Health Canada Santé Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2021-2022

April 1 2021 - March 31 2022

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 2017-2018 to 2021-2022. 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.[1] 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.

- The Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was repealed and replaced on February 27, 2022 by the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations to allow sponsors to continue conducting clinical trials authorized under the interim order and ensure all authorizations, suspensions and exemptions for clinical trials issued under the interim order will remain in effect. The number of CTA and CTA-As received under the interim order and transition regulations are included in the Quarterly Drug Submission Performance Reports for the Pharmaceutical Drugs Directorate (PDD) 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 and the number of applications and amendments in review under the ISAD Interim Order are included in the Quarterly Drug Submission Performance Reports for the Pharmaceutical Drugs Directorate (PDD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD).

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

Some of the highlights of the 2021-2022 report are:

A performance standard of 100% was achieved for DIN-D submissions with 263 submissions with a review cycle completion that met the target date. A performance standard of 99.98% was achieved for DINA submissions, with one of 61 submissions with a review cycle completion cleared after the target date. A performance standard of 87.5% was achieved for ANDS submissions, with one of 8 submissions with a review cycle completion cleared after the target date.

NDED achieved a performance standard of 99.99% for cost recovered submissions with 2/568 submissions completed after the target dates.

A performance standard of 29% was achieved for disinfectant related PDC submissions with 81/114 submissions with a screening cycle completion cleared after the target date. A performance standard of 99% was achieved for OTC related PDC submissions with 6/197 submissions with a screening cycle completion cleared after the target date.

NDED achieved a performance standard of 72% for non-cost recovered PDC submissions with 87/311 submissions with a screening cycle completion cleared after the target date.

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

• The number of DINA submissions received decreased by 44% in 2021-2022 (92) compared to 2020-2021 (165). Decreases were uniform across all DINA submission types.

• The number of DINF submissions received decreased by 44% in 2021-2022 (127) compared to 2020-2021 (227).

• The number of PDC submissions received decreased by 47% in 2021-2022 (208) compared to 2020-2021 (396).

• No NDS submissions were received in 2021-2022 compared to 10 in 2020-2021.

• The number of SNDS submissions received in 2021-2022 (38) increased by 31% compared to 2020-2021 (29).

• The number of ANDS submissions received remained consistent in 2021-2022 (7) compared to 2020-2021 (7).

• The number of SANDS submissions received in 2021-2022 (38) decreased by 36% compared to 2020-2021 (59). A significant decrease in SANDS Admin and SANDS Label Update Generic categories accounts for this decrease.

• NC submissions were discontinued in 2019-2020. Therefore, no NC submission was filed in 2021-2022.

Overall, the total non-prescription drug submissions received decreased by 41% during 2021-2022 (510) compared to 2020-2021 (864). This significant decrease follows an all time high volume of submissions received in 2019-2020 and 2020-2021 in response to the COVID 19 pandemic. The volume of submissions received in 2021-2022 is now slightly lower than pre-pandemic fiscal years (742 in 2015-2016; 699 in 2016-2017; 658 in 2017-2018; and 616 in 2018-2019), and is reflective of the completion of the Plain Language Labelling (PLL) implementation.

Disinfectant Drugs:

• The number of DIND submissions received decreased by 54% in 2021-2022 (404) compared to 2020-2021 (879). The volume of DIND submissions received in 2020-2021 represented an all time high for this type of submission. Full Review submissions with Data and Labelling Standard (Monograph) submissions accounted for the majority of these increases: 220 Full Reviews and 372 Labelling Standards were received in 2020-2021 compared to 48 and 30 received in 2019-2020, and 140 and 63 received in 2021-2022, 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 decreased by 39% in 2021-2022 (88) compared to 2020-2021 (143). The volume of PDC submissions received 2020-2021 represented an all time high for this type of submission.

• The number of disinfectant NDS-D submissions received increased by 40% in 2021-2022 (7) compared to 2020-2021 (5). This represents a significant increase compared to previous FYs: 2017-2018 (2), 2018-2019 (2), 2019-2020 (1).

• The number of disinfectant SNDS-D submissions received increased significantly in 2021-2022 (3) compared to 2020-2021 (1). No SNDS-D submission was received in previous FYs.

Overall, the total disinfectant drug submissions received during 2021-2022 (502) is at 201% compared to the pre-COVID-19 pandemic, i.e., average for 2017-2018 (299), 2018-2019 (213) and 2019-2020 (236). The surge of disinfectant drug submissions received in 2020-2021 (1027) was reduce to its 51% in 2021-2022 (502) reflecting on the decrease in demand for disinfectant products as we come out of the COVID-19 pandemic. It is important to note that full review submissions with larger data packages represented 28% of all disinfectant drug submissions which is an increase by 8% compared to the average representation of full review submissions pre- and during COVID-19 pandemic, i.e., full review submissions were 16% (2017-2018), 23% (2018-2019), 20% (2019-2020) and 21% (2020-2021) of all disinfectant submissions. Short-term backlogs for the screening components of full review submissions and of post-Division 1 Authorization Change (PDC) submissions were noted in 2021-2022. Although these backlogs did not impact the final cost recovery decisions, increased full review submissions in 2021-2022 had a significant impact on the workload.

General Information

There are several steps involved in the drug submission review[2] and approval process:

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

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

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

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

For new drugs, **approvals** are Notice of Compliances (NOC) Issued or Issuable which are reported in the Decisions' section. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to changes from Prescription to NonPrescription or due to Patented Medicines (NOC) Regulations.

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

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

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

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

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

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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.
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug - Category discontinued.
Labelling Only	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Labelling Only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment.
Administrative Submission	Submissions in support of a manufacturer or product name change.
Disinfectants	Submissions and applications that include data in support of a disinfectant.

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.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS - Category discontinued.

For further information, please consult the Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications.

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

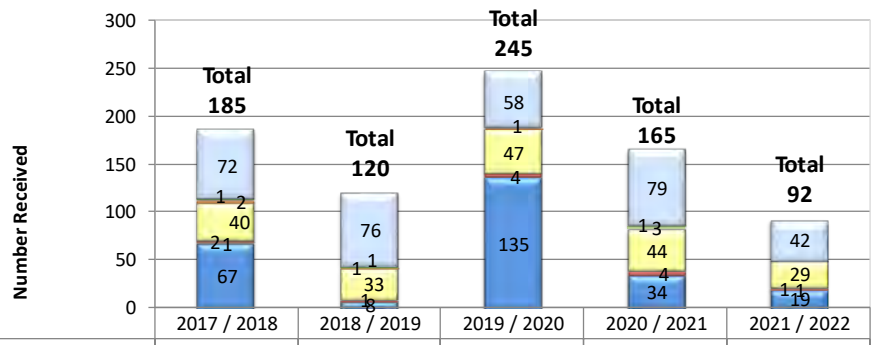
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER

RECEIVED

DINA: Number Received by Fee Category

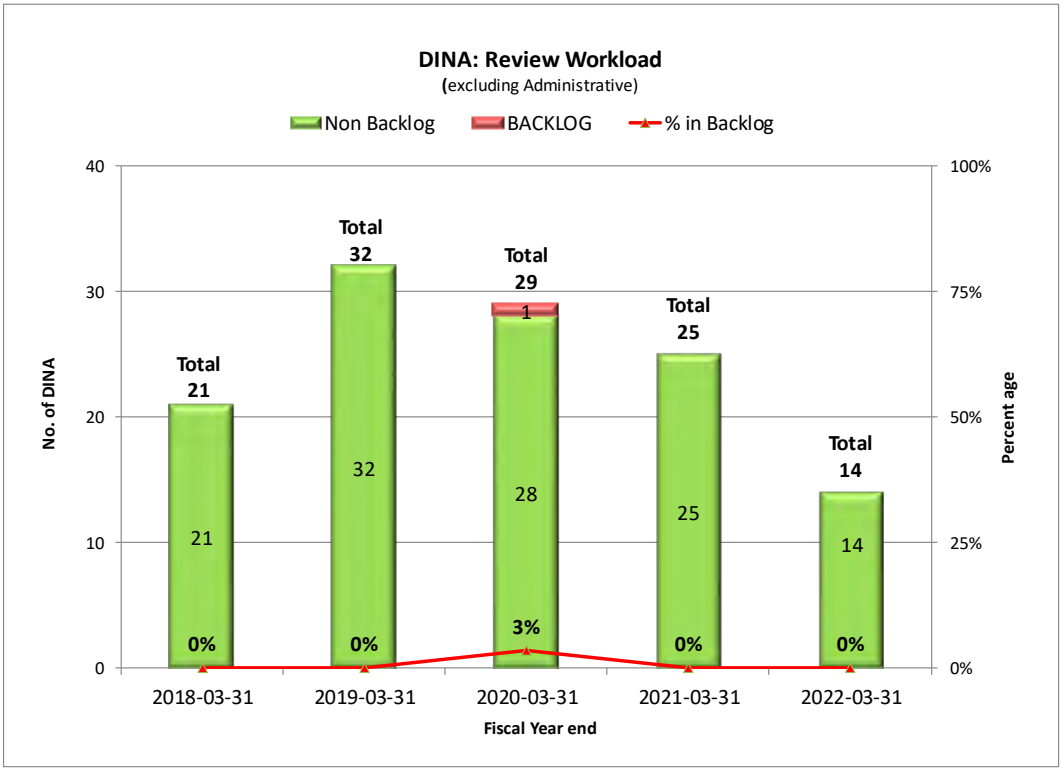


	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
LABELLING ONLY	72	76	58	79	42
CLINICAL OR NON-CLINICAL AND CHEMISTRY - MANUFACTURING	1	1	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY-MANUFACTURING	0	0	0	3	0
PUBLISHED DATA ONLY	2	1	1	0	0
LABELLING STANDARD	40	33	47	44	29
CHEMISTRY AND MANUFACTURING	2	1	4	4	1
CLINICAL OR NON CLINICAL-DATA	1	0	0	0	1
ADMINISTRATIVE	67	8	135	34	19
Total	185	120	245	165	92

Fiscal Year

WORKLOAD

DINA: Review Workload

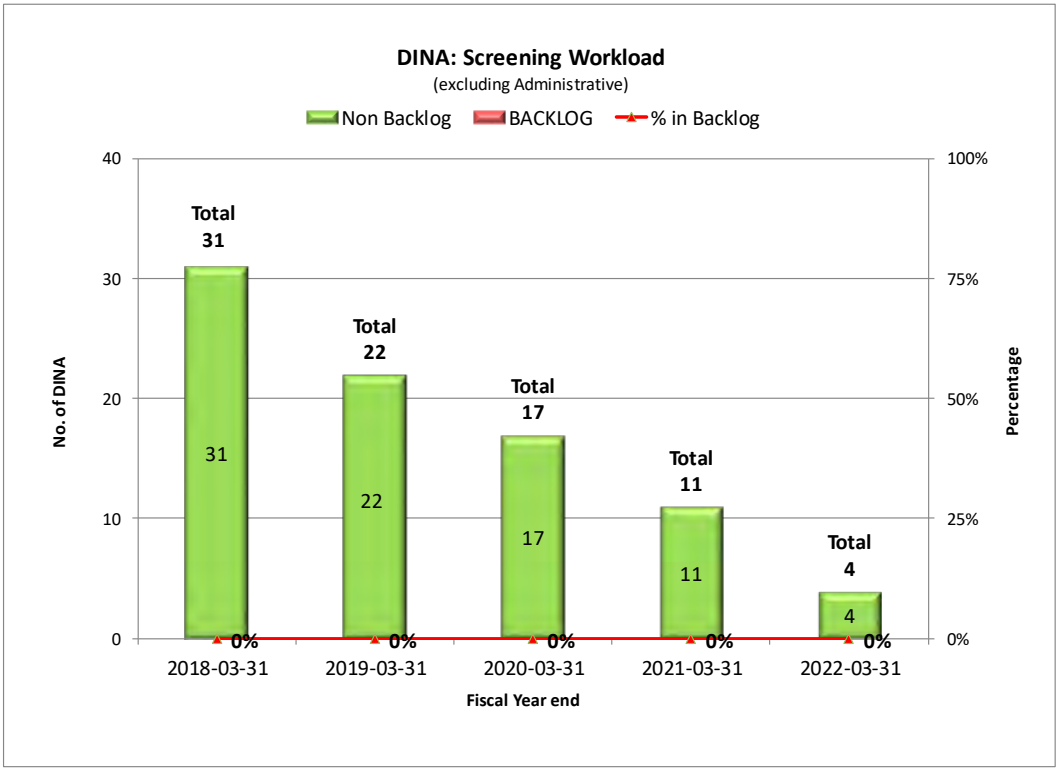


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Labelling Only	19	32	27	17	14
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	1	0	2	4	0
Backlog	*0*	*0*	*1*	*0*	*0*
Clinical or Non-Clinical Data	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	0	0	0	3	0
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	1	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**21**	**32**	**29**	**25**	**14**
Non Backlog	**21**	**32**	**28**	**25**	**14**
BACKLOG	**0**	**0**	**1**	**0**	**0**
% in Backlog	**0%**	**0%**	**3%**	**0%**	**0%**

WORKLOAD

DINA: Screening Workload

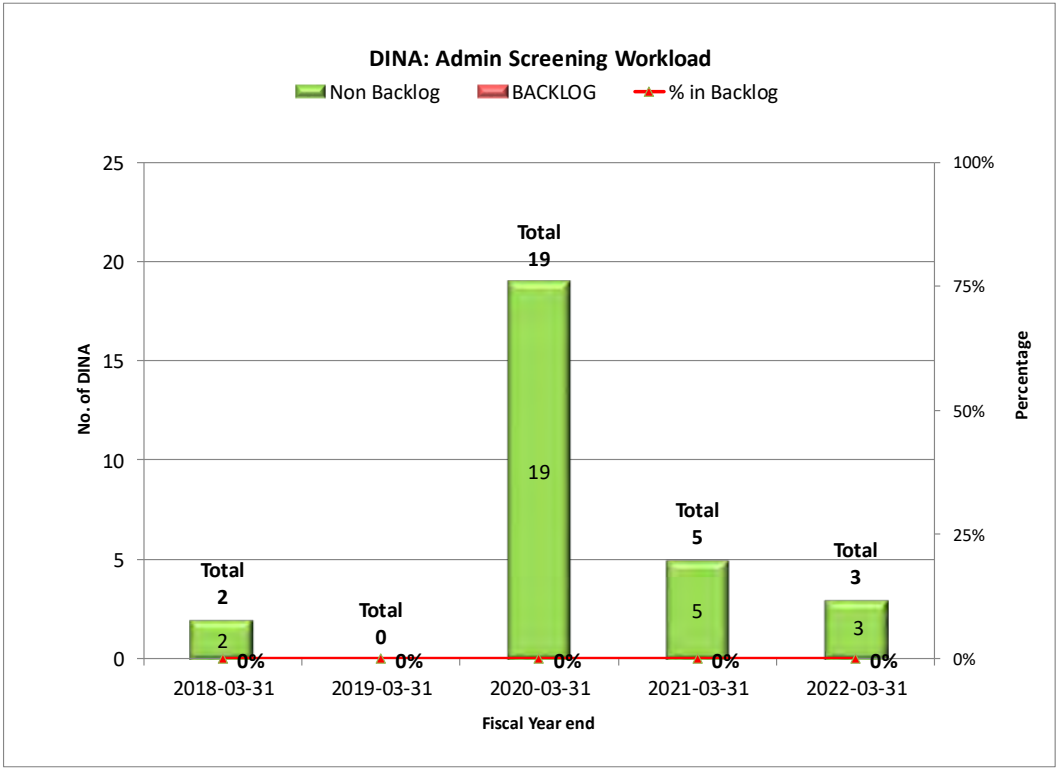


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Labelling Only	21	15	3	8	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	10	6	12	3	3
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	0	0	1	0	1
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	0	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**31**	**22**	**17**	**11**	**4**
Non Backlog	**31**	**22**	**17**	**11**	**4**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Administrative	2	0	19	5	3
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**2**	**0**	**19**	**5**	**3**
Non Backlog	**2**	**0**	**19**	**5**	**3**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

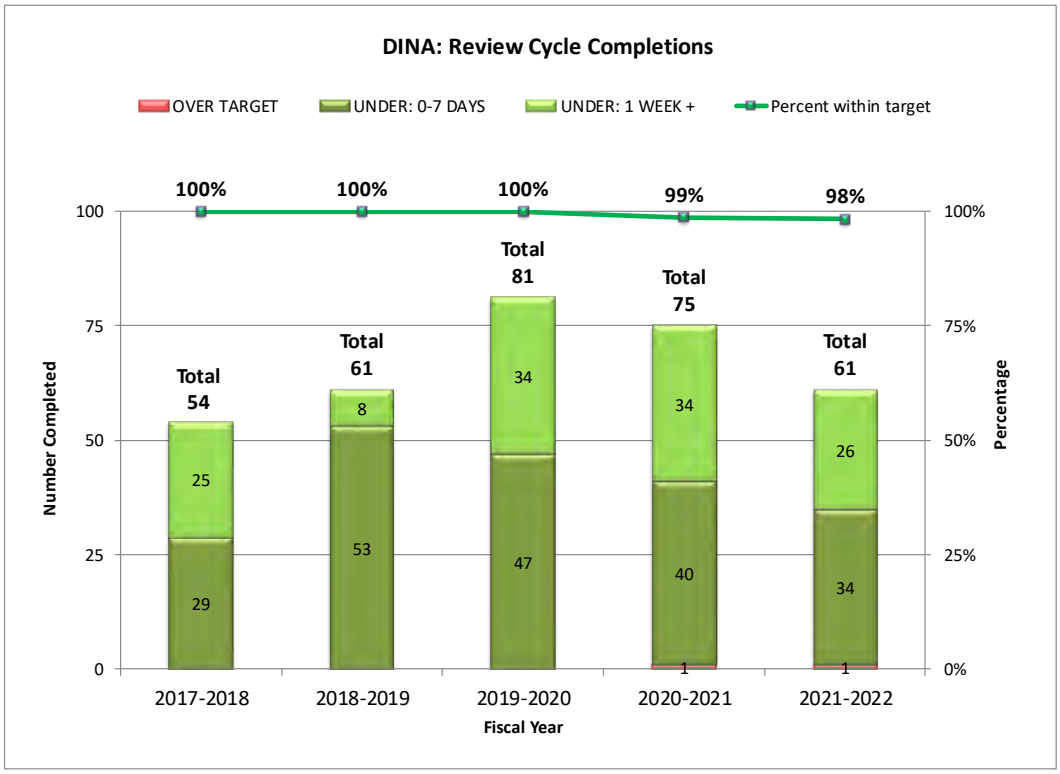
DECISIONS

DINA: Number of Decisions by Fee Category

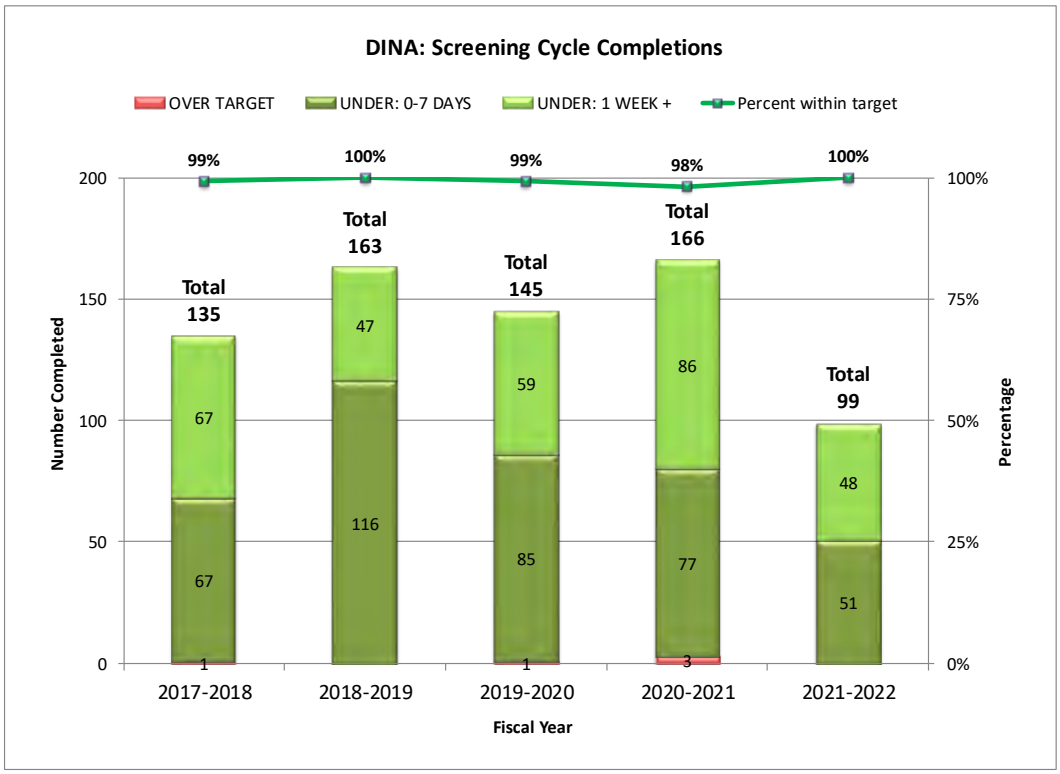
User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	32	0	106	38	13
	NO OBJECTION LETTER	0	0	0	2	2
	REJECTION LETTER (SCR)	2	0	1	1	0
	SCREENING DEFICIENCY NOTICE	4	2	19	3	2
	CANCELLATION LETTER	36	10	7	5	5
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	3	0	0	0	2
	NO OBJECTION LETTER	0	3	0	2	2
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	4	0	0	0	1
	CANCELLATION LETTER	4	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	1	2	3	0
	WITHDRAWAL NO RESP TO NON	0	0	0	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	1	0	0	0
	NO OBJECTION LETTER	1	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	2	1	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	1
	CANCELLATION LETTER	0	1	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	2
	SCREENING DEFICIENCY NOTICE	0	0	0	2	0
	NO OBJECTION LETTER	0	0	0	0	1
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	1	0	0	1
	NOTIFICATION FORM DIN SUB	0	1	0	0	1
LABELLING ONLY	NOTIFICATION FORM DIN SUB	36	45	66	63	42
	NO OBJECTION LETTER	2	3	10	6	6
	NOTICE OF NON-COMPLIANCE	0	6	3	1	3
	CANCELLATION LETTER	15	4	9	16	6
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	REJECTION LETTER (SCR)	1	7	0	1	0
	SCREENING DEFICIENCY NOTICE	30	24	8	11	6
	NOTICE OF DEFICIENCY	1	2	0	0	0
	WITHDRAWAL NO RESP TO NOD	0	1	0	0	0
	WITHDRAWAL NO RESP TO NON	0	1	1	0	0
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	29	30	34	42	16
	NO OBJECTION LETTER	0	0	1	0	0
	CANCELLATION LETTER	0	5	5	11	13
	REJECTION LETTER (SCR)	0	1	1	0	0
	SCREENING DEFICIENCY NOTICE	14	25	9	14	14
PUBLISHED DATA	NOTIFICATION FORM DIN SUB	1	1	0	1	0
	SCREENING DEFICIENCY NOTICE	2	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	0
	CANCELLATION LETTER	0	1	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

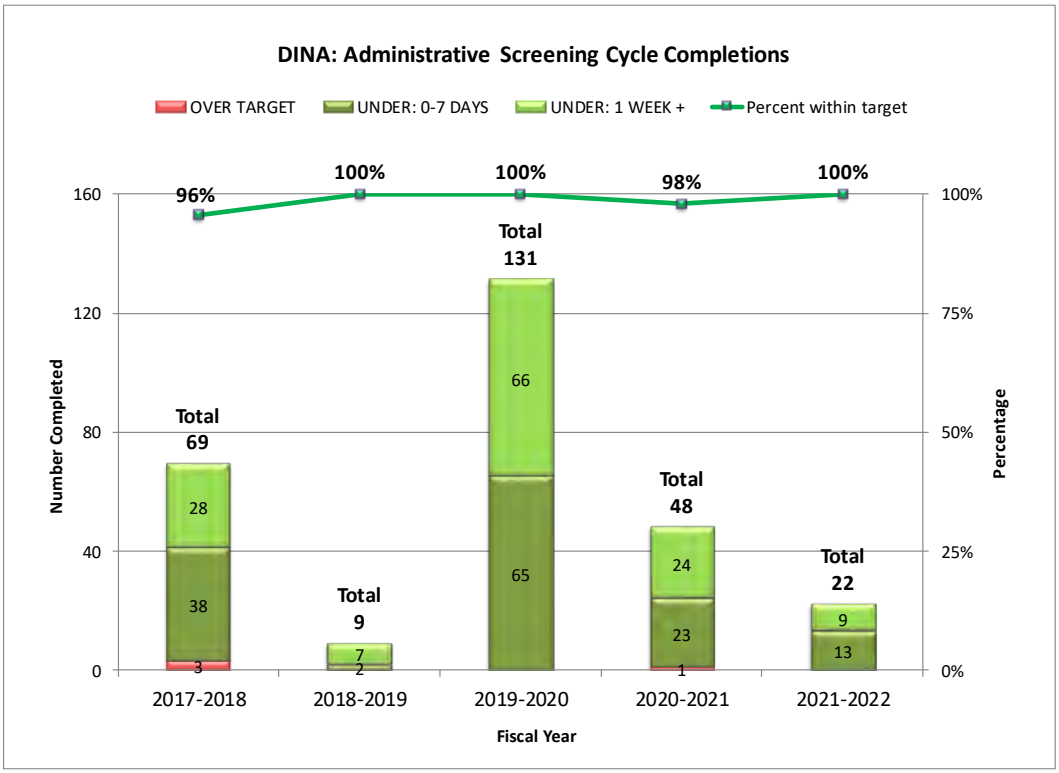


DINA: Screening Cycle Completions



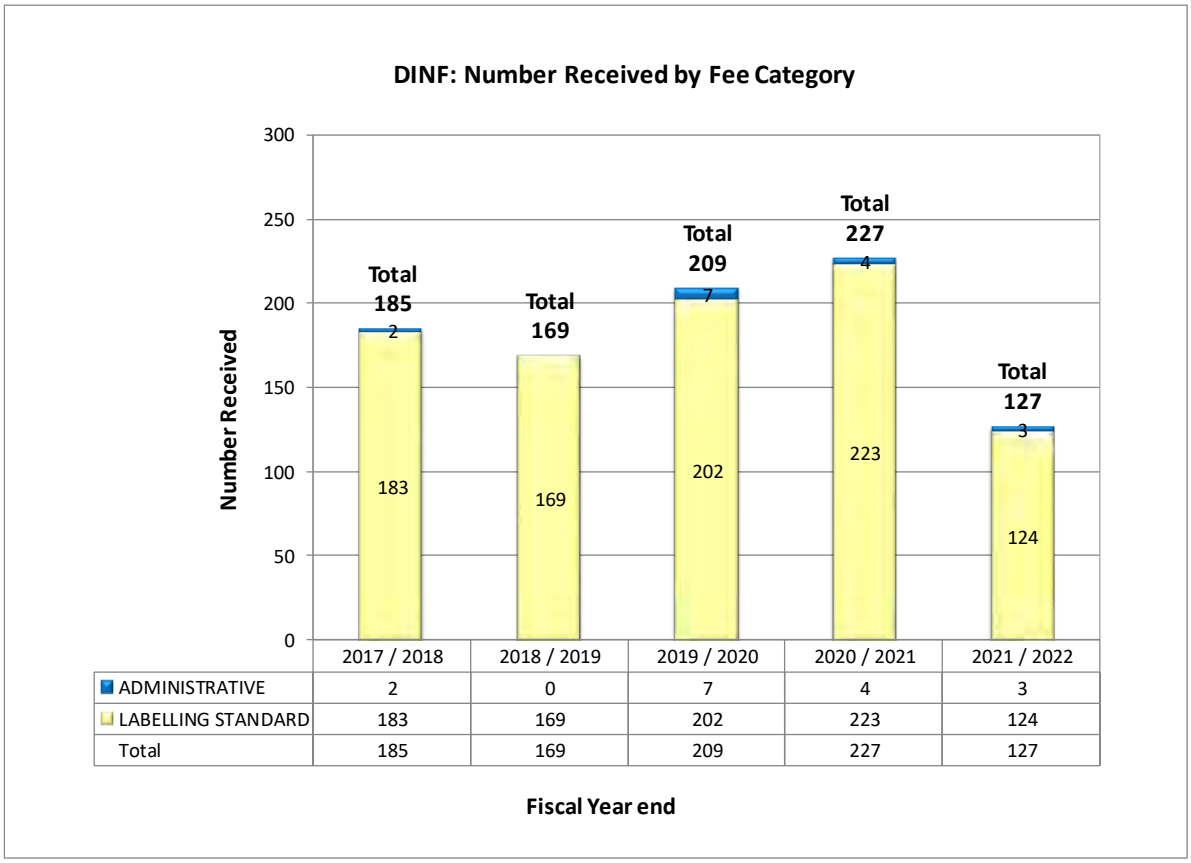
PERFORMANCE

DINA: Administrative-Screening Cycle Completions



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

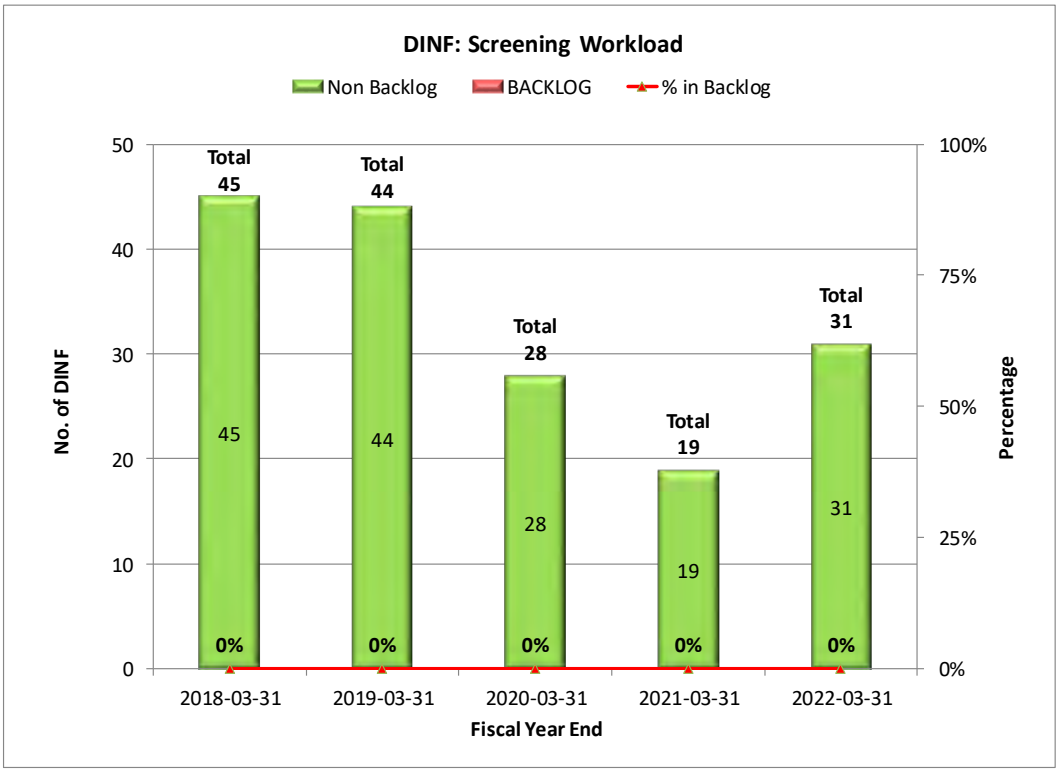
DINF: Number Received by Fee Category



	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
ADMINISTRATIVE	2	0	7	4	3
LABELLING STANDARD	183	169	202	223	124
Total	185	169	209	227	127

WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Labelling Standard	45	44	28	18	31
Backlog	*0*	*0*	*0*	*0*	*0*
Administrative	0	0	0	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**45**	**44**	**28**	**19**	**31**
Non Backlog	**45**	**44**	**28**	**19**	**31**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

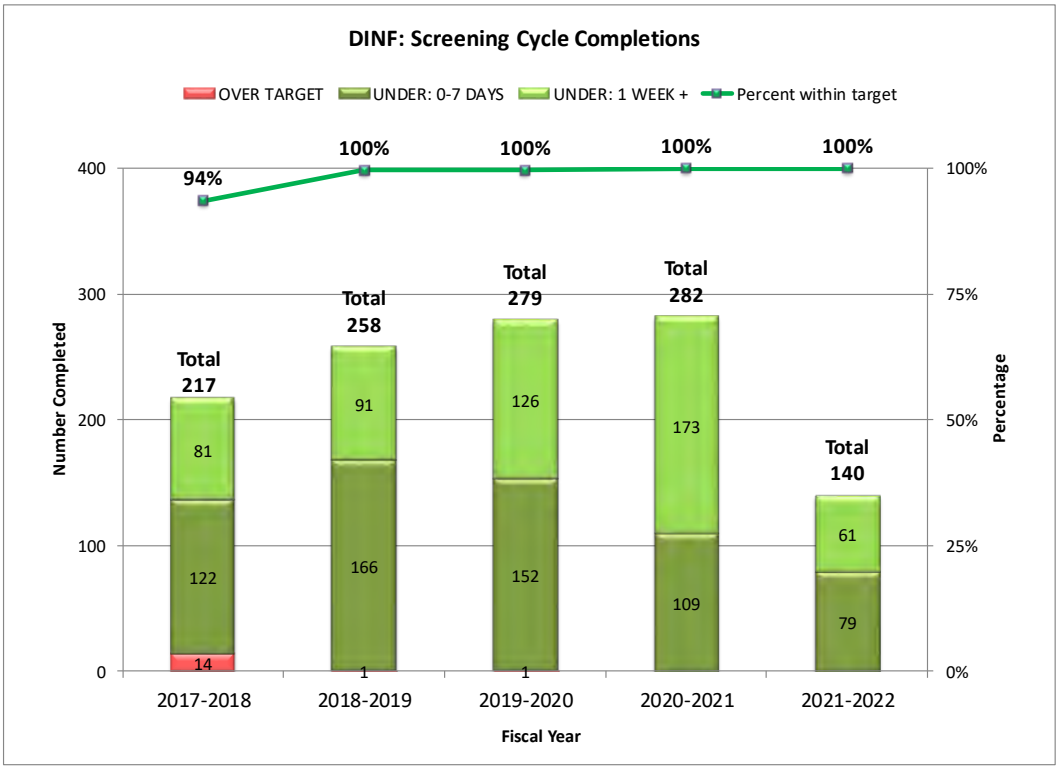
DECISIONS

DINF: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	134	143	193	200	98
	NO OBJECTION LETTER	1	2	18	3	0
	NEW DRUG LETTER SCREEN	1	0	1	1	0
	CANCELLATION LETTER	6	13	10	36	7
	REJECTION LETTER (SCR)	4	13	6	3	2
	SCREENING DEFICIENCY NOTICE	75	105	59	50	36
ADMINISTRATIVE	CANCELLATION LETTER	2	0	1	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	3	3
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
	REJECTION LETTER (SCR)	0	0	0	0	0

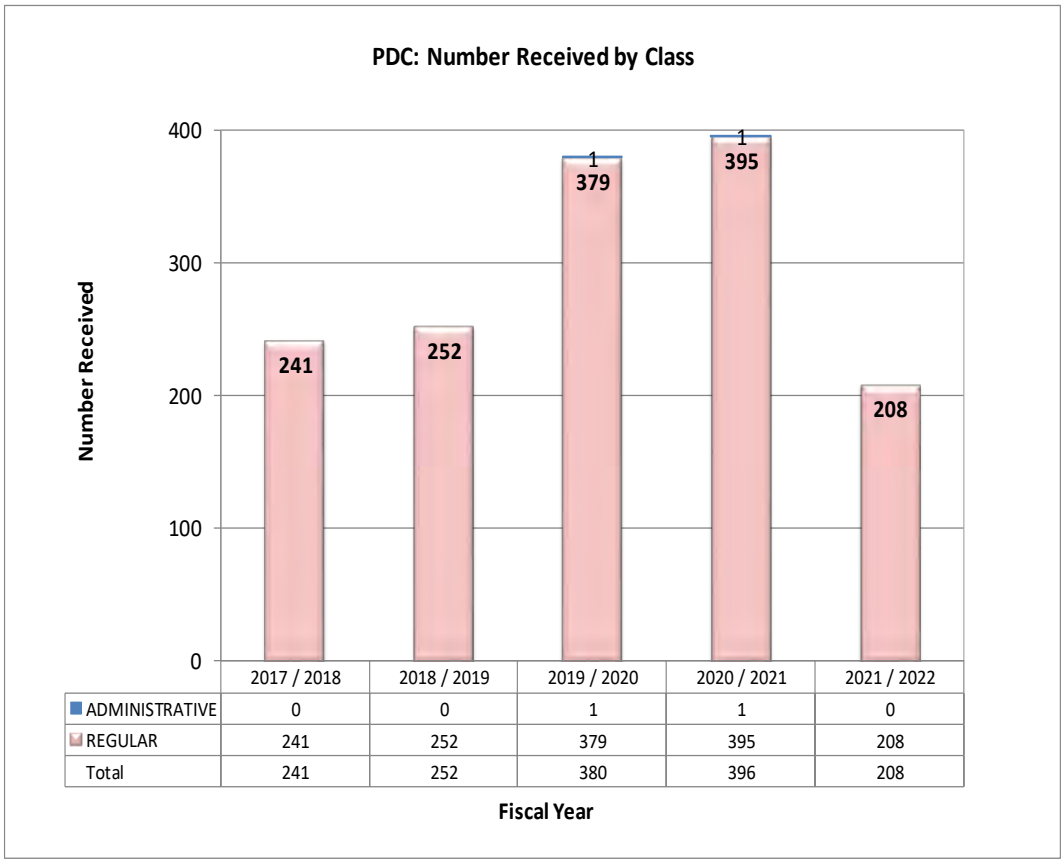
PERFORMANCE

DINF: Screening Cycle Completions



PDC: POST AUTHORIZATION DIVISION 1 CHANGE RECEIVED

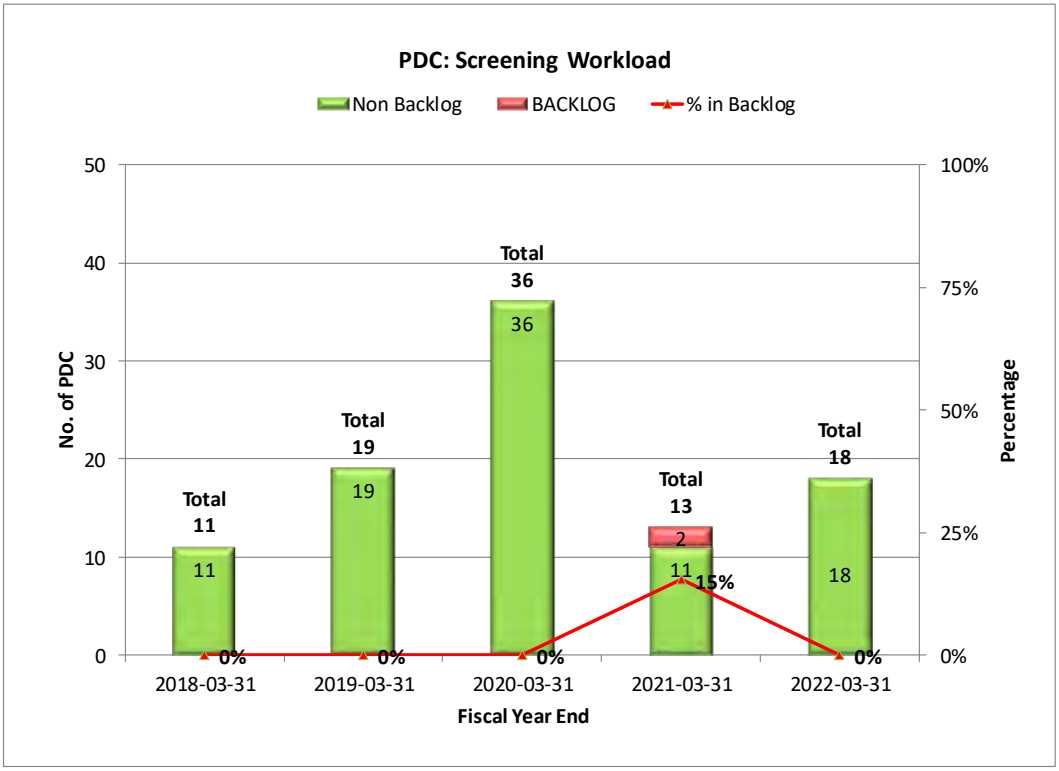
PDC: Number Received by Class



	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
ADMINISTRATIVE	0	0	1	1	0
REGULAR	241	252	379	395	208
Total	241	252	380	396	208

WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Regular	11	19	36	13	18
Backlog	*0*	*0*	*0*	*2*	*0*
Total	**11**	**19**	**36**	**13**	**18**
Non Backlog	**11**	**19**	**36**	**11**	**18**
BACKLOG	**0**	**0**	**0**	**2**	**0**
% in Backlog	**0%**	**0%**	**0%**	**15%**	**0%**

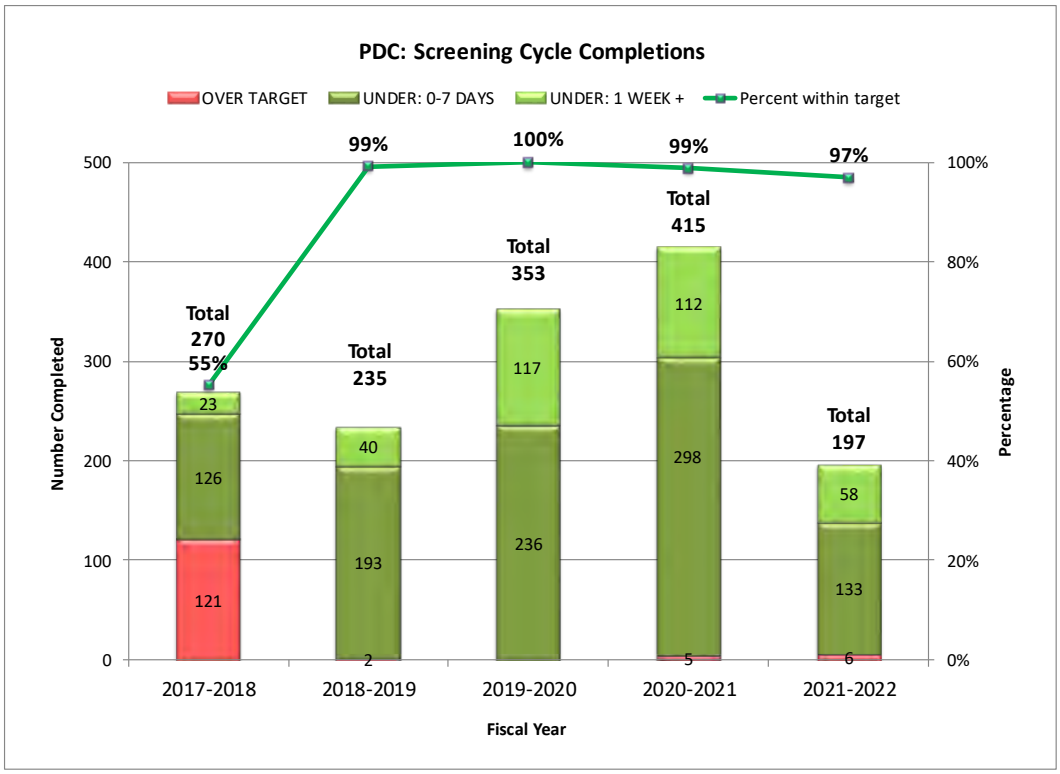
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
REGULAR	NO OBJECTION LETTER	256	175	294	384	171
	NOT SATISFACTORY NOTICE	9	35	37	19	13
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	CANCELLATION LETTER	5	26	25	14	13
	REJECTION LETTER (SCR)	0	1	1	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
ADMINISTRATIVE	NO OBJECTION LETTER	0	0	1	0	0

PERFORMANCE

PDC: Screening Cycle Completions



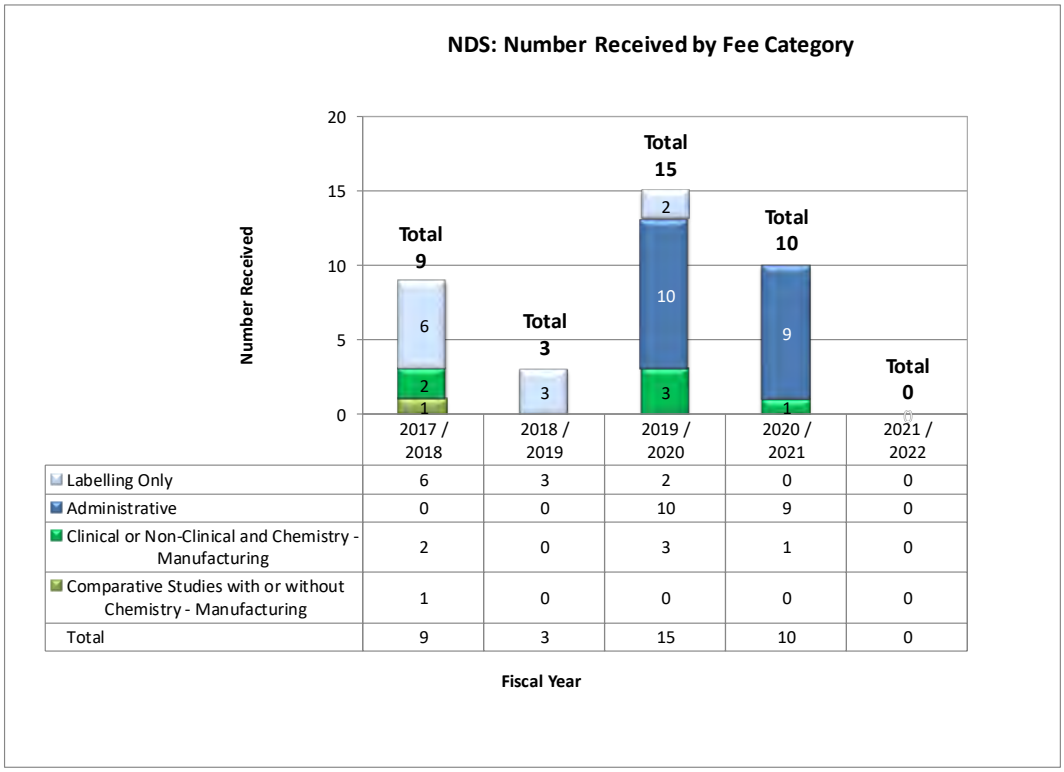
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS: NEW DRUG SUBMISSION

RECEIVED

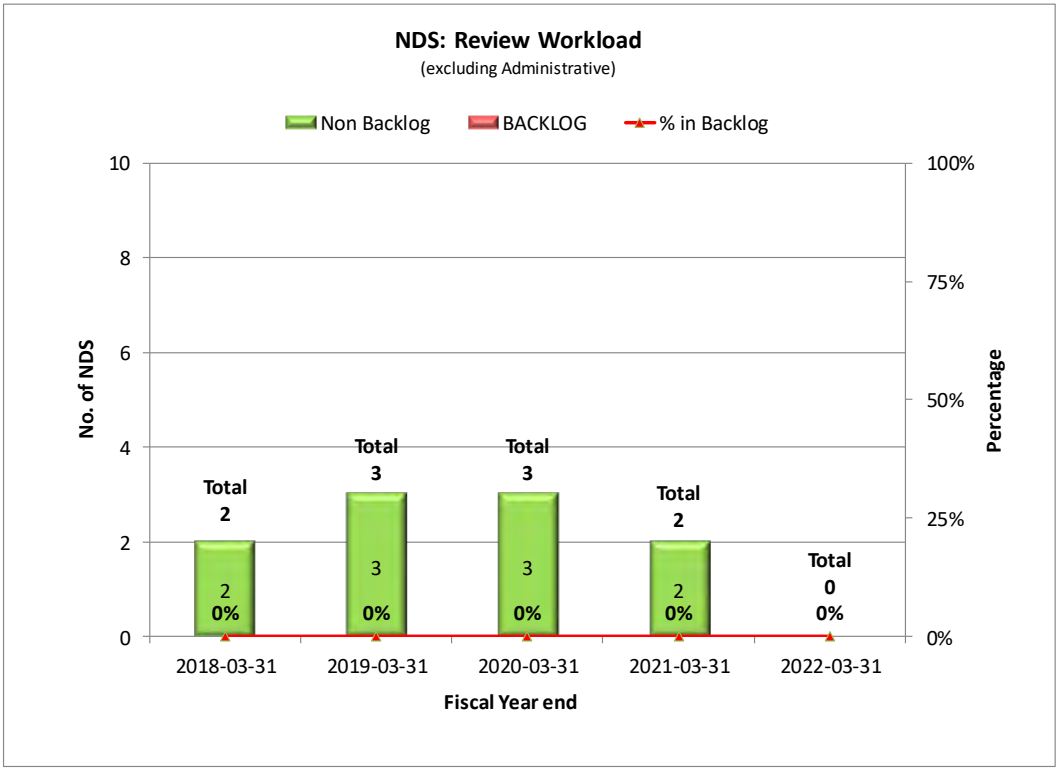
NDS: Number Received by Fee Category



	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Labelling Only	6	3	2	0	0
Administrative	0	0	10	9	0
Clinical or Non-Clinical and Chemistry - Manufacturing	2	0	3	1	0
Comparative Studies with or without Chemistry - Manufacturing	1	0	0	0	0
Total	9	3	15	10	0

WORKLOAD

NDS: Review Workload

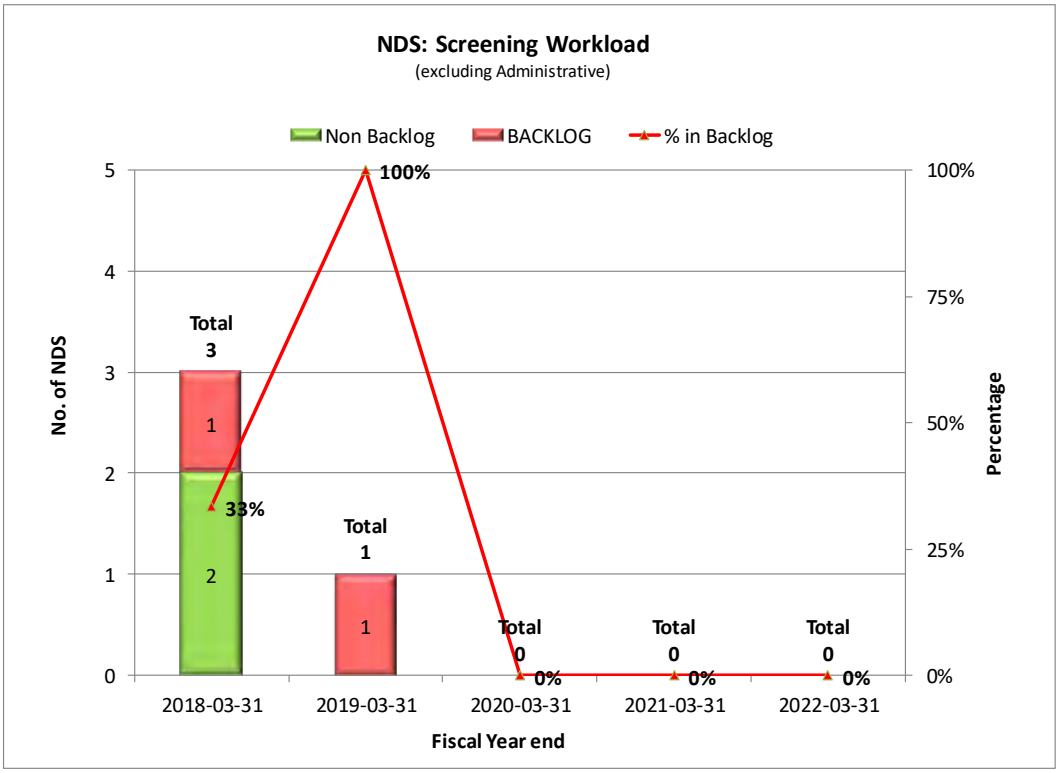


NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	1	3	2	0
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	1	2	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**2**	**3**	**3**	**2**	**0**
Non Backlog	**2**	**3**	**3**	**2**	**0**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Labelling Only	1	1	0	0	0
Backlog	*1*	*1*	*0*	*0*	*0*
Clinical or Non-Clinical /C&M	1	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without C&M	1	0	0	0	0
Backlog	0	0	0	0	0
Total	**3**	**1**	**0**	**0**	**0**
Non Backlog	**2**	**0**	**0**	**0**	**0**
BACKLOG	**1**	**1**	**0**	**0**	**0**
% in Backlog	**33%**	**100%**	**0%**	**0%**	**0%**

DECISIONS

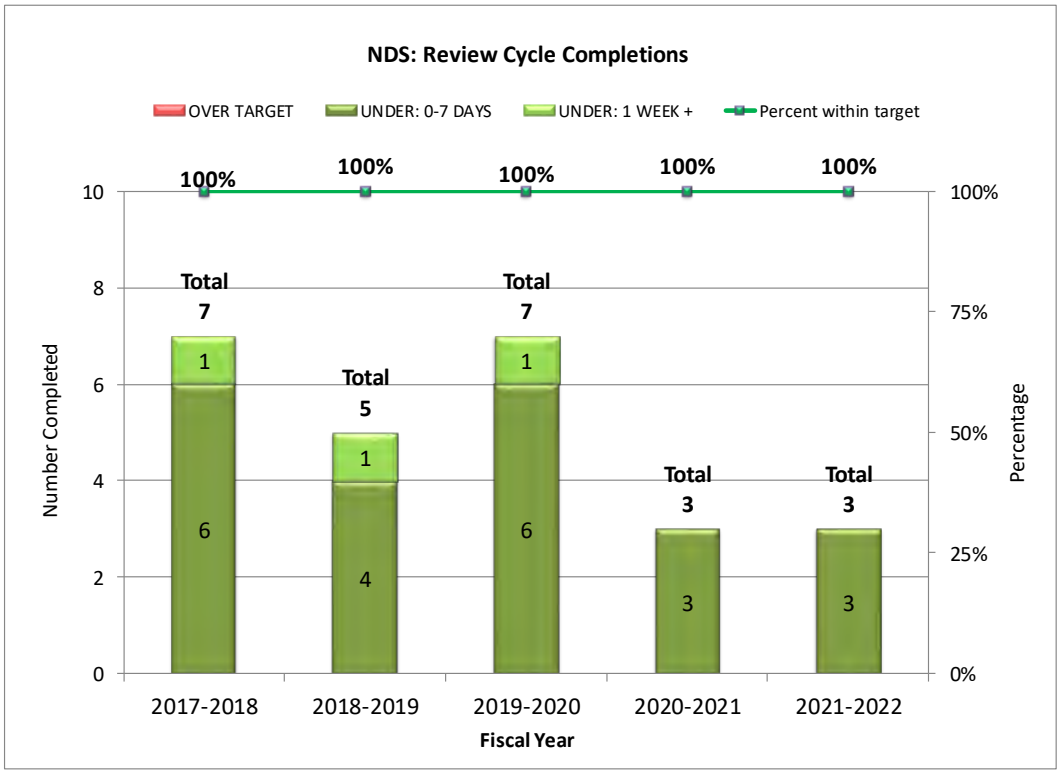
NDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	3	16	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	1	0	1	0
	CANCELLATION LETTER	0	0	0	0	1
	NOC ON HOLD (SWITCH)*	0	0	0	0	1
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	1	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	2	1
	NOTICE OF DEFICIENCY	0	0	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	1	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	6	2	4	0	0
	CANCELLATION LETTER	1	0	1	0	0
	SCREENING DEFICIENCY NOTICE	3	1	1	0	0
	NOTICE OF NON-COMPLIANCE	0	1	1	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	0	0	0

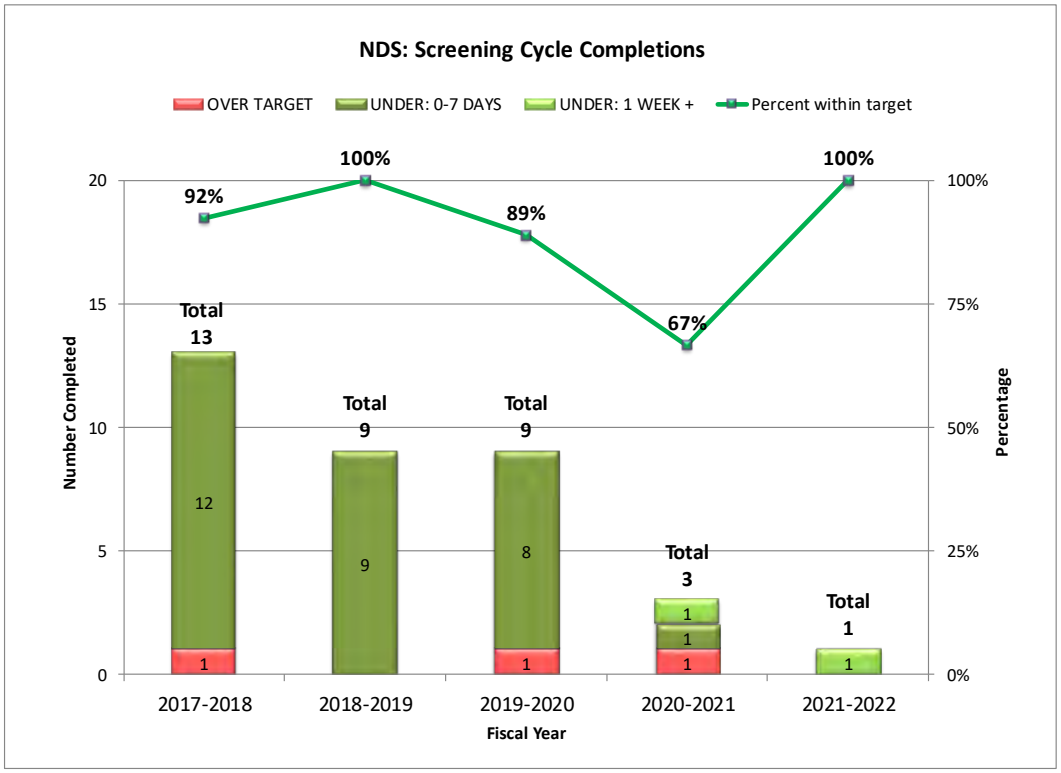
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions



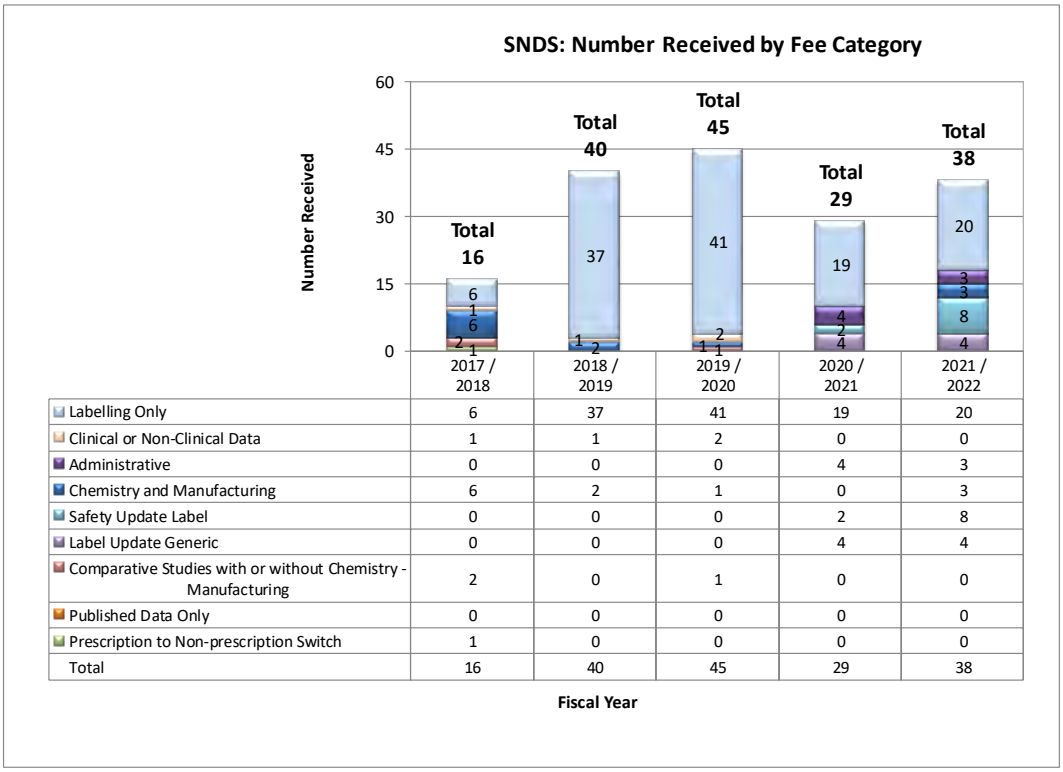
NDS: Screening Cycle Completions



SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION

RECEIVED

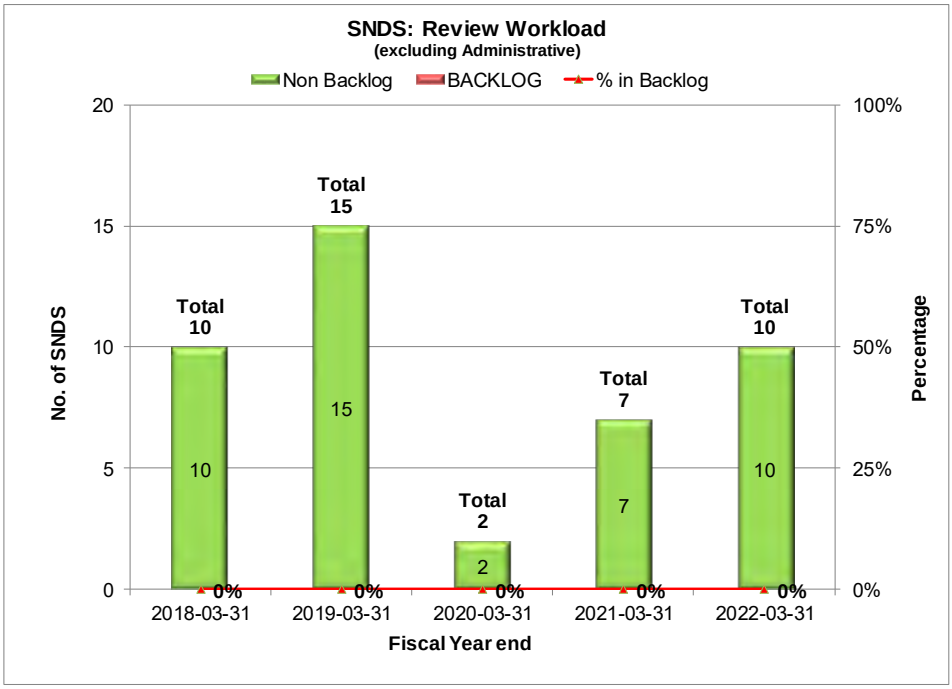
SNDS: Number Received by Fee Category



	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Labelling Only	6	37	41	19	20
Clinical or Non-Clinical Data	1	1	2	0	0
Administrative	0	0	0	4	3
Chemistry and Manufacturing	6	2	1	0	3
Safety Update Label	0	0	0	2	8
Label Update Generic	0	0	0	4	4
Comparative Studies with or without Chemistry - Manufacturing	2	0	1	0	0
Published Data Only	0	0	0	0	0
Prescription to Non-prescription Switch	1	0	0	0	0
Total	16	40	45	29	38

WORKLOAD

SNDS: Review Workload

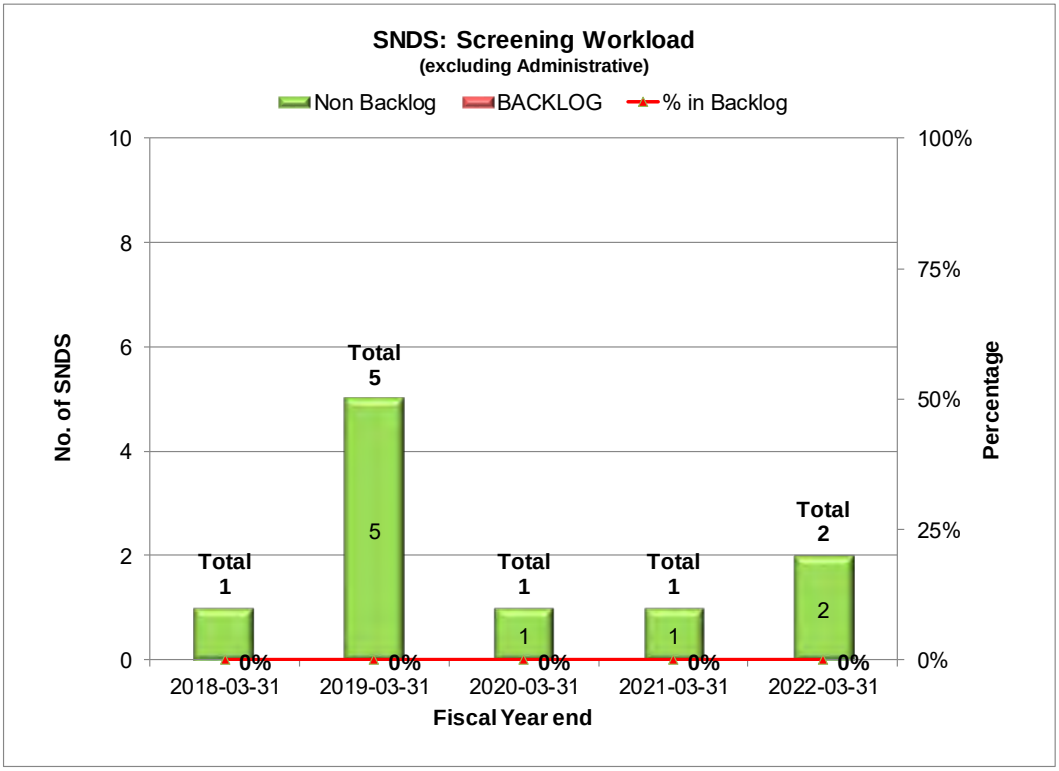


SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Labelling Only	2	12	0	4	6
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data Only	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	4	2	2	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	2	0
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	0	1	2
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	*1*	*1*	*0*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies with or without C&M	*2*	*0*	*0*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Prescription to Non-Prescription Switch	*1*	*0*	*0*	*0*	*0*
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**10**	**15**	**2**	**7**	**10**
Non Backlog	**10**	**15**	**2**	**7**	**10**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Chemistry and Manufacturing	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	5	1	1	2
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**5**	**1**	**1**	**2**
Non Backlog	**1**	**5**	**1**	**1**	**2**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

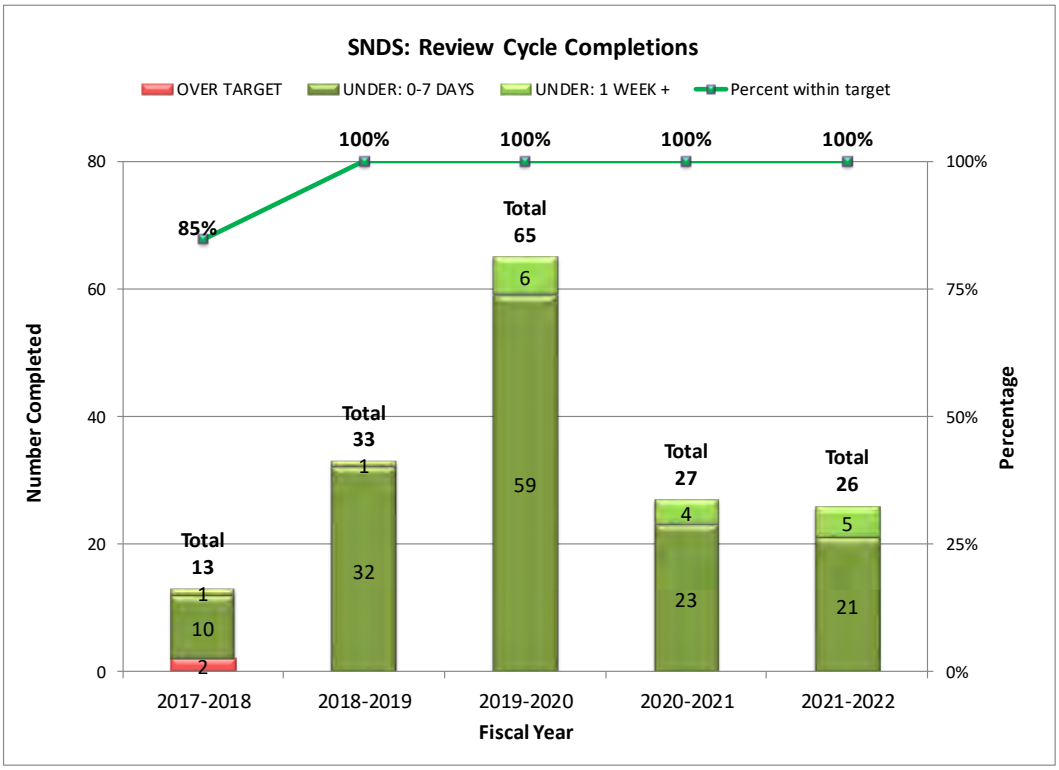
SNDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	1	0	0
	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF COMPLIANCE*	0	1	2	1	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF COMPLIANCE*	3	5	1	2	1
	NOTICE OF NON-COMPLIANCE	0	1	2	0	0
	SCREENING DEFICIENCY NOTICE	5	2	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	2	0	0	0
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	1	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	4	1
	SCREENING DEFICIENCY NOTICE	0	0	0	2	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	1	0	0	0
	NOTICE OF COMPLIANCE*	6	13	53	20	14
	SCREENING DEFICIENCY NOTICE	3	5	11	1	5
	CANCELLATION LETTER	0	3	4	1	2
	NOTICE OF DEFICIENCY	0	1	0	0	0
	NOTICE OF NON-COMPLIANCE	1	7	5	0	1
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	0	0	2	3
	CANCELLATION LETTER	0	0	0	0	3
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
SAFETY UPDATE LABEL	NOTICE OF COMPLIANCE*	0	0	0	1	6
	SCREENING DEFICIENCY NOTICE	0	0	0	0	6
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	1	0	0	0
	CANCELLATION LETTER	0	1	0	0	0
PUBLISHED DATA ONLY	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	2	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

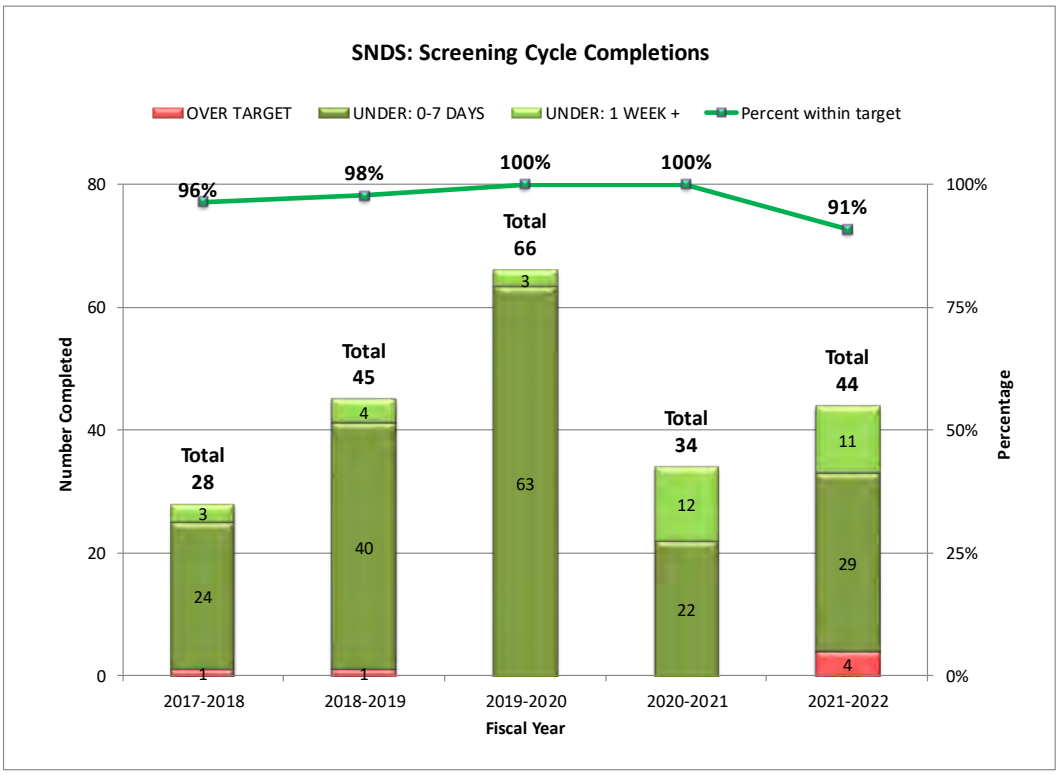
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: Review Cycle Completions



SNDS: Screening Cycle Completions



ANDS: ABBREVIATED NEW DRUG SUBMISSION

RECEIVED

ANDS: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Administrative	0	0	2	2	2
Chemistry and Manufacturing	0	0	0	1	1
Comparative Studies with or without Chemistry - Manufacturing	0	0	3	2	2
Labelling Only	0	0	2	2	2
Total	**0**	**0**	**7**	**7**	**7**

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Comparative Studies with or without C&M	0	0	2	2	1
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	1	1	1
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**3**	**4**	**3**
Non Backlog	**0**	**0**	**3**	**4**	**3**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Comparative Studies with or without C&M	0	0	1	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**1**	**1**	**0**
Non Backlog	**0**	**0**	**1**	**1**	**0**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Administrative	0	0	0	1	2
Non Backlog	**0**	**0**	**0**	**1**	**2**
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
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
2021-2022	1	6	1	88%	8

ANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
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
2021-2022	0	8	1	100%	9

ANDS: Administrative Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	1	0	100%	0
2020-2021	0	1	0	100%	1
2021-2022	0	0	1	100%	1

DECISIONS

ANDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1	1	1
	SCREENING DEFICIENCY NOTICE	0	0	1	1	0
	REJECTION LETTER (SCR)	0	0	0	1	0
CHEMISTRY AND MANUFACTURING	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	2	0	1
	NOTICE OF COMPLIANCE*	0	0	0	2	2
	NOTICE OF NON-COMPLIANCE	0	0	0	1	2
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	1	2	2
	SCREENING DEFICIENCY NOTICE	0	0	1	2	1

*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 DRUG SUBMISSION

RECEIVED

SANDS: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Administrative	0	0	7	15	3
Chemistry and Manufacturing	0	0	1	5	2
Label Update Generic	0	0	0	10	2
Labelling Only	0	0	16	29	31
Total	**0**	**0**	**24**	**59**	**38**

WORKLOAD

SANDS: Review Workload

SANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Chemistry & Manufacturing	0	0	0	4	0
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	0	0	0	2	1
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	6	7	8
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**6**	**13**	**9**
Non Backlog	**0**	**0**	**6**	**13**	**9**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Chemistry & Manufacturing	0	0	1	0	2
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	0	0	1	4	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**2**	**4**	**2**
Non Backlog	**0**	**0**	**2**	**4**	**2**
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
ADMINISTRATIVE	0	0	5	2	1
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
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
2021-2022	0	34	6	100%	40

SANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
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
2021-2022	0	26	16	100%	42

SANDS: Administrative Screening Performance

ADMIN SCREENING	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
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
2021-2022	0	3	1	100%	4

DECISIONS

SANDS: Number of Decisions by Fee Category

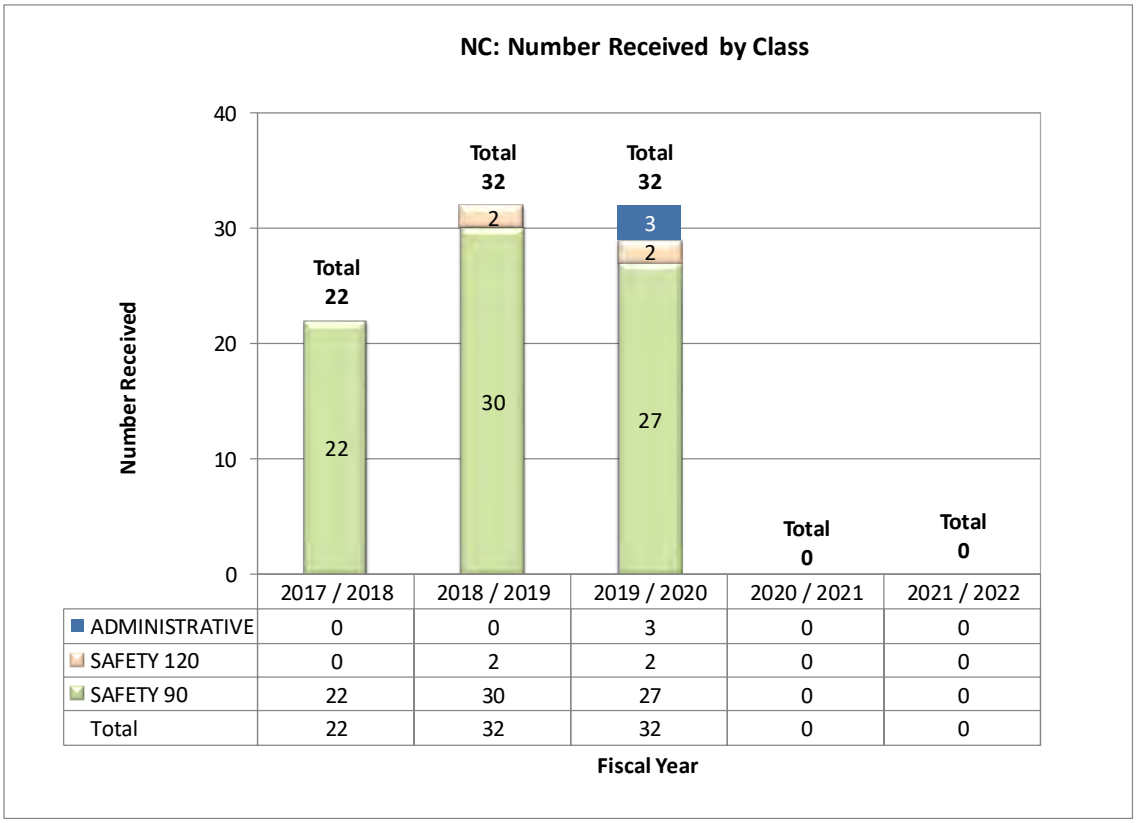
User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	0	0	2	17	4
	CANCELLATION LETTER	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	2	0
CHEMISTRY AND MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	3	1
	NOTICE OF COMPLIANCE*	0	0	0	0	3
	NOTICE OF NON-COMPLIANCE	0	0	0	0	2
LABELLING ONLY	CANCELLATION LETTER	0	0	1	2	1
	NOTICE OF COMPLIANCE*	0	0	7	25	33
	SCREENING DEFICIENCY NOTICE	0	0	8	4	3
LABEL UPDATE GENERIC	CANCELLATION LETTER	0	0	0	5	1
	NOTICE OF COMPLIANCE*	0	0	0	3	2
	SCREENING DEFICIENCY NOTICE	0	0	0	4	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).

NC: NOTIFIABLE CHANGE

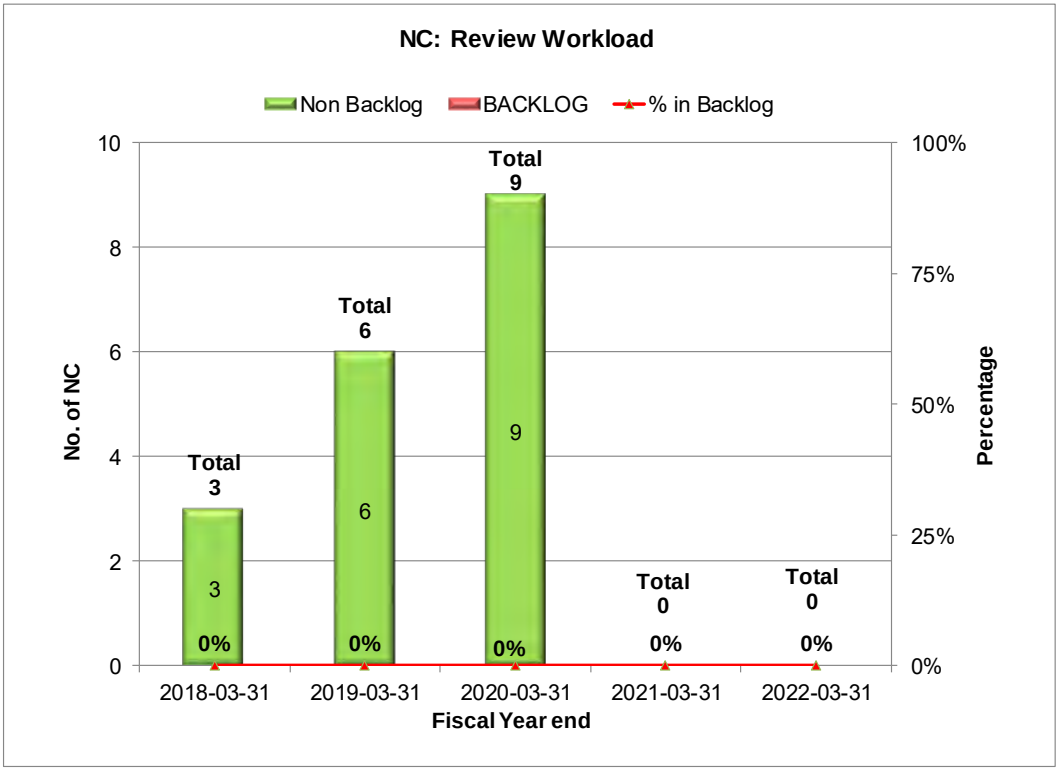
RECEIVED

NC: Number Received by Class



WORKLOAD

NC: Review Workload

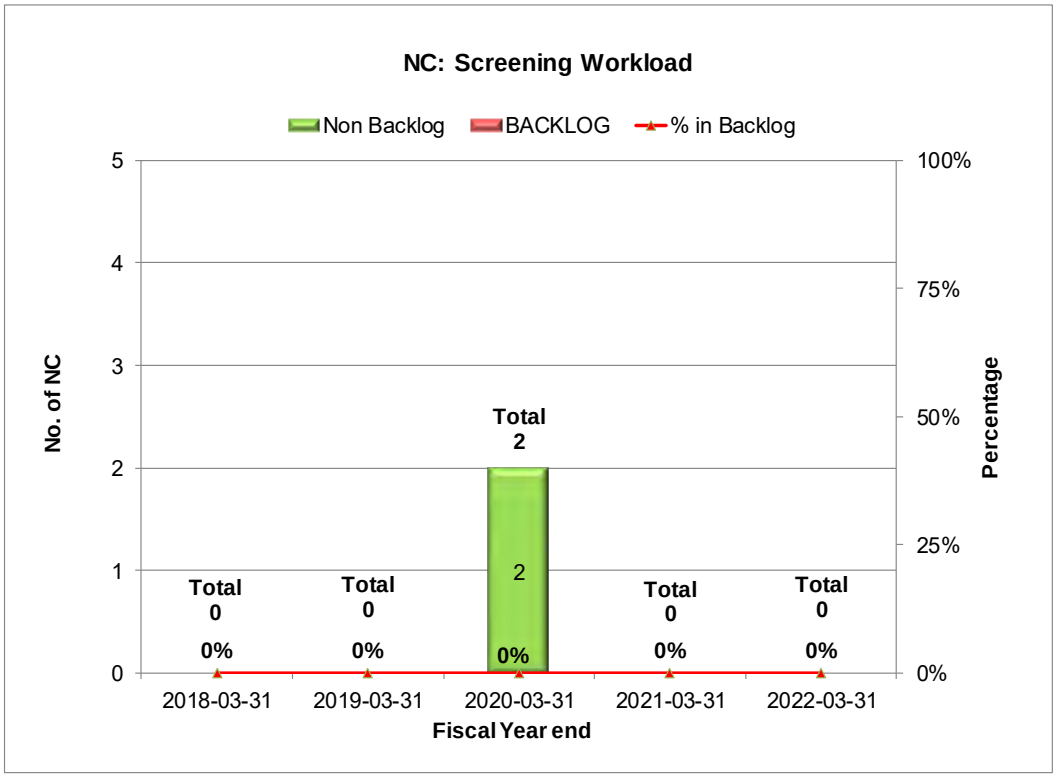


NC: Review Workload by Class

NC: REVIEW WORKLOAD BY CLASS and Fiscal Year end					
CLASS	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
SAFETY 90	3	4	8	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY 120	0	2	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**3**	**6**	**9**	**0**	**0**
Non Backlog	**3**	**6**	**9**	**0**	**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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
SAFETY 90	0	0	2	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**2**	**0**	**0**
Non Backlog	**0**	**0**	**2**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

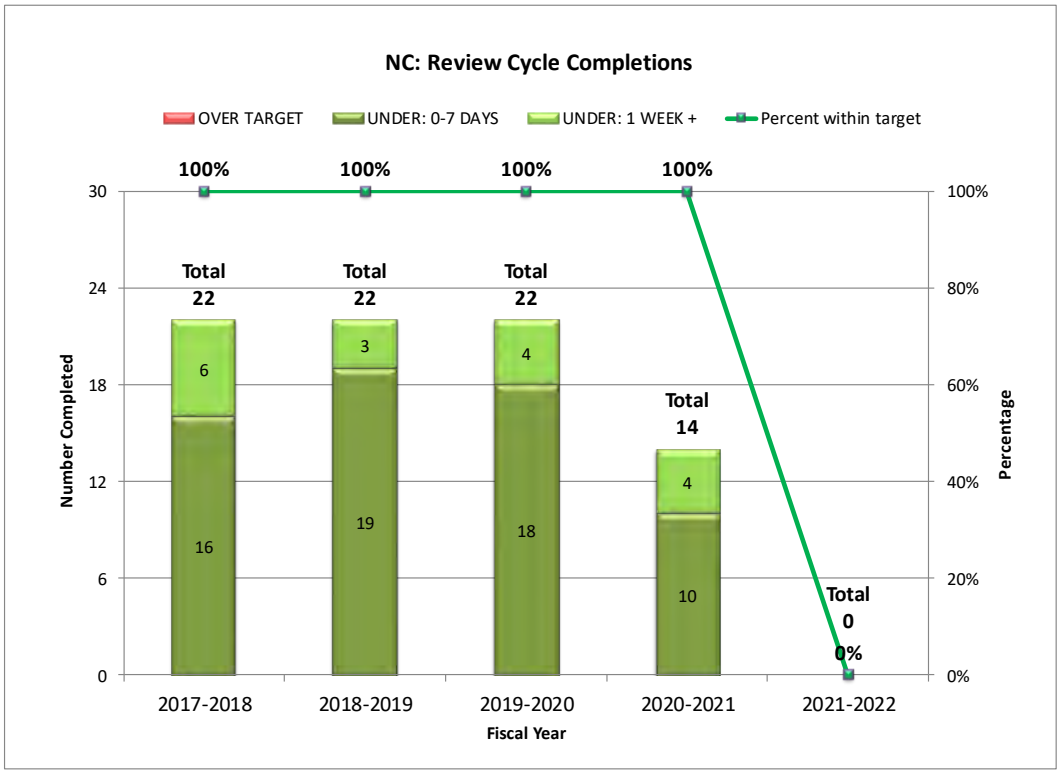
DECISIONS

NC: Number of Decisions by Class

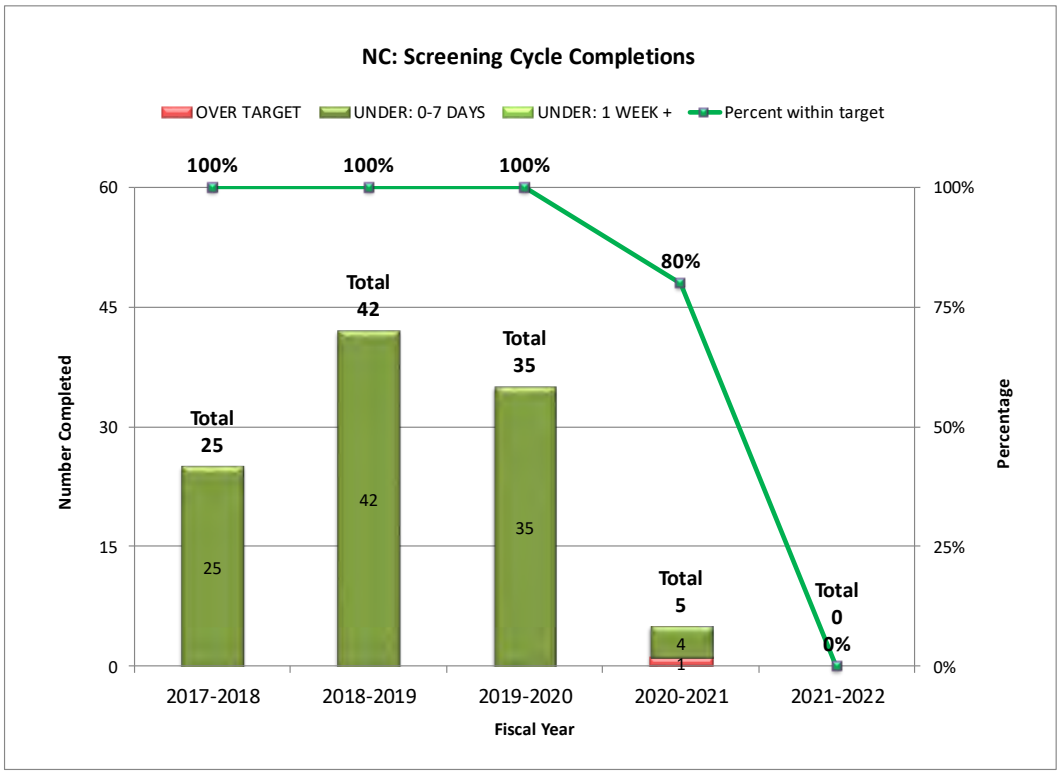
Class	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1	0	0
	NO OBJECTION LETTER	0	0	2	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
SAFETY 90	NO OBJECTION LETTER	20	19	19	13	0
	CANCELLATION LETTER	2	8	2	0	0
	REJECTION LETTER (SCR)	1	1	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	5	16	8	0	0
	NC-HOLD (SWITCH)	0	0	0	0	0
SAFETY 120	CANCELLATION LETTER	1	0	1	0	0
	NO OBJECTION LETTER	0	0	2	1	0

PERFORMANCE

NC: Review Cycle Completions



NC: Screening Cycle Completions



PRE-MEETINGS

MPDIN: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Clinical or Non-Clinical Data	0	0	2	1	1
Chemistry and Manufacturing	0	0	0	4	0
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	0	1	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	1	0
Total	***0***	***0***	***2***	***7***	***1***

MPNDS: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	4	1	5
Comparative Studies with or without Chemistry - Manufacturing	0	0	2	0	0
Prescription to Non-Prescription Switch	0	0	0	1	0
Total	***0***	***0***	***6***	***2***	***5***

MPSNDS: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
Clinical or Non-Clinical Data	0	0	1	0	0
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	0	0	3
Chemistry and Manufacturing	0	0	0	2	1
Total	***0***	***0***	***1***	***2***	***4***

PART 2: DISINFECTANT PRODUCTS

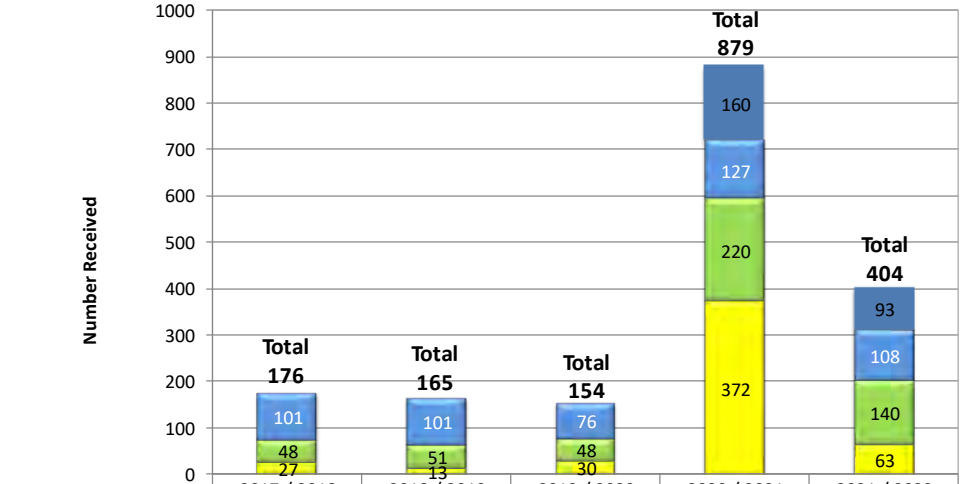
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

RECEIVED

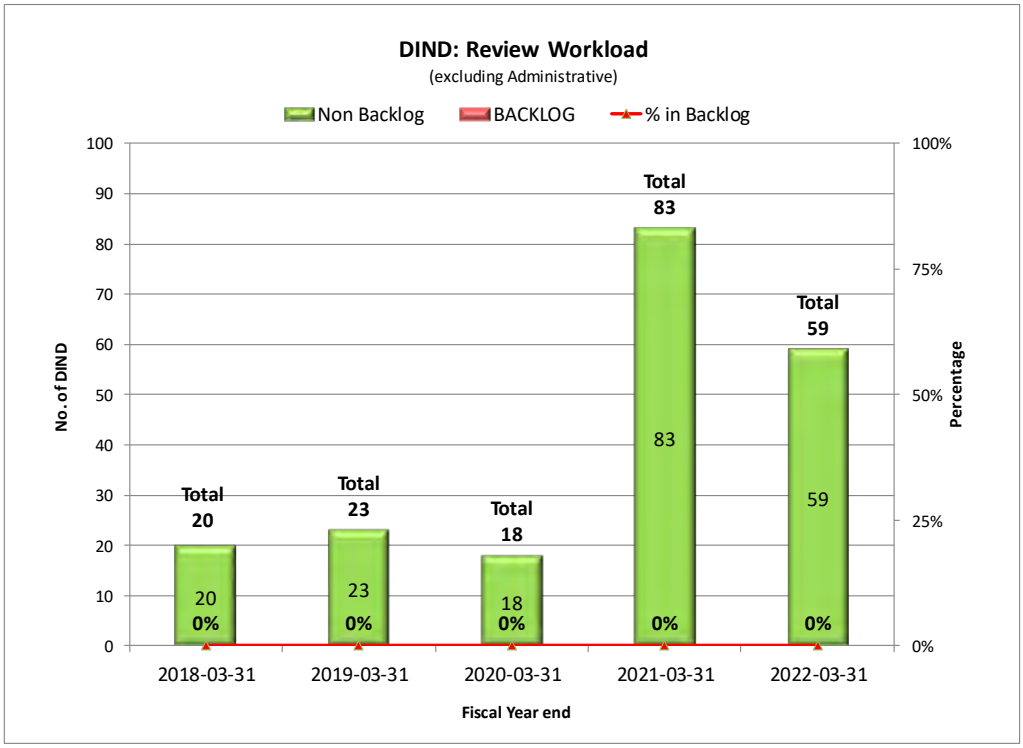
DIND-Disinfectant Products: Number Received by Fee Category



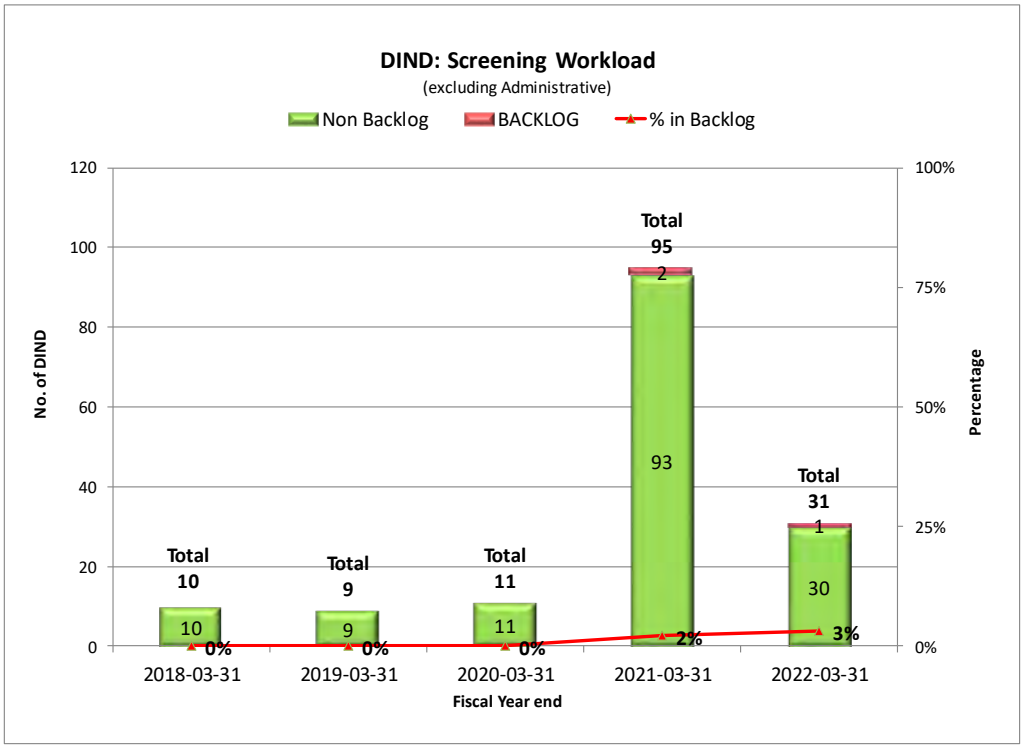
	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
LABELLING ONLY	0	0	0	160	93
ADMINISTRATIVE	101	101	76	127	108
DISINFECTANTS	48	51	48	220	140
LABELLING STANDARD	27	13	30	372	63
Total	176	165	154	879	404

WORKLOAD

DIND-Disinfectant Products: Review Workload

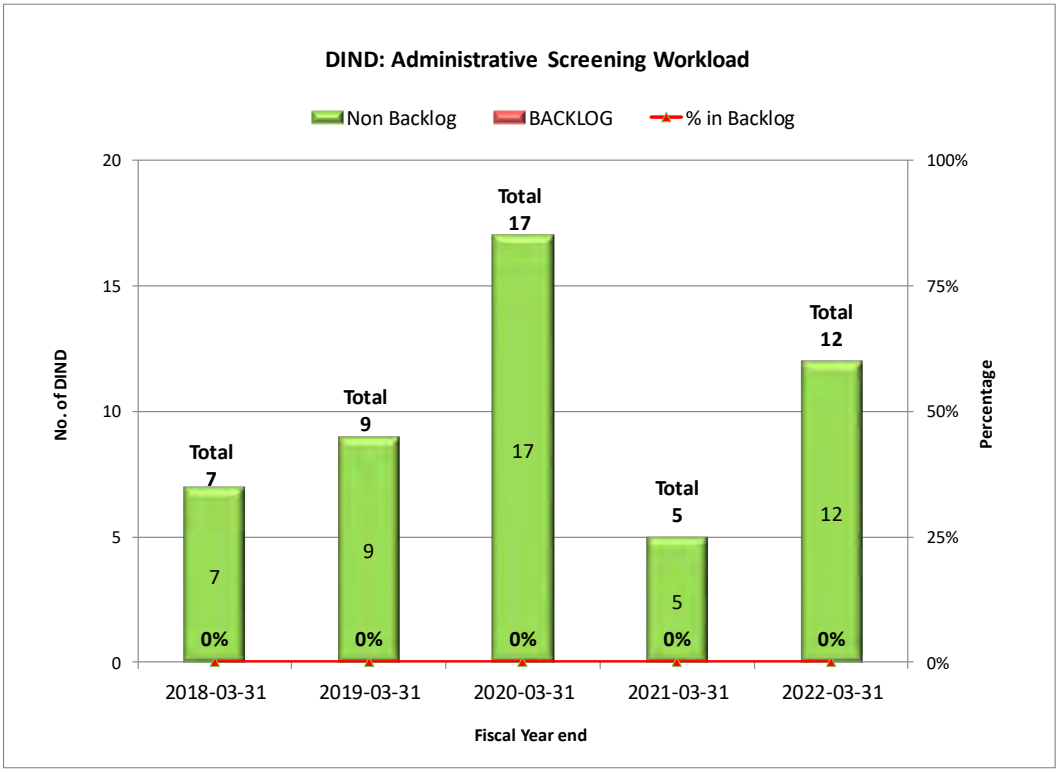


DIND-Disinfectant Products: Screening Workload



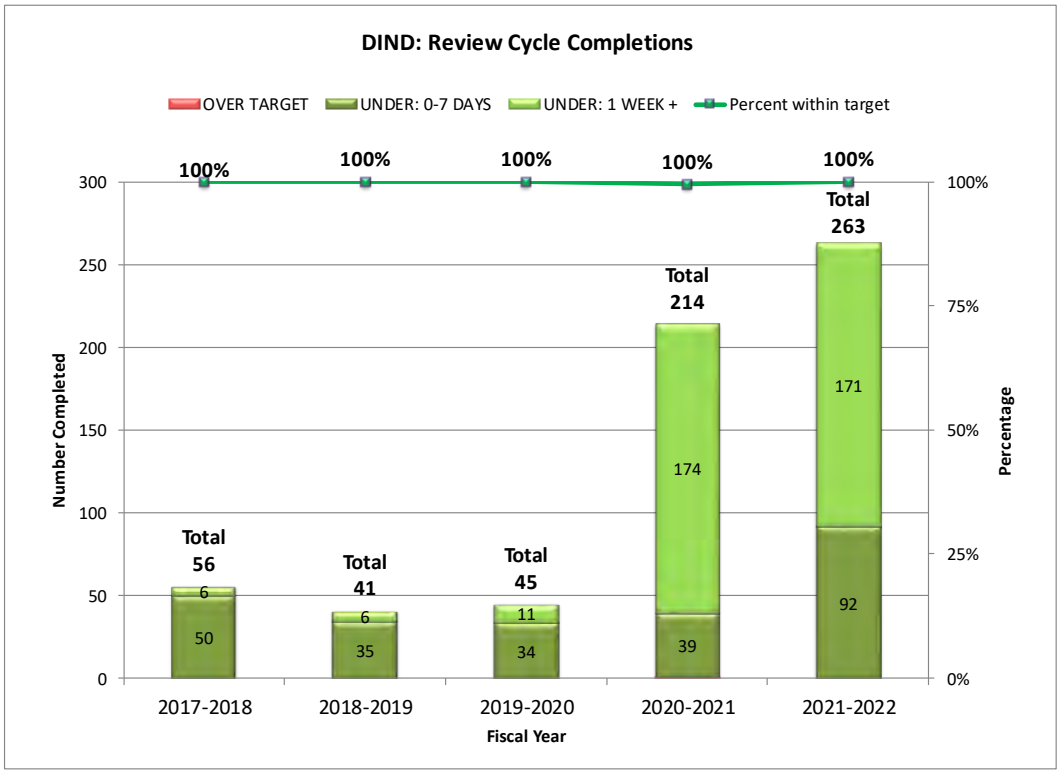
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

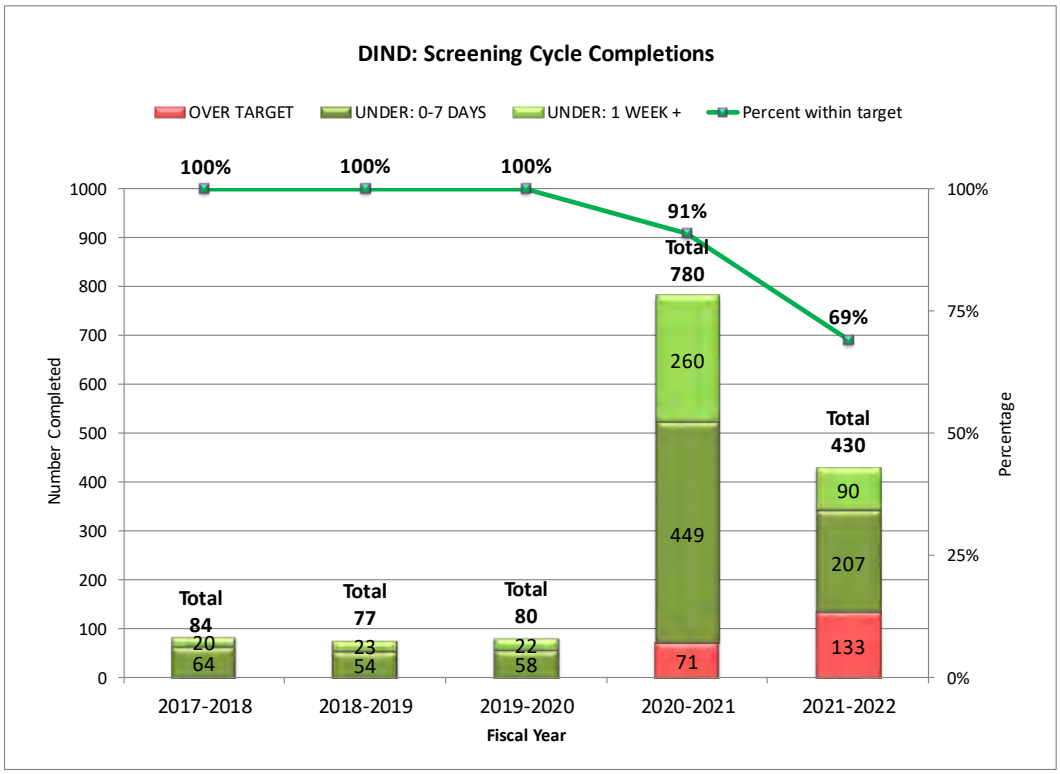


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

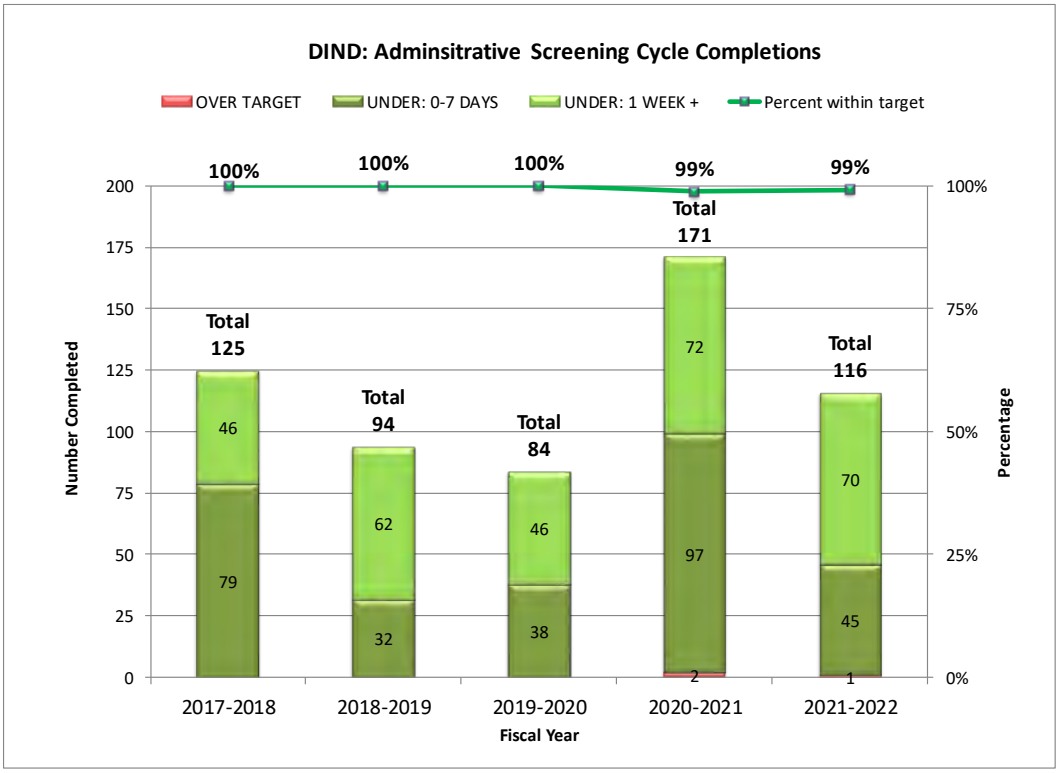


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



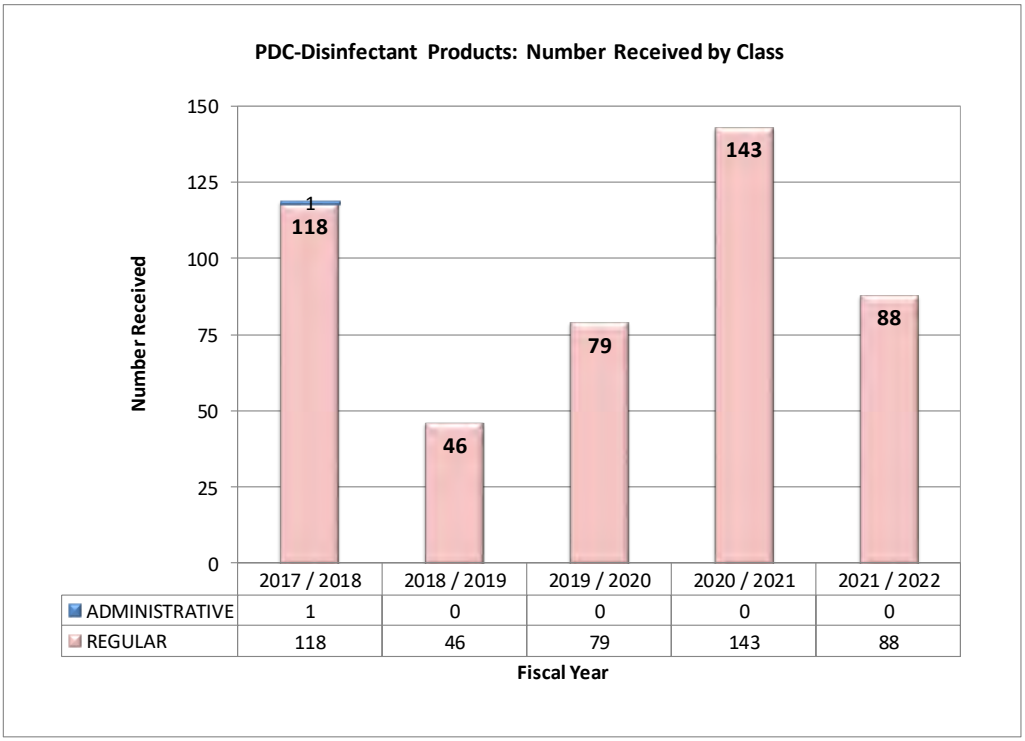
DECISIONS

DIND-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	94	62	62	87	70
	NO OBJECTION LETTER	0	9	2	13	11
	CANCELLATION LETTER	2	8	0	25	27
	REJECTION LETTER (SCR)	15	1	4	8	2
	SCREENING DEFICIENCY NOTICE	20	22	19	52	19
DISINFECTANTS	NOTIFICATION FORM DIN SUB	37	33	39	36	65
	NO OBJECTION LETTER	17	8	6	73	69
	CANCELLATION LETTER	3	4	1	19	28
	NEW DRUG LETTER SCREEN	0	0	0	2	0
	NOTICE OF DEFICIENCY	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	1	0	0	4	8
	SCREENING DEFICIENCY NOTICE	5	8	5	41	48
	REJECTION LETTER (SCR)	1	0	2	13	11
LABELLING ONLY	CANCELLATION LETTER	0	0	0	19	9
	NO OBJECTION LETTER	0	0	0	6	22
	NOTICE OF NON-COMPLIANCE	0	0	0	4	6
	NOTIFICATION FORM DIN SUB	0	0	0	88	89
	REJECTION LETTER (SCR)	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	16	6
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	20	14	23	269	76
	NO OBJECTION LETTER	1	0	0	3	1
	CANCELLATION LETTER	0	0	0	42	22
	NEW DRUG LETTER SCREEN	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	10	5	9	95	24
	REJECTION LETTER (SCR)	3	4	0	17	2

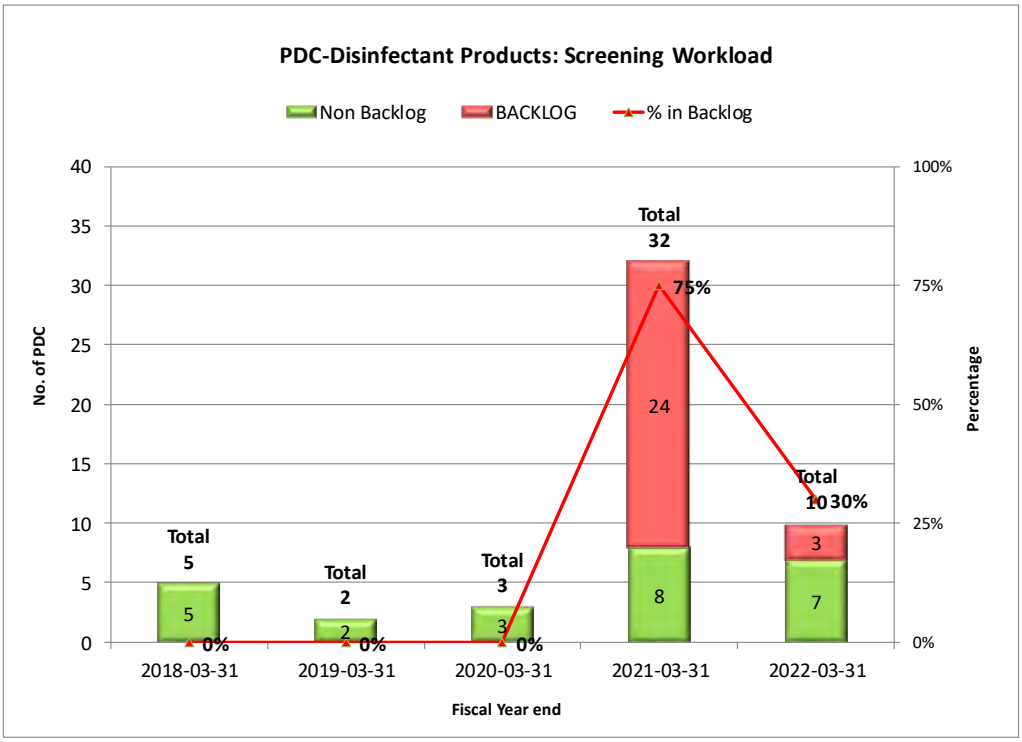
PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS RECEIVED

PDC-Disinfectant Products: Received by Class



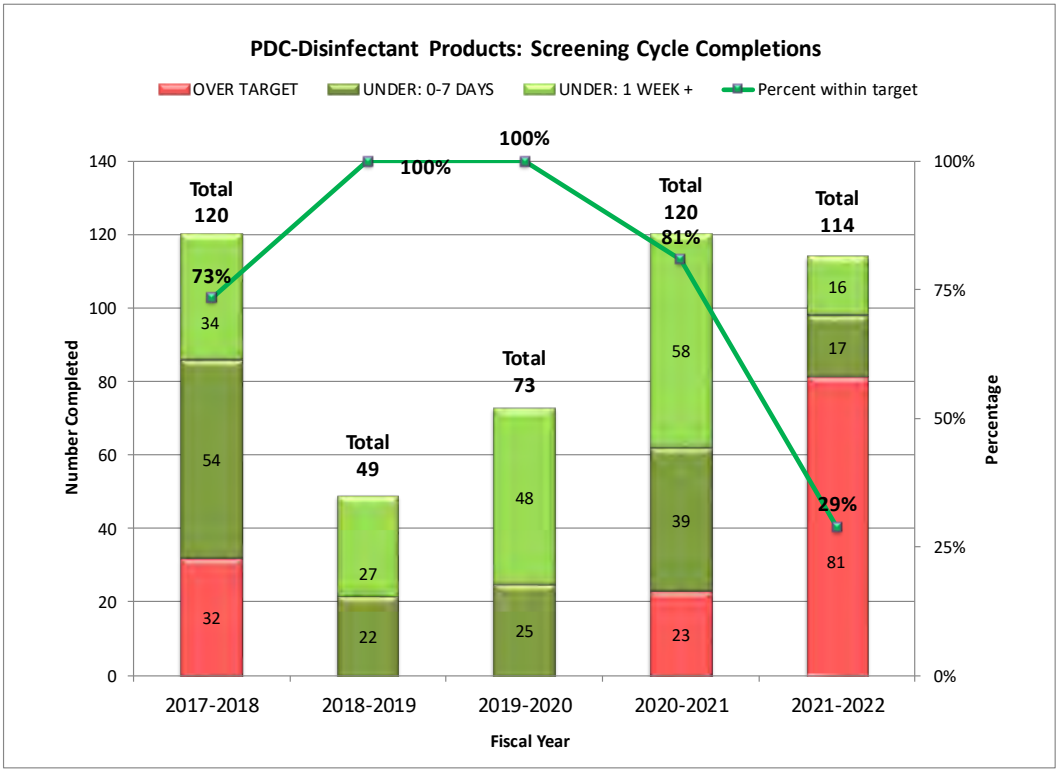
WORKLOAD

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	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	CANCELLATION LETTER	1	0	0	0	0
REGULAR	NO OBJECTION LETTER	78	39	62	94	85
	NOT SATISFACTORY NOTICE	35	9	6	18	10
	CANCELLATION LETTER	0	0	3	5	19
	NOTIFICATION FORM DIN SUB	4	0	0	0	0
	REJECTION LETTER (SCR)	4	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	1	0	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

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
DISINFECTANTS	2	1	1	5	7
ADMINISTRATIVE	0	1	0	0	0
Total	***2***	***2***	***1***	***5***	***7***

WORKLOAD

NDS-Disinfectant Products: Review Workload

NDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Disinfectants	2	1	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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Disinfectants	0	1	0	1	0
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	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
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
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
2021-2022	0	1	2	100%	3

NDS-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
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
2021-2022	5	5	0	50%	10

NDS-Disinfectant Products: Administrative-Screening Performance

ADMIN SCREENING	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
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
2021-2022	0	0	0	-	0

DECISIONS

NDS-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	0	0
DISINFECTANTS	NOTICE OF COMPLIANCE*	1	1	0	1	1
	NOTICE OF NON-COMPLIANCE	0	1	1	0	0
	NOTICE OF DEFICIENCY	3	0	0	0	2
	NOD WITHDRAWAL LETTER	1	0	0	0	0
	REJECTION LETTER (SCR)	2	0	1	1	0
	CANCELLATION LETTER	0	0	1	0	5
	SCREENING DEFICIENCY NOTICE	3	0	1	3	7

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

SNDS-D: SUPPLEMENT TO A NEW DRUG SUBMISSION - DISINFECTANT PRODUCTS

RECEIVED

SNDS-Disinfectant Products: Number Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
DISINFECTANTS	0	0	0	1	2
LABELLING ONLY	0	0	0	0	1
Total	***0***	***0***	***0***	***1***	***3***

WORKLOAD

SNDS-Disinfectant Products: Review Workload

SNDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Disinfectants	0	0	0	1	2
BACKLOG	0	0	0	0	0
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

PERFORMANCE

SNDS-Disinfectant Products: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0
2020-2021	0	0	0	-	0
2021-2022	0	0	2	100%	2

SNDS-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0
2020-2021	0	0	0	-	0
2021-2022	2	1	1	50%	4

DECISIONS

SNDS-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
DISINFECTANTS	NOTICE OF COMPLIANCE*	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	0	1

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

PRE-MEETINGS - DISINFECTANT PRODUCTS

MPDIN-Disinfectant Products: Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
CLINICAL OR NON-CLINICAL DATA	0	0	1	1	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY -MANUFACTURING	0	0	6	5	7
CHEMISTRY AND MANUFACTURING	0	0	0	1	0
Total	***0***	***0***	***7***	***7***	***7***

MPNDS-Disinfectant Products: Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	1	1
CHEMISTRY AND MANIFACTURING	0	0	0	2	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	1
Total	***0***	***0***	***0***	***3***	***2***

MPSNDS-Disinfectant Products: Received by Fee Category

User Fee Category	2017 / 2018	2018 / 2019	2019 / 2020	2020 / 2021	2021 / 2022
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0