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Natural and Non-Prescription Health Products Directorate

Drug Submission Performance
Quarterly Report
October - December
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 October - December 2020 to October - December 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](#).¹ This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.
- There was a significant increase in the volume of [Drug Identification Number Applications for Disinfectant products \(DIND\) received](#).
- 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)).
- 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 the Quarterly Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD).

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

- 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, safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as a Notifiable change) for submissions based only on clinical or non-clinical data.
- The Notifiable Change (NC) section of this report has been removed since NCs were phased out as of April 2020, and no NCs have since been received, nor are present in review or screening workload going forward.

Some of the highlights of the October - December 2021 report are:

Non-prescription Drug Submissions:

- 29 DINA submissions were received in Q3 2021-2022. This represents a 18% increase compared to Q2 2021-2022 (24), a 21% increase compared to Q1 2021-2022 (23) and a 43% decrease compared to Q3 2020-2021 (51).
- 25 DINF submissions were received in Q3 2021-2022. This represents a 47% decrease when compared to Q2 2021-2022 (47), a 60% increase compared to Q1 2021-2022 (15) and a 37% decrease compared to Q3 2020-2021 (40).
- 31 PDC submissions were received in Q3 2021-2022. This represents a 40% decrease compared to Q2 2021-2022 (52), a 60% decrease compared to Q1 2021-2022 (77) and a 71% decrease compared to Q3 2020-2021 (107).
- 0 NDS submissions were received in Q3, Q2 and Q1 2021-2022 while 1 NDS submission was received in Q4 2020-2021 and 0 were received in Q3 2020-2021.
- 7 SNDS submissions were received in Q3 2021-2022. This represents a 15% increase compared to Q2 2021-2022 (6), a 42% decrease compared to Q1 2021-2022 (12) and a 40% increase compared to Q3 2020-2021 (5).
- 1 ANDS submission was received in Q3 2021 and Q2 2021-2022, respectively. This represents a 75% decrease compared to Q1 2021-2022 (4) and a 100% increase compared to Q3 2020-2021 (2).
- 8 SANDS submissions were received in Q3 2021-2022. This represents a 39% decrease compared to Q2 2021-2022 (13), a 33% decrease compared to Q1 2021-2022 (12) and a 58% decrease compared to Q3 2020-2021 (19).

Overall, the total non-prescription drug submissions received in Q3 2021-2022 (101) decreased by 29% compared to Q2 2021-2022 (143) and Q1 2021-2022 (143), and decreased by 55% when compared to Q3 2020-2021 (224).

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. The spike observed in PDC submissions received in Q1 2021-2022 in response to outreach to sponsors for plain language labelling (PLL) stabilized as the retail-level PLL deadline of June 30, 2021 has passed.

Performance against review targets for non-prescription drug submissions reviewed in Q3 remained very good, as backlogs were avoided in most categories. This quarter also marked the second occurrence in as many years that cost-recovered OTC submissions were eligible for a submission pause between December and January to accommodate personnel absences at the close of the calendar year.

Disinfectant Drug Submissions:

- 82 DIN-D submissions were received in Q3 2021-2022. This represents a 4% increase compared to Q2 2021-2022 (79), a 47% decrease compared to Q1 2021-2022 (156) and a 61% decrease compared to Q3 2020-2021 (211).
- 23 PDC submissions were received in Q3 2021-2022. This represents a 13% increase compared to Q2 2021-2022 (20), a 8% decrease compared to Q1 2021-2022 (25) and a 23% decrease compared to Q3 2020-2021 (30).
- 3 NDS-D submissions were received in Q3 2021-2022. This represents a 33% increase compared to Q2 2021-2022 (2) and a 200% increase compared to Q1 2021-2022 (1) and Q3 2020-2021 (1).
- No SNDS-D submissions were received in Q3 2021-2022. 2 SNDS-D submissions were received in Q2 2021-2022 which represented a significant increase compared to Q1 2021-2022 (1) and Q3 2020-2021 (1).

Overall, the total disinfectant drug submissions received in Q3 2021-2022 (108) increased by 5% compared to Q2 2021-2022 (103), decreased by 41% compared to Q1 2021-2022 (182) and decreased by 56% compared to Q3 2020-2021 (243).

The volume of submissions received in Q3 2021-2022 (108) decreased compared to Q3 2020-2021 (243) but remained higher than pre-pandemic volumes, despite the continued reduction in received submission volume over the fiscal year. The submissions received in Q3 2021-2022 were evenly distributed among the submission streams like observed in Q2 2021-2022. This is in contrast to Q3 and Q4 2020-2021 and Q1 2021-2022 where the majority of the submissions received were full reviews.

In Q4 2020-2021, the Full Review workload (83) was 4.6x higher than pre-COVID volumes. This resulted in short-term backlogs for the screening components of 23% of Full Review submissions, in order to shift resources within the review team to meet expedited COVID review targets and other cost-recovered performance standards. As expedited timelines ended October 1, 2021, the screening cycle completions over target for Full Review submissions were expected to decrease by Q3 2021-2022. There is a 74% decrease of screening cycle completions over target for Full Review submissions in Q3 2021-2022 (14) compared to Q2 2021-2022.

Despite total submissions received decreasing in Q3 2021-2022, the Q3 full review workload (80) was still 4x higher than pre-COVID and represented 64% of the active workload.

Overall, the reduced volume of PDCs in Q2 and Q3 2021-2022 is in line with in the last three quarters of FY 2020-2021 and 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. As expedited timelines ended October 1, 2021-2022 the screening cycle completions over target for PDC submissions were expected to decrease but the volumes in Q2 2021-2022 (15) and Q3 2021-2022 (17) remained significantly high. This was not achieved mostly because sponsors are requesting more complex changes under PDC submissions (e.g. changes to non-medicinal ingredients that may require confirmatory data).

These require more in-depth review leading to challenges in meeting the 30 days performance standard. Meeting these targets by the end of Q4 2021-2022 will depend on the changes requested in PDC submissions. Although there was a general decrease in submissions received in Q2 and Q3 2021-2022 compared to FY 2020-2021, significant increase in submissions received was seen in the NDS-D (5) and SNDS-D (2) submissions category over the last two quarters. This represents a significant increase compared to Q1 2021-2022, Q4 2020-2021 and Q2 2020-2021 (1).

General Information

There are several steps involved in the drug submission review² 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**³ is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken to complete a cycle (excluding any pause days⁴) is compared to a set [performance standard](#) which is based on the type of submission, class and cycle (status).

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

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

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

⁴ In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance (effective date: April 1, 2020).

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

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ACRONYMS

Submission Types

ANDS	- Abbreviated New Drug Submission
CTA	- Clinical Trial Application
CTA-A	- Clinical Trial Application - Amendment
DINA	- Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	- Application for a Drug Identification Number for a biological product
DIND	- Application for a Drug Identification Number for a disinfectant product
DINF	- Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	- Abbreviated Extraordinary Use New Drug Submission
EUNDS	- Extraordinary Use New Drug Submission
EUSANDS	- Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	- Supplement to an Extraordinary Use New Drug Submission
MPNDS	- Pre-Submission Meeting New Drug Submission
MPSNDS	- Pre-Submission Meeting Supplement to a New Drug Submission
NC	- Notifiable Change
NDS	- New Drug Submission
NDS-D	- New Drug Submission for Disinfectant products
PDC	- Post-authorization Division 1 Change for a pharmaceutical product
PDC-B	- Post-authorization Division 1 Change for a 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
New active substance	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
Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance
Comparative studies	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
Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance
Switch status from prescription drug to non-prescription drug	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
Labelling only	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)

Fee Category	Description
Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment
Administrative submission	Submissions in support of a 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)
Disinfectant – full review	Submissions, other than those described in item 12, that include data in support of a disinfectant
Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug
Drug identification number application - labelling standards	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
Published data only	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

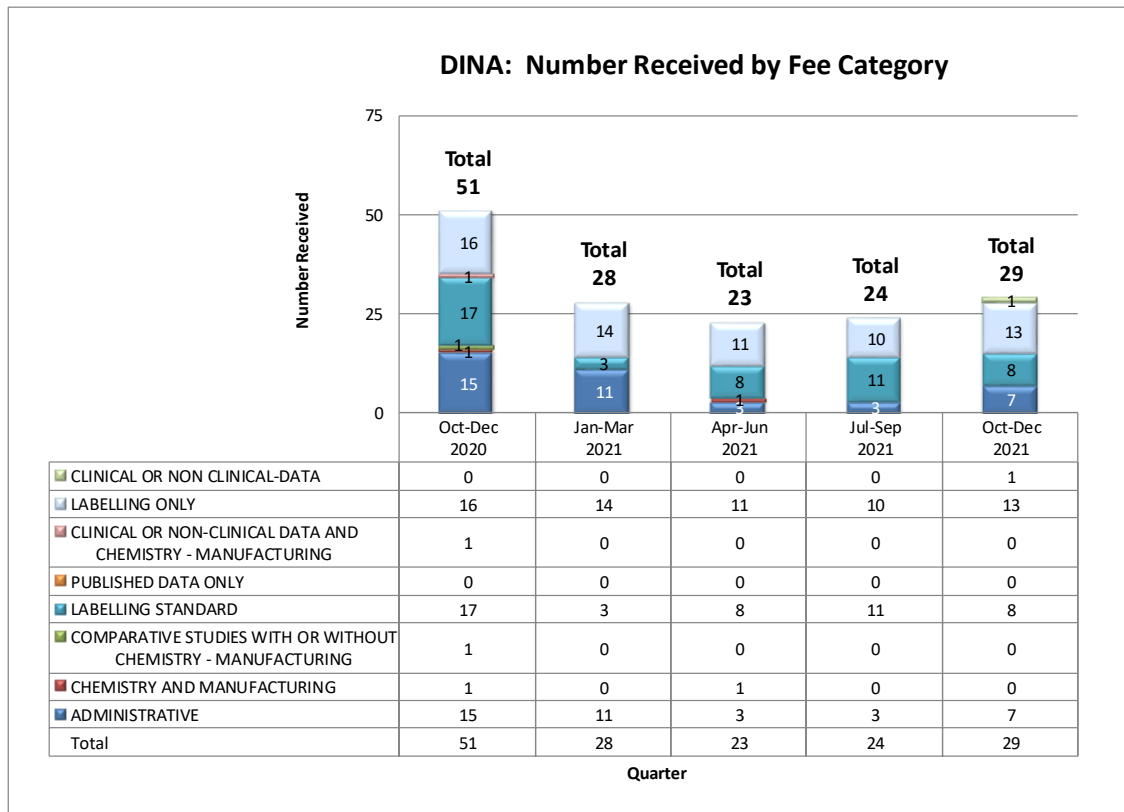
Over the counter (OTC) Drugs

NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

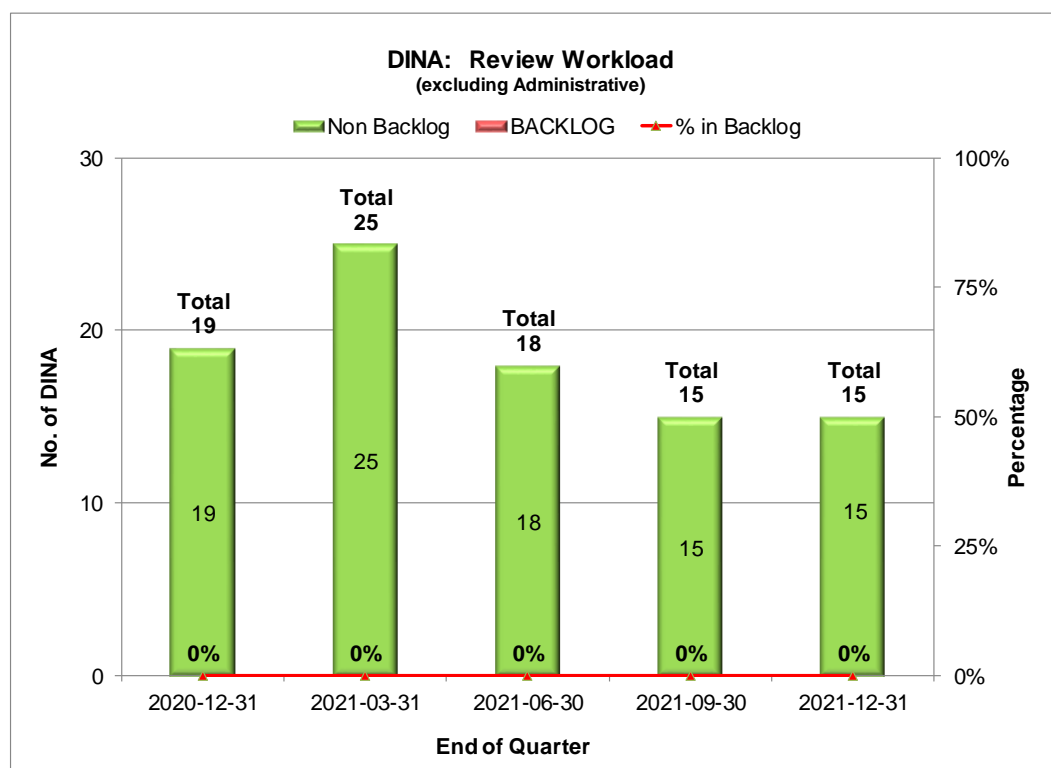
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

DINA: Number Received by Fee Category



WORKLOAD

DINA: Review Workload

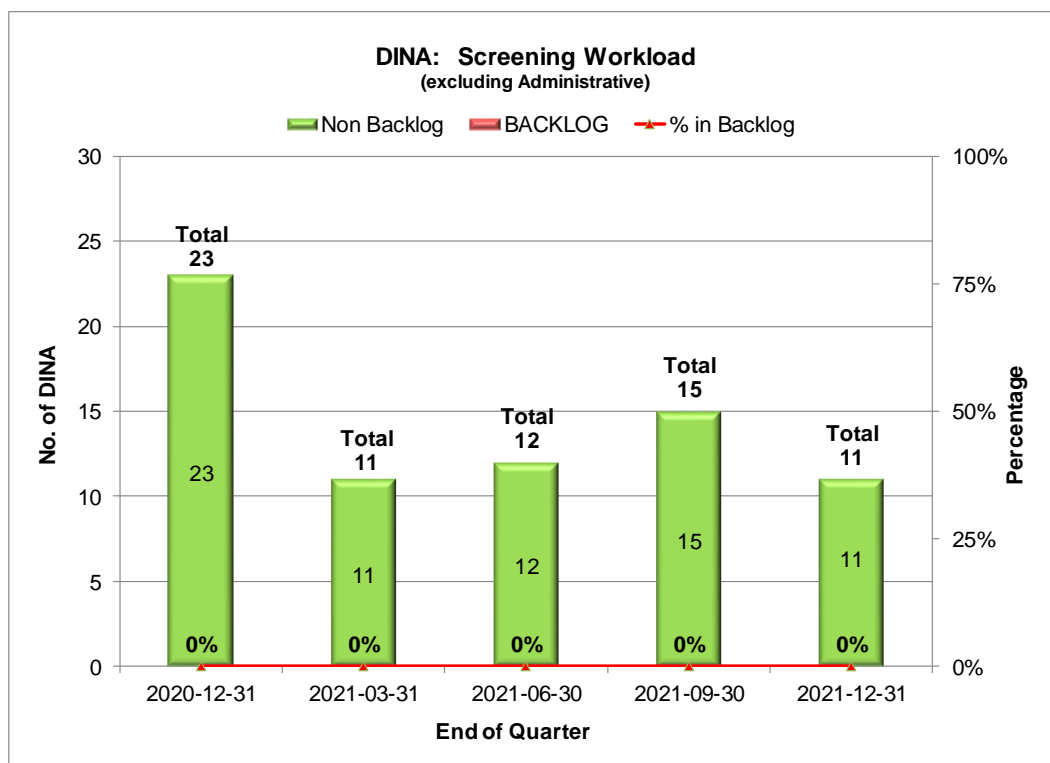


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Chemistry and Manufacturing	2	4	4	1	1
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	1	0	1	1
Backlog	0	0	0	0	0
Labelling Only	14	17	13	13	13
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	2	3	1	0	0
Backlog	0	0	0	0	0
Total	19	25	18	15	15
Non Backlog	19	25	18	15	15
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Screening Workload

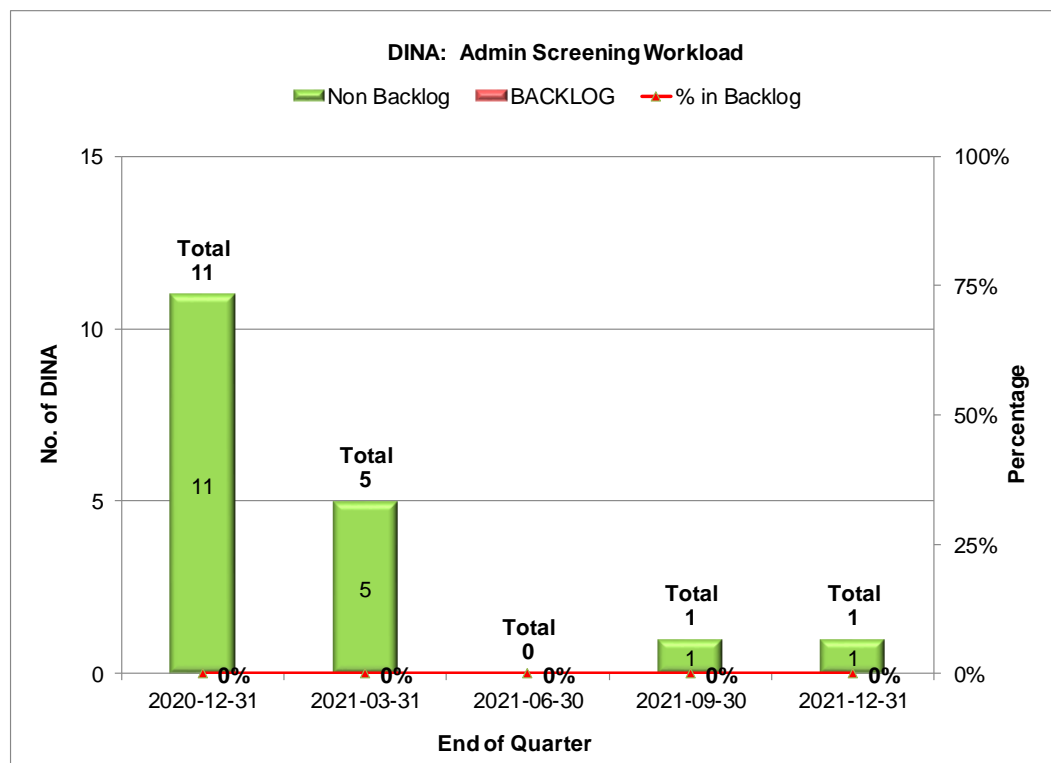


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Chemistry and Manufacturing	2	0	1	0	0
Backlog	0	0	0	0	0
Labelling Only	10	8	6	6	7
Backlog	0	0	0	0	0
Labelling Standard	11	3	5	9	3
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Total	23	11	12	15	11
Non Backlog	23	11	12	15	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Administrative-Screening Workload



DINA: Administrative-Screening Workload by Fee Category

DINA: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Administrative	11	5	0	1	1
<i>Backlog</i>	0	0	0	0	0
Total	11	5	0	1	1
Non Backlog	11	5	0	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

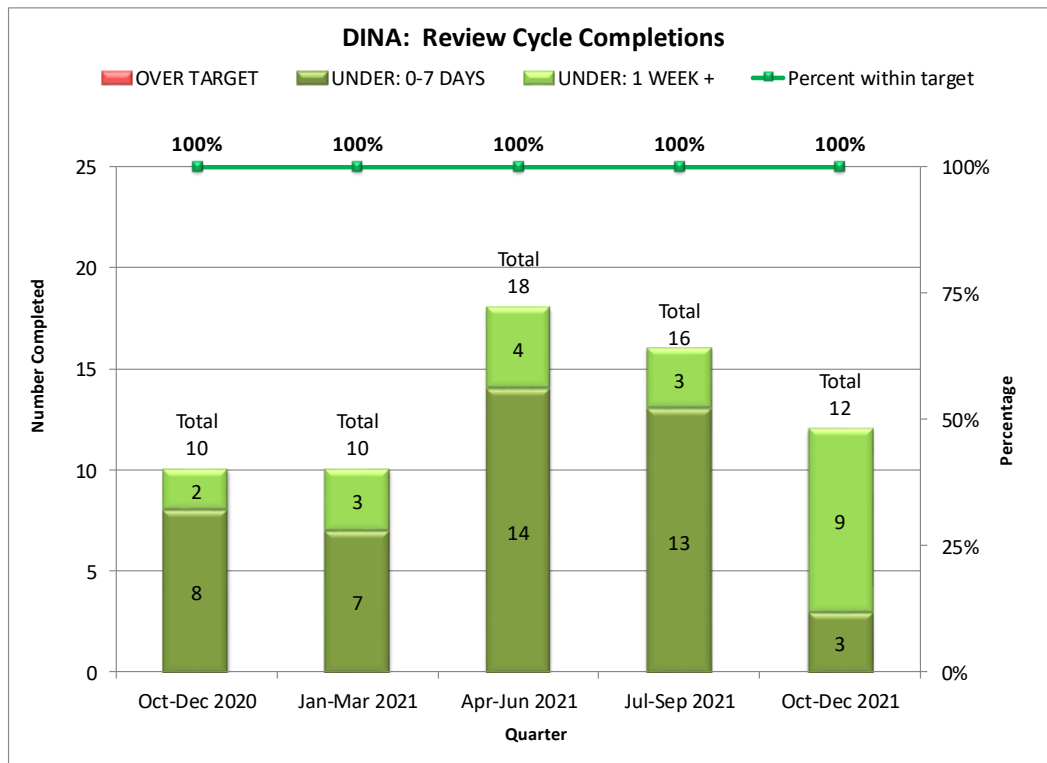
DECISIONS

DINA: Number of Decisions by Fee Category

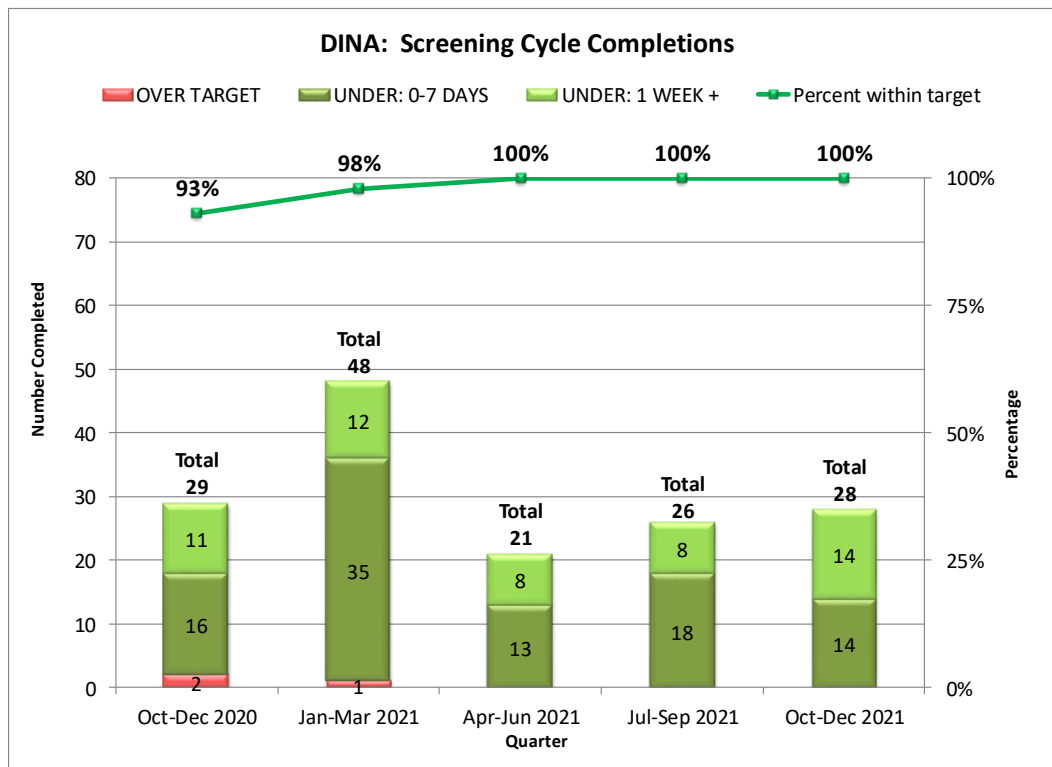
Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	3	2	0	3
	NOTIFICATION FORM DIN SUB	2	13	6	2	4
	REJECTION LETTER (SCR)	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	3	0	0	1	0
	NO OBJECTION LETTER	1	0	2	0	0
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	2	0
	NO OBJECTION LETTER	1	0	0	2	0
	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	3	0	0	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	1	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	1	1	0
	NO OBJECTION LETTER	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	CANCELLATION LETTER	2	2	2	1	1
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	1	1	4	1	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	13	8	11	10	12
	REJECTION LETTER (SCR)	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	2	1	2	2	2
LABELLING STANDARD	CANCELLATION LETTER	3	2	3	0	7
	NO OBJECTION LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	9	9	2	9	2
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	2	2	2	1	8
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	1	0	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

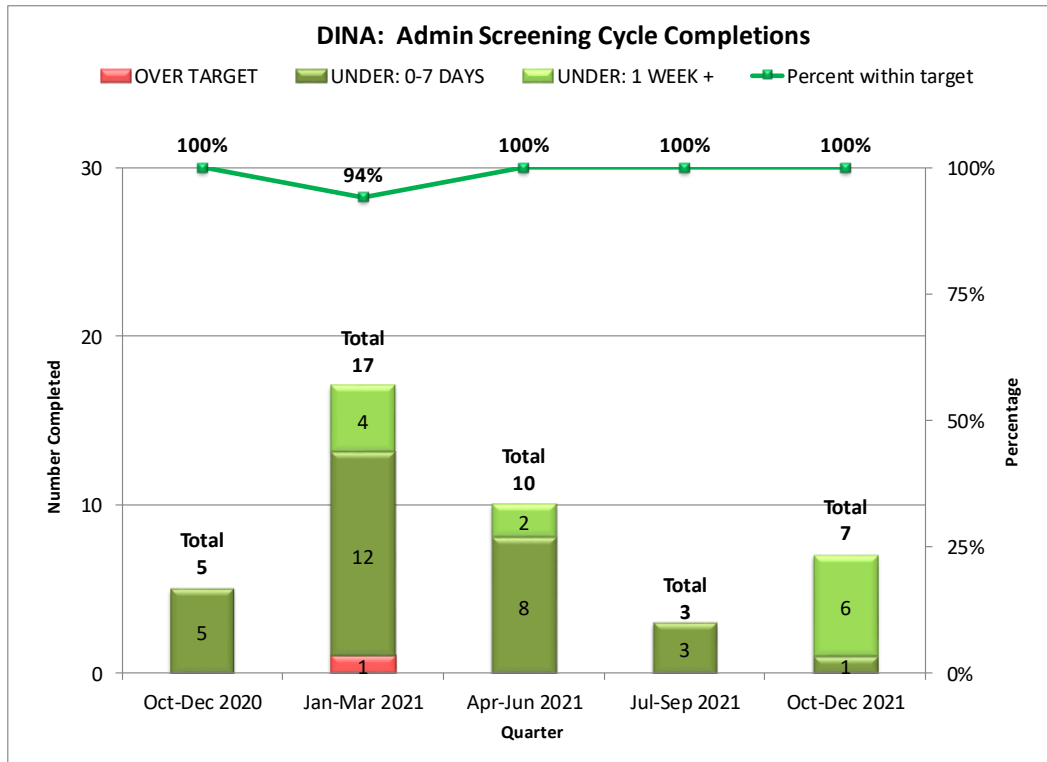


DINA: Screening Cycle Completions



PERFORMANCE

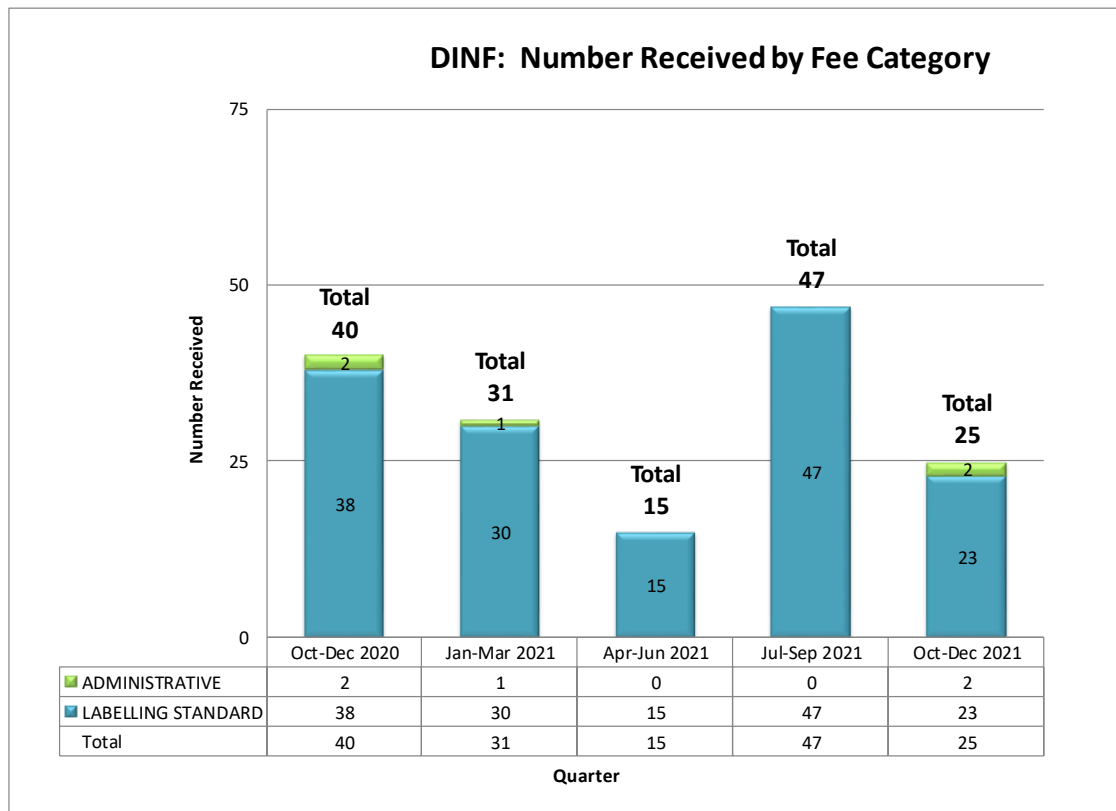
DINA: Administrative-Screening Cycle Completions



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

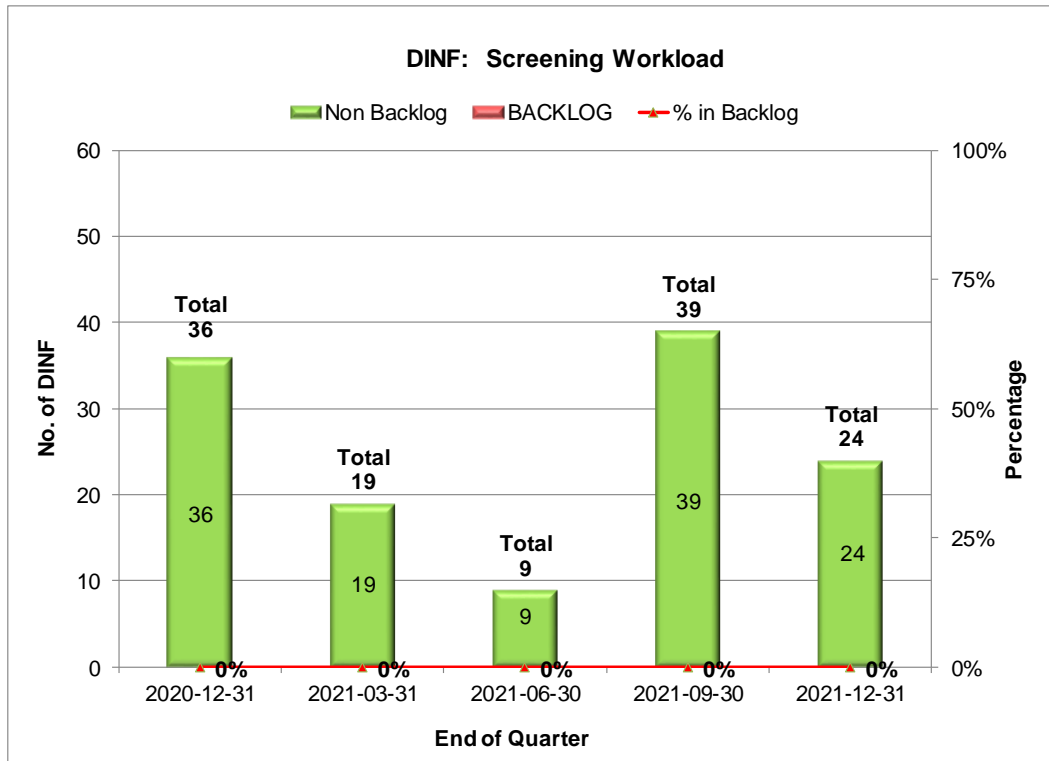
RECEIVED

DINF: Number Received by Fee Category



WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Standard	36	18	9	39	24
<i>Backlog</i>	0	0	0	0	0
Administrative	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	36	19	9	39	24
Non Backlog	36	19	9	39	24
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

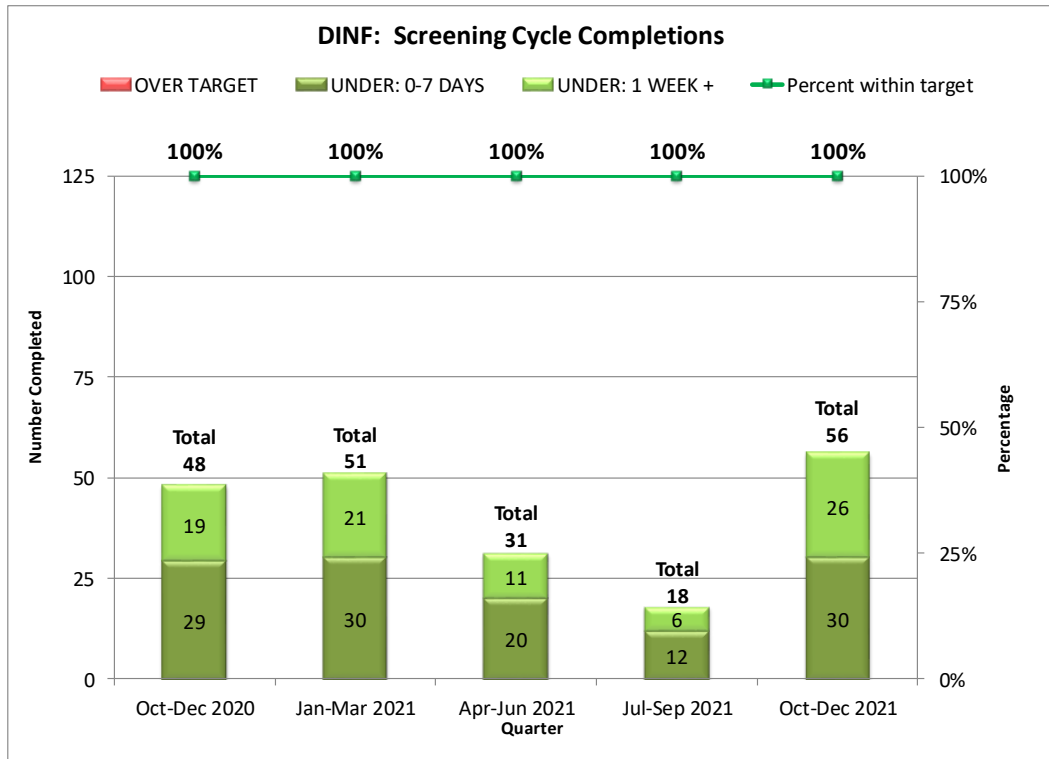
DECISIONS

DINF: Number of Decisions by Fee Category

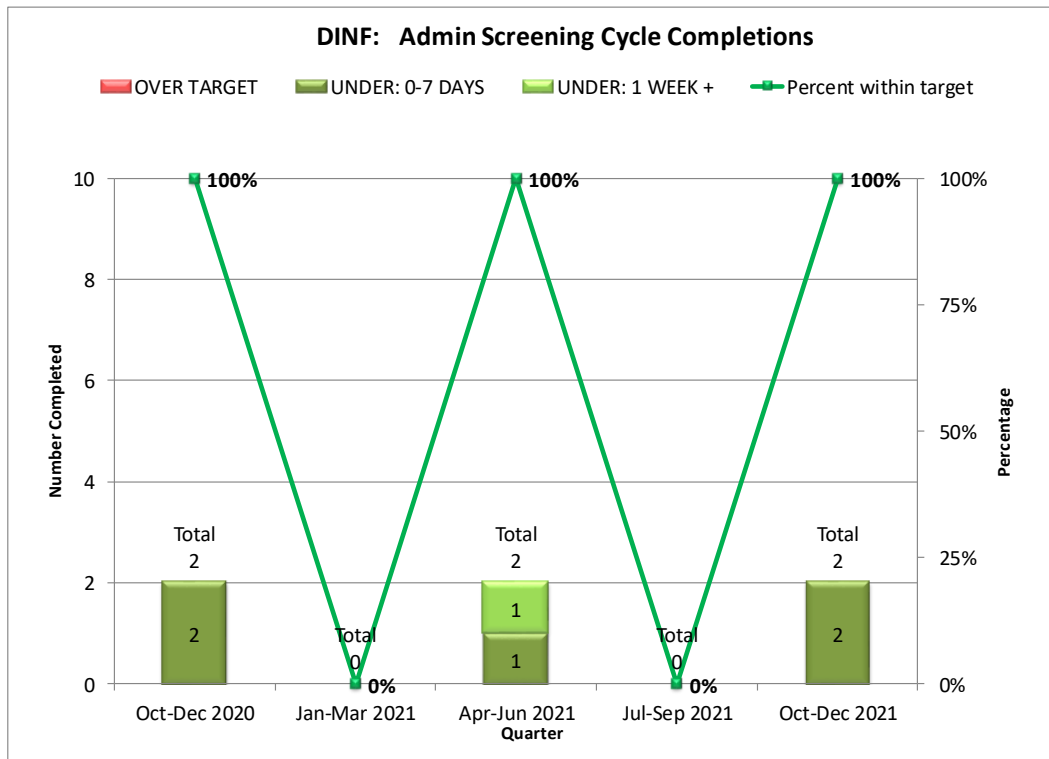
Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
LABELLING STANDARD	CANCELLATION LETTER	6	8	2	0	4
	NO OBJECTION LETTER	0	0	0	0	0
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	52	40	21	17	34
	REJECTION LETTER (SCR)	1	2	0	0	2
	SCREENING DEFICIENCY NOTICE	21	6	8	1	19
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	3	0	1	0	2
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	CANCELLATION LETTER	0	0	0	0	0

PERFORMANCE

DINF: Screening Cycle Completions



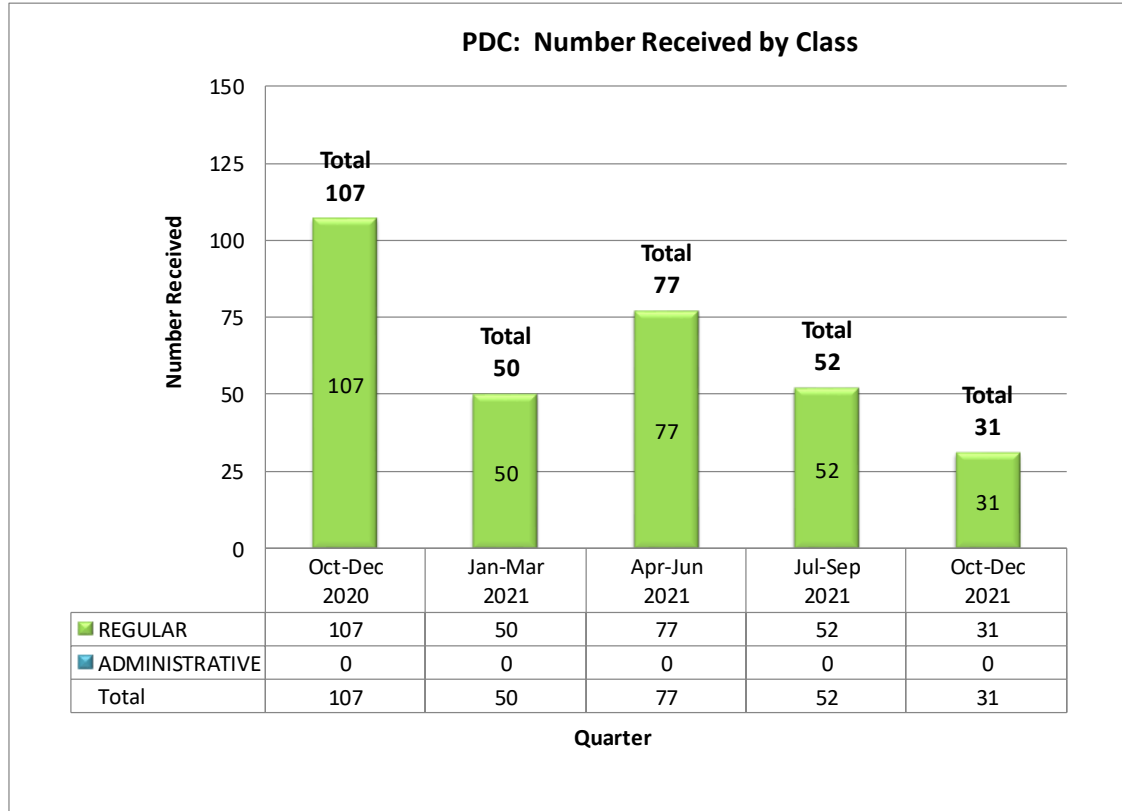
DINF: Admin-Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

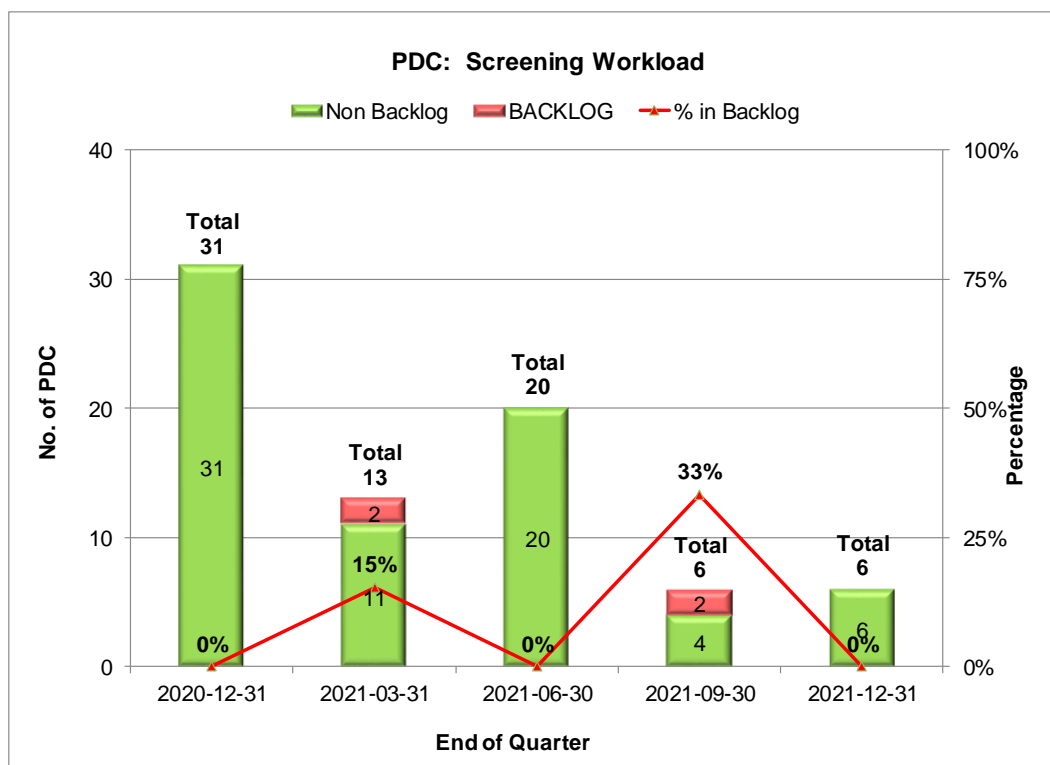
RECEIVED

PDC: Received by Class



WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS By End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Regular	31	13	20	6	6
Backlog	0	2	0	2	0
Administrative	0	0	0	0	0
Backlog	0	0	0	0	0
Total	31	13	20	6	6
Non Backlog	31	11	20	4	6
BACKLOG	0	2	0	2	0
% in Backlog	0%	15%	0%	33%	0%

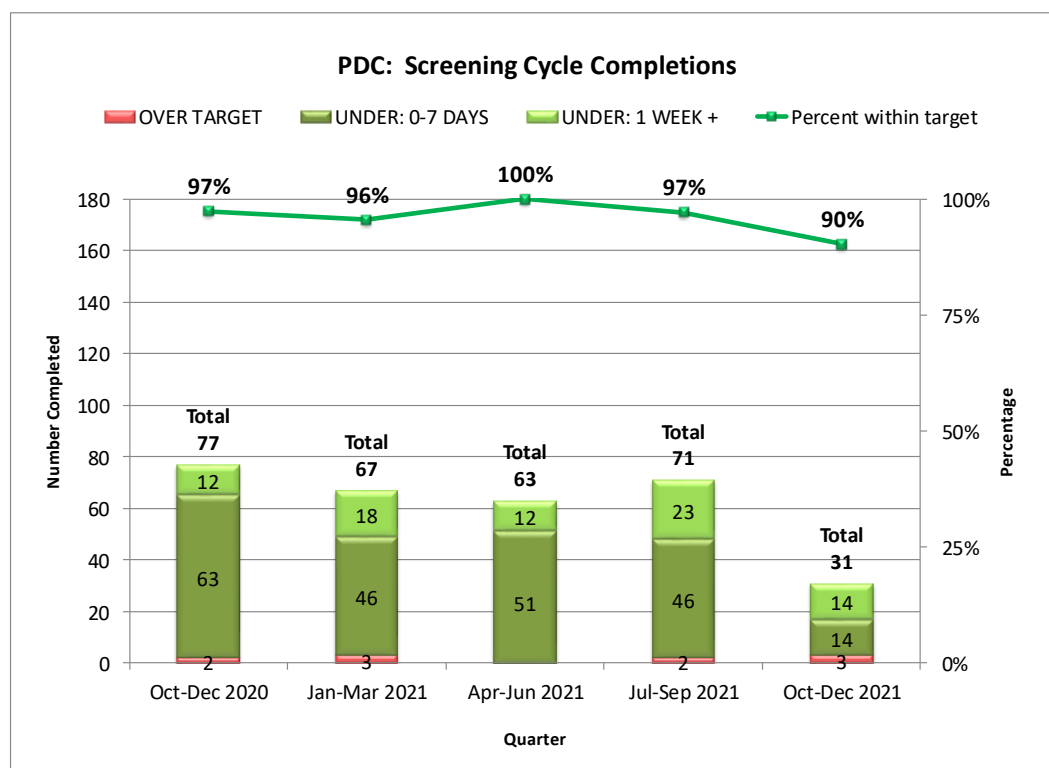
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
REGULAR	CANCELLATION LETTER	1	3	4	3	2
	NO OBJECTION LETTER	112	62	51	66	28
	NOT SATISFACTORY NOTICE	5	2	8	2	1
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

PERFORMANCE

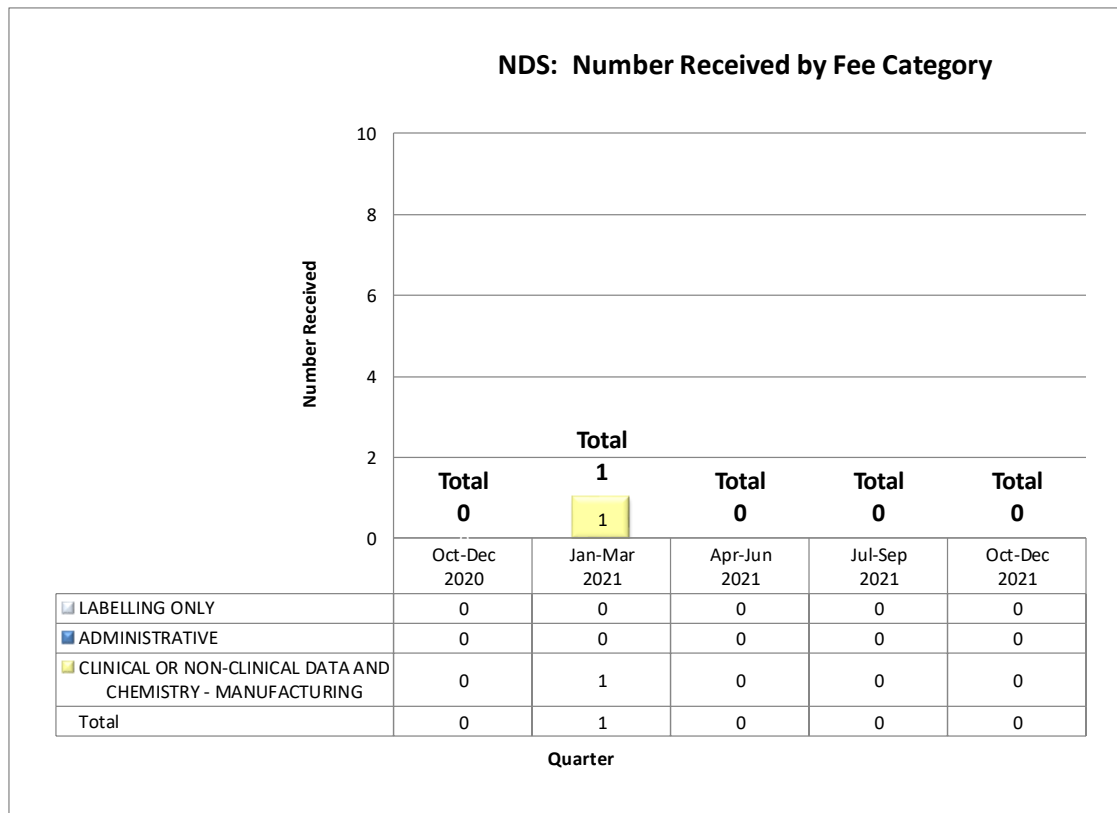
PDC: Screening Cycle Completions



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

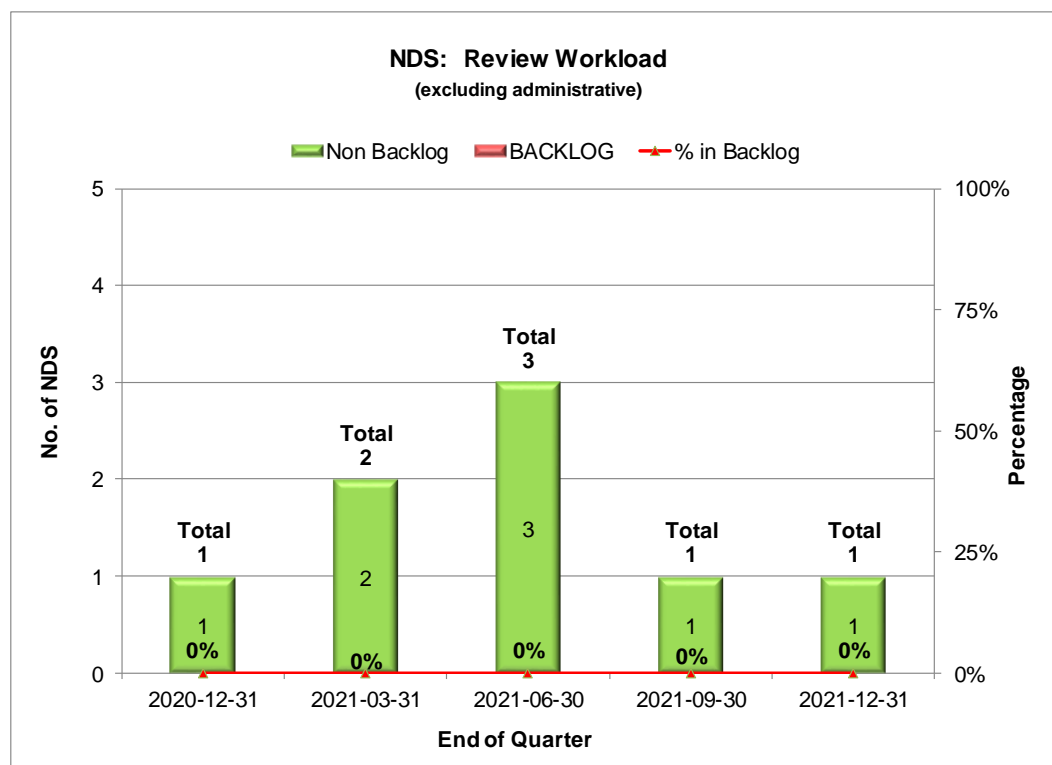
NDS: NEW DRUG SUBMISSION RECEIVED

NDS: Number Received by Fee Category



WORKLOAD

NDS: Review Workload

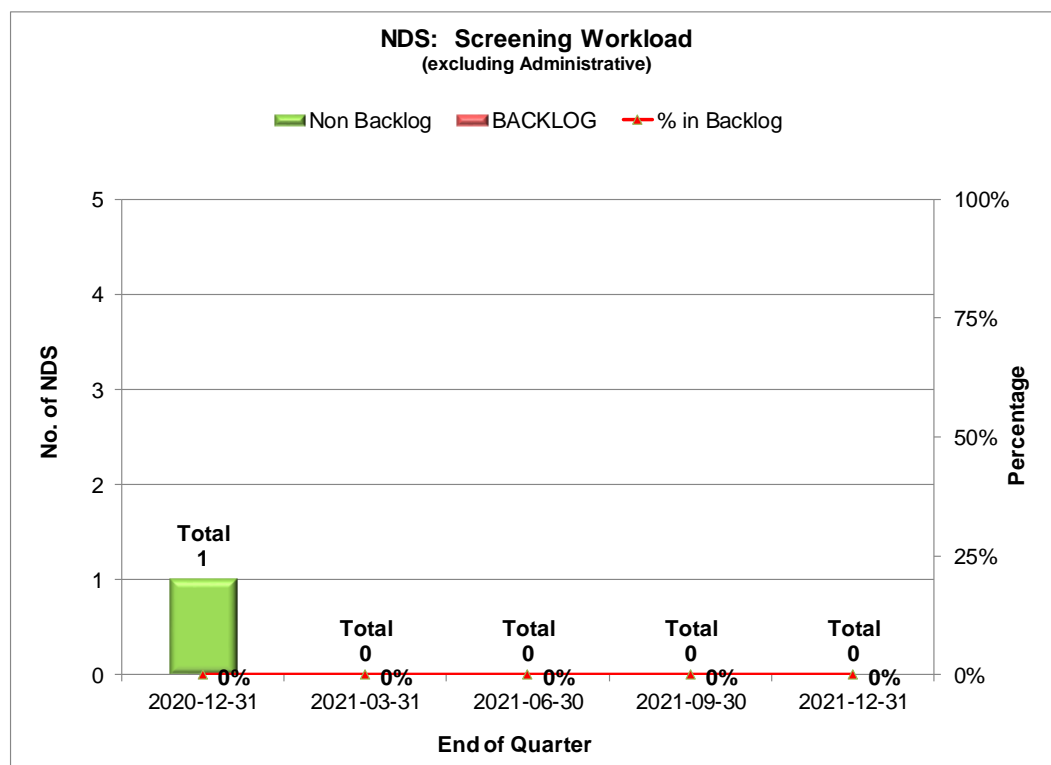


NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	2	3	1	1
<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
Total	1	2	3	1	1
Non Backlog	1	2	3	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NDS: Screening Workload



NDS: Screening Workload by Fee Category

NDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	0	0	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
Total	1	0	0	0	0
Non Backlog	1	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

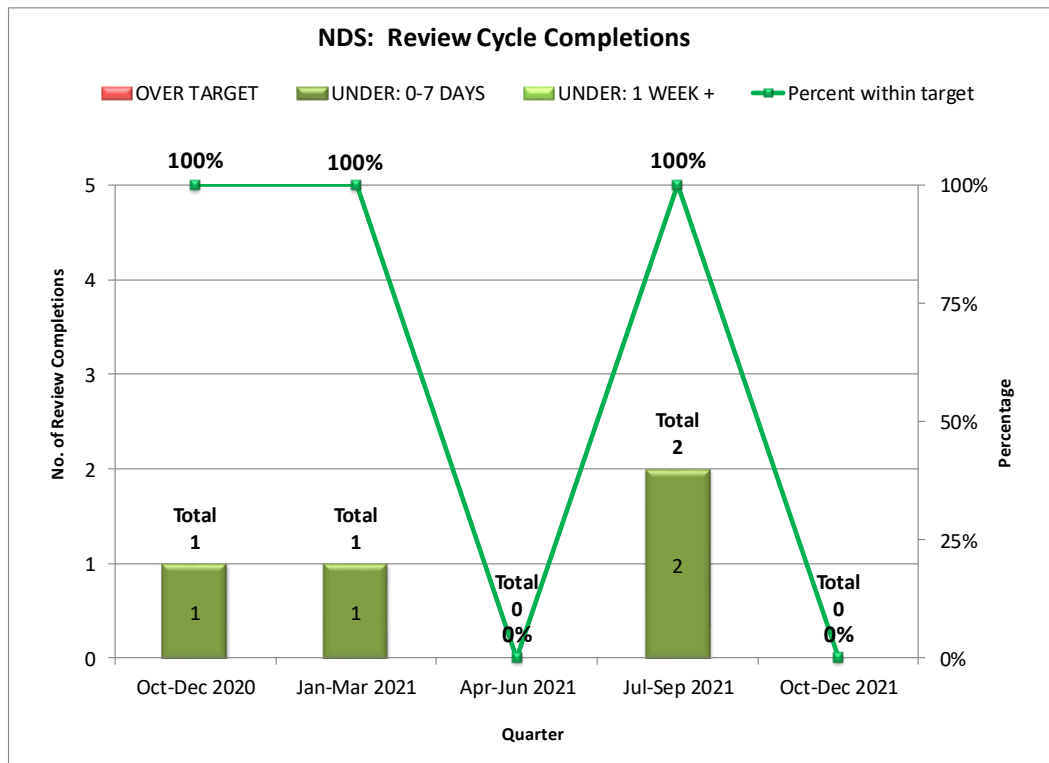
NDS: Number of Decisions by Fee Category

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 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
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	CANCELLATION LETTER	0	0	1	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	1	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
	NOC ON HOLD (SWITCH)*	0	0	0	1	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

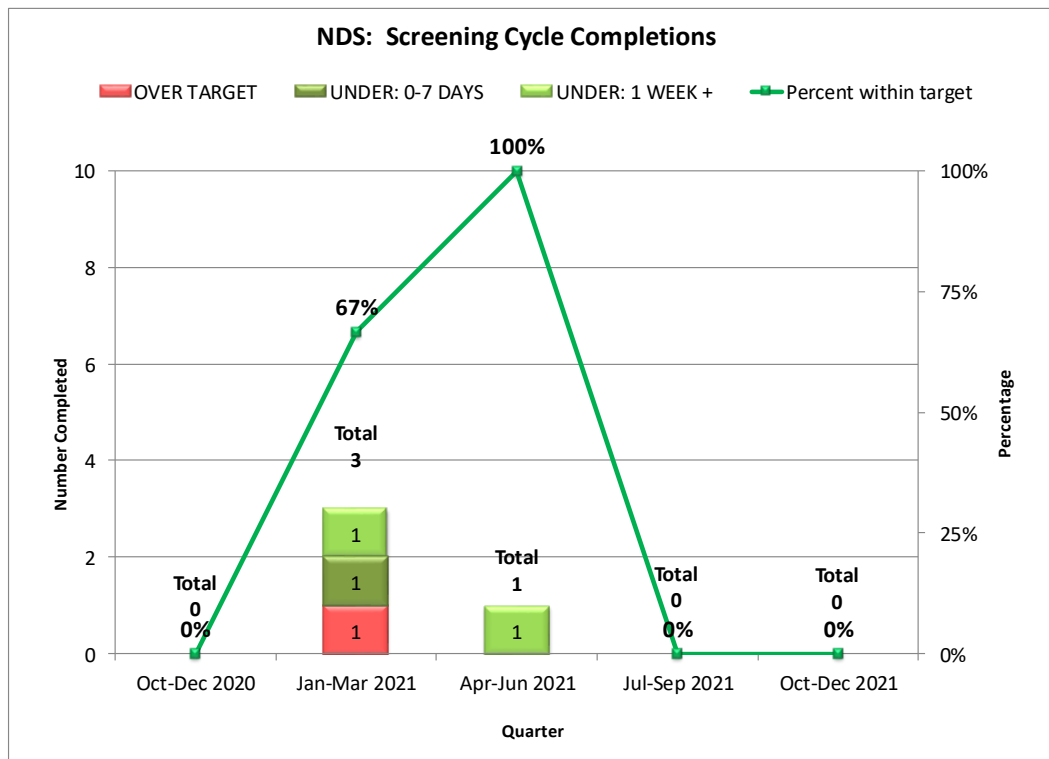
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions

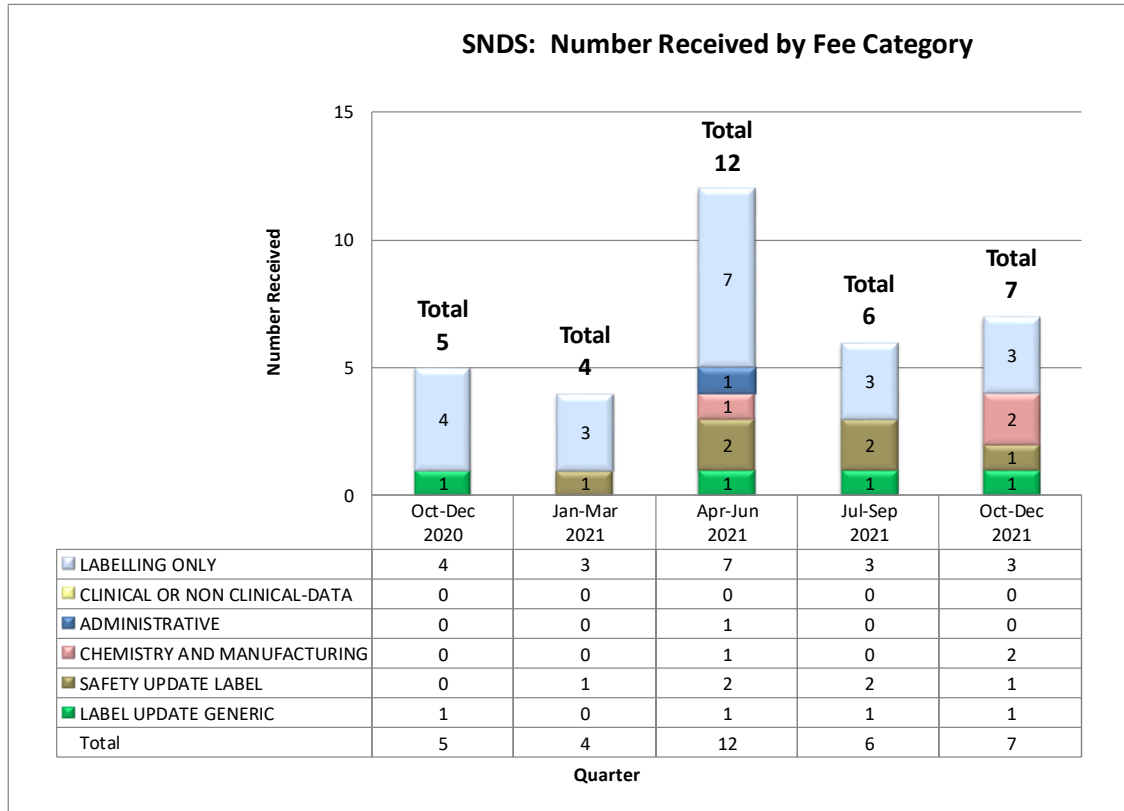


NDS: Screening Cycle Completions



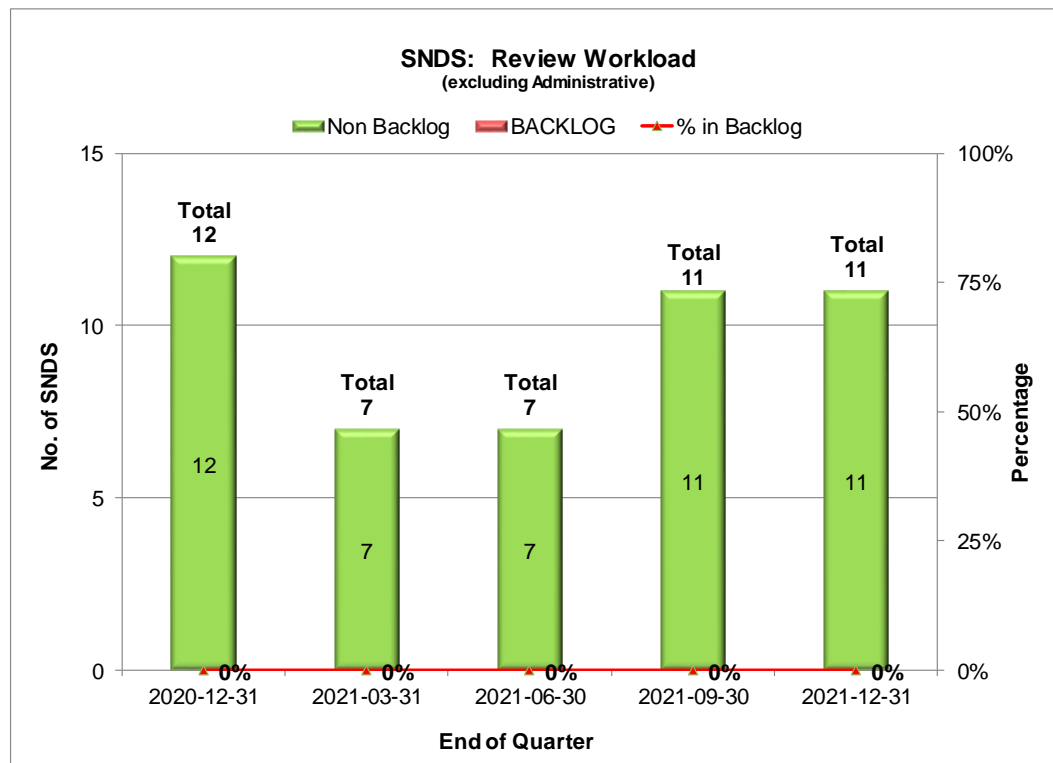
SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

SNDS: Number Received by Fee Category



WORKLOAD

SNDS: Review Workload

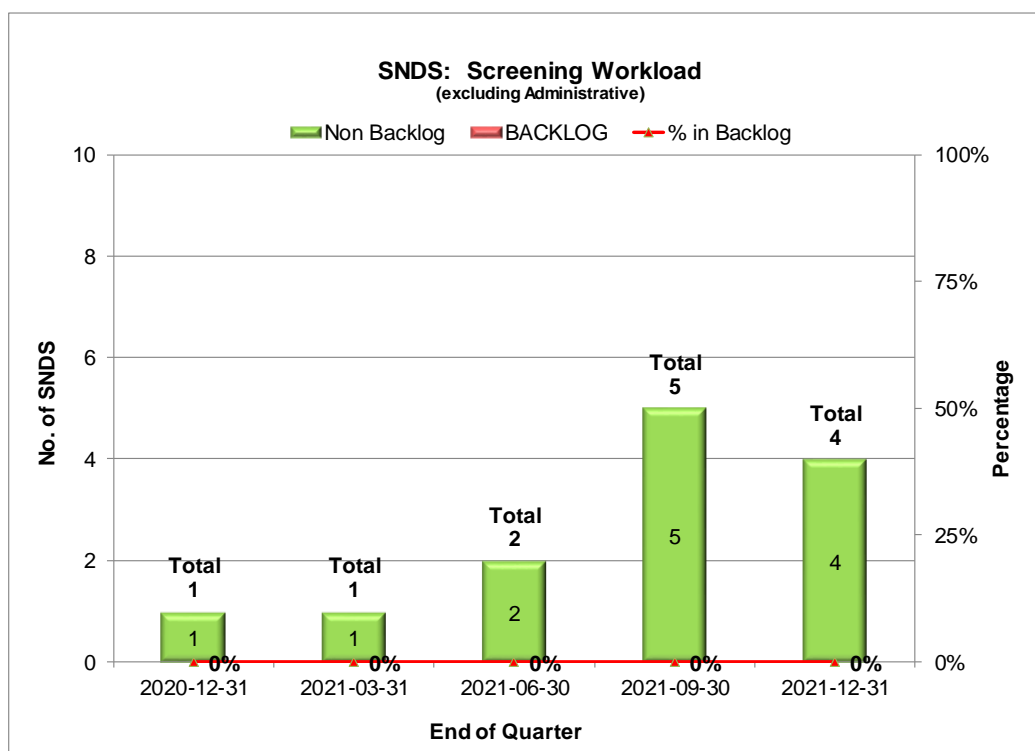


SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Clinical or Non-Clinical Data	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	10	4	5	9	6
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	1	1	0
Backlog	0	0	0	0	0
Label Update Generic	1	2	0	0	1
Backlog	0	0	0	0	0
Safety Update Label	1	1	1	1	4
Backlog	0	0	0	0	0
Total	12	7	7	11	11
Non Backlog	12	7	7	11	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

SNDS: Screening Workload



SNDS: Screening Workload by Fee Category

SNDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Chemistry and Manufacturing	0	0	0	0	2
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	0	1	2	2	1
Backlog	0	0	0	0	0
Label Update Generic	1	0	0	0	0
Backlog	0	0	0	0	0
Safety Update Label	0	0	0	3	1
Backlog	0	0	0	0	0
Total	1	1	2	5	4
Non Backlog	1	1	2	5	4
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

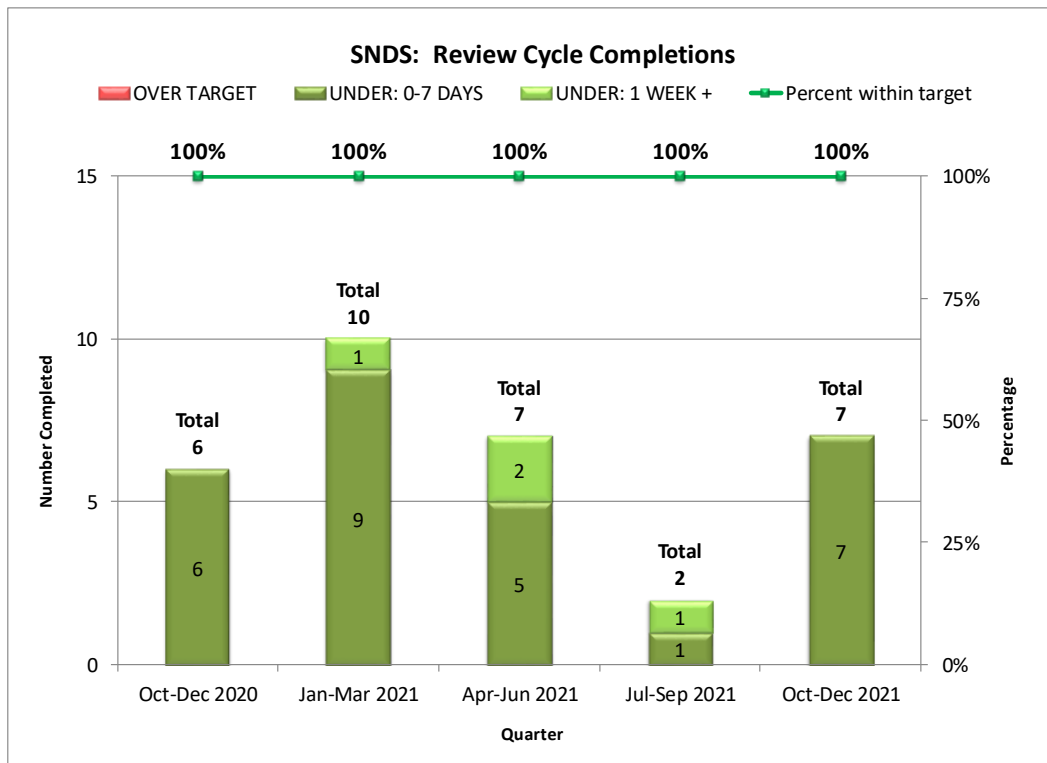
SNDS: Number of Decision by Fee Category

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	1
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*	5	8	4	1	4
	SCREENING DEFICIENCY NOTICE	0	0	1	3	2
	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	1	0	2	1	0
	CANCELLATION LETTER	0	0	0	0	2
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
SAFETY UPDATE LABEL	NOTICE OF COMPLIANCE*	0	1	1	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	3	0
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	2	0	1	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

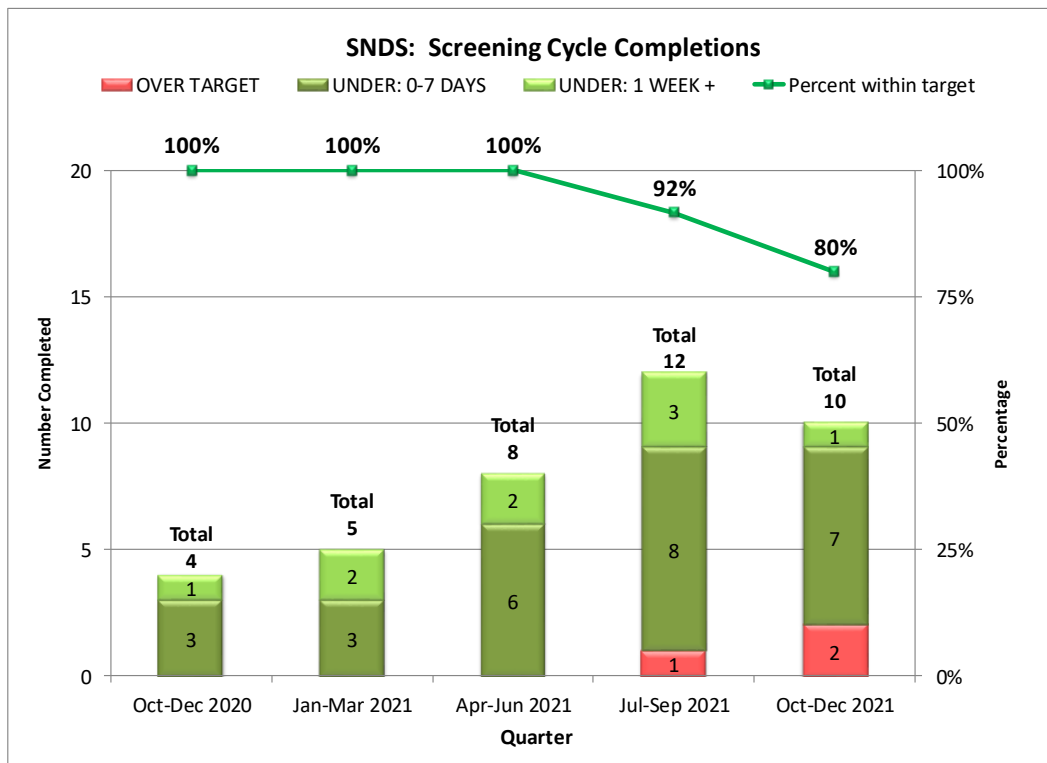
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

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	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
LABELLING ONLY	1	0	1	0	1
ADMINISTRATIVE	0	1	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	1	1	2	1	0
CHEMISTRY AND MANUFACTURING	0	0	1	0	0
<i>Total</i>	2	2	4	1	1

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Only	0	1	2	1	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	2	2	2	3
<i>Backlog</i>	0	0	0	0	1
Chemistry and Manufacturing	1	1	0	1	2
<i>Backlog</i>	0	0	0	0	0
Total	2	4	4	4	5
Non Backlog	2	4	4	4	4
BACKLOG	0	0	0	0	1
% in Backlog	0%	0%	0%	0%	20%

ANDS: Screening Workload

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

ANDS: Administrative-Screening Workload

ANDS: ADMINISTRATIVE SCREENING WORKLOAD By End of Quarter					
	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Total	0	1	0	0	0
Non Backlog	0	1	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE**ANDS: Review Performance**

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

ANDS: Screening Performance

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

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

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

*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	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
ADMINISTRATIVE	6	2	1	0	0
CHEMISTRY AND MANUFACTURING	0	1	0	0	0
LABEL UPDATE GENERIC	3	2	0	0	1
LABELLING ONLY	10	5	11	13	7
<i>Total</i>	19	10	12	13	8

WORKLOAD

SANDS: Review Workload

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Only	11	7	12	9	16
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	2	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	4	4	1	1	0
<i>Backlog</i>	0	0	0	0	0
Total	17	13	13	10	16
Non Backlog	17	13	13	10	16
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Screening Workload

SANDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Only	6	4	3	7	2
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	1	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	7	4	3	7	3
Non Backlog	7	4	3	7	3
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Administrative-Screening Workload

SANDS: ADMINISTRATIVE-SCREENING WORKLOAD by End of Quarter					
	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Total	2	2	0	0	0
Non Backlog	2	2	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE**SANDS: Review Performance**

SANDS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2020	0	2	0	100%	2
Jan-Mar 2021	0	10	0	100%	10
Apr-Jun 2021	0	11	1	100%	12
Jul-Sep 2021	0	8	1	100%	9
Oct-Dec 2021	0	4	2	100%	6

SANDS: Screening Performance

SANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2020	0	7	3	100%	10
Jan-Mar 2021	1	10	3	93%	14
Apr-Jun 2021	0	3	12	100%	15
Jul-Sep 2021	0	7	0	100%	7
Oct-Dec 2021	0	11	2	100%	13

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

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
LABELLING ONLY	NOTICE OF COMPLIANCE *	4	10	6	9	5
	SCREENING DEFICIENCY NOTICE	0	2	3	0	0
	CANCELLATION LETTER	0	1	0	0	1
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	6	3	3	0	0
	CANCELLATION LETTER	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	2	0	0	0	0
CHEMISTRY AND MANUFACTURING	SCREENING DEFICIENCY NOTICE	2	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	2	0	1
	NOTICE OF NON-COMPLIANCE	0	0	2	0	0
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	2	0	2	0	0
	CANCELLATION LETTER	2	3	0	0	0
	SCREENING DEFICIENCY NOTICE	2	2	0	0	0

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

PRE-MEETINGS**MPDIN: Number Received by Fee Category**

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

MPNDS: Number Received by Fee Category

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

MPSNDS: Number Received by Fee Category

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

PART 2: DISINFECTANT PRODUCTS

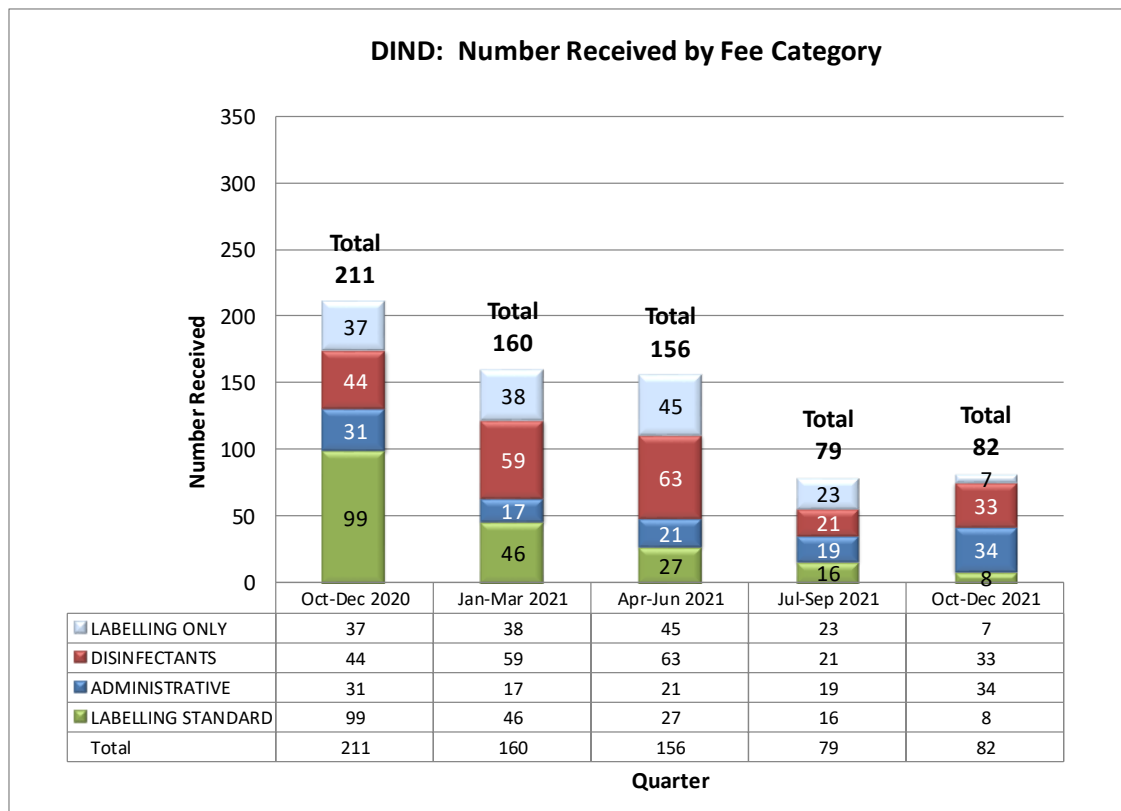
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

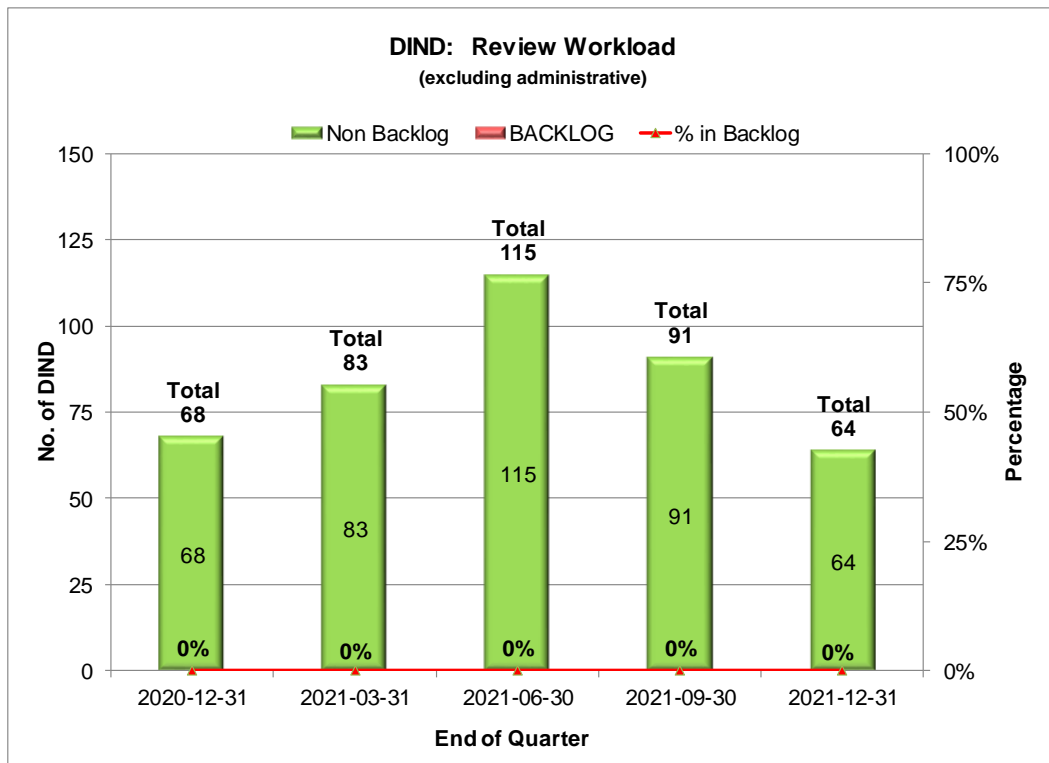
RECEIVED

DIND-Disinfectant Products: Number Received by Fee Category

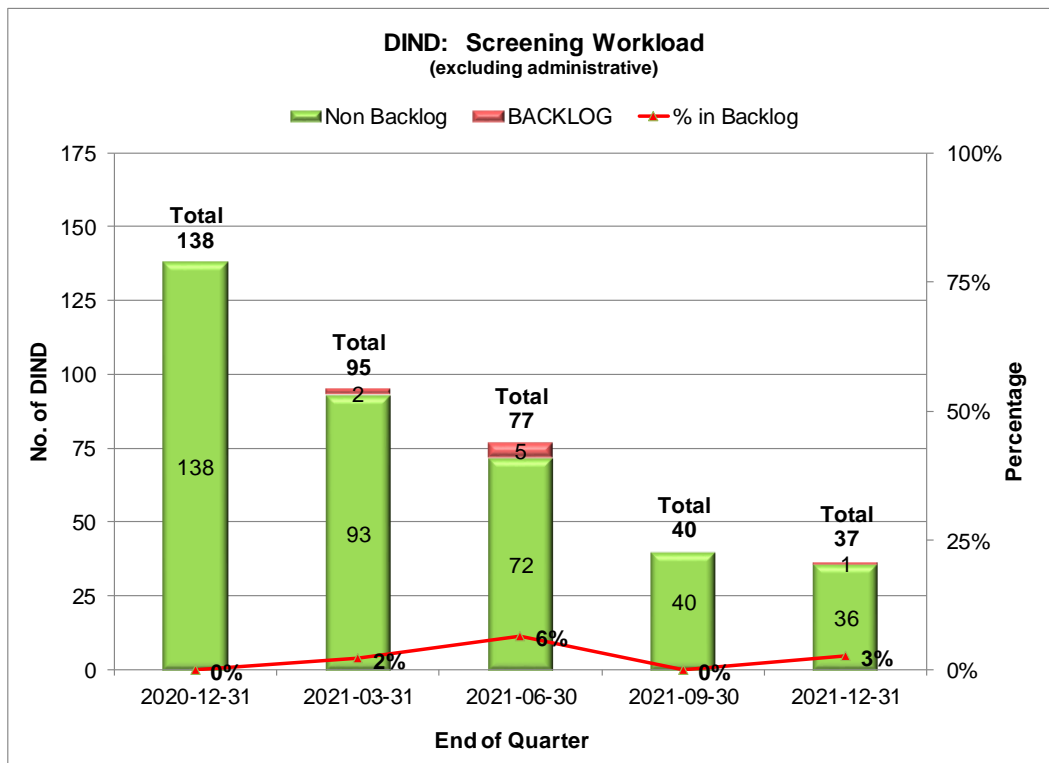


WORKLOAD

DIND-Disinfectant Products: Review Workload

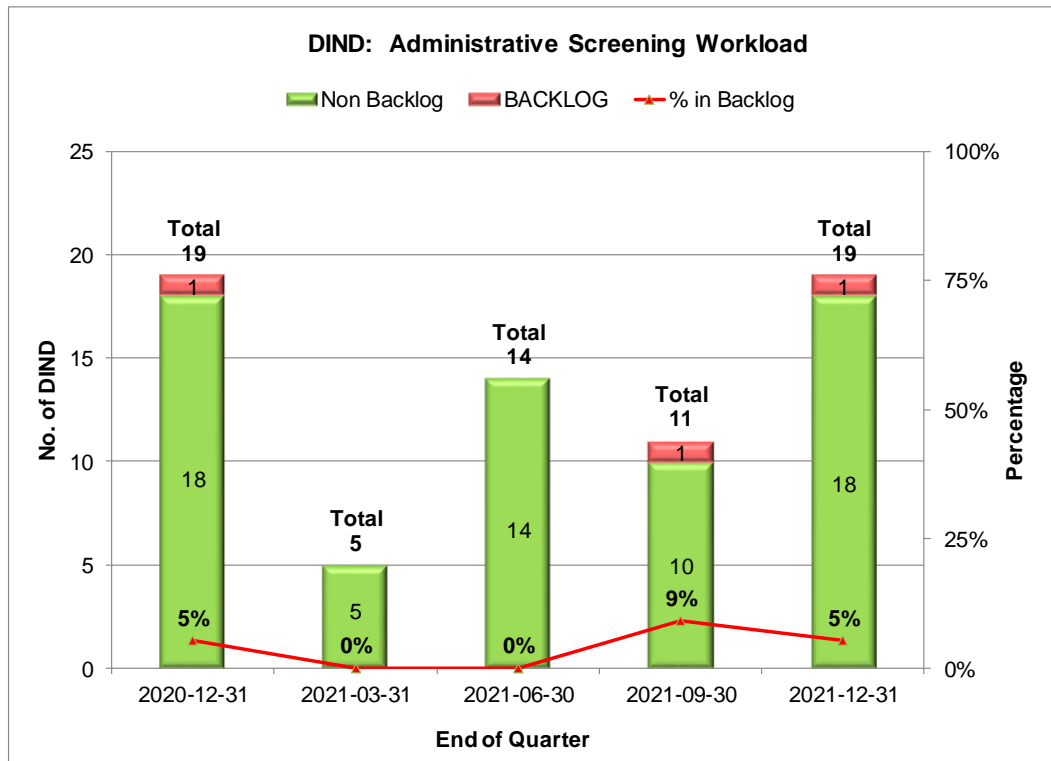


DIND-Disinfectant Products: Screening Workload



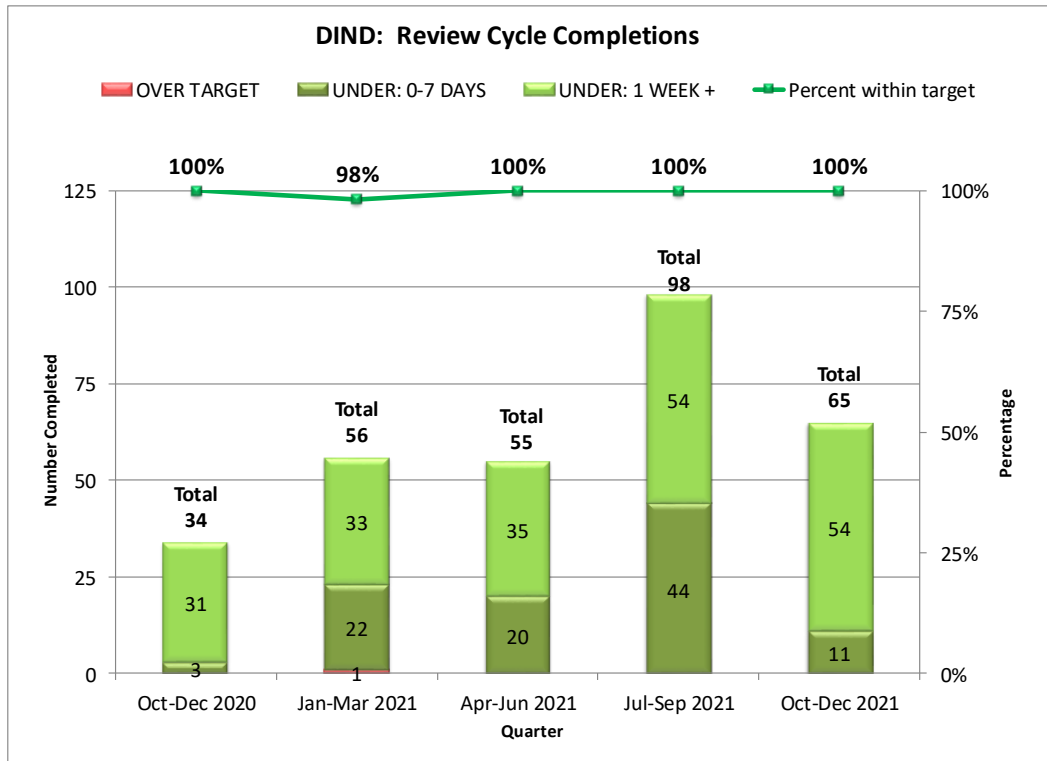
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

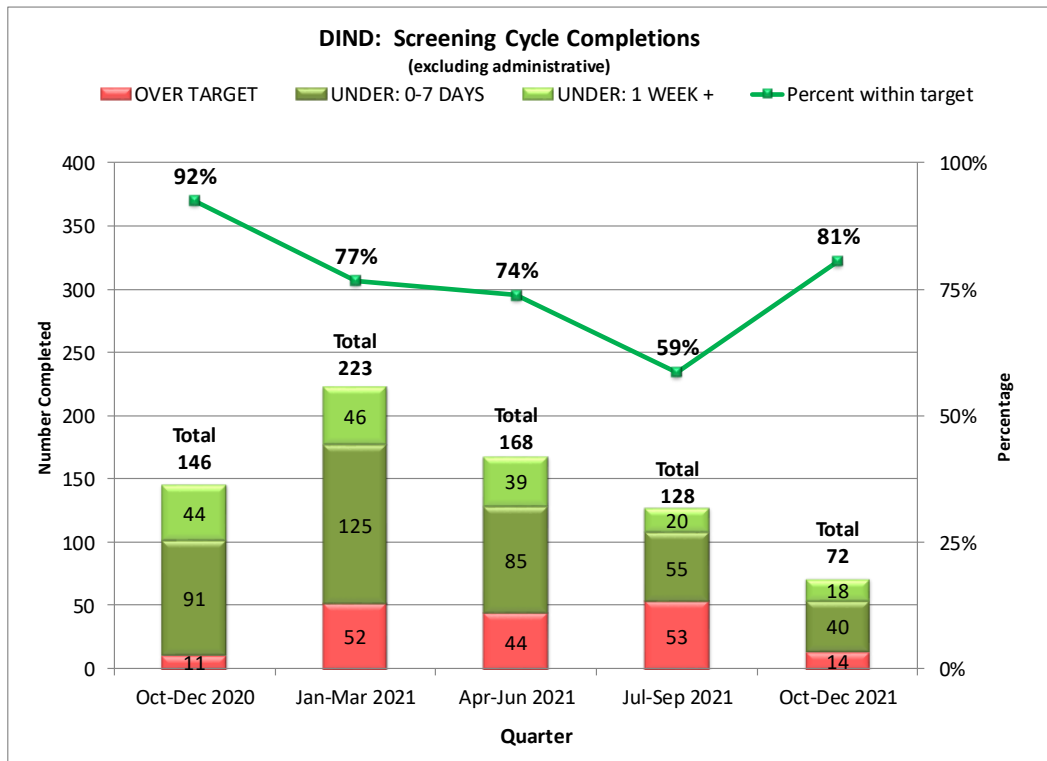


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

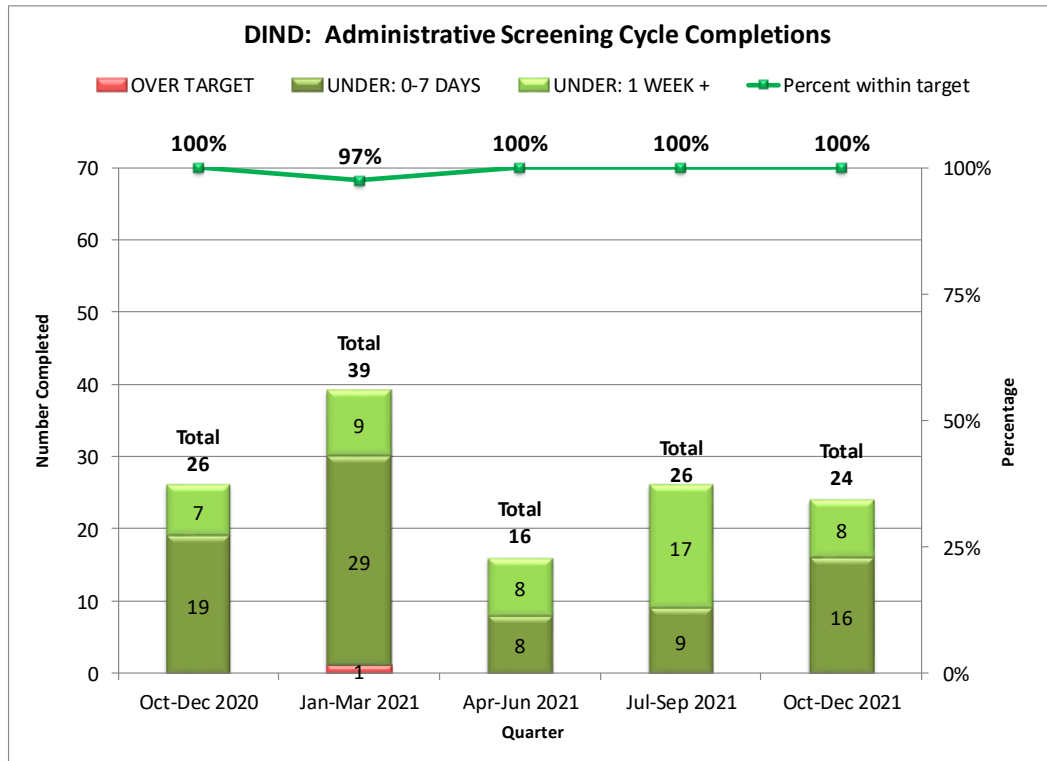


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



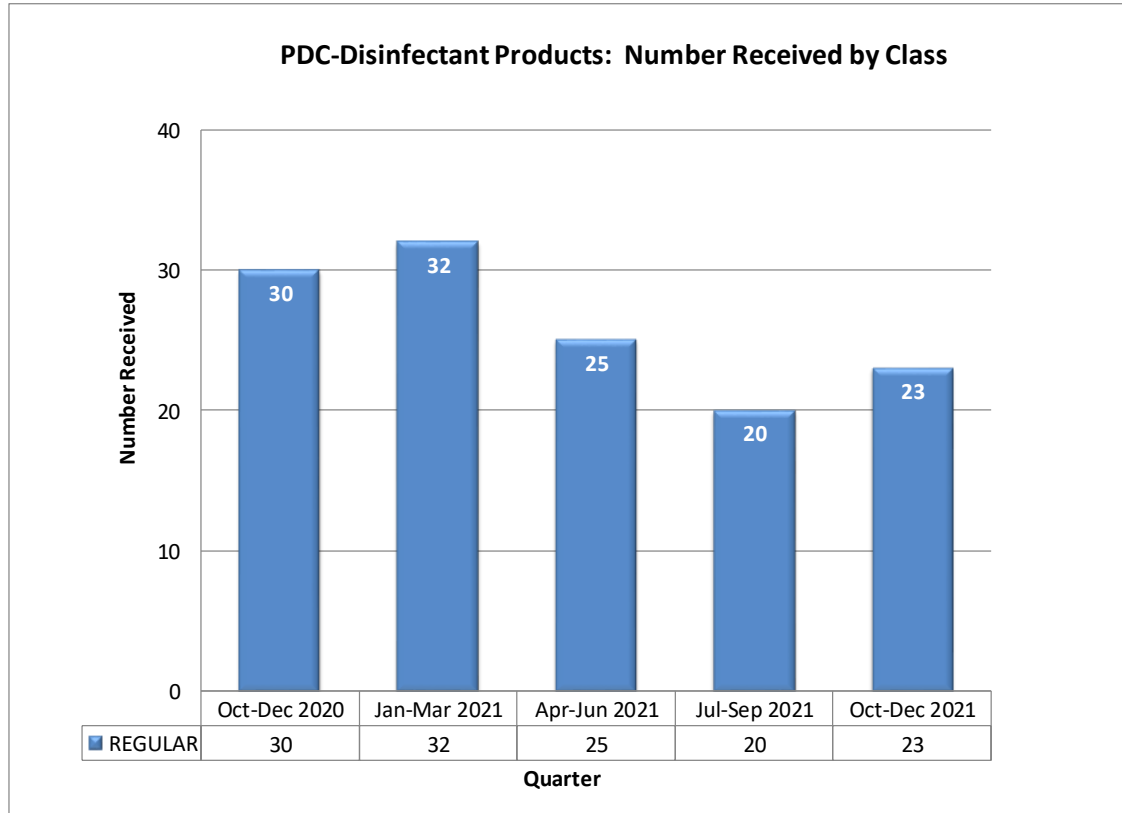
DECISIONS**DIND-Disinfectant Products: Number of Decisions by Fee Category**

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
ADMINISTRATIVE	CANCELLATION LETTER	4	8	7	9	2
	NO OBJECTION LETTER	0	0	1	3	7
	NOTIFICATION FORM DIN SUB	17	22	8	10	12
	REJECTION LETTER (SCR)	1	4	2	0	0
	SCREENING DEFICIENCY NOTICE	20	10	4	10	3
DISINFECTANTS	NO OBJECTION LETTER	22	12	19	22	13
	CANCELLATION LETTER	4	9	7	12	6
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	1	0	0
	NOTICE OF NON-COMPLIANCE	3	1	2	2	2
	NOTIFICATION FORM DIN SUB	5	12	12	16	21
	SCREENING DEFICIENCY NOTICE	12	11	22	13	7
	REJECTION LETTER (SCR)	8	1	1	4	4
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	59	79	35	19	11
	NO OBJECTION LETTER	0	2	1	0	0
	SCREENING DEFICIENCY NOTICE	40	22	9	9	5
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	REJECTION LETTER (SCR)	3	7	0	1	1
	CANCELLATION LETTER	6	13	10	4	4
DISINFECTANT LABELLING ONLY	NOTIFICATION FORM DIN SUB	22	27	18	43	18
	NO OBJECTION LETTER	1	1	0	12	8
	CANCELLATION LETTER	2	10	5	1	0
	SCREEN. DEFICIENCY NOTICE	5	7	0	2	4
	NOTICE OF NON-COMPLIANCE	2	2	3	2	1
	REJECTION LETTER (SCR)	1	0	0	0	0

PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

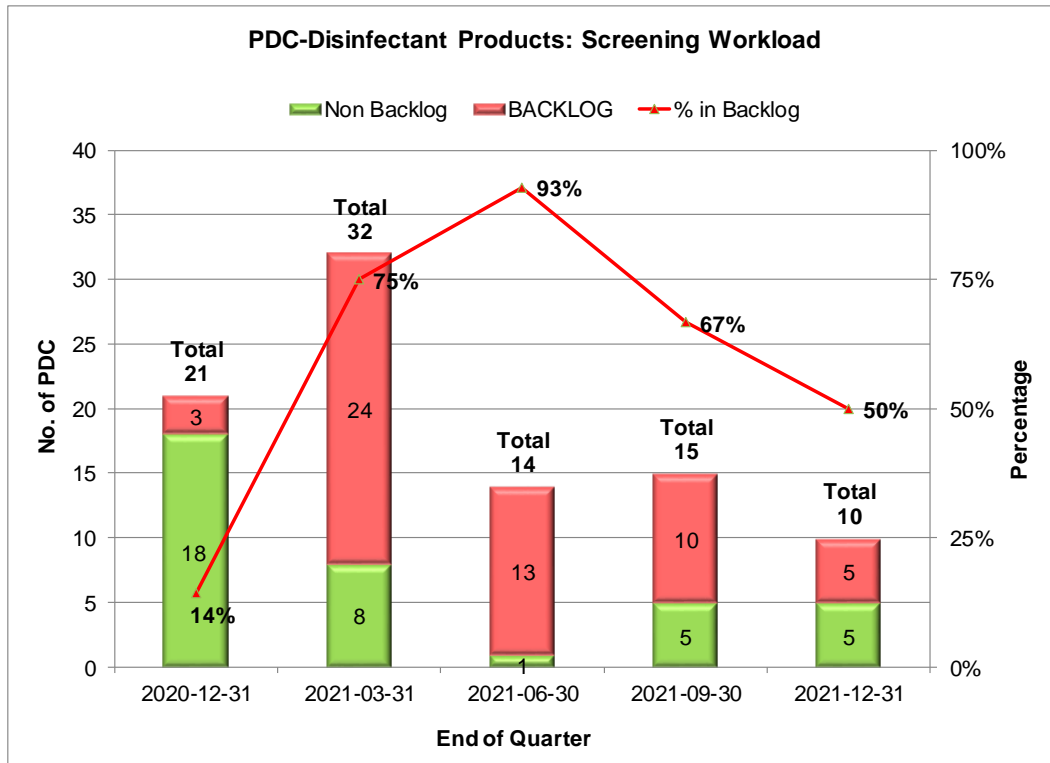
RECEIVED

PDC-Disinfectant Products: Received by Fee Class



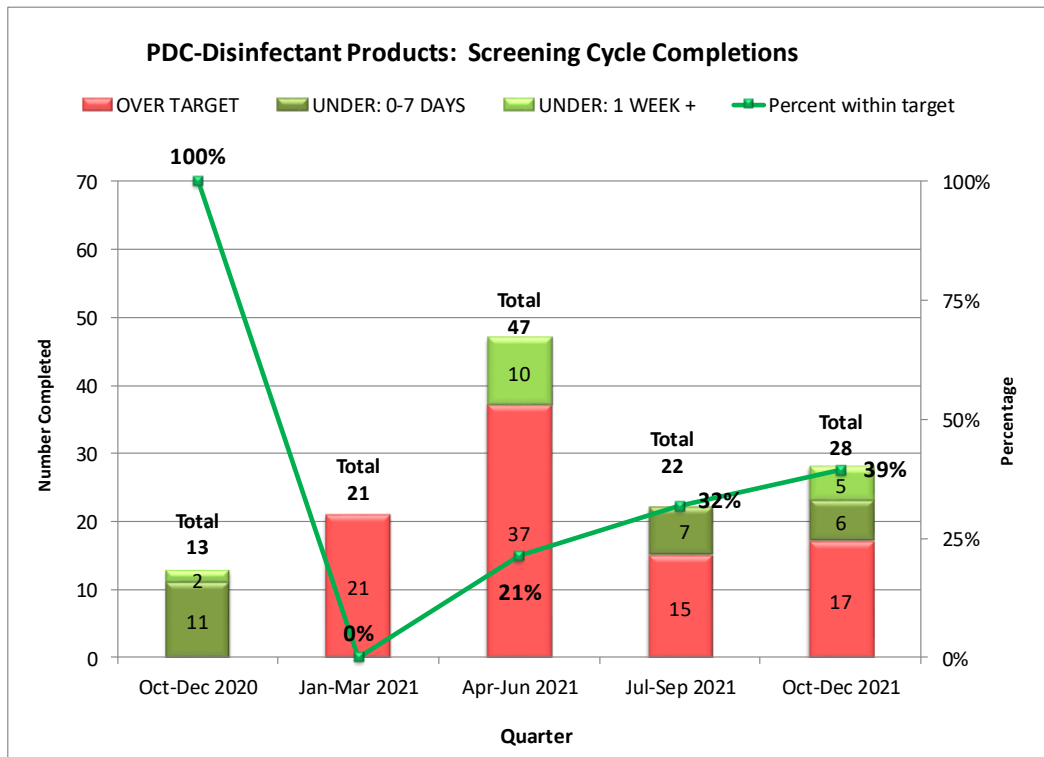
WORKLOAD

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	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
REGULAR	CANCELLATION LETTER	2	1	11	3	5
	NO OBJECTION LETTER	14	17	30	13	22
	NOT SATISFACTORY NOTICE	5	2	6	3	1
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	REJECTION LETTER (SCR)	0	1	0	0	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	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
ADMINISTRATIVE	0	0	0	0	0
DISINFECTANTS	1	1	1	2	3
<i>Total</i>	1	1	1	2	3

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

NDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Disinfectants	0	1	2	3	1
<i>Backlog</i>	0	0	0	0	0
Total	0	1	2	3	1
Non Backlog	0	1	2	3	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Screening Workload

NDS-D Disinfectant Products: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Disinfectants	1	1	1	2	1
<i>Backlog</i>	0	0	0	1	0
Total	1	1	1	2	1
Non Backlog	1	1	1	1	1
BACKLOG	0	0	0	1	0
% in Backlog	0%	0%	0%	50%	0%

NDS-Disinfectant Products: Administrative-Screening Workload

NDS-D: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Administrative	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	0
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

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

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

NDS-Disinfectant Products: Screening Performance

NDS-D SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Oct-Dec 2020	0	1	0	100%	1
Jan-Mar 2021	1	1	0	50%	2
Apr-Jun 2021	2	1	0	33%	3
Jul-Sep 2021	0	1	0	100%	1
Oct-Dec 2021	2	2	0	50%	4

NDS-Disinfectant Products: Administrative-Screening Performance

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

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

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 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	1
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	1
	CANCELLATION LETTER	0	0	0	0	3
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	1	2	0	4

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

SUBMISSIONS RECEIVED

SNDS-Disinfectant Products: Number Received by Fee Category

SNDS-D - SUPPLEMENT TO A NEW DRUG SUBMISSION DISINFECTANT PRODUCTS					
Fee Category	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
DISINFECTANTS	1	0	1	1	0
LABELLING ONLY DISINFECTANT	0	0	0	1	0
<i>Total</i>	<i>1</i>	<i>0</i>	<i>1</i>	<i>2</i>	<i>0</i>

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

SNDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Disinfectants	1	1	1	0	2
<i>Backlog</i>	0	0	0	0	0
Total	1	1	1	0	2
Non Backlog	1	1	1	0	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SNDS-Disinfectant Products: Screening Workload

SNDS-D Disinfectant Products: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Disinfectants	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
Disinfectant Label Only	0	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
Total	0	0	1	2	0
Non Backlog	0	0	1	2	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

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

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

SNDS-Disinfectant Products: Screening Performance

SNDS-D SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Oct-Dec 2020	0	0	1	100%	1
Jan-Mar 2021	0	0	0	-	0
Apr-Jun 2021	0	0	0	-	0
Jul-Sep 2021	1	0	0	0%	1
Oct-Dec 2021	1	1	1	67%	3

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

Fee Category	Decision Document Type	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
DISINFECTANTS	NOTICE OF COMPLIANCE*	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
DISINFECTANT LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	0	1

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

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

MPNDS-Disinfectant Products: Received by Fee Category

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

MPSNDS-Disinfectant Products: Received by Fee Category

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