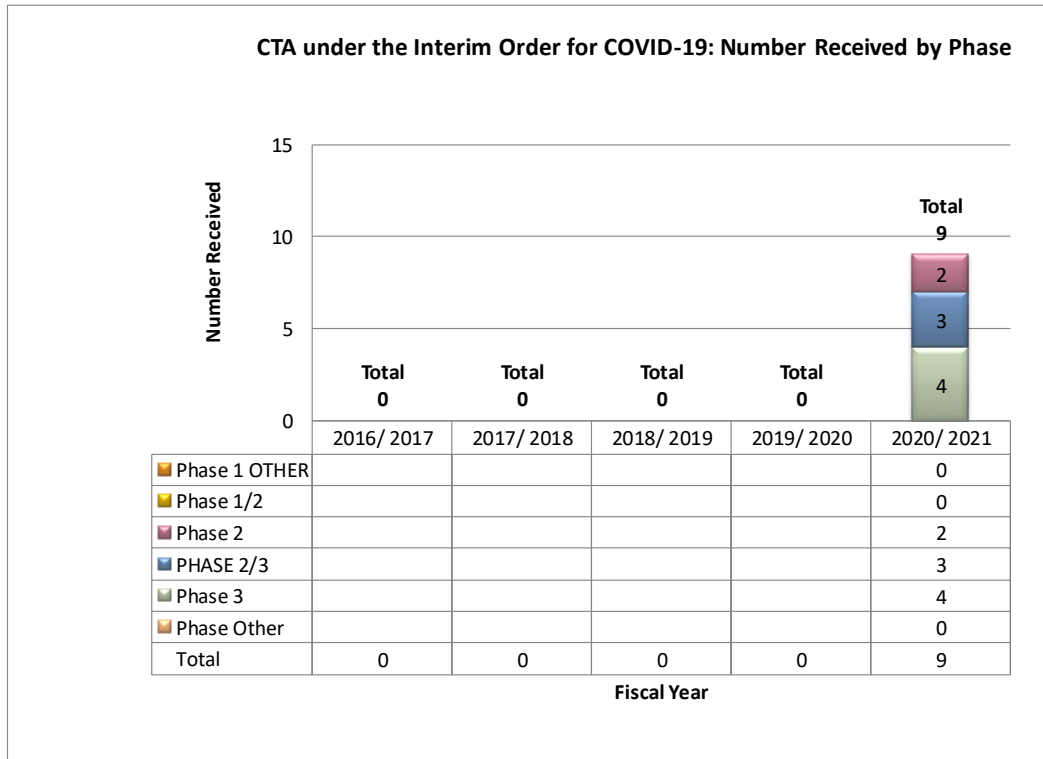


CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target

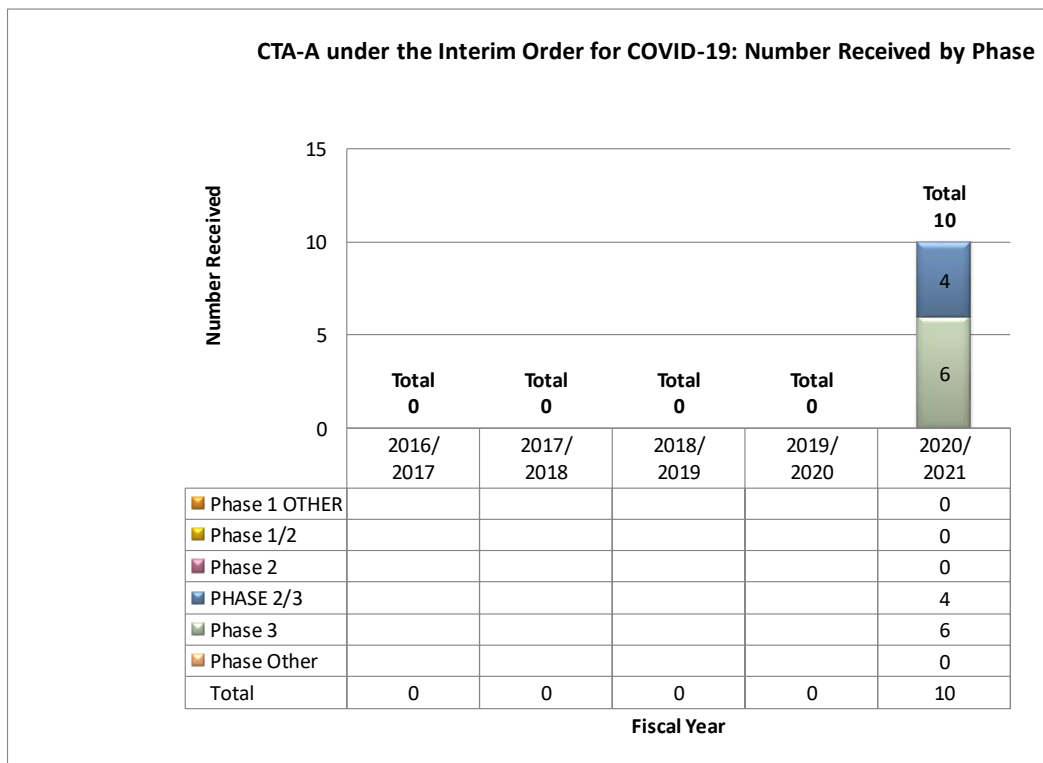


CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

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



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

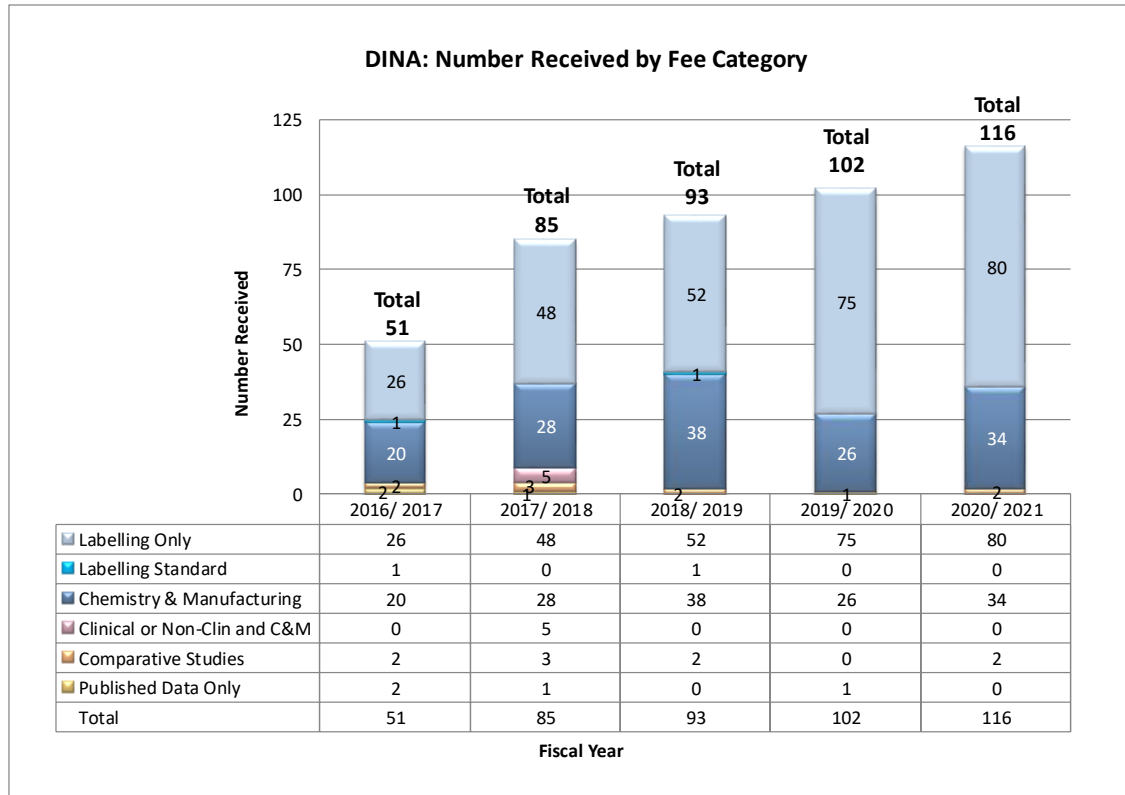


DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

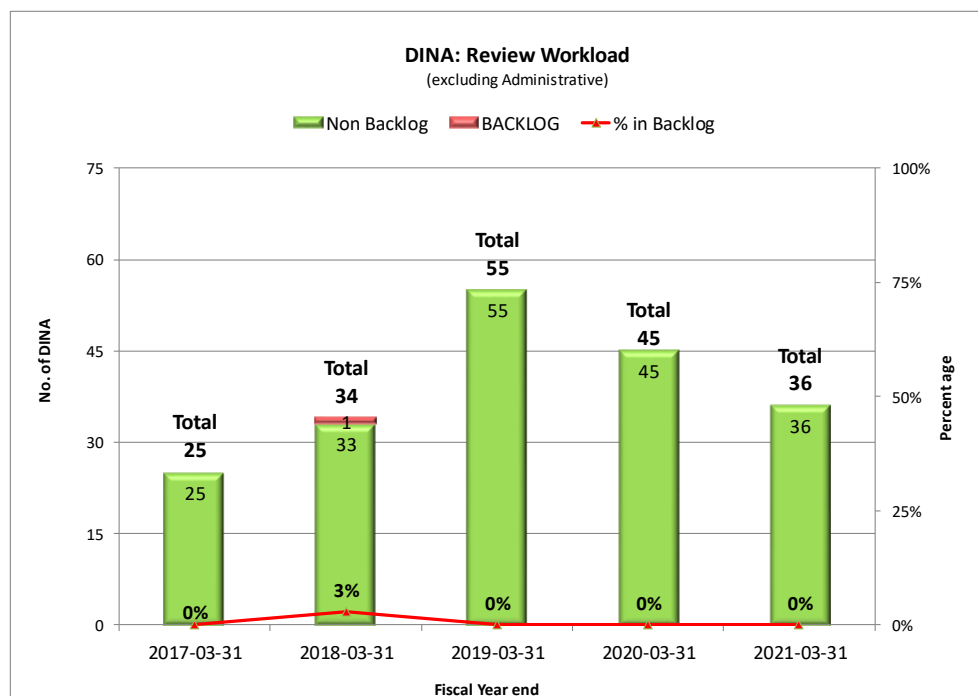
DINA: Number Received by Fee Category



TPD's non-prescription (or over-the-counter) and disinfectant drug review functions were moved to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013 and are now reported in the NNHPD Drug Submission Performance Annual Report.

REVIEW WORKLOAD

DINA: Review Workload

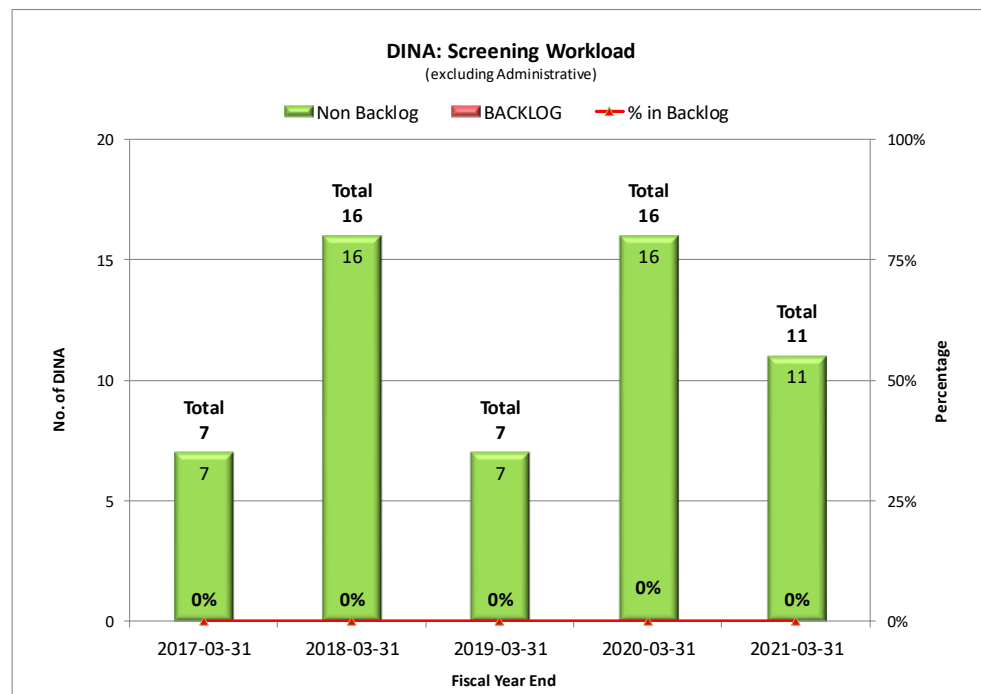


DINA: Review Workload by Fee Category

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

SCREENING WORKLOAD

DINA: Screening Workload



DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Only	4	8	3	10	7
<i>Backlog</i>	0	0	0	0	0
Labelling Standard	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	2	4	3	6	4
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clin and C&M	0	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	1	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	7	16	7	16	11
Non Backlog	7	16	7	16	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

DINA: Number of Decisions by Fee Category

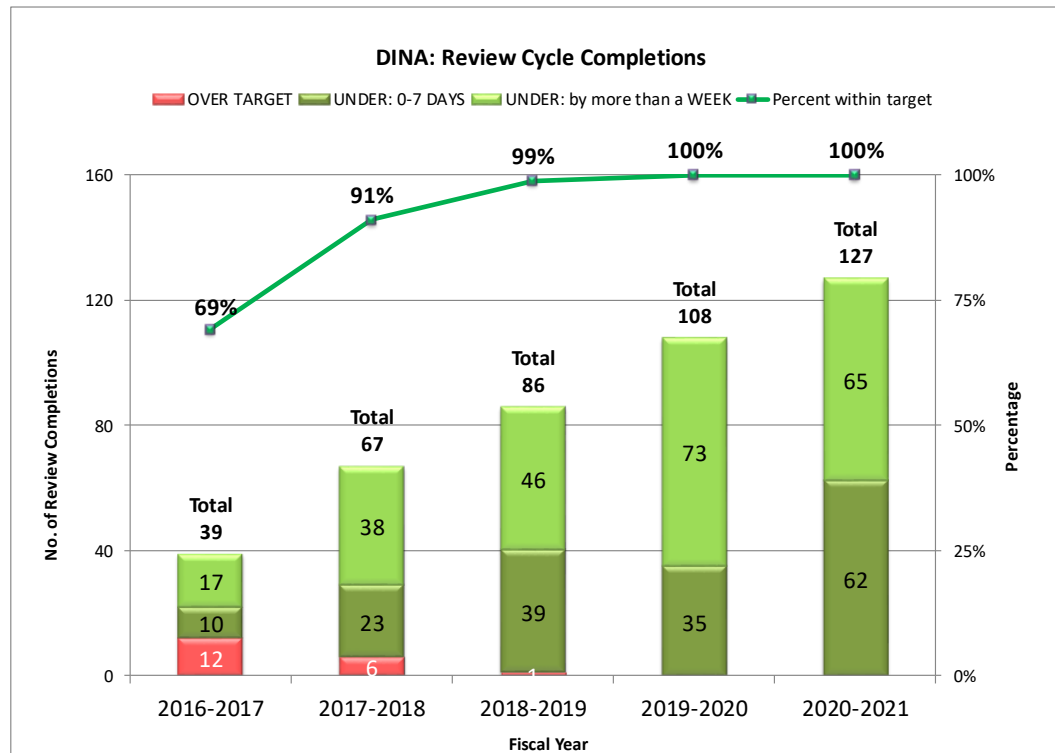
CATEGORY / DOCUMENT TYPE	2016- 2017	2017- 2018	2018- 2019	2019- 2020	2020- 2021
DINA - LABELLING ONLY					
NOTIFICATION FORM/DIN ISSUED	3	12	9	2	19
NO OBJECTION LETTER	4	25	29	59	71
CANCELLED BY COMPANY	6	3	7	2	6
NOTICE OF DEFICIENCY	1	-	-	-	1
NOTICE OF NON-COMPLIANCE	1	-	2	-	-
REJECTION LETTER (SCREENING)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

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS**DINA: Request for Reconsideration of Final Decisions**

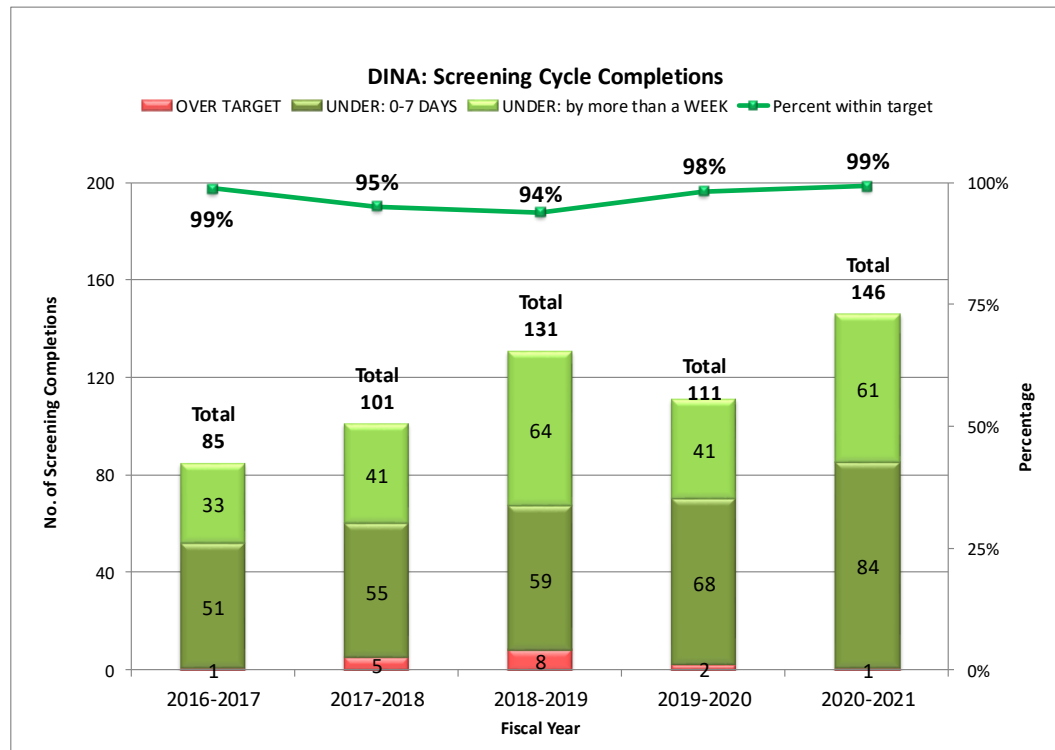
DINA - Reconsideration of Final Decisions by Year Requested							
Fiscal Year of Request (April 1 - March 31)							
Breakdown by Reconsideration Decision	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Final Decision in Dispute	Submission Status (as of June 2021)
Total Received	1	1	0	0	0		
<i>Total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

PERFORMANCE

DINA: Review Cycle Completions

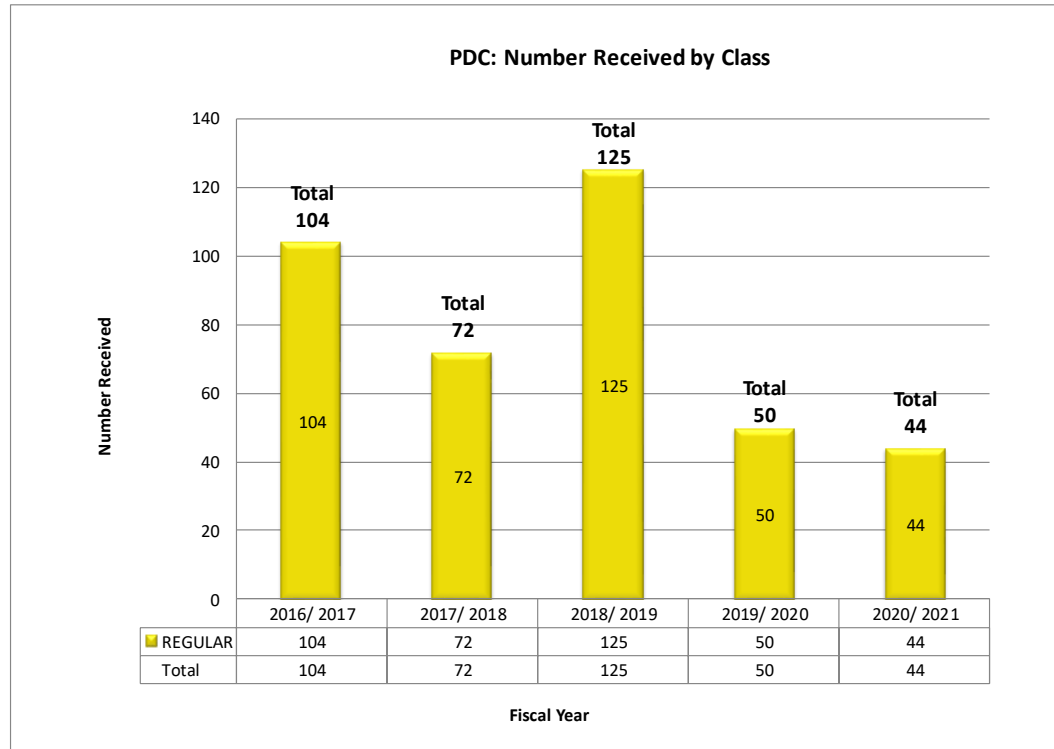


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE RECEIVED

PDC: Number Received



DECISIONS

PDC: Number of Decision by Type

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

REQUEST FOR RECONSIDERATION OF FINAL DECISIONS

PDC: Request for Reconsideration of Final Decisions

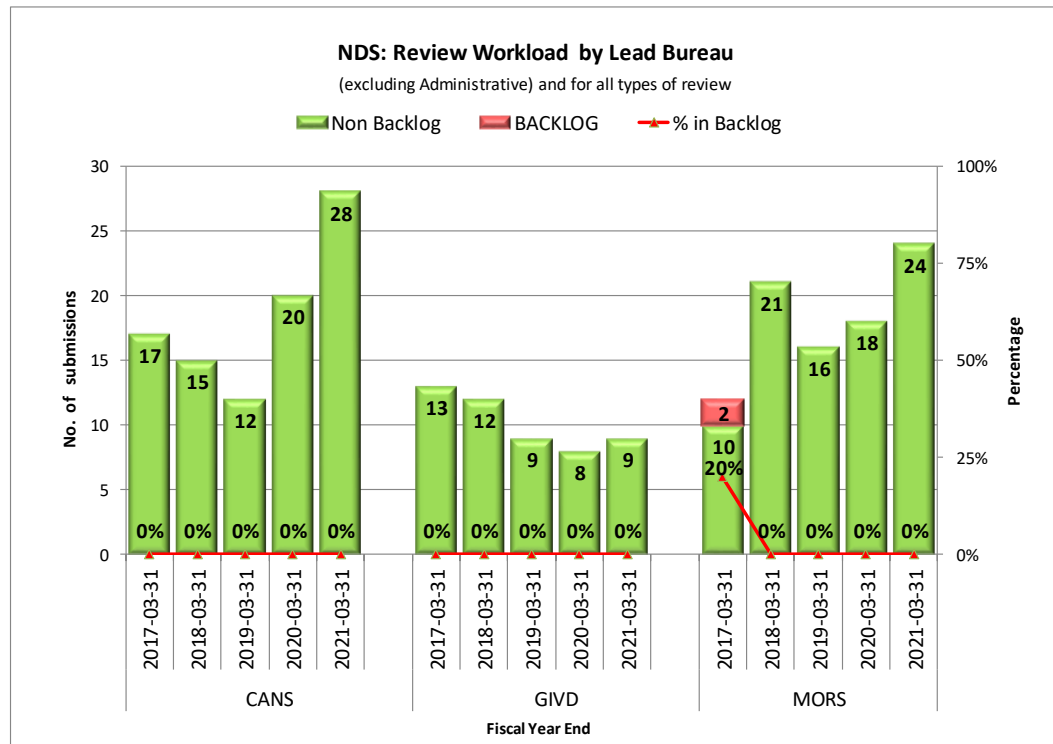
PDC - Reconsideration of Final Decisions by Year Requested					
Fiscal Year of Request (April 1 - March 31)					
	2016- 2017	2017- 2018	2018- 2019	2019- 2020	2020- 2021
Total Received	0	0	0	0	0

APPENDIX A - Lead Bureau Summaries

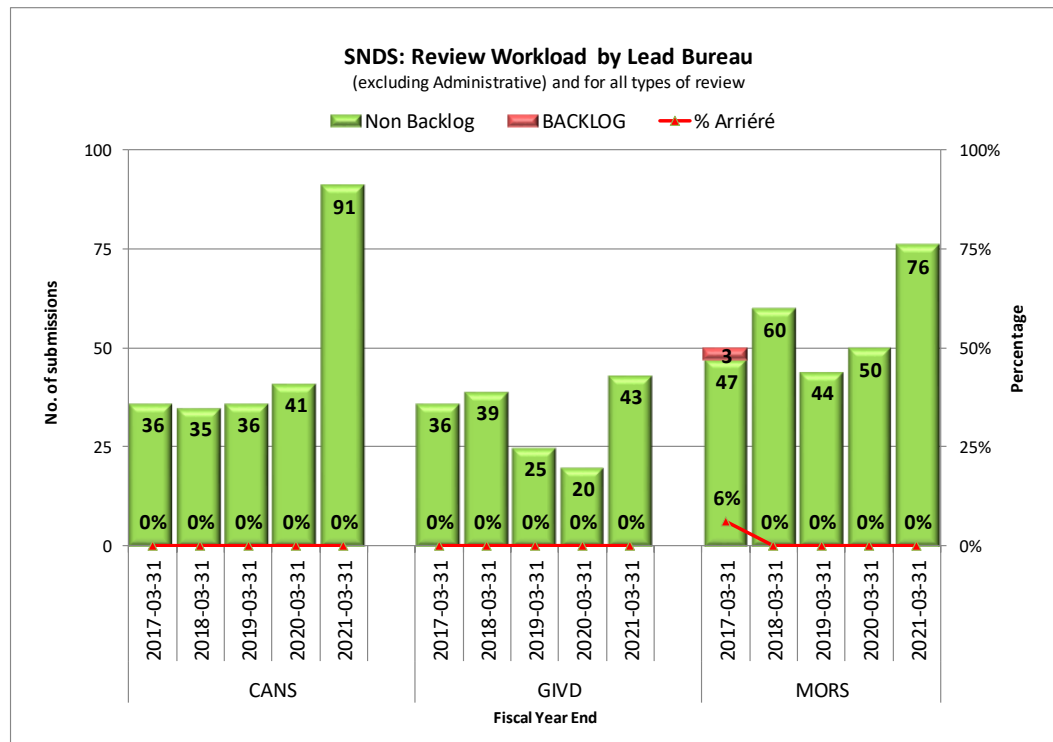
NDS & SNDS

WORKLOAD by Lead Bureau

NDS: Review Workload by Lead Bureau

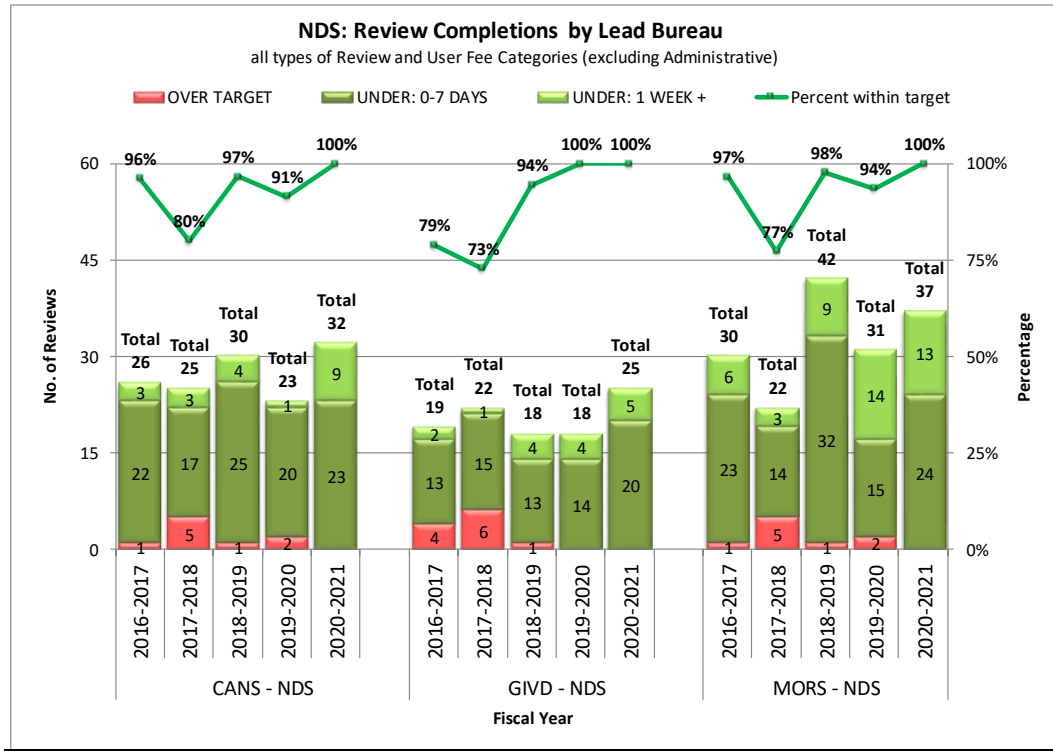


SNDS: Review Workload by Lead Bureau

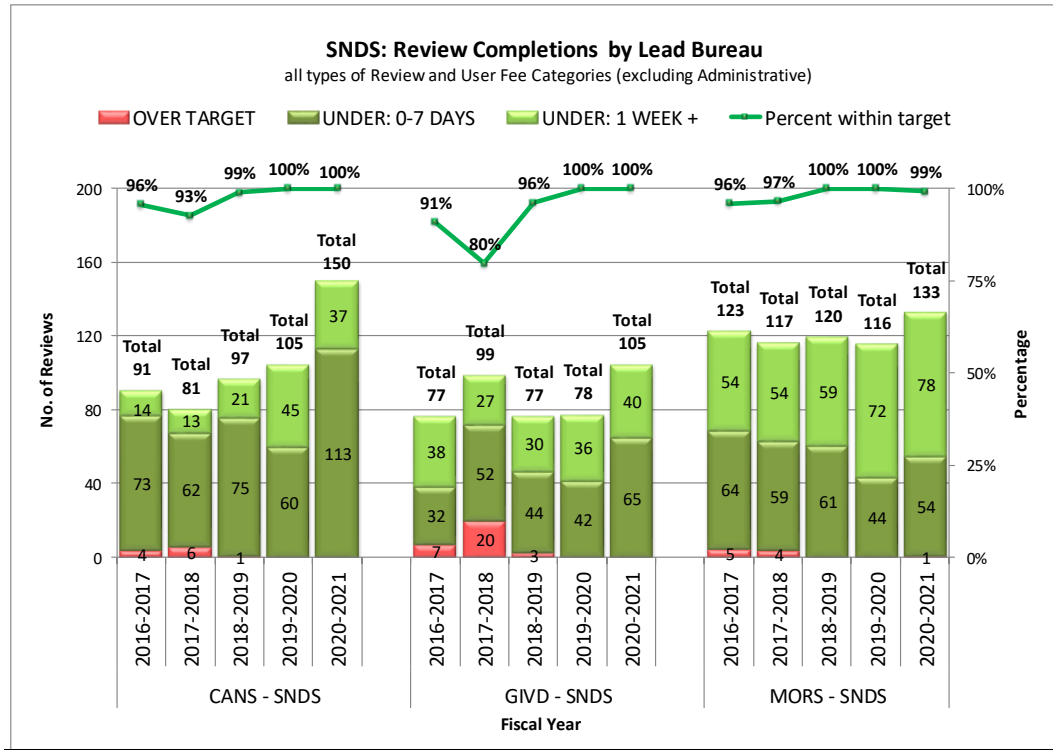


PERFORMANCE by Lead Bureau

NDS: Review Performance by Lead Bureau

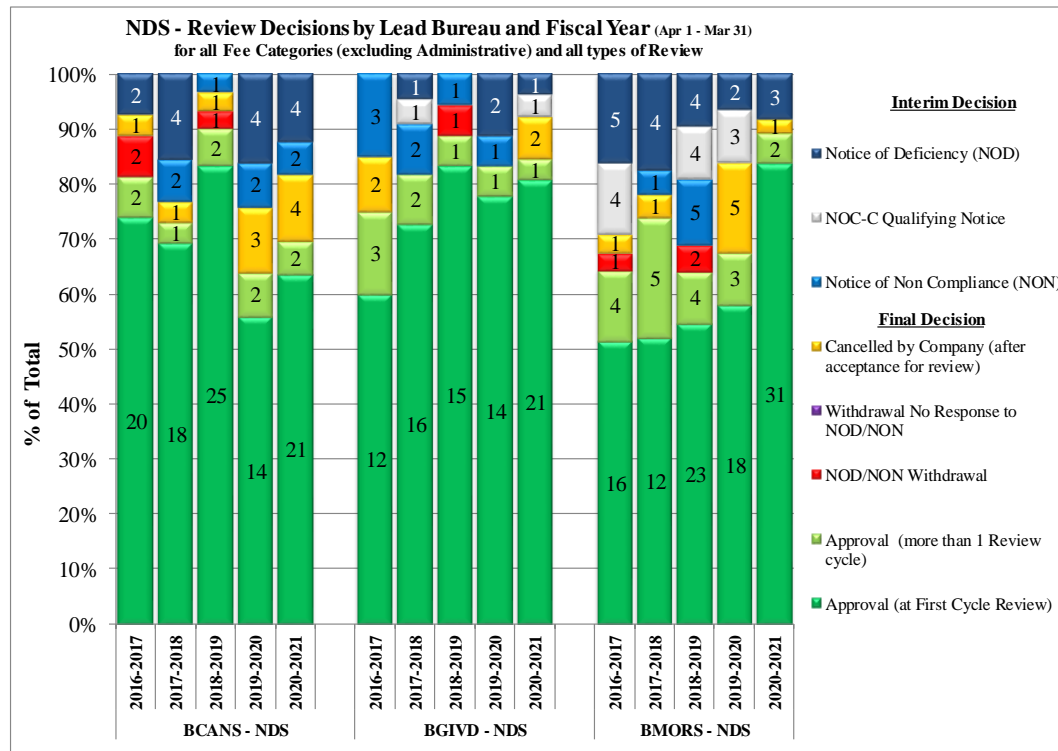


SNDS: Review Performance by Lead Bureau

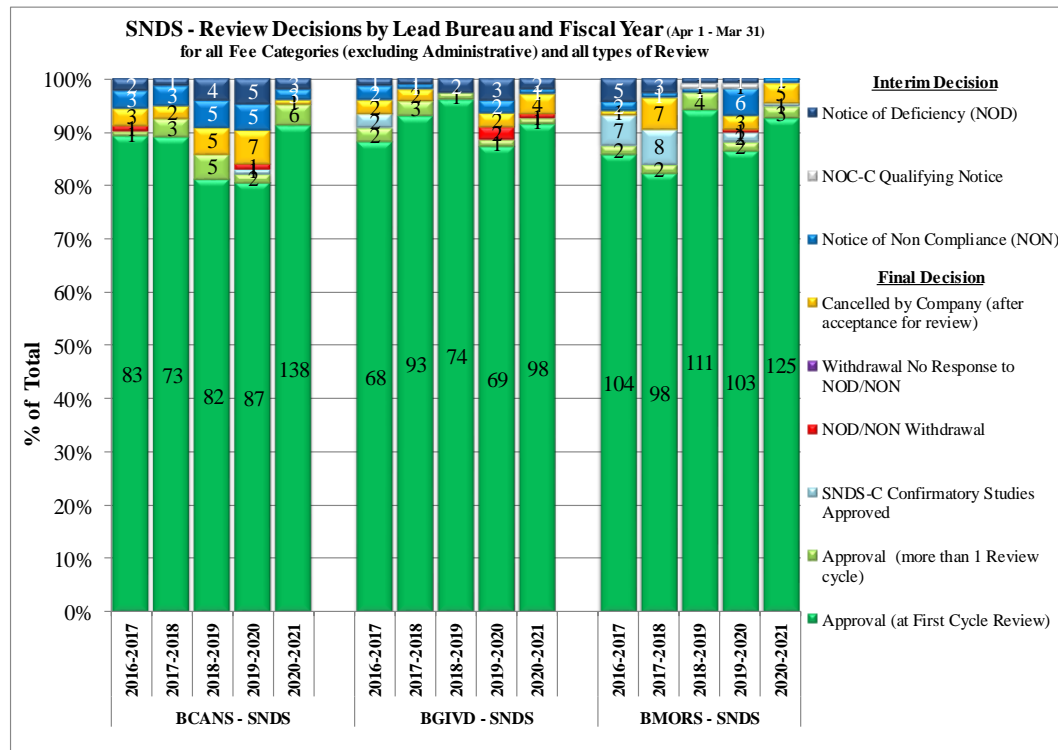


REVIEW DECISIONS by Lead Bureau

NDS: Review Decisions by Lead Bureau

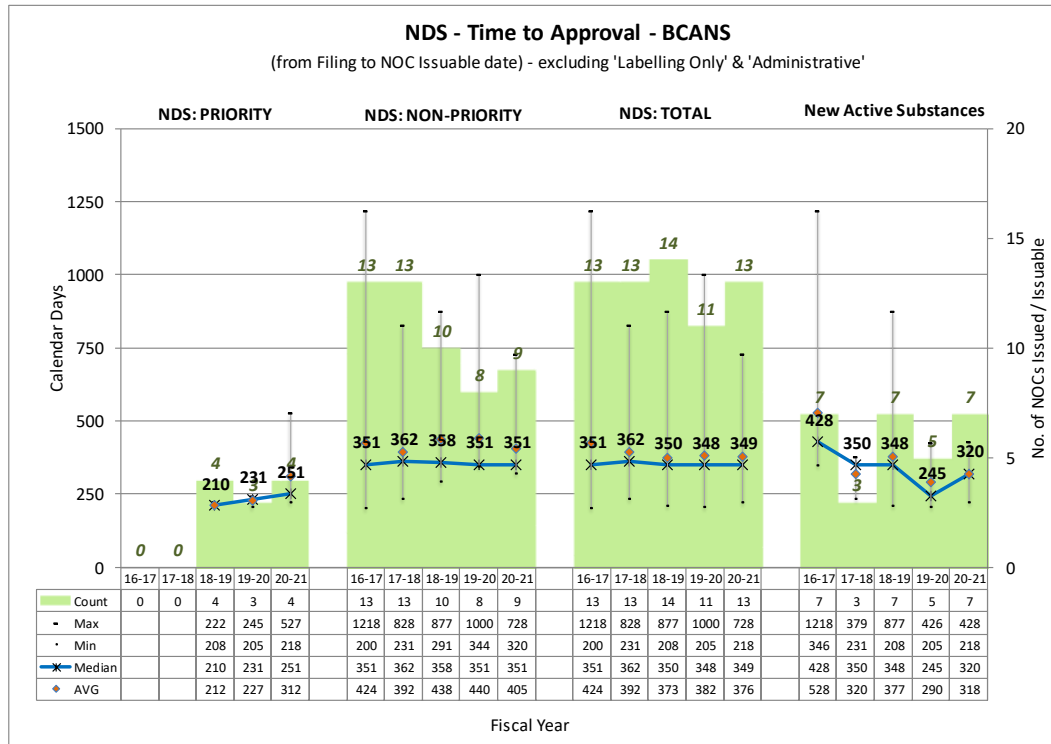


SNDS: Review Decisions by Lead Bureau

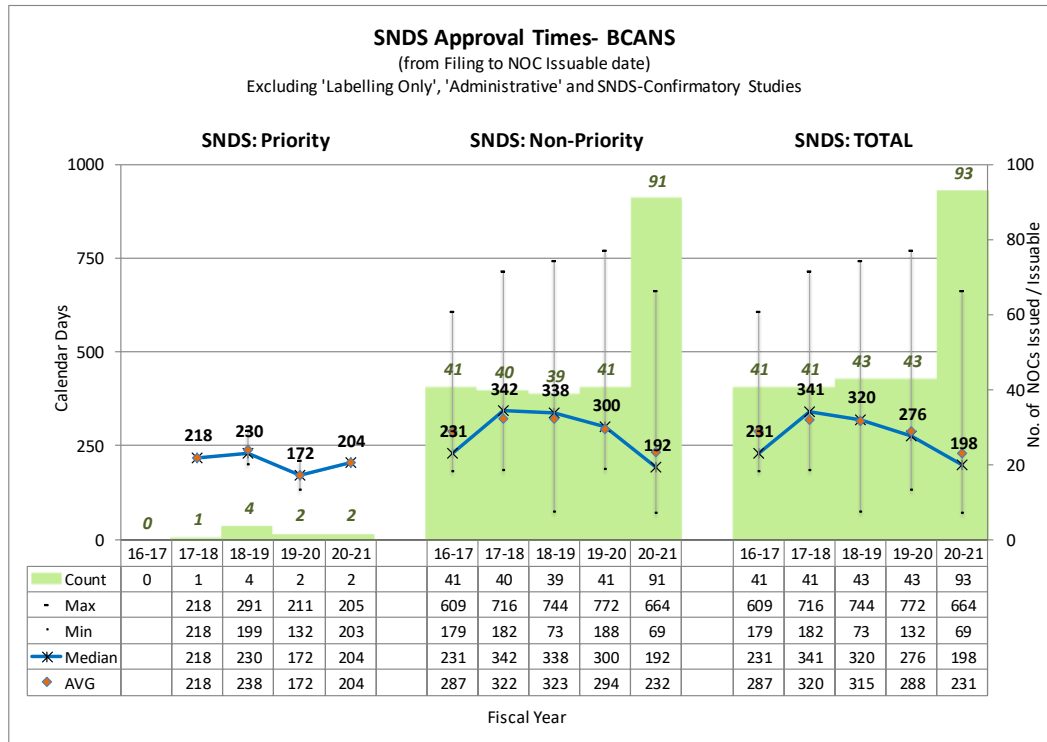


APPROVALS: Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)

NDS Time to Approval: BCANS



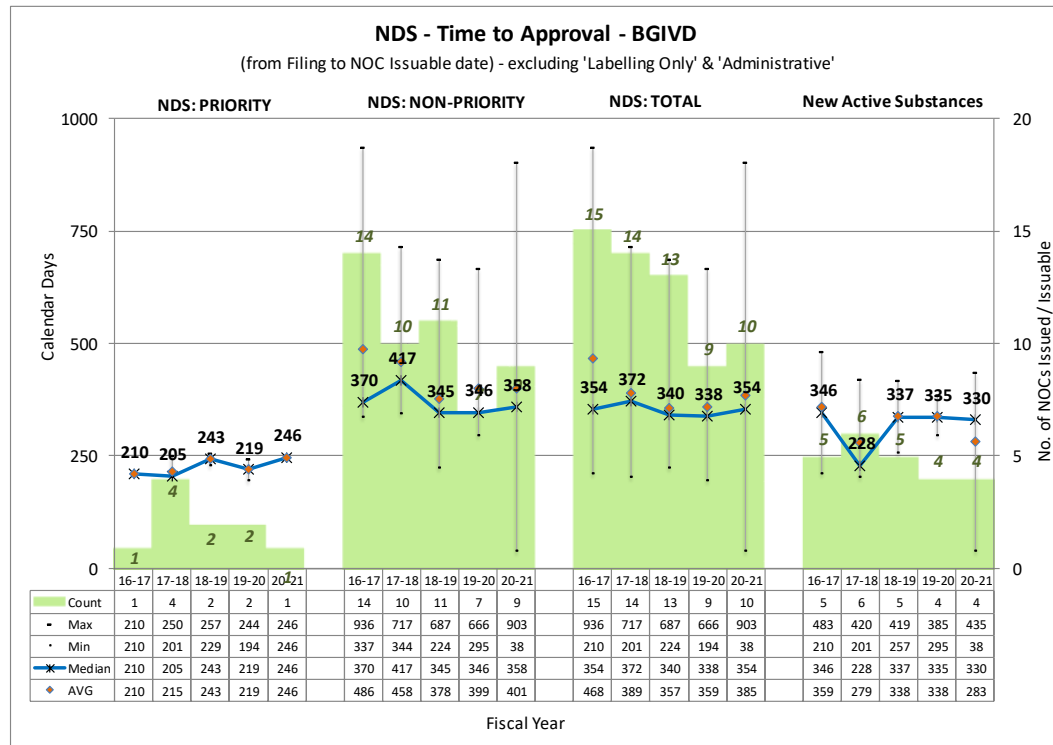
SNDS Time to Approval: BCANS



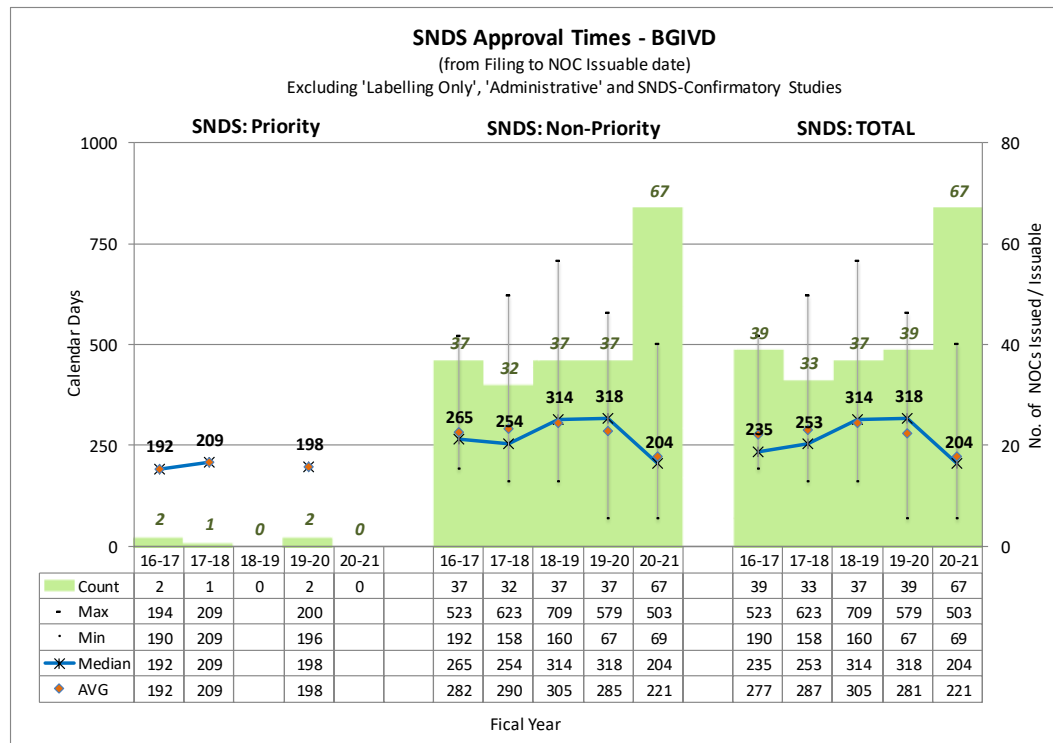
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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

NDS Time to Approval: BGIVD



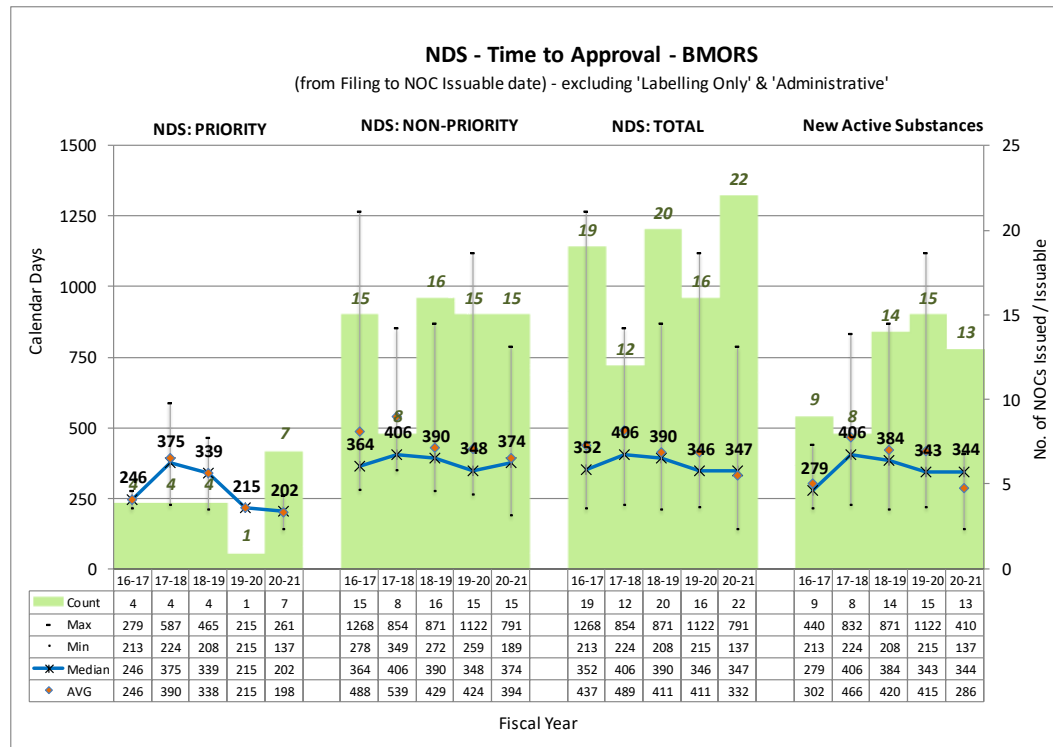
SNDS Time to Approval: BGIVD



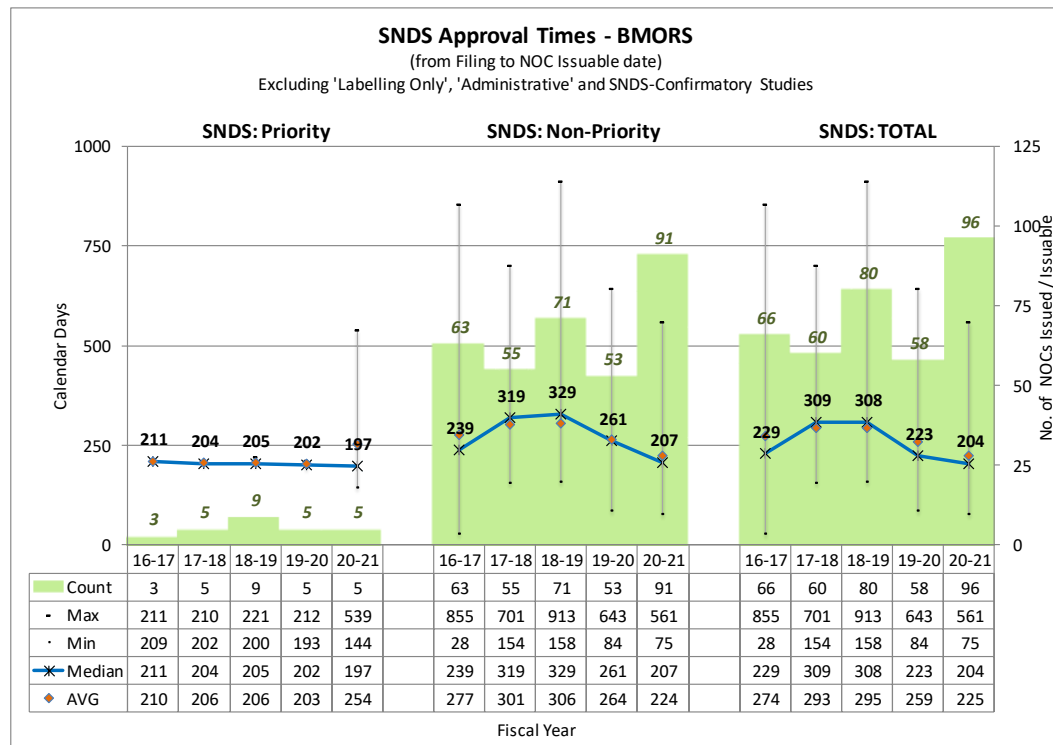
Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor.

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

NDS Time to Approval: BMORS



SNDS Time to Approval: BMORS

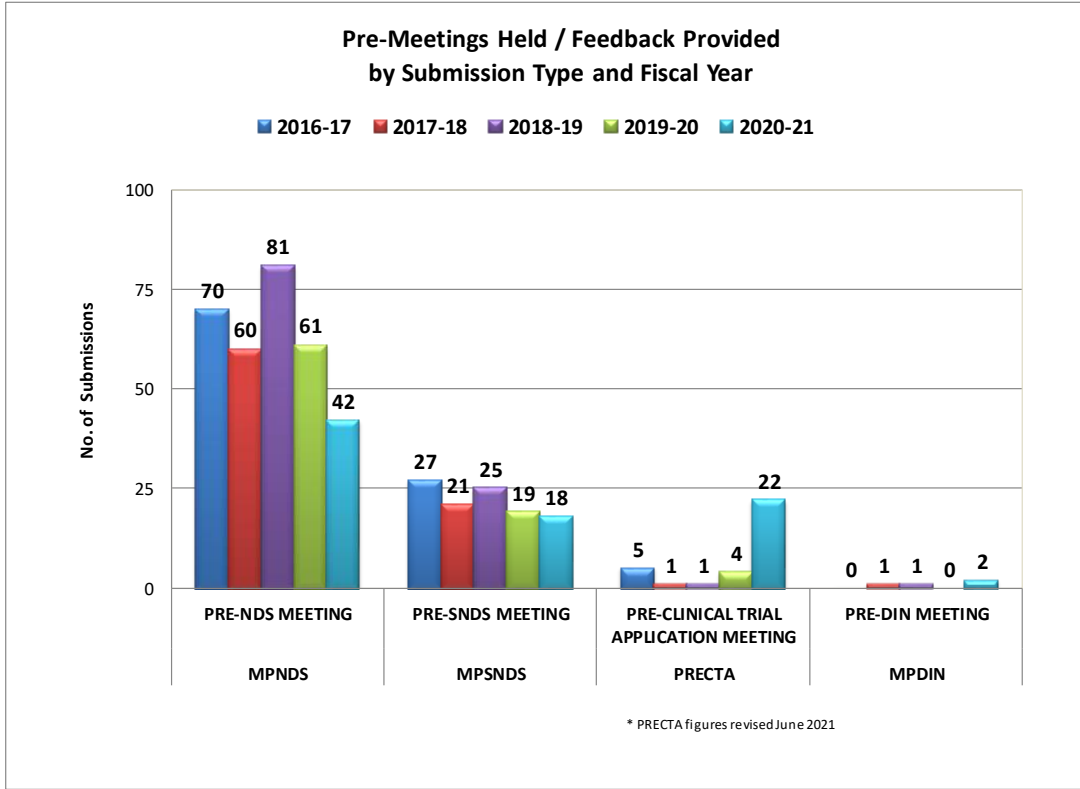


Approval Time is the total number of calendar days between a submission's filing date (CR date) and the approval date, and includes any time awaiting a response from the sponsor

APPENDIX B: PRE-SUBMISSION MEETINGS

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Pre-Submission Meetings Held / Feedback Provided



¹² Prior to filing a submission, a sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the [Guidance for Industry: Management of Drug Submissions](#)

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