Health Canada Santé Canada

# Natural and Non-Prescription Health Products Directorate

## Drug Submission Performance Quarterly Report January - March 2022

Canada

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Direction des produits de santé naturels et sans ordonnance - Rapport trimestriel du rendement des présentations de drogue - janvier - mars 2022

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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 January - March 2021 to January - March 2022. Statistics are provided by Submission Type and show the number received, the number in workload and the number of licensing decisions issued over that period.

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

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately, in 2019, HPFB had implemented new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format.[1] This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.

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

- The Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was repealed and replaced on February 27, 2022 by the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations to allow sponsors to continue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

- The Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed and the number of applications and amendments in review under the ISAD Interim Order are included in the Quarterly Drug Submission Performance Reports for the Pharmaceutical Drugs Directorate (PDD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD).

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

- 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 January - March 2022 report are:

**Non-prescription Drug Submissions:**

• 15 DINA submissions were received in Q4 2021-2022. This represents a 48% decrease compared to Q3 2021-2022 (29), a 38% decrease compared to Q2 and Q1 2021-2022 (24), and a 47% decrease compared to Q4 2020-2021 (28).

• 39 DINF submissions were received in Q4 2021-2022. This represents a 56% increase compared to Q3 2021-2022 (25), a 17% decrease when compared to Q2 2021-2022 (47), a 244% increase compared to Q1 2021-2022 (16) and a 26% increase compared to Q4 2020-2021 (31).

• 48 PDC submissions were received in Q4 2021-2022. This represents a 55% increase compared to Q3 2021-2022 (31), a 8% decrease compared to Q2 2021-2022 (52), a 38% decrease compared to Q1 2021-2022 (77) and a 4% decrease compared to Q4 2020-2021 (50).

• No NDS submissions were received in Q4, Q3, Q2 and Q1 2021-2022, while 1 NDS submission was received in Q4 2020-2021.

• 10 SNDS submissions were received in Q4 2021-2022. This represents a 43% increase compared to Q3 2021-2022 (7), a 25% increase compared to Q2 2021-2022 (8), a 23% decrease compared to Q1 2021-2022 (13) and a 250% increase compared to Q4 2020-2021 (4).

• 2 ANDS submissions were received in Q4 2021-2022. This represents twice the ANDS submissions received in Q3 2021-2022 (1) and Q2 2021-2022 (1), respectively. This represents a 33% decrease compared to Q1 2021-2022 (3) and no difference compared to Q4 2020-2021 (2).

• 8 SANDS submissions were received in Q4 2021-2022 and Q3 2021-2022, respectively. This represents a 27% decrease compared to Q2 and Q1 2021-2022 (11), and a 20% decrease compared to Q4 2020-2021 (10).

Overall, the total non-prescription drug submissions received in Q4 2021-2022 (122) increased by 21% compared to Q3 2021-2022 (101), decreased by 15% compared to Q2 2021-2022 (143) and Q1 2021-2022 (144), and decreased by 3% when compared to Q4 2020-2021 (126).

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 Q4 2021-2022 remained very good, as backlogs were avoided in most categories.

**Disinfectant Drug Submissions:**
87 DIN-D submission were received in Q4 2021-2022. This represents a 6% increase compared to Q3 2021-2022 (82), a 10% increase compared to Q2 2021-2022 (79), a 44% decrease compared to Q1 2021-2022 (156) and a 46% decrease compared to Q4 2020-2021 (160).

• 19 PDC submissions were received in Q4 2021-2022. This represents a 17% decrease compared to Q3 2021-2022 (23), a 5% decrease compared to Q2 2021-2022 (20), a 27% decrease compared to Q1 2021-2022 (26) and a 41% decrease compared to Q4 2020-2021 (32).

• 1 NDS-D submission was received in Q4 2021-2022. This represents a 67% decrease compared to Q3 2021-2022 (3), a 50% decrease compare to Q2 2021-2022 (2) and no difference compared to Q1 2021-2022 (1) and Q4 2020-2021 (1).

• No SNDS-D submissions were received in Q4 2021-2022 and Q3 2021-2022. 2 SNDS-D submissions were received in Q2 2021-2022 which represented a significant increase compared to Q1 2021-2022 (1). No SNDS-D submissions were received in Q4 2020-2021.

Overall, the total disinfectant drug submissions received in Q4 2021-2022 (107) decreased by 1% compared to Q3 2021-2022 (108), increased by 4% compared to Q2 2021-2022 (103), decreased by 42% compared to Q1 2021-2022 (183) and decreased by 45% compared to Q3 2020-2021 (195).

The volume of submissions received in Q4 2021-2022 (107) decreased compared to Q4 2020-2021 (195) but remained higher than pre-pandemic volumes, despite the continued reduction in received submission volume over the fiscal year. The submissions received in Q4 2021-2022 were evenly distributed among the submission streams as observed in Q3 and Q2 2021-2022. This is in contrast to Q3 and Q4 2020-2021 and Q1 2021-2022 where the majority of the submission received were full reviews.

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. Although this was observed for Q3 2021-2022, due to larger data packages, there was a 256% increase in screening cycle completions over target for Full Review submissions in Q4 2021-2022 (23) compared to Q3 2021-2022 (9).

Despite total submissions received decreasing in Q3 2021-2022, and Q4 2021-2022 full review submissions have represented over 60% of the workload consistently over the four quarters of FY 2021-2022 Furthermore, full review submissions received following the end of expedited deadlines have had larger data packages given that sponsors were limited to only three pathogens to have their submissions expedited.

Overall, the reduced volume of PDCs in Q2, Q3 and Q4 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 expedited timelines ended October 1, 2021-2022 the screening cycle completions over target for PDC submissions were expected to decrease, however the volumes in Q2 2021-2022 (15), Q3 2021-2022 (17) and Q4 2021-2022 (19) have 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) that require more in-depth review leading to challenges in meeting the 30 days performance standard.

Although there was a general decrease in submissions received in Q2, Q3 and Q4 2021-2022 compared to FY 2020-2021, significant increase in submissions received was seen in the NDS-D (6) and SNDS-D (2) submissions category over the last three quarters. This represents a significant increase compared to Q1 2021-2022 (1), Q4 2020-2021 (1) and Q2 2020-2021 (1).

## General Information

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

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

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

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

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

For new drugs, **approvals** are Notice of Compliances (NOC) Issued or Issuable which are reported in the Decisions' section. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to changes from Prescription to 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 days[4]) is compared to a set performance standard which is based on the type of submission, class and cycle (status).

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

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

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

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

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

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

# ACRONYMS

## Submission Types

| | | |
|---|---|---|
| ANDS | - | Abbreviated New Drug Submission |
| CTA | - | Clinical Trial Application |
| CTA-A | - | Clinical Trial Application - Amendment |
| DINA | - | Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard |
| DINB | - | Application for a Drug Identification Number for a biological product |
| DIND | - | Application for a Drug Identification Number for a disinfectant product |
| DINF | - | Application for a Drug Identification Number for a Category IV Monograph Product |
| EUANDS | - | Abbreviated Extraordinary Use New Drug Submission |
| EUNDS | - | Extraordinary Use New Drug Submission |
| EUSANDS | - | Supplement to an Abbreviated Extraordinary Use New Drug Submission |
| EUSNDS | - | Supplement to an Extraordinary Use New Drug Submission |
| MPNDS | - | Pre-Submission Meeting New Drug Submission |
| MPSNDS | - | Pre-Submission Meeting Supplement to a New Drug Submission |
| NC | - | Notifiable Change |
| NDS | - | New Drug Submission |
| NDS-D | - | New Drug Submission for Disinfectant products |
| PDC | - | Post-authorization Division 1 Change for a pharmaceutical product |
| PDC-B | - | Post-authorization Division 1 Change for a 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 |

| Fee Category | Description |
|---|---|
| **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) |
| **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.

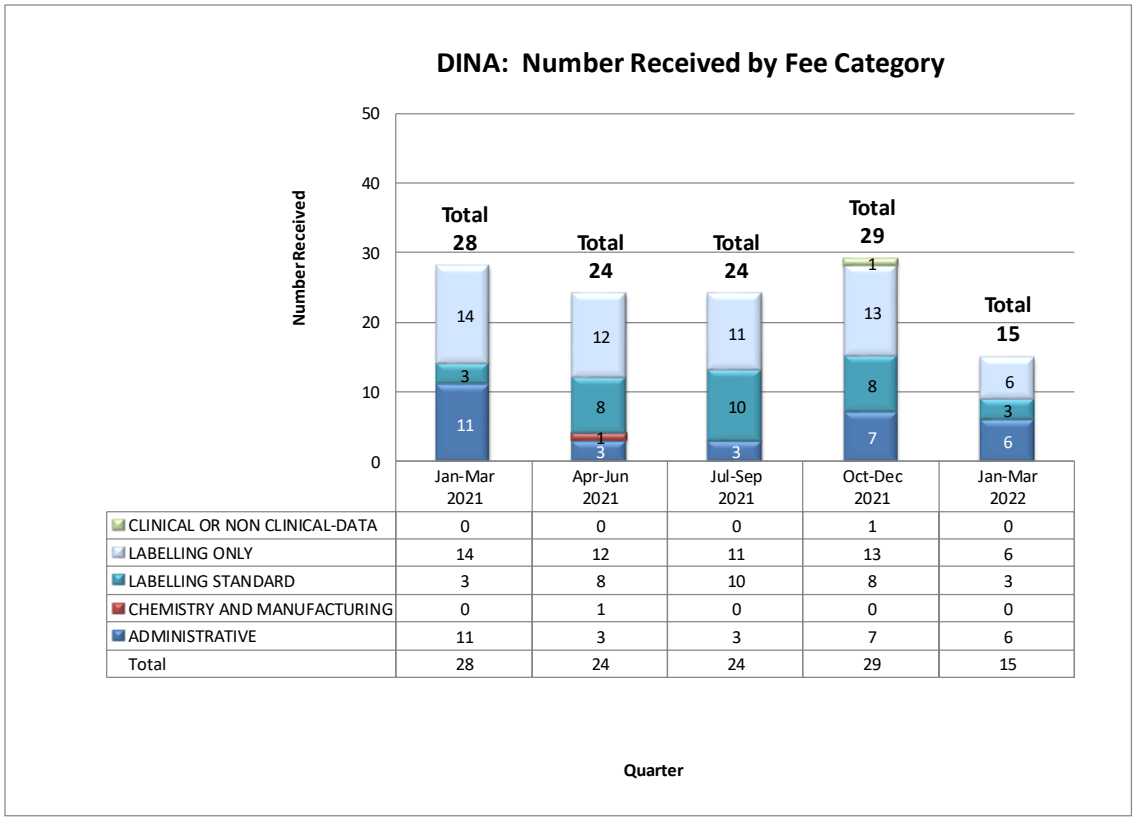
# PART 1: NON-PRESCRIPTION DRUGS
# Over the counter (OTC) Drugs

## 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

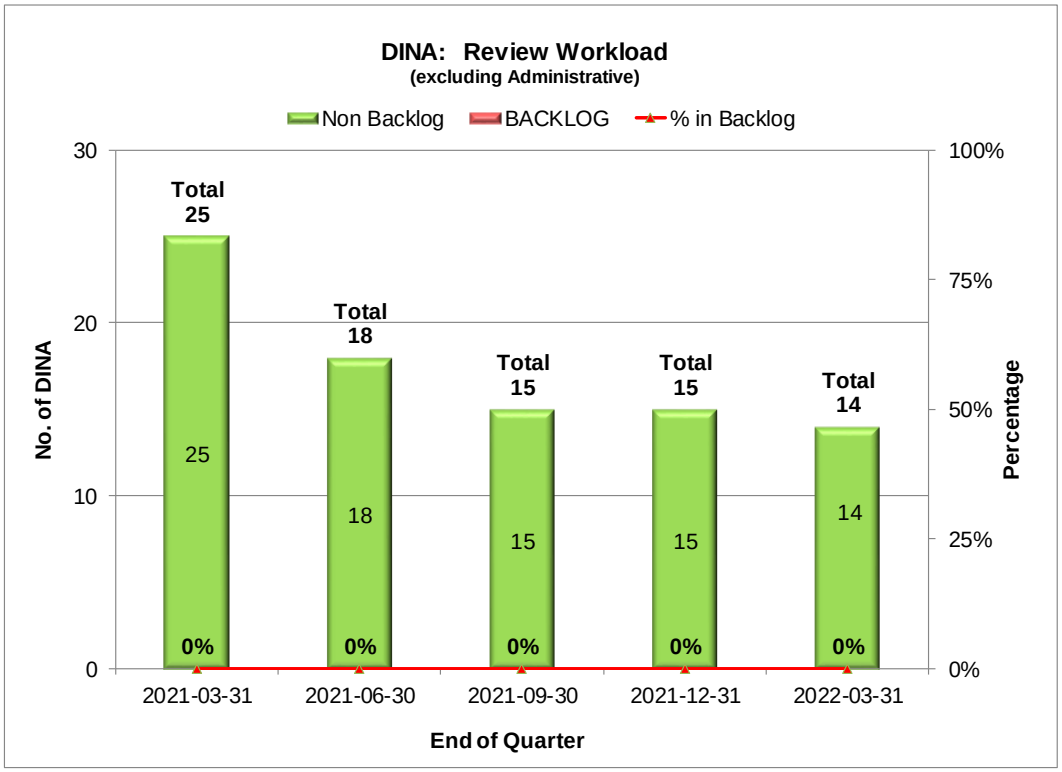
## DINA: Number Received by Fee Category




| | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|
| CLINICAL OR NON CLINICAL-DATA | 0 | 0 | 0 | 1 | 0 |
| LABELLING ONLY | 14 | 12 | 11 | 13 | 6 |
| LABELLING STANDARD | 3 | 8 | 10 | 8 | 3 |
| CHEMISTRY AND MANUFACTURING | 0 | 1 | 0 | 0 | 0 |
| ADMINISTRATIVE | 11 | 3 | 3 | 7 | 6 |
| Total | 28 | 24 | 24 | 29 | 15 |

# WORKLOAD

## DINA: Review Workload

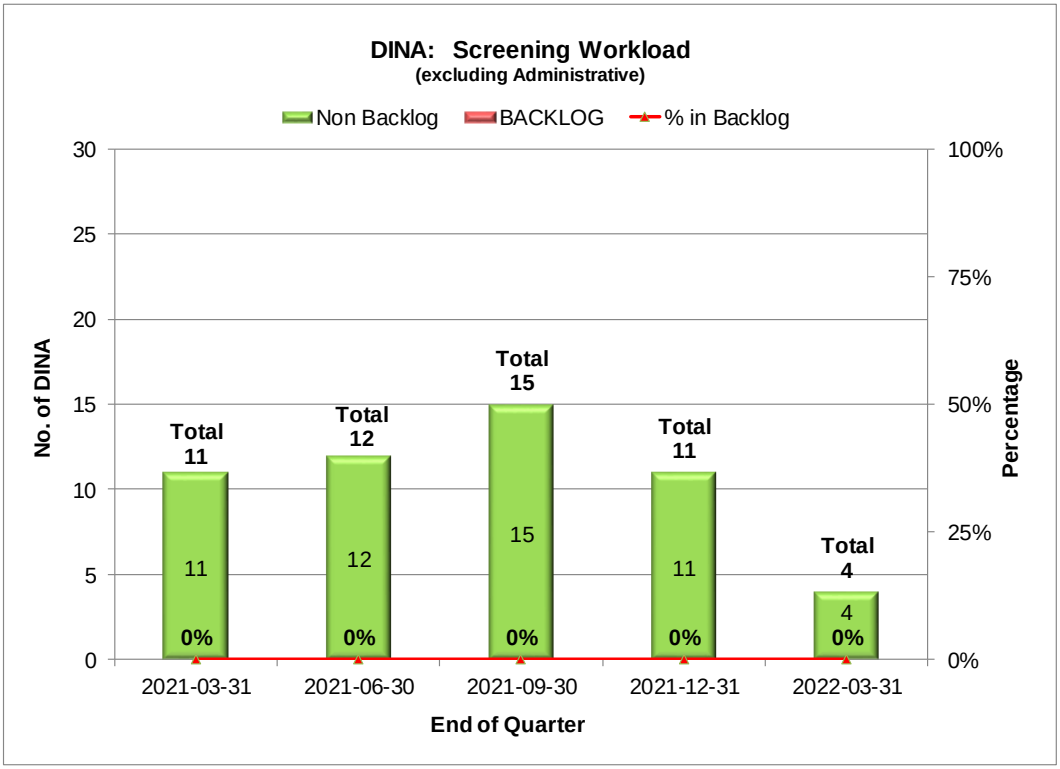



## DINA: Review Workload by Fee Category

| DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Chemistry and Manufacturing** | **4** | **4** | **1** | **1** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Clinical or Non-Clinical Data and Chemistry - Manufacturing** | ***1*** | ***0*** | ***1*** | ***1*** | ***0*** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Only** | **17** | **13** | **13** | **13** | **14** |
| *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** | **3** | **1** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **25** | **18** | **15** | **15** | **14** |
| **Non Backlog** | *25* | *18* | *15* | *15* | *14* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

# WORKLOAD

## DINA: Screening Workload

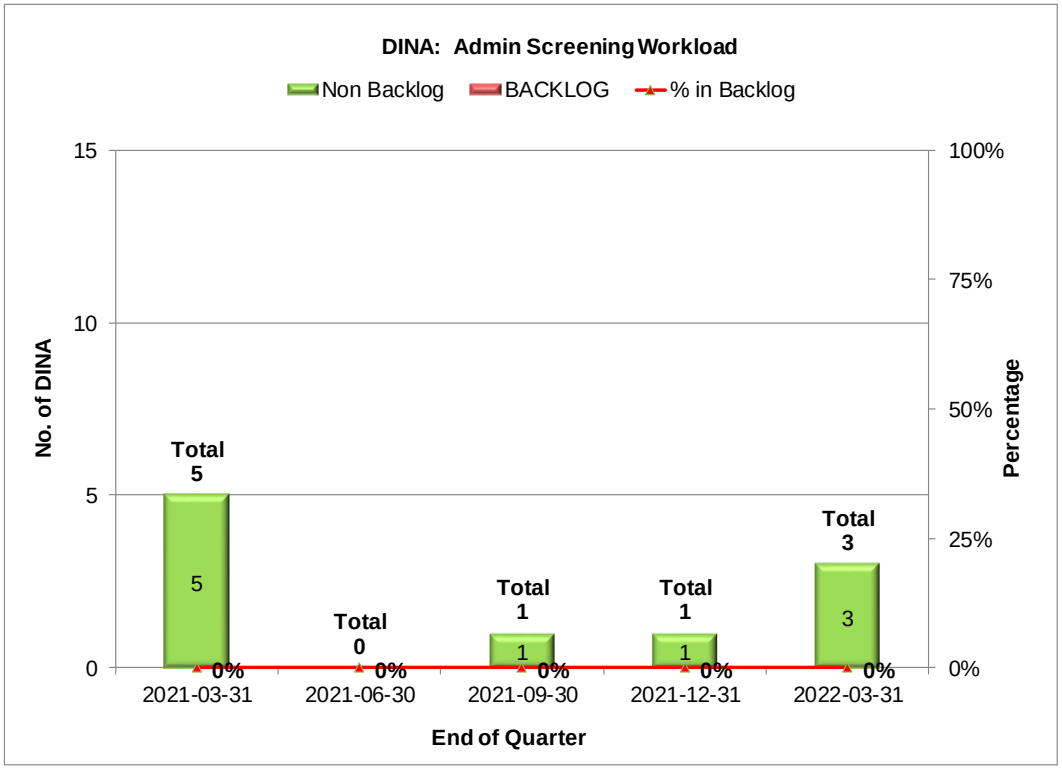



## DINA: Screening Workload by Fee Category

| DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Chemistry and Manufacturing** | **0** | **1** | **0** | **0** | **1** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Only** | **8** | **6** | **6** | **7** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Standard** | **3** | **5** | **9** | **3** | **3** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Published Data** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **11** | **12** | **15** | **11** | **4** |
| Non Backlog | *11* | *12* | *15* | *11* | *4* |
| BACKLOG | **0** | **0** | **0** | **0** | **0** |
| % in Backlog | **0%** | **0%** | **0%** | **0%** | **0%** |

# WORKLOAD

## DINA: Administrative-Screening Workload




## DINA: Administrative-Screening Workload by Fee Category

| DINA: ADMIN SCREENING WORKLOAD by End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Administrative** | **5** | **0** | **1** | **1** | **3** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **5** | **0** | **1** | **1** | **3** |
| **Non Backlog** | *5* | *0* | *1* | *1* | *3* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

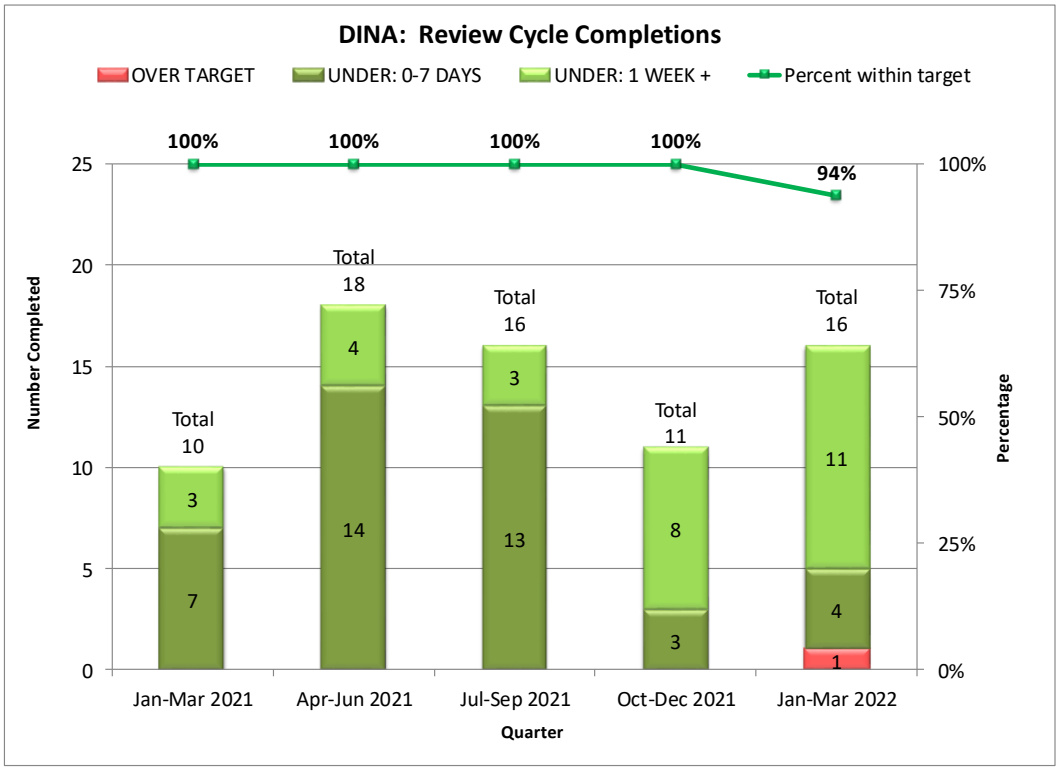
# DECISIONS

## DINA: Number of Decisions by Fee Category

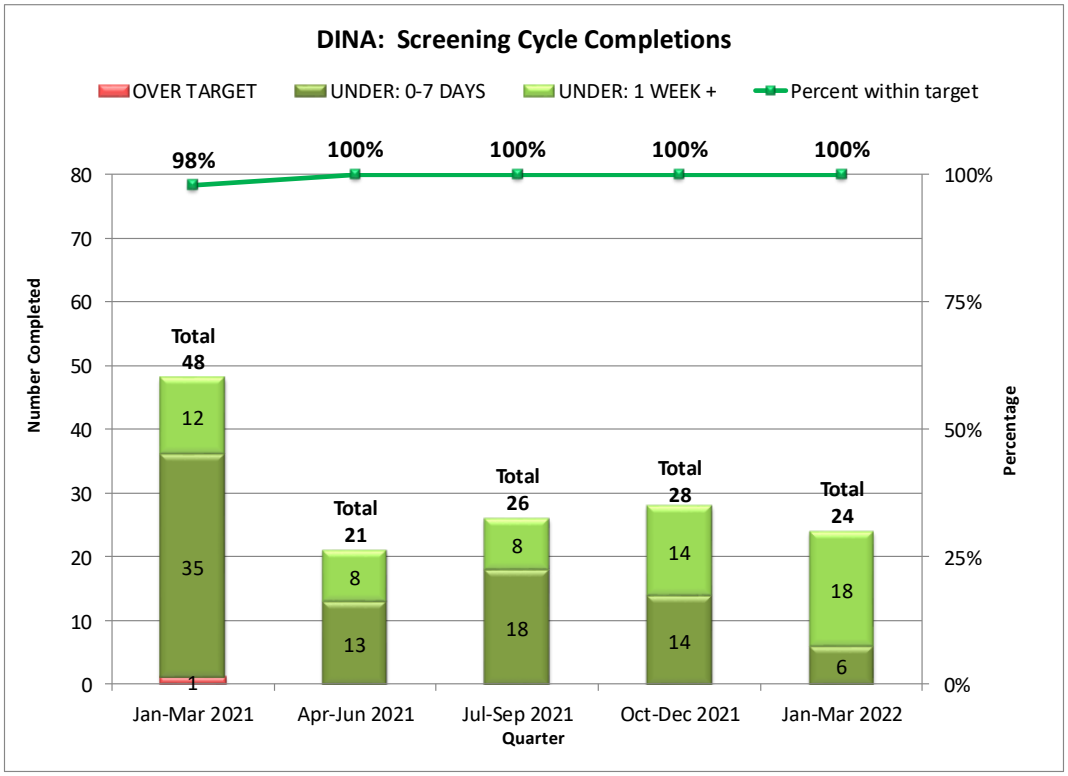
| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| ADMINISTRATIVE | CANCELLATION LETTER | 3 | 2 | 0 | 3 | 0 |
| | NOTIFICATION FORM DIN SUB | 13 | 6 | 2 | 4 | 1 |
| | REJECTION LETTER (SCR) | 1 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 1 | 0 | 1 |
| | NO OBJECTION LETTER | 0 | 2 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | NOTICE OF DEFICIENCY | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF NON-COMPLIANCE | 0 | 0 | 0 | 0 | 1 |
| | NOTIFICATION FORM DIN SUB | 0 | 0 | 2 | 0 | 0 |
| | NO OBJECTION LETTER | 0 | 0 | 2 | 0 | 0 |
| CLINICAL OR NON-CLINICAL DATA | NOTIFICATION FORM DIN SUB | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 1 |
| CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF NON-COMPLIANCE | 0 | 1 | 0 | 0 | 0 |
| | NOTIFICATION FORM DIN SUB | 0 | 0 | 0 | 0 | 1 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | NOTIFICATION FORM DIN SUB | 0 | 1 | 1 | 0 | 0 |
| | NO OBJECTION LETTER | 0 | 1 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| LABELLING ONLY | CANCELLATION LETTER | 2 | 2 | 1 | 1 | 2 |
| | DIN INCORR SUBTYPE-CLASS | 0 | 0 | 0 | 0 | 0 |
| | NO OBJECTION LETTER | 1 | 4 | 1 | 0 | 1 |
| | NOTICE OF NON-COMPLIANCE | 0 | 0 | 0 | 0 | 3 |
| | NOTICE OF DEFICIENCY | 0 | 0 | 0 | 0 | 0 |
| | NOTIFICATION FORM DIN SUB | 8 | 11 | 10 | 11 | 10 |
| | REJECTION LETTER (SCR) | 1 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 1 | 2 | 2 | 2 | 0 |
| LABELLING STANDARD | CANCELLATION LETTER | 2 | 3 | 0 | 7 | 3 |
| | NO OBJECTION LETTER | 0 | 0 | 0 | 0 | 0 |
| | NOTIFICATION FORM DIN SUB | 9 | 2 | 9 | 2 | 3 |
| | REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 2 | 2 | 1 | 8 | 3 |
| 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 | 0 | 0 | 0 |

## PERFORMANCE

### DINA: Review Cycle Completions

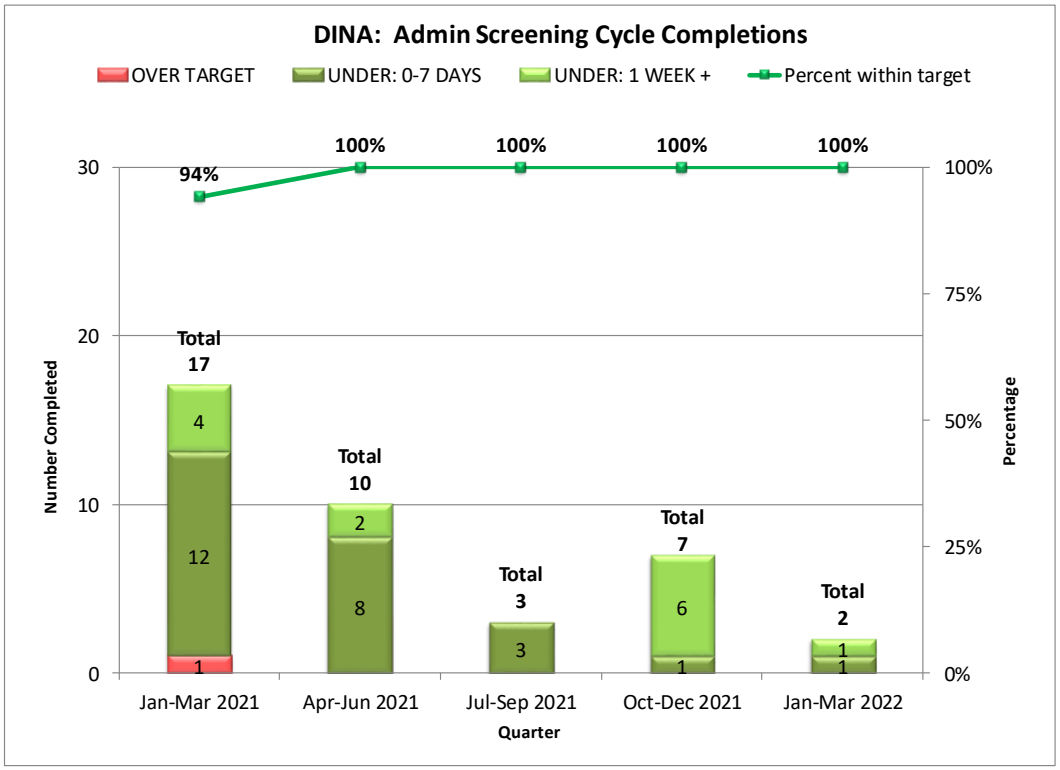



### DINA: Screening Cycle Completions



# PERFORMANCE

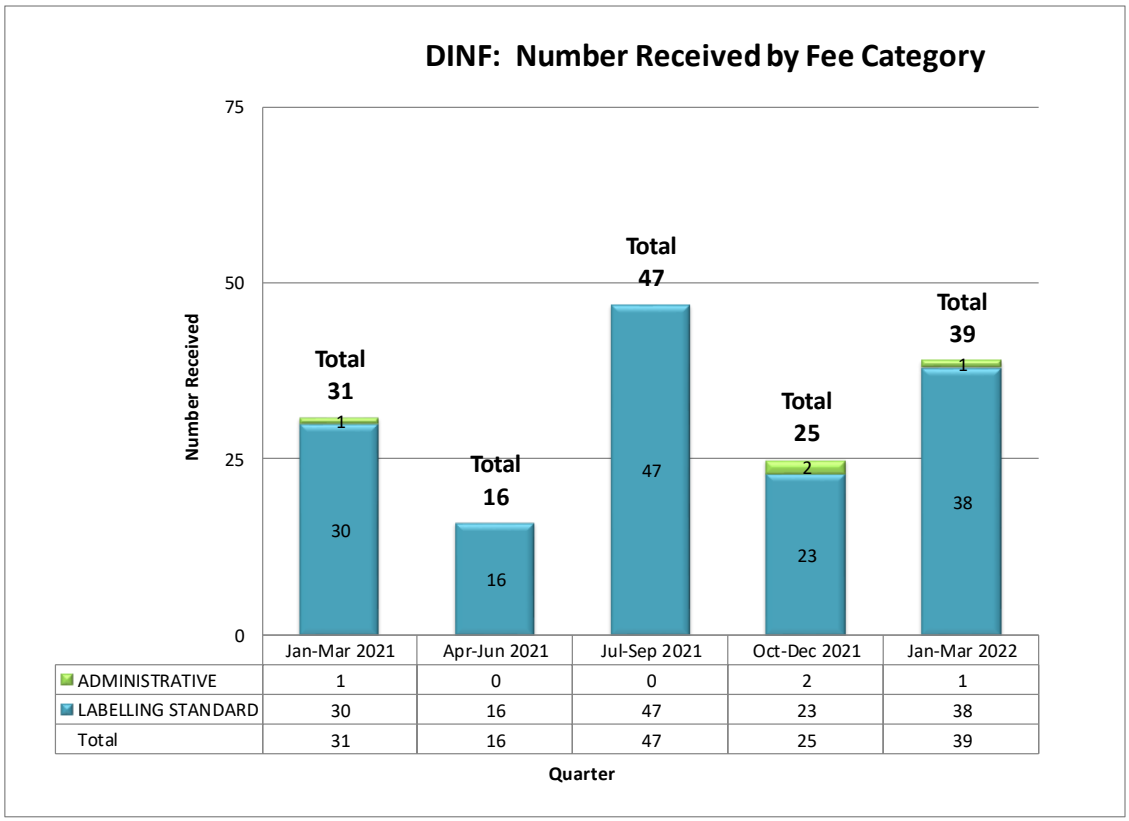
## DINA: Administrative-Screening Cycle Completions



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

## RECEIVED

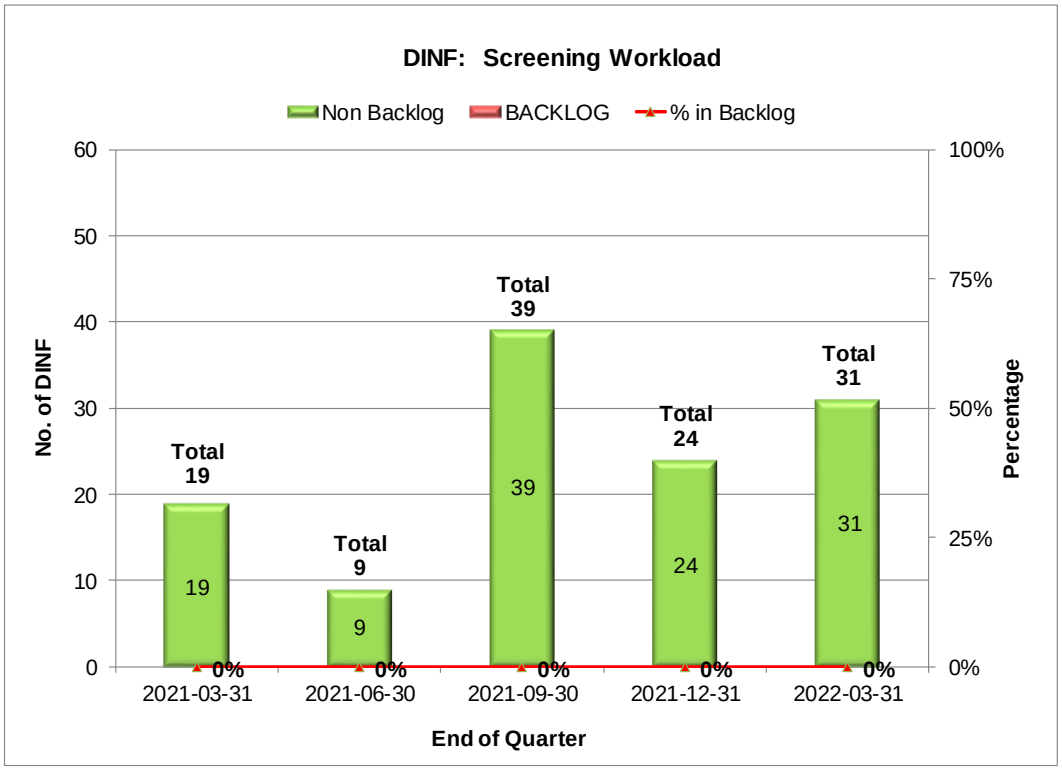
### DINF: Number Received by Fee Category




| | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|
| ADMINISTRATIVE | 1 | 0 | 0 | 2 | 1 |
| LABELLING STANDARD | 30 | 16 | 47 | 23 | 38 |
| Total | 31 | 16 | 47 | 25 | 39 |

## WORKLOAD

### DINF: Screening Workload




### DINF: Screening Workload by Fee Category

| DINF: SCREENING WORKLOAD BY FEE CATEGORY and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Labelling Standard** | **18** | **9** | **39** | **24** | **31** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Administrative** | **1** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **19** | **9** | **39** | **24** | **31** |
| **Non Backlog** | *19* | *9* | *39* | *24* | *31* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

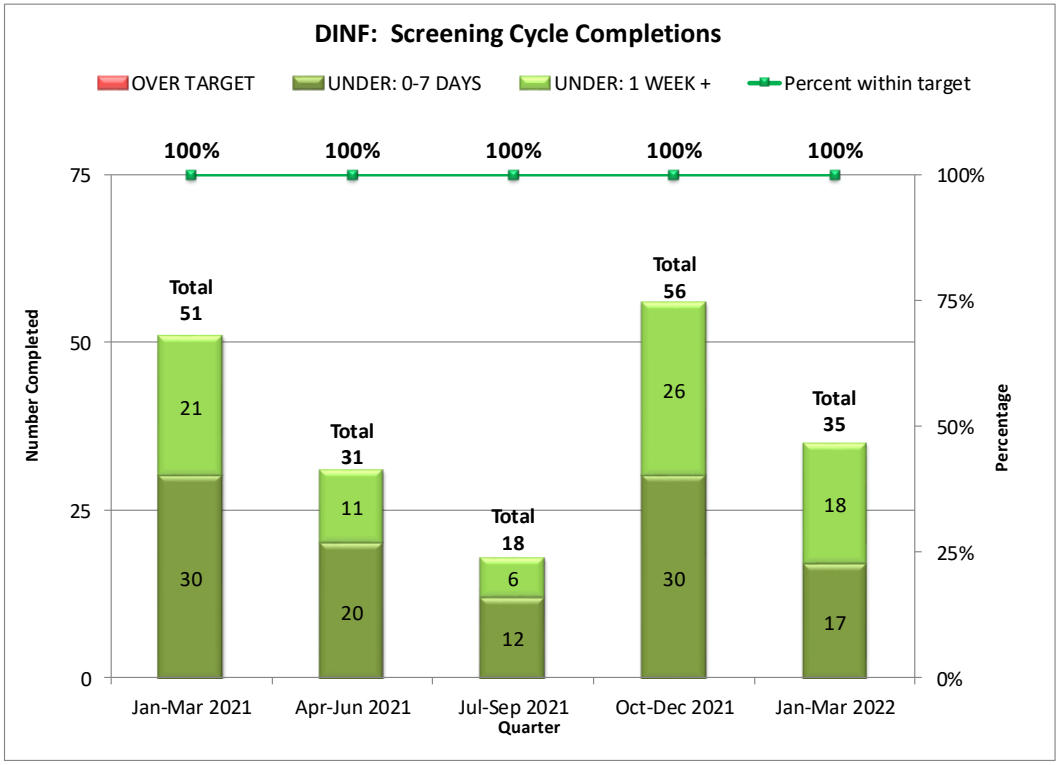
# DECISIONS

## DINF: Number of Decisions by Fee Category

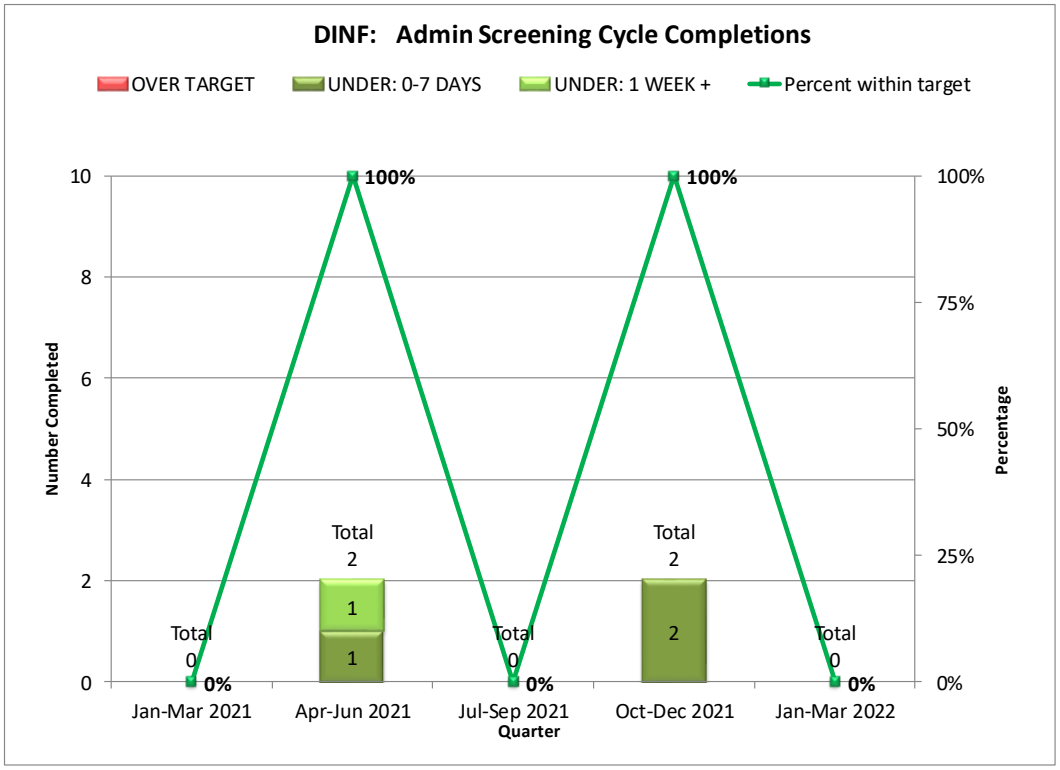
| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| LABELLING STANDARD | CANCELLATION LETTER | 8 | 2 | 0 | 4 | 1 |
| | NO OBJECTION LETTER | 0 | 0 | 0 | 0 | 0 |
| | NEW DRUG LETTER SCREEN | 0 | 0 | 0 | 0 | 0 |
| | NOTIFICATION FORM DIN SUB | 40 | 21 | 17 | 34 | 26 |
| | REJECTION LETTER (SCR) | 2 | 0 | 0 | 2 | 0 |
| | SCREENING DEFICIENCY NOTICE | 6 | 8 | 1 | 19 | 8 |
| | | | | | | |
| ADMINISTRATIVE | REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| | NOTIFICATION FORM DIN SUB | 0 | 1 | 0 | 2 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 1 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 0 | 0 |

# PERFORMANCE

## DINF: Screening Cycle Completions



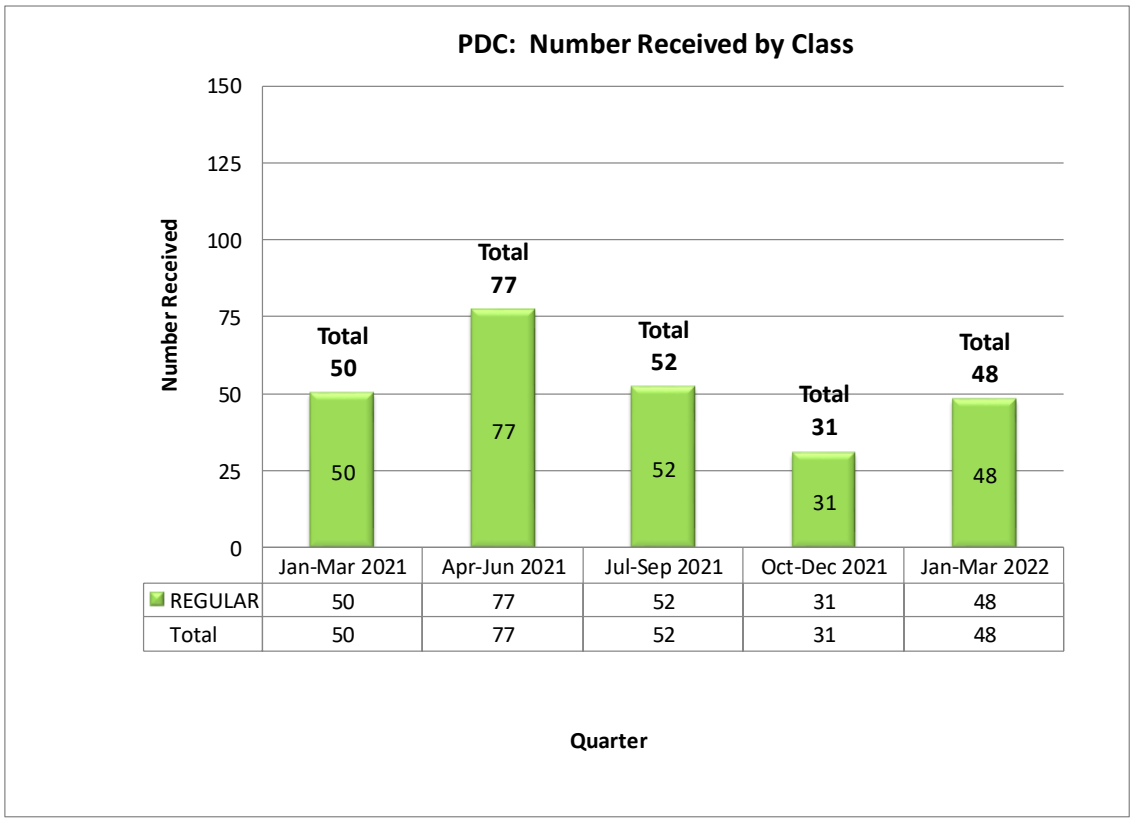

## DINF: Admin-Screening Cycle Completions



# PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

## RECEIVED

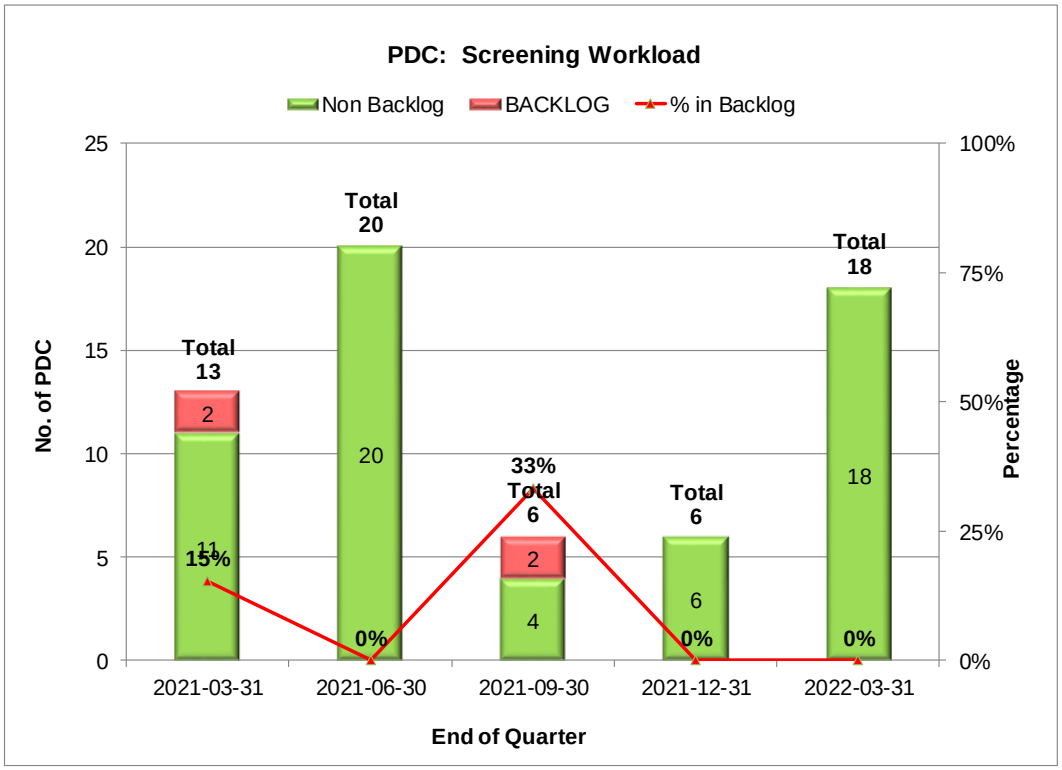
### PDC: Received by Class




| | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|
| REGULAR | 50 | 77 | 52 | 31 | 48 |
| Total | 50 | 77 | 52 | 31 | 48 |

## WORKLOAD

### PDC: Screening Workload




### PDC: Screening Workload by Class

| PDC: SCREENING WORKLOAD BY CLASS<br>By End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Regular** | **13** | **20** | **6** | **6** | **18** |
| *Backlog* | *2* | *0* | *2* | *0* | *0* |
| **Administrative** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **13** | **20** | **6** | **6** | **18** |
| **Non Backlog** | *11* | *20* | *4* | *6* | *18* |
| **BACKLOG** | **2** | **0** | **2** | **0** | **0** |
| **% in Backlog** | **15%** | **0%** | **33%** | **0%** | **0%** |

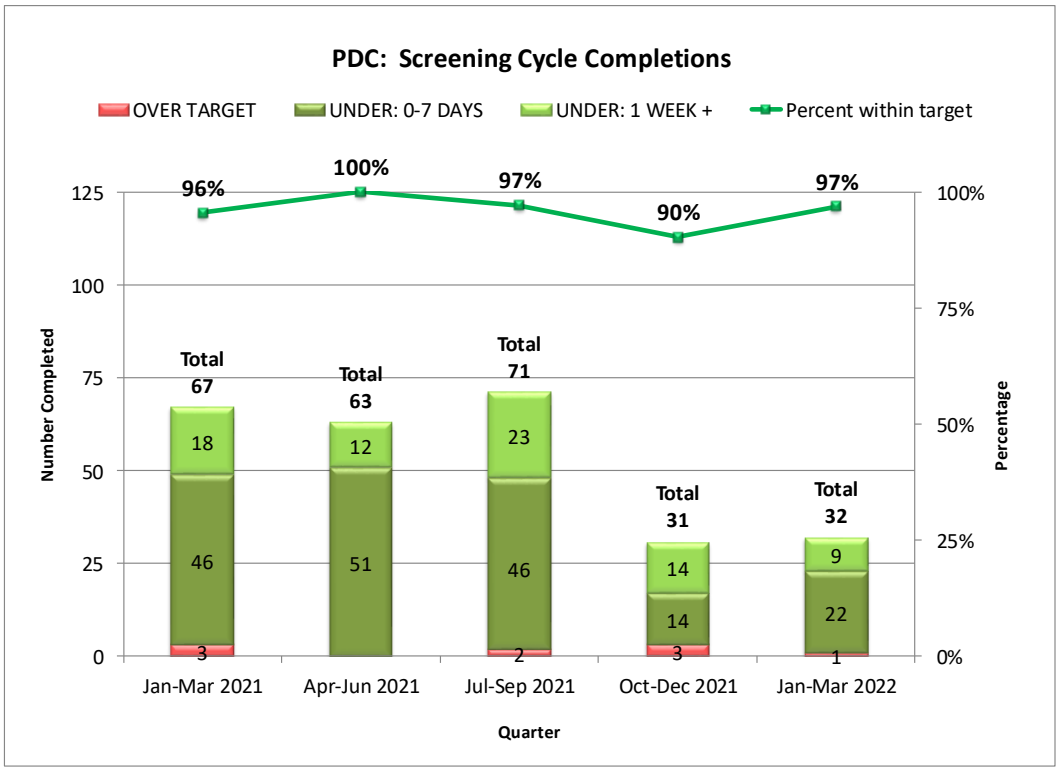
# DECISIONS

## PDC: Number of Decisions by Class

| Class | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| REGULAR | CANCELLATION LETTER | 3 | 4 | 3 | 2 | 4 |
| | NO OBJECTION LETTER | 62 | 51 | 66 | 28 | 26 |
| | NOT SATISFACTORY NOTICE | 2 | 8 | 2 | 1 | 2 |
| | REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |

# PERFORMANCE

## PDC: Screening Cycle Completions

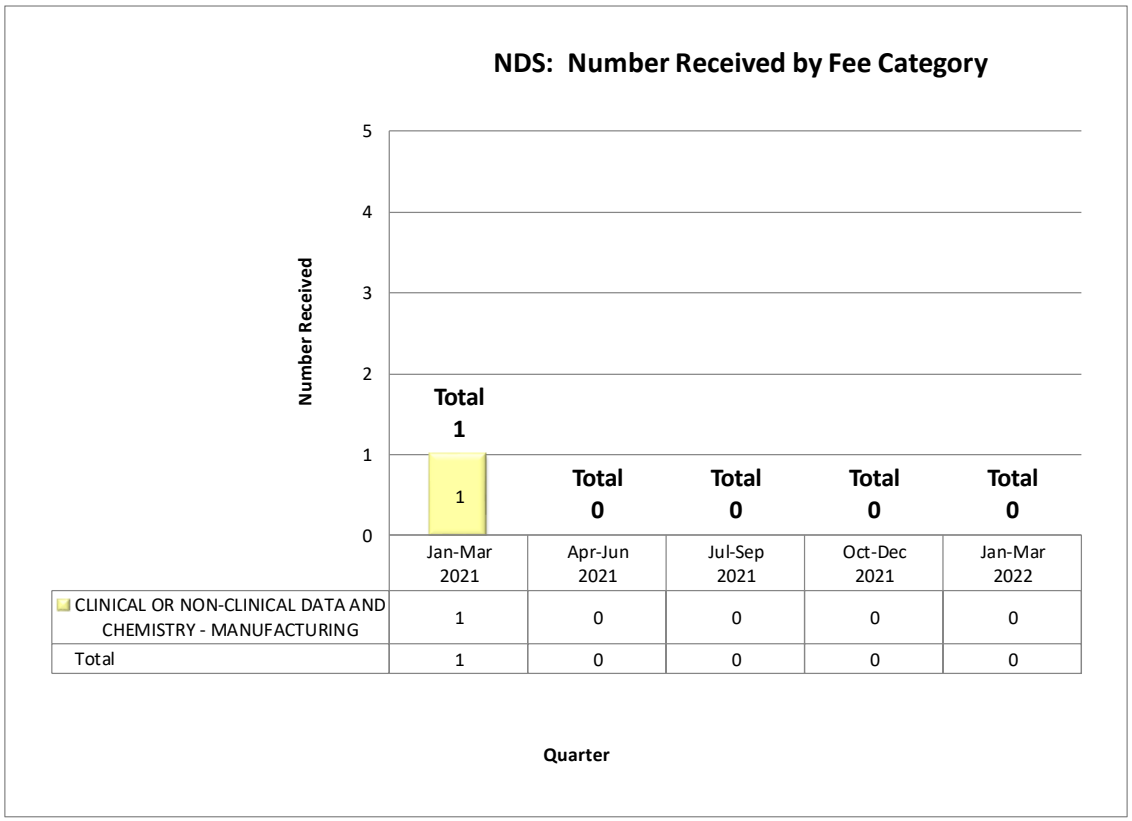


# NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8 in Part C of the *Food and Drug Regulations*

# NDS: NEW DRUG SUBMISSION

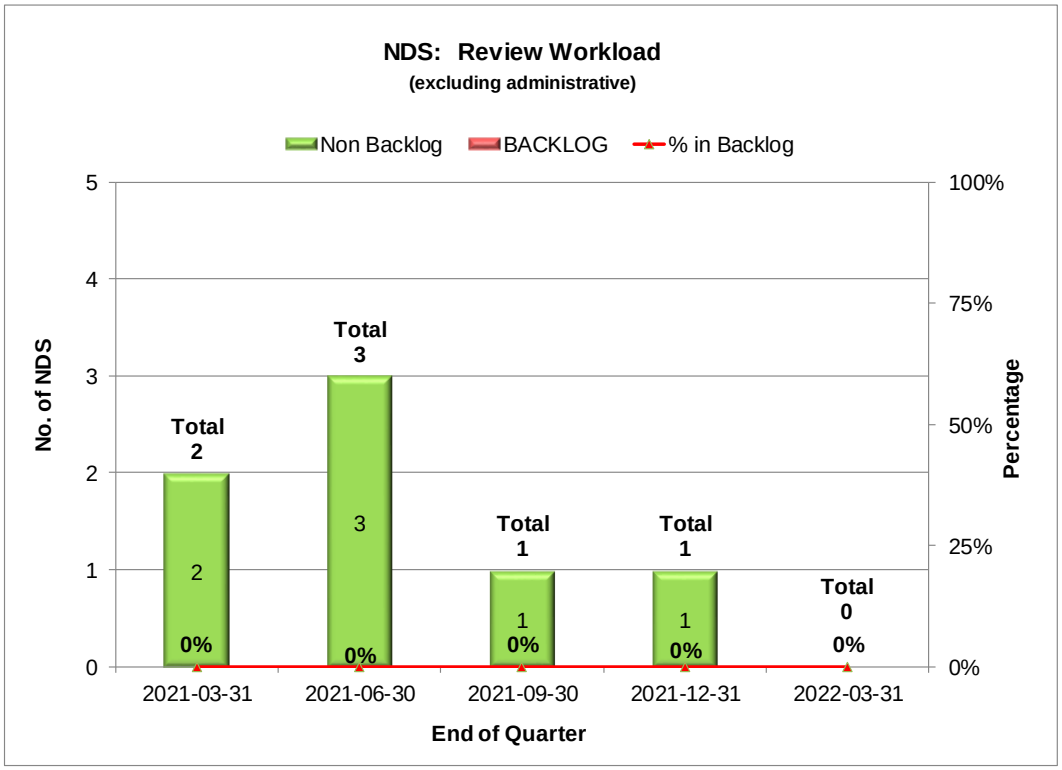
# RECEIVED

## NDS: Number Received by Fee Category



# WORKLOAD

## NDS: Review Workload

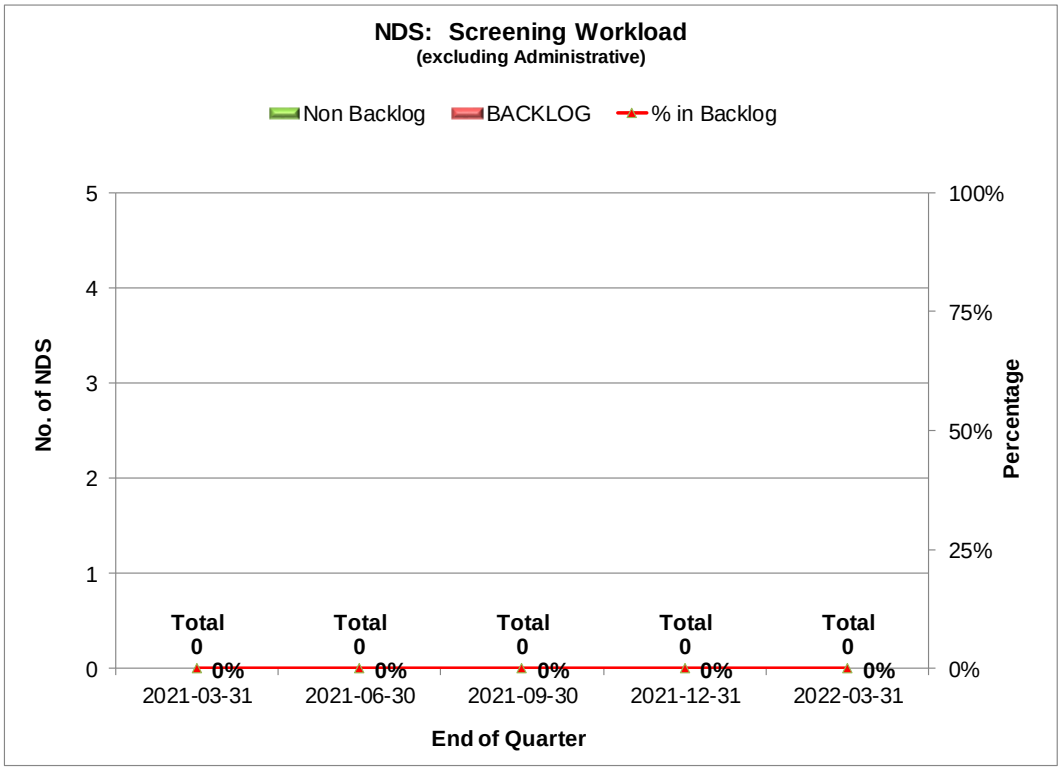



## NDS: Review Workload by Fee Category

| NDS: REVIEW WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Clinical or Non-Clinical Data and Chemistry - Manufacturing** | **2** | **3** | **1** | **1** | **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* |
| **Labelling Only** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **2** | **3** | **1** | **1** | **0** |
| **Non Backlog** | *2* | *3* | *1* | *1* | *0* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

## WORKLOAD

### NDS: Screening Workload




### NDS: Screening Workload by Fee Category

| NDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Clinical or Non-Clinical Data and Chemistry - Manufacturing** | ***0*** | ***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** | **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%** |

# DECISIONS

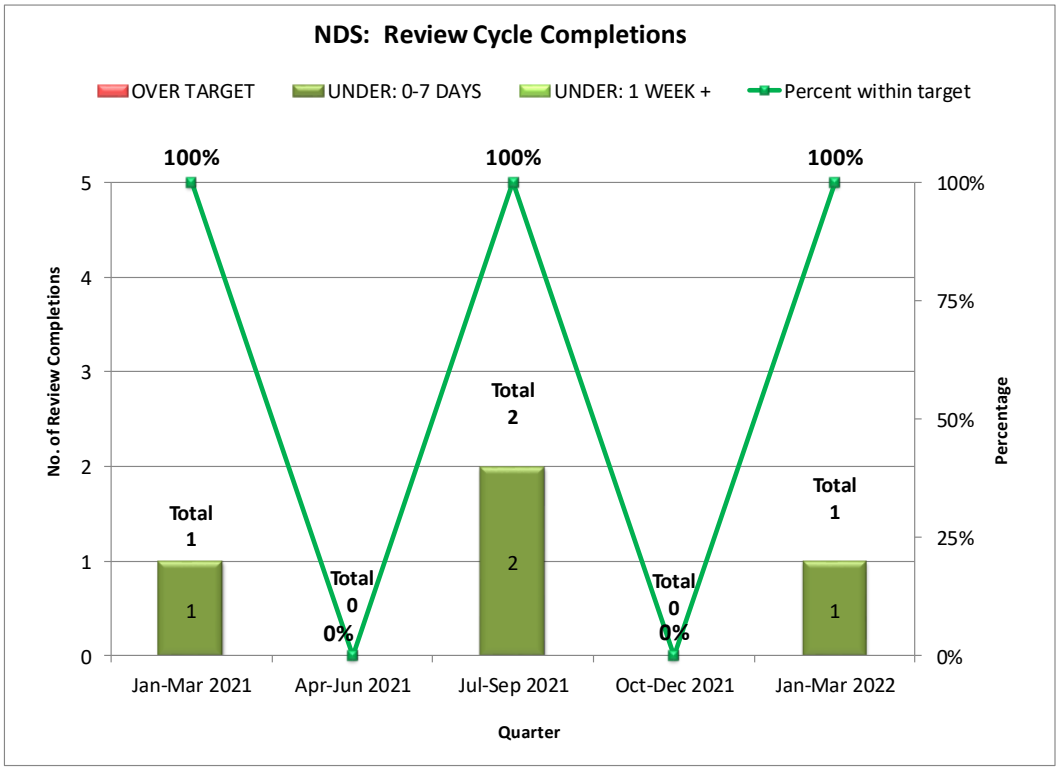
## NDS: Number of Decisions by Fee Category

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| 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 | 1 | 0 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 0 | 1 | 0 | 0 | 0 |
| | NOTICE OF DEFICIENCY | 0 | 0 | 0 | 0 | 0 |
| | NOD WITHDRAWAL LETTER | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF NON-COMPLIANCE | 1 | 0 | 0 | 0 | 1 |
| | NOTICE OF COMPLIANCE* | 0 | 0 | 1 | 0 | 0 |
| | NOC ON HOLD (SWITCH)* | 0 | 0 | 1 | 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 |

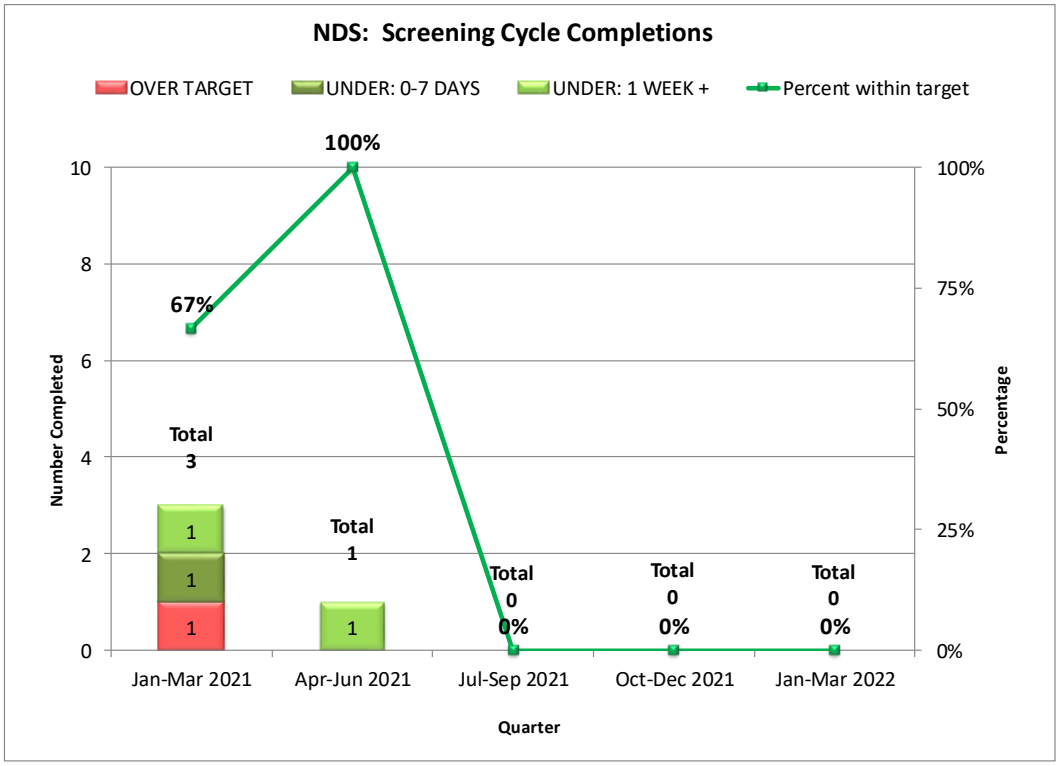
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

## PERFORMANCE

### NDS: Review Cycle Completions



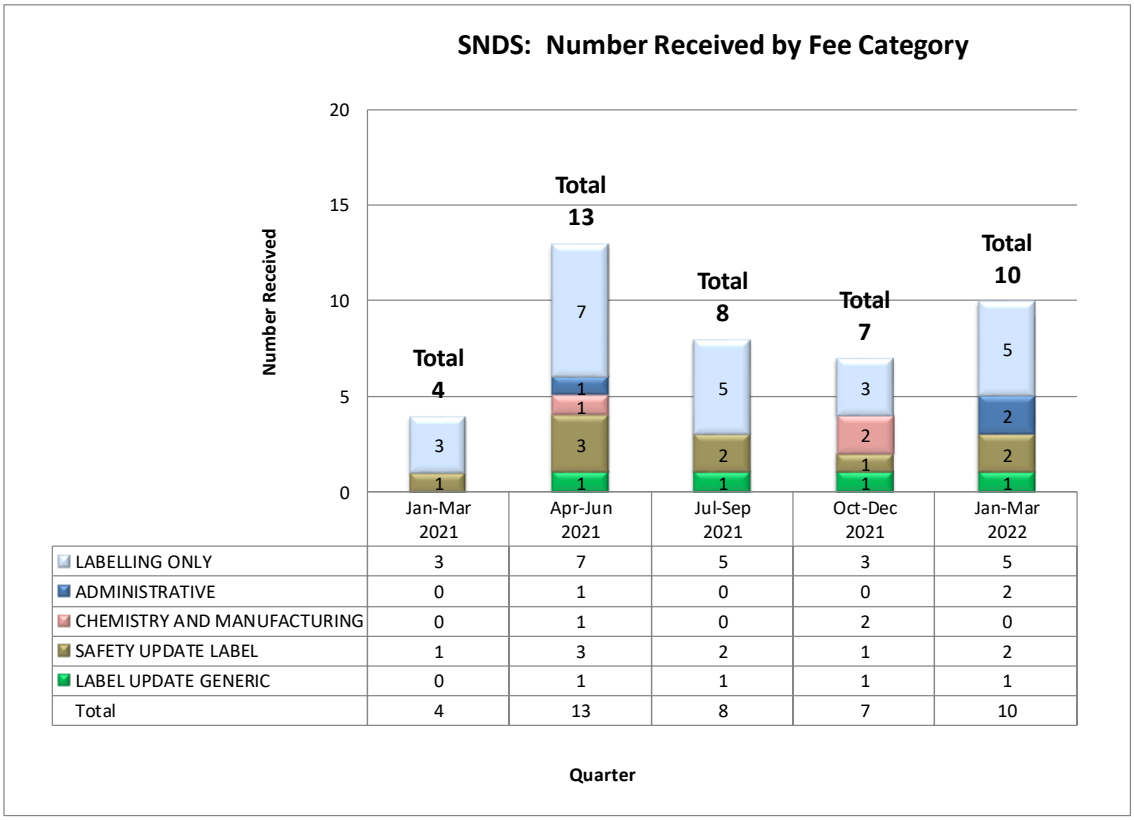

### NDS: Screening Cycle Completions



# SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION

# RECEIVED

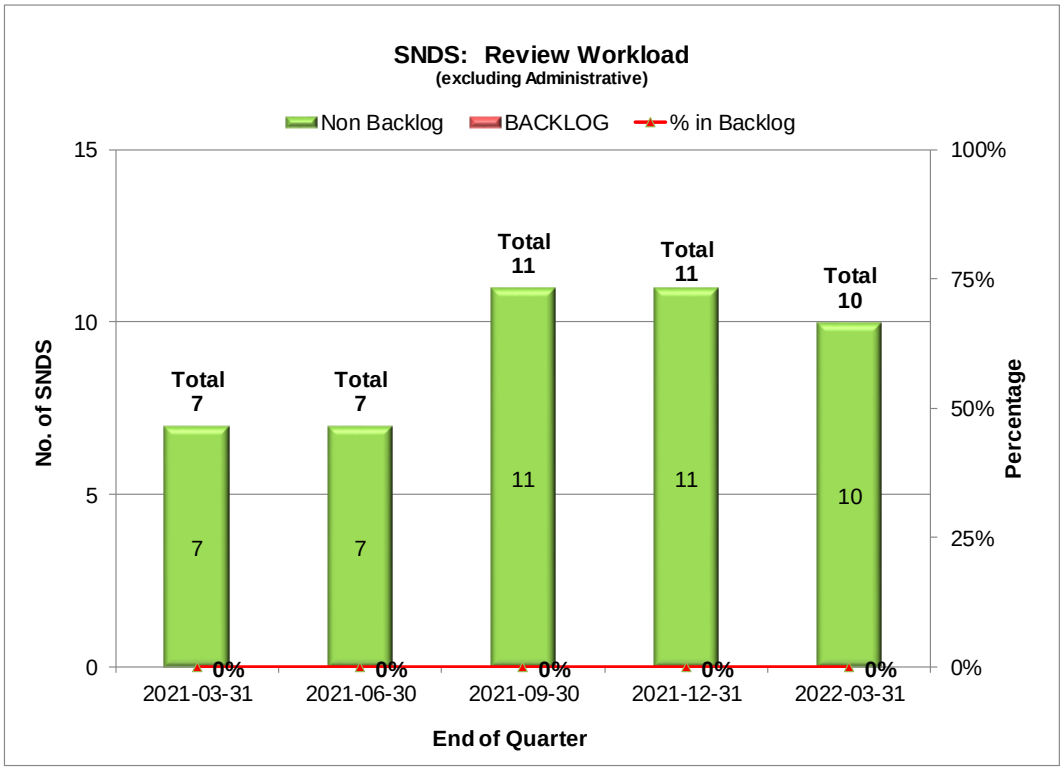
## SNDS: Number Received by Fee Category




| | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|
| LABELLING ONLY | 3 | 7 | 5 | 3 | 5 |
| ADMINISTRATIVE | 0 | 1 | 0 | 0 | 2 |
| CHEMISTRY AND MANUFACTURING | 0 | 1 | 0 | 2 | 0 |
| SAFETY UPDATE LABEL | 1 | 3 | 2 | 1 | 2 |
| LABEL UPDATE GENERIC | 0 | 1 | 1 | 1 | 1 |
| Total | 4 | 13 | 8 | 7 | 10 |

# WORKLOAD

## SNDS: Review Workload

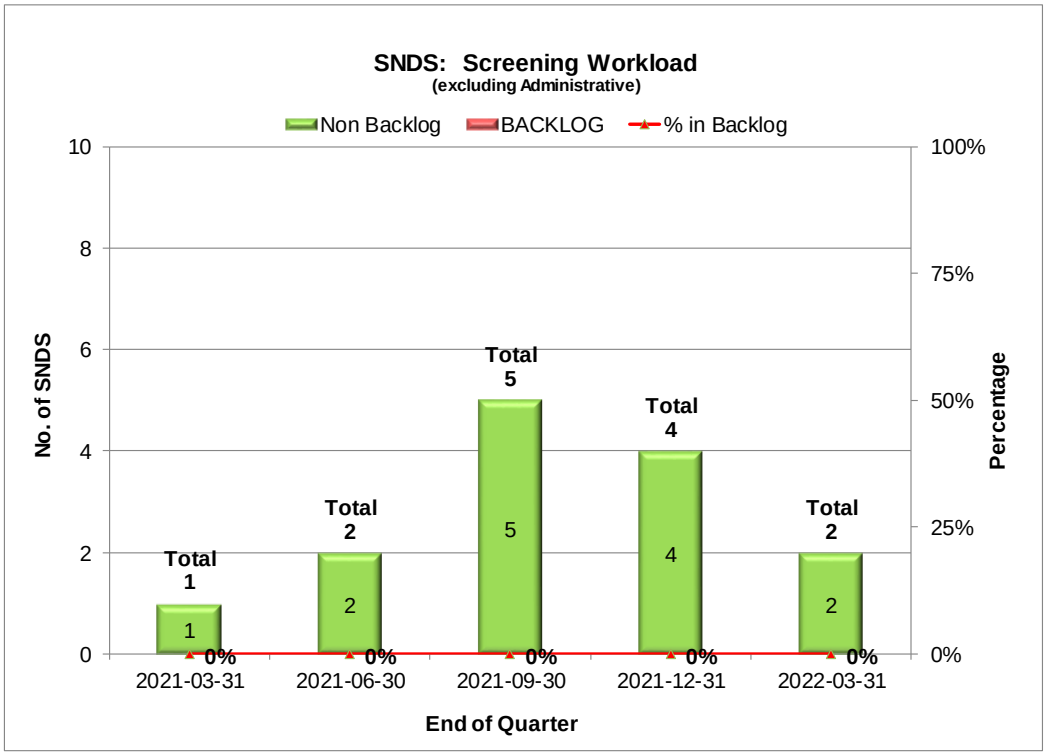



## SNDS: Review Workload by Fee Category

| SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Clinical or Non-Clinical Data** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Only** | **4** | **5** | **9** | **6** | **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** | **1** | **1** | **0** | **2** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Label Update Generic** | **2** | **0** | **0** | **1** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Safety Update Label** | **1** | **1** | **1** | **4** | **2** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **7** | **7** | **11** | **11** | **10** |
| **Non Backlog** | *7* | *7* | *11* | *11* | *10* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

## WORKLOAD

### SNDS: Screening Workload




### SNDS: Screening Workload by Fee Category

| SNDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| **FEE CATEGORY** | **2021-03-31** | **2021-06-30** | **2021-09-30** | **2021-12-31** | **2022-03-31** |
| **Chemistry and Manufacturing** | **0** | **0** | **0** | **2** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Clinical or Non-Clinical Data** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Labelling Only** | **1** | **2** | **2** | **1** | **2** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Label Update Generic** | **0** | **0** | **0** | **0** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Safety Update Label** | **0** | **0** | **3** | **1** | **0** |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| **Total** | **1** | **2** | **5** | **4** | **2** |
| **Non Backlog** | *1* | *2* | *5* | *4* | *2* |
| **BACKLOG** | **0** | **0** | **0** | **0** | **0** |
| **% in Backlog** | **0%** | **0%** | **0%** | **0%** | **0%** |

# DECISIONS

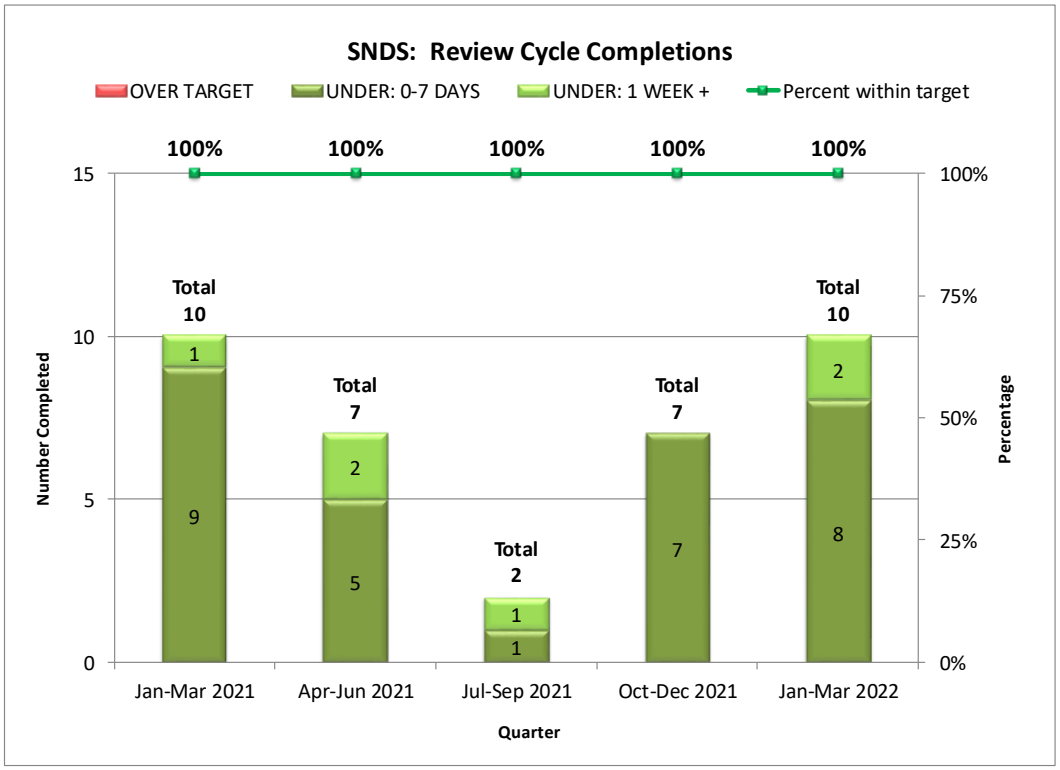
## SNDS: Number of Decision by Fee Category

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| CLINICAL OR NON-CLINICAL DATA | 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 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 1 | 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* | 8 | 4 | 1 | 4 | 5 |
| | SCREENING DEFICIENCY NOTICE | 0 | 1 | 2 | 2 | 0 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 1 | 1 |
| | NOTICE OF NON-COMPLIANCE | 0 | 0 | 0 | 1 | 0 |
| LABEL UPDATE GENERIC | NOTICE OF COMPLIANCE* | 0 | 2 | 1 | 0 | 0 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 2 | 1 |
| | NOTICE OF NON-COMPLIANCE | 1 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 1 | 0 | 0 |
| SAFETY UPDATE LABEL | NOTICE OF COMPLIANCE* | 1 | 1 | 0 | 1 | 4 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 4 | 0 | 2 |
| ADMINISTRATIVE | CANCELLATION LETTER | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF COMPLIANCE* | 0 | 1 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | NOTICE OF NON-COMPLIANCE | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF COMPLIANCE* | 0 | 0 | 0 | 1 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 1 |

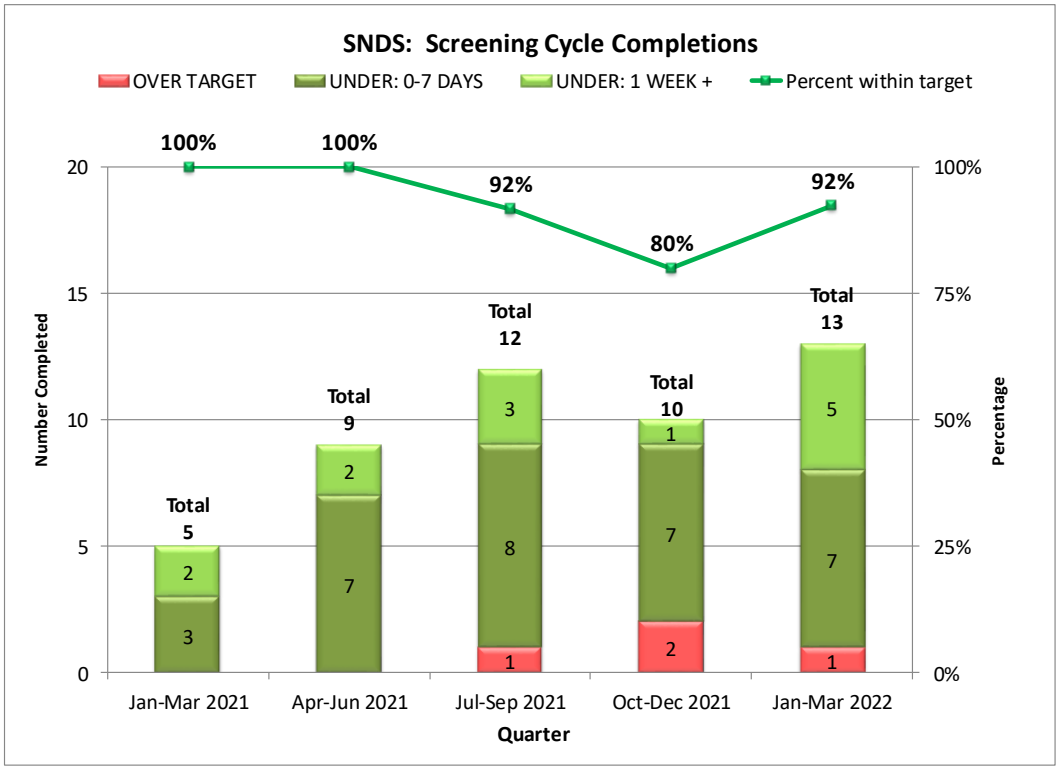
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

# 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** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| LABELLING ONLY | 0 | 1 | 0 | 1 | 0 |
| ADMINISTRATIVE | 1 | 0 | 0 | 0 | 2 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | 1 | 1 | 1 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | 0 | 1 | 0 | 0 | 0 |
| ***Total*** | ***2*** | ***3*** | ***1*** | ***1*** | ***2*** |

# WORKLOAD

## ANDS: Review Workload

| ANDS: REVIEW WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Labelling Only | 1 | 2 | 1 | 0 | 1 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Comparative Studies with or without Chemistry - Manufacturing | 2 | 2 | 2 | 3 | 1 |
| *Backlog* | *0* | *0* | *0* | *1* | *0* |
| Chemistry and Manufacturing | 1 | 0 | 1 | 2 | 1 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 4 | 4 | 4 | 6 | 3 |
| Non Backlog | *4* | *4* | *4* | *5* | *3* |
| BACKLOG | 0 | 0 | 0 | 1 | 0 |
| % in Backlog | 0% | 0% | 0% | 17% | 0% |

## ANDS: Screening Workload

| ANDS: SCREENING WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Comparative Studies with or without Chemistry - Manufacturing | 1 | 1 | 1 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Labelling Only | 0 | 0 | 0 | 1 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Chemistry and Manufacturing | 0 | 1 | 0 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 1 | 2 | 1 | 1 | 0 |
| Non Backlog | *1* | *2* | *1* | *1* | *0* |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

## ANDS: Administrative-Screening Workload

| ANDS: ADMINISTRATIVE SCREENING WORKLOAD<br>By End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Total | 1 | 0 | 0 | 0 | 2 |
| Non Backlog | *1* | *0* | *0* | *0* | *2* |
| 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 |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 1 | 1 | 1 | 67% | 3 |

## ANDS: Screening Performance

| ANDS SCREENING Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent within Target | Total |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 2 | 0 | 100% | 2 |

# DECISIONS

## ANDS: Number of Decision by Fee Category

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| ADMINISTRATIVE | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 0 | 1 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| LABELLING ONLY | NOTICE OF COMPLIANCE* | 0 | 0 | 1 | 1 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 1 |
| CHEMISTRY AND MANUFACTURING | NOTICE OF NON-COMPLIANCE | 0 | 1 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 0 | 1 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | SCREENING DEFICIENCY NOTICE | 0 | 0 | 1 | 0 | 0 |
| | NOTICE OF COMPLIANCE* | 0 | 1 | 1 | 0 | 0 |
| | NOTICE OF NON-COMPLIANCE | 0 | 0 | 0 | 0 | 2 |

*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** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| ADMINISTRATIVE | 2 | 1 | 0 | 0 | 2 |
| CHEMISTRY AND MANUFACTURING | 1 | 0 | 0 | 0 | 2 |
| LABEL UPDATE GENERIC | 2 | 0 | 0 | 1 | 1 |
| LABELLING ONLY | 5 | 10 | 11 | 7 | 3 |
| ***Total*** | ***10*** | ***11*** | ***11*** | ***8*** | ***8*** |

# WORKLOAD

## SANDS: Review Workload

| SANDS: REVIEW WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Labelling Only | 7 | 12 | 9 | 16 | 8 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Label Update Generic | 2 | 0 | 0 | 0 | 1 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Chemistry and Manufacturing | 4 | 1 | 1 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 13 | 13 | 10 | 16 | 9 |
| Non Backlog | *13* | *13* | *10* | *16* | *9* |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

## SANDS: Screening Workload

| SANDS: SCREENING WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Labelling Only | 4 | 3 | 7 | 2 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Chemistry and Manufacturing | 0 | 0 | 0 | 0 | 2 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Label Update Generic | 0 | 0 | 0 | 1 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 4 | 3 | 7 | 3 | 2 |
| Non Backlog | *4* | *3* | *7* | *3* | *2* |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

## SANDS: Administrative-Screening Workload

| SANDS: ADMINISTRATIVE-SCREENING WORKLOAD<br>by End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Total | 2 | 0 | 0 | 0 | 1 |
| Non Backlog | *2* | *0* | *0* | *0* | *1* |
| 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 |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 11 | 2 | 100% | 13 |

### SANDS: Screening Performance

| SANDS SCREENING Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent within Target | Total |
|---|---|---|---|---|---|
| Jan-Mar 2021 | 1 | 10 | 3 | 93% | 14 |
| Apr-Jun 2021 | 0 | 2 | 12 | 100% | 14 |
| Jul-Sep 2021 | 0 | 7 | 0 | 100% | 7 |
| Oct-Dec 2021 | 0 | 11 | 2 | 100% | 13 |
| Jan-Mar 2022 | 0 | 6 | 2 | 100% | 8 |

## DECISIONS

### SANDS: Number of Decision by Fee Category

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| LABELLING ONLY | NOTICE OF COMPLIANCE * | 10 | 6 | 9 | 5 | 13 |
| | SCREENING DEFICIENCY NOTICE | 2 | 3 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 1 | 0 | 0 | 1 | 0 |
| ADMINISTRATIVE | NOTICE OF COMPLIANCE* | 3 | 3 | 0 | 0 | 1 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | SCREENING DEFICIENCY NOTICE | 1 | 0 | 0 | 0 | 1 |
| | NOTICE OF COMPLIANCE* | 0 | 2 | 0 | 1 | 0 |
| | NOTICE OF NON-COMPLIANCE | 0 | 2 | 0 | 0 | 0 |
| LABEL UPDATE GENERIC | NOTICE OF COMPLIANCE* | 0 | 2 | 0 | 0 | 0 |
| | CANCELLATION LETTER | 3 | 0 | 0 | 0 | 1 |
| | SCREENING DEFICIENCY NOTICE | 2 | 0 | 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 | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
| CLINICAL OR NON-CLINICAL DATA | 0 | 0 | 0 | 0 | 1 |
| CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING | 1 | 0 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | 1 | 0 | 0 | 0 | 0 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | 1 | 0 | 0 | 0 | 0 |
| *Total* | ***3*** | ***0*** | ***0*** | ***0*** | ***1*** |

## MPNDS: Number Received by Fee Category

| PRE - NDS MEETING (MPNDS) | | | | | |
|---|---|---|---|---|---|
| Fee Category | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
| CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING | 1 | 2 | 2 | 1 | 0 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | 0 | 0 | 0 | 0 | 0 |
| PRESCRIPTION TO NON-PRESCRIPTION SWITCH | 0 | 0 | 0 | 0 | 0 |
| *Total* | ***1*** | ***2*** | ***2*** | ***1*** | ***0*** |

## MPSNDS: Number Received by Fee Category

| PRE - SNDS MEETING (MPSNDS) | | | | | |
|---|---|---|---|---|---|
| Fee Category | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
| CLINICAL OR NON-CLINICAL DATA | 0 | 0 | 0 | 0 | 0 |
| CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING | 0 | 2 | 0 | 0 | 1 |
| CHEMISTRY AND MANUFACTURING | 1 | 0 | 0 | 1 | 0 |
| *Total* | ***1*** | ***2*** | ***0*** | ***1*** | ***1*** |

# PART 2: DISINFECTANT PRODUCTS

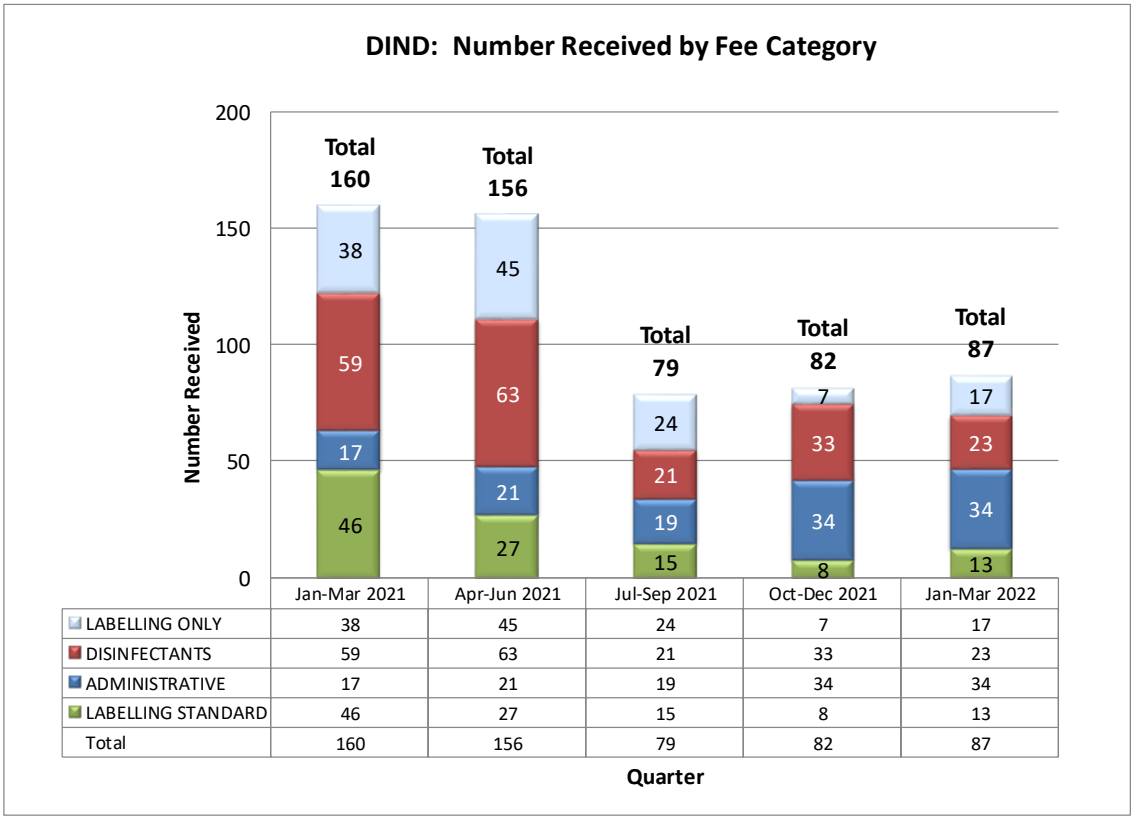
## DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

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

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

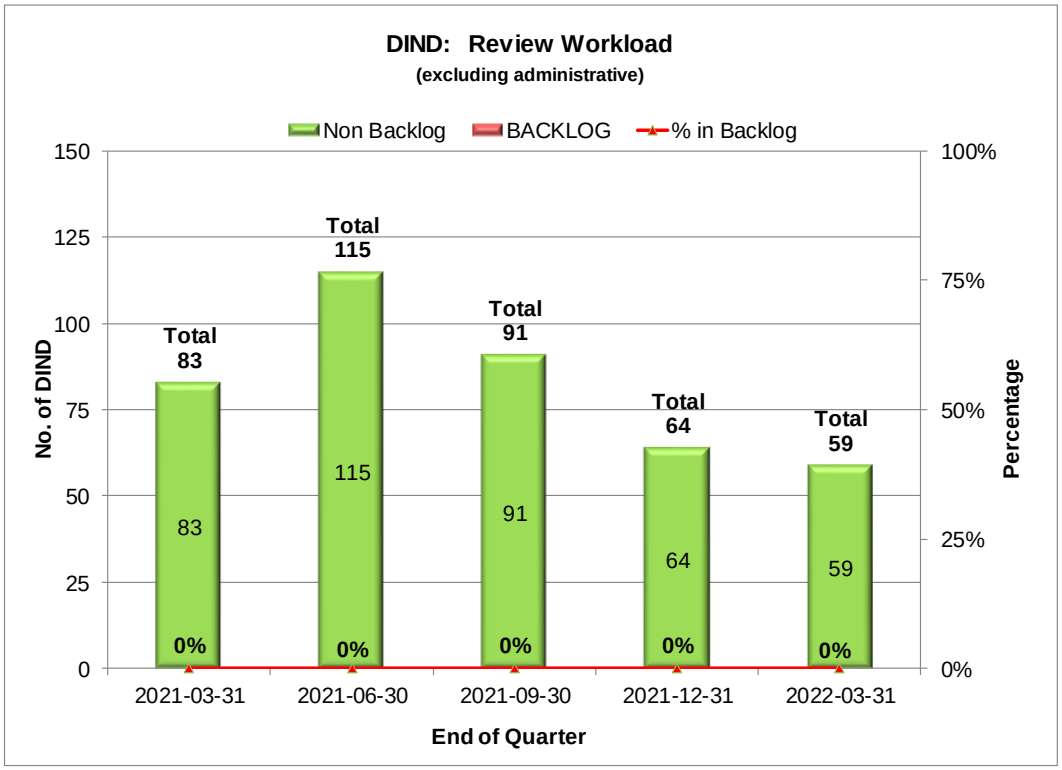
## RECEIVED

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

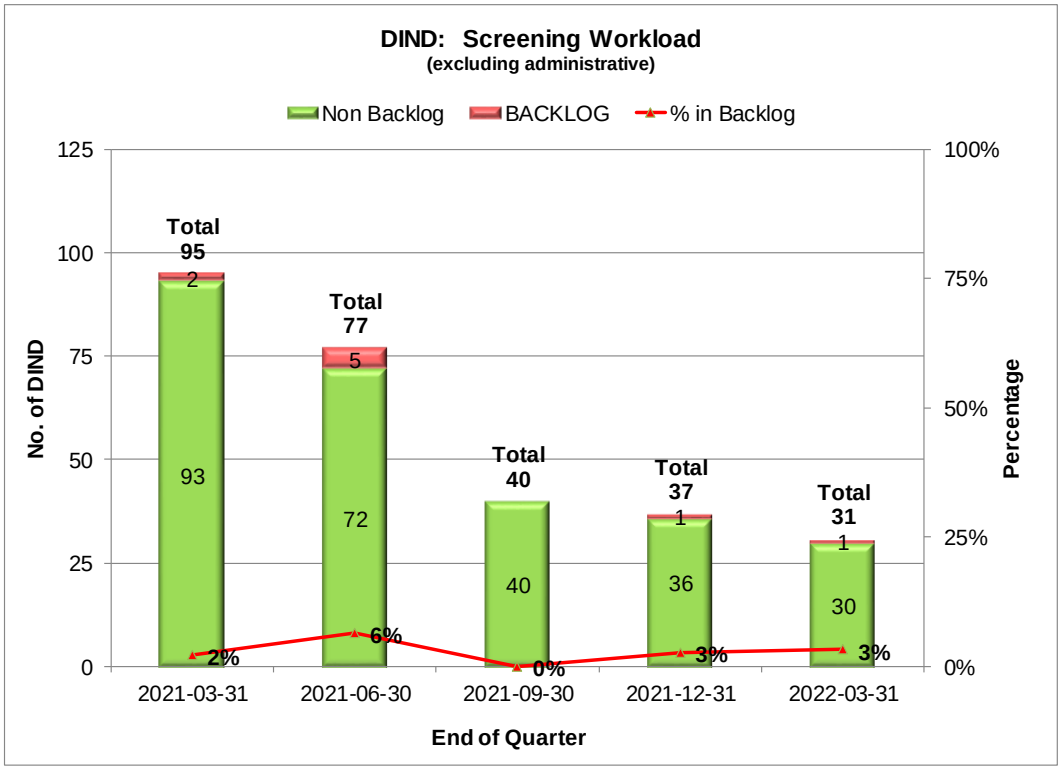


## WORKLOAD

### DIND-Disinfectant Products: Review Workload

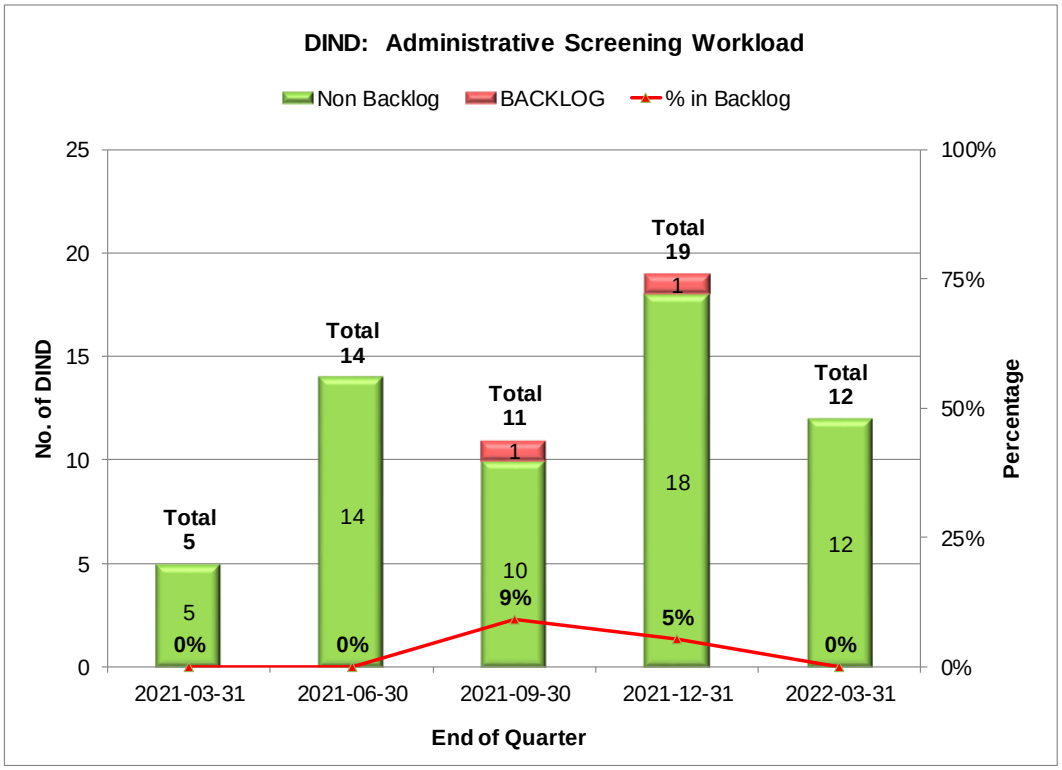



### DIND-Disinfectant Products: Screening Workload



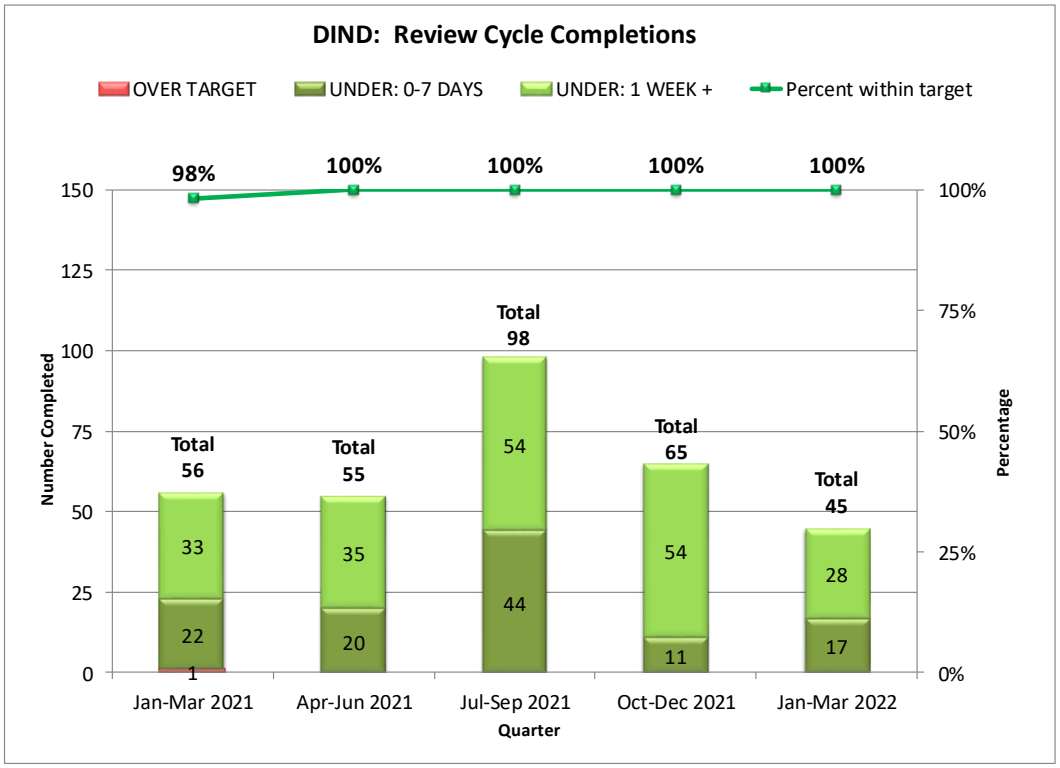
## WORKLOAD

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

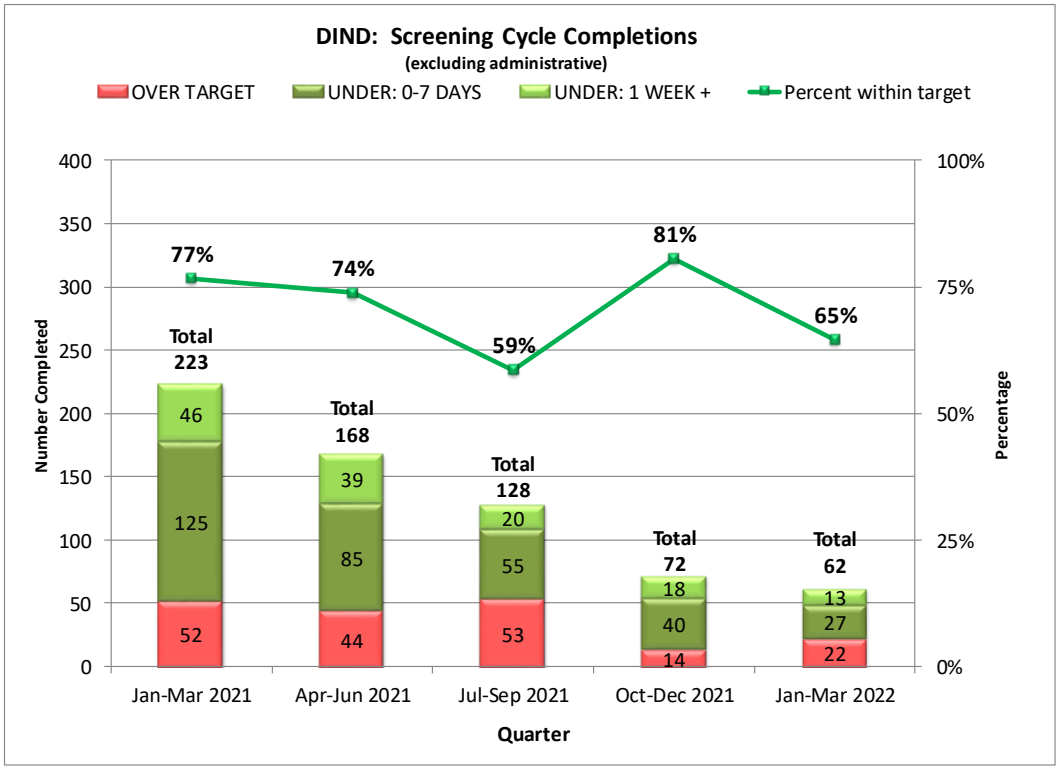


# PERFORMANCE

## DIND-Disinfectant Products: Review Cycle Completions

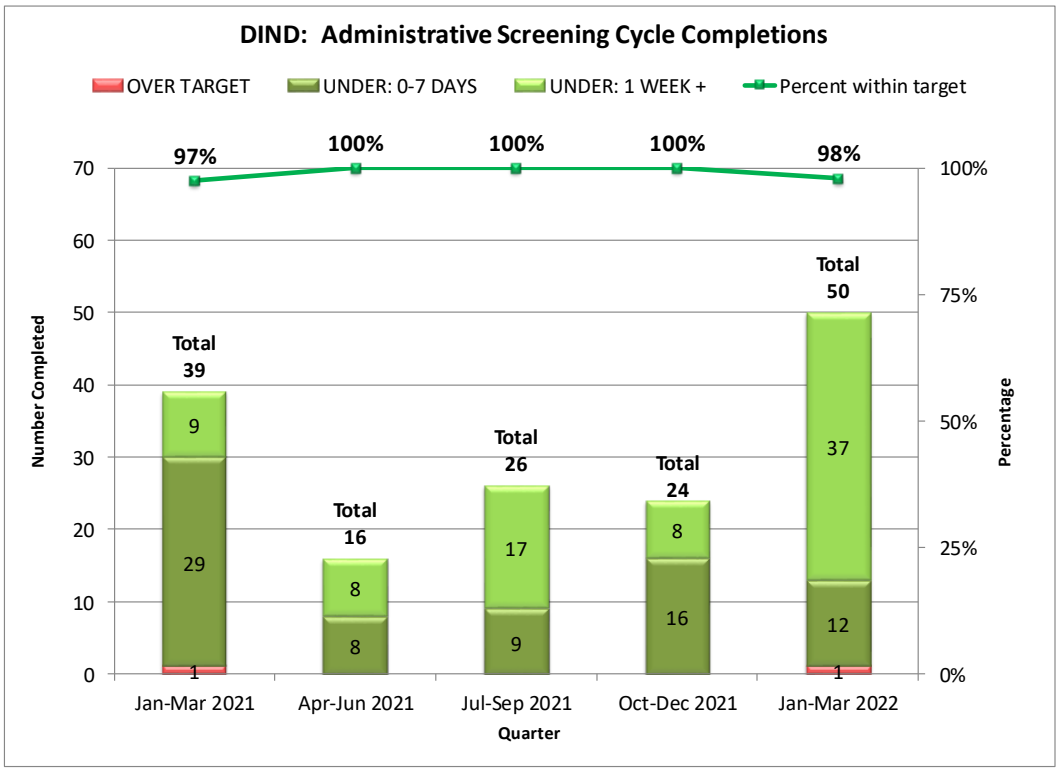



## DIND-Disinfectant Products: Screening Cycle Completions



## PERFORMANCE

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



# DECISIONS

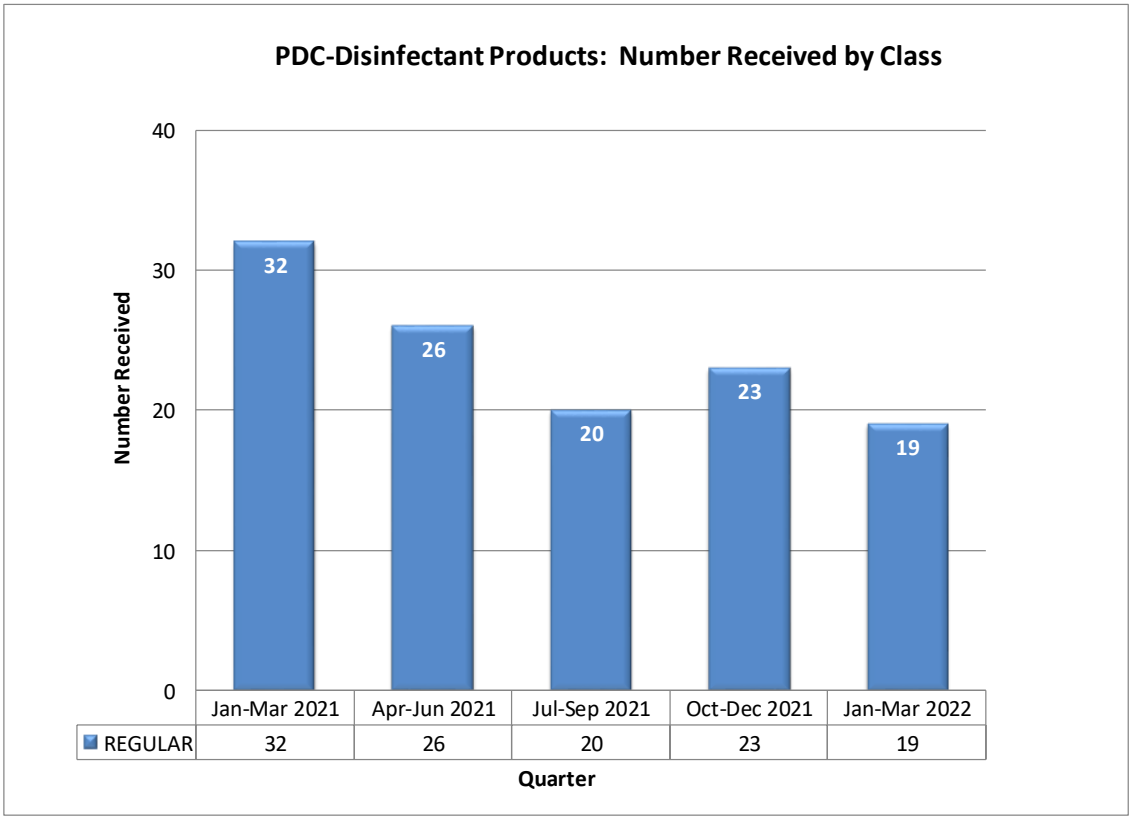
## DIND-Disinfectant Products: Number of Decisions by Fee Category

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| ADMINISTRATIVE | CANCELLATION LETTER | 8 | 7 | 9 | 2 | 9 |
| | NO OBJECTION LETTER | 0 | 1 | 3 | 7 | 0 |
| | NOTIFICATION FORM DIN SUB | 22 | 8 | 10 | 12 | 40 |
| | REJECTION LETTER (SCR) | 4 | 2 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 10 | 4 | 10 | 3 | 2 |
| DISINFECTANTS | NO OBJECTION LETTER | 12 | 19 | 22 | 13 | 15 |
| | CANCELLATION LETTER | 9 | 7 | 12 | 6 | 3 |
| | NEW DRUG LETTER SCREEN | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF DEFICIENCY | 0 | 1 | 0 | 0 | 0 |
| | NOTICE OF NON-COMPLIANCE | 1 | 2 | 2 | 2 | 2 |
| | NOTIFICATION FORM DIN SUB | 12 | 12 | 16 | 21 | 16 |
| | SCREENING DEFICIENCY NOTICE | 11 | 22 | 13 | 7 | 6 |
| | REJECTION LETTER (SCR) | 1 | 1 | 4 | 4 | 2 |
| LABELLING STANDARD | NOTIFICATION FORM DIN SUB | 79 | 35 | 19 | 11 | 11 |
| | NO OBJECTION LETTER | 2 | 1 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 22 | 9 | 9 | 5 | 1 |
| | NEW DRUG LETTER SCREEN | 0 | 0 | 0 | 0 | 0 |
| | REJECTION LETTER (SCR) | 7 | 0 | 1 | 1 | 0 |
| | CANCELLATION LETTER | 13 | 10 | 4 | 4 | 4 |
| DISINFECTANT LABELLING ONLY | NOTIFICATION FORM DIN SUB | 27 | 18 | 43 | 18 | 10 |
| | NO OBJECTION LETTER | 1 | 0 | 12 | 8 | 2 |
| | CANCELLATION LETTER | 10 | 5 | 1 | 0 | 3 |
| | SCREEN. DEFICIENCY NOTICE | 7 | 0 | 2 | 4 | 0 |
| | NOTICE OF NON-COMPLIANCE | 2 | 3 | 2 | 1 | 0 |
| | REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |

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

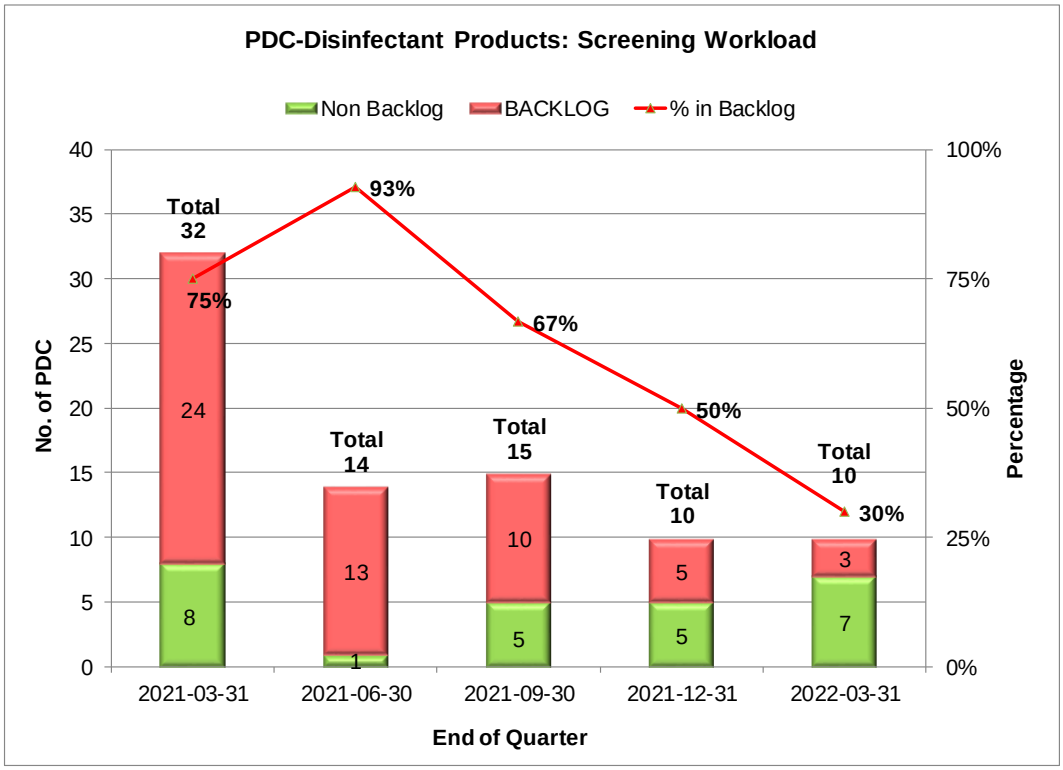
## RECEIVED

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



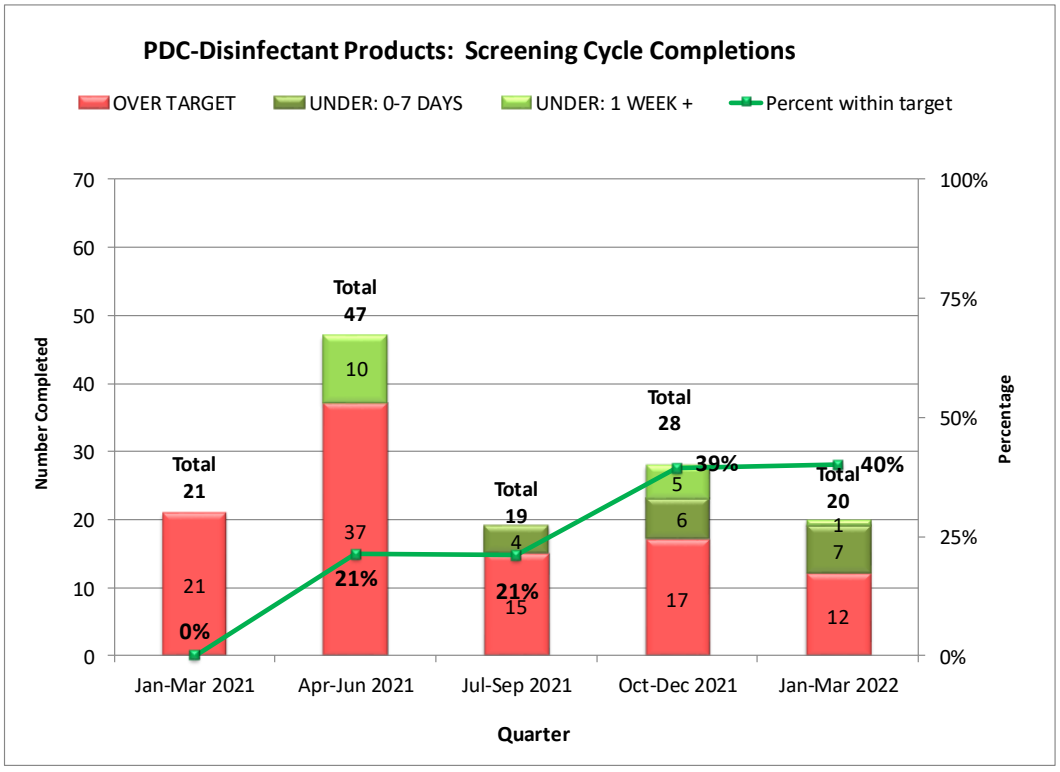
## WORKLOAD

### 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 | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| ADMINISTRATIVE | CANCELLATION LETTER | 0 | 0 | 0 | 0 | 0 |
| REGULAR | CANCELLATION LETTER | 1 | 11 | 3 | 5 | 0 |
| | NO OBJECTION LETTER | 17 | 30 | 13 | 22 | 20 |
| | NOT SATISFACTORY NOTICE | 2 | 6 | 3 | 1 | 0 |
| | NOTIFICATION FORM DIN SUB | 0 | 0 | 0 | 0 | 0 |
| | REJECTION LETTER (SCR) | 1 | 0 | 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<br>DISINFECTANT PRODUCTS | | | | | |
|---|---|---|---|---|---|
| **Fee Category** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| ADMINISTRATIVE | 0 | 0 | 0 | 0 | 0 |
| DISINFECTANTS | 1 | 1 | 2 | 3 | 1 |
| ***Total*** | ***1*** | ***1*** | ***2*** | ***3*** | ***1*** |

# WORKLOAD

## NDS-Disinfectant Products: Review Workload

| NDS-D Disinfectant Products: REVIEW WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Disinfectants | 1 | 2 | 3 | 1 | 1 |
| *Backlog* | *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% |

## NDS-Disinfectant Products: Screening Workload

| NDS-D Disinfectant Products: SCREENING WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Disinfectants | 1 | 1 | 2 | 1 | 0 |
| *Backlog* | *0* | *0* | *1* | *0* | *0* |
| Total | 1 | 1 | 2 | 1 | 0 |
| Non Backlog | *1* | *1* | *1* | *1* | *0* |
| BACKLOG | 0 | 0 | 1 | 0 | 0 |
| % in Backlog | 0% | 0% | 50% | 0% | 0% |

## NDS-Disinfectant Products: Administrative-Screening Workload

| NDS-D: ADMIN SCREENING WORKLOAD<br>by End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Administrative | 0 | 0 | 0 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 0 | 0 | 0 | 0 | 0 |
| Non Backlog | *0* | *0* | *0* | *0* | *0* |
| BACKLOG | 0 | 0 | 0 | 0 | 0 |
| % in Backlog | 0% | 0% | 0% | 0% | 0% |

## PERFORMANCE

### NDS-Disinfectant Products: Review Performance

| NDS-D REVIEW Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent within Target | Total |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 0 | 1 | 100% | 1 |

### NDS-Disinfectant Products: Screening Performance

| NDS-D SCREENING Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent with Target | Total |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 1 | 1 | 0 | 50% | 2 |

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

| NDS-D ADMIN SCREENING Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent with Target | Total |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 0 | 0 | - | 0 |

## DECISIONS

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

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| 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 | 1 | 1 |
| | NOD WITHDRAWAL LETTER | 0 | 0 | 0 | 0 | 0 |
| | NOTICE OF COMPLIANCE* | 0 | 0 | 0 | 1 | 0 |
| | CANCELLATION LETTER | 0 | 0 | 0 | 3 | 2 |
| | REJECTION LETTER (SCR) | 0 | 0 | 0 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 1 | 2 | 0 | 4 | 1 |

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

# 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** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| DISINFECTANTS | 0 | 1 | 1 | 0 | 0 |
| LABELLING ONLY DISINFECTANT | 0 | 0 | 1 | 0 | 0 |
| ***Total*** | ***0*** | ***1*** | ***2*** | ***0*** | ***0*** |

# WORKLOAD

## SNDS-Disinfectant Products: Review Workload

| SNDS-D Disinfectant Products: REVIEW WORKLOAD<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Disinfectants | 1 | 1 | 0 | 2 | 2 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 1 | 1 | 0 | 2 | 2 |
| Non Backlog | *1* | *1* | *0* | *2* | *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<br>BY FEE CATEGORY (excluding Administrative) and End of Quarter | | | | | |
|---|---|---|---|---|---|
| FEE CATEGORY | 2021-03-31 | 2021-06-30 | 2021-09-30 | 2021-12-31 | 2022-03-31 |
| Disinfectants | 0 | 1 | 1 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Disinfectant Label Only | 0 | 0 | 1 | 0 | 0 |
| *Backlog* | *0* | *0* | *0* | *0* | *0* |
| Total | 0 | 1 | 2 | 0 | 0 |
| Non Backlog | *0* | *1* | *2* | *0* | *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 |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 0 | 0 | - | 0 |

### SNDS-Disinfectant Products: Screening Performance

| SNDS-D SCREENING Quarter | OVER TARGET | UNDER: 0-7 DAYS | UNDER: 1 WEEK + | Percent with Target | Total |
|---|---|---|---|---|---|
| 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 |
| Jan-Mar 2022 | 0 | 0 | 0 | - | 0 |

## DECISIONS

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

| Fee Category | Decision Document Type | Jan-Mar 2021 | Apr-Jun 2021 | Jul-Sep 2021 | Oct-Dec 2021 | Jan-Mar 2022 |
|---|---|---|---|---|---|---|
| **DISINFECTANTS** | NOTICE OF COMPLIANCE* | 0 | 0 | 1 | 0 | 0 |
| | SCREENING DEFICIENCY NOTICE | 0 | 0 | 1 | 0 | 0 |
| **DISINFECTANT LABELLING ONLY** | NOTICE OF COMPLIANCE* | 0 | 0 | 0 | 1 | 0 |

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

# PRE-MEETINGS - DISINFECTANT PRODUCTS

## MPDIN-Disinfectant Products: Received by Fee Category

| PRE - DIN MEETING (MPDIN)<br>DISINFECTANT PRODUCTS | | | | | |
|---|---|---|---|---|---|
| **Fee Category** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| CLINICAL OR NON-CLINICAL DATA | 0 | 0 | 0 | 0 | 0 |
| CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING | 1 | 5 | 2 | 0 | 0 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | 0 | 0 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | 0 | 0 | 0 | 0 | 0 |
| ***Total*** | ***1*** | ***5*** | ***2*** | ***0*** | ***0*** |

## MPNDS-Disinfectant Products: Received by Fee Category

| PRE - NDS MEETING (MPNDS)<br>DISINFECTANT PRODUCTS | | | | | |
|---|---|---|---|---|---|
| **Fee Category** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING | 0 | 1 | 0 | 0 | 0 |
| COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING | 0 | 1 | 0 | 0 | 0 |
| CHEMISTRY AND MANUFACTURING | 1 | 0 | 0 | 0 | 0 |
| ***Total*** | ***1*** | ***2*** | ***0*** | ***0*** | ***0*** |

## MPSNDS-Disinfectant Products: Received by Fee Category

| PRE - SNDS MEETING (MPSNDS)<br>DISINFECTANT PRODUCTS | | | | | |
|---|---|---|---|---|---|
| **Fee Category** | **Jan-Mar 2021** | **Apr-Jun 2021** | **Jul-Sep 2021** | **Oct-Dec 2021** | **Jan-Mar 2022** |
| CLINICAL OR NON-CLINICAL DATA | 0 | 0 | 0 | 0 | 0 |