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# Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual  
Report

Fiscal Year

2021-2022

April 1 2021 - March 31 2022



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

Également disponible en français sous le titre :  
Direction des produits de santé naturels et sans ordonnance - Rapport annuel du rendement des présentations de drogue - Exercice financier 2021-2022

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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](#).<sup>1</sup> 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- The [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was repealed and replaced on February 27, 2022 by the [Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations](#) to allow sponsors to continue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).

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<sup>1</sup> [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<sup>2</sup> 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**<sup>3</sup> 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<sup>4</sup>) 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.](#)

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<sup>2</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

<sup>3</sup> 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.

<sup>4</sup> 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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Email: [osip-bppi@hc-sc.gc.ca](mailto:osip-bppi@hc-sc.gc.ca)

# 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
<b>New Active Substance (NAS)</b>	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.
<b>Clinical or Non-Clinical Data and Chemistry and Manufacturing data</b>	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or Non-Clinical Data Only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
<b>Comparative Studies</b>	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.
<b>Chemistry and Manufacturing Data Only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or nonclinical data only, in support of safety updates to the labelling</b>	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.
<b>Switch from Prescription to Nonprescription Status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient on the <a href="#">Prescription Drug List</a> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug - Category discontinued.
<b>Labelling Only</b>	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
<b>Labelling Only (generic drugs)</b>	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.
<b>Administrative Submission</b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants</b>	Submissions and applications that include data in support of a disinfectant.



<b>Labelling only (disinfectants)</b>	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.
<b>Drug Identification Number (DIN) - Labelling Standards</b>	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.
<b>Published Data Only</b>	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](#).

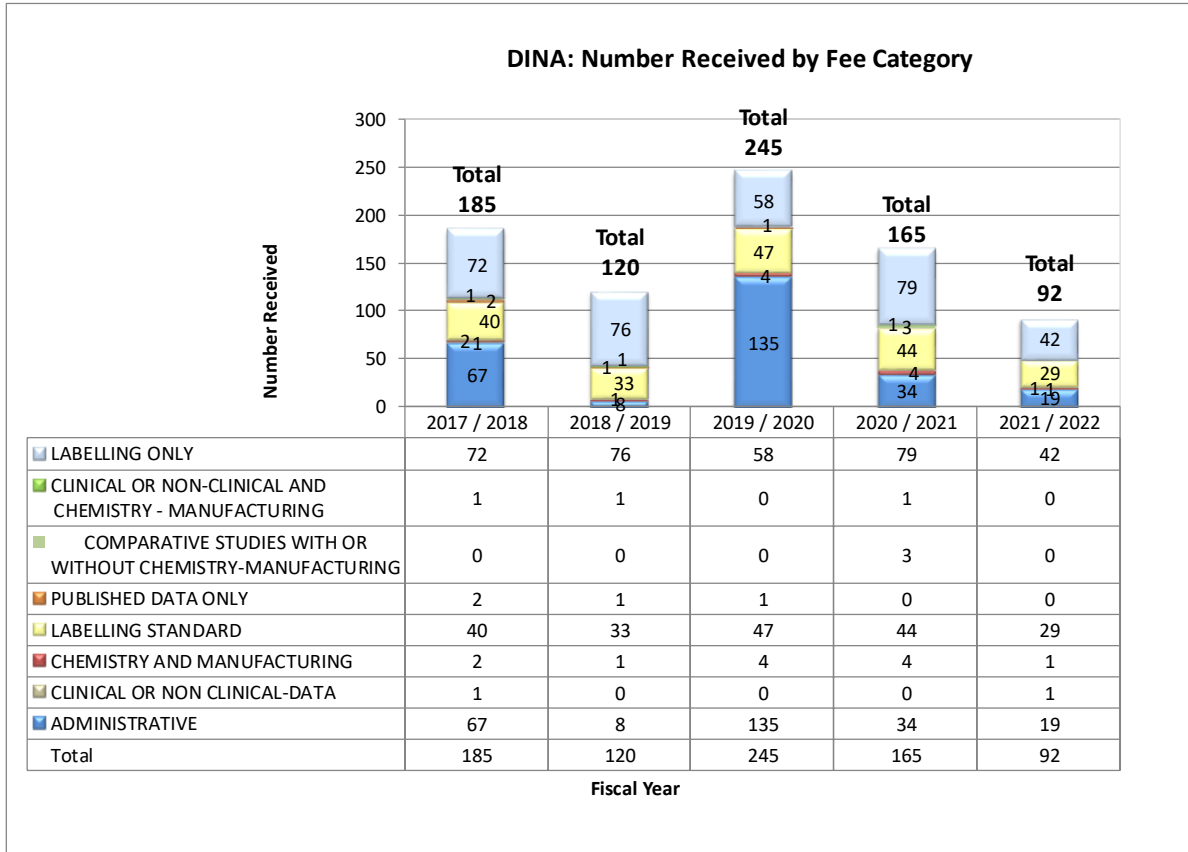
# **PART 1: NON PRESCRIPTION DRUGS** ***Over the Counter (OTC) Drugs***

## **NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1**

**in Part C of the *Food and Drug Regulations***

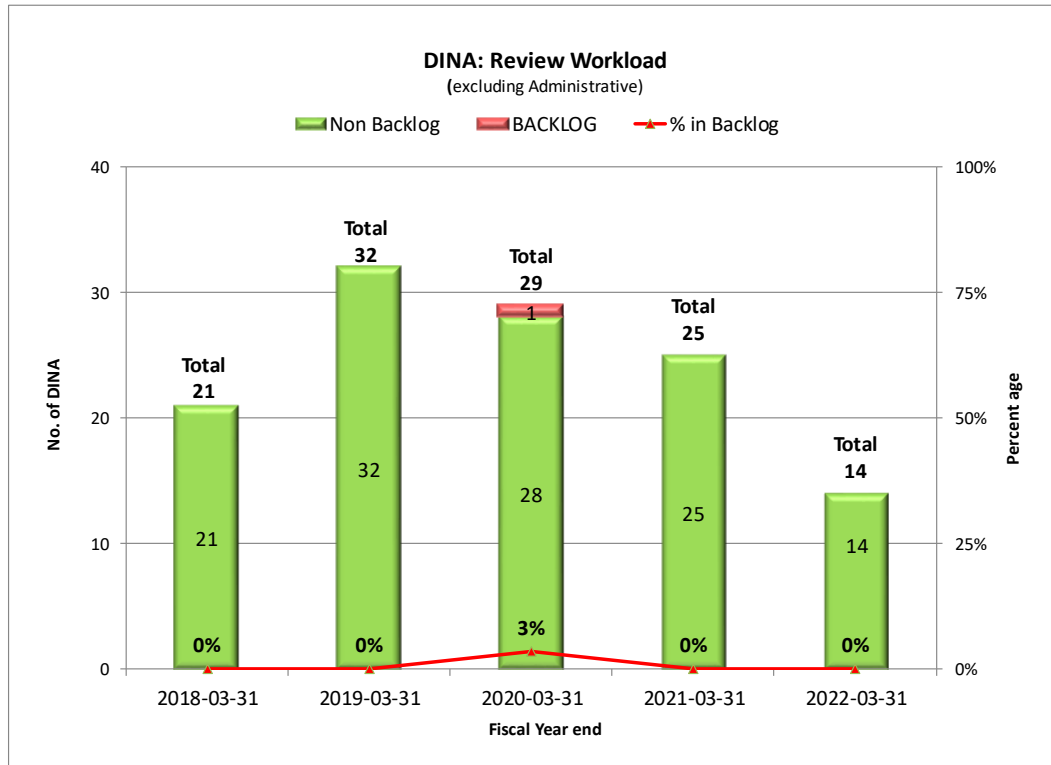
**DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER  
RECEIVED**

**DINA: Number Received by Fee Category**



## WORKLOAD

### DINA: Review Workload

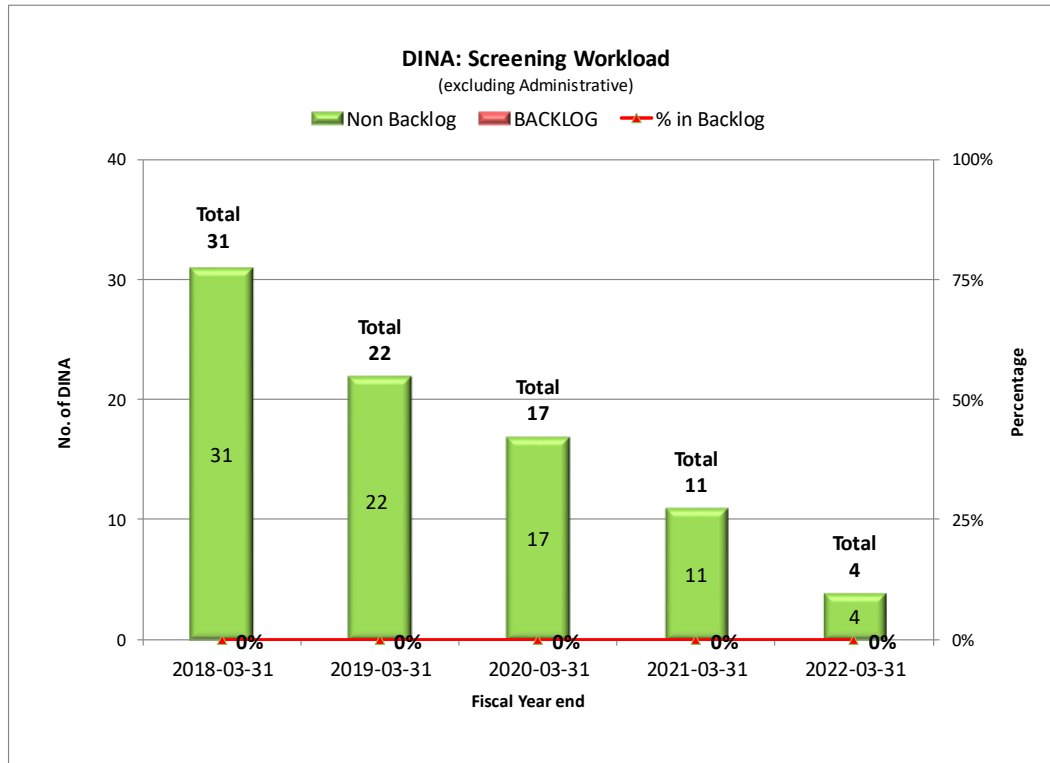


### DINA: Review Workload by Fee Category

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
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	1	0	2	4	0
<i>Backlog</i>	0	0	1	0	0
Clinical or Non-Clinical Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies	0	0	0	3	0
<i>Backlog</i>	0	0	0	0	0
Published Data Only	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical /C&M	1	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>21</b>	<b>32</b>	<b>29</b>	<b>25</b>	<b>14</b>
Non Backlog	21	32	28	25	14
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>3%</b>	<b>0%</b>	<b>0%</b>

## WORKLOAD

### DINA: Screening Workload

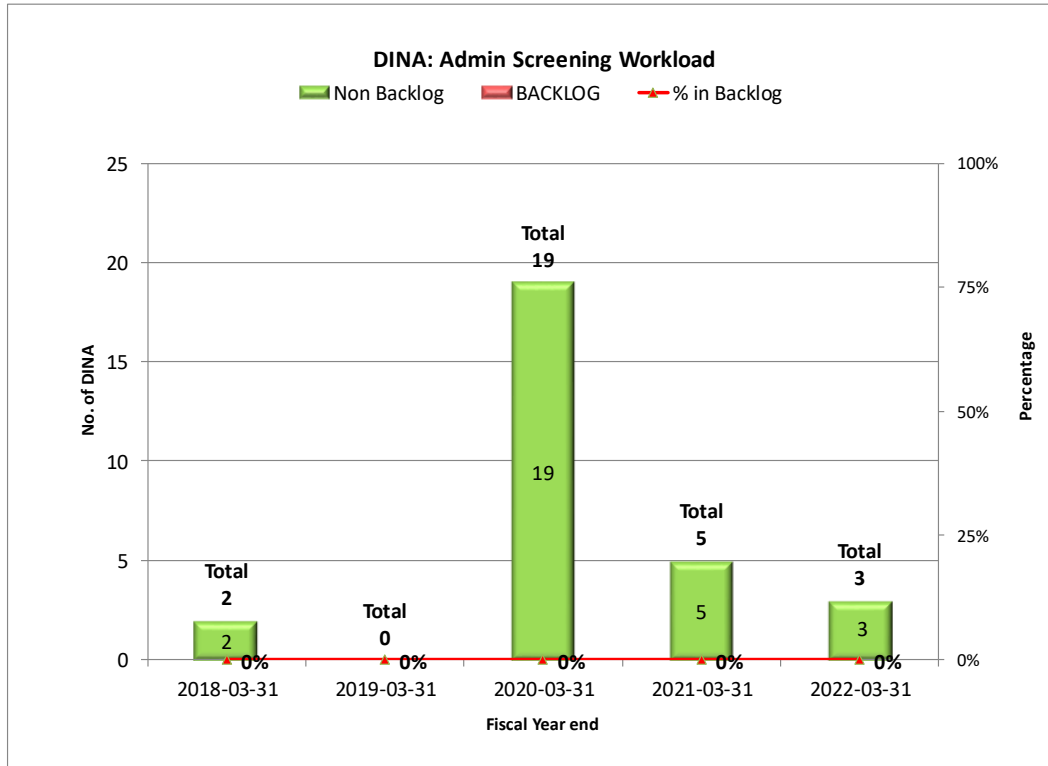


### DINA: Screening Workload by Fee Category

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
<i>Backlog</i>	0	0	0	0	0
Labelling Standard	10	6	12	3	3
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	1	0	1
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Published Data Only	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>31</b>	<b>22</b>	<b>17</b>	<b>11</b>	<b>4</b>
Non Backlog	31	22	17	11	4
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## 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
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>2</b>	<b>0</b>	<b>19</b>	<b>5</b>	<b>3</b>
Non Backlog	2	0	19	5	3
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

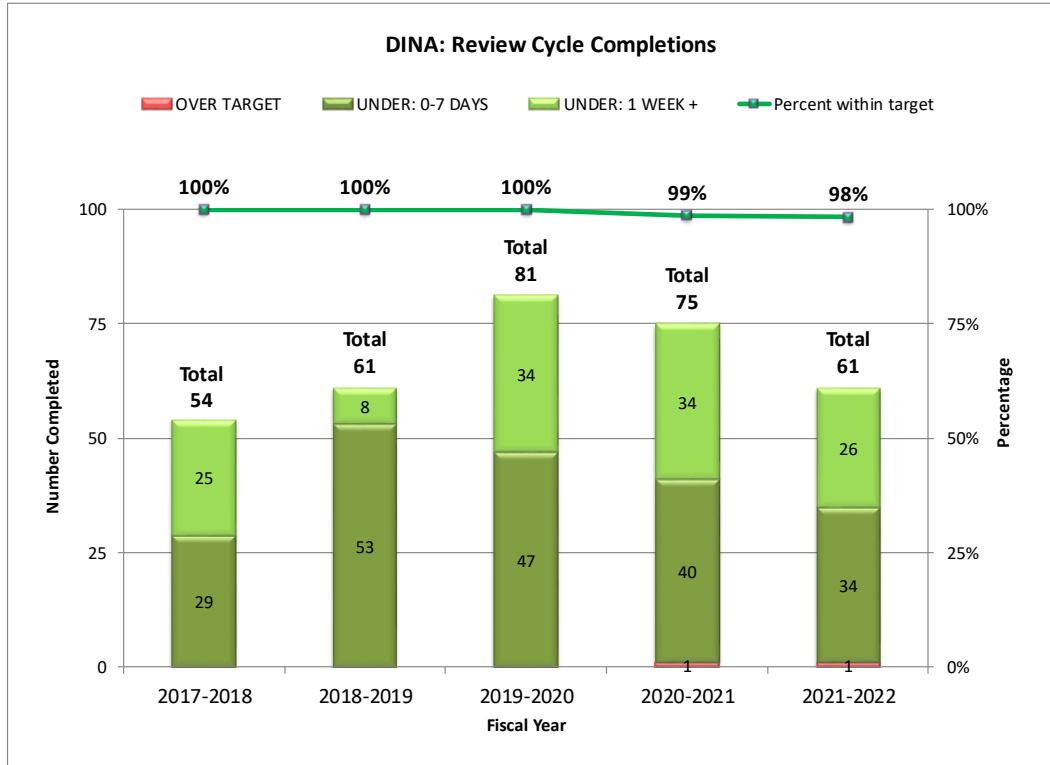
## DECISIONS

### DINA: Number of Decisions by Fee Category

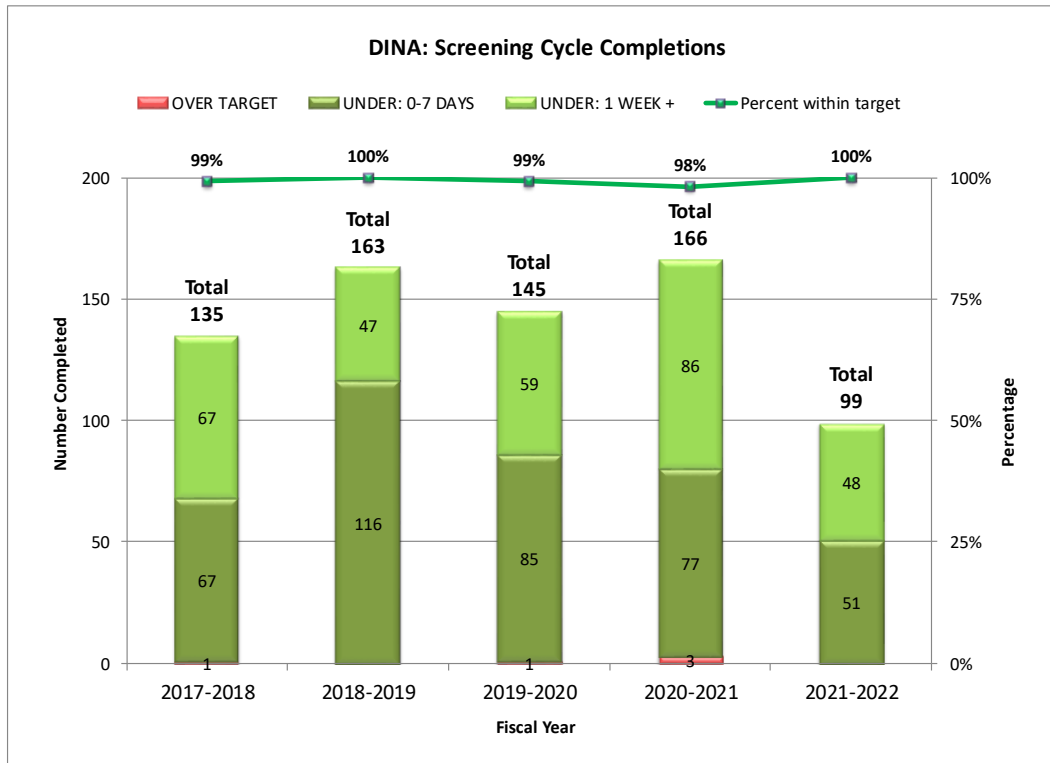
User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
<b>ADMINISTRATIVE</b>	NOTIFICATION FORM DIN SUB	32	0	106	38	13
	NO OBJECTION LETTER	0	0	0	2	2
	REJECTION LETTER (SCR)	2	0	1	1	0
	SCREENING DEFICIENCY NOTICE	4	2	19	3	2
	CANCELLATION LETTER	36	10	7	5	5
<b>CHEMISTRY AND MANUFACTURING</b>	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
<b>CLINICAL OR NON-CLINICAL DATA</b>	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
<b>COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING</b>	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
<b>CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING</b>	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
<b>LABELLING ONLY</b>	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	
<b>LABELLING STANDARD</b>	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
<b>PUBLISHED DATA</b>	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



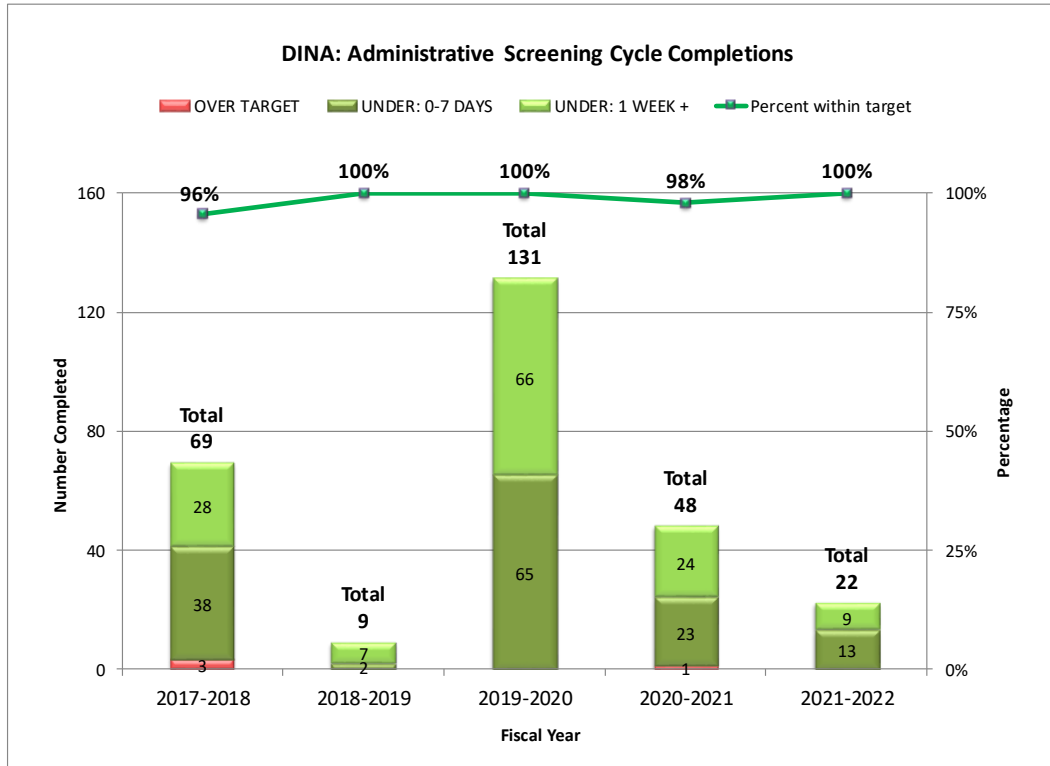
### DINA: Screening Cycle Completions





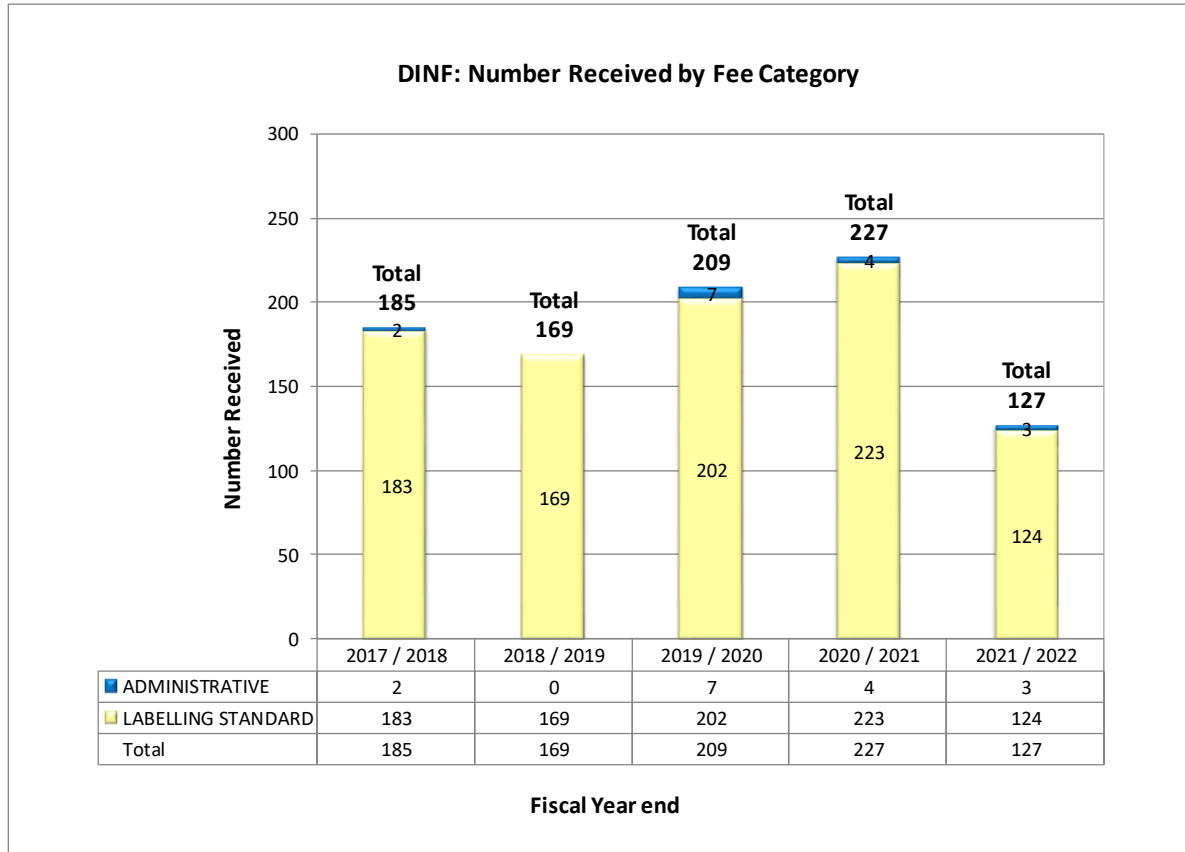
**PERFORMANCE**

**DINA: Administrative-Screening Cycle Completions**



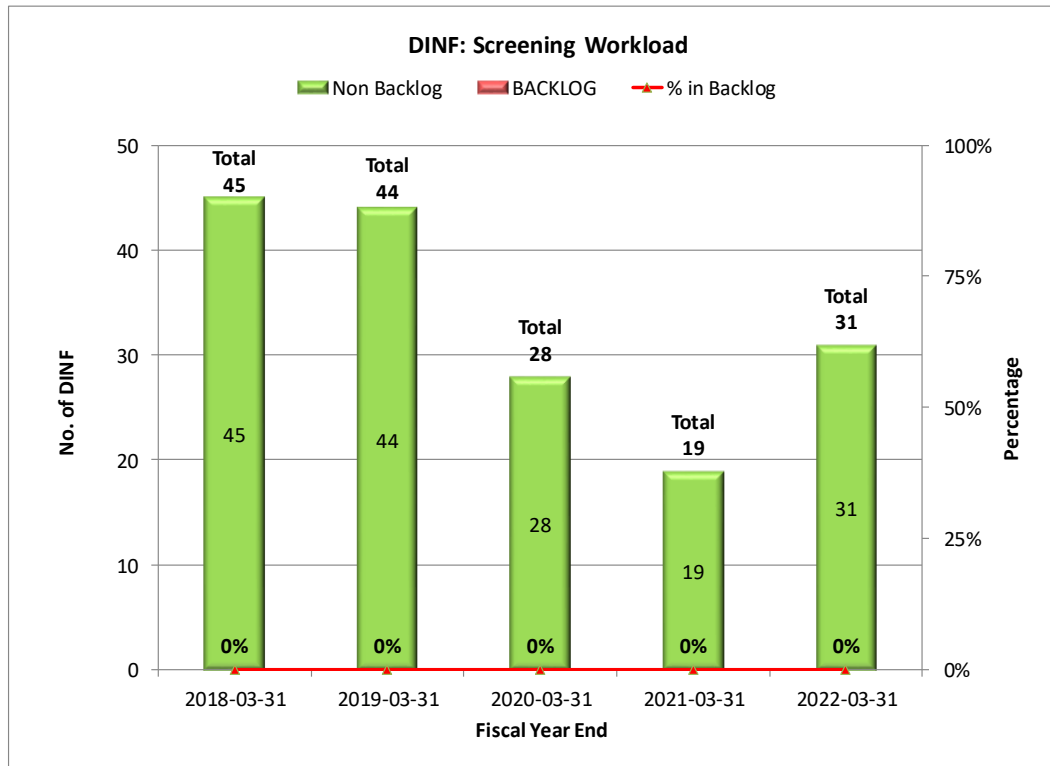
**DINF: APPLICATION FOR A DIN FOR A CATEGORY IV MONOGRAPH PRODUCT  
RECEIVED**

**DINF: Number Received by Fee Category**



## 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
<i>Backlog</i>	0	0	0	0	0
Administrative	0	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>45</b>	<b>44</b>	<b>28</b>	<b>19</b>	<b>31</b>
Non Backlog	45	44	28	19	31
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

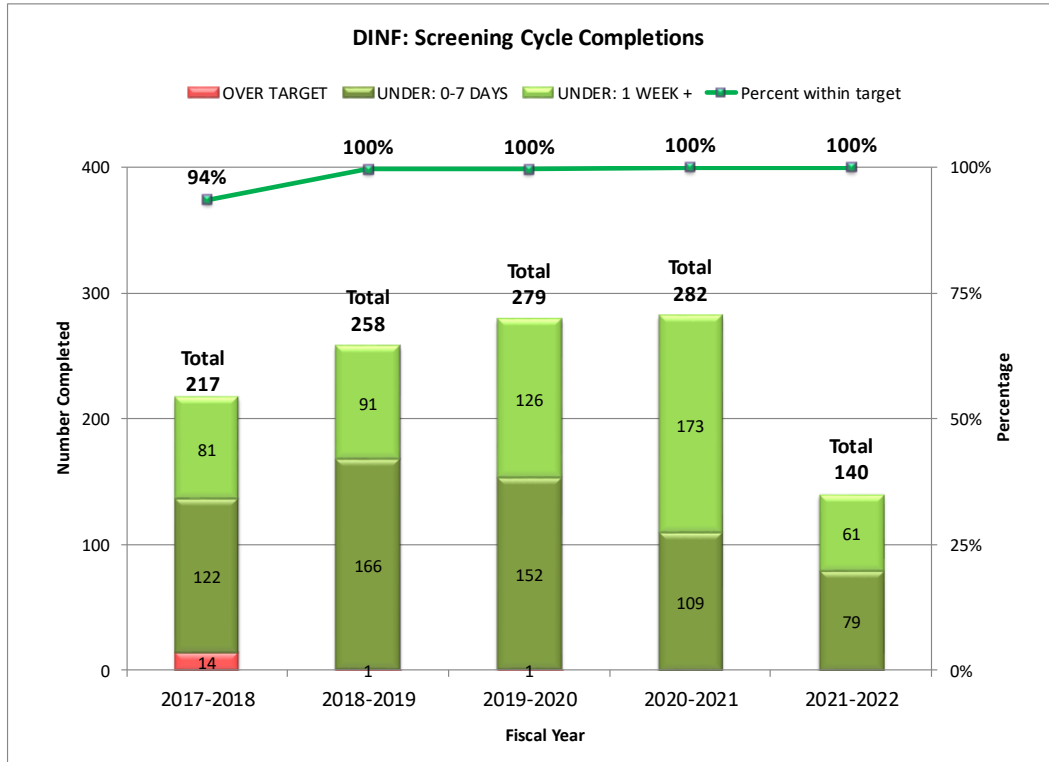
## DECISIONS

### DINF: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
<b>LABELLING STANDARD</b>	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
<b>ADMINISTRATIVE</b>	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

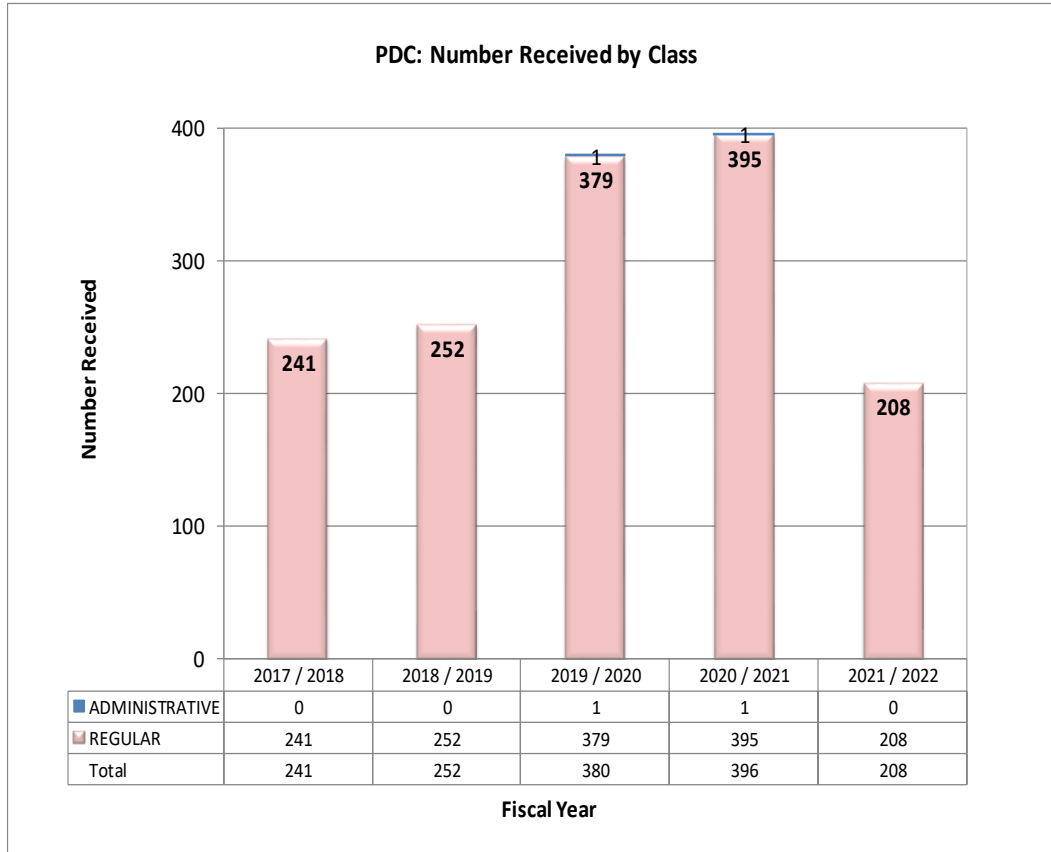
## PERFORMANCE

### DINF: Screening Cycle Completions



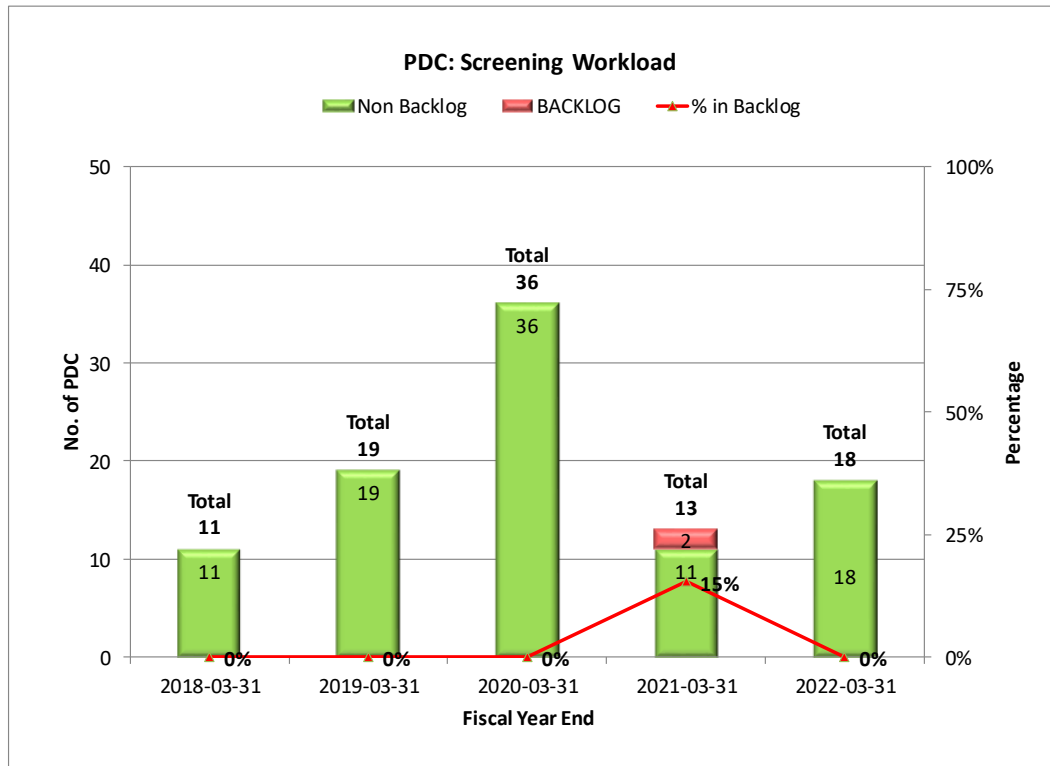
**PDC: POST AUTHORIZATION DIVISION 1 CHANGE  
RECEIVED**

**PDC: Number Received by Class**



## 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
<i>Backlog</i>	0	0	0	2	0
<b>Total</b>	<b>11</b>	<b>19</b>	<b>36</b>	<b>13</b>	<b>18</b>
Non Backlog	11	19	36	11	18
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>15%</b>	<b>0%</b>

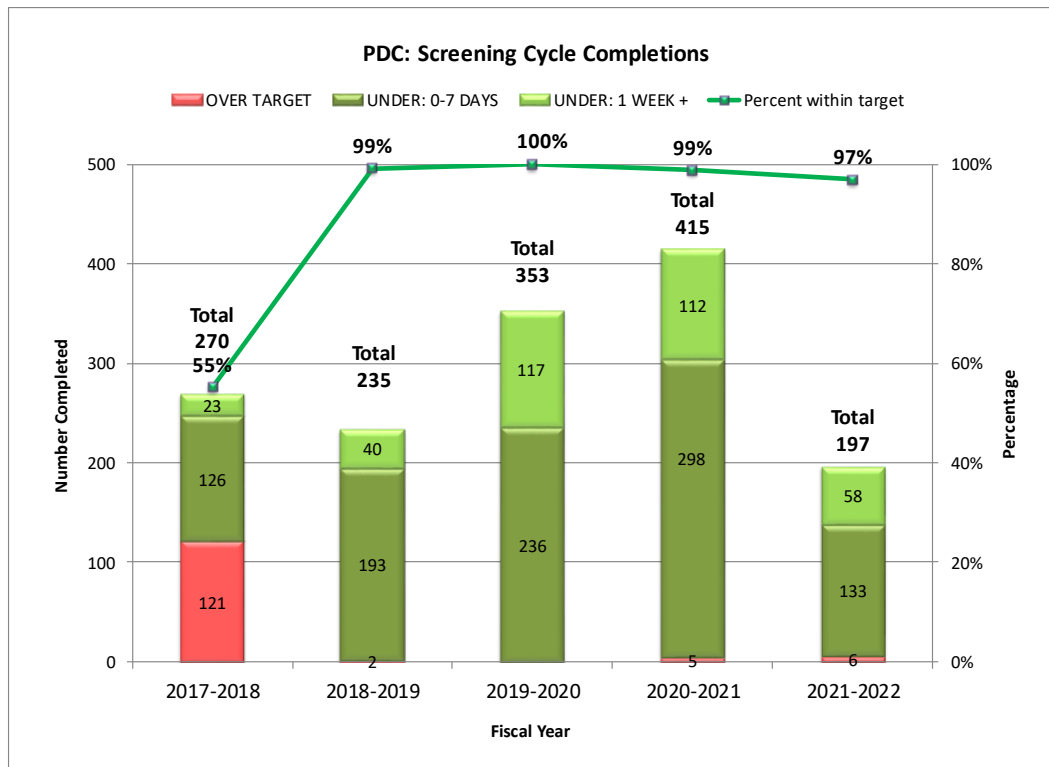
## DECISIONS

### 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

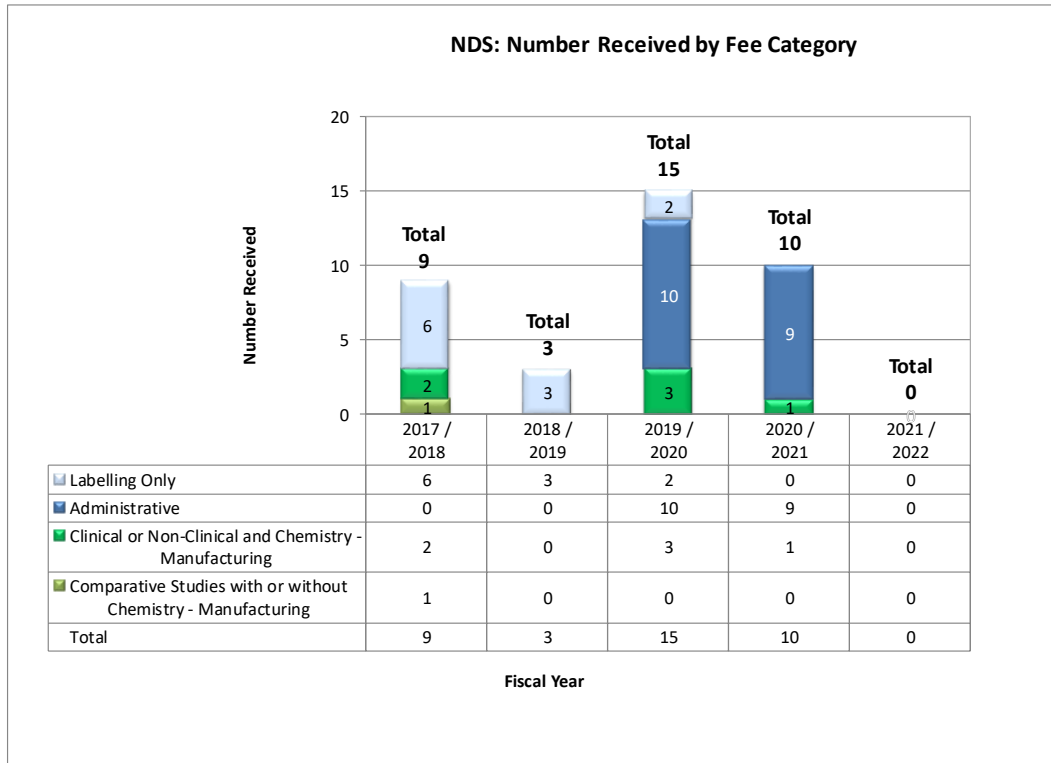




**NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8**  
in Part C of the *Food and Drug Regulations*

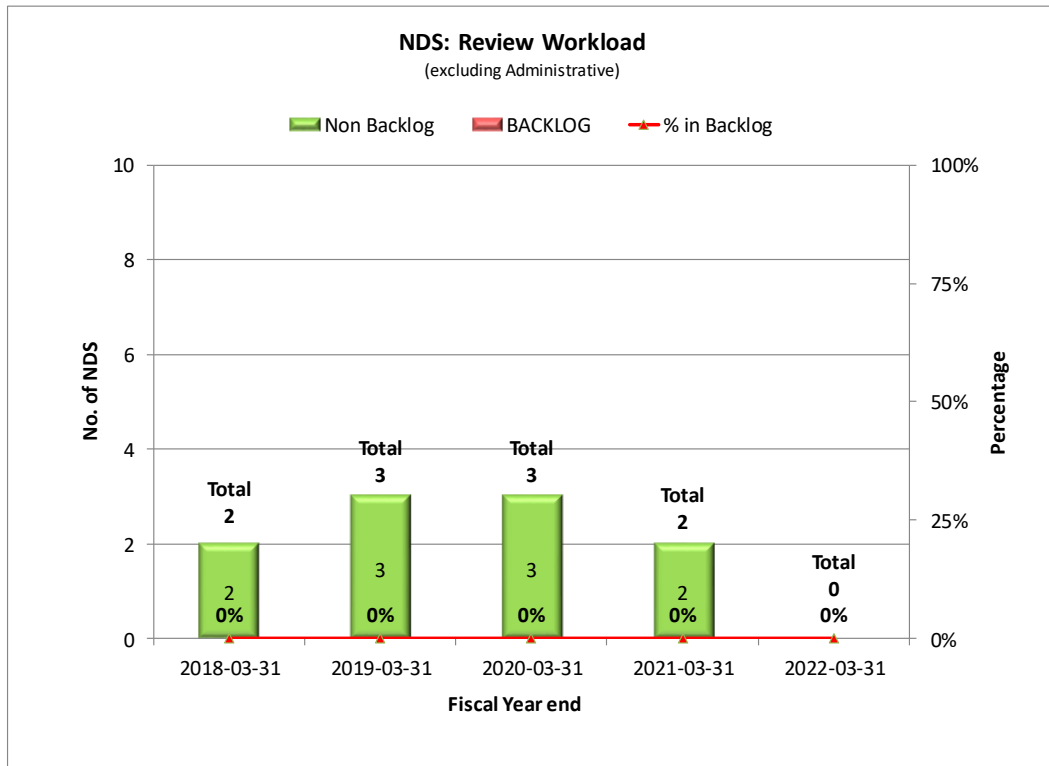
## NDS: NEW DRUG SUBMISSION RECEIVED

### NDS: Number Received by Fee Category



## WORKLOAD

### NDS: Review Workload

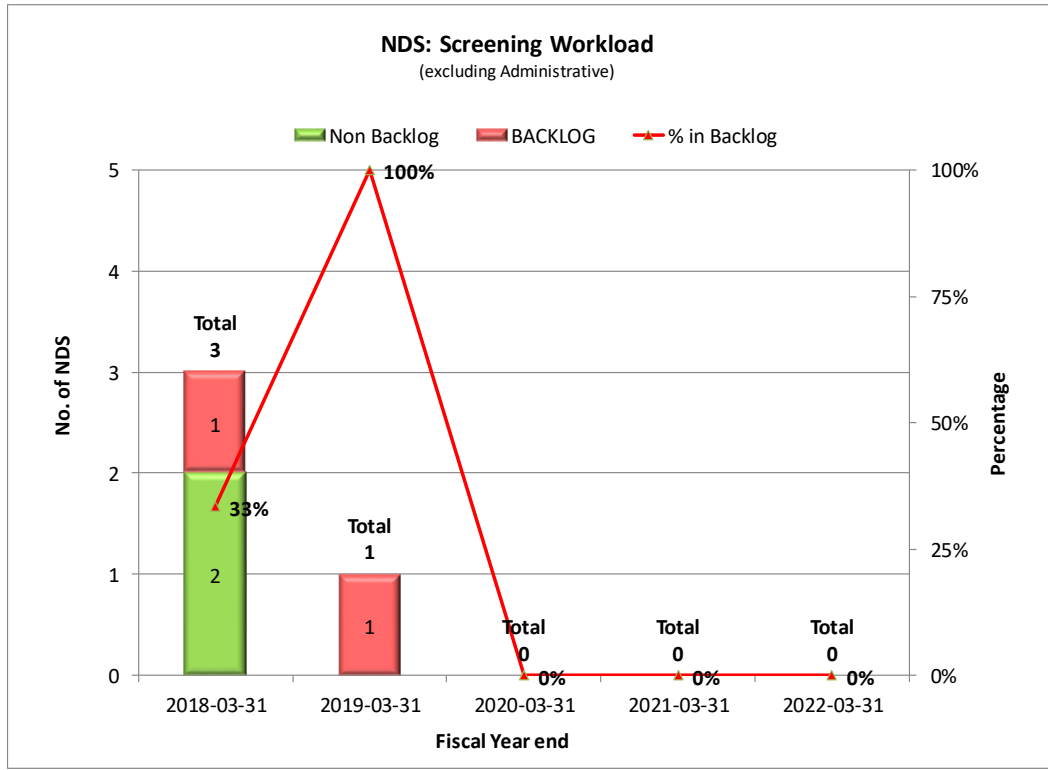


### NDS: Review Workload by Fee Category

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
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without C&M	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	1	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>2</b>	<b>0</b>
Non Backlog	2	3	3	2	0
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## 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
<i>Backlog</i>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
Clinical or Non-Clinical /C&M	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without C&M	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>3</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
Non Backlog	2	0	0	0	0
<b>BACKLOG</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>33%</b>	<b>100%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## DECISIONS

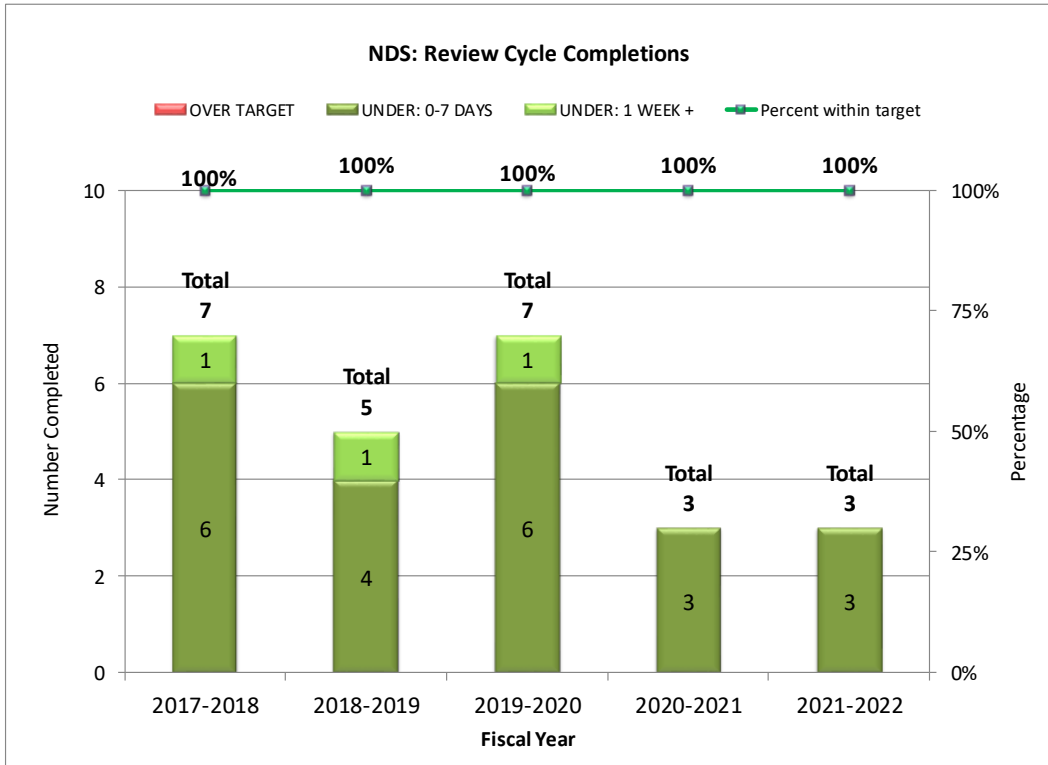
### NDS: Number of Decisions by Fee Category

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

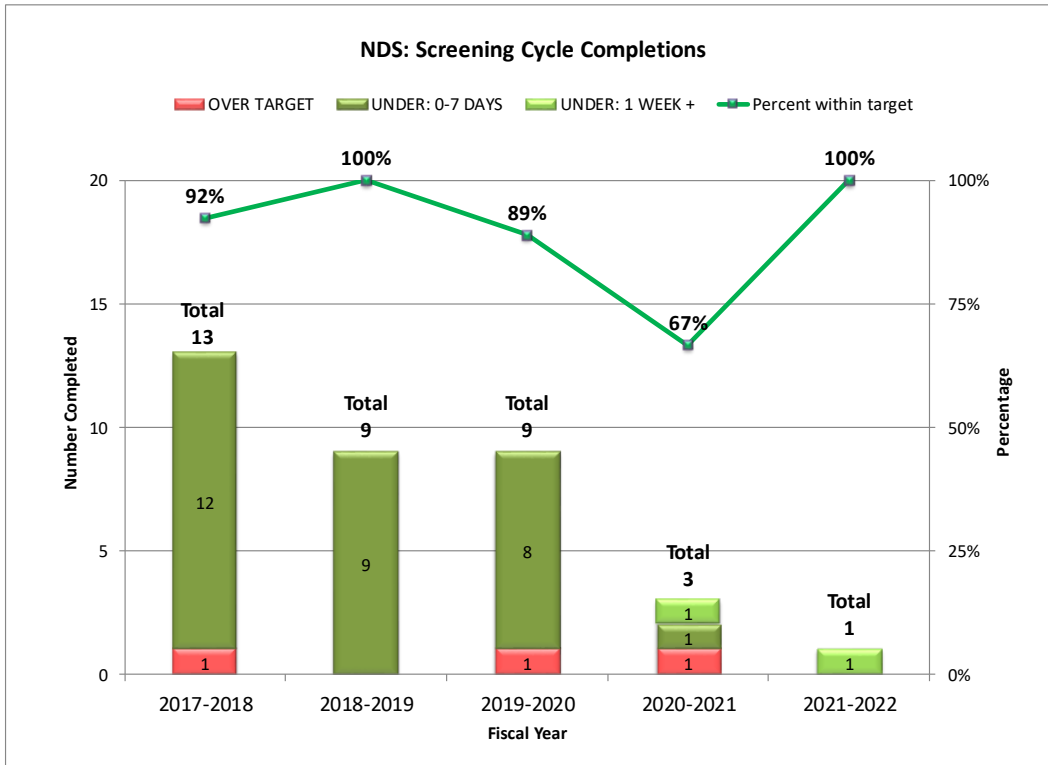
\*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

**PERFORMANCE**

**NDS: Review Cycle Completions**

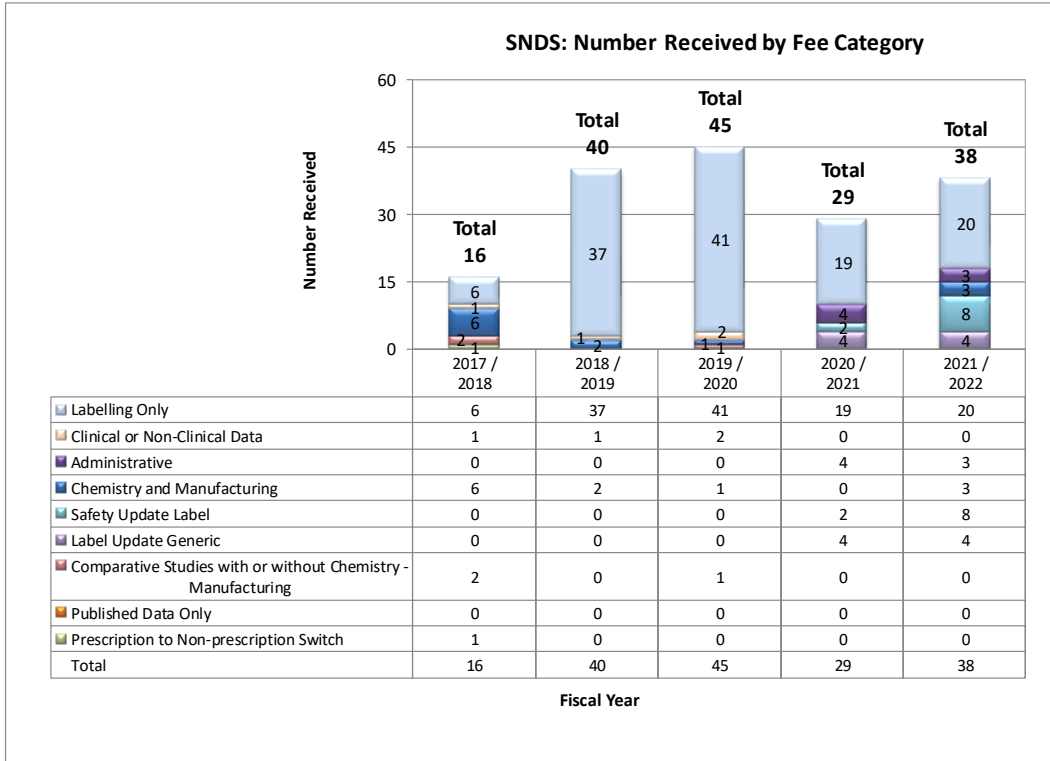


**NDS: Screening Cycle Completions**



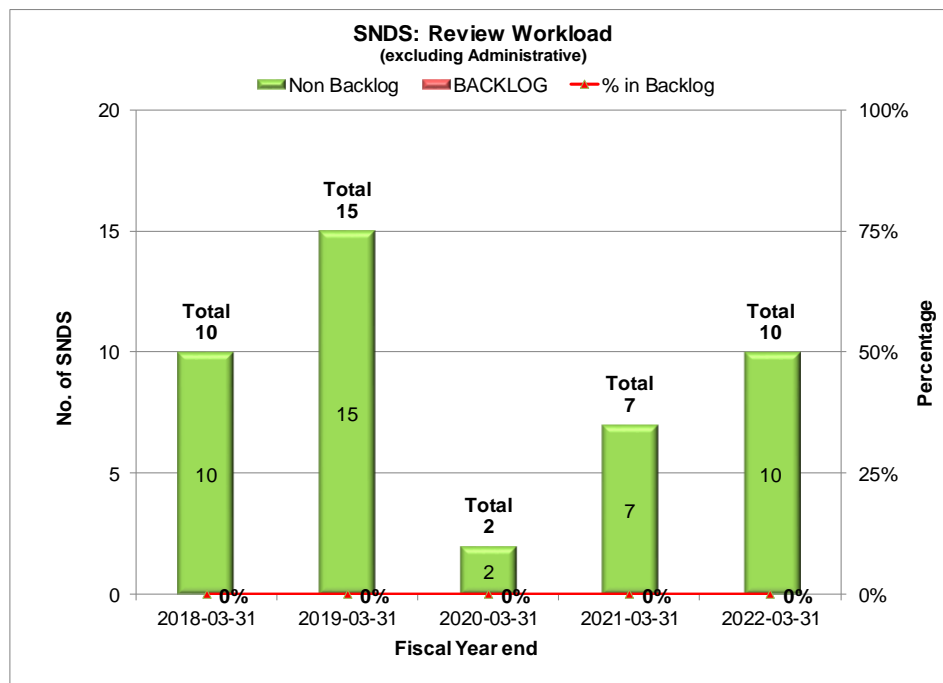
## SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

### SNDS: Number Received by Fee Category



## WORKLOAD

### SNDS: Review Workload



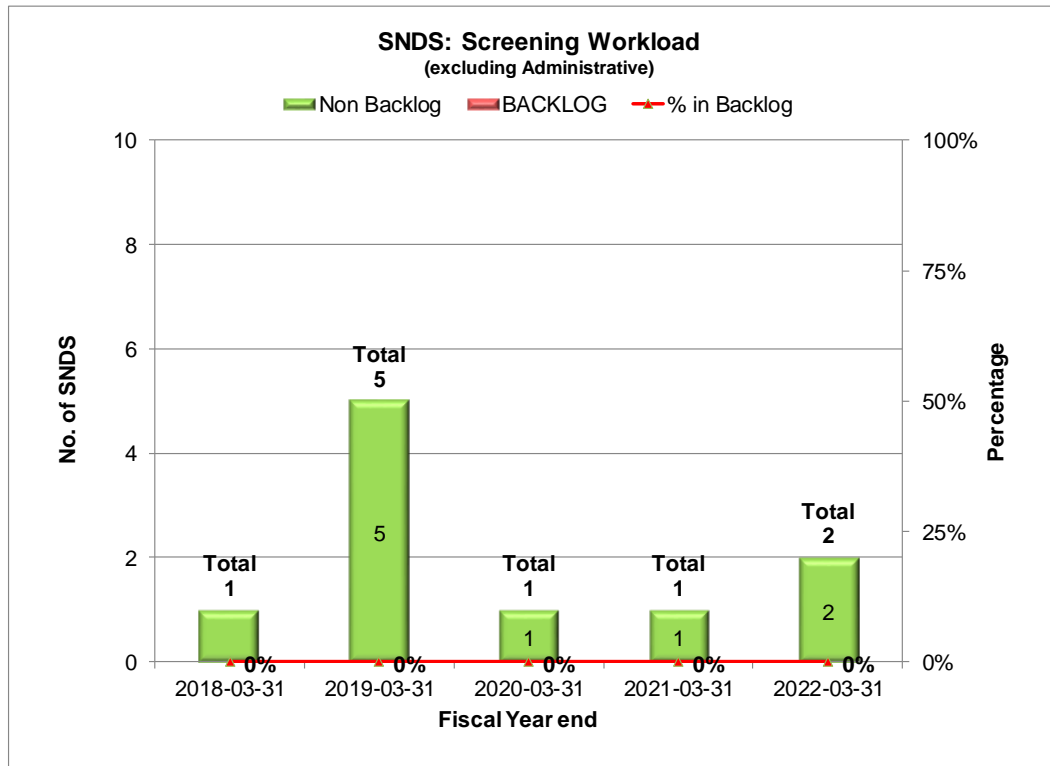
### SNDS: Review Workload by Fee Category

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



## 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
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	5	1	1	2
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>1</b>	<b>2</b>
Non Backlog	1	5	1	1	2
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## DECISIONS

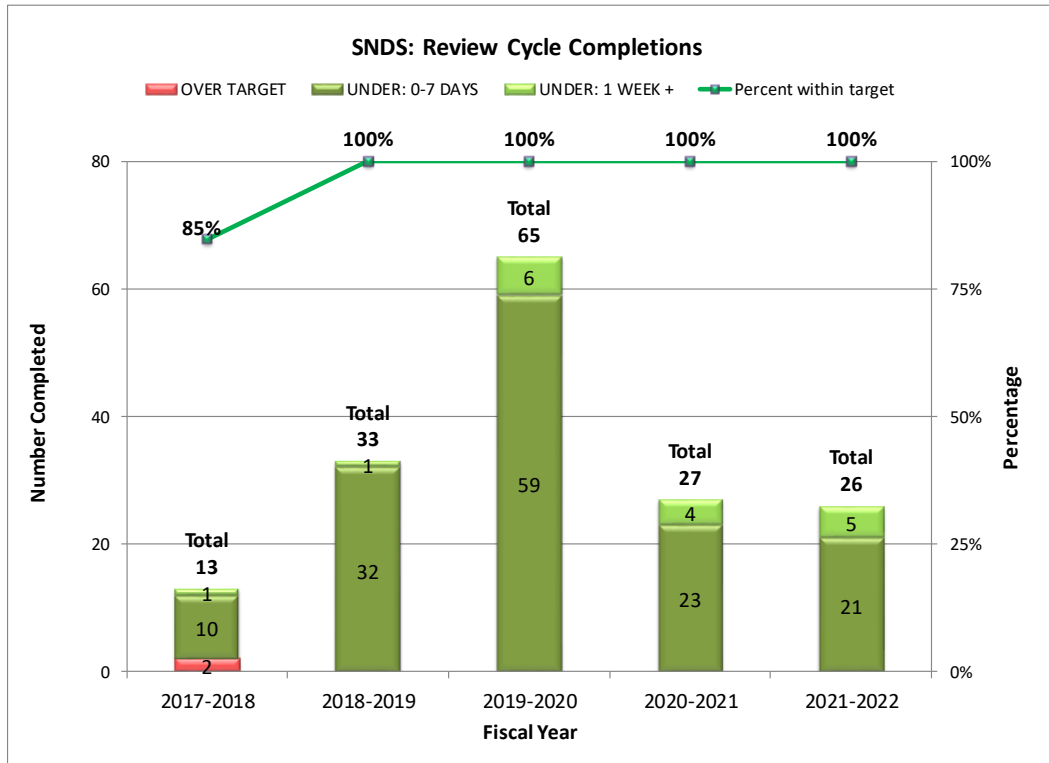
### SNDS: Number of Decisions by Fee Category

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

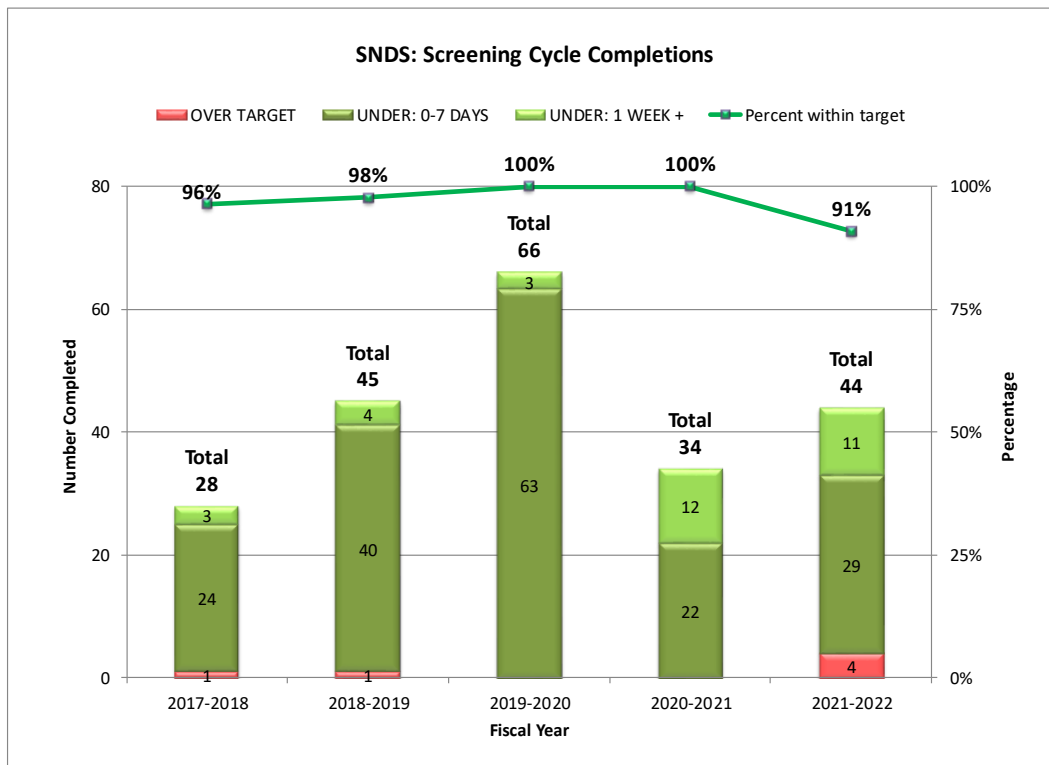
\*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

## 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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>7</b>	<b>7</b>	<b>7</b>

## 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
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	1	1
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	1	1	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>4</b>	<b>3</b>
Non Backlog	0	0	3	4	3
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### 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
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>
Non Backlog	0	0	1	1	0
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### 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
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**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
<b>ADMINISTRATIVE</b>	CANCELLATION LETTER	0	0	1	1	1
	SCREENING DEFICIENCY NOTICE	0	0	1	1	0
	REJECTION LETTER (SCR)	0	0	0	1	0
<b>CHEMISTRY AND MANUFACTURING</b>	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
<b>COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING</b>	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
<b>LABELLING ONLY</b>	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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>24</b>	<b>59</b>	<b>38</b>



## WORKLOAD

### SANDS: Review Workload

<b>SANDS: REVIEW WORKLOAD</b>					
<b>BY USER FEE CATEGORY and Fiscal Year End</b>					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Chemistry & Manufacturing	0	0	0	4	0
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	0	0	2	1
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	6	7	8
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>6</b>	<b>13</b>	<b>9</b>
Non Backlog	0	0	6	13	9
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### SANDS: Screening Workload

<b>SANDS: SCREENING WORKLOAD</b>					
<b>BY USER FEE CATEGORY and Fiscal Year End</b>					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
Chemistry & Manufacturing	0	0	1	0	2
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	1	4	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>4</b>	<b>2</b>
Non Backlog	0	0	2	4	2
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### SANDS: Administrative-Screening Workload

<b>SANDS: ADMINISTRATIVE SCREENING WORKLOAD</b>					
<b>BY USER FEE CATEGORY and Fiscal Year End</b>					
FEE CATEGORY	2018-03-31	2019-03-31	2020-03-31	2021-03-31	2022-03-31
ADMINISTRATIVE	0	0	5	2	1
<i>Backlog</i>	0	0	0	0	0
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**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

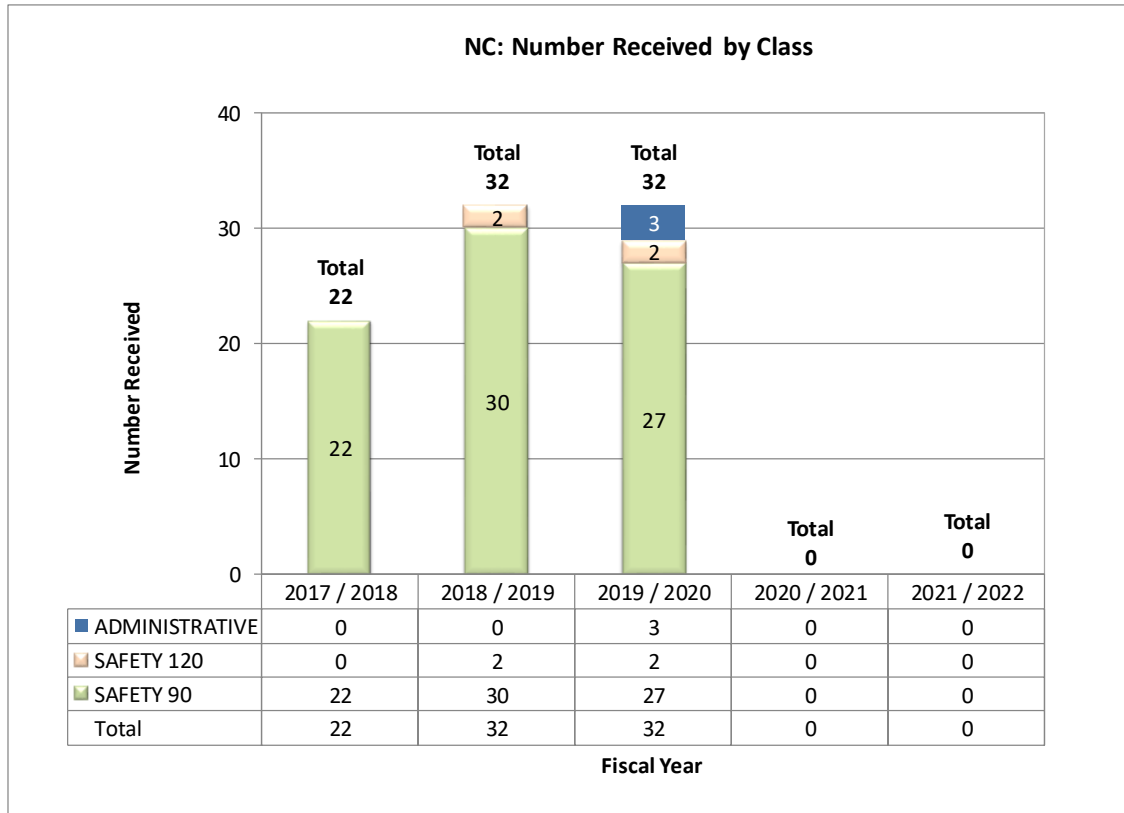
### SANDS: Number of Decisions by Fee Category

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

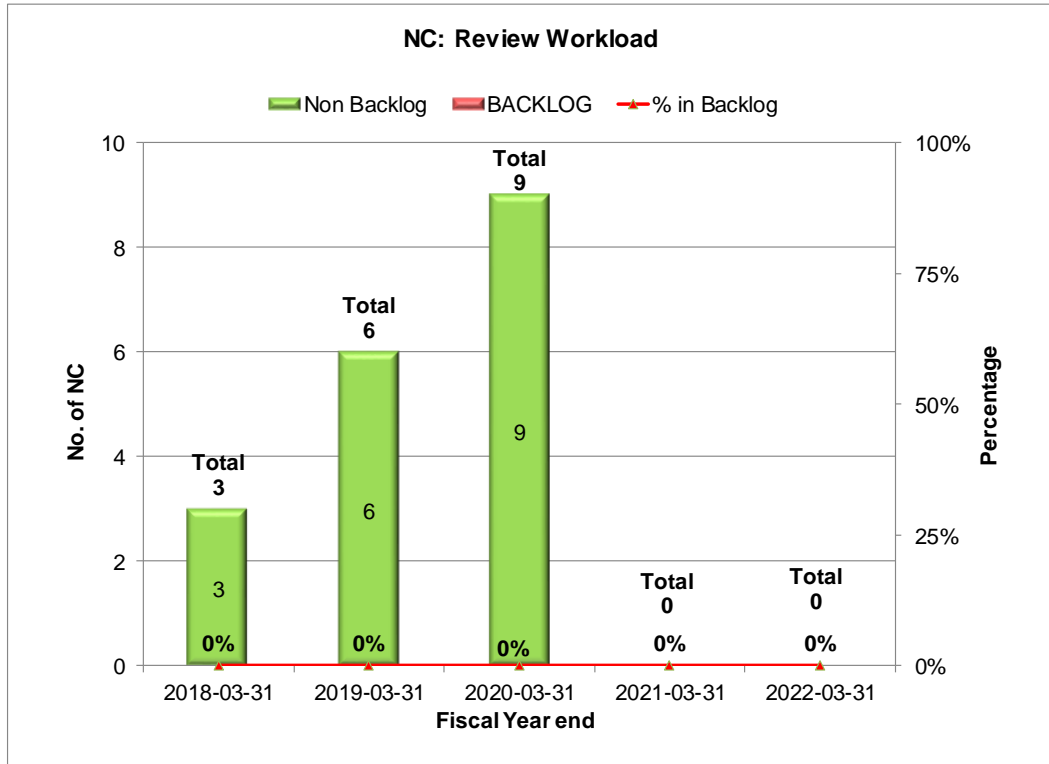
**NC: NOTIFIABLE CHANGE  
RECEIVED**

**NC: Number Received by Class**



## WORKLOAD

### NC: Review Workload

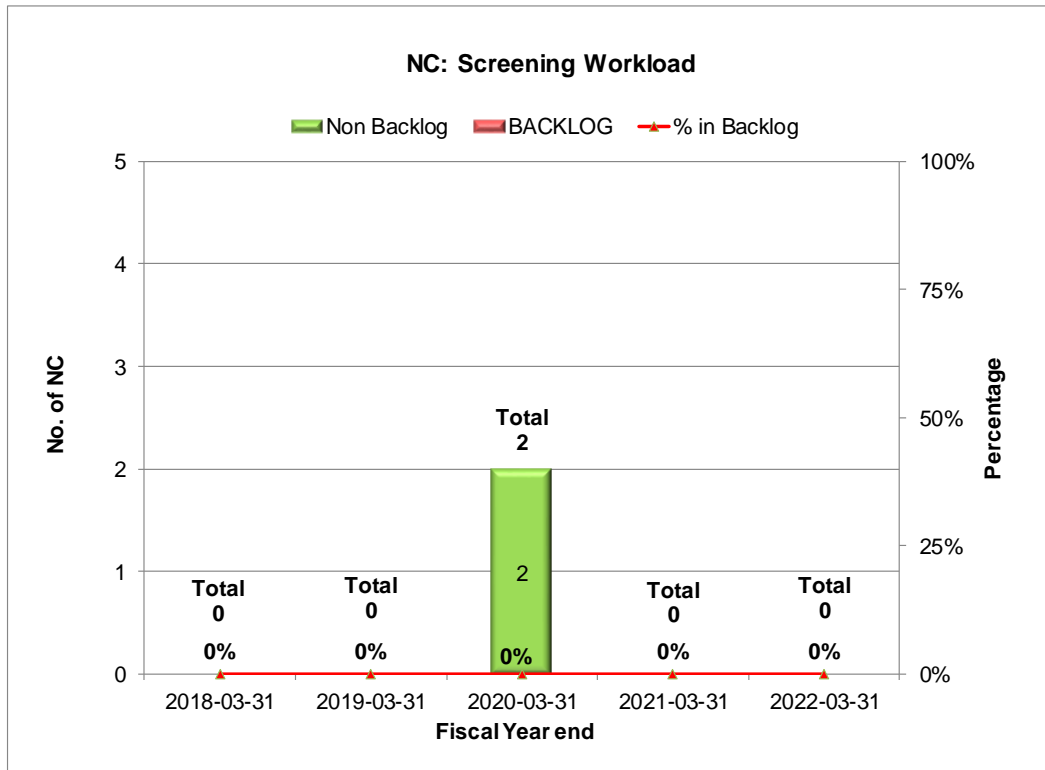


### NC: Review Workload by Class

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
<i>Backlog</i>	0	0	0	0	0
SAFETY 120	0	2	1	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>3</b>	<b>6</b>	<b>9</b>	<b>0</b>	<b>0</b>
Non Backlog	3	6	9	0	0
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## 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
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>
Non Backlog	0	0	2	0	0
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

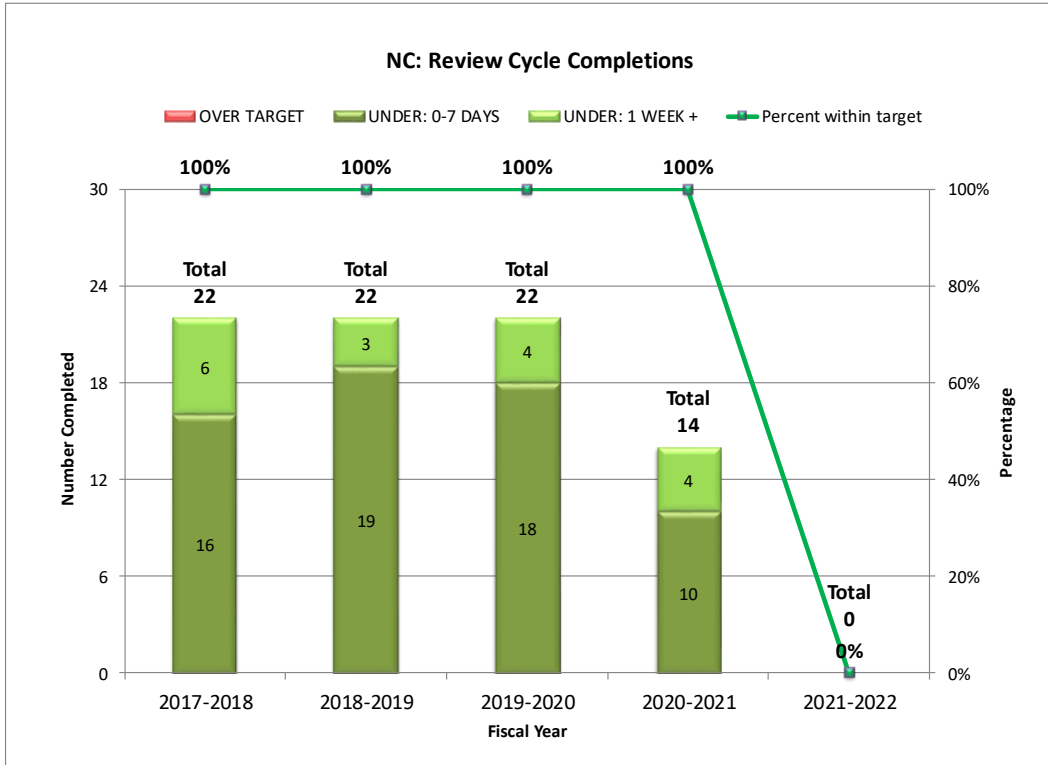
**DECISIONS**

**NC: Number of Decisions by Class**

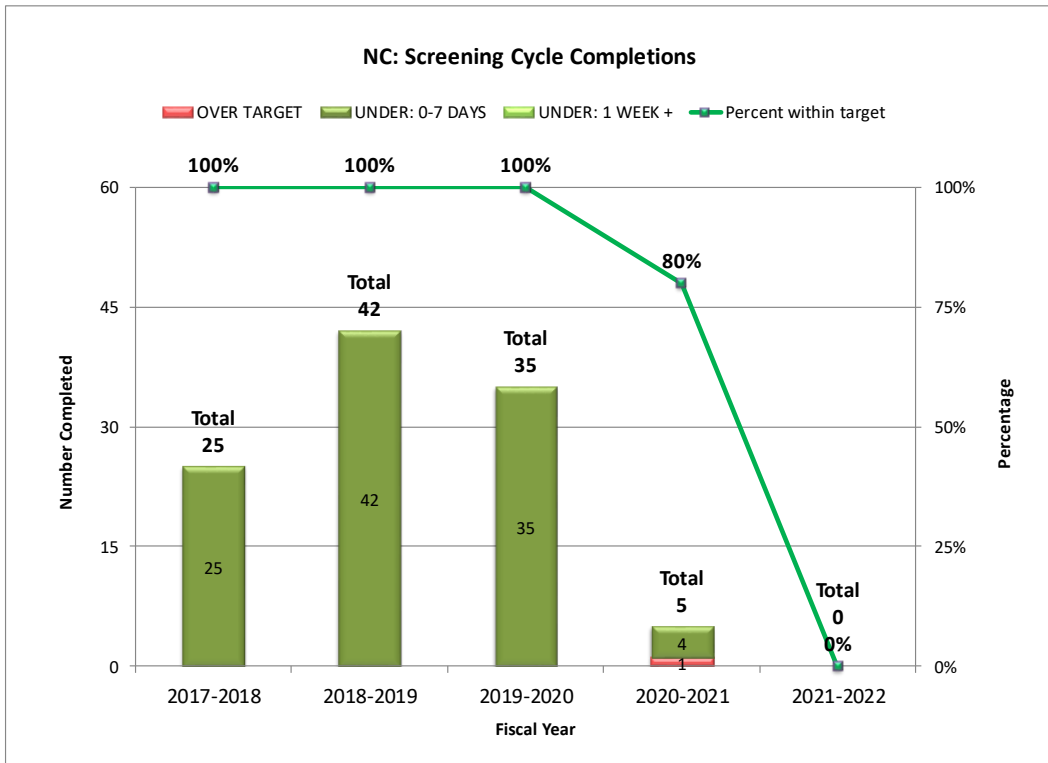
Class	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
<b>ADMINISTRATIVE</b>	CANCELLATION LETTER	0	0	1	0	0
	NO OBJECTION LETTER	0	0	2	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
<b>SAFETY 90</b>	NO OBJECTION LETTER	20	19	19	13	0
	CANCELLATION LETTER	2	8	2	0	0
	REJECTION LETTER (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
<b>SAFETY 120</b>	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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>7</b>	<b>1</b>

**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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>6</b>	<b>2</b>	<b>5</b>

**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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>4</b>

# **PART 2: DISINFECTANT PRODUCTS**

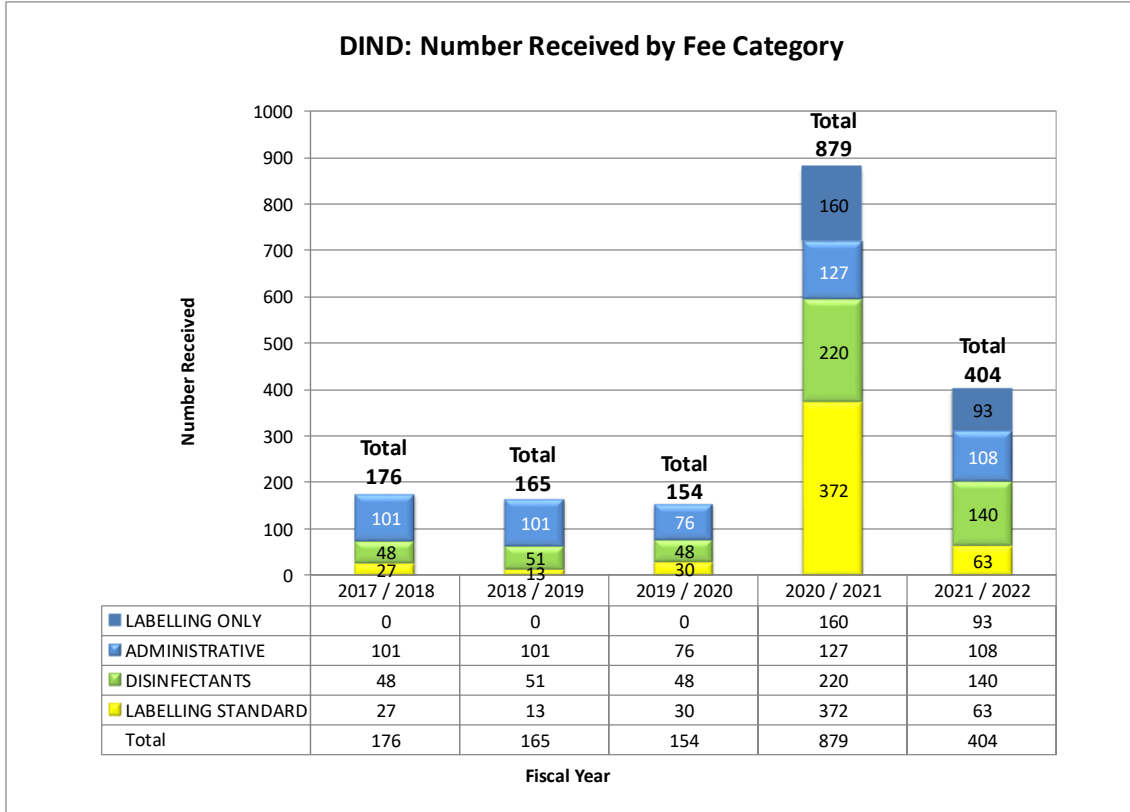
## **DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1**

**in Part C of the *Food and Drug Regulations***

**DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER -  
DISINFECTANT PRODUCTS**

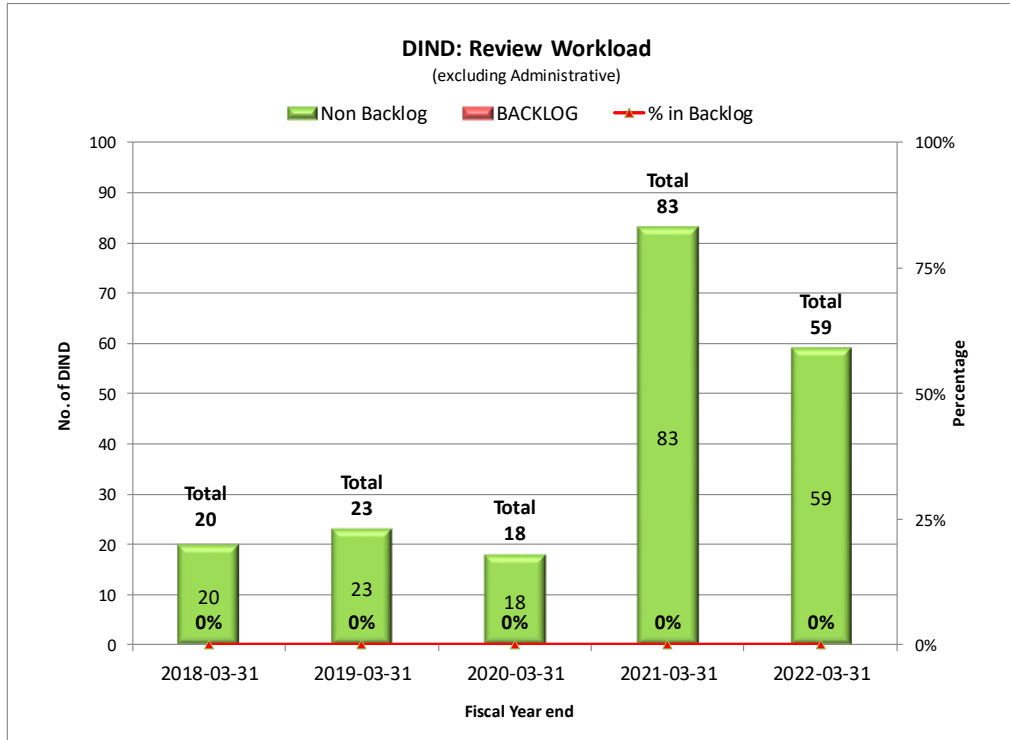
**RECEIVED**

**DIND-Disinfectant Products: Number Received by Fee Category**

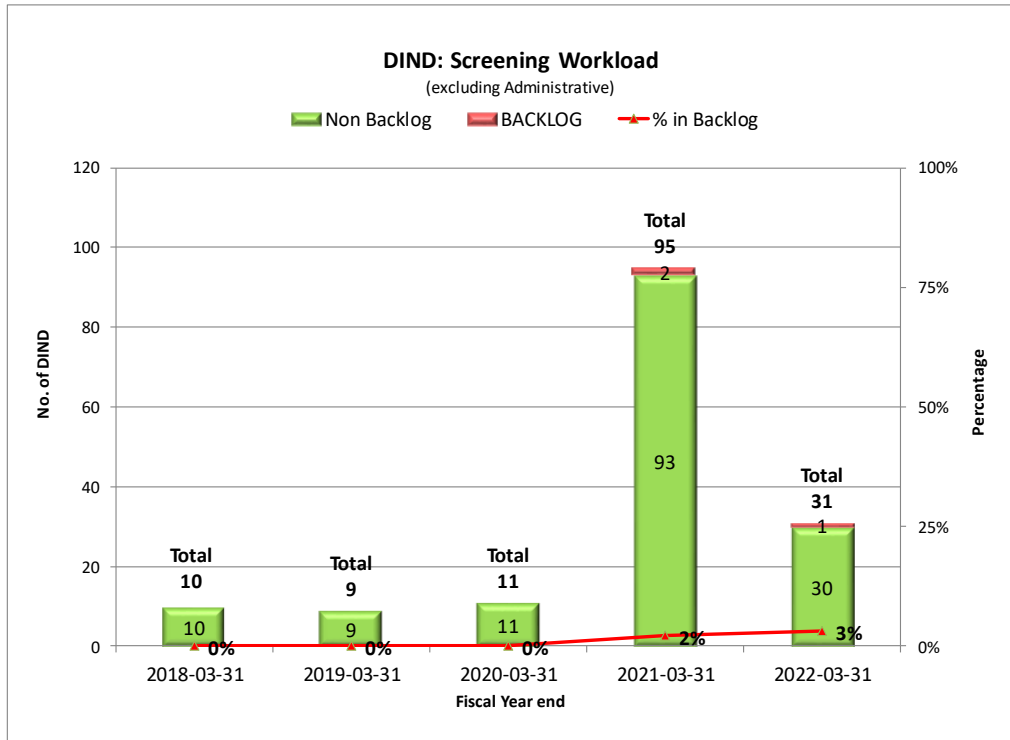


## WORKLOAD

### DIND-Disinfectant Products: Review Workload

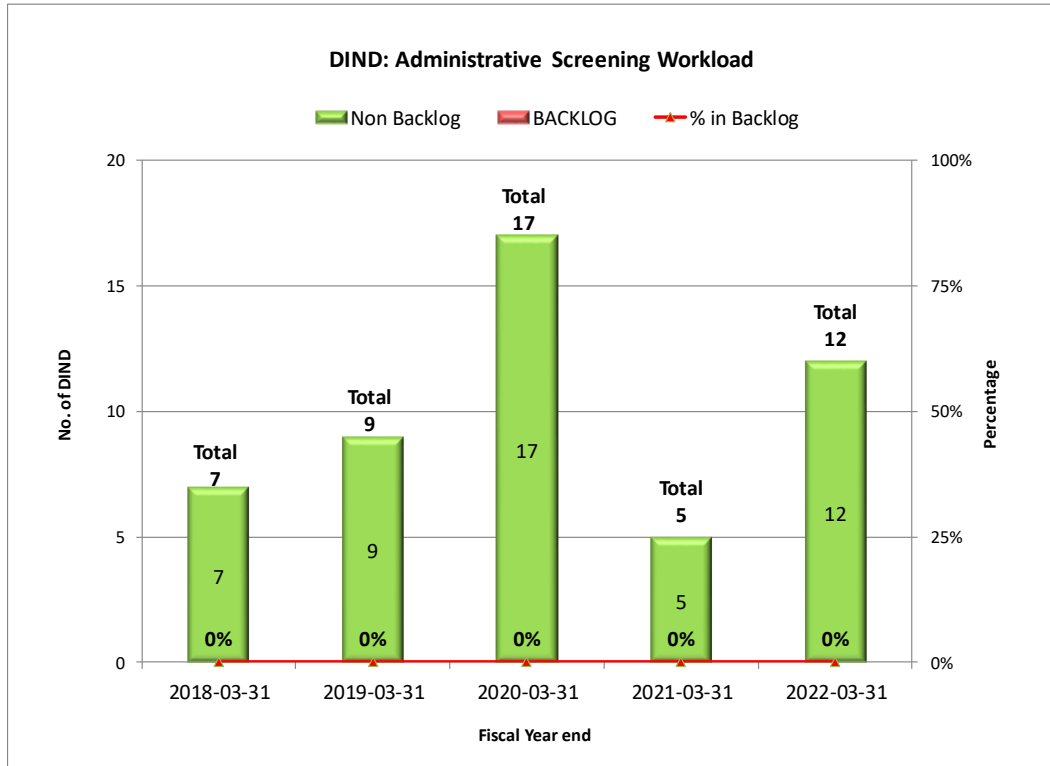


### DIND-Disinfectant Products: Screening Workload



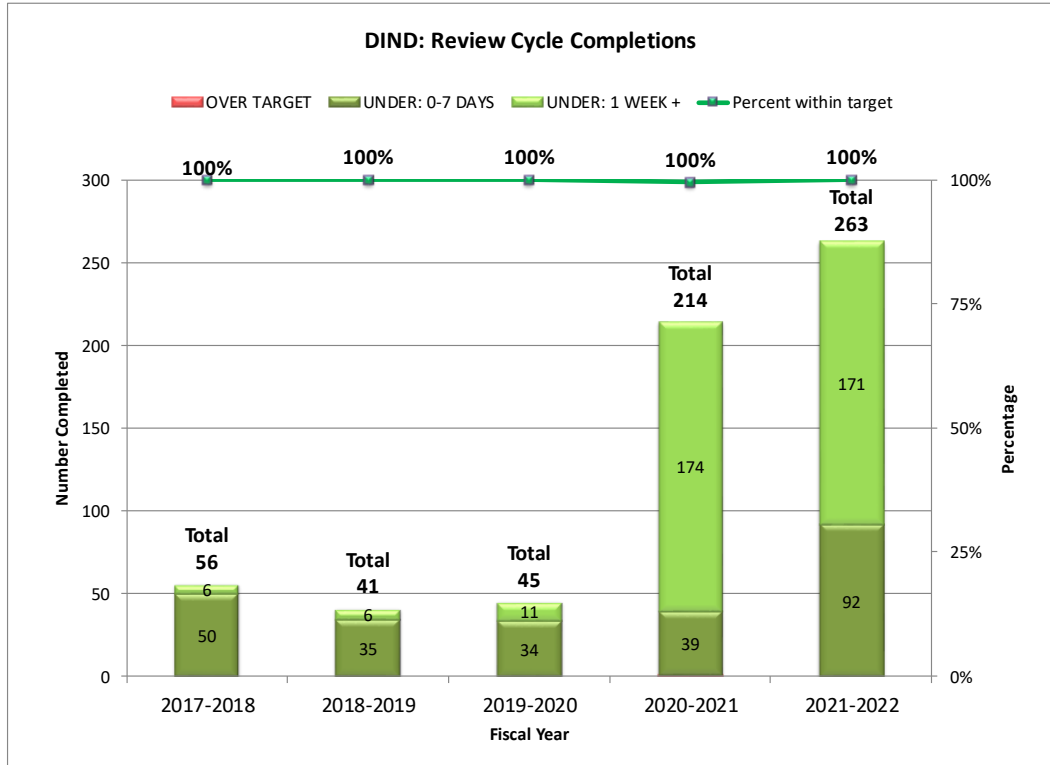
## WORKLOAD

### DIND-Disinfectant Products: Administrative-Screening Workload

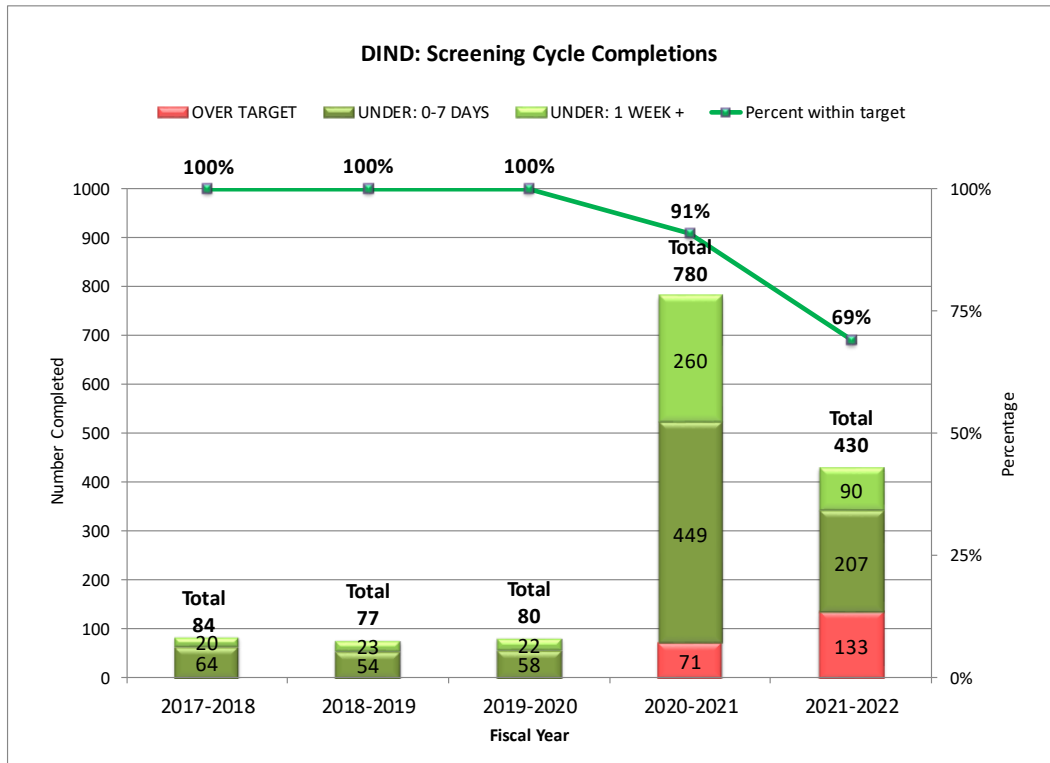


## PERFORMANCE

### DIND-Disinfectant Products: Review Cycle Completions

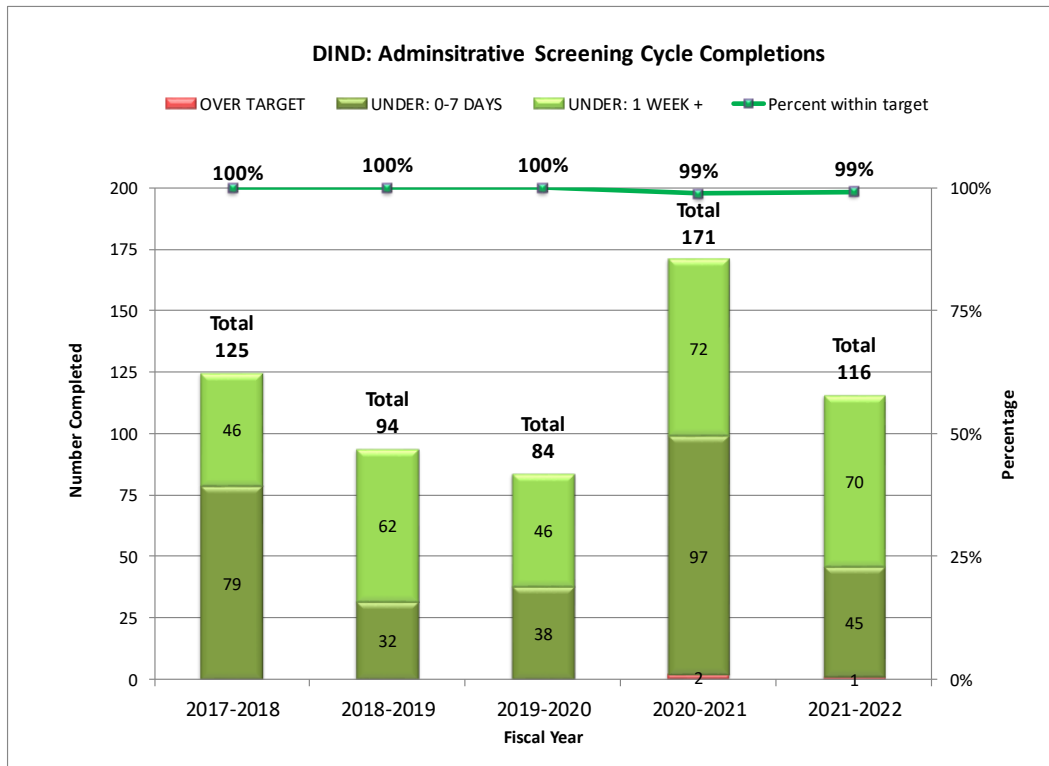


### DIND-Disinfectant Products: Screening Cycle Completions



## PERFORMANCE

### DIND-Disinfectant Products: Administrative-Screening Cycle Completions



**DECISIONS**

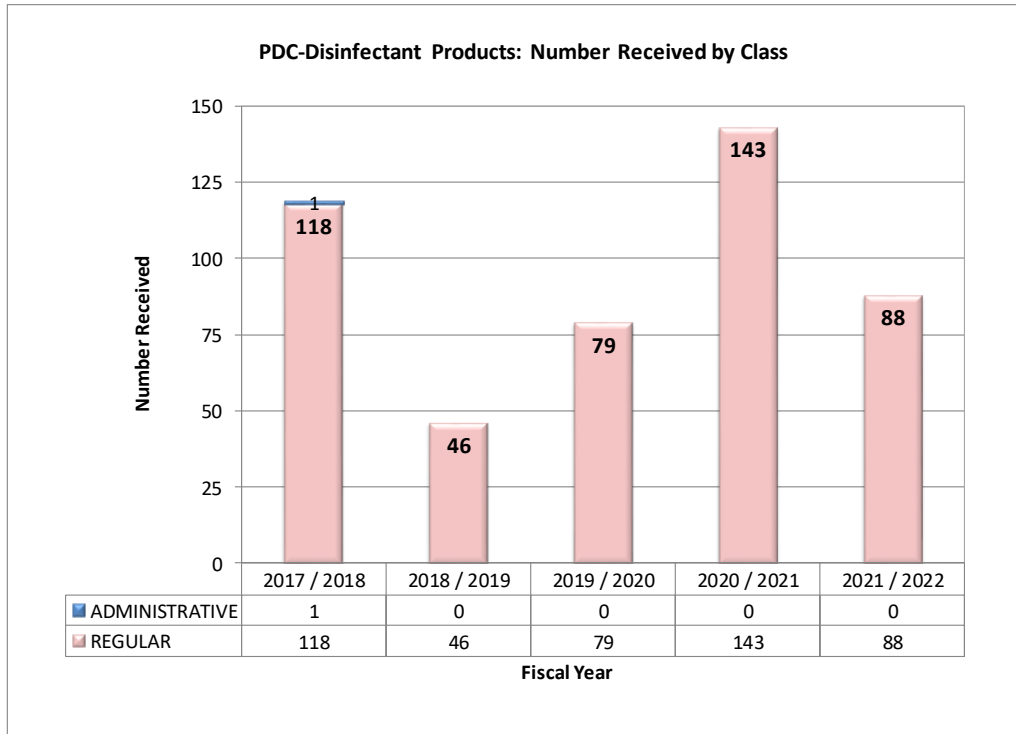
**DIND-Disinfectant Products: Number of Decisions by Fee Category**

User Fee Category	Decision Document Type	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022
<b>ADMINISTRATIVE</b>	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
<b>DISINFECTANTS</b>	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
<b>LABELLING ONLY</b>	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
<b>LABELLING STANDARD</b>	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



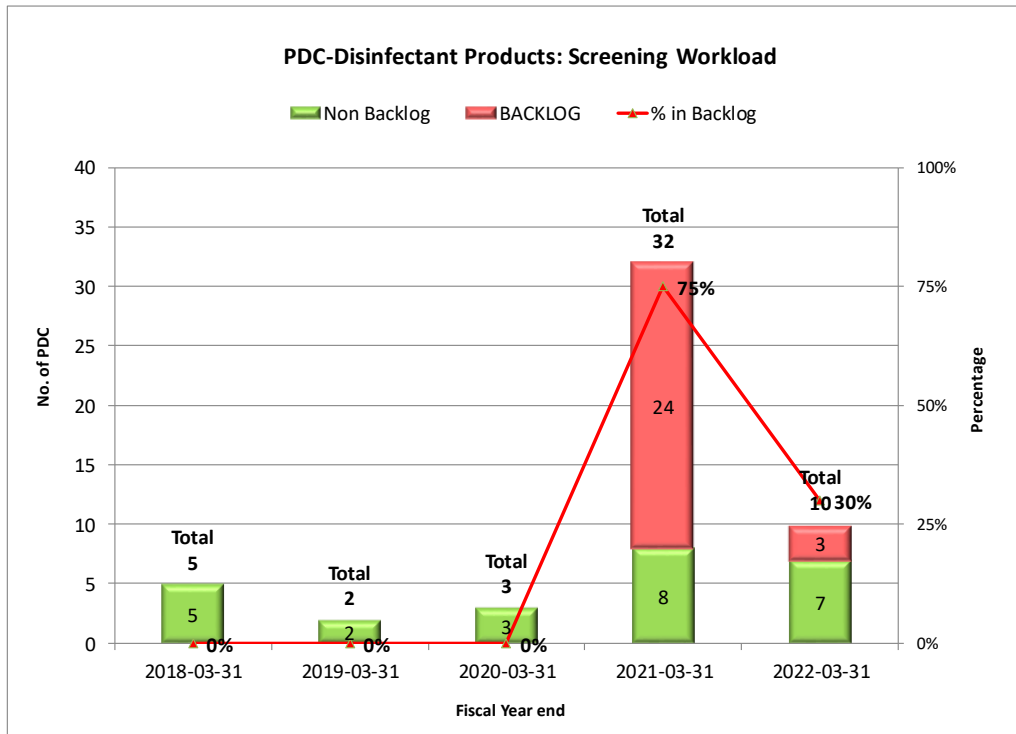
**PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS RECEIVED**

**PDC-Disinfectant Products: Received by Class**



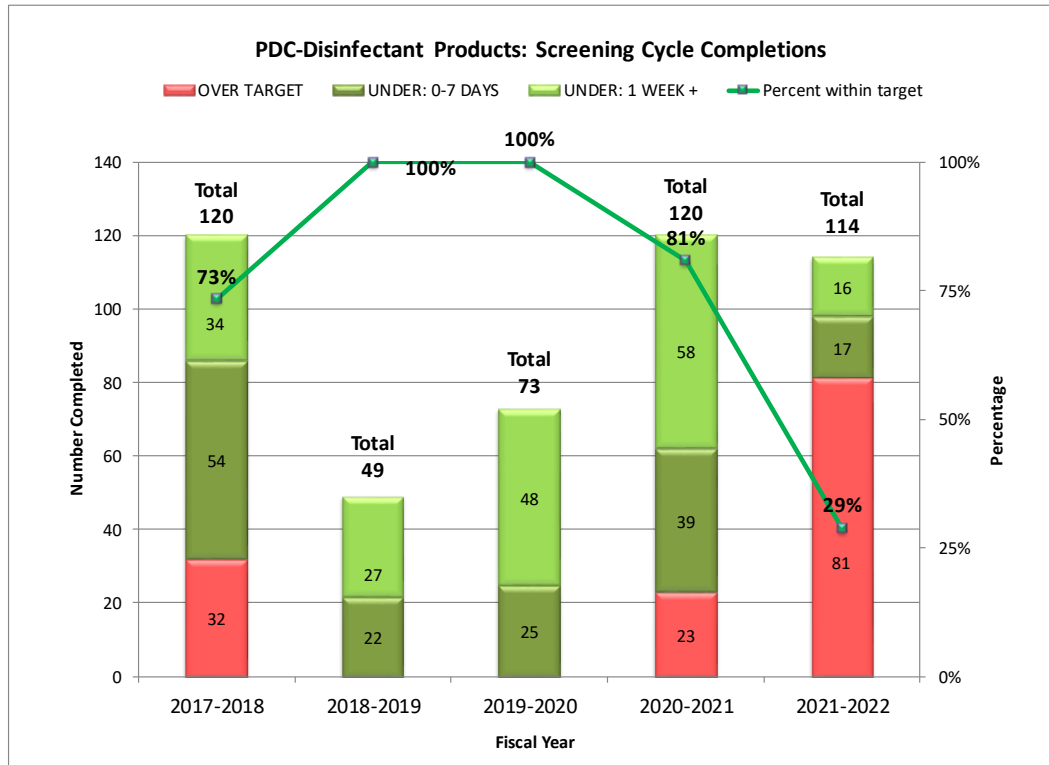
**WORKLOAD**

**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
<i>Total</i>	<b>2</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>7</b>

**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
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**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
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**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
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**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
<b>ADMINISTRATIVE</b>	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	0	0
<b>DISINFECTANTS</b>	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
<i>Total</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>3</i>

**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
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## 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
<b>DISINFECTANTS</b>	NOTICE OF COMPLIANCE*	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
<b>LABELLING ONLY</b>	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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>7</b>	<b>7</b>	<b>7</b>

### 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 MANUFACTURING	0	0	0	2	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	1
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>2</b>

### 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

