Health Canada Santé Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2020-2021

April 1 2020 - March 31 2021

Canada

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OVERVIEW

The NNHPD Annual Drug Submission Performance Report reflects Non-Prescription and Disinfectant 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 and the number of licensing decisions issued over that period.

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.

- There was a significant increase in the volume of Drug Identification Number Applications for Disinfectant products (DIND) received.

- 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. (see the Annual Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD)).

- 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. (see the Annual Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD)).

- 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).

Some of the highlights of the 2020-2021 report are:

A performance standard of 99.99% was achieved for DIN-D submissions with 1/214 submissions completed after the target date. A performance standard of 98% was achieved for DINA submissions with 1/75 submissions cleared after the target date. A performance target of 80% was achieved for ANDS submissions with 1/5 submission completed after the target date.

NDED achieved a performance standard of 99.99% for cost recovered submissions with 3/876 submissions completed after the target dates.

A performance standard of 81% was achieved for disinfectant related PDC submissions with 23/120 submissions completed after the target date and a performance standard of 98% was achieved for OTC s.

NDED achieved a performance standard of 99.95% was achieved for non-cost recovered submissions with 28/535 submissions completed after the target date.

Non-Prescription (Over the Counter - OTC) Drugs:

• The number of DINA submissions received decreased by 33% in 2020-2021 (165) compared to 2019-2020 (245). Administrative DINA submissions account for the majority of this decrease: 34 received in 2020-2021 and 135 received in 2019-2020.

• A 1% increase was observed in the number of DINF submissions received in 2020-2021 (227) compared to 2019-2020 (209).

• The number of PDC submission received increased 1% from the previous year: 396 in 2020-2021 compared to 380 in 2019-2020.

• The number of NDS submissions received decreased by 33% in 2020-2021 (10) compared to 2019-2020 (15). The number of NDS submissions received in 2020-2021 is still significantly higher than in 2018-2019 (3).

• The number of ANDS submissions received remained consistent in 2020-2021 (7) compared to 2019-2020 (7).

• The number of SANDS submissions received in 2020-2021 (59) increased by 245% compared to 2019-2020 (24). There was a significant increase of SANDS Label Update Generic in 2020-2021 (10) compared to 2019-2020 (0).

• NC submissions were discontinued in 2019-2020. Therefore, no NC submission was filed in 2020-2021.

Overall, the total non-prescription drug submissions received decreased by 7% during 2020-2021 (864) compared to 2019-2020 (926). This small decrease follows an all time high volume of submissions received in 2019-2020 but remains significantly higher than the total number of non-prescription drug submissions received in the previous 4 fiscal years (742 in 2015-2016; 699 in 2016-2017; 658 in 2017-2018; and 616 in 2018-2019). The higher volume of submissions received in the last two fiscal years can be associated with the implementation of the Plain Language Labelling (PLL) requirements that came into force for non-prescription drugs on June 13, 2017, and with the increased demand for hand sanitizers in response to the global COVID-19 pandemic.

Disinfectant Drugs:

• The number of DIND submissions received increased by 571% in 2020-2021 (879) compared to 2019-2020 (154). This volume of DIND submissions received represents an all time high for this type of submission. Full Review with Data and Labelling Standard (Monograph) DIND submissions account for the majority of these increases: 220 Full Reviews and 372 Labelling Standards received in 2020-2021 compared to 48 and 30 received in 2019-2020, respectively. The new DIND Labelling Only submission category saw significant volumes received, as non-administrative licensing agreements were diverted away from the DIND Administrative stream.

• The number of PDC submissions received for disinfectant products increased by 181% in 2020-2021 (143) compared to 2020-2021 (79). This volume of PDC submissions received represents an all time high for this type of submission.

• The number of disinfectant NDS-D submissions significantly increased by 500% in 2020-2021 (5) compared to 2019-2020 (1).

Overall, the total disinfectant drug submissions received increased by 439% during 2020-2021 (1027) compared to 2019-2020 (234). This significant increase in the total volume of disinfectant drug submission received can be associated with the demand for disinfectant products in response the COVID-19 pandemic. In comparing fiscal year 2020-2021 to the previous 4 fiscal years (2016-2020), the volumes of disinfectant drug submissions received were 228, 218, 234 and then 1027. The number of submissions received in 2020-2021 FY is more than the number of submissions received for the totality of the 2016, 2017, 2018 and 2019 FYs. As a result, short-term backlogs for the screening components of 9% of Full Review and 19% of PDC submissions were seen late in 2020-2021, in order to shift resources within the review team to meet expedited COVID review targets and other cost-recovered performance standards. These did not impact the final cost recovery decisions and deadlines for the affected DIND submissions.

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 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 changes from Prescription to Non-Prescription or due to Patented Medicines (NOC) Regulations.

A **review cycle completion**[2] 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[3] 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.

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

[2] 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.

[3] 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. 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"[4] submissions.

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

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

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

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
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
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
NOA	-	Notice of Authorization
NOA-TC	-	Notice of Authorization with Terms and Conditions

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.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[5]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[6]	Submissions in support of a manufacturer or product name change.
Disinfectants[7]	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

[5] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling
[6] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)
[7] 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.

PART 1: NON PRESCRIPTION DRUGS
Over the Counter (OTC) Drugs

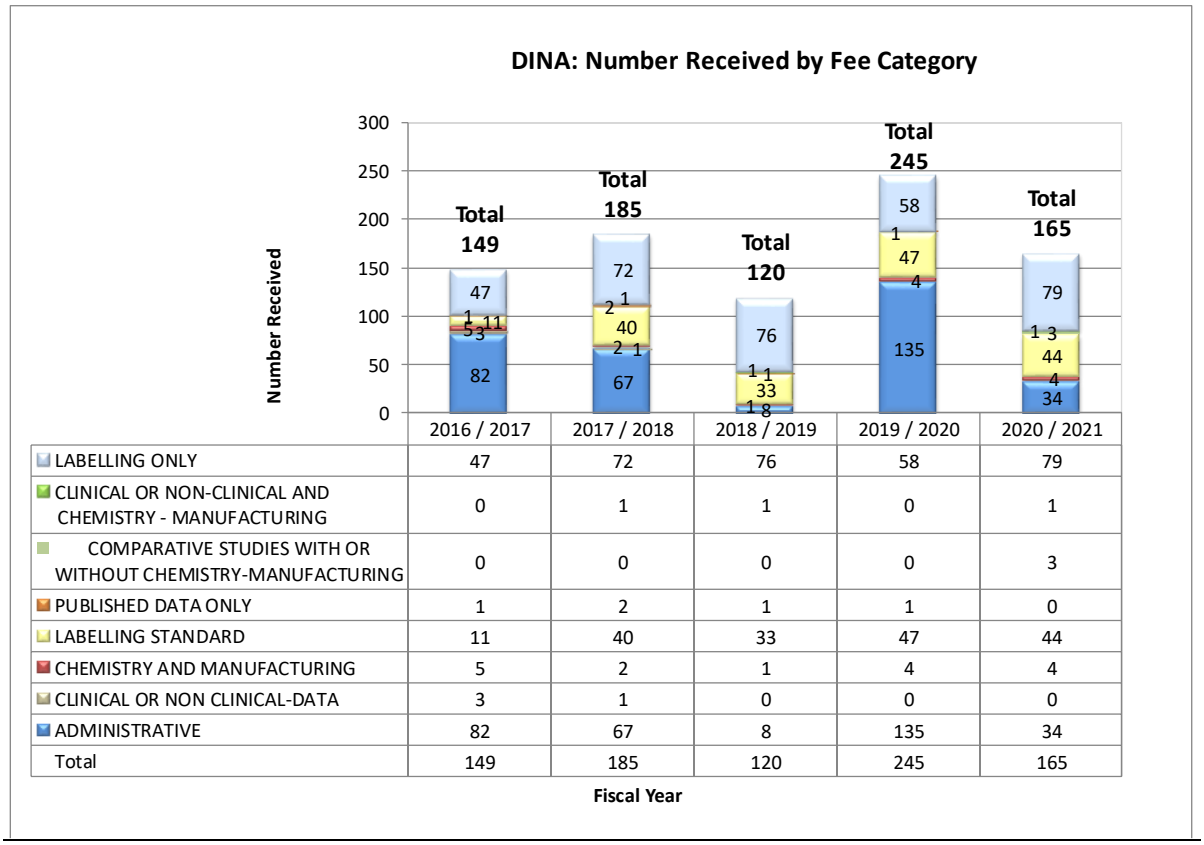
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

RECEIVED

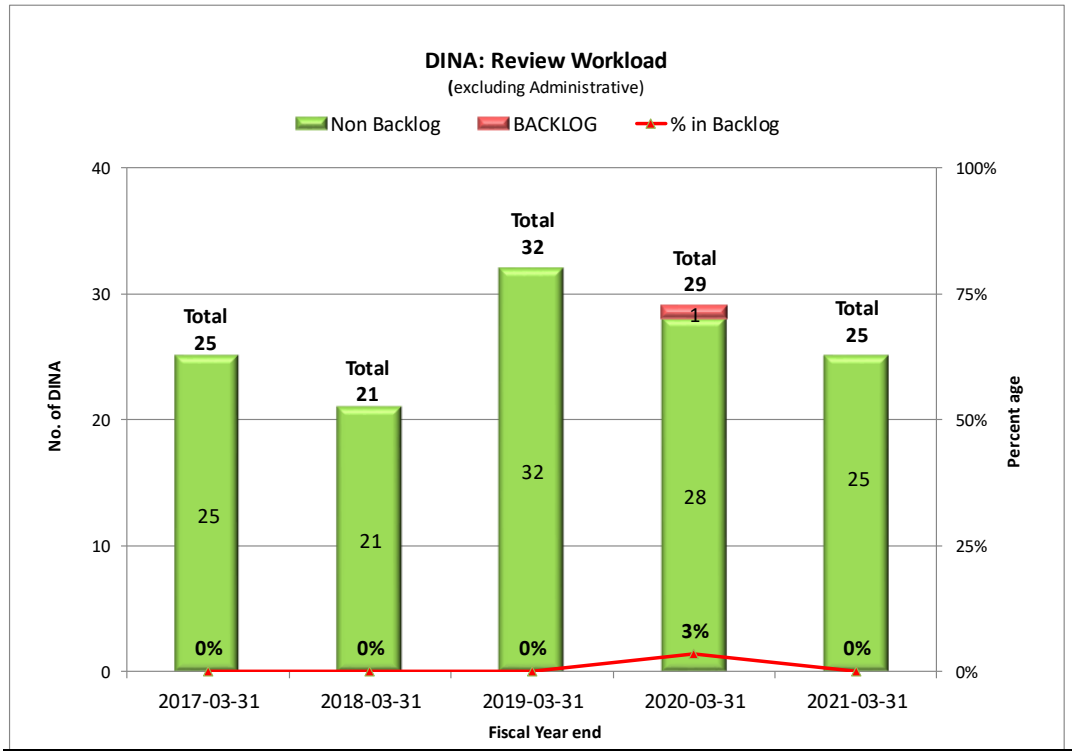
DINA: Number Received by Fee Category



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
LABELLING ONLY	47	72	76	58	79
CLINICAL OR NON-CLINICAL AND CHEMISTRY - MANUFACTURING	0	1	1	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY-MANUFACTURING	0	0	0	0	3
PUBLISHED DATA ONLY	1	2	1	1	0
LABELLING STANDARD	11	40	33	47	44
CHEMISTRY AND MANUFACTURING	5	2	1	4	4
CLINICAL OR NON CLINICAL-DATA	3	1	0	0	0
ADMINISTRATIVE	82	67	8	135	34
Total	149	185	120	245	165

WORKLOAD

DINA: Review Workload

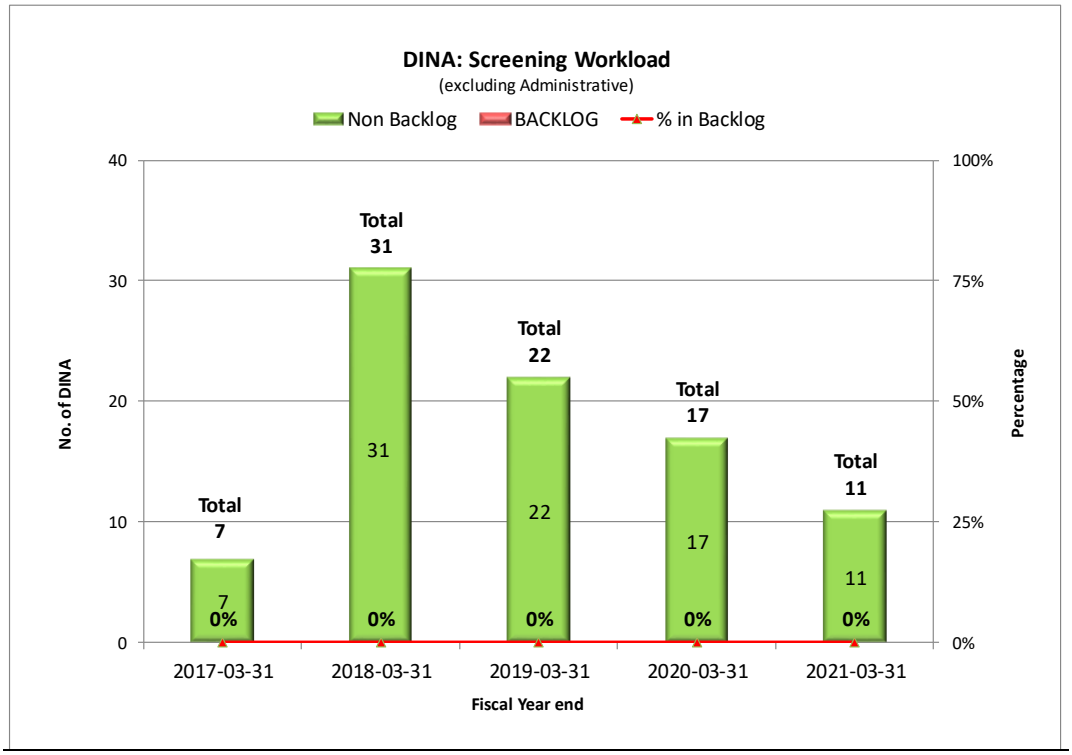


DINA: Review Workload by Fee Category

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	18	19	32	27	17
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	5	1	0	2	4
Backlog	*0*	*0*	*0*	*1*	*0*
Clinical or Non-Clinical Data	2	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	0	0	0	3
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clinical /C&M	0	1	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	25	21	32	29	25
Non Backlog	25	21	32	28	25
BACKLOG	0	0	0	**1**	0
% in Backlog	0%	0%	0%	**3%**	0%

WORKLOAD

DINA: Screening Workload

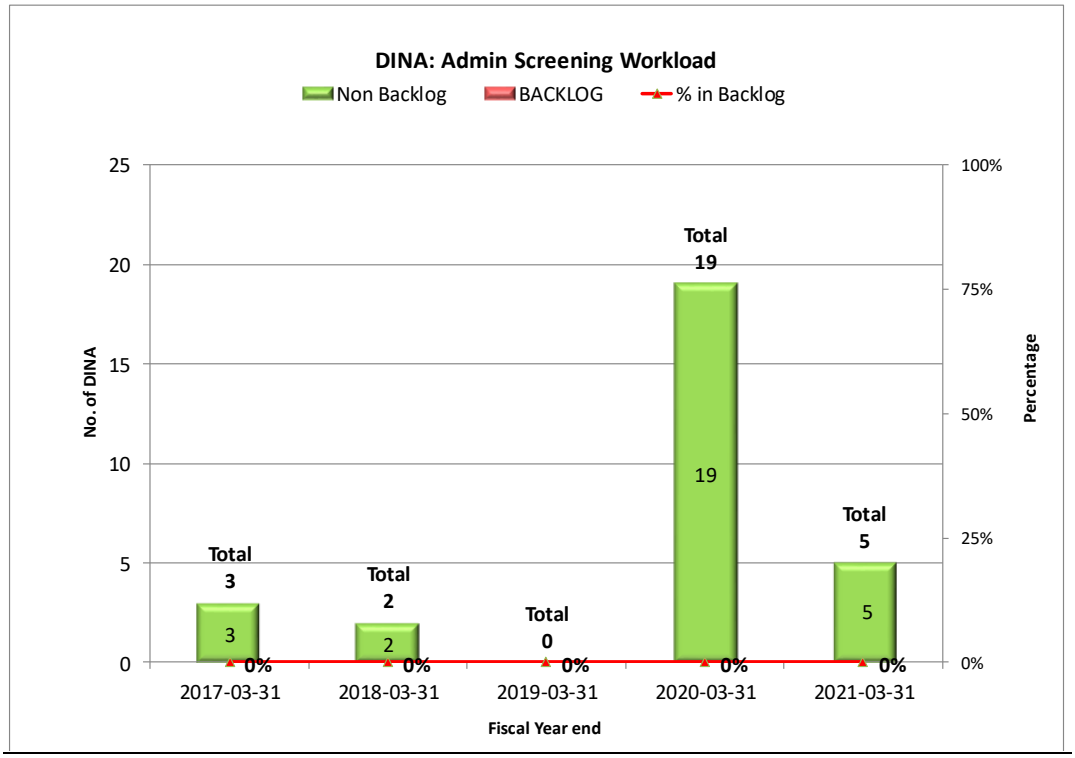


DINA: Screening Workload by Fee Category

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	21	15	3	8
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	0	10	6	12	3
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	0	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	2	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	1	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	7	31	22	17	11
Non Backlog	7	31	22	17	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Administrative-Screening Workload



DINA: Administrative-Screening Workload by Fee Category

DINA: ADMIN SCREENING WORKLOAD by Fiscal Year end					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Administrative	3	2	0	19	5
Backlog	*0*	*0*	*0*	*0*	*0*
Total	3	2	0	19	5
Non Backlog	3	2	0	19	5
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

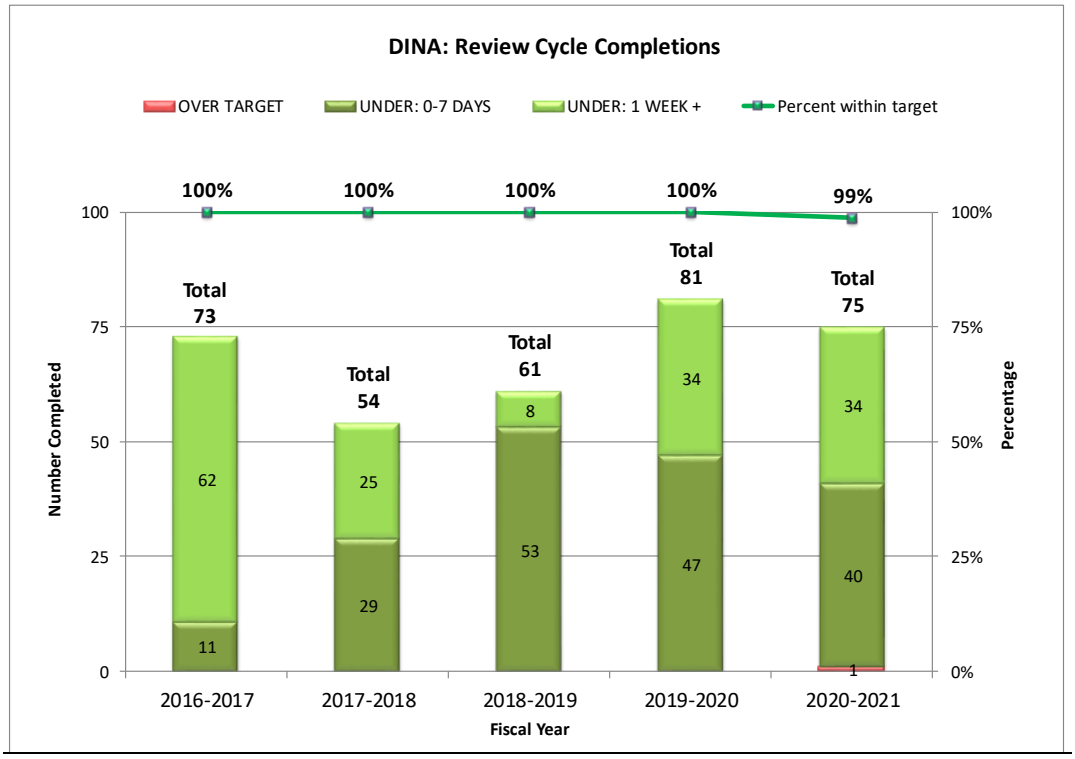
DECISIONS

DINA: Number of Decisions by Fee Category

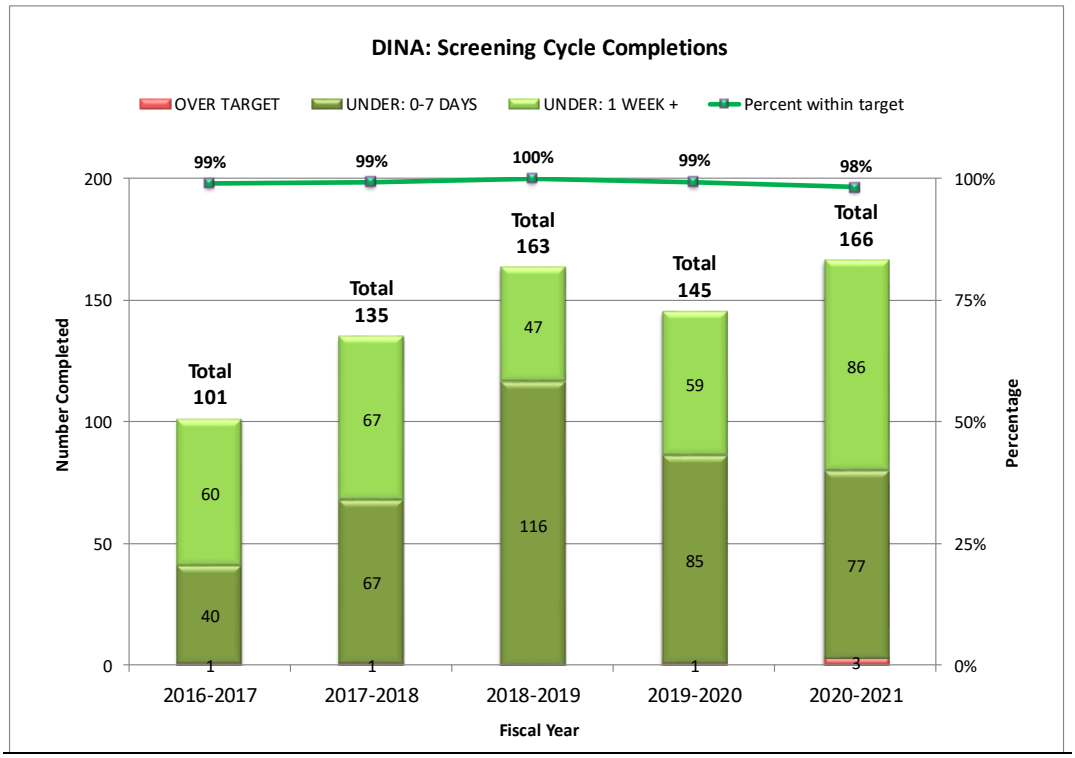
User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	80	32	0	106	38
	NO OBJECTION LETTER	2	0	0	0	2
	REJECTION LETTER (SCR)	9	2	0	1	1
	SCREENING DEFICIENCY NOTICE	5	4	2	19	3
	CANCELLATION LETTER	3	36	10	7	5
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	1	3	0	0	
	NO OBJECTION LETTER	0	0	3	0	2
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	4	4	0	0	0
	CANCELLATION LETTER	2	4	0	1	1
	SCREENING DEFICIENCY NOTICE	3	0	1	2	3
	WITHDRAWAL NO RESP TO NON	1	0	0	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	2	0	1	0
	NO OBJECTION LETTER	0	1	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	1	2	1	0	0
	SCREENING DEFICIENCY NOTICE	1	1	0	0	0
	CANCELLATION LETTER	0	0	1	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	1	0	1	0
	NOTICE OF NON-COMPLIANCE	0	0	1	0	0
	NOTIFICATION FORM DIN SUB	0	0	1	0	0
LABELLING ONLY	NOTIFICATION FORM DIN SUB	39	36	45	66	63
	NO OBJECTION LETTER	22	2	3	10	6
	NOTICE OF NON-COMPLIANCE	2	0	6	3	1
	CANCELLATION LETTER	7	15	4	9	16
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	REJECTION LETTER (SCR)	5	1	7	0	1
	SCREENING DEFICIENCY NOTICE	15	30	24	8	11
	NOTICE OF DEFICIENCY	0	1	2	0	0
	WITHDRAWAL NO RESP TO NOD	0	0	1	0	0
	WITHDRAWAL NO RESP TO NON	0	0	1	1	0
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	13	29	30	34	42
	NO OBJECTION LETTER	1	0	0	1	0
	CANCELLATION LETTER	1	0	5	5	11
	REJECTION LETTER (SCR)	0	0	1	1	0
	SCREENING DEFICIENCY NOTICE	1	14	25	9	14
PUBLISHED DATA	NOTIFICATION FORM DIN SUB	2	1	1	0	1
	SCREENING DEFICIENCY NOTICE	0	2	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NON WITHDRAWAL LETTER	1	0	0	0	0
	CANCELLATION LETTER	0	0	1	0	0

PERFORMANCE

DINA: Review Cycle Completions

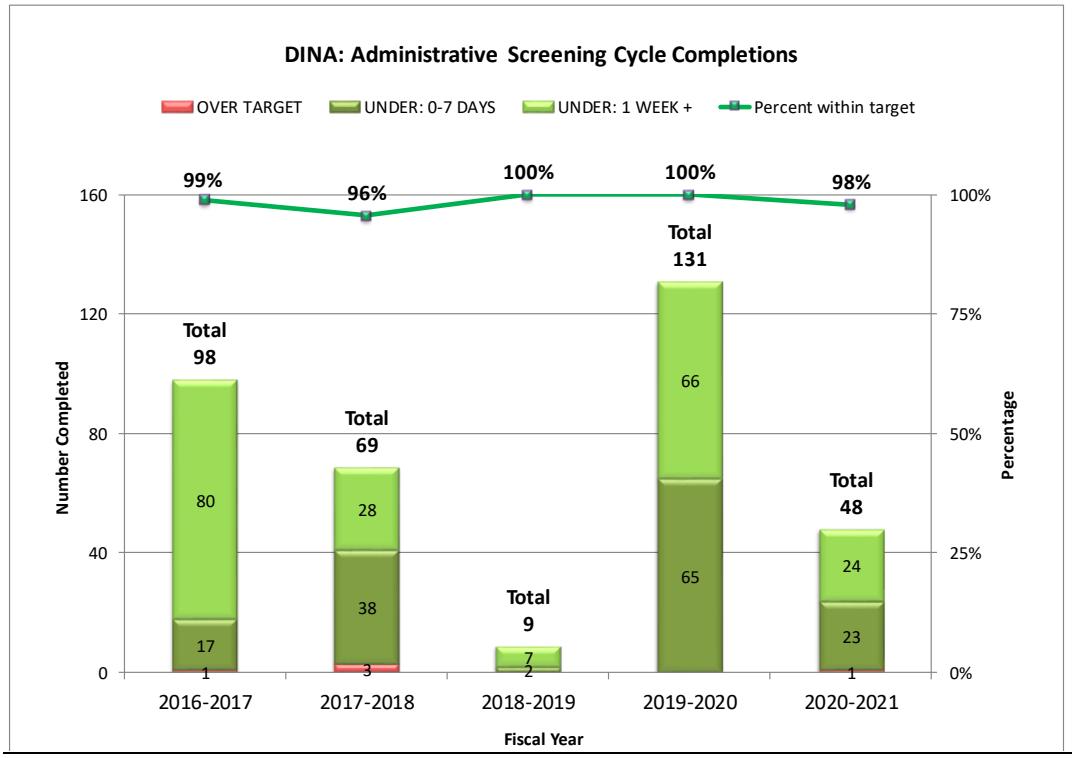


DINA: Screening Cycle Completions



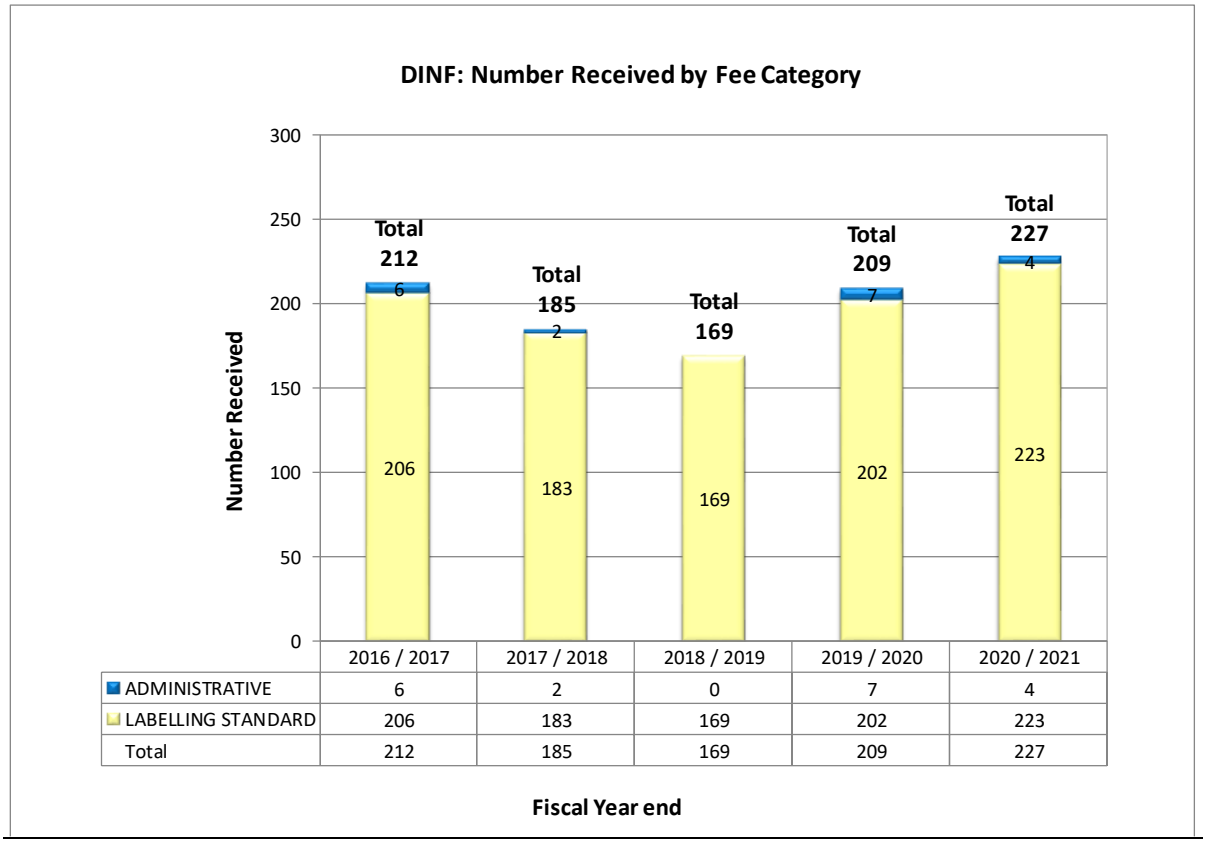
PERFORMANCE

DINA: Administrative-Screening Cycle Completions



DINF: APPLICATION FOR A DIN FOR A CATEGORY IV MONOGRAPH PRODUCT RECEIVED

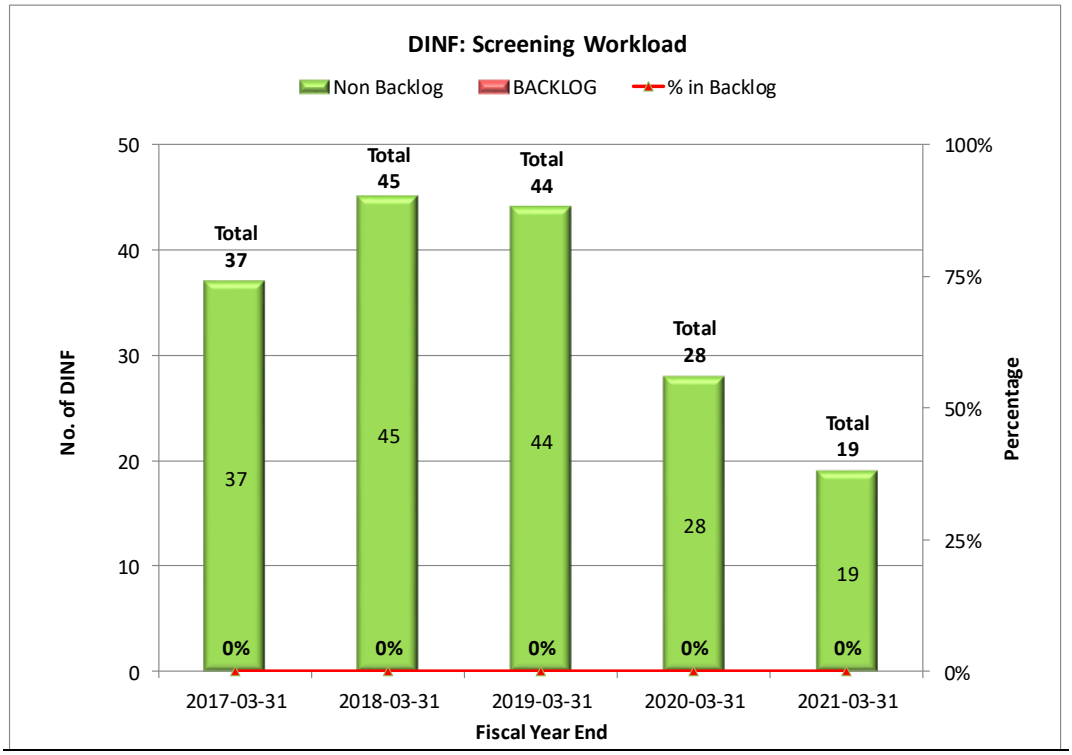
DINF: Number Received by Fee Category



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
ADMINISTRATIVE	6	2	0	7	4
LABELLING STANDARD	206	183	169	202	223
Total	212	185	169	209	227

WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and Fiscal Year end					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Labelling Standard	35	45	44	28	18
Backlog	*0*	*0*	*0*	*0*	*0*
Administrative	2	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	37	45	44	28	19
Non Backlog	37	45	44	28	19
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

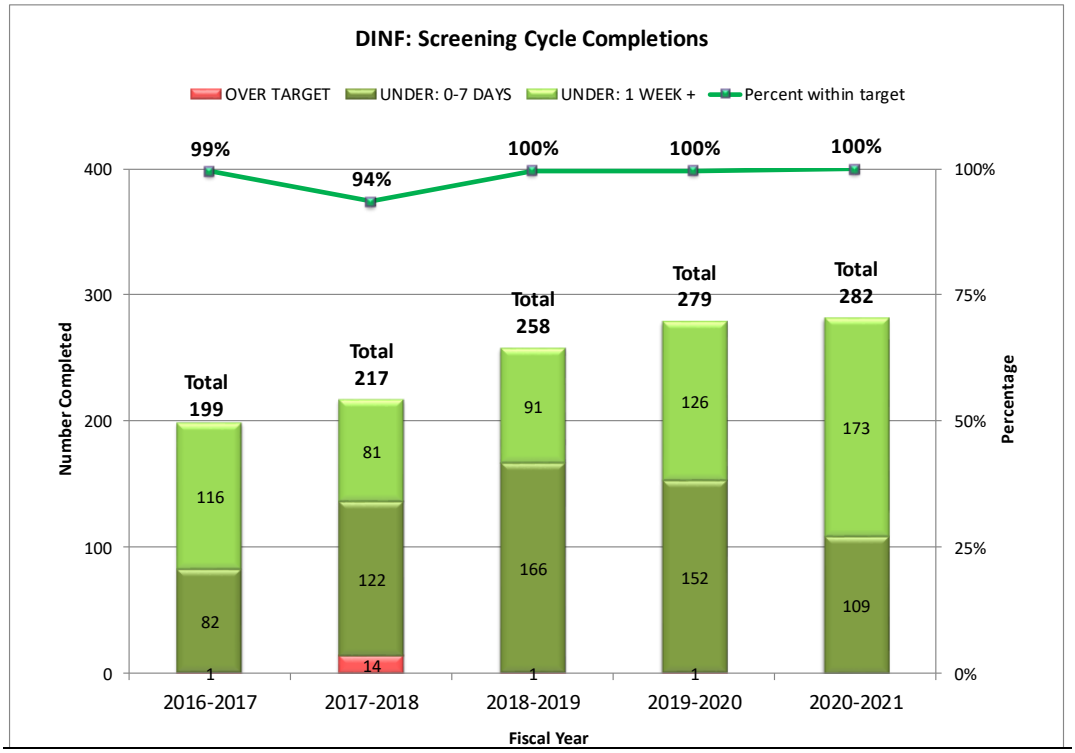
DECISIONS

DINF: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	152	134	143	193	200
	NO OBJECTION LETTER	1	1	2	18	3
	NEW DRUG LETTER SCREEN	0	1	0	1	1
	CANCELLATION LETTER	15	6	13	10	36
	REJECTION LETTER (SCR)	8	4	13	6	3
	SCREENING DEFICIENCY NOTICE	30	75	105	59	50
ADMINISTRATIVE	CANCELLATION LETTER	0	2	0	1	0
	NOTIFICATION FORM DIN SUB	2	0	0	0	3
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	REJECTION LETTER (SCR)	1	0	0	0	0

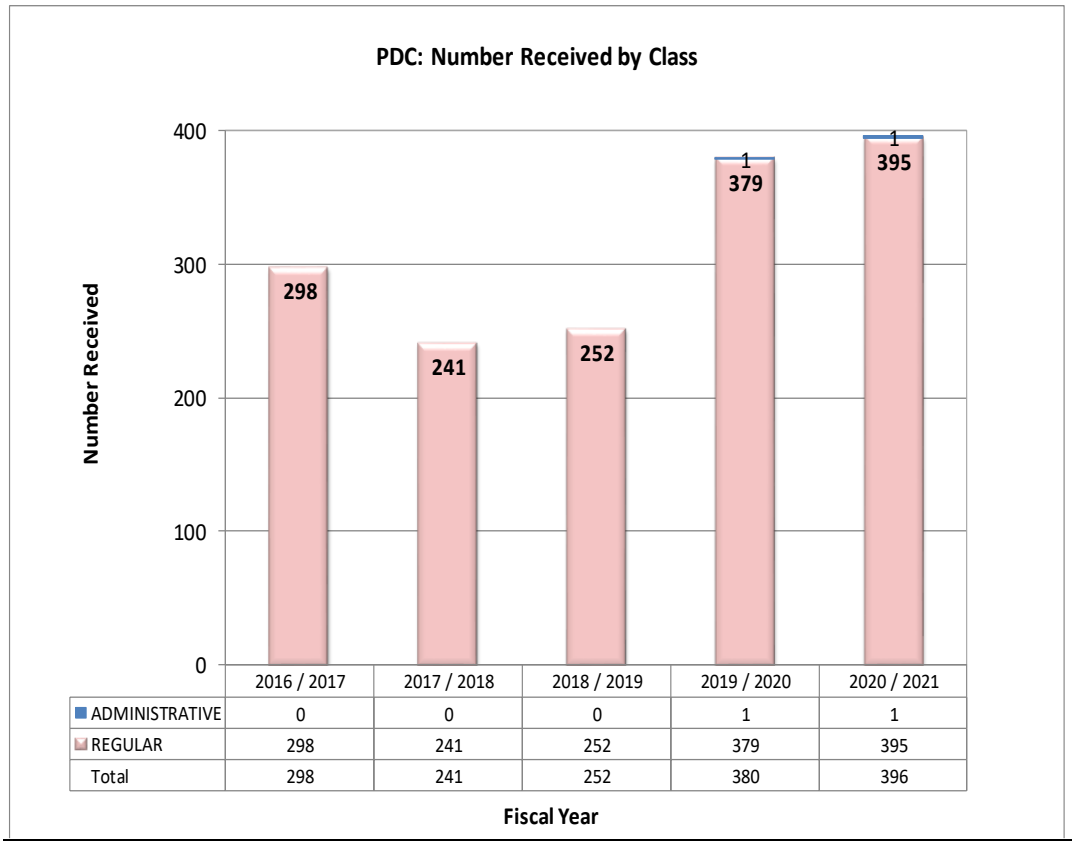
PERFORMANCE

DINF: Screening Cycle Completions



PDC: POST AUTHORIZATION DIVISION 1 CHANGE RECEIVED

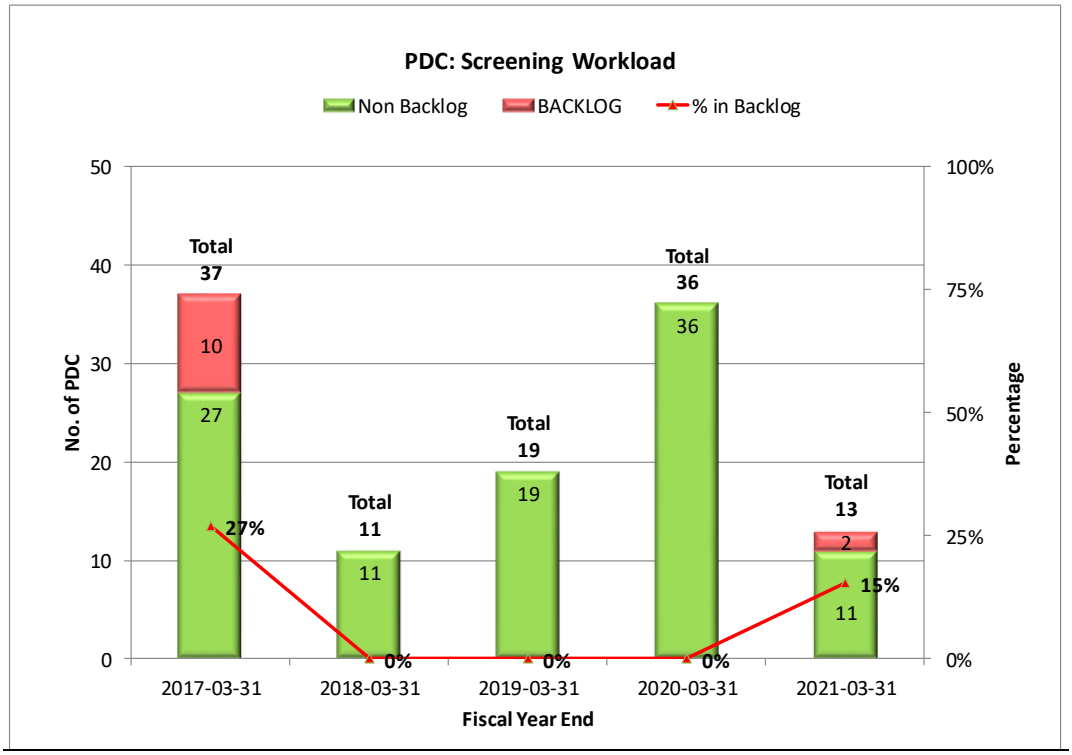
PDC: Number Received by Class



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
ADMINISTRATIVE	0	0	0	1	1
REGULAR	298	241	252	379	395
Total	298	241	252	380	396

WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Regular	37	11	19	36	13
Backlog	*10*	*0*	*0*	*0*	*2*
Total	37	11	19	36	13
Non Backlog	27	11	19	36	11
BACKLOG	**10**	0	0	0	**2**
% in Backlog	**27%**	0%	0%	0%	**15%**

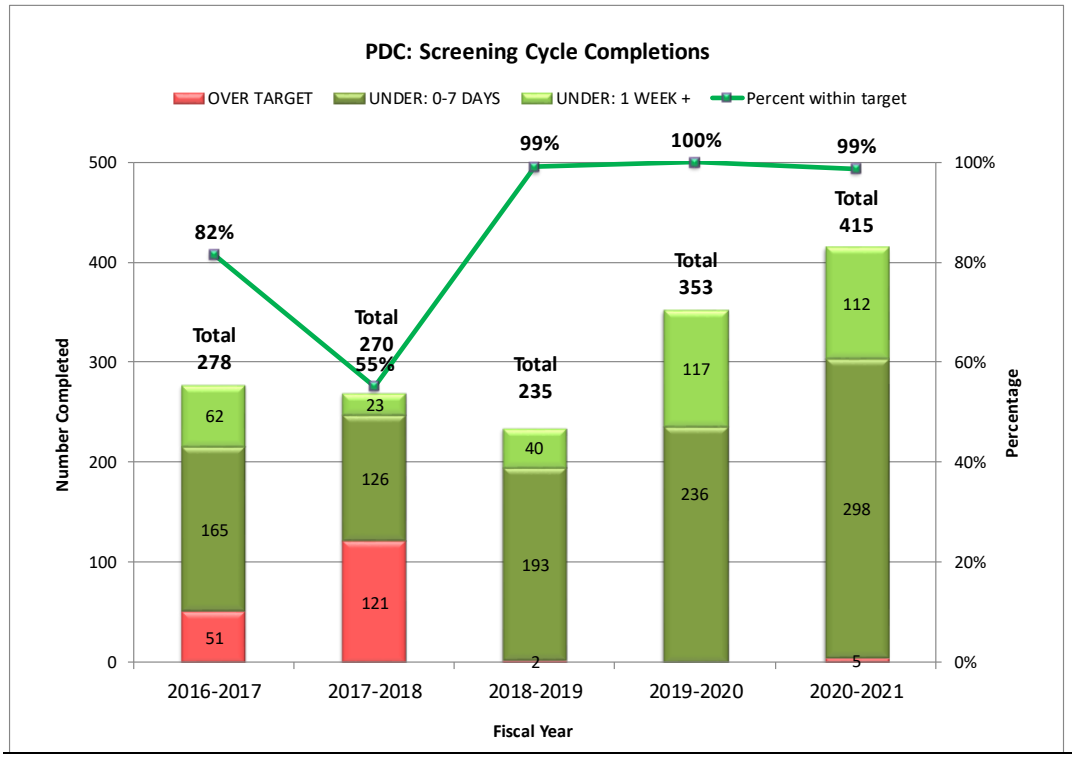
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
REGULAR	NO OBJECTION LETTER	268	256	175	294	384
	NOT SATISFACTORY NOTICE	9	9	35	37	19
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	CANCELLATION LETTER	3	5	26	25	14
	REJECTION LETTER (SCR)	0	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
ADMINISTRATIVE	NO OBJECTION LETTER	0	0	0	1	0

PERFORMANCE

PDC: Screening Cycle Completions



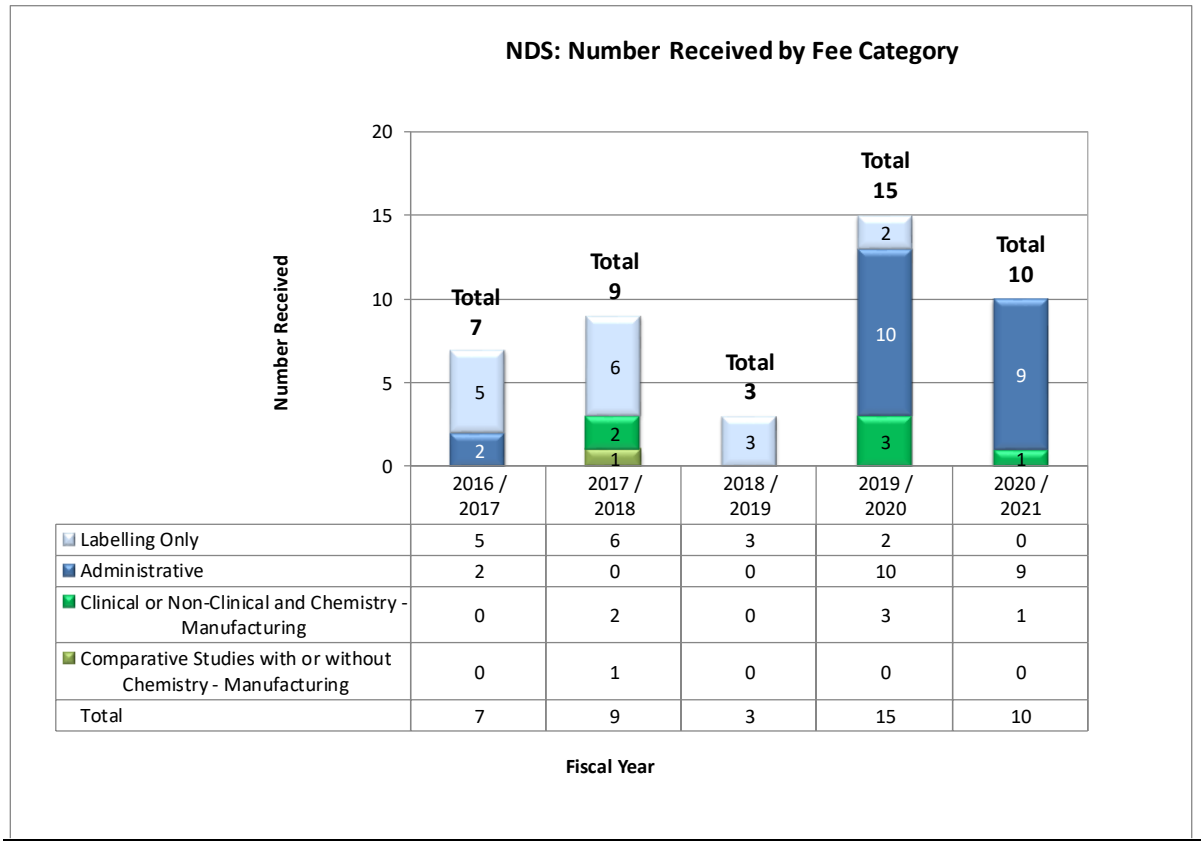
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS: NEW DRUG SUBMISSION

RECEIVED

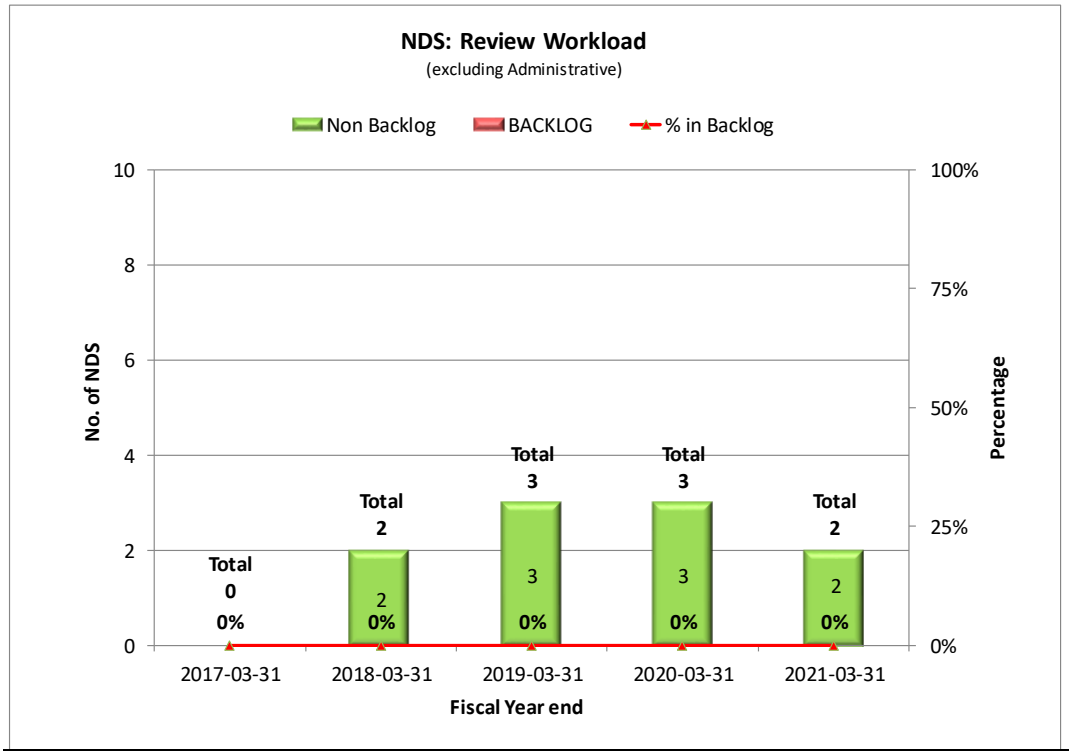
NDS: Number Received by Fee Category



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
Labelling Only	5	6	3	2	0
Administrative	2	0	0	10	9
Clinical or Non-Clinical and Chemistry - Manufacturing	0	2	0	3	1
Comparative Studies with or without Chemistry - Manufacturing	0	1	0	0	0
Total	7	9	3	15	10

WORKLOAD

NDS: Review Workload

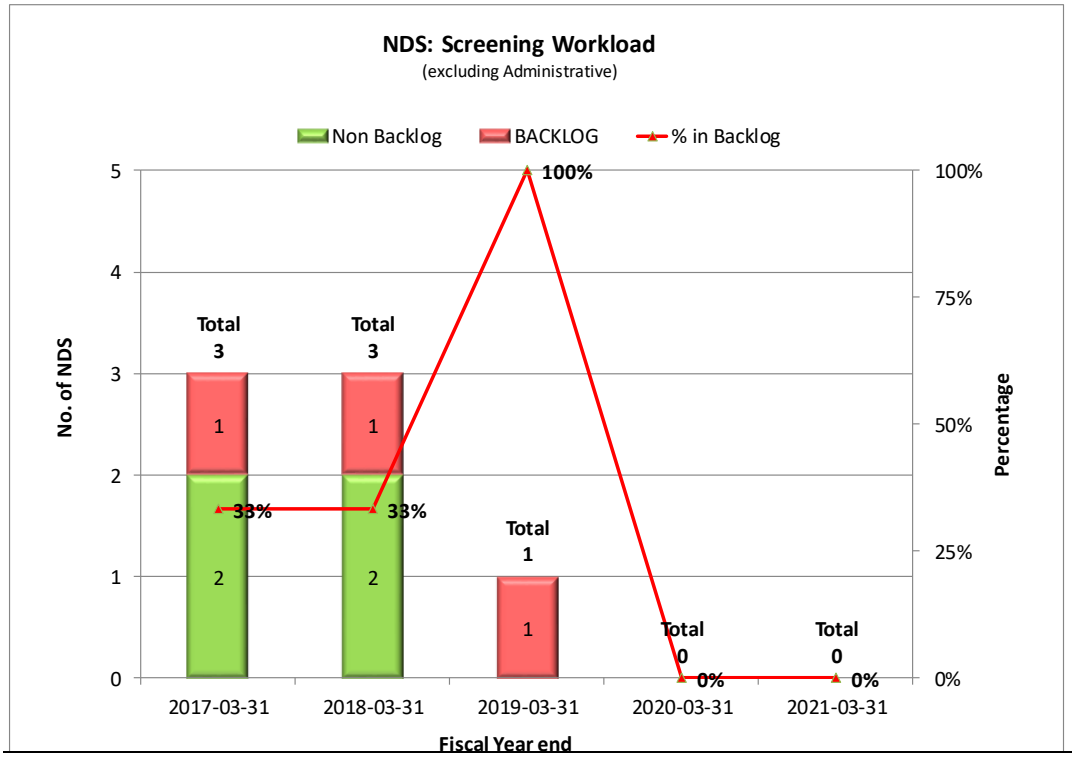


NDS: Review Workload by Fee Category

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-Clinical Data and Chemistry - Manufacturing	0	1	1	3	2
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies with or without C&M	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	1	2	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	2	3	3	2
Non Backlog	0	2	3	3	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NDS: Screening Workload



NDS: Screening Workload by Fee Category

NDS: 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	3	1	1	0	0
Backlog	*1*	*1*	*1*	*0*	*0*
Clinical or Non-Clinical /C&M	0	1	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without C&M	0	1	0	0	0
Backlog	0	0	0	0	0
Total	3	3	1	0	0
Non Backlog	2	2	0	0	0
BACKLOG	**1**	**1**	**1**	0	0
% in Backlog	**33%**	**33%**	**100%**	0%	0%

DECISIONS

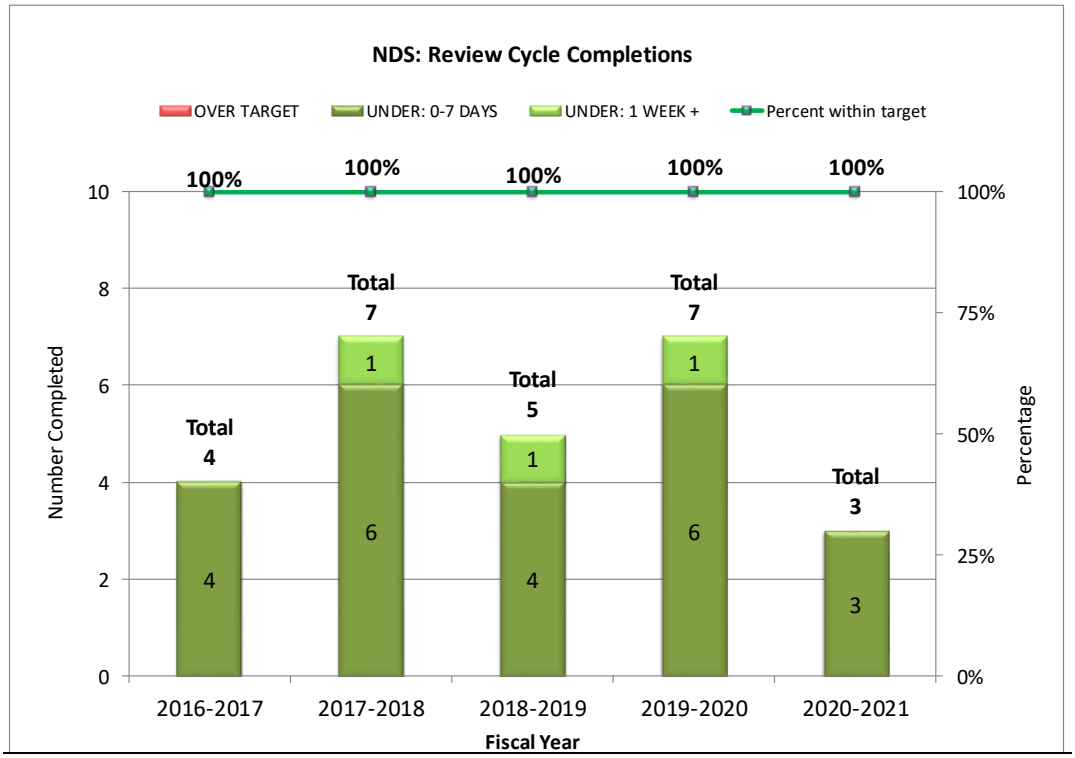
NDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	CANCELLATION LETTER	2	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	3	16
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	1	1	0	1
	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	1	1	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	2
	NOTICE OF DEFICIENCY	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	3	6	2	4	0
	CANCELLATION LETTER	0	1	0	1	0
	SCREENING DEFICIENCY NOTICE	2	3	1	1	0
	NOTICE OF NON-COMPLIANCE	0	0	1	1	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	0	0	0

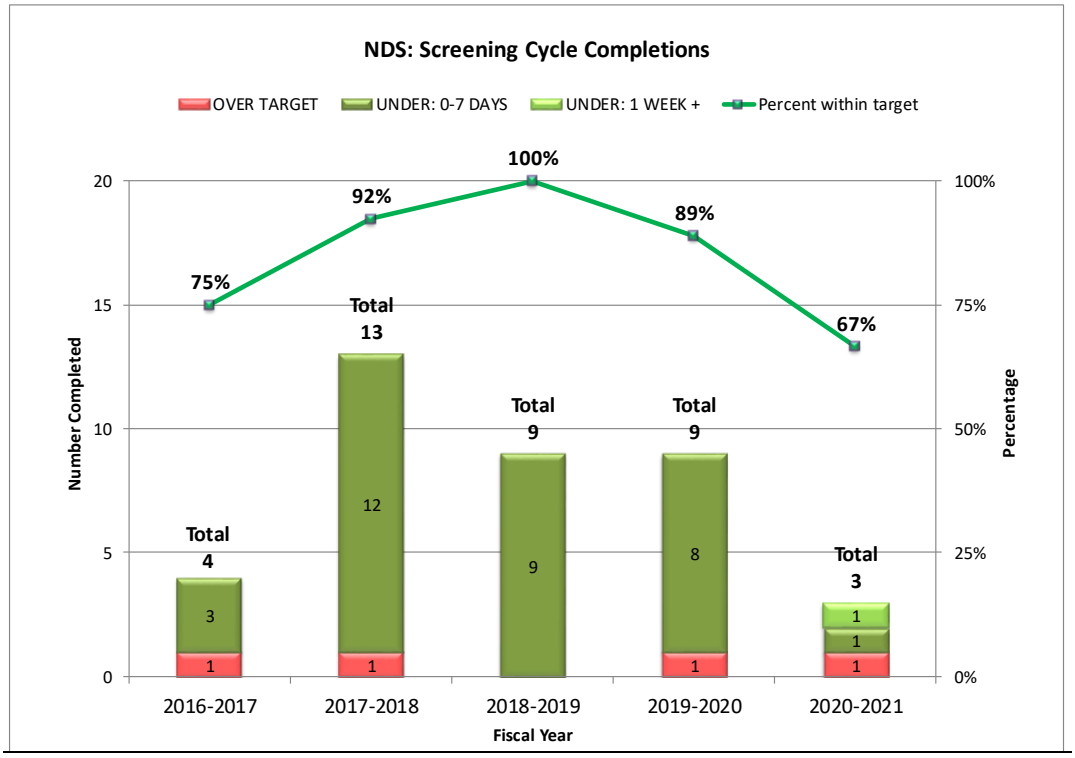
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions



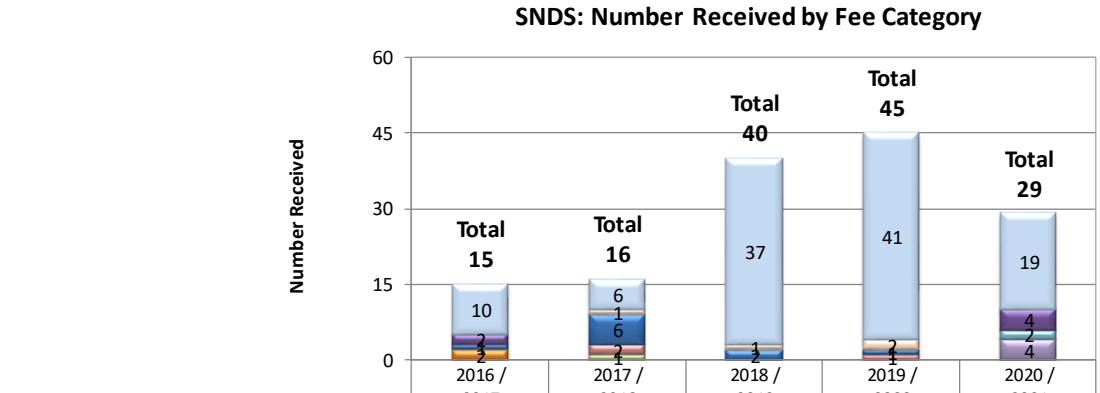
NDS: Screening Cycle Completions



SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION

RECEIVED

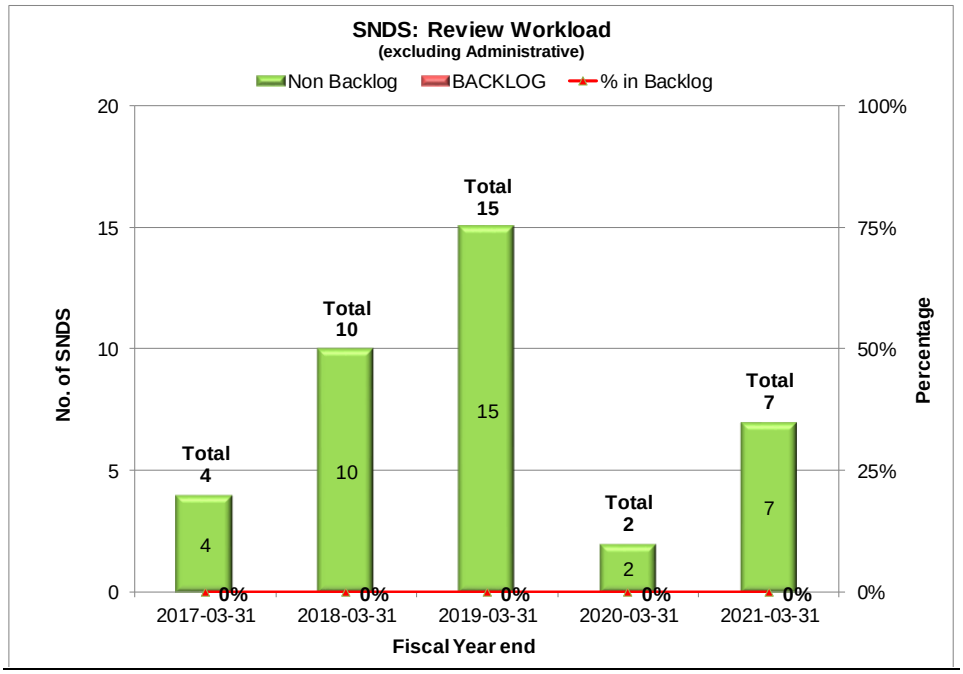
SNDS: Number Received by Fee Category



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
Labelling Only	10	6	37	41	19
Clinical or Non-Clinical Data	0	1	1	2	0
Administrative	2	0	0	0	4
Chemistry and Manufacturing	1	6	2	1	0
Safety Update Label	0	0	0	0	2
Label Update Generic	0	0	0	0	4
Comparative Studies with or without Chemistry - Manufacturing	0	2	0	1	0
Published Data Only	2	0	0	0	0
Prescription to Non-prescription Switch	0	1	0	0	0
Total	15	16	40	45	29

WORKLOAD

SNDS: Review Workload

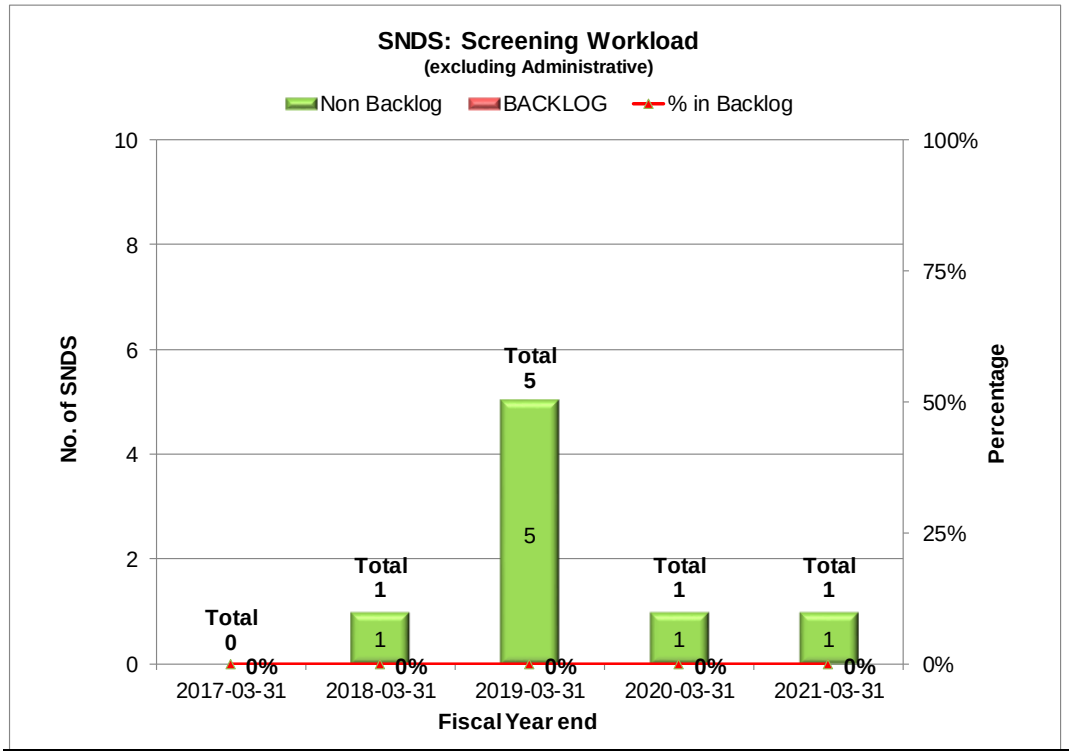


SNDS: Review Workload by Fee Category

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	1	2	12	0	4
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	2	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	1	4	2	2	0
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	*0*	*1*	*1*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies with or without C&M	*0*	*2*	*0*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Prescription to Non-Prescription Switch	*0*	*1*	*0*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Total	4	10	15	2	7
Non Backlog	4	10	15	2	7
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

SNDS: Screening Workload



SNDS: Screening Workload by Fee Category

SNDS: 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
Chemistry and Manufacturing	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	5	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	1	5	1	1
Non Backlog	0	1	5	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

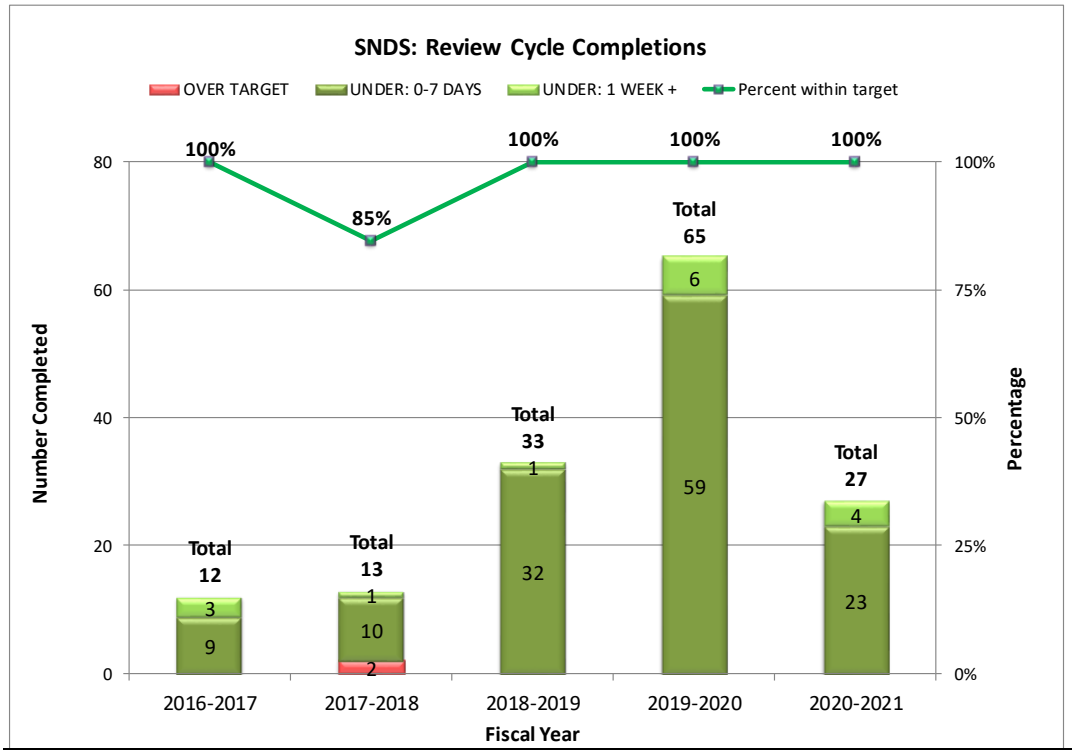
SNDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	1	0
	NOTICE OF COMPLIANCE*	0	0	1	2	1
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	1	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF COMPLIANCE*	2	3	5	1	2
	NOTICE OF NON-COMPLIANCE	1	0	1	2	0
	SCREENING DEFICIENCY NOTICE	1	5	2	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	2	0	0
	NOTICE OF DEFICIENCY	0	1	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
ADMINISTRATIVE	CANCELLATION LETTER	2	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	4
	SCREENING DEFICIENCY NOTICE	2	0	0	0	2
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	0	1	0	0
	NOTICE OF COMPLIANCE*	5	6	13	53	20
	SCREENING DEFICIENCY NOTICE	3	3	5	11	1
	CANCELLATION LETTER	4	0	3	4	1
	NOTICE OF DEFICIENCY	1	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	1	7	5	0
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	0	0	0	2
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
SAFETY UPDATE LABEL	NOTICE OF COMPLIANCE*	0	0	0	0	1
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	1	0	0
	CANCELLATION LETTER	0	0	1	0	0
PUBLISHED DATA ONLY	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	2	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0

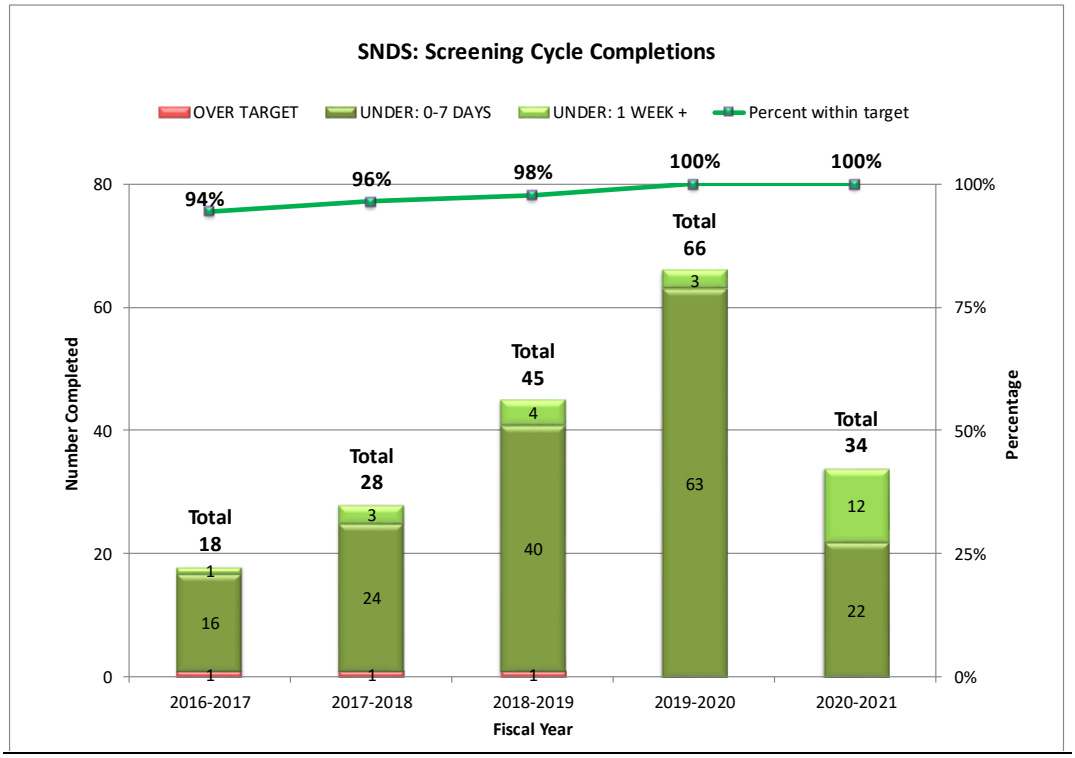
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: Review Cycle Completions



SNDS: Screening Cycle Completions



ANDS: ABBREVIATED NEW DRDUG SUBMISSION

RECEIVED

ANDS: Number Received by Fee Category

ABBREVIATED NEW DRUG SUBMISSION (ANDS)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
Administrative	0	0	0	2	2
Chemistry and Manufacturing	0	0	0	0	1
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	3	2
Labelling Only	0	0	0	2	2
Total	**0**	**0**	**0**	**7**	**7**

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Comparative Studies with or without C&M	0	0	0	2	2
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	0	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	0	0	3	4
Non Backlog	0	0	0	3	4
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

ANDS: Screening Workload

ANDS: SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Comparative Studies with or without C&M	0	0	0	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	0	0	1	1
Non Backlog	0	0	0	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

ANDS: Administrative-Screening Workload

ANDS: ADMINISTRATIVE SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Administrative	0	0	0	0	1
Non Backlog	0	0	0	0	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

ANDS: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	1	0	100%	1
2020-2021	1	4	0	80%	5

ANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	7	0	100%	7
2020-2021	0	5	3	100%	8

ANDS: Administrative Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	1	0	100%	1
2020-2021	0	1	0	100%	1

DECISIONS

ANDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	1	1
	SCREENING DEFICIENCY NOTICE	0	0	0	1	1
	REJECTION LETTER (SCR)	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	2	0
	NOTICE OF COMPLIANCE*	0	0	0	0	2
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	1	2
	SCREENING DEFICIENCY NOTICE	0	0	0	1	2

*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRDUG SUBMISSION

RECEIVED

SANDS: Number Received by Fee Category

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION (SANDS)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
Administrative	0	0	0	7	15
Chemistry and Manufacturing	0	0	0	1	5
Label Update Generic	0	0	0	0	10
Labelling Only	0	0	0	16	29
Total	***0***	***0***	***0***	***24***	***59***

WORKLOAD

SANDS: Review Workload

SANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Chemistry & Manufacturing	0	0	0	0	4
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	0	6	7
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	0	0	6	13
Non Backlog	0	0	0	6	13
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Screening Workload

SANDS: SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Chemistry & Manufacturing	0	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	0	1	4
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	0	0	2	4
Non Backlog	0	0	0	2	4
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Administrative-Screening Workload

SANDS: ADMINISTRATIVE SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
ADMINISTRATIVE	0	0	0	5	2
Backlog	*0*	*0*	*0*	*0*	*0*
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

SANDS: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	6	1	100%	7
2020-2021	0	24	5	100%	29

SANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	1	21	0	95%	22
2020-2021	2	23	24	96%	49

SANDS: Administrative Screening Performance

ADMIN SCREENING	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	2	0	100%	2
2020-2021	0	14	6	100%	20

DECISIONS

SANDS: Number of Decisions by Fee Category

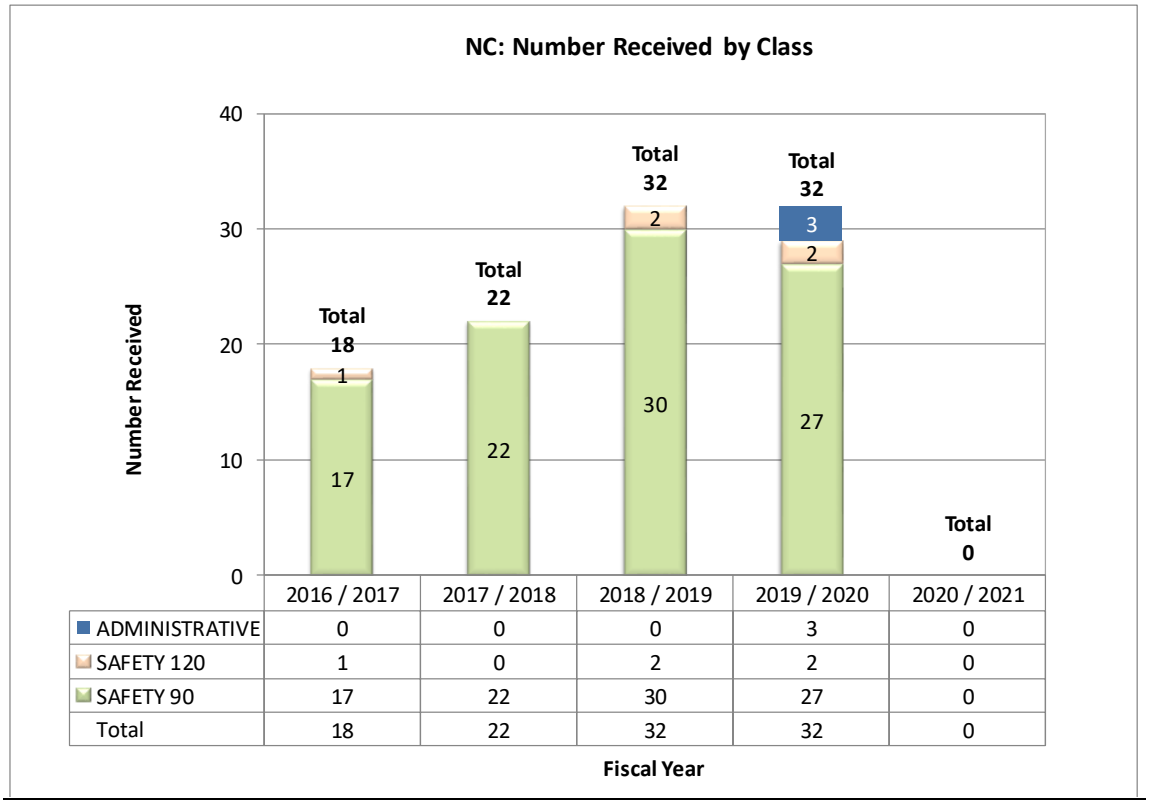
User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	0	0	0	2	17
	CANCELLATION LETTER	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
CHEMISTRY AND MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	3
LABELLING ONLY	CANCELLATION LETTER	0	0	0	1	2
	NOTICE OF COMPLIANCE*	0	0	0	7	25
	SCREENING DEFICIENCY NOTICE	0	0	0	8	4
LABEL UPDATE GENERIC	CANCELLATION LETTER	0	0	0	0	5
	NOTICE OF COMPLIANCE*	0	0	0	0	3
	SCREENING DEFICIENCY NOTICE	0	0	0	0	4

*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

NC: NOTIFIABLE CHANGE

RECEIVED

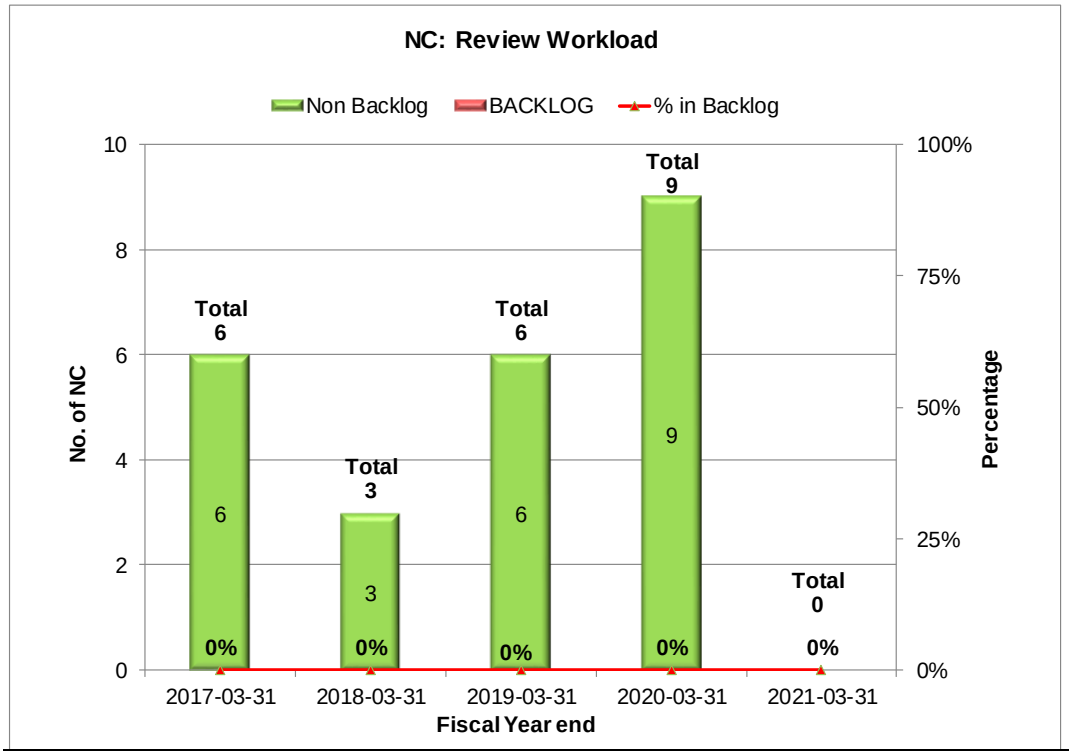
NC: Number Received by Class



	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
ADMINISTRATIVE	0	0	0	3	0
SAFETY 120	1	0	2	2	0
SAFETY 90	17	22	30	27	0
Total	18	22	32	32	0

WORKLOAD

NC: Review Workload

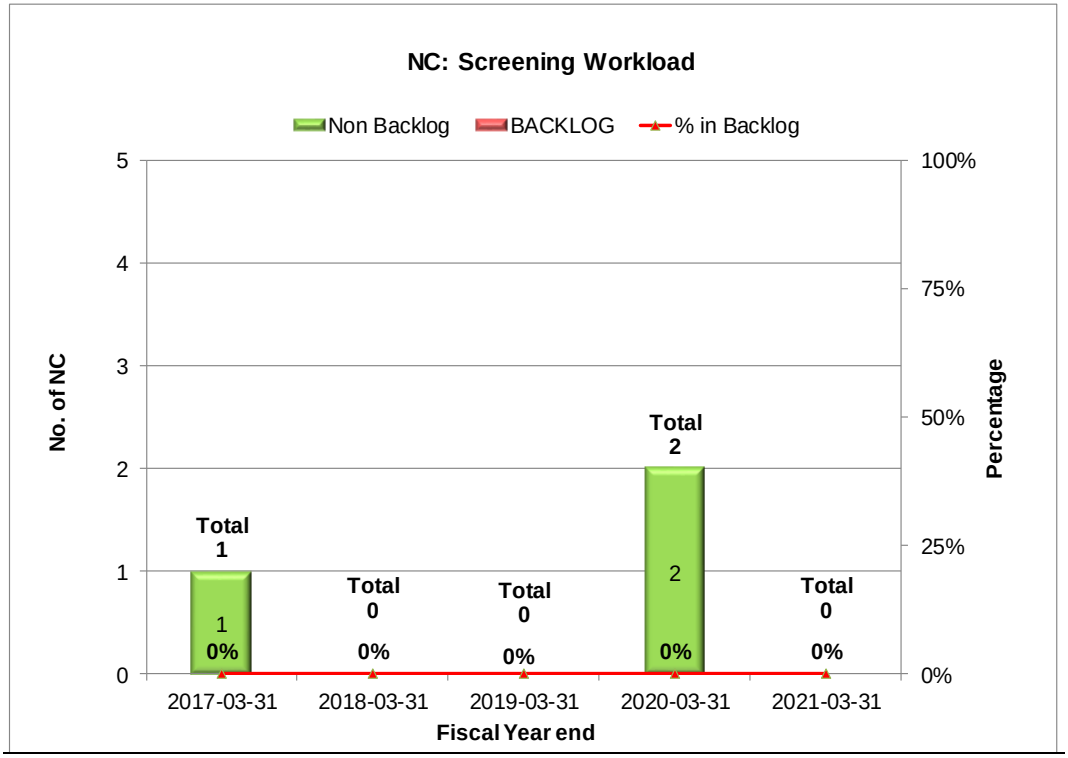


NC: Review Workload by Class

NC: REVIEW WORKLOAD BY CLASS and Fiscal Year end					
CLASS	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
SAFETY 90	5	3	4	8	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY 120	1	0	2	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	6	3	6	9	0
Non Backlog	6	3	6	9	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NC: Screening Workload



NC: Screening Workload by Class

NC: SCREENING WORKLOAD BY CLASS and Fiscal Year end					
CLASS	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
SAFETY 90	1	0	0	2	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	1	0	0	2	0
Non Backlog	1	0	0	2	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

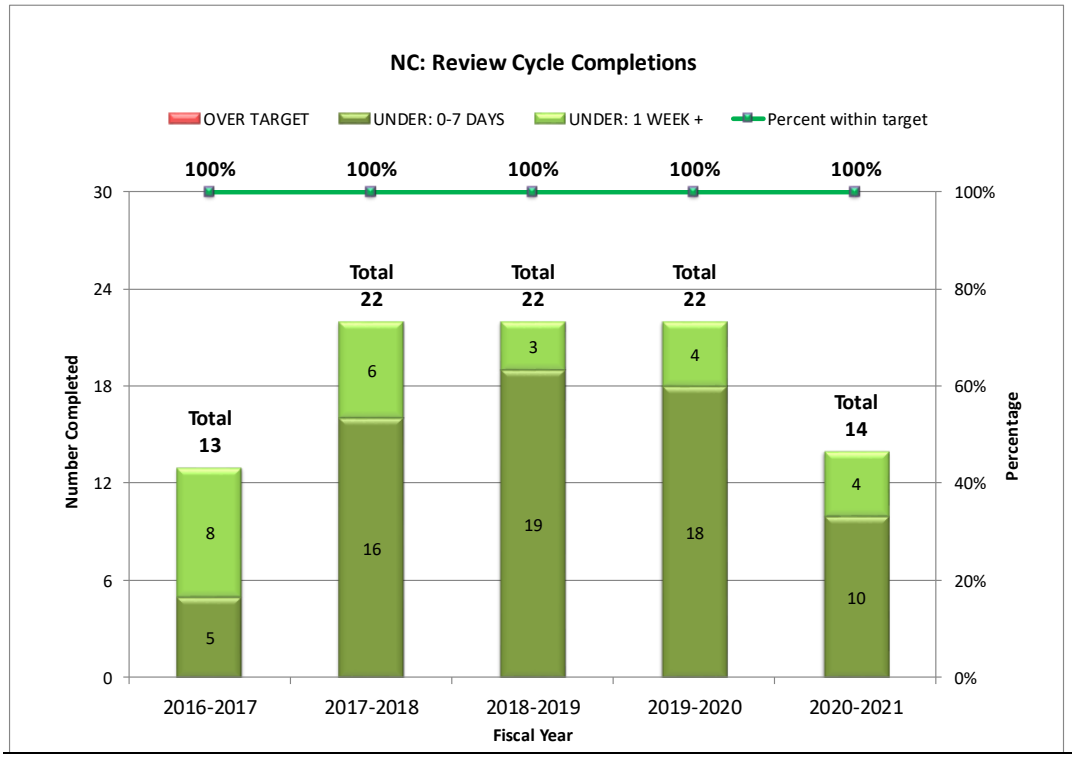
DECISIONS

NC: Number of Decisions by Class

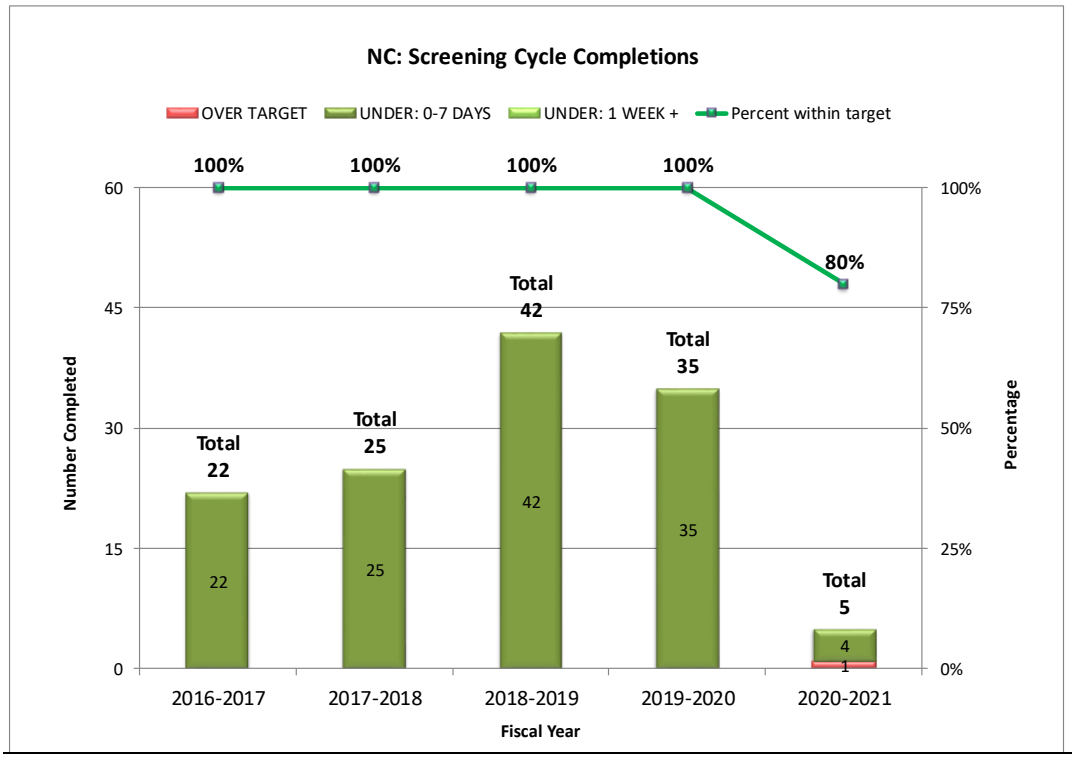
Class	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	1	0
	NO OBJECTION LETTER	0	0	0	2	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
SAFETY 90	NO OBJECTION LETTER	13	20	19	19	13
	CANCELLATION LETTER	1	2	8	2	0
	REJECTION LETTER (SCR)	1	1	1	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	4	5	16	8	0
	NC-HOLD (SWITCH)	0	0	0	0	0
SAFETY 120	CANCELLATION LETTER	0	1	0	1	0
	NO OBJECTION LETTER	0	0	0	2	1

PERFORMANCE

NC: Review Cycle Completions



NC: Screening Cycle Completions



PRE-MEETINGS

MPDIN: Number Received by Fee Category

PRE - DIN MEETING (MPDIN)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
Clinical or Non-Clinical Data	0	0	0	2	1
Chemistry and Manufacturing	0	0	0	0	4
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	0	0	1
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	1
Total	***0***	***0***	***0***	***2***	***7***

MPNDS: Number Received by Fee Category

PRE - NDS MEETING (MPNDS)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	0	4	1
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	2	0
Prescription to Non-Prescription Switch	0	0	0	0	1
Total	***0***	***0***	***0***	***6***	***2***

MPSNDS: Number Received by Fee Category

PRE - SNDS MEETING (MPSNDS)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
Clinical or Non-Clinical Data	0	0	0	1	0
Chemistry and Manufacturing	0	0	0	0	2
Total	***0***	***0***	***0***	***1***	***2***

PART 2: DISINFECTANT PRODUCTS

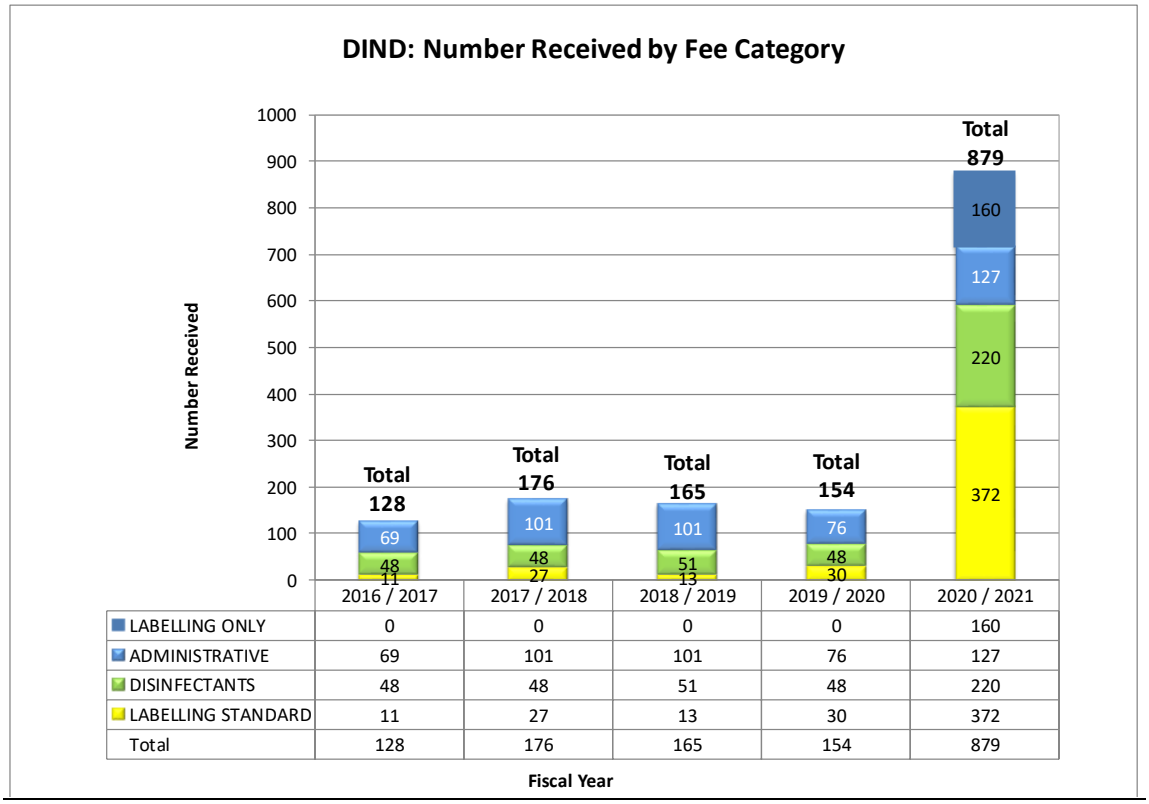
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

RECEIVED

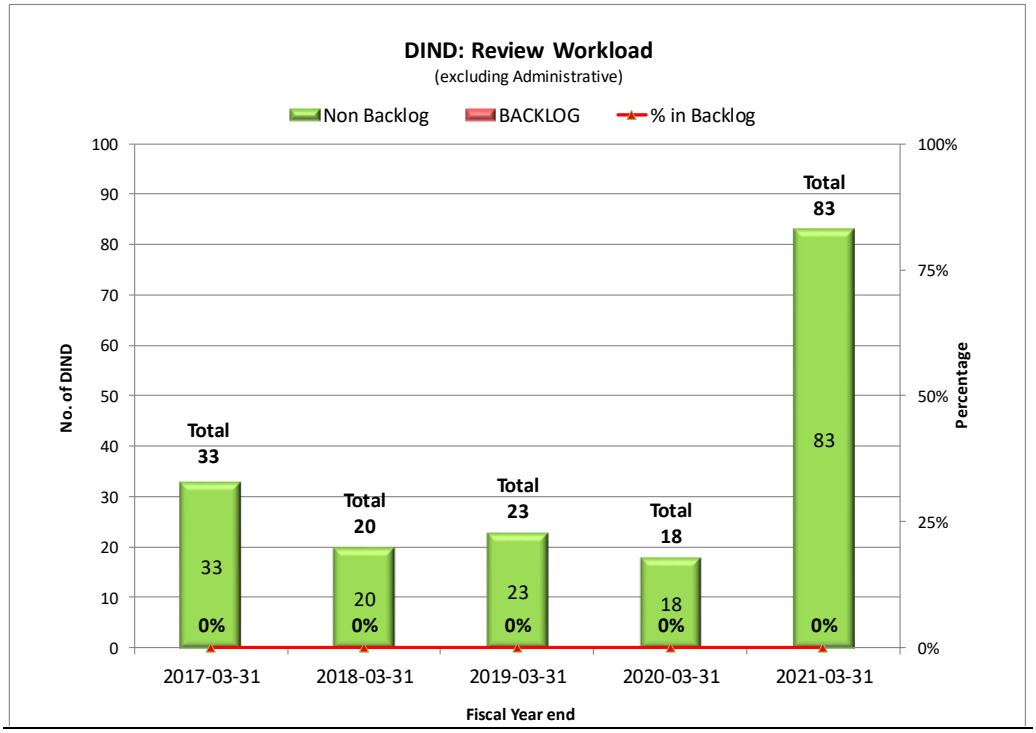
DIND-Disinfectant Products: Number Received by Fee Category



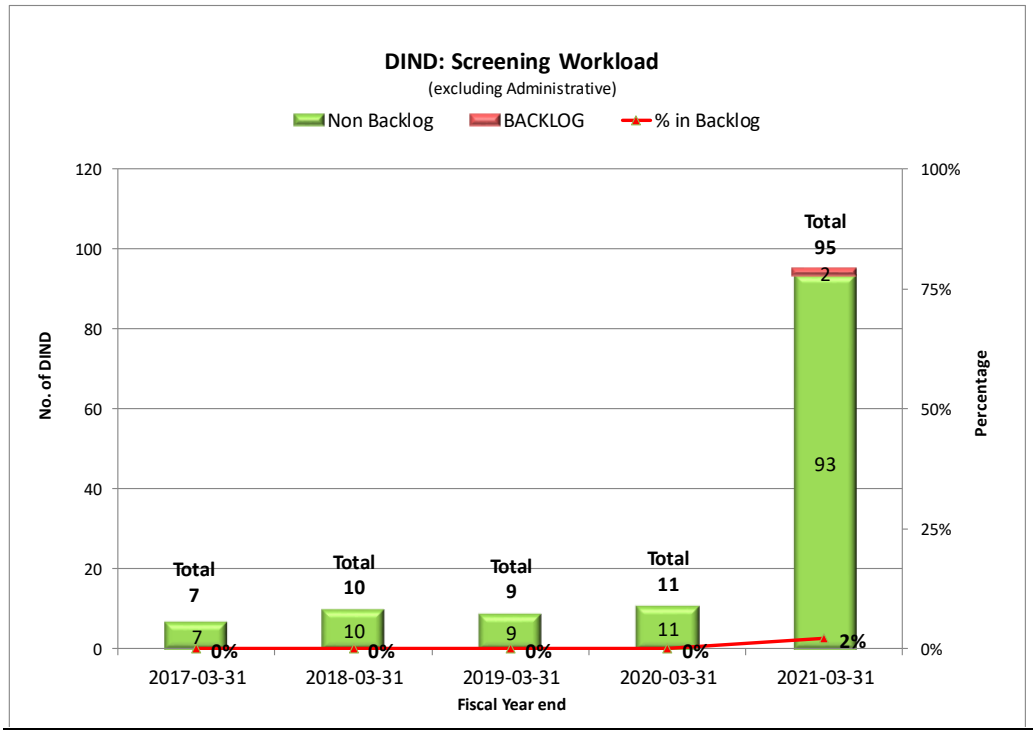
	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021
LABELLING ONLY	0	0	0	0	160
ADMINISTRATIVE	69	101	101	76	127
DISINFECTANTS	48	48	51	48	220
LABELLING STANDARD	11	27	13	30	372
Total	128	176	165	154	879

WORKLOAD

DIND-Disinfectant Products: Review Workload

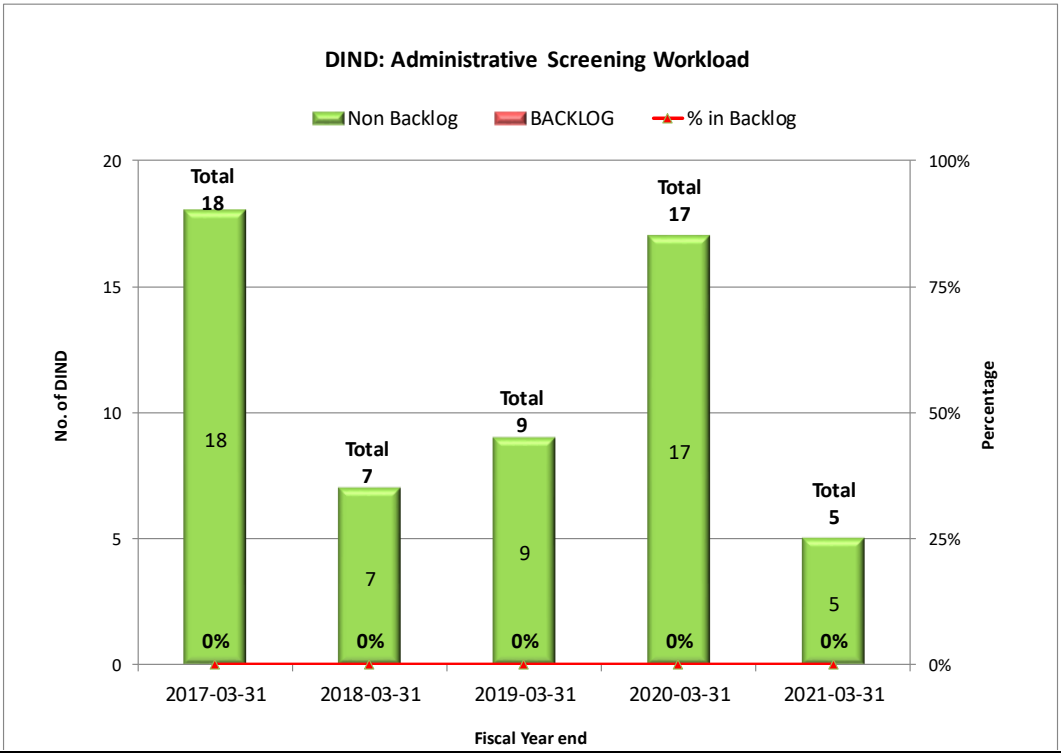


DIND-Disinfectant Products: Screening Workload



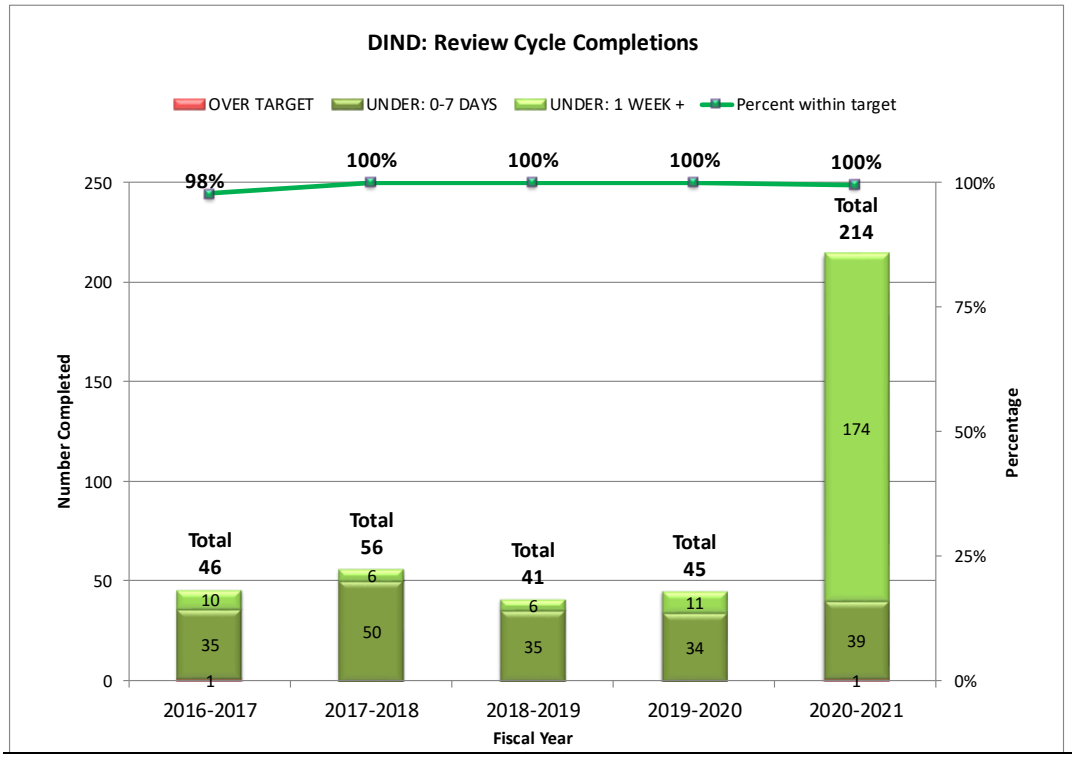
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

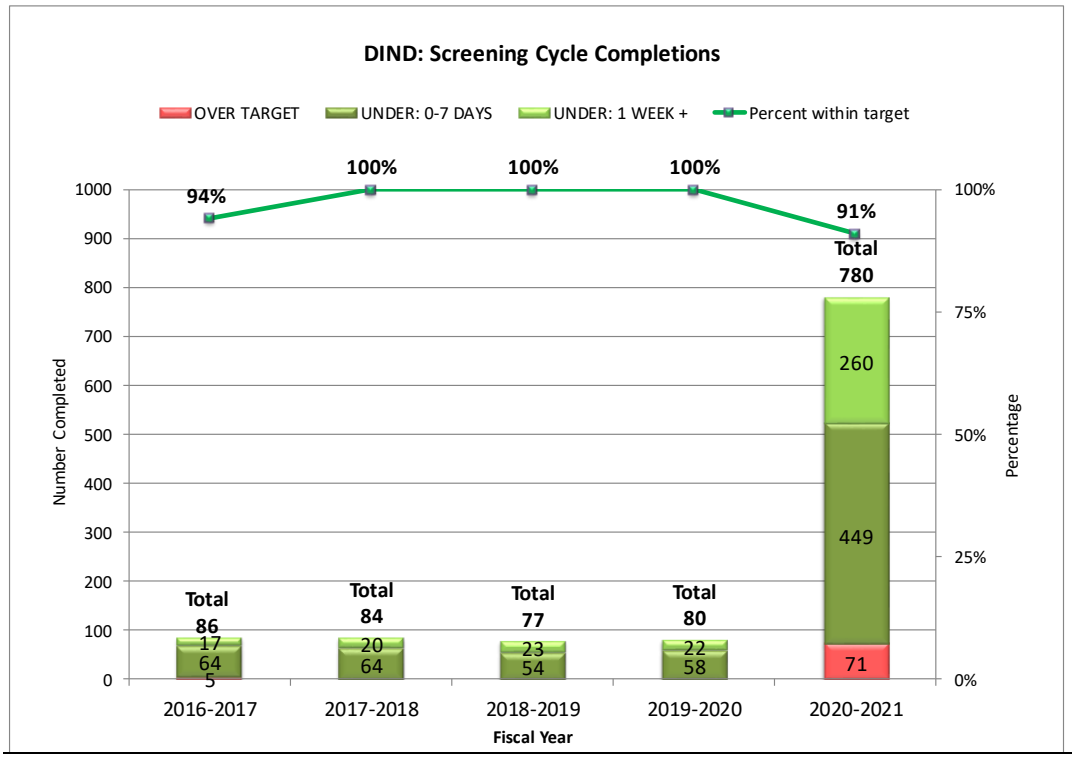


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

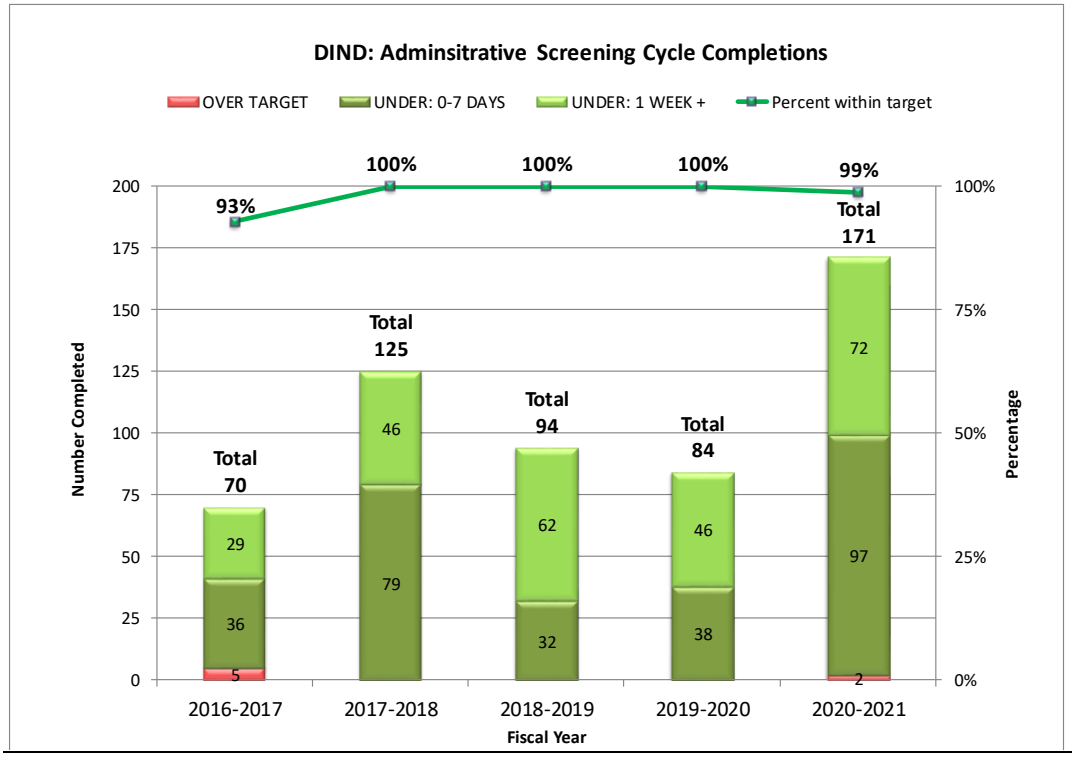


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



DECISIONS

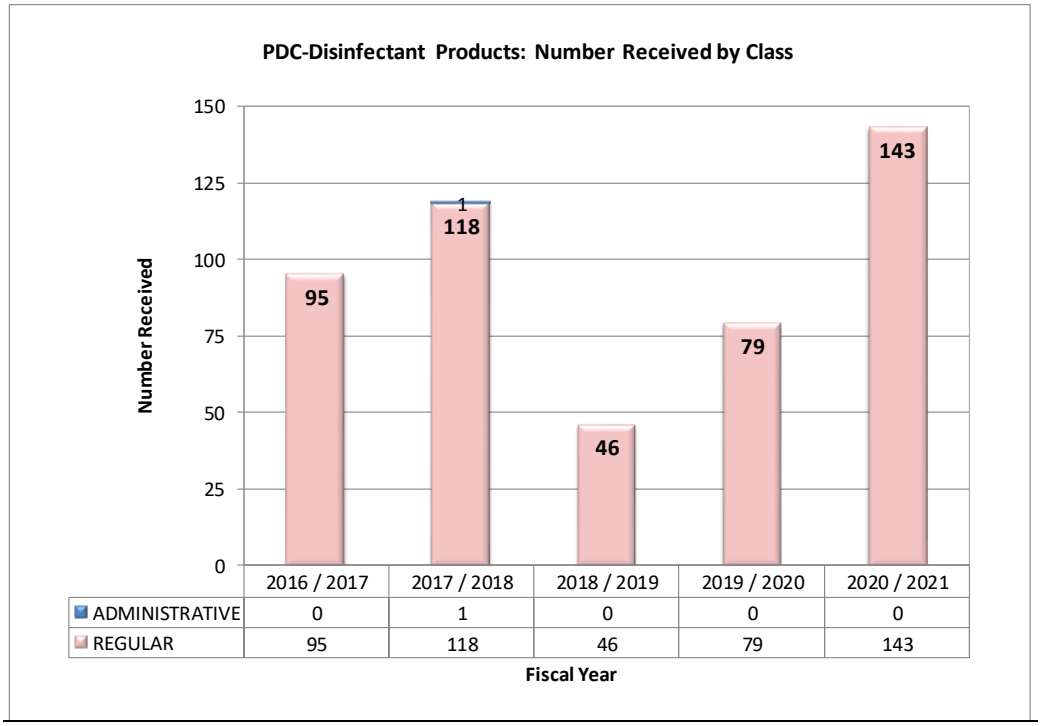
DIND-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	43	94	62	62	87
	NO OBJECTION LETTER	3	0	9	2	13
	CANCELLATION LETTER	1	2	8	0	25
	REJECTION LETTER (SCR)	9	15	1	4	8
	SCREENING DEFICIENCY NOTICE	18	20	22	19	52
DISINFECTANTS	NOTIFICATION FORM DIN SUB	27	37	33	39	36
	NO OBJECTION LETTER	9	17	8	6	73
	CANCELLATION LETTER	1	3	4	1	19
	NEW DRUG LETTER SCREEN	0	0	0	0	2
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	9	1	0	0	4
	SCREENING DEFICIENCY NOTICE	20	5	8	5	41
	REJECTION LETTER (SCR)	6	1	0	2	13
LABELLING ONLY	CANCELLATION LETTER	0	0	0	0	19
	NO OBJECTION LETTER	0	0	0	0	6
	NOTICE OF NON-COMPLIANCE	0	0	0	0	4
	NOTIFICATION FORM DIN SUB	0	0	0	0	88
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	16
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	8	20	14	23	269
	NO OBJECTION LETTER	0	1	0	0	3
	CANCELLATION LETTER	0	0	0	0	42
	NEW DRUG LETTER SCREEN	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	4	10	5	9	95
	REJECTION LETTER (SCR)	1	3	4	0	17

PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

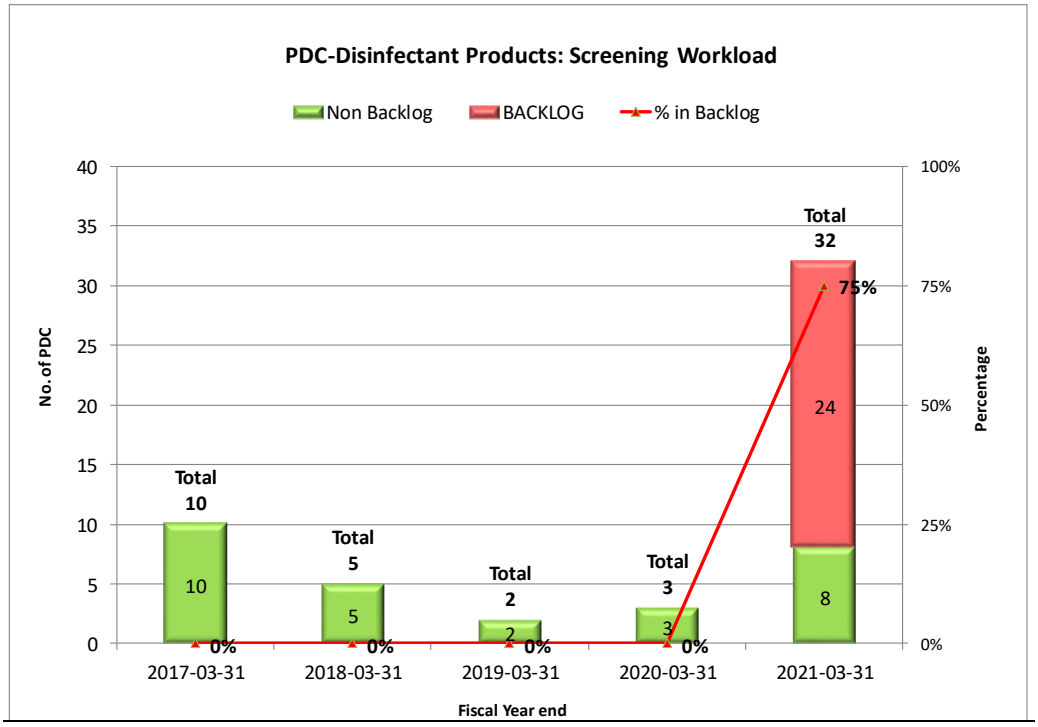
RECEIVED

PDC-Disinfectant Products: Received by Class



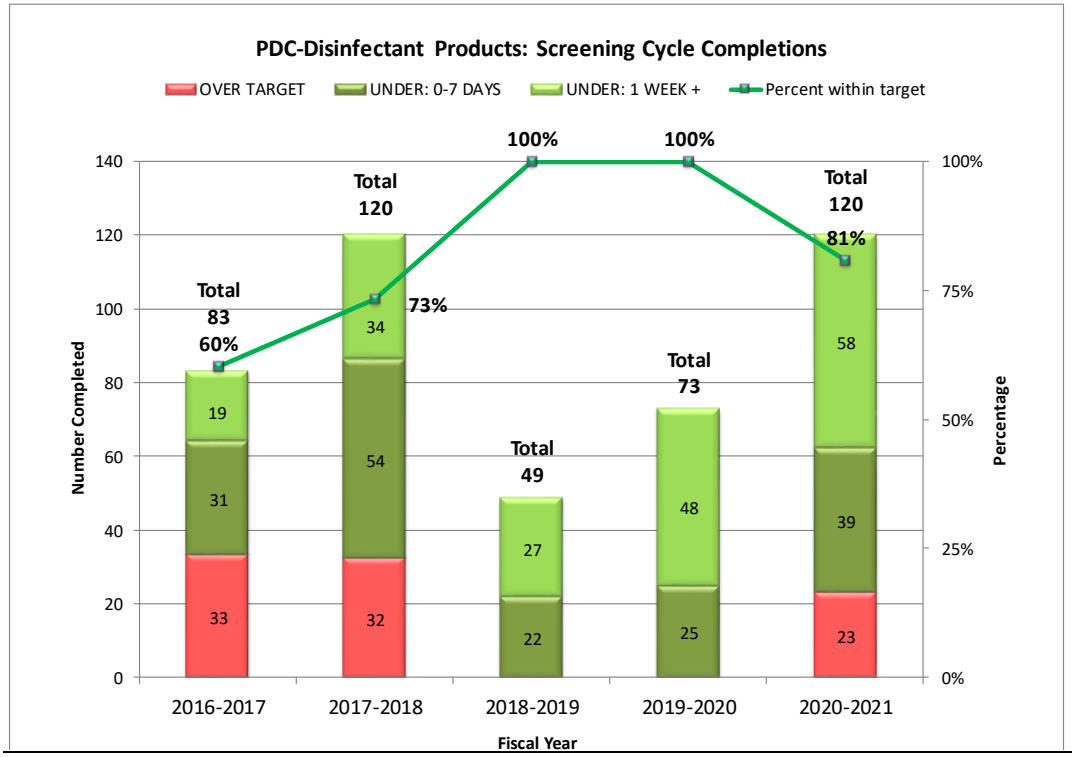
WORKLOAD

PDC-Disinfectant Products: Screening Workload



PERFORMANCE

PDC-Disinfectant Products: Screening Cycle Completions



DECISIONS

PDC-Disinfectant Products: Number of Decisions by Class

Class	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	1	0	0	0
REGULAR	NO OBJECTION LETTER	41	78	39	62	94
	NOT SATISFACTORY NOTICE	38	35	9	6	18
	CANCELLATION LETTER	1	0	0	3	5
	NOTIFICATION FORM DIN SUB	2	4	0	0	0
	REJECTION LETTER (SCR)	1	4	0	1	1
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0

DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS-D: NEW DRUG SUBMISSION - DISINFECTANT PRODUCTS

RECEIVED

NDS-Disinfectant Products: Number Received by Fee Category

NEW DRUG SUBMISSION DISINFECTANT PRODUCTS (NDS-D)					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
DISINFECTANTS	4	2	1	1	5
ADMINISTRATIVE	1	0	1	0	0
Total	***5***	***2***	***2***	***1***	***5***

WORKLOAD

NDS-Disinfectant Products: Review Workload

NDS-D Disinfectant Products: 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
Dinsinfectants	3	2	1	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Screening Workload

NDS-D Disinfectant Products: 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
Dinsinfectants	2	0	1	0	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Administrative-Screening Workload

NDS-D Disinfectant Products: ADMIN SCREENING WORKLOAD by Fiscal Year end					
FEE CATEGORY	2017-03-31	2018-03-31	2019-03-31	2020-03-31	2021-03-31
Administrative	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NDS-Disinfectant Products: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	3	0	100%	3
2018-2019	0	1	1	100%	2
2019-2020	0	1	1	100%	2
2020-2021	0	1	0	100%	1

NDS-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	6	100%	6
2017-2018	0	9	0	100%	9
2018-2019	0	1	0	100%	1
2019-2020	0	4	0	100%	4
2020-2021	1	3	0	75%	4

NDS-Disinfectant Products: Administrative-Screening Performance

ADMIN SCREENING	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	1	0	0	0%	1
2017-2018	0	0	0	-	0
2018-2019	0	2	0	100%	2
2019-2020	0	0	0	-	0
2020-2021	0	0	0	-	0

DECISIONS

NDS-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
ADMINISTRATIVE	CANCELLATION LETTER	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	1	0	0
	NOTICE OF COMPLIANCE*	0	0	1	0	0
DISINFECTANTS	NOTICE OF COMPLIANCE*	0	1	1	0	1
	NOTICE OF NON-COMPLIANCE	0	0	1	1	0
	NOTICE OF DEFICIENCY	0	3	0	0	0
	NOD WITHDRAWAL LETTER	0	1	0	0	0
	REJECTION LETTER (SCR)	0	2	0	1	1
	CANCELLATION LETTER	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	3	3	0	1	3

*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

NC: NOTIFIABLE CHANGE - DISINFECTANT PRODUCTS

RECEIVED

NC-Disinfectant Products: Received by Class

NOTIFIABLE CHANGE- DISINFECTANT PRODUCTS					
Class	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
SAFETY 90	0	1	0	0	0

WORKLOAD

NC-Disinfectant Products: Review Workload

NC-Disinfectant Products: REVIEW WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
SAFETY-90	0	0	0	0	0
Backlog	0	0	0	0	0
Total	**0**	**0**	**0**	**0**	**0**
Non Backlog	**0**	**0**	**0**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

NC-Disinfectant Products: Screening Workload

NC-Disinfectant Products: SCREENING WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	**2017-03-31**	**2018-03-31**	**2019-03-31**	**2020-03-31**	**2021-03-31**
SAFETY-90	0	0	0	0	0
Backlog	0	0	0	0	0
Total	**0**	**0**	**0**	**0**	**0**
Non Backlog	**0**	**0**	**0**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

PERFORMANCE

NC-Disinfectant Products: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	0	1	100%	1
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0
2020-2021	0	0	0	-	0

NC-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2016-2017	0	0	0	-	0
2017-2018	0	1	0	100%	1
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0
2020-2021	0	0	0	-	0

DECISIONS

NC-Disinfectant Products: Number of Decisions by Class

Class	Decision Document Type	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
SAFETY 90	NO OBJECTION LETTER	0	1	0	0	0

PRE-MEETINGS - DISIFECTANT PRODUCTS

MPNDS-Disinfectant Products: Received by Fee Category

PRE-NDS MEETING (MPNDS) DISINFECTANT PRODUCTS					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	1
CHEMISTRY AND MANIFACTURING	0	0	0	0	2
Total	***0***	***0***	***0***	***0***	***3***

MPSNDS-Disinfectant Products: Received by Fee Category

PRE-SNDS MEETING (MPSNDS) DISINFECTANT PRODUCTS					
User Fee Category	**2016 / 2017**	**2017 / 2018**	**2018 / 2019**	**2019 / 2020**	**2020 / 2021**
CLINICAL OR NON-CLINICAL DATA	0	0	1	0	0