



Health  
Canada

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# Natural and Non-Prescription Health Products Directorate

Drug Submission Performance  
Quarterly Report  
April - June  
2021



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# OVERVIEW

The NNHPD Quarterly Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive quarters from April - June 2020 to April - June 2021. Statistics are provided by Submission Type and show the number received, the number in workload and the number of licensing decisions issued over that period.

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

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately, in 2019, HPFB had implemented [new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format](#).<sup>1</sup> This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.
- The publication of the Quarterly Drug Submission Performance Report was cancelled for two quarters (there were no reports published for Q4 Jan-Mar 2020 and Q1 Apr-June 2020), however figures for the past three quarters are provided in this report.
- There was a significant increase in the volume of [Drug Identification Number Applications for Disinfectant products \(DIND\) received](#).
- An [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was approved and on August 13, 2020 the Minister of Health approved an [order to temporarily extend the default period to review clinical trial applications and amendments](#) from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. (see the Quarterly Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) 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 \(CESG\)](#)

- The [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#) (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report. (see the Quarterly Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD)).
- On April 1, 2020, revised fees were implemented in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*. In addition, submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as an NC).

Some of the highlights of the April - June 2021 report are:

**Non-prescription Drug Submissions:**

- 23 DINA submissions were received in Q1 2021-2022. This represents a 15% decrease compared to Q4 2020-2021 (27) and a 60% decrease compared to Q1 2020-2021 (58).
- 15 DINF submissions were received in Q1 2021-2022. This represents a 52% decrease compared to Q4 2020-2021 (31) and a 81% decrease compared to Q1 2020-2021 (78).
- 77 PDC submissions were received in Q1 2021-2022. This represents a 54% increase compared to Q4 2020-2021 (50) and a 33% decrease compared to Q1 2020-2021 (114).
- 0 NDS submissions were received in Q1 2021-2022 while 1 NDS submission was received in Q4 2020-2021 and 9 were received in Q1 2020-2021.
- 12 SNDS submissions were received in Q1 2021-2022. This represents a 200% increase compared to Q4 2020-2021 (4) and a 50% increase compared to Q1 2020-2021 (8).
- 4 ANDS submissions were received in Q1 2021-2022. This represents a 100% increase compared to Q4 2020-2021 (2) and a 300% increase compared to Q1 2020-2021 (1).
- 12 SANDS submissions were received in Q1 2021-2022. This represents a 20% increase compared to Q4 2020-2021 (10) and a 50% decrease compared to Q1 2020-2021 (8).
- 10 NC submissions were received in Q1 2020-2021. None were received in Q2, Q3, Q4 2020-2021 and Q1 2021-2022 as this fee line was discontinued. This fee category no longer applies to non-prescription drug submissions, and will no longer be included in the NNHPD Drug Submission Performance Quarterly Reports.

Overall, the total non-prescription drug submissions received increased by 10% in Q1 2021-2022 (143) when compared to Q4 2020-2021 (130) and decreased by 48% when compared to Q1 2020-2021 (276).

The non-prescription drug submission workload is following the expected trajectory of a post-pandemic setting. The volume of COVID-19 hand sanitizers has returned to pre-pandemic volumes. In response to recent outreach to sponsors for plain language labelling (PLL), there was an increase of PDC submissions to update the labels of non-prescription drugs in advance of the retail-level PLL deadline (June 30, 2021).

## Disinfectant Drug Submissions:

- 156 DIN-D submissions were received in Q1 2021-2022. This represents a 3% decrease compared to Q4 2020-2021 (160) and a 41% decrease compared to Q1 2020-2021 (264).
- 25 PDC submissions were received in Q1 2021-2022. This represents a 22% decrease compared to Q4 2020-2021 and a 54% decrease compared to Q1 2021-2022 (54).
- The number of NDS-D remained the same in Q1 2021-2022 (1) compared to Q4 2020-2021 (1), Q3 2020-2021 (1), Q2 2020-2021 (1) and Q1 2020-2021 (1).
- No SNDS-D or NCs were received in Q1 2021-2022 and Q4 2020-2021. 1 SNDS-D was received in Q3 2020-2021 (1).

Overall, the total disinfectant drug submissions received decreased by 7% in Q1 2021-2022 (182) when compared to Q4 2020-2021 (195) and decreased by 43% when compared to Q1 2020-2021 (319).

The volume of submissions received in Q4 remained significantly higher (2.9x) than pre-pandemic volumes, despite the continued reduction in received submission volume over the fiscal year, compared to the all time high of 4.8x seen in Q1 2020-2021. As a result, the total number of disinfectant drug submissions received in Q4 remained higher than ever, mainly attributed to the ongoing COVID-19 pandemic. For some submission types, such as DINs and PDCs, the numbers received in each of the first three quarters of FY 2020-2021 are representative of the total numbers received for previous full FYs.

The majority of submissions received in Q3 and Q4 are for Full Reviews (with and without supporting data), compared to Q1 and Q2 when the majority of submissions were Labelling Standard (Monograph) and Administrative updates. In Q4, the Full Review workload (83) was 4.6x higher than pre-COVID volumes, with a continued increase seen from Q2 to Q3 to Q4. This resulted in short-term backlogs for the screening components of 23% of Full Review submissions in Q4, in order to shift resources within the review team to meet expedited COVID review targets and other cost-recovered performance standards.

Similarly, the received volume of DIND Labelling Standard submissions spiked in Q2 2020-2021 (122) to 13.6x pre-COVID volumes (9), and remained very high over Q3 2020-2021 (11x pre-COVID), while decreasing significantly in Q4 but still being 5.1x pre-COVID. This sustained increase in DIND Labelling Standard submissions over FY 2020-2021 is explained by the continued need for general disinfectants as part of the ongoing COVID-19 response. Less DIND Labelling Standard submissions were received in the last 3 quarters as a result of a corresponding shift to more Full Review submissions being received with specific data in support of SARS-CoV-2 label claims. Due to the lack of availability of a test strain for SARS-CoV-2 testing during Q1 2020-2021, in addition to the lock-down of non-essential services (i.e. laboratories) early in the pandemic, this led to a significant increase of Full Review applications during Q2 2020-2021 when a test strain became available and laboratories were no longer in lock down.

The number of PDCs spiked in Q1 2020-2021 (54) compared to pre-pandemic volumes (20), and then decreased by approximately half in Q2 to come closer to pre-pandemic volumes. This sudden increase is explained by a large volume of applications for the addition of indirect SARS-CoV-2 claims to the labels of existing disinfectants as a first line response to the COVID-19 pandemic. The number of PDCs in Q3 2020-2021 remained consistent with Q2 2020-2021, and a small increase was seen in the number of PDCs in Q4 2020-2021. Overall the reduced volume of PDCs in the last three quarters of 2020-2021 are more in line with volumes received pre-pandemic, and demonstrate a shift in submission types received over the course of the COVID-19 pandemic. As a result of sustained all time highs in submission volumes received, short-term backlogs for all PDCs was utilized in Q4 2020-2021, in order to shift resources within the review team to meet expedited COVID-19 related review targets and other cost-recovered performance standards.

Overall, a sustained increase in the total active submission volume of DIND applications was seen over fiscal year 2020-2021, with screening completion volumes in Q2 and Q4 being 9.7 to 13.1x the pre-pandemic volumes. The significant increases in Q3 and Q4 2020-2021 of DIND Full Review submissions with efficacy data, with complex review requirements, explains the sustained 5.8x higher active submission queue volume compared to pre-pandemic, given that DIND Full Review submissions have longer performance standards often spanning multiple quarters.

In comparing fiscal year 2020-2021 to the previous 4 pre-pandemic fiscal years (2016-2020), the numbers of disinfectant drug submissions received were 228, 218, 234 and then 1030. The number of submissions received in the first quarter of the 2020-2021 FY alone is more than the number of submissions received for the totality of the 2016, 2017, 2018 and 2019 FYs. With the total number of submissions received in FY 2020-2021 at 1030, this represents more than 4x the total number of submissions received in the totality of the 2016, 2017, 2018 and 2019 FYs.

## 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 Non-Prescription 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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# 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 biologic drug product
PRNDS	- Request for Priority Review Status: New Drug Submission
PRSNDS	- Request for Priority Review Status: Supplemental New Drug Submission
SANDS	- Supplement to an Abbreviated New Drug Submission
SANDS-C	- Supplement to an Abbreviated New Drug Submission - Confirmatory
SNDS	- Supplement to a New Drug Submission
SNDS-C	- Supplement to a New Drug Submission - Confirmatory
SNDS-D	- Supplement to a New Drug Submission for Disinfectant products



## 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	Description
<b>New active substance</b>	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph
<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 new active substance
<b>Clinical or nonclinical data only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance
<b>Comparative studies</b>	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance
<b>Chemistry and manufacturing data only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance
<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 status from prescription drug to non-prescription drug</b>	Submissions based only on data that support the modification or removing of a medicinal ingredient listed in Schedule F of the Food and Drug Regulations (i.e. identical claim for existing drug) - Category discontinued

Fee Category	Description
<b>Labelling only</b>	Submissions, other than those described in item 9, 12 or 13, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative 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 change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the Food and Drugs Act)
<b>Disinfectant – full review</b>	Submissions, other than those described in item 12, 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 application - labelling standards</b>	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph 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 new active substance - 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**

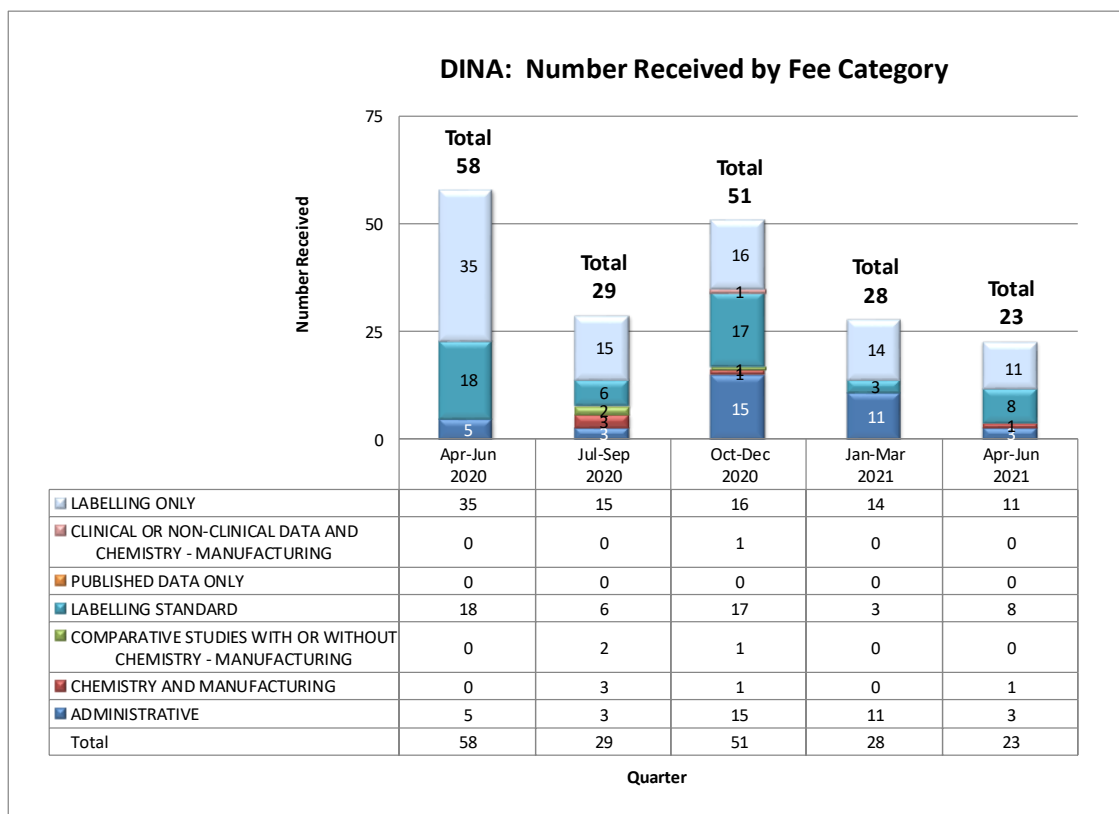
### **Over the counter (OTC) Drugs**

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

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

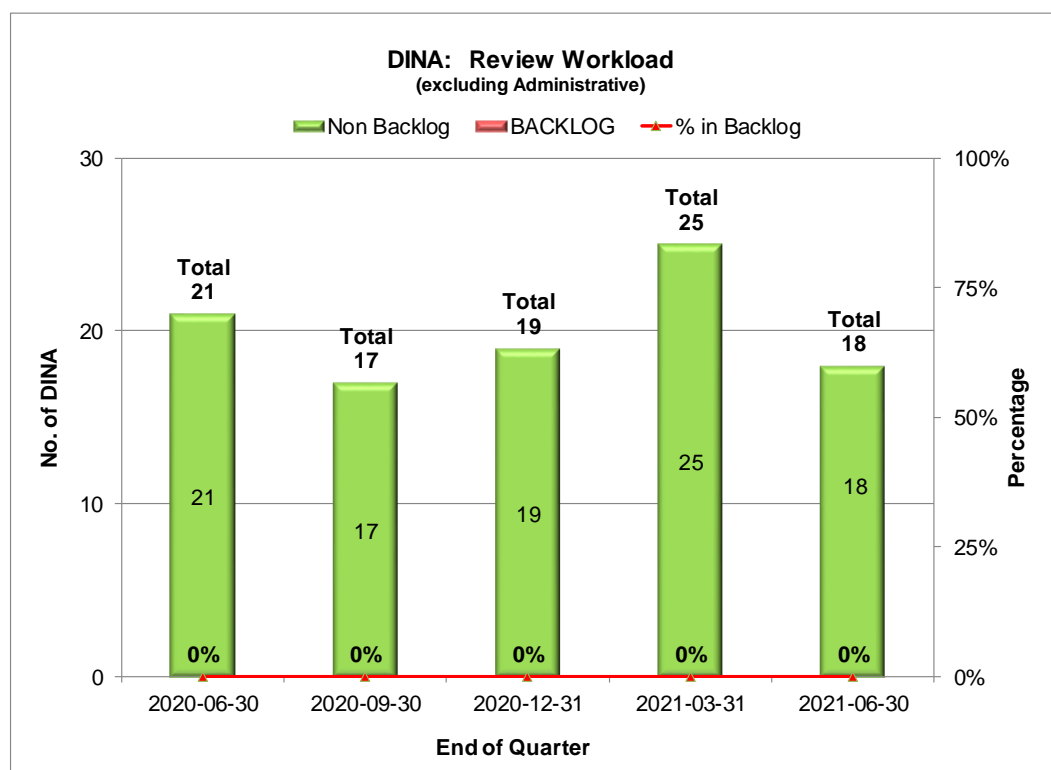
## DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

### DINA: Number Received by Fee Category



## WORKLOAD

### DINA: Review Workload

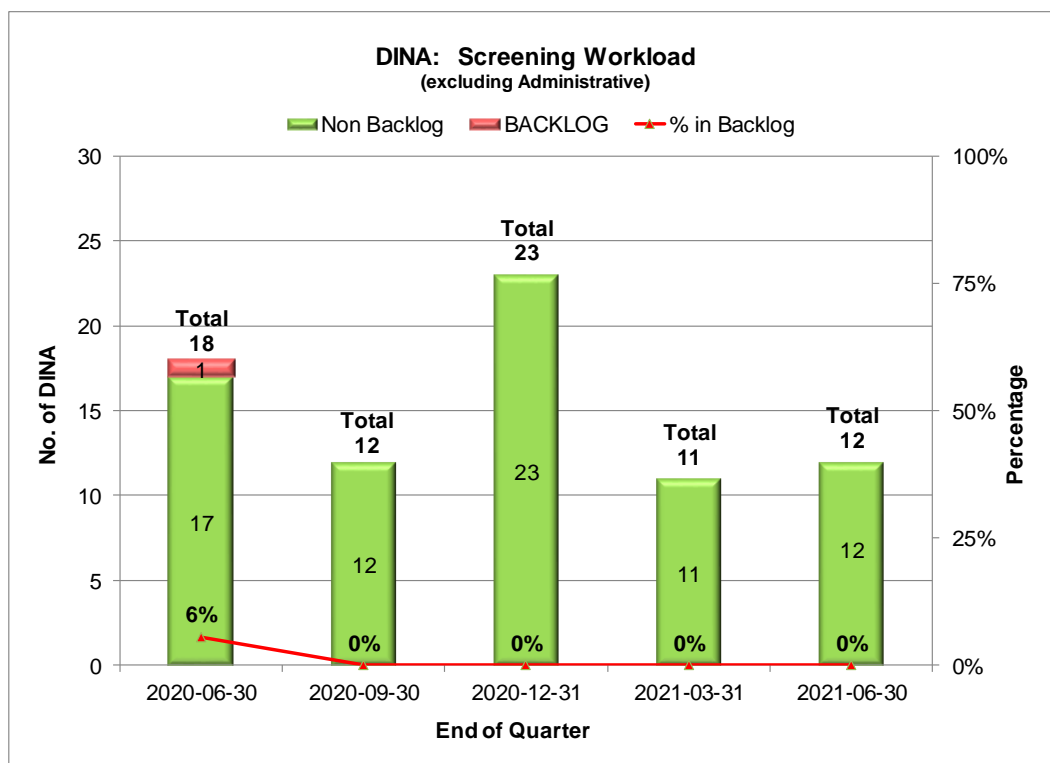


### DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Chemistry and Manufacturing	1	1	2	4	4
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	1	1	0
Backlog	0	0	0	0	0
Labelling Only	19	14	14	17	13
Backlog	0	0	0	0	0
Published Data	1	1	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	1	2	3	1
Backlog	0	0	0	0	0
<b>Total</b>	<b>21</b>	<b>17</b>	<b>19</b>	<b>25</b>	<b>18</b>
<b>Non Backlog</b>	<b>21</b>	<b>17</b>	<b>19</b>	<b>25</b>	<b>18</b>
<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: Screening Workload

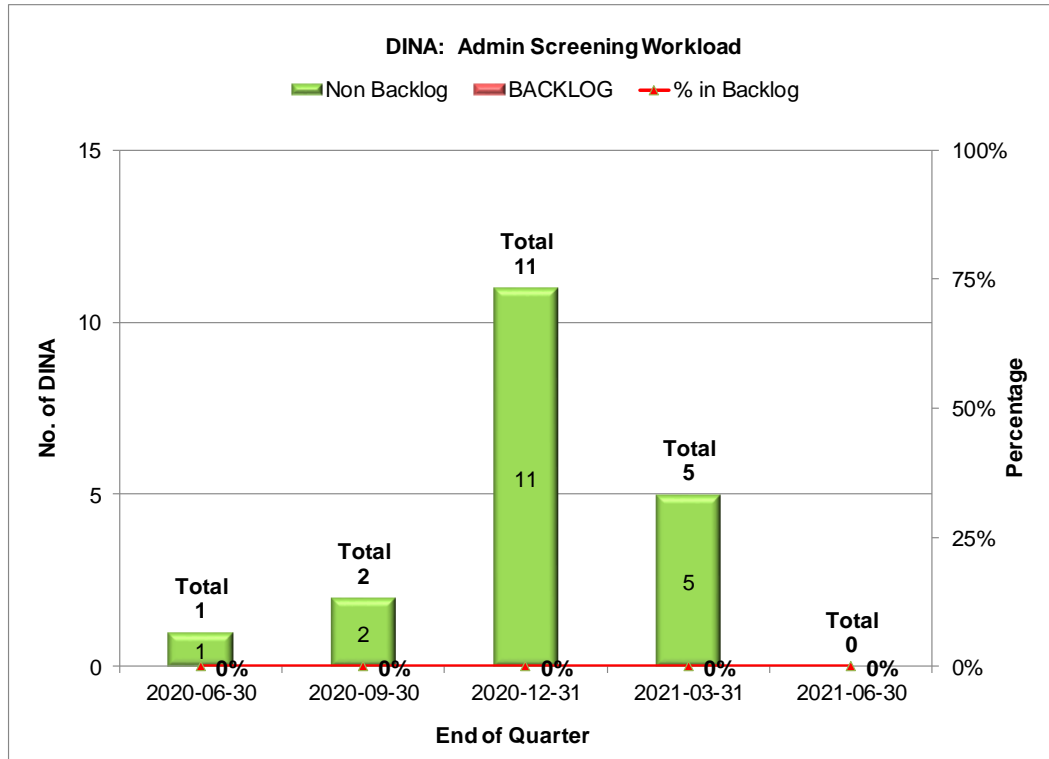


### DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Chemistry and Manufacturing	0	3	2	0	1
Backlog	0	0	0	0	0
Labelling Only	13	4	10	8	6
Backlog	1	0	0	0	0
Labelling Standard	5	5	11	3	5
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
<b>Total</b>	<b>18</b>	<b>12</b>	<b>23</b>	<b>11</b>	<b>12</b>
Non Backlog	17	12	23	11	12
<b>BACKLOG</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>6%</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 End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Administrative	1	2	11	5	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>1</b>	<b>2</b>	<b>11</b>	<b>5</b>	<b>0</b>
Non Backlog	1	2	11	5	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>



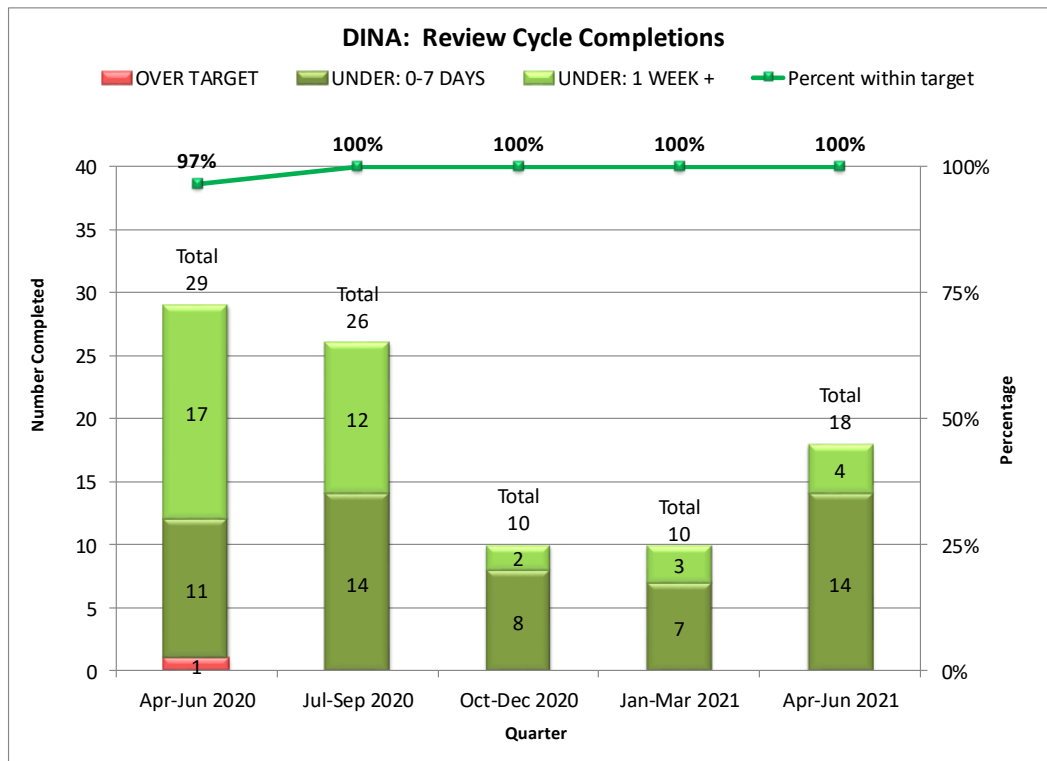
## DECISIONS

## DINA: Number of Decisions by Fee Category

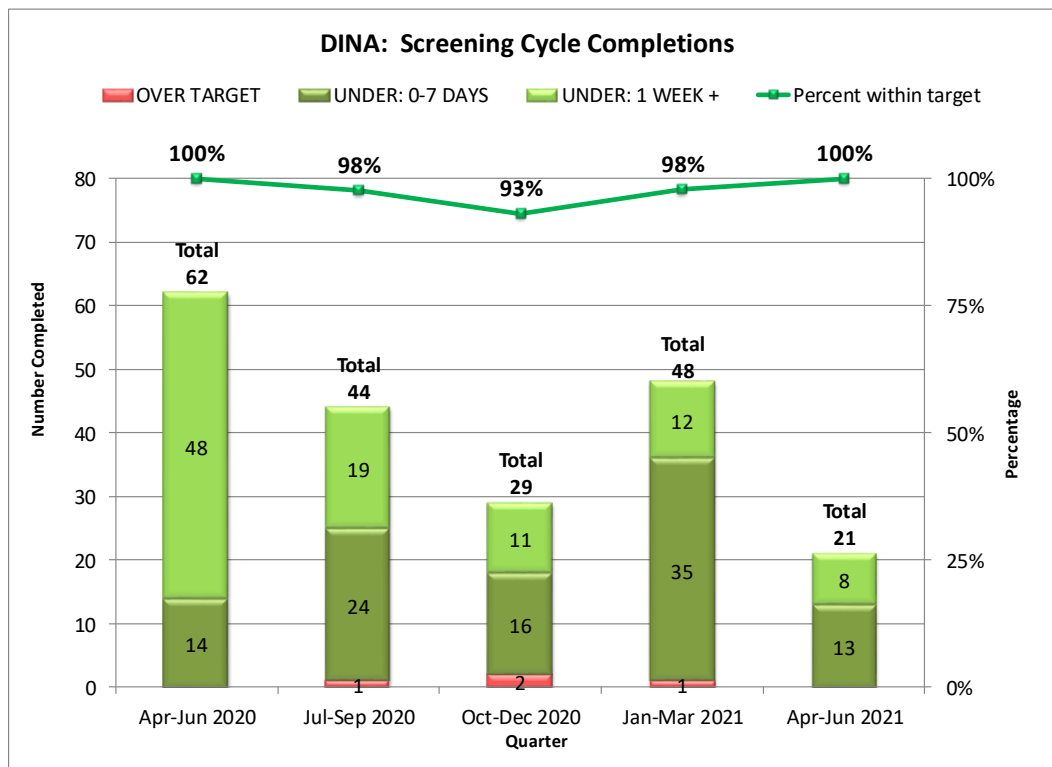
Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	CANCELLATION LETTER	1	1	0	3	2
	NOTIFICATION FORM DIN SUB	22	1	2	13	6
	REJECTION LETTER (SCR)	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	3	0	0
	NO OBJECTION LETTER	0	1	1	0	2
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	1	0	1	0	0
	CANCELLATION LETTER	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	3	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	0	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	1
	NO OBJECTION LETTER	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	2	0	0	0
LABELLING ONLY	CANCELLATION LETTER	9	3	2	2	2
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	3	1	1	1	4
	NOTICE OF NON-COMPLIANCE	1	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	23	19	13	8	11
	REJECTION LETTER (SCR)	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	3	5	2	1	2
LABELLING STANDARD	CANCELLATION LETTER	6	0	3	2	3
	NO OBJECTION LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	18	6	9	9	2
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	8	2	2	2	2
PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	1	0	0

## PERFORMANCE

### DINA: Review Cycle Completions

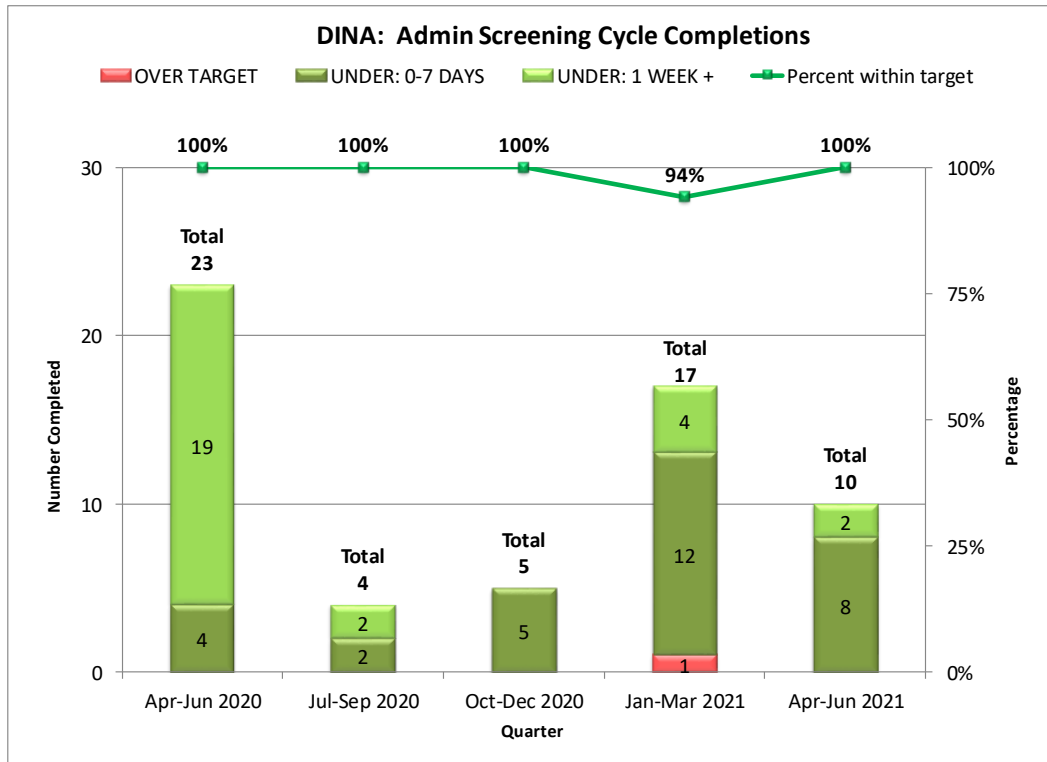


### DINA: Screening Cycle Completions



## PERFORMANCE

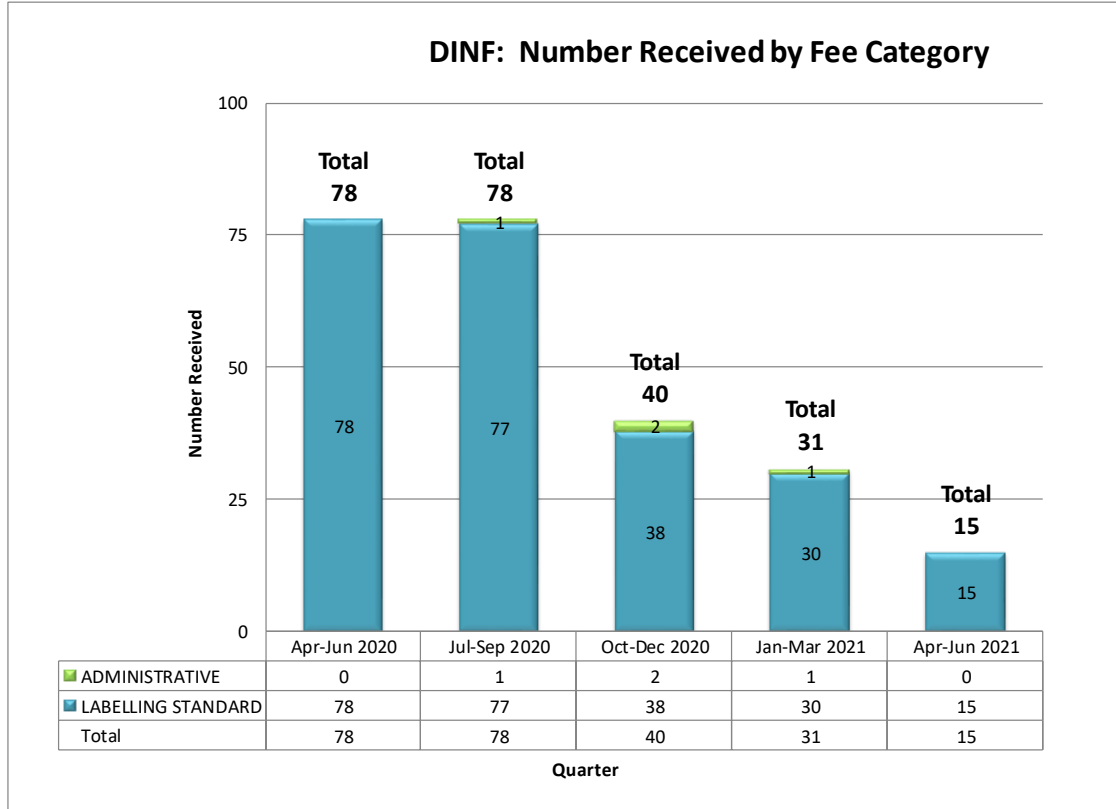
### DINA: Administrative-Screening Cycle Completions



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

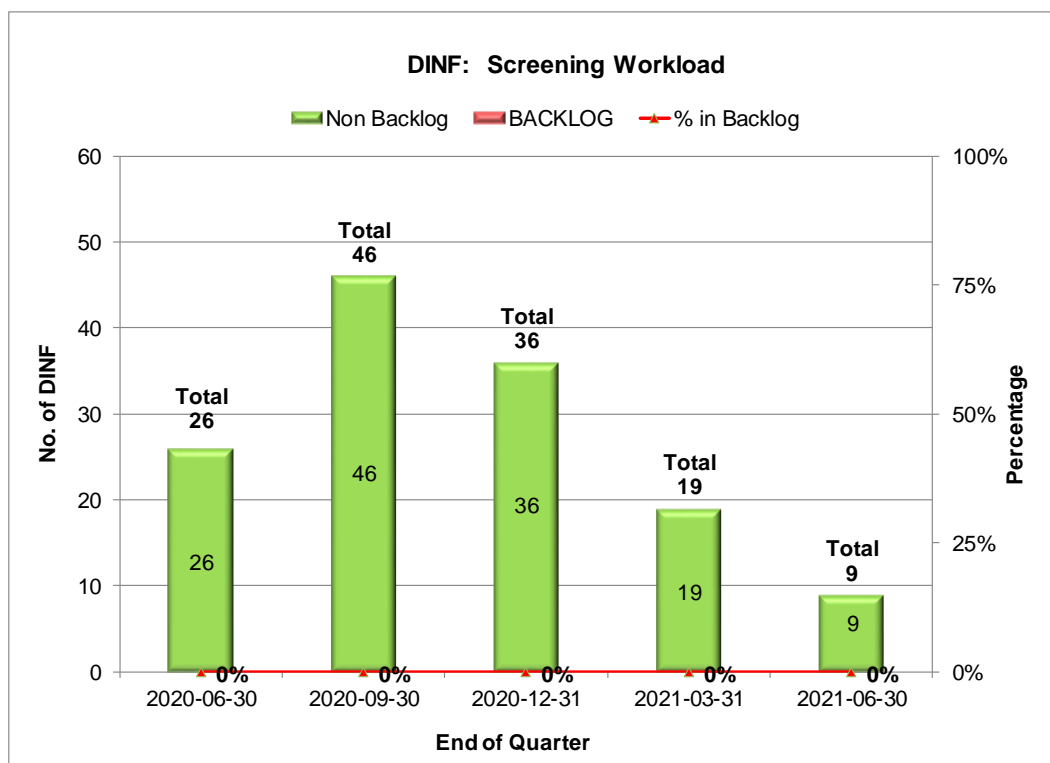
### RECEIVED

#### DINF: Number Received by Fee Category



## WORKLOAD

### DINF: Screening Workload



### DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Labelling Standard	26	45	36	18	9
<i>Backlog</i>	0	0	0	0	0
Administrative	0	1	0	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>26</b>	<b>46</b>	<b>36</b>	<b>19</b>	<b>9</b>
Non Backlog	26	46	36	19	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>

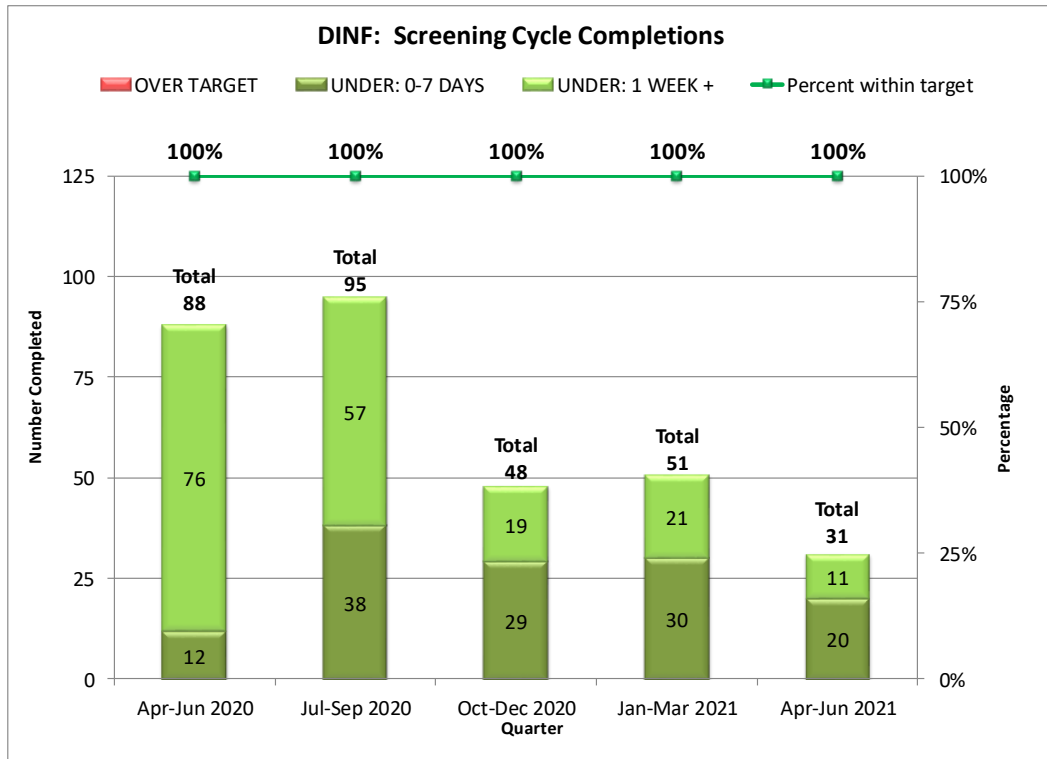
## DECISIONS

### DINF: Number of Decisions by Fee Category

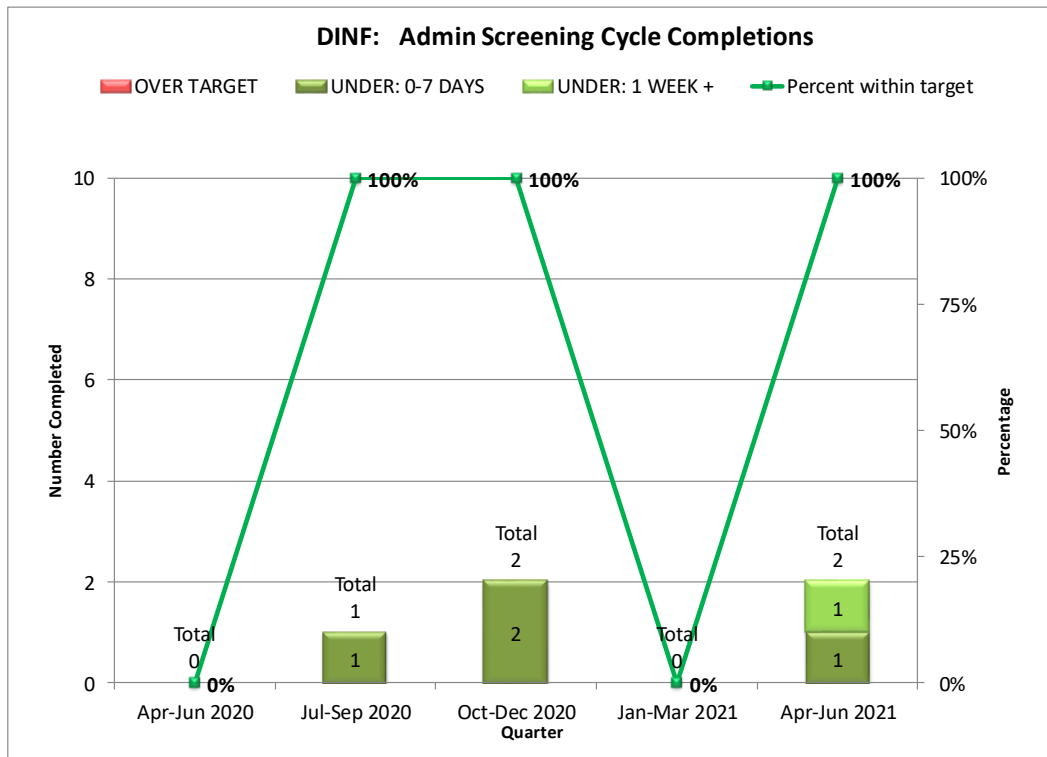
Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
LABELLING STANDARD	CANCELLATION LETTER	15	7	6	8	2
	NO OBJECTION LETTER	3	0	0	0	0
	NEW DRUG LETTER SCREEN	1	0	0	0	0
	NOTIFICATION FORM DIN SUB	56	52	52	40	21
	REJECTION LETTER (SCR)	0	0	1	2	0
	SCREENING DEFICIENCY NOTICE	18	5	21	6	8
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	3	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
	CANCELLATION LETTER	0	0	0	0	0

## PERFORMANCE

### DINF: Screening Cycle Completions



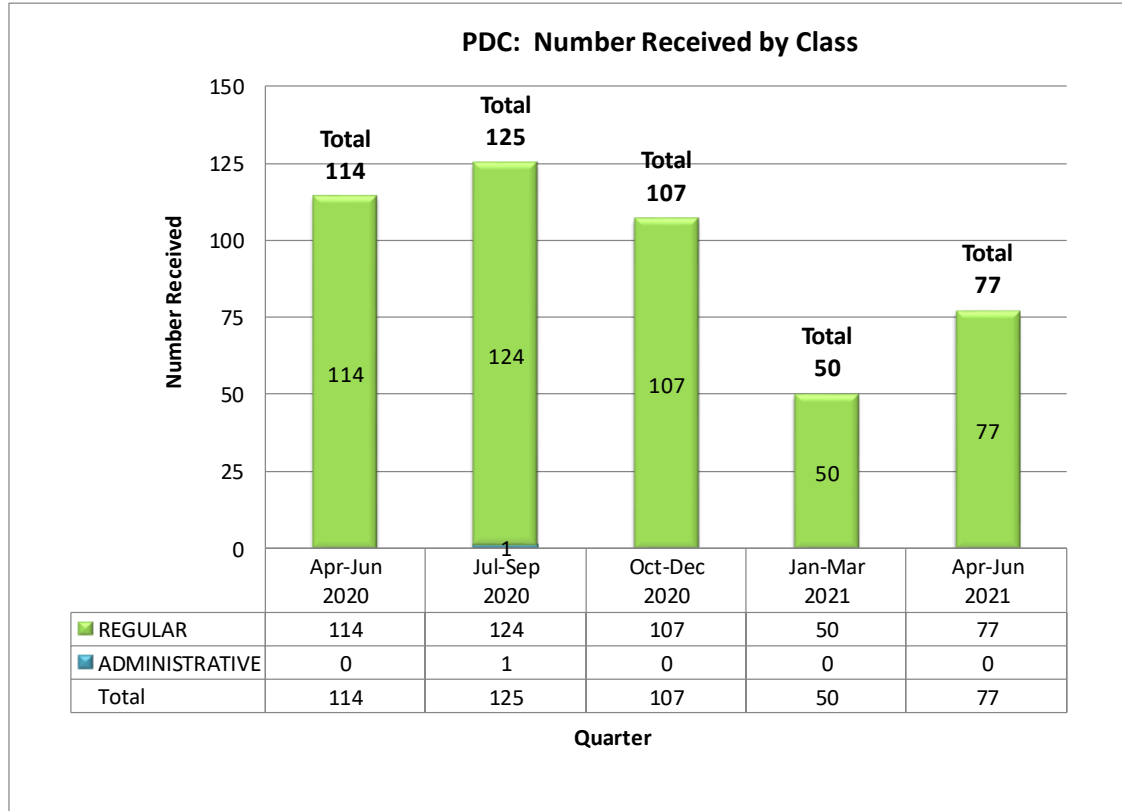
### DINF: Admin-Screening Cycle Completions



## PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

### RECEIVED

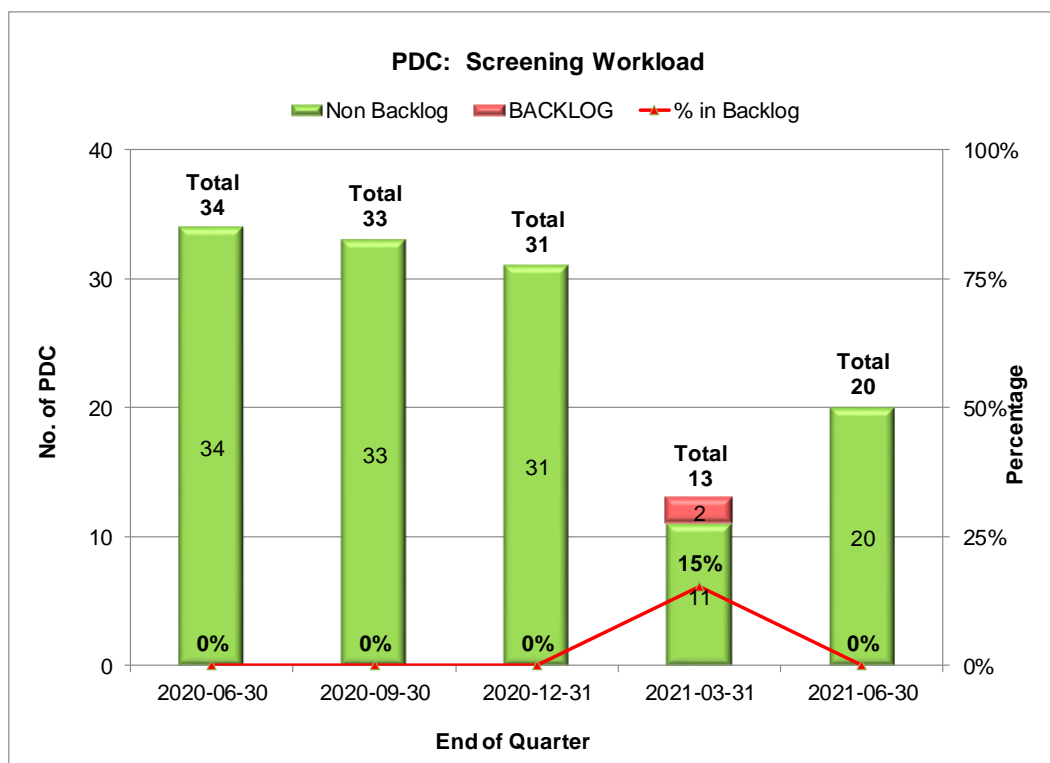
#### PDC: Received by Class





## WORKLOAD

### PDC: Screening Workload



### PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS By End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Regular	34	33	31	13	20
Backlog	0	0	0	2	0
Administrative	0	0	0	0	0
Backlog	0	0	0	0	0
Total	34	33	31	13	20
Non Backlog	34	33	31	11	20
BACKLOG	0	0	0	2	0
% in Backlog	0%	0%	0%	15%	0%

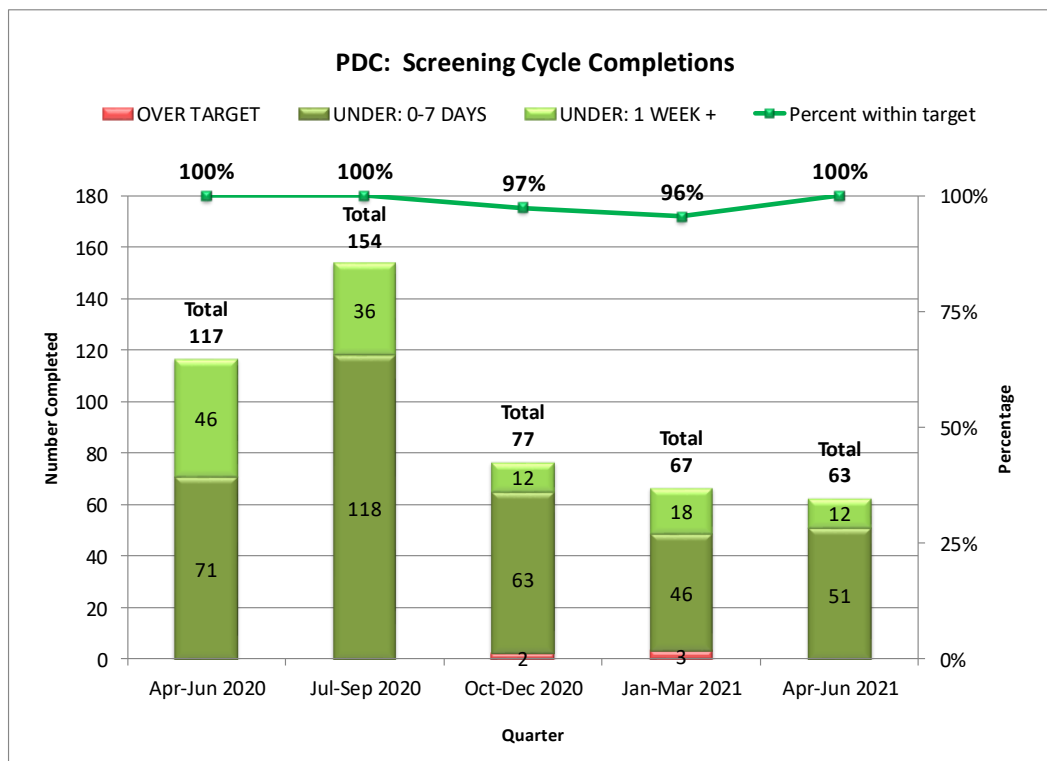
## DECISIONS

### PDC: Number of Decisions by Class

Class	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
REGULAR	CANCELLATION LETTER	5	5	1	3	4
	NO OBJECTION LETTER	107	103	112	62	51
	NOT SATISFACTORY NOTICE	5	7	5	2	8
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING STANDARD	NO OBJECTION LETTER	0	0	0	0	0

## PERFORMANCE

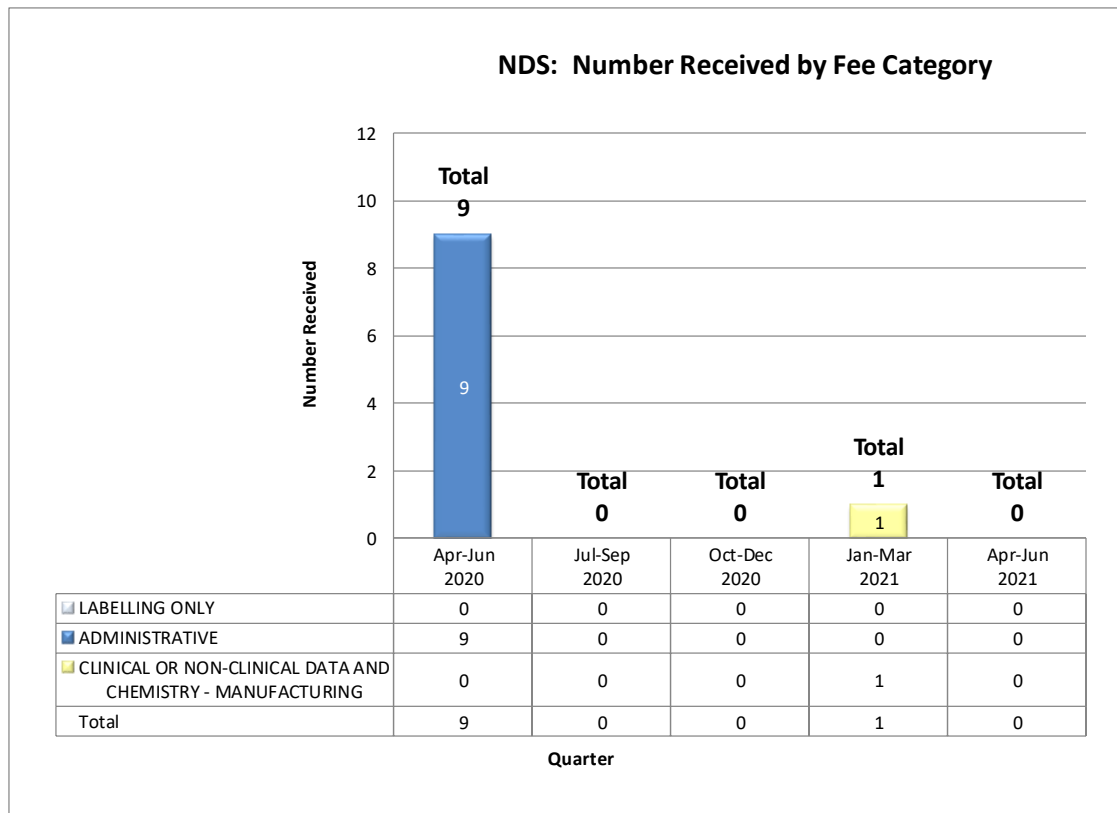
### PDC: Screening Cycle Completions



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

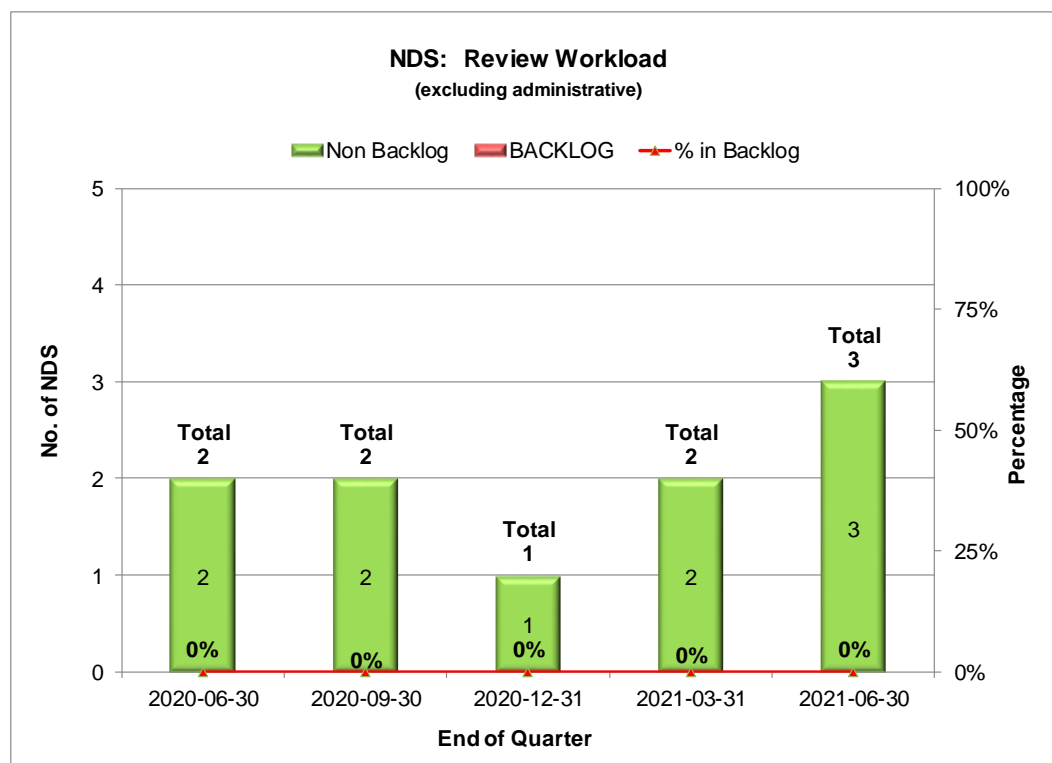
## NDS: NEW DRUG SUBMISSION RECEIVED

### NDS: Number Received by Fee Category



## WORKLOAD

### NDS: Review Workload

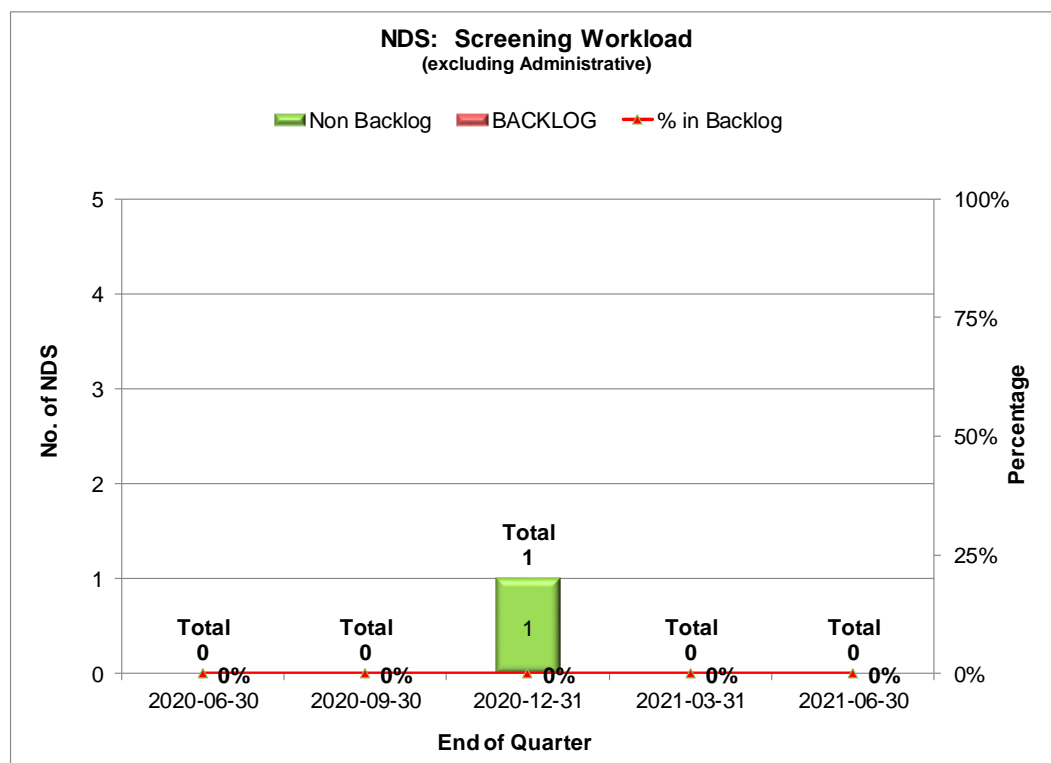


### NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Clinical or Non-Clinical Data and Chemistry - Manufacturing	2	2	1	2	3
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>Non Backlog</b>	2	2	1	2	3
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

## WORKLOAD

### NDS: Screening Workload



### NDS: Screening Workload by Fee Category

NDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	1	0	0
Backlog	0	0	0	0	0
Labelling Only	0	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>Non Backlog</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
<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

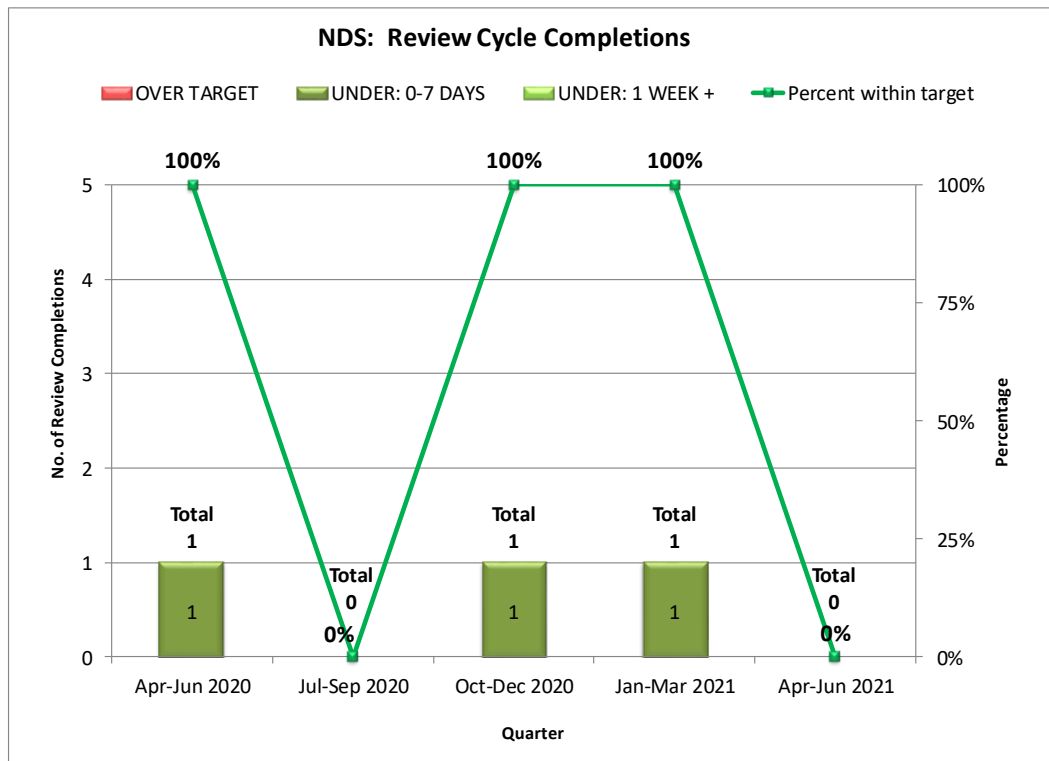
## NDS: Number of Decisions by Fee Category

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	11	5	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	1	1	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
	NOC ON HOLD (SWITCH)*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

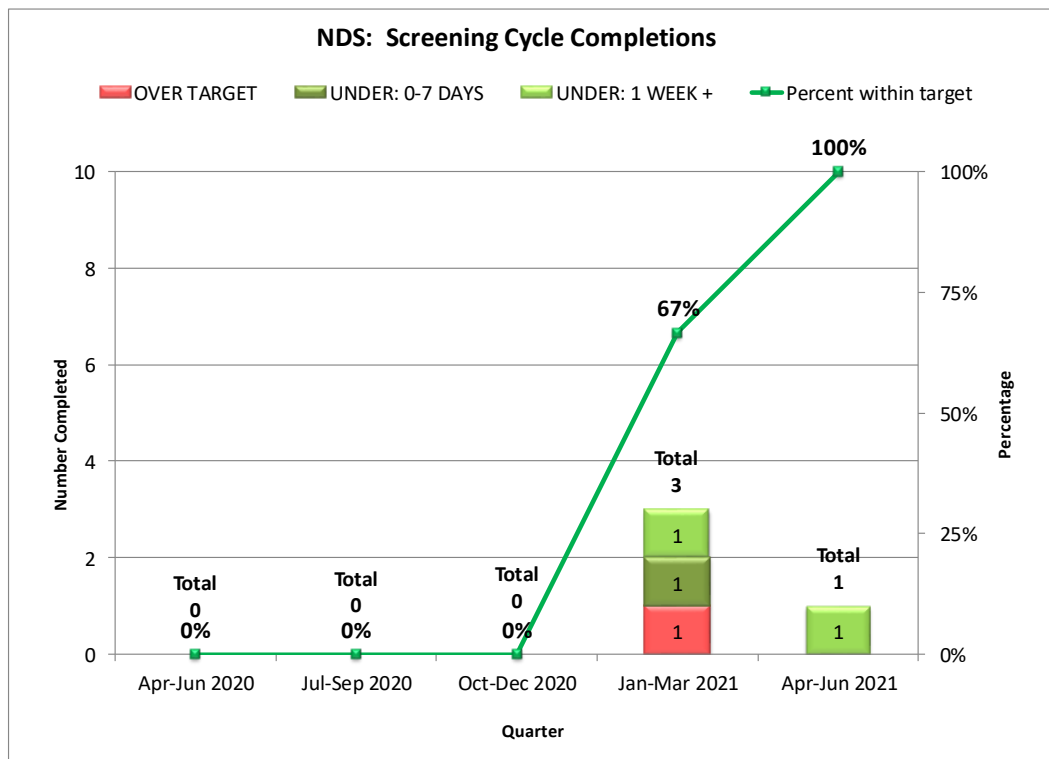
\*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

## PERFORMANCE

### NDS: Review Cycle Completions



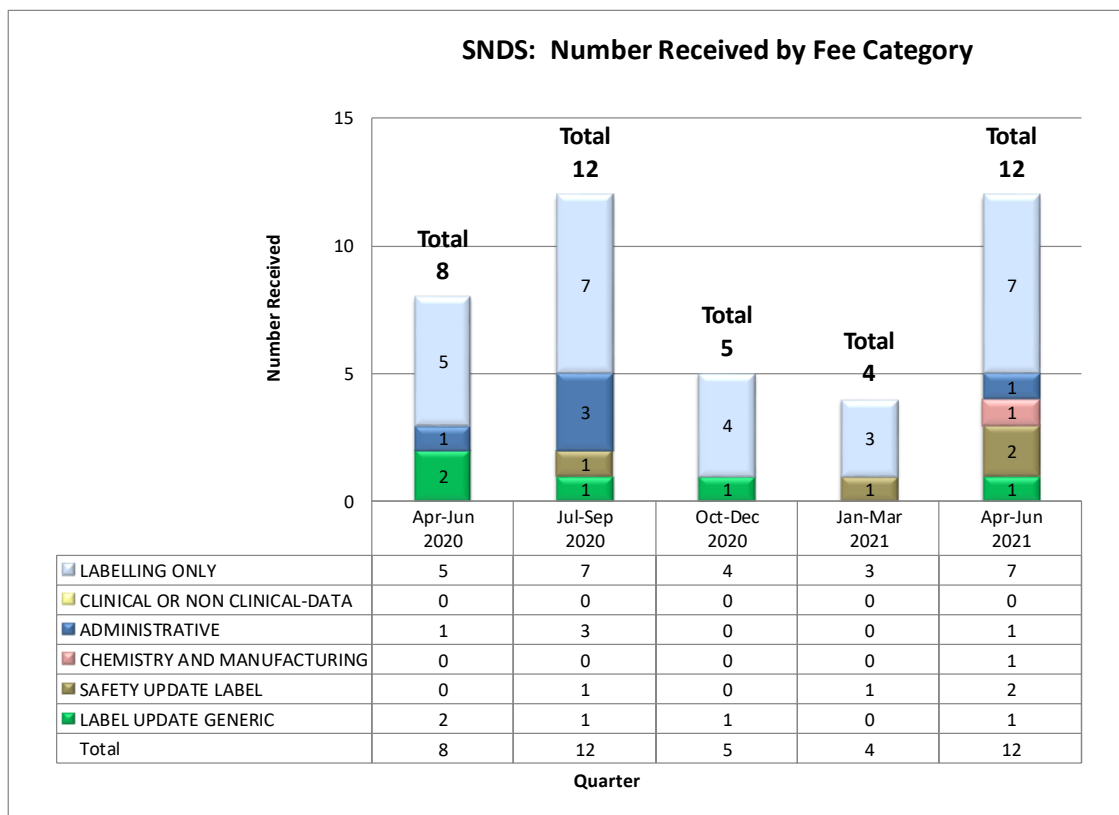
### NDS: Screening Cycle Completions





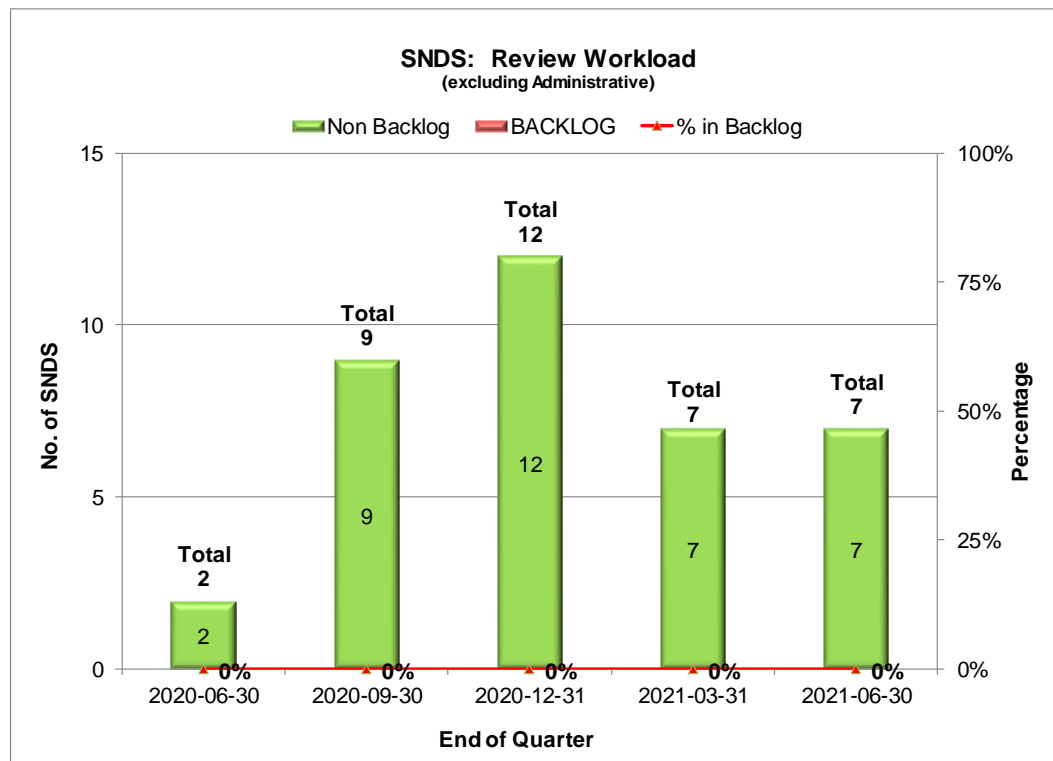
## SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

### SNDS: Number Received by Fee Category



## WORKLOAD

### SNDS: Review Workload

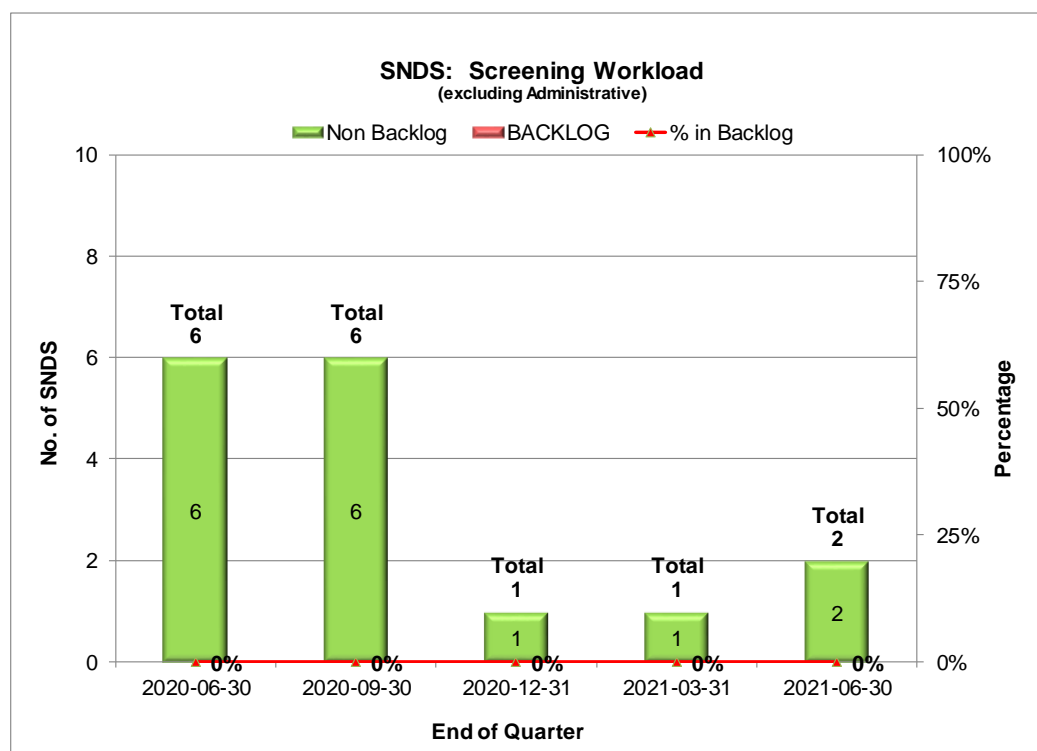


### SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Clinical or Non-Clinical Data	0	1	0	0	0
Backlog	0	0	0	0	0
Labelling Only	1	7	10	4	5
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	1
Backlog	0	0	0	0	0
Label Update Generic	1	1	1	2	0
Backlog	0	0	0	0	0
Safety Update Label	0	0	1	1	1
Backlog	0	0	0	0	0
<b>Total</b>	<b>2</b>	<b>9</b>	<b>12</b>	<b>7</b>	<b>7</b>
<b>Non Backlog</b>	<b>2</b>	<b>9</b>	<b>12</b>	<b>7</b>	<b>7</b>
<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 End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Chemistry and Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data	1	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	4	4	0	1	2
Backlog	0	0	0	0	0
Label Update Generic	1	1	1	0	0
Backlog	0	0	0	0	0
Safety Update Label	0	1	0	0	0
Backlog	0	0	0	0	0
<b>Total</b>	<b>6</b>	<b>6</b>	<b>1</b>	<b>1</b>	<b>2</b>
Non Backlog	6	6	1	1	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

## DECISIONS

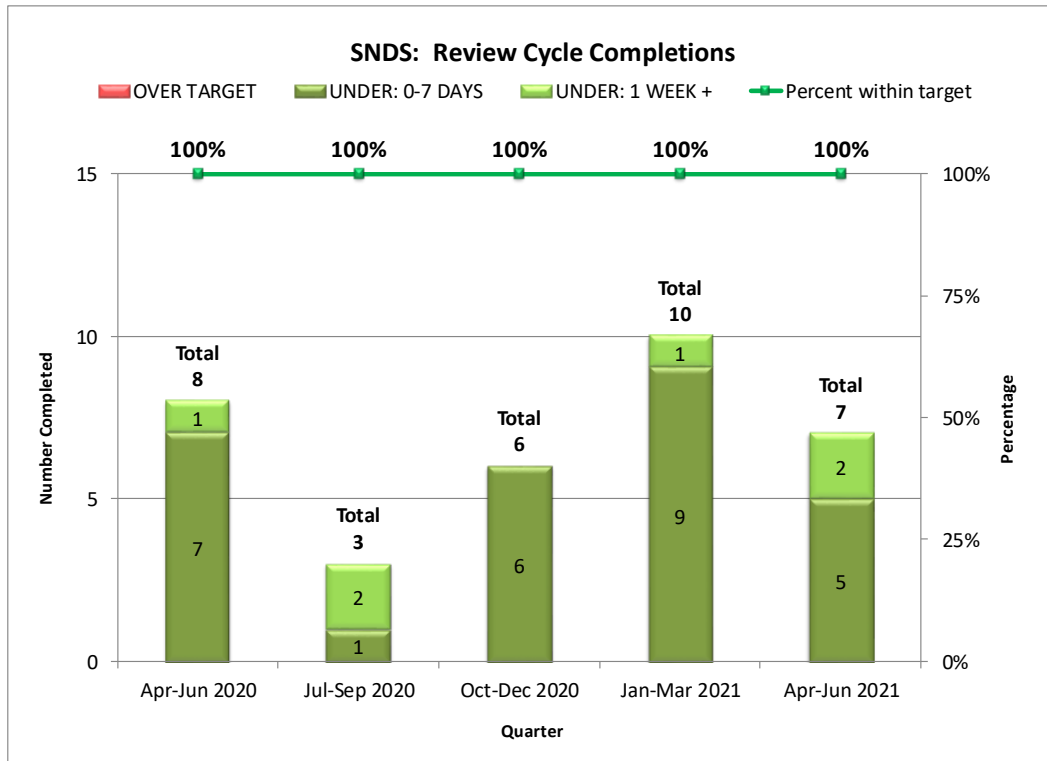
## SNDS: Number of Decision by Fee Category

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	6	1	5	8	4
	SCREENING DEFICIENCY NOTICE	0	1	0	0	1
	CANCELLATION LETTER	1	0	0	0	0
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	1	1	0	2
	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
SAFETY UPDATE LABEL	NOTICE OF COMPLIANCE*	0	0	0	1	1
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	1	0	0	0
	NOTICE OF COMPLIANCE*	0	2	2	0	1
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	2	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

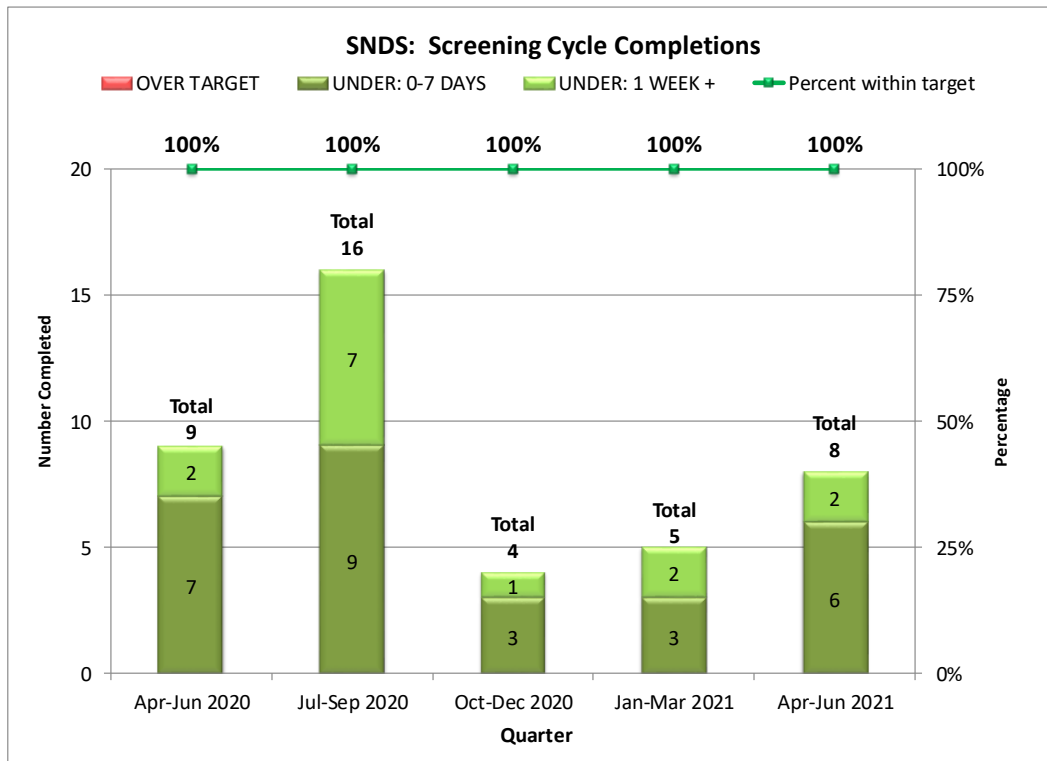
\*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

## PERFORMANCE

### SNDS: Review Cycle Completions



### SNDS: Screening Cycle Completions



**ANDS: ABBREVIATED NEW DRUG SUBMISSION****RECEIVED****ANDS: Number Received by Fee Category**

ABBREVIATED NEW DRUG SUBMISSION (ANDS)					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
LABELLING ONLY	1	0	1	0	1
ADMINISTRATIVE	0	1	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	1	1	2
CHEMISTRY AND MANUFACTURING	0	1	0	0	1
<b>Total</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>4</b>

## WORKLOAD

### ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Labelling Only	1	0	0	1	2
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	2	1	1	2	2
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>4</b>
<b>Non Backlog</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>4</b>
<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 FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Comparative Studies with or without Chemistry - Manufacturing	0	0	1	1	1
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	1	0	0	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>2</b>
<b>Non Backlog</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>2</b>
<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 End of Quarter					
	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
<b>Total</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>
<b>Non Backlog</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>
<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**

ANDS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	1	1	0	50%	2
Jul-Sep 2020	0	3	0	100%	3
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	2	0	100%	2

**ANDS: Screening Performance**

ANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	0	1	2	100%	3
Jul-Sep 2020	0	1	0	100%	1
Oct-Dec 2020	0	1	1	100%	2
Jan-Mar 2021	0	2	0	100%	2
Apr-Jun 2021	0	2	0	100%	2

**DECISIONS****ANDS: Number of Decision by Fee Category**

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	CANCELLATION LETTER	1	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	1	1	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	1	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	1	0	1

\*Approvals are the NOCs Issued or Issuable at the conclusion of review.



## SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRUG SUBMISSION

RECEIVED

### SANDS: Number Received by Fee Category

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION (SANDS)					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	0	7	6	2	1
CHEMISTRY AND MANUFACTURING	0	4	0	1	0
LABEL UPDATE GENERIC	1	4	3	2	0
LABELLING ONLY	7	7	10	5	11
<i>Total</i>	<b>8</b>	<b>22</b>	<b>19</b>	<b>10</b>	<b>12</b>

**WORKLOAD****SANDS: Review Workload**

<b>SANDS: REVIEW WORKLOAD</b> <b>BY FEE CATEGORY (excluding Administrative) and End of Quarter</b>					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Labelling Only	5	6	11	7	12
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	1	2	2	2	0
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	2	4	4	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>6</b>	<b>8</b>	<b>13</b>	<b>9</b>	<b>13</b>
<b>Non Backlog</b>	<b>6</b>	<b>8</b>	<b>13</b>	<b>9</b>	<b>13</b>
<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 FEE CATEGORY (excluding Administrative) and End of Quarter</b>					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Labelling Only	3	5	6	4	3
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	2	1	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>3</b>	<b>9</b>	<b>7</b>	<b>4</b>	<b>3</b>
<b>Non Backlog</b>	<b>3</b>	<b>9</b>	<b>7</b>	<b>4</b>	<b>3</b>
<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 End of Quarter</b>					
	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
<b>Total</b>	<b>0</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>0</b>
<b>Non Backlog</b>	<b>0</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>0</b>
<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****SANDS: Review Performance**

SANDS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	0	8	0	100%	8
Jul-Sep 2020	0	4	5	100%	9
Oct-Dec 2020	0	2	0	100%	2
Jan-Mar 2021	0	10	0	100%	10
Apr-Jun 2021	0	11	1	100%	12

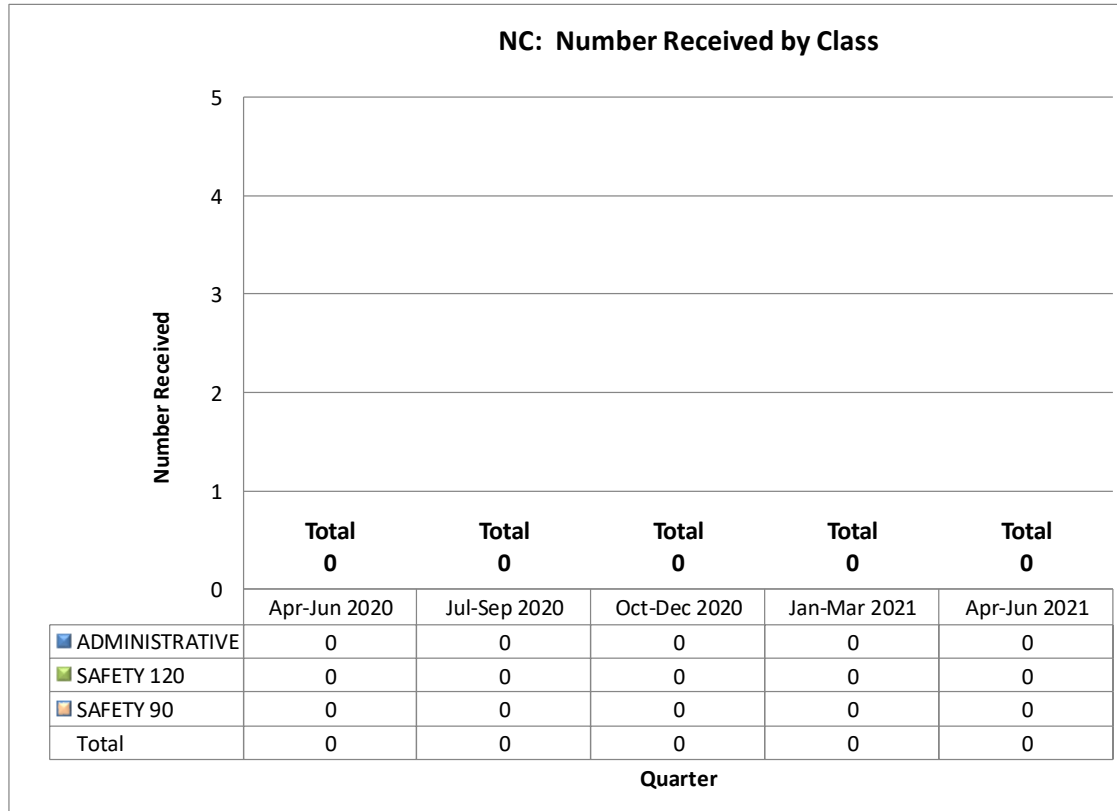
**SANDS: Screening Performance**

SANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	1	3	5	89%	9
Jul-Sep 2020	0	6	13	100%	19
Oct-Dec 2020	0	7	3	100%	10
Jan-Mar 2021	1	10	3	93%	14
Apr-Jun 2021	0	3	12	100%	15

**DECISIONS****SANDS: Number of Decision by Fee Category**

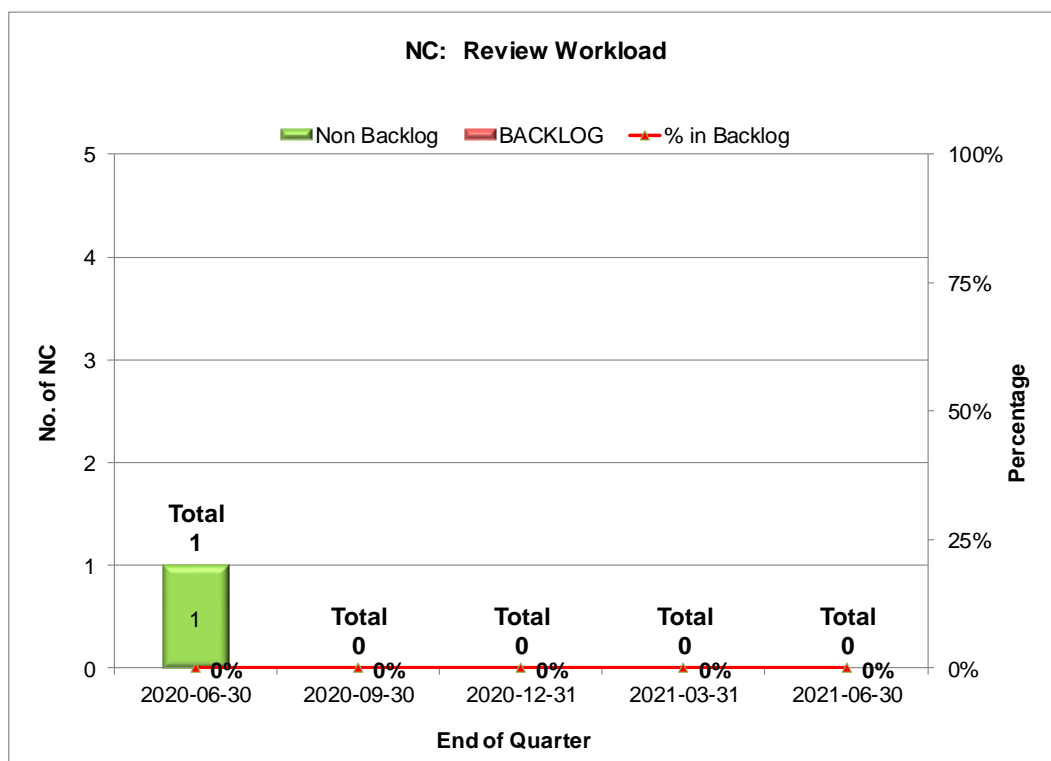
Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
LABELLING ONLY	NOTICE OF COMPLIANCE *	8	3	4	10	6
	SCREENING DEFICIENCY NOTICE	1	1	0	2	3
	CANCELLATION LETTER	0	1	0	1	0
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	5	3	6	3	3
	CANCELLATION LETTER	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	0	2	0	0
CHEMISTRY AND MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	2	1	0
	NOTICE OF COMPLIANCE*	0	0	0	0	2
	NOTICE OF NON-COMPLIANCE	0	0	0	0	2
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	1	2	0	2
	CANCELLATION LETTER	0	0	2	3	0
	SCREENING DEFICIENCY NOTICE	0	0	2	2	0

\*Approvals are the NOCs Issued or Issuable at the conclusion of review.

**NC: NOTIFIABLE CHANGE****RECEIVED****NC: Number Received by Class**

## WORKLOAD

### NC: Review Workload

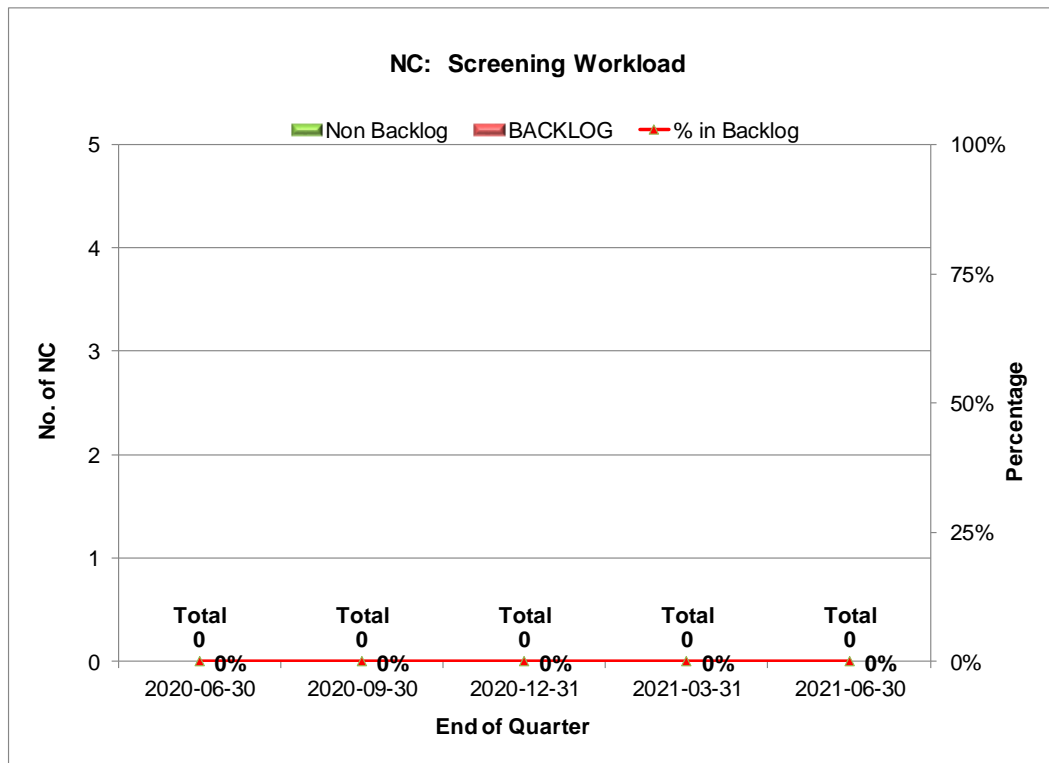


### NC: Review Workload by class

NC: REVIEW WORKLOAD BY CLASS and End of Quarter					
Class	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Safety 90	1	0	0	0	0
Backlog	0	0	0	0	0
Safety 120	0	0	0	0	0
Backlog	0	0	0	0	0
<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Non Backlog	1	0	0	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 End of Quarter					
Class	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
<b>Safety 90</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	0	0	0	0	0
<b>Non Backlog</b>	0	0	0	0	0
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

**NC: Administrative Screening Workload**

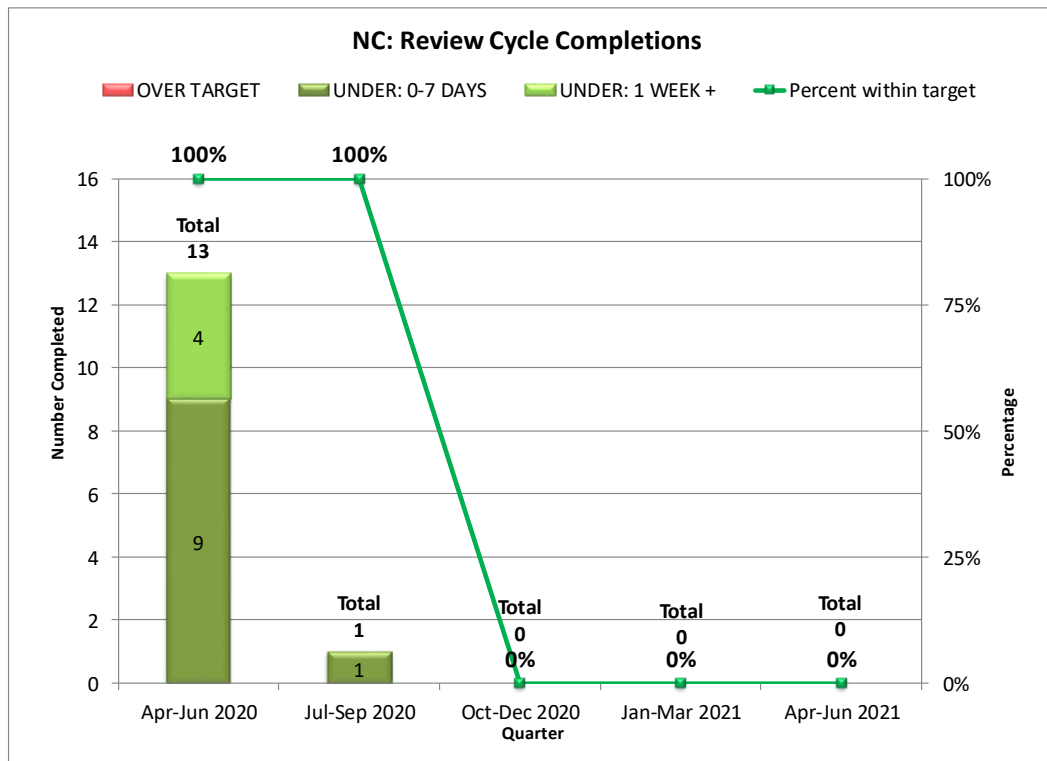
<b>NC: ADMIN SCREENING WORKLOAD</b>					
<b>By End of Quarter</b>					
<b>Class</b>	<b>2020-06-30</b>	<b>2020-09-30</b>	<b>2020-12-31</b>	<b>2021-03-31</b>	<b>2021-06-30</b>
<b>Administrative</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Non Backlog</b>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<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**

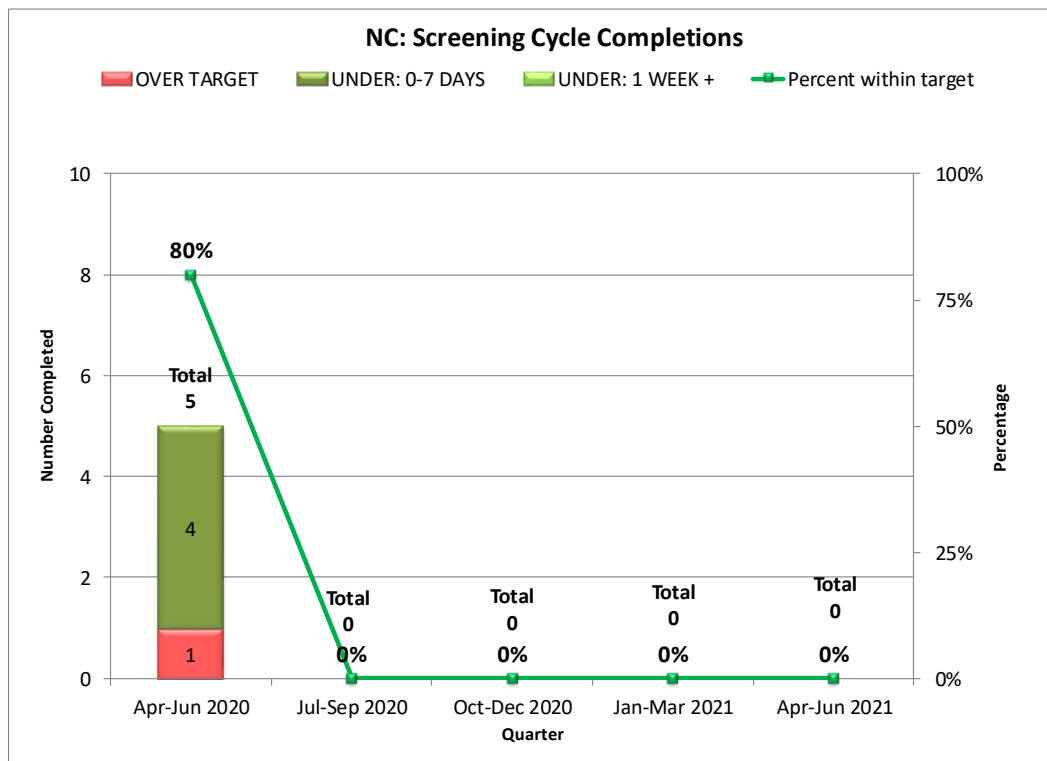
<b>CLASS</b>	<b>Decision Document Type</b>	<b>Apr-Jun 2020</b>	<b>Jul-Sep 2020</b>	<b>Oct-Dec 2020</b>	<b>Jan-Mar 2021</b>	<b>Apr-Jun 2021</b>
<b>ADMINISTRATIVE</b>	NO OBJECTION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
<b>SAFETY 90</b>	NO OBJECTION LETTER	12	1	0	0	0
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
<b>SAFETY 120</b>	CANCELLATION LETTER	0	0	0	0	0
	NO OBJECTION LETTER	1	0	0	0	0

## PERFORMANCE

### NC: Review Cycle Completions



### NC: Screening Cycle Completions





## PRE-MEETINGS

### MPDIN: Number Received by Fee Category

PRE - DIN MEETING (MPDIN)					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	1	0
CHEMISTRY AND MANUFACTURING	0	1	2	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	0	1	0
<b>Total</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>0</b>

### MPNDS: Number Received by Fee Category

PRE - NDS MEETING (MPNDS)					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	1	2
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	0	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	1	0	0	0	0
<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>

### MPSNDS: Number Received by Fee Category

PRE - SNDS MEETING (MPSNDS)					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	2
CHEMISTRY AND MANUFACTURING	0	0	1	1	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>

## **PART 2: DISINFECTANT PRODUCTS**

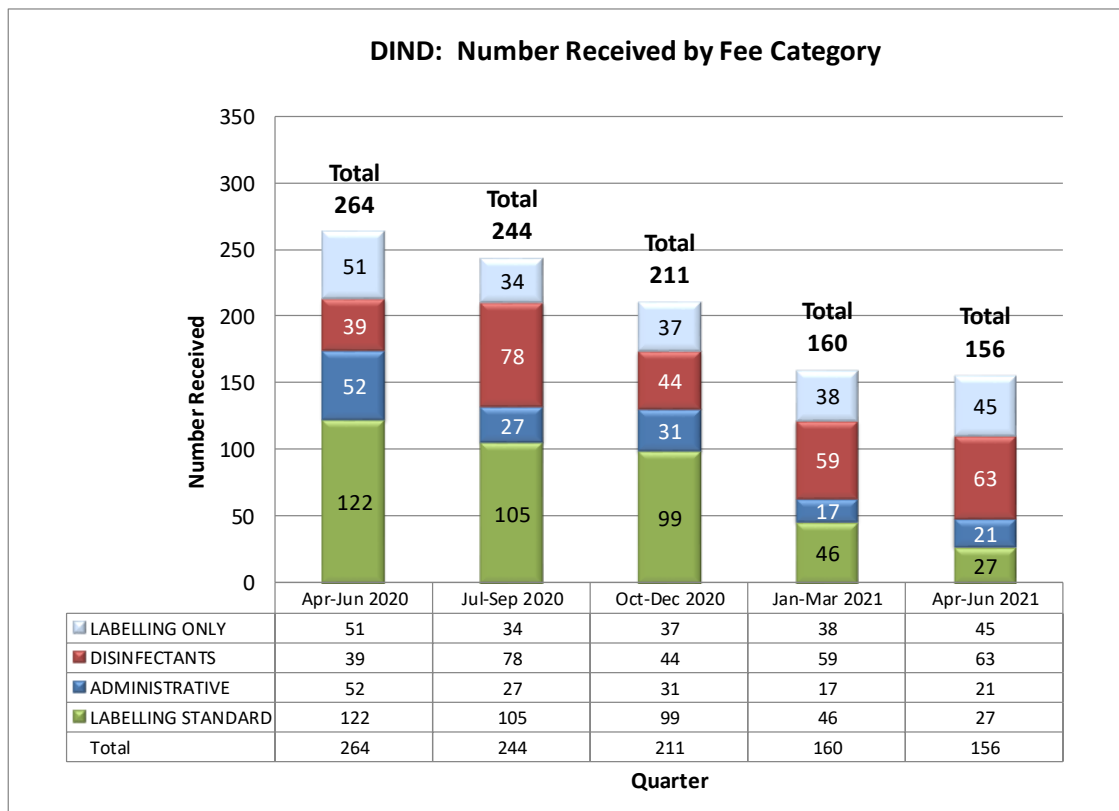
### **DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1**

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

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

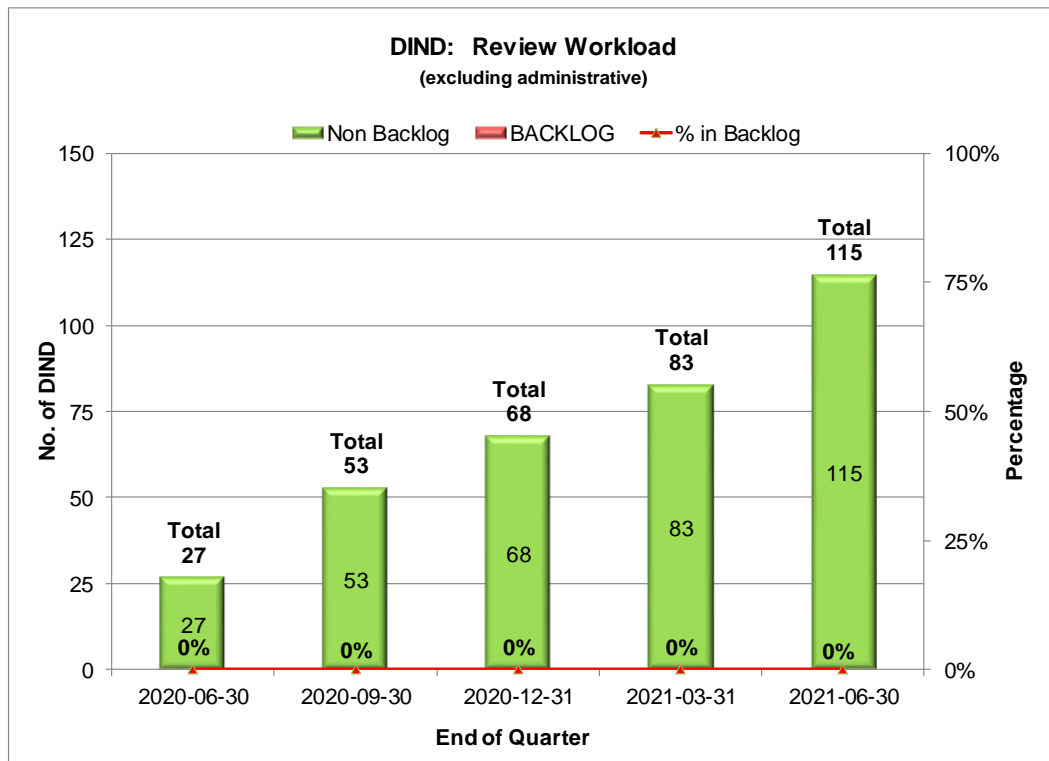
### RECEIVED

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

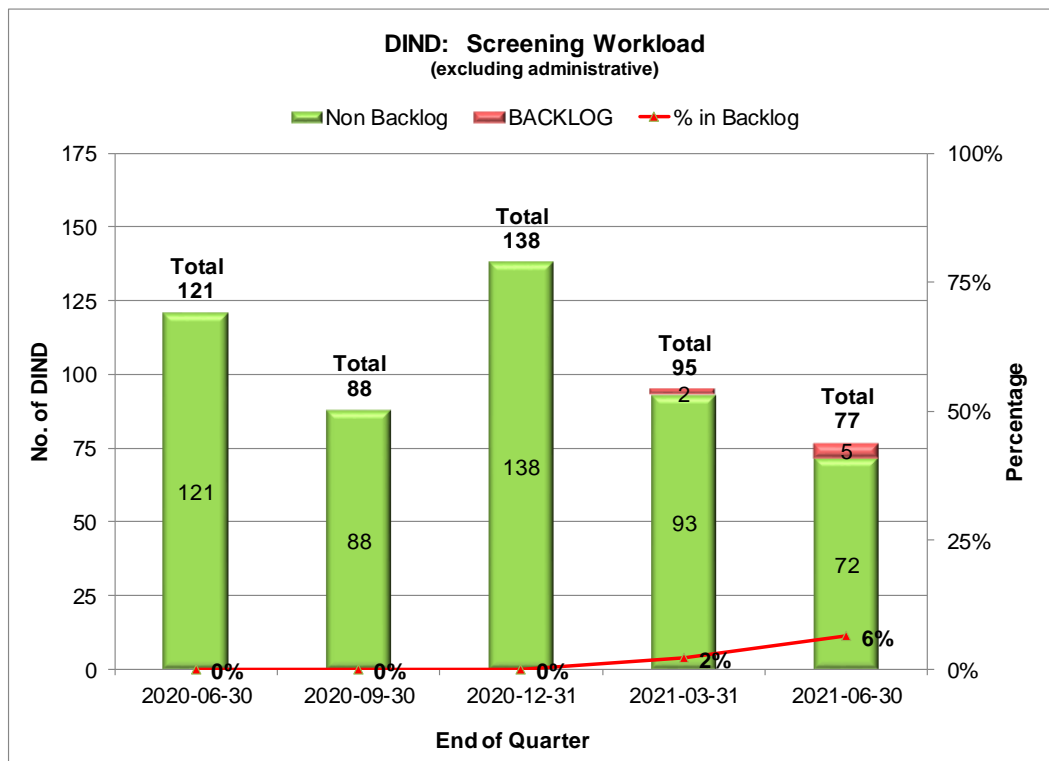


## WORKLOAD

### DIND-Disinfectant Products: Review Workload

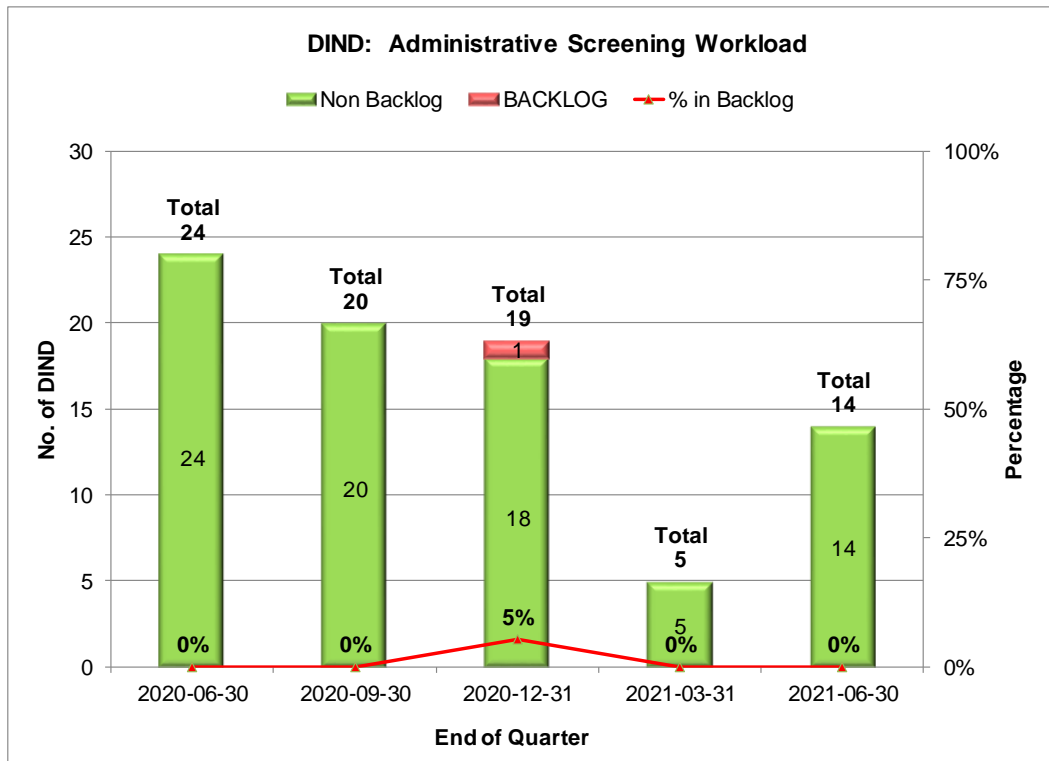


### DIND-Disinfectant Products: Screening Workload



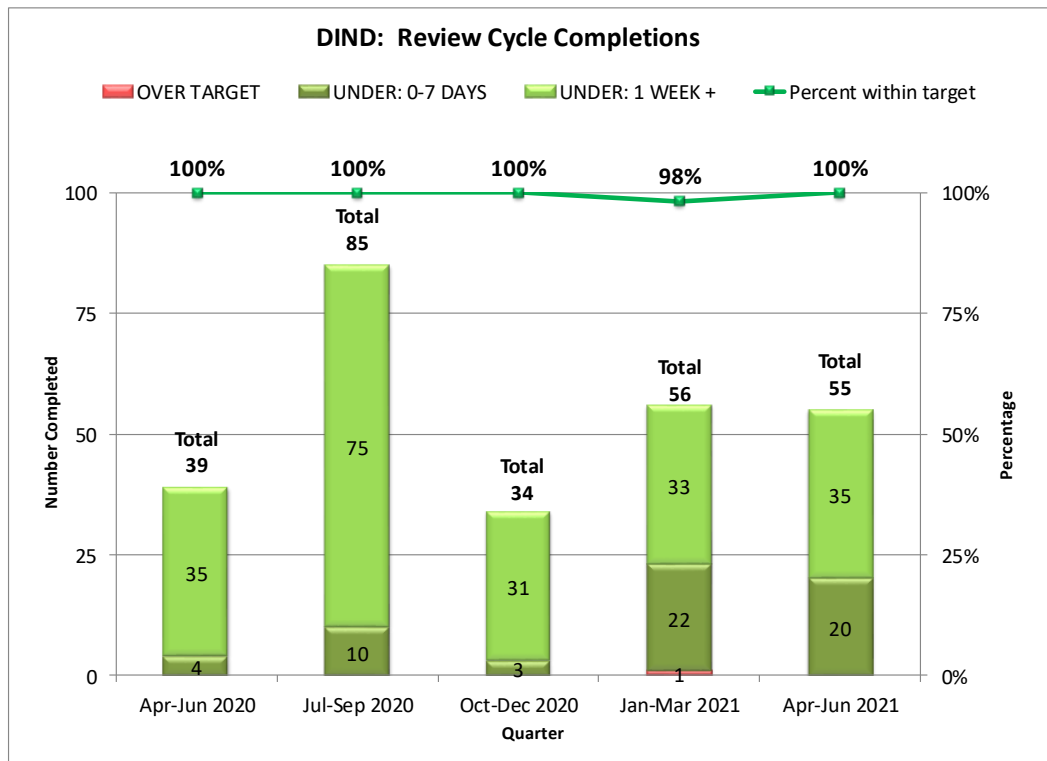
## WORKLOAD

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

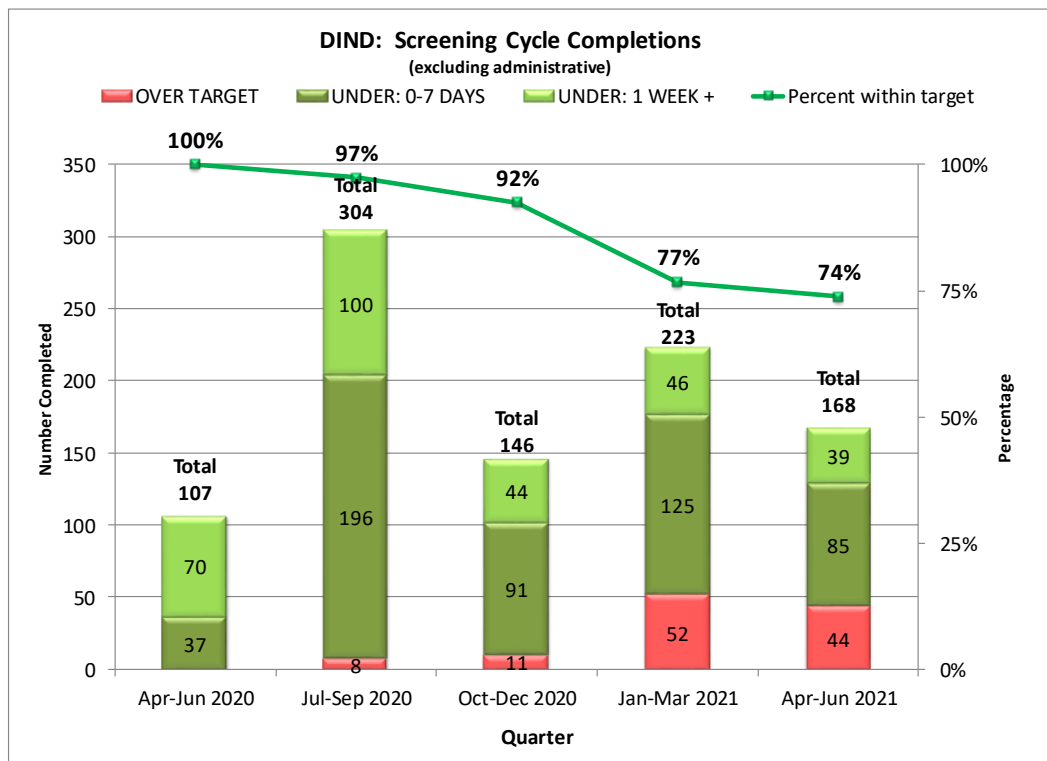


## PERFORMANCE

### DIND-Disinfectant Products: Review Cycle Completions

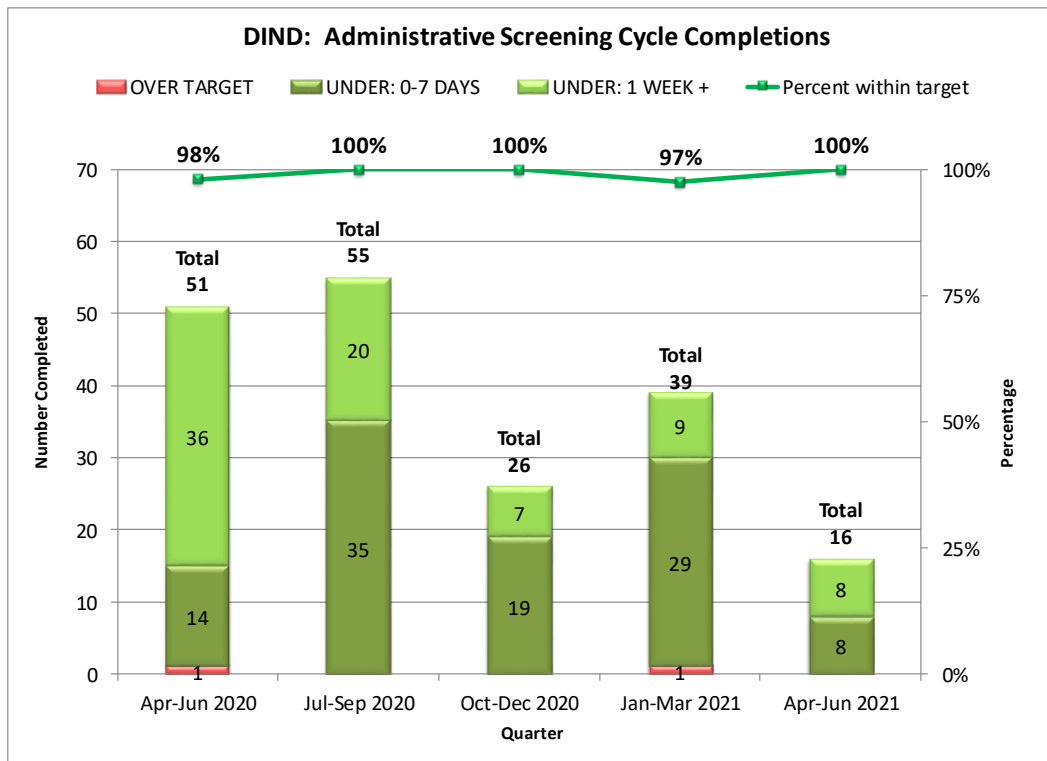


### DIND-Disinfectant Products: Screening Cycle Completions



## PERFORMANCE

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



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

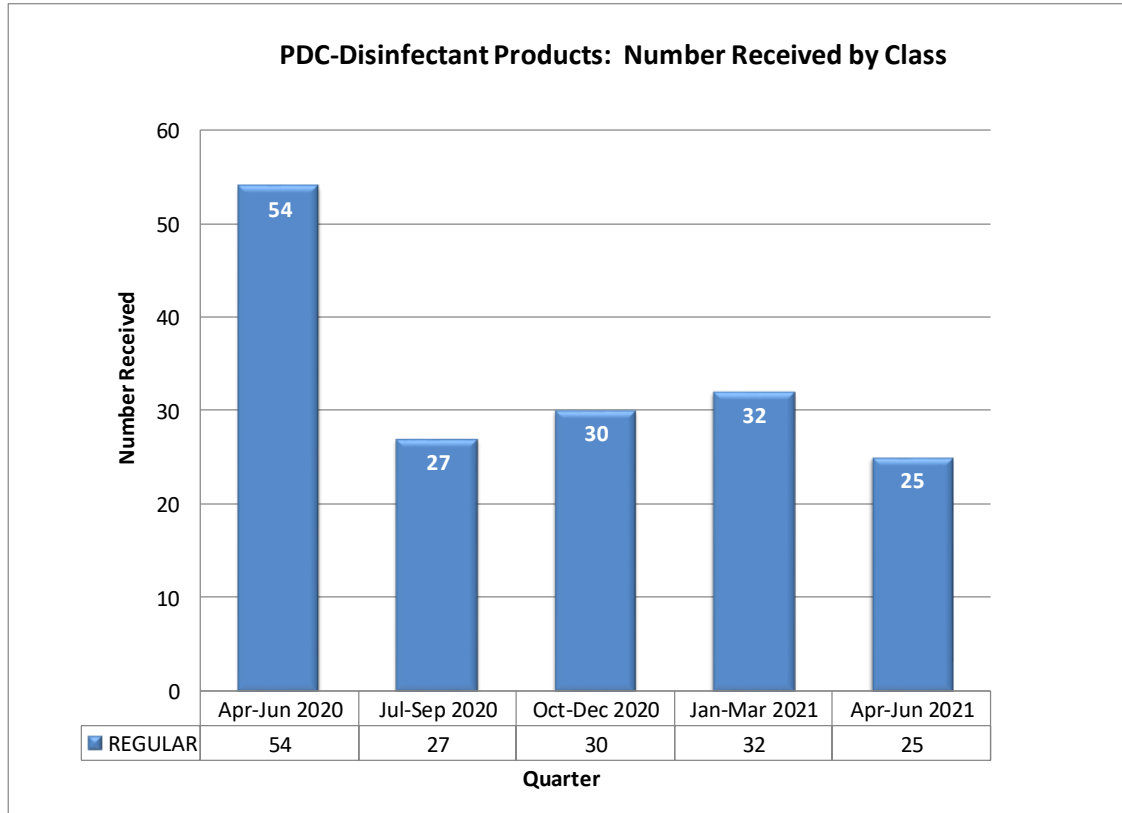
Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
<b>ADMINISTRATIVE</b>	CANCELLATION LETTER	5	8	4	8	7
	NO OBJECTION LETTER	4	9	0	0	1
	NOTIFICATION FORM DIN SUB	33	15	17	22	8
	REJECTION LETTER (SCR)	1	2	1	4	2
	SCREENING DEFICIENCY NOTICE	11	11	20	10	4
<b>DISINFECTANTS</b>	NO OBJECTION LETTER	11	28	22	12	19
	CANCELLATION LETTER	3	3	4	9	7
	NEW DRUG LETTER SCREEN	2	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	3	1	2
	NOTIFICATION FORM DIN SUB	8	11	5	12	12
	SCREENING DEFICIENCY NOTICE	6	12	12	11	22
	REJECTION LETTER (SCR)	0	4	8	1	1
<b>LABELLING STANDARD</b>	NOTIFICATION FORM DIN SUB	27	104	59	79	35
	NO OBJECTION LETTER	0	1	0	2	1
	SCREENING DEFICIENCY NOTICE	11	22	40	22	9
	NEW DRUG LETTER SCREEN	1	0	0	0	0
	REJECTION LETTER (SCR)	0	7	3	7	0
	CANCELLATION LETTER	8	15	6	13	10
<b>DISINFECTANT LABELLING ONLY</b>	NOTIFICATION FORM DIN SUB	16	22	22	27	18
	NO OBJECTION LETTER	2	2	1	1	0
	CANCELLATION LETTER	3	4	2	10	5
	SCREEN. DEFICIENCY NOTICE	2	2	5	7	0
	NOTICE OF NON-COMPLIANCE	0	0	2	2	3
	REJECTION LETTER (SCR)	0	0	1	0	0



## PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

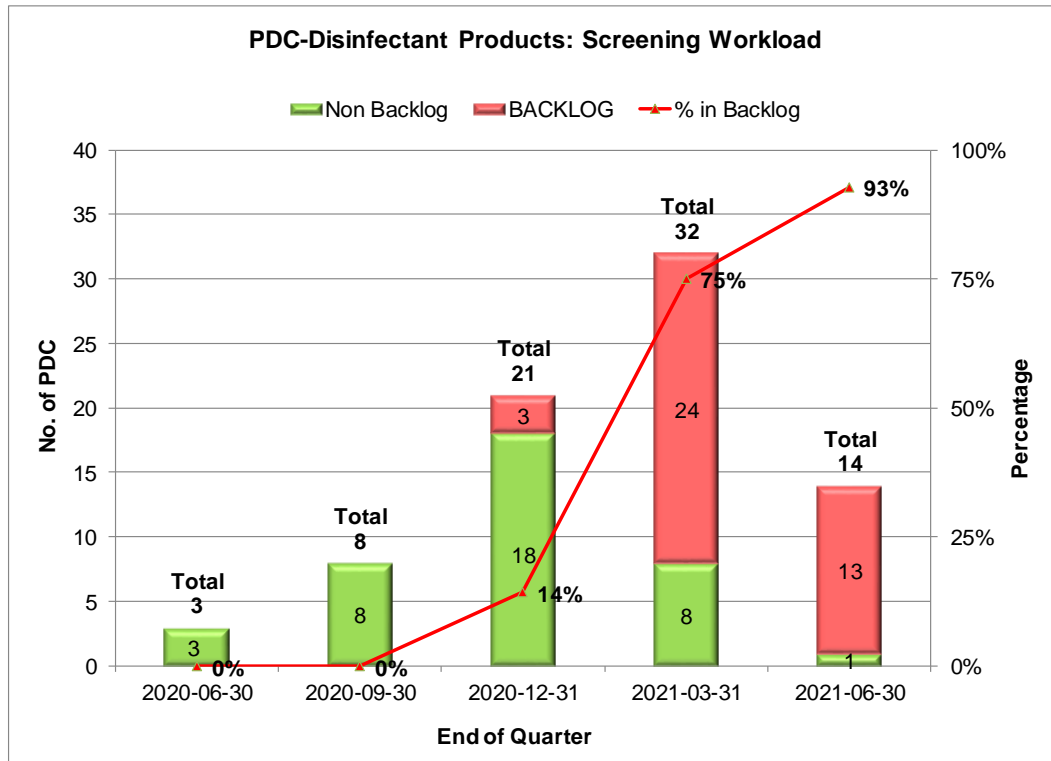
### RECEIVED

#### PDC-Disinfectant Products: Received by Fee Class



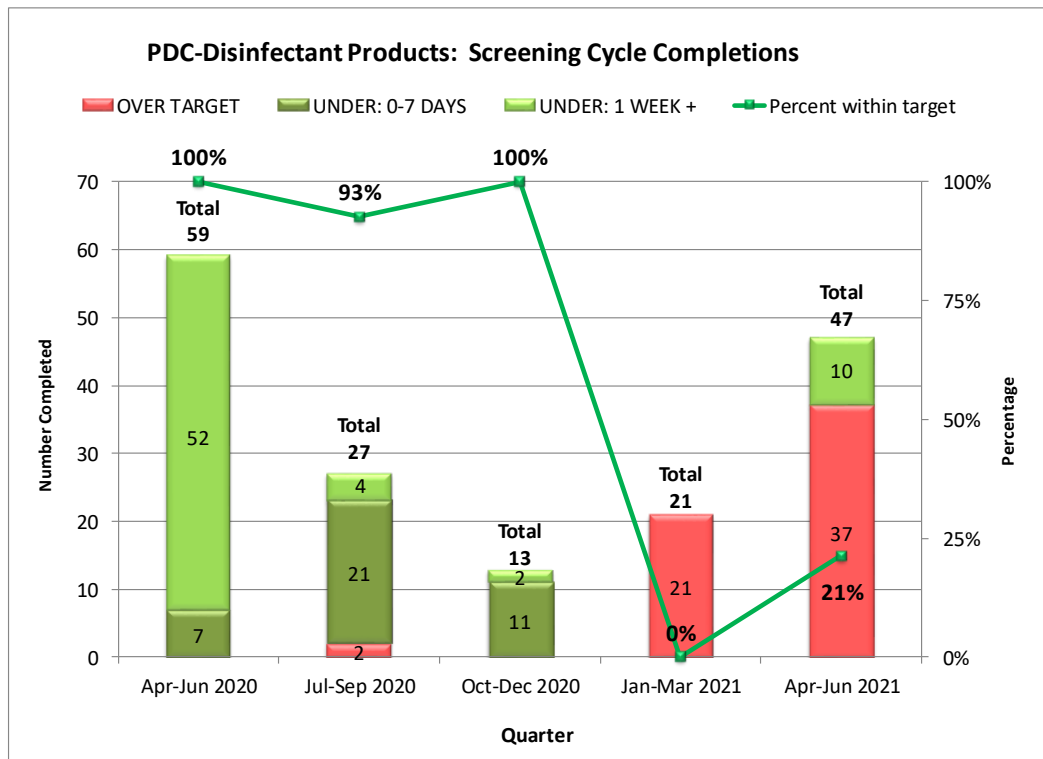
## WORKLOAD

### PDC-Disinfectant Products: Screening Workload



## PERFORMANCE

### PDC-Disinfectant Products: Screening Cycle Completions



**DECISIONS****PDC-Disinfectant Product: Number of Decisions by Fee Category**

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
REGULAR	CANCELLATION LETTER	2	0	2	1	11
	NO OBJECTION LETTER	48	15	14	17	30
	NOT SATISFACTORY NOTICE	9	2	5	2	6
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	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****SUBMISSIONS RECEIVED****NDS-Disinfectant Products: Number Received by Fee Category**

NDS-D - NEW DRUG SUBMISSION DISINFECTANT PRODUCTS					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	0	0	0	0	0
DISINFECTANTS	2	1	1	1	1
<i>Total</i>	<b>2</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>

**WORKLOAD****NDS-Disinfectant Products: Review Workload**

NDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Disinfectants	1	0	0	1	2
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>
<b>Non Backlog</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>
<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 End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Disinfectants	0	1	1	1	1
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Non Backlog</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<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: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Administrative	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Non Backlog</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<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**

NDS-D REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	1	0	100%	1
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	0	0	-	0

**NDS-Disinfectant Products: Screening Performance**

NDS-D SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Apr-Jun 2020	0	1	0	100%	1
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	1	0	100%	1
Jan-Mar 2021	1	1	0	50%	2
Apr-Jun 2021	2	1	0	33%	3

**NDS-Disinfectant Products: Administrative-Screening Performance**

NDS-D ADMIN SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	0	0	-	0

## DECISIONS

## NDS-Disinfectant Products: Number of Decisions by Fee Category

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
DISINFECTANTS	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
	REJECTION LETTER (SCR)	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	1	1	2

\* Approvals are the NOCs Issued or Issuable at the conclusion of review.



**NC: NOTIFIABLE CHANGE - DISINFECTANT PRODUCTS****RECEIVED****NC-Disinfectant Products: Received by Class**

NOTIFIABLE CHANGE- DISINFECTANT PRODUCTS					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
SAFETY 90	0	0	0	0	0

**WORKLOAD****NC-Disinfectant Products: Review Workload**

NC-Disinfectant Products: REVIEW WORKLOAD (excluding Administrative) by End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
SAFETY 90	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	0	0	0	0	0
<b>Non Backlog</b>	0	0	0	0	0
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

**NC-Disinfectant Products: Screening Workload**

NC-Disinfectant Products: SCREENING WORKLOAD (excluding Administrative) by End of Quarter					
FEE CATEGORY	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
SAFETY 90	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	0	0	0	0	0
<b>Non Backlog</b>	0	0	0	0	0
<b>BACKLOG</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

**PERFORMANCE****NC-Disinfectant Products: Review Performance**

NC-DIS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	0	0	-	0

**NC-Disinfectant Products: Screening Performance**

NC-DIS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	0	0	-	0

**DECISIONS****NC-Disinfectant Products: Number of Decisions by Class**

Fee Category	Decision Document Type	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
SAFETY 90	NO OBJECTION LETTER	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

**PRE-MEETINGS - DISINFECTANT PRODUCTS****MPDIN-Disinfectant Products: Received by Fee Category**

PRE - DIN MEETING (MPDIN) DISINFECTANT PRODUCTS					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA	1	0	0	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	3	0	1	1	5
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	0	0	1
CHEMISTRY AND MANUFACTURING	0	0	1	0	0
<b>Total</b>	<b>4</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>6</b>

**MPNDS-Disinfectant Products: Received by Fee Category**

PRE - NDS MEETING (MPNDS) DISINFECTANT PRODUCTS					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	1	0	1
CHEMISTRY AND MANUFACTURING	0	0	1	1	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>1</b>

**MPSNDS-Disinfectant Products: Received by Fee Category**

PRE - SNDS MEETING (MPSNDS) DISINFECTANT PRODUCTS					
Fee Category	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	0