



Health
Canada

Santé
Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance
Quarterly Report
January - March
2021



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

Également disponible en français sous le titre :
Direction des produits de santé naturels et sans ordonnance - Rapport trimestriel du rendement des présentations de drogue - janvier - mars 2021

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, Ontario K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2021

Publication date: July 2021

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat H167-3E-PDF
ISSN 2561-5556
Pub 210099

Table of Contents

OVERVIEW	9
ACRONYMS	16
Submission Types	16
Documents	17
FEE CATEGORIES	18
PART 1: NON-PRESCRIPTION DRUGS	20
NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1	20
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER	21
RECEIVED	21
DINA: Number Received by Fee Category	21
WORKLOAD	22
DINA: Review Workload	22
DINA: Review Workload by Fee Category	22
DINA: Screening Workload	23
DINA: Screening Workload by Fee Category	23
DINA: Administrative-Screening Workload	24
DINA: Administrative-Screening Workload by Fee Category	24
DECISIONS	25
DINA: Number of Decisions by Fee Category	25
PERFORMANCE	26
DINA: Review Cycle Completions	26
DINA: Screening Cycle Completions	26
DINA: Administrative-Screening Cycle Completions	27
DINF: APPLICATION FOR A DIN FOR A CATEGORY IV MONOGRAPH PRODUCT	28
RECEIVED	28
DINF: Number Received by Fee Category	28

WORKLOAD	29
DINF: Screening Workload	29
DINF: Screening Workload by Fee Category	29
DECISIONS	30
DINF: Number of Decisions by Fee Category	30
PERFORMANCE.....	31
DINF: Screening Cycle Completions	31
DINF: Admin-Screening Cycle Completions	31
PDC: POST-AUTHORIZATION DIVISION 1 CHANGE.....	32
RECEIVED	32
PDC: Received by Class	32
WORKLOAD	33
PDC: Screening Workload.....	33
PDC: Screening Workload by Class	33
DECISIONS	34
PDC: Number of Decisions by Class.....	34
PERFORMANCE.....	34
PDC: Screening Cycle Completions	34
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8.....	35
NDS: NEW DRUG SUBMISSION.....	36
RECEIVED	36
NDS: Number Received by Fee Category	36
WORKLOAD	37
NDS: Review Workload	37
NDS: Review Workload by Fee Category	37
NDS: Screening Workload	38
NDS: Screening Workload by Fee Category	38
DECISIONS	39
NDS: Number of Decisions by Fee Category	39
PERFORMANCE.....	40
NDS: Review Cycle Completions	40
NDS: Screening Cycle Completions.....	40

SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION	41
RECEIVED.....	41
SNDS: Number Received by Fee Category.....	41
WORKLOAD	42
SNDS: Review Workload.....	42
SNDS: Review Workload by Fee Category	42
SNDS: Screening Workload.....	43
SNDS: Screening Workload by Fee Category.....	43
DECISIONS	44
SNDS: Number of Decision by Fee Category	44
PERFORMANCE	45
SNDS: Review Cycle Completions	45
SNDS: Screening Cycle Completions	45
ANDS: ABBREVIATED NEW DRUG SUBMISSION	46
RECEIVED.....	46
ANDS: Number Received by Fee Category	46
WORKLOAD	47
ANDS: Review Workload	47
ANDS: Screening Workload	47
ANDS: Administrative-Screening Workload	47
PERFORMANCE	48
ANDS: Review Performance.....	48
ANDS: Screening Performance	48
DECISIONS	48
ANDS: Number of Decision by Fee Category	48
SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRUG SUBMISSION	49
RECEIVED.....	49
SANDS: Number Received by Fee Category	49
WORKLOAD	50
SANDS: Review Workload.....	50
SANDS: Screening Workload	50
SANDS: Administrative-Screening Workload	50

PERFORMANCE.....	51
SANDS: Review Performance.....	51
SANDS: Screening Performance	51
DECISIONS	51
SANDS: Number of Decision by Fee Category	51
NC: NOTIFIABLE CHANGE	52
RECEIVED	52
NC: Number Received by Class	52
WORKLOAD	53
NC: Review Workload.....	53
NC: Review Workload by class.....	53
NC: Screening Workload.....	54
NC: Screening Workload by Class	54
NC: Administrative Screening Workload.....	55
DECISIONS	55
NC: Number of Decisions by Class	55
PERFORMANCE.....	56
NC: Review Cycle Completions.....	56
NC: Screening Cycle Completions	56
PRE-MEETINGS	57
MPDIN: Number Received by Fee Category	57
MPNDS: Number Received by Fee Category	57
MPSNDS: Number Received by Fee Category	57
PART 2: DISINFECTANT PRODUCTS	58
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1	58
DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS.....	59
RECEIVED	59
DIND-Disinfectant Products: Number Received by Fee Category	59

WORKLOAD	60
DIND-Disinfectant Products: Review Workload	60
DIND-Disinfectant Products: Screening Workload.....	60
DIND-Disinfectant Products: Administrative-Screening Workload	61
PERFORMANCE	62
DIND-Disinfectant Products: Review Cycle Completions.....	62
DIND-Disinfectant Products: Screening Cycle Completions	62
DIND-Disinfectant Products: Administrative-Screening Cycle Completions.....	63
DECISIONS	64
DIND-Disinfectant Products: Number of Decisions by Fee Category	64
 PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS.....	 65
RECEIVED.....	65
PDC-Disinfectant Products: Received by Fee Class	65
WORKLOAD	66
PDC-Disinfectant Products: Screening Workload.....	66
PERFORMANCE	66
PDC-Disinfectant Products: Screening Cycle Completions	66
DECISIONS	67
PDC-Disinfectant Product: Number of Decisions by Fee Category	67
 DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8.....	 68
 NDS-D: NEW DRUG SUBMISSION - DISINFECTANT PRODUCTS	 69
SUBMISSIONS RECEIVED.....	69
NDS-Disinfectant Products: Number Received by Fee Category	69
WORKLOAD	70
NDS-Disinfectant Products: Review Workload	70
NDS-Disinfectant Products: Screening Workload.....	70
NDS-Disinfectant Products: Administrative-Screening Workload	70
PERFORMANCE	71
NDS-Disinfectant Products: Review Performance	71
NDS-Disinfectant Products: Screening Performance	71
NDS-Disinfectant Products: Administrative-Screening Performance	71

DECISIONS	72
NDS-Disinfectant Products: Number of Decisions by Fee Category	72
NC: NOTIFIABLE CHANGE - DISINFECTANT PRODUCTS	73
RECEIVED	73
NC-Disinfectant Products: Received by Class.....	73
WORKLOAD	74
NC-Disinfectant Products: Review Workload	74
NC-Disinfectant Products: Screening Workload	74
PERFORMANCE.....	75
NC-Disinfectant Products: Review Performance	75
NC-Disinfectant Products: Screening Performance.....	75
DECISIONS	75
NC-Disinfectant Products: Number of Decisions by Class	75
PRE-MEETINGS - DISINFECTANT PRODUCTS	76
MPDIN-Disinfectant Products: Received by Fee Category.....	76
MPNDS-Disinfectant Products: Received by Fee Category.....	76
MPSNDS-Disinfectant Products: Received by Fee Category.....	76

OVERVIEW

The NNHPD Quarterly Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive quarters from January - March 2020 to January - March 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.
- The publication of the Quarterly Drug Submission Performance Report was cancelled for two quarters (there were no reports published for Q4 Jan-Mar 2020 and Q1 Apr-June 2020), however figures for the past three quarters are provided in this report.
- There was a significant increase in the volume of [Drug Identification Number Applications for Disinfectant products \(DIND\) received](#).
- An [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19](#) was approved and on August 13, 2020 the Minister of Health approved an [order to temporarily extend the default period to review clinical trial applications and amendments](#) from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. (see the Quarterly Drug Submission Performance Reports for the Therapeutic Products Directorate (TPD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD)).

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

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

Some of the highlights of the January - March 2021 report are:

Non-prescription Drug Submissions:

- There was a 55% decrease in the number of DINA submissions received in Q2 2020-2021 (26) compared to Q1 2020-2021 (58), a 96% increase when comparing Q3 2020-2021 (51) to Q2 2020-2021 and a 47% decrease when comparing Q4 2020-2021 (27) to Q2 2020-2021.
- There was a 3% increase in the number of DINF submissions received in Q2 2020-2021 (80) compared to Q1 2020-2021 (78), a 50% decrease when comparing Q3 2020-2021 (40) to Q2 2020-2021 and a 22.5% decrease when comparing Q4 2020-2021 (31) to Q3 2020-2021.
- There was a 10% increase in the number of PDC submissions received in Q2 2020-2021 (125) compared to Q1 2020-2021 (114), a 14% decrease when comparing Q3 2020-2021 (107) to Q2 2020-2021 and a 53% decrease when comparing Q4 2020-2021 (50) to Q3 2020-2021.
- There was a 100% decrease in the number of NDS submissions received in Q2 2020-2021 (0) compared to Q1 2020-2021 (9), no change when comparing Q3 2020-2021 (0) to Q2 2020-2021 and an undefined increase when comparing Q4 2020-2021 (1) to Q3 2020-2021.
- There was a 50% increase in the number of SNDS submissions received in Q2 2020-2021 (12) compared to Q1 2020-2021 (8), a 58% decrease when comparing Q3 2020-2021 (5) to Q2 2020-2021 and a 20% decrease when comparing Q4 2020-2021 (4) to Q3 2020-2021.
- There was a 100% increase in the number of ANDS submissions received in Q2 2020-2021 (2) compared to Q1 2020-2021 (1), no change when comparing Q3 2020-2021 (2) to Q2 2020-2021 and no change when comparing Q4 2020-2021 (2) to Q3 2020-2021.
- There was a 175% increase in the number of SANDS submissions received in Q2 2020-2021 (21) compared to Q1 2020-2021 (8), a 10% decrease when comparing Q3 2020-2021 (19) to Q2 2020-2021 and a 47% decrease when comparing Q4 2020-2021 (10) to Q3 2020-2021.
- There was a 233% increase in the number of NC submissions received in Q1 2020-2021 (10) compared to Q4 2019-2020 (3), and none were received in Q2, Q3 and Q4 2020-2021 as this fee line was discontinued.

Overall, the total non-prescription drug submissions received decreased by 3% in Q2 2020-2021 (267) when compared to Q1 2020-2021 (276), decreased by 16% from Q2 2020-2021 to Q3 2020-2021 (224) and decreased by 42% when comparing Q4 2020-2021(130) to Q3 2020-2021.

The decrease in overall submissions from Q3 2020-2021 to Q4 2020-2021 reflects a continued reduction in non-prescription drug hand sanitizer submissions, and fewer PDC submissions related to plain language labelling implementation. Nonetheless, the volumes in Q1, Q2 and Q3 2020-2021 brought the total number of non-prescription drug submissions received to its highest to date per quarter. The increase was mainly due to a high volume of submissions for non-alcohol based hand sanitizer in response to the COVID-19 pandemic. As these submissions began to taper in Q3 2020-2021 and into Q4 2020-2021, the workload began to stabilize at pre-pandemic volumes.

Disinfectant Drug Submissions:

- There was an 8% decrease in the number of DIND submissions received in Q2 2020-2021 (244) compared to Q1 2020-2021 (264), a 13% decrease when comparing Q3 2020-2021 (214) to Q2 2020-2021, and a 24% decrease when comparing Q4 2020-2021 (160) to Q3 2020-2021.
- There was a 54% decrease in the number of PDC-D submissions received in Q2 2020-2021 (25) compared to Q1 2020-2021 (54), a 17% increase when comparing Q3 2020-2021 (30) to Q2 2020-2021, and a 7% increase when comparing Q4 2020-2021 (32) to Q3 2020-2021.
- The number of NDS-D remained the same in Q4 2020-2021 (1) compared to Q3 2020-2021 (1), Q2 2020-2021 (1) and Q1 2020-2021 (1).
- There were no SNDS-D or NCs received for Q1 2020-2021 (0), Q2 2020-2021 (0) and Q4 2020-2021 (0), and 1 SNDS-D received for Q3 2020-2021 (1).

Overall, the total disinfectant drug submissions received decreased by 21% from Q3 2020-2021(242) to Q4 2020-2021 (195). The volume of submissions received in Q4 remained significantly higher (2.9x) than pre-pandemic volumes, despite the continued reduction in received submission volume over the fiscal year, compared to the all time high of 4.8x seen in Q1 2020-2021. As a result, the total number of disinfectant drug submissions received in Q4 remained higher than ever, mainly attributed to the ongoing COVID-19 pandemic. For some submission types, such as DINDs and PDCs, the numbers received in each of the first three quarters of FY 2020-2021 are representative of the total numbers received for previous full FYs.

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

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

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

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

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

General Information

There are several steps involved in the drug submission 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:

Office of Submissions and Intellectual Property, Resource Management and Operations
Directorate
Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: hc.osip-bppi.sc@canada.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

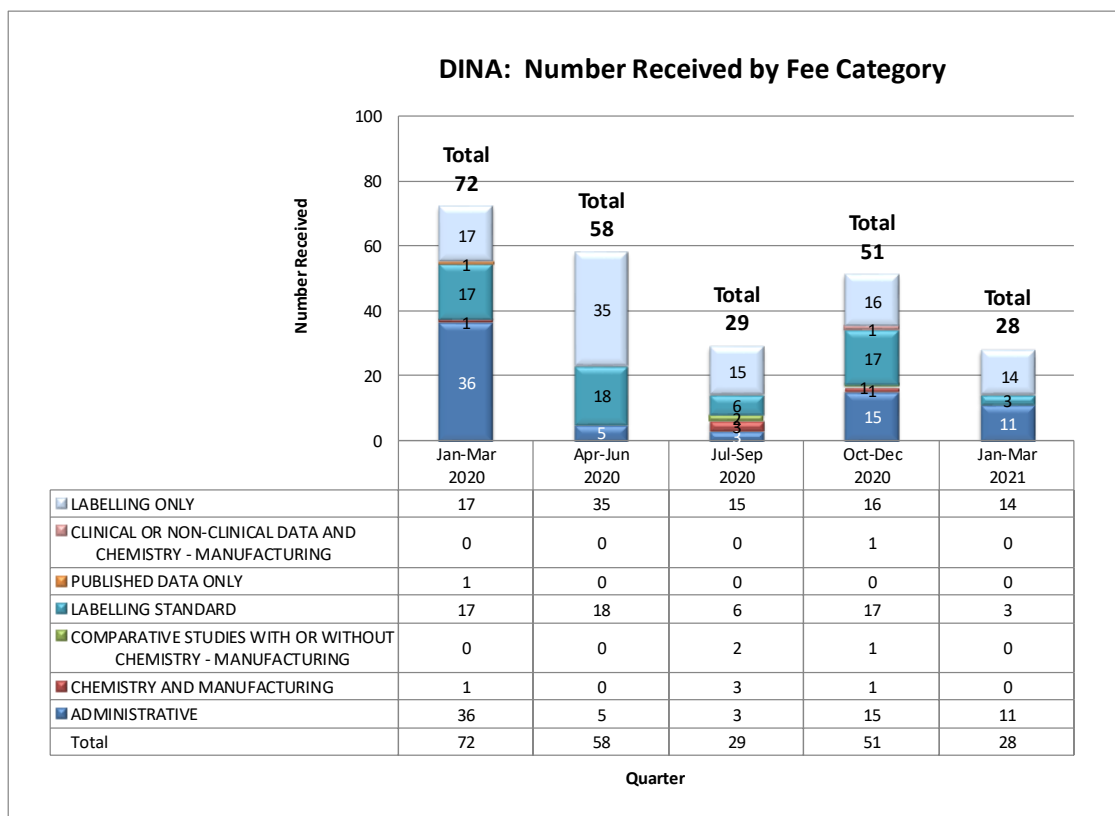
Over the counter (OTC) Drugs

NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

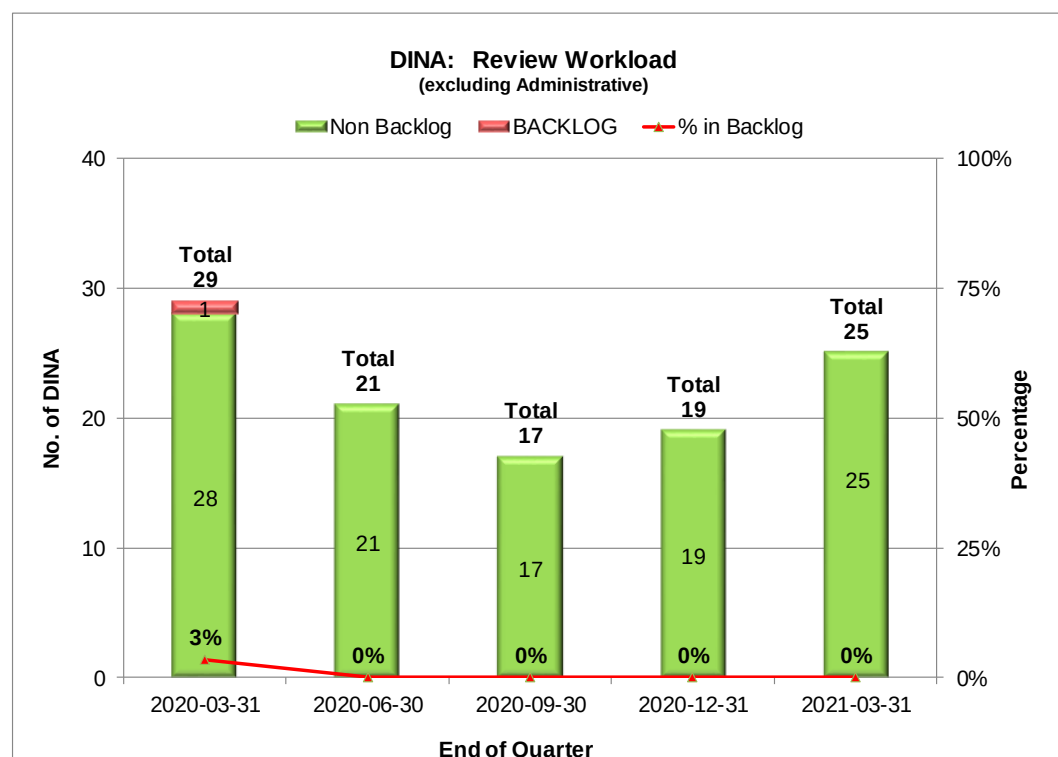
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

DINA: Number Received by Fee Category



WORKLOAD

DINA: Review Workload

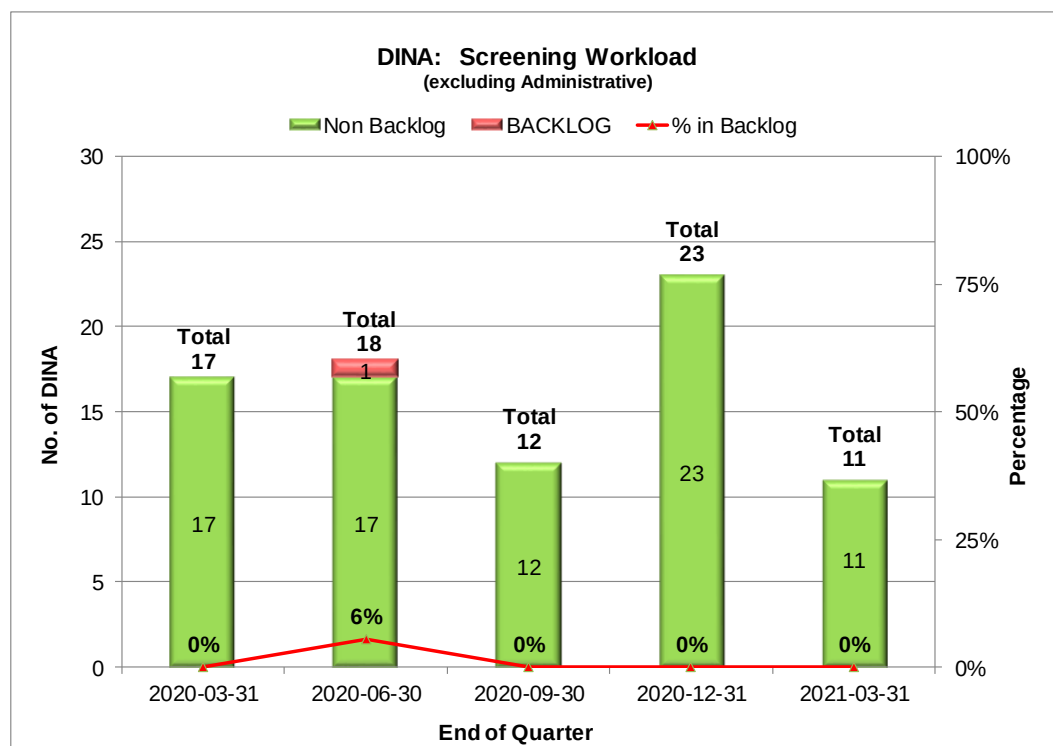


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Chemistry and Manufacturing	2	1	1	2	4
Backlog	1	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	0	1	1
Backlog	0	0	0	0	0
Labelling Only	27	19	14	14	17
Backlog	0	0	0	0	0
Published Data	0	1	1	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	1	2	3
Backlog	0	0	0	0	0
Total	29	21	17	19	25
Non Backlog	28	21	17	19	25
BACKLOG	1	0	0	0	0
% in Backlog	3%	0%	0%	0%	0%

WORKLOAD

DINA: Screening Workload

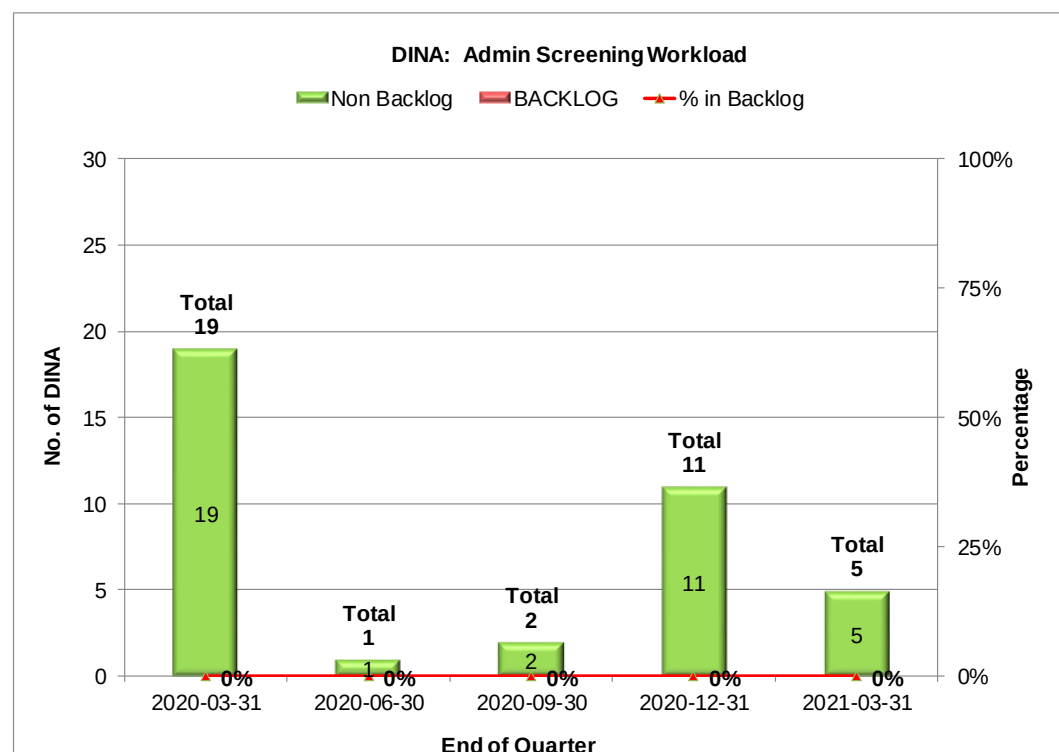


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Chemistry and Manufacturing	1	0	3	2	0
Backlog	0	0	0	0	0
Labelling Only	4	13	4	10	8
Backlog	0	1	0	0	0
Labelling Standard	11	5	5	11	3
Backlog	0	0	0	0	0
Published Data	1	0	0	0	0
Backlog	0	0	0	0	0
Total	17	18	12	23	11
Non Backlog	17	17	12	23	11
BACKLOG	0	1	0	0	0
% in Backlog	0%	6%	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	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Administrative	19	1	2	11	5
<i>Backlog</i>	0	0	0	0	0
Total	19	1	2	11	5
Non Backlog	19	1	2	11	5
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

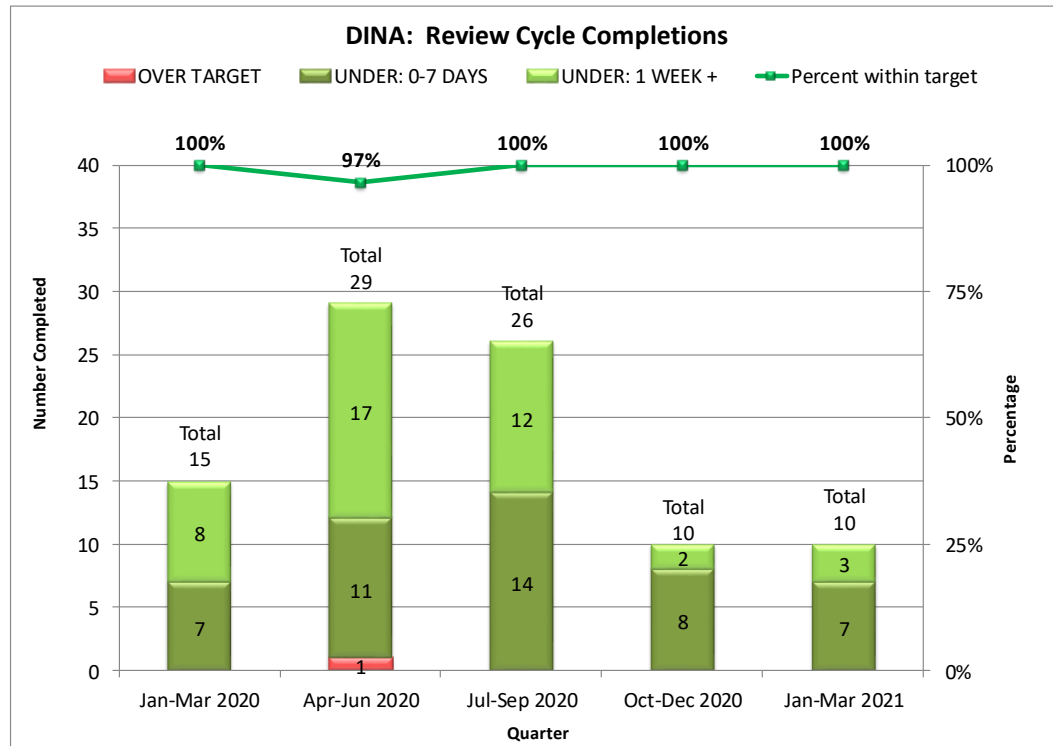
DECISIONS

DINA: Number of Decisions by Fee Category

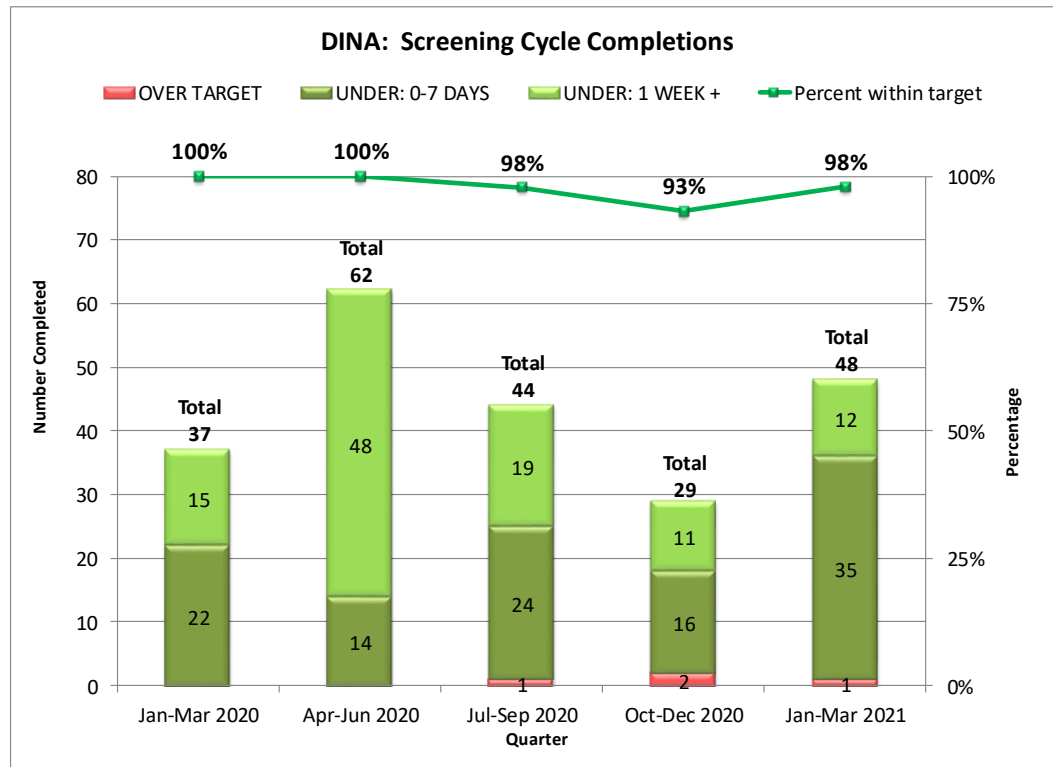
Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	1	1	0	3
	NOTIFICATION FORM DIN SUB	72	22	1	2	13
	REJECTION LETTER (SCR)	1	0	0	0	1
	SCREENING DEFICIENCY NOTICE	5	0	0	3	0
	NO OBJECTION LETTER	0	0	1	1	0
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	0	1	0	1	0
	CANCELLATION LETTER	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	3	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
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	2	0	0
LABELLING ONLY	CANCELLATION LETTER	2	9	3	2	2
	DIN IN CORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	5	3	1	1	1
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	11	23	19	13	8
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	3	5	2	1
LABELLING STANDARD	CANCELLATION LETTER	3	6	0	3	2
	NO OBJECTION LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	10	18	6	9	9
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	5	8	2	2	2
PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	1	0

PERFORMANCE

DINA: Review Cycle Completions

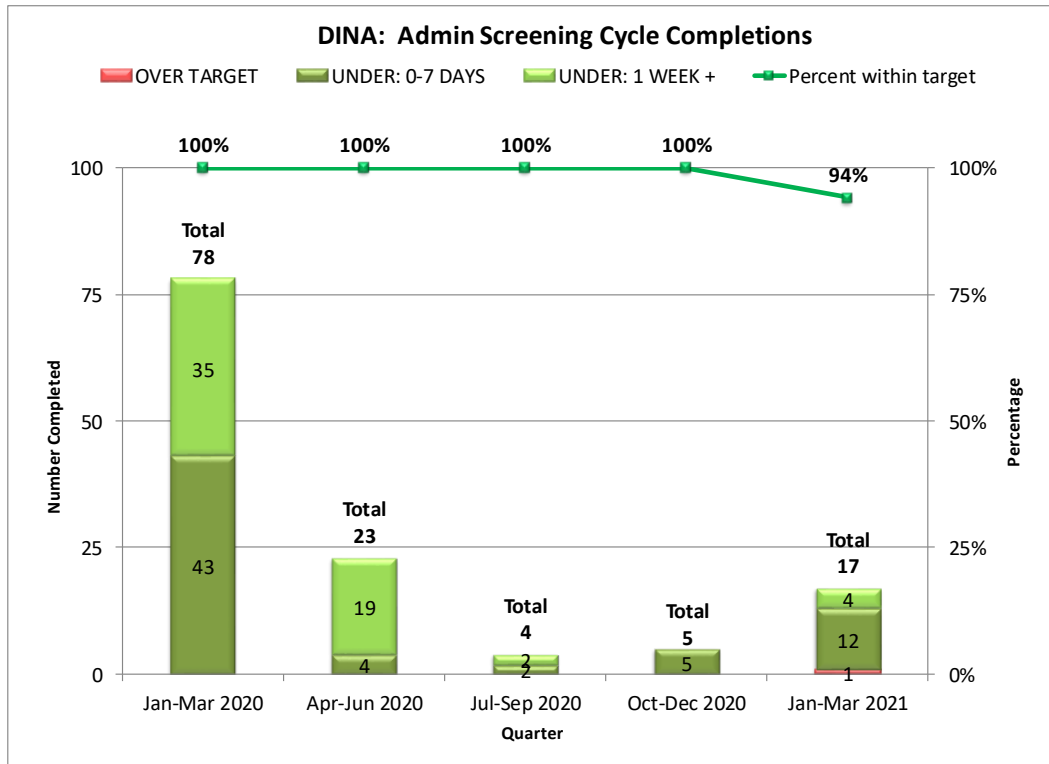


DINA: Screening Cycle Completions



PERFORMANCE

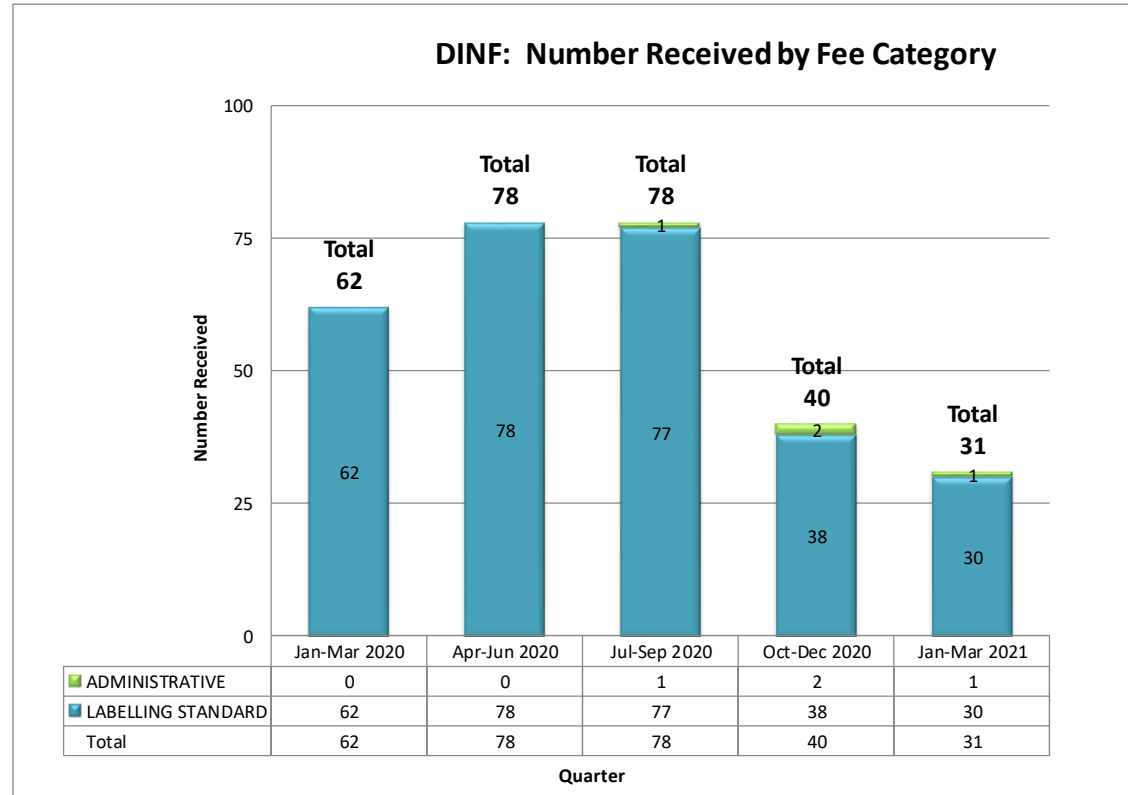
DINA: Administrative-Screening Cycle Completions



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

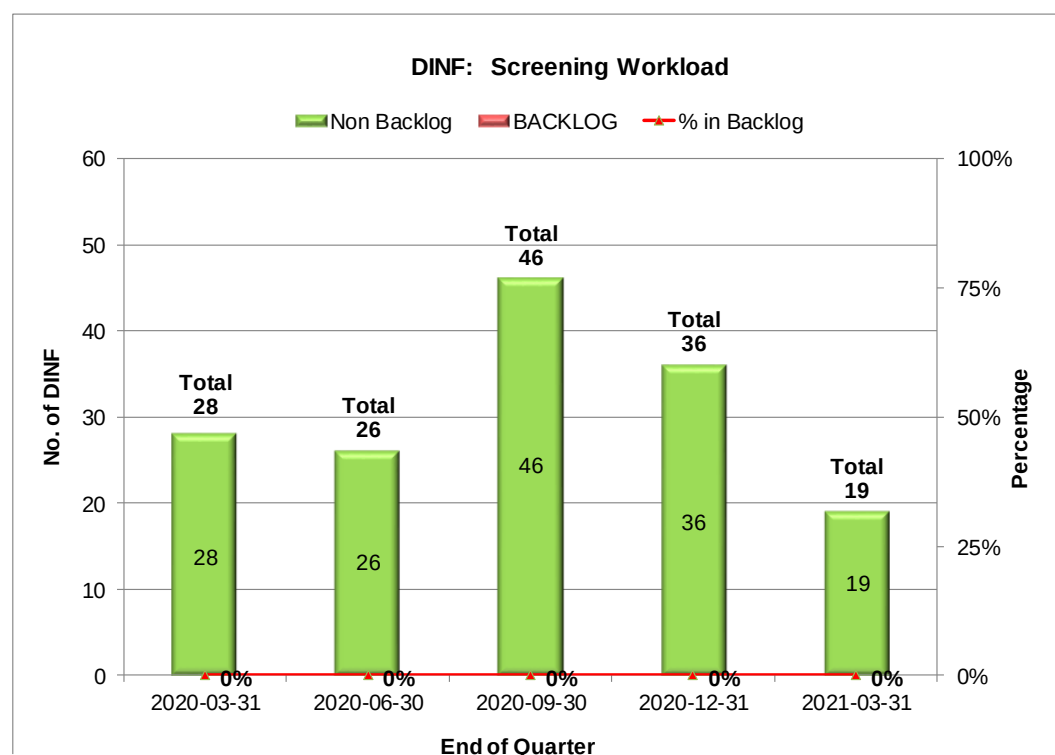
RECEIVED

DINF: Number Received by Fee Category



WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

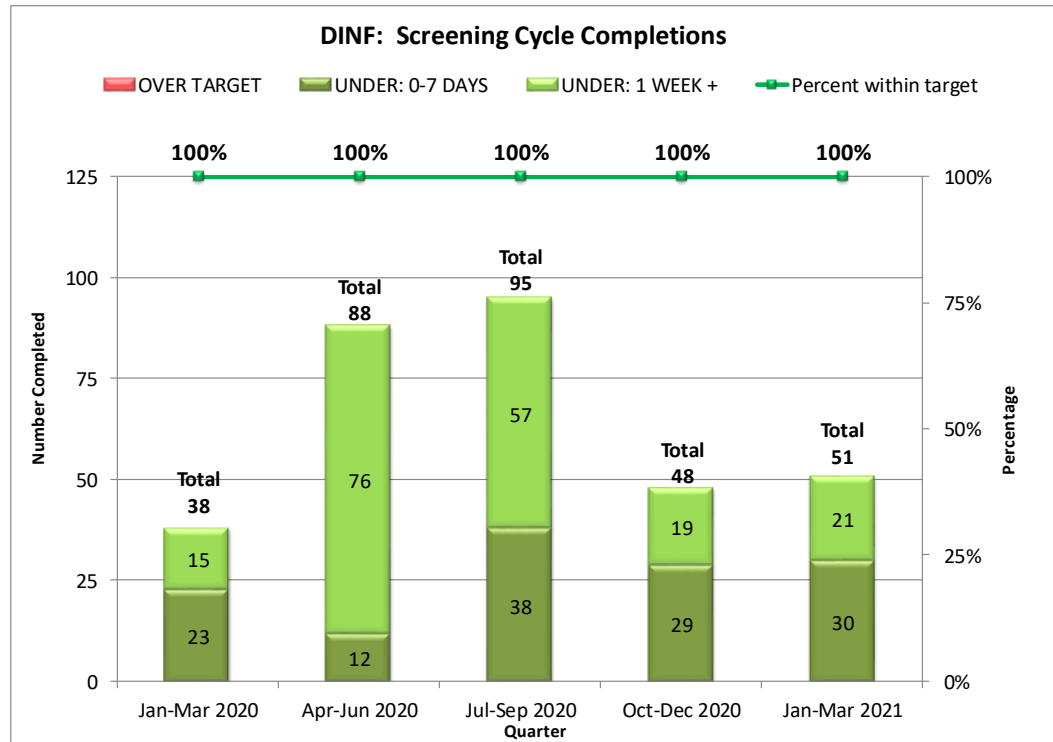
DINF: SCREENING WORKLOAD BY FEE CATEGORY and End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Standard	28	26	45	36	18
Backlog	0	0	0	0	0
Administrative	0	0	1	0	1
Backlog	0	0	0	0	0
Total	28	26	46	36	19
Non Backlog	28	26	46	36	19
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS**DINF: Number of Decisions by Fee Category**

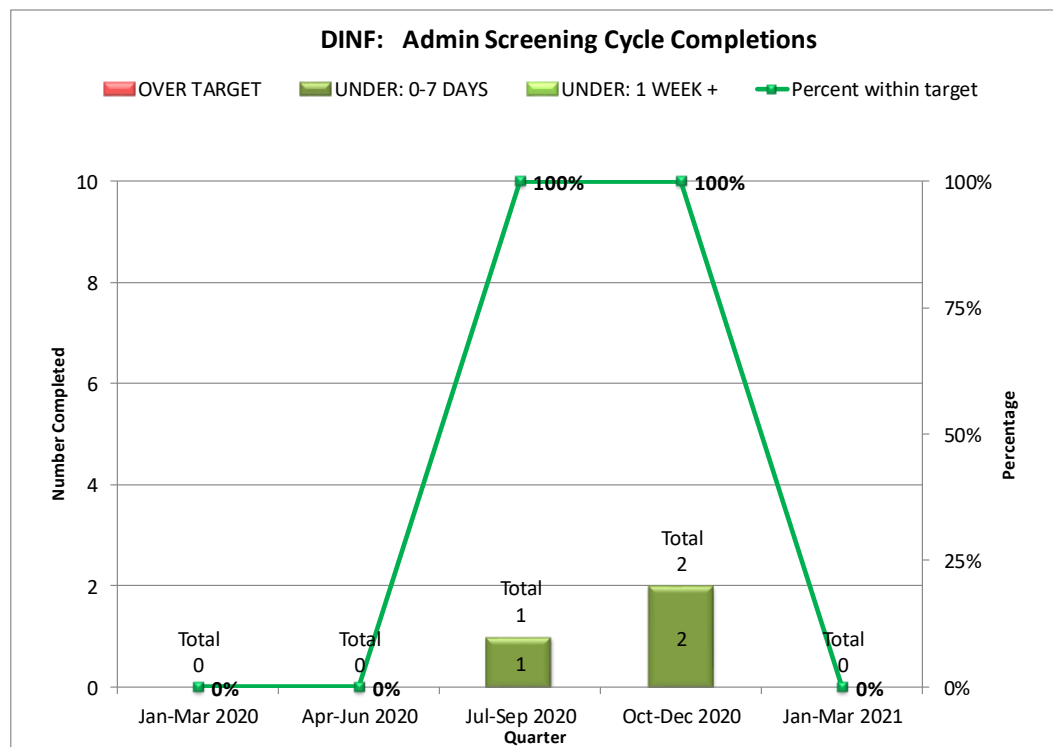
Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
LABELLING STANDARD	CANCELLATION LETTER	1	15	7	6	8
	NO OBJECTION LETTER	0	3	0	0	0
	NEW DRUG LETTER SCREEN	0	1	0	0	0
	NOTIFICATION FORM DIN SUB	32	56	52	52	40
	REJECTION LETTER (SCR)	1	0	0	1	2
	SCREENING DEFICIENCY NOTICE	4	18	5	21	6
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	3	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

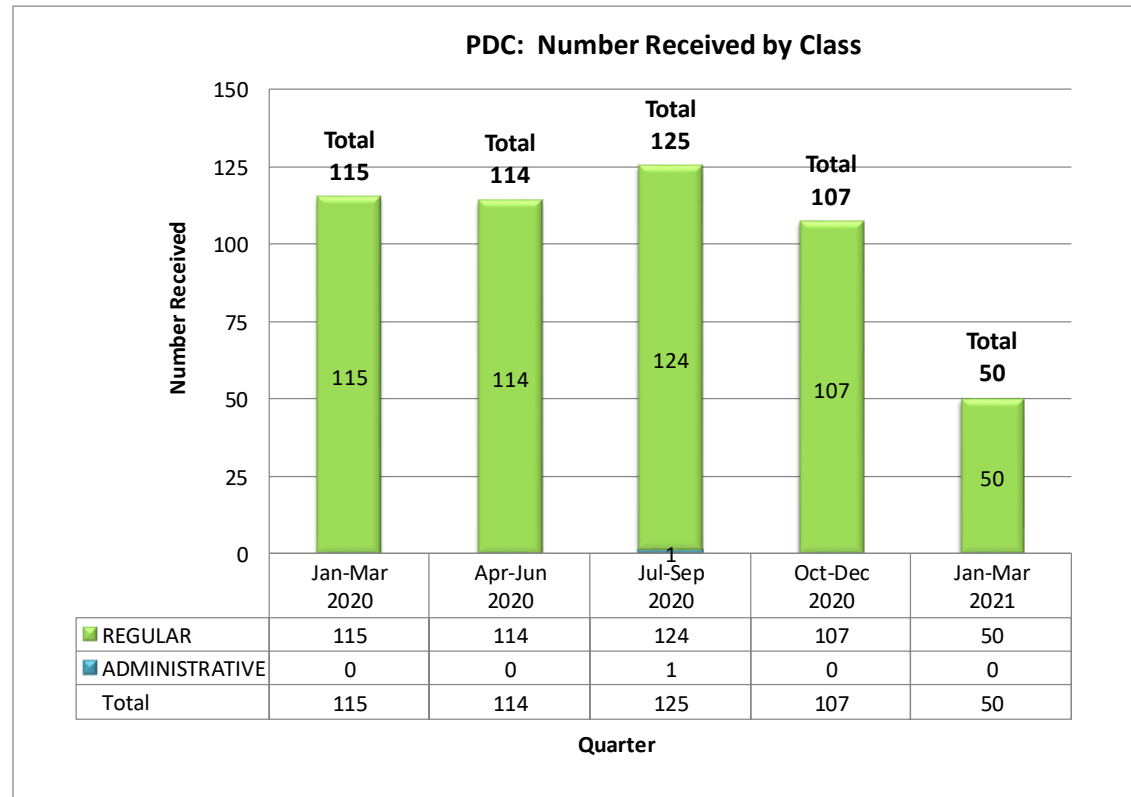
PERFORMANCE

DINF: Screening Cycle Completions



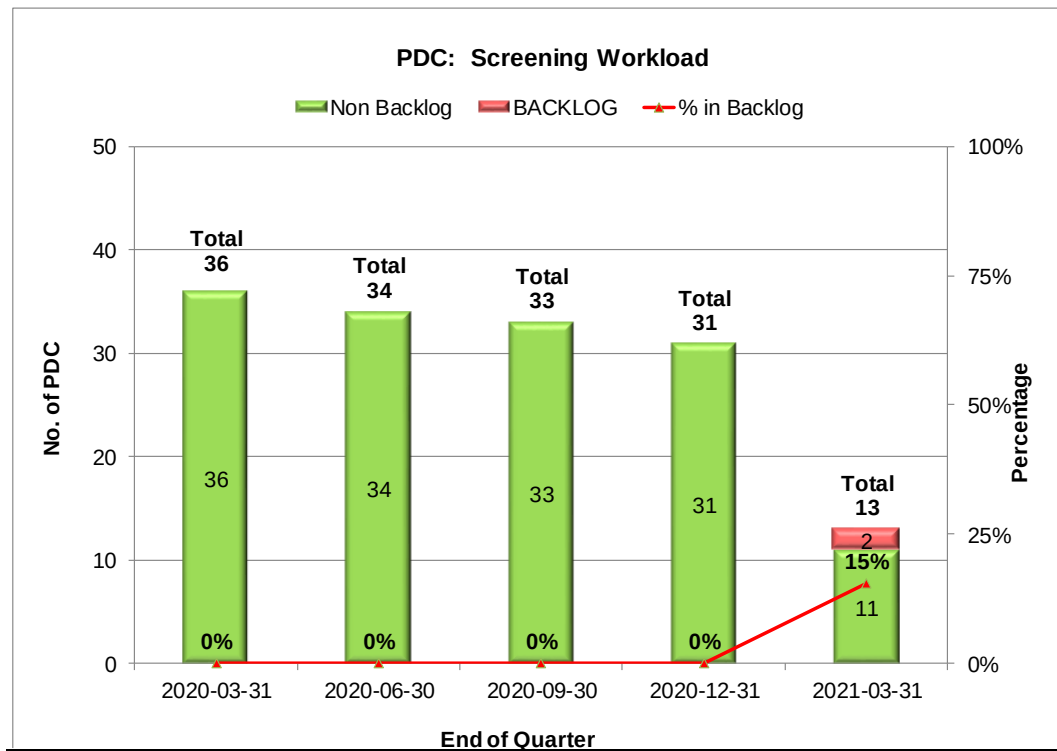
DINF: Admin-Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE**RECEIVED****PDC: Received by Class**

WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS By End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Regular	36	34	33	31	13
Backlog	0	0	0	0	2
Administrative	0	0	0	0	0
Backlog	0	0	0	0	0
Total	36	34	33	31	13
Non Backlog	36	34	33	31	11
BACKLOG	0	0	0	0	2
% in Backlog	0%	0%	0%	0%	15%

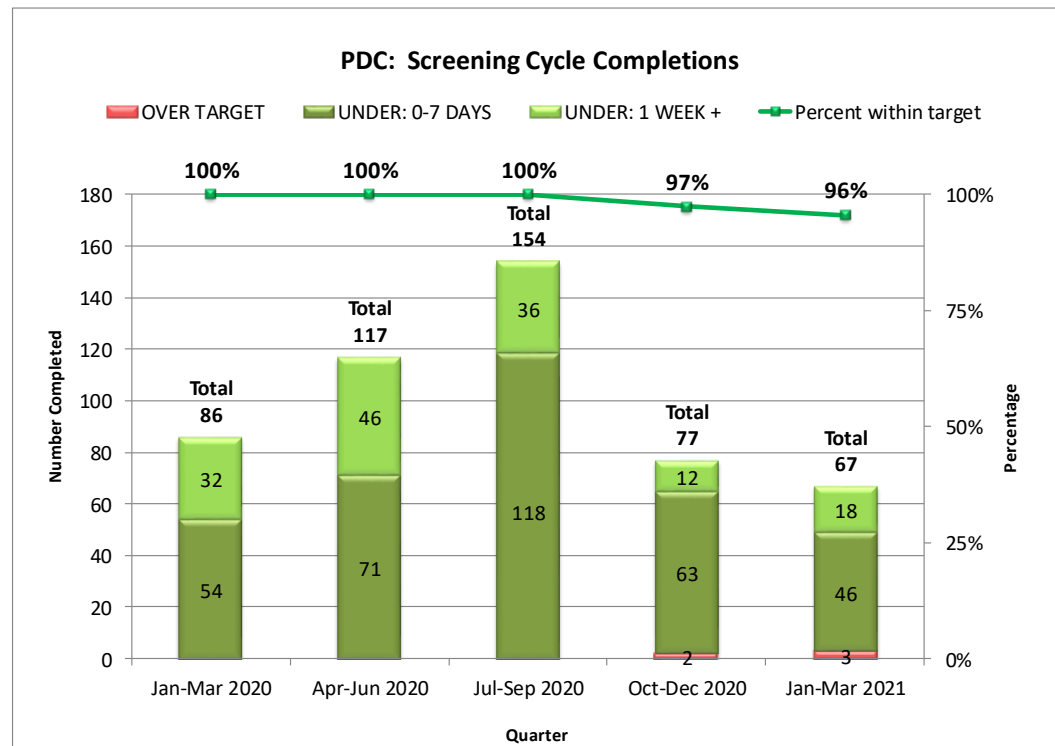
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
REGULAR	CANCELLATION LETTER	6	5	5	1	3
	NO OBJECTION LETTER	66	107	103	112	62
	NOT SATISFACTORY NOTICE	14	5	7	5	2
	REJECTION LETTER (SCR)	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING STANDARD	NO OBJECTION LETTER	0	0	0	0	0

PERFORMANCE

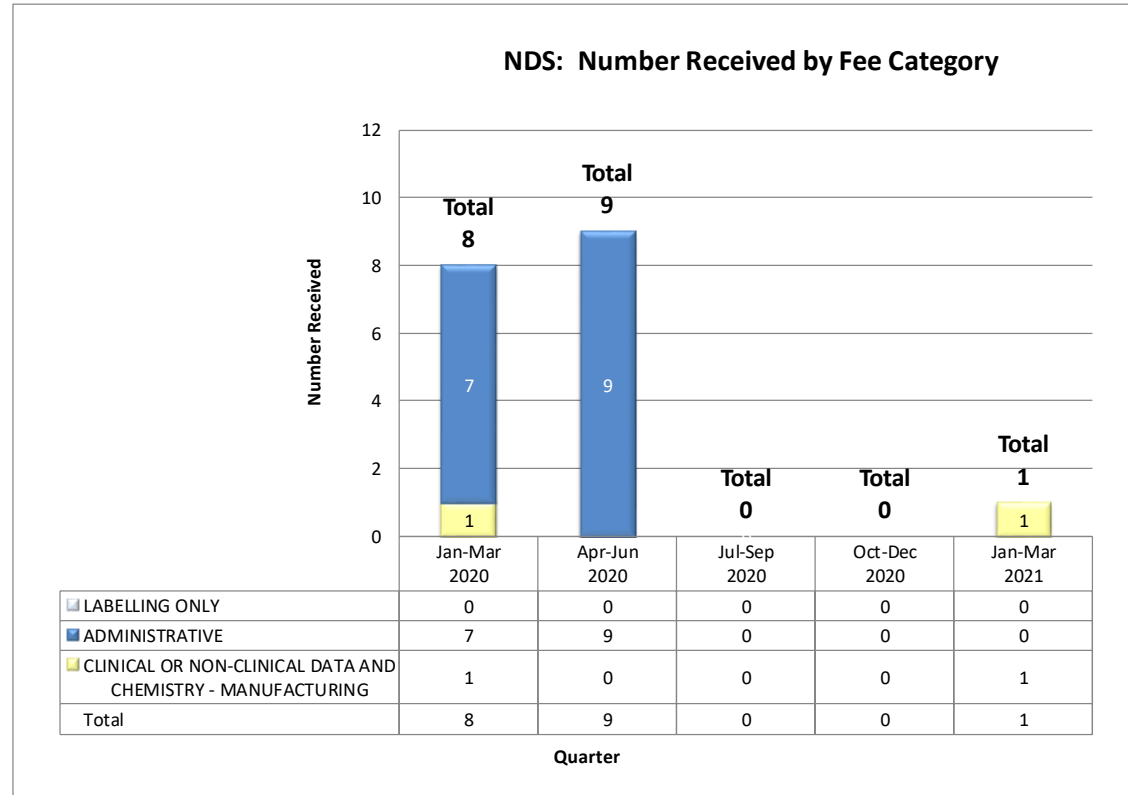
PDC: Screening Cycle Completions



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

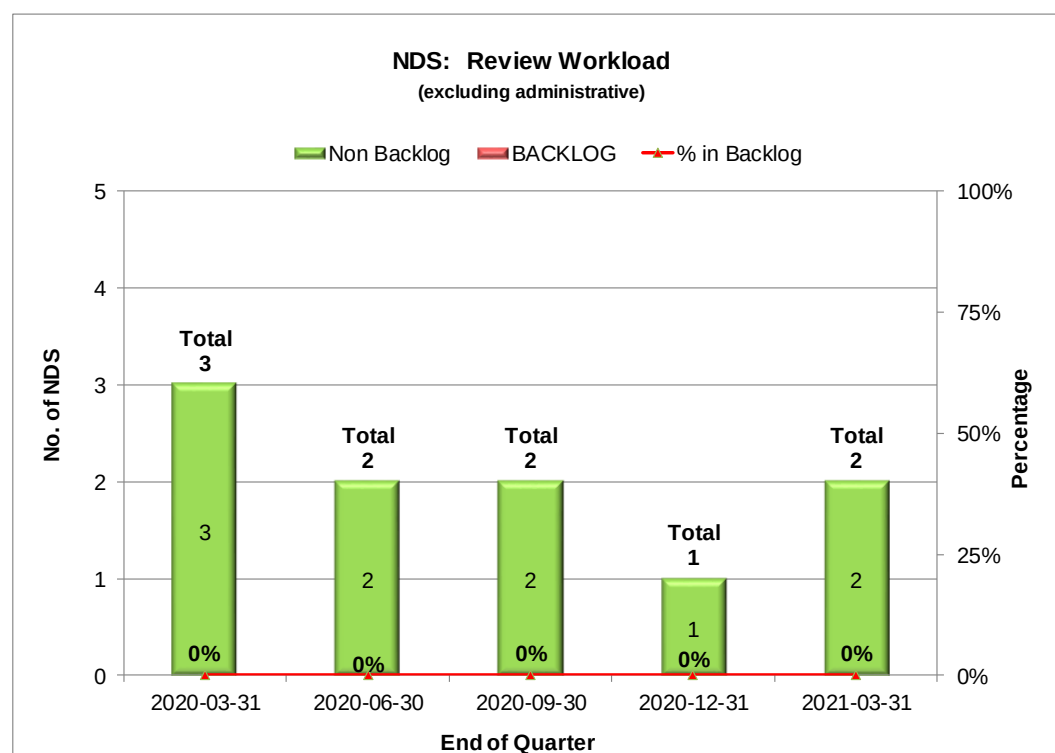
NDS: NEW DRUG SUBMISSION RECEIVED

NDS: Number Received by Fee Category



WORKLOAD

NDS: Review Workload

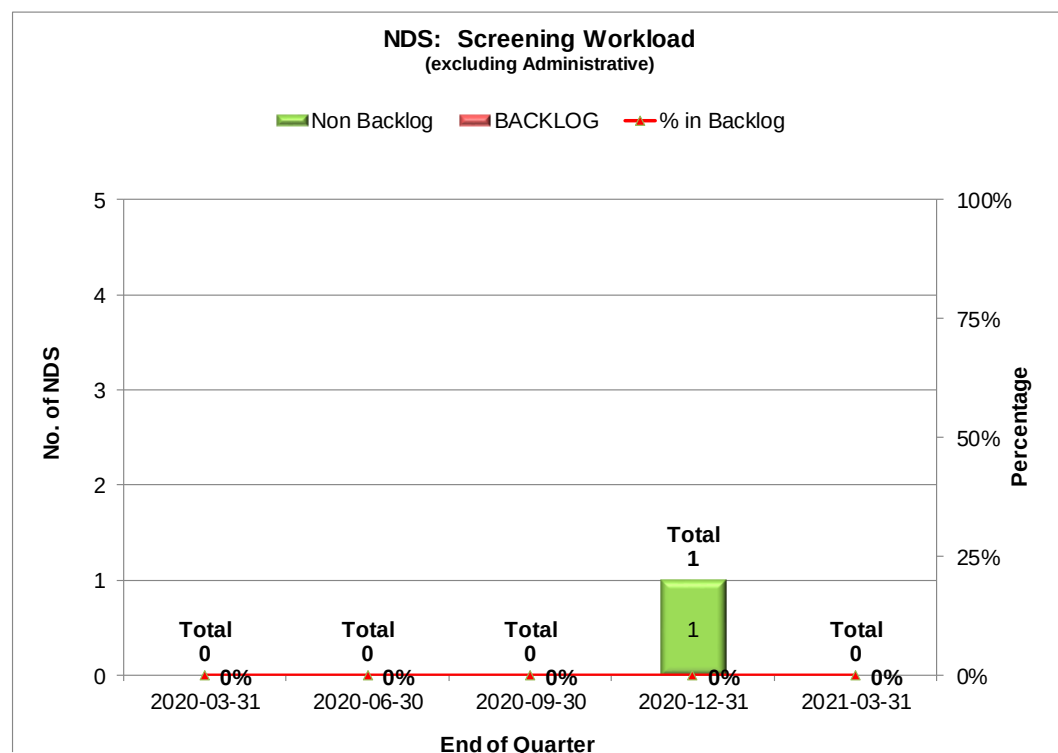


NDS: Review Workload by Fee Category

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

DECISIONS

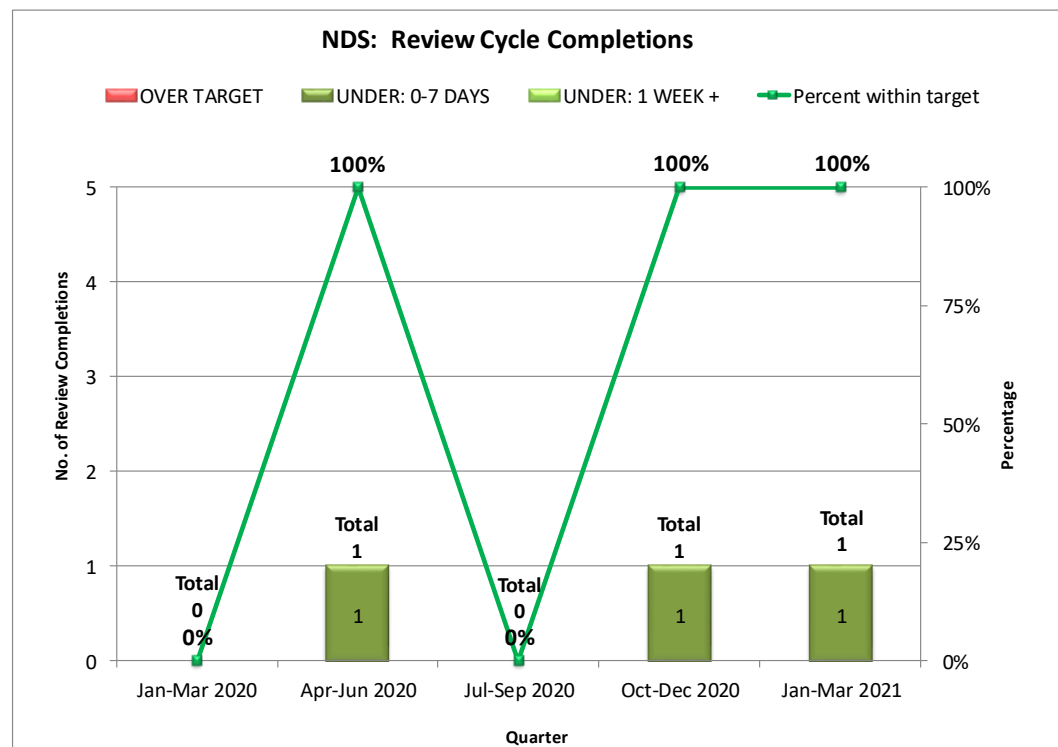
NDS: Number of Decisions by Fee Category

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

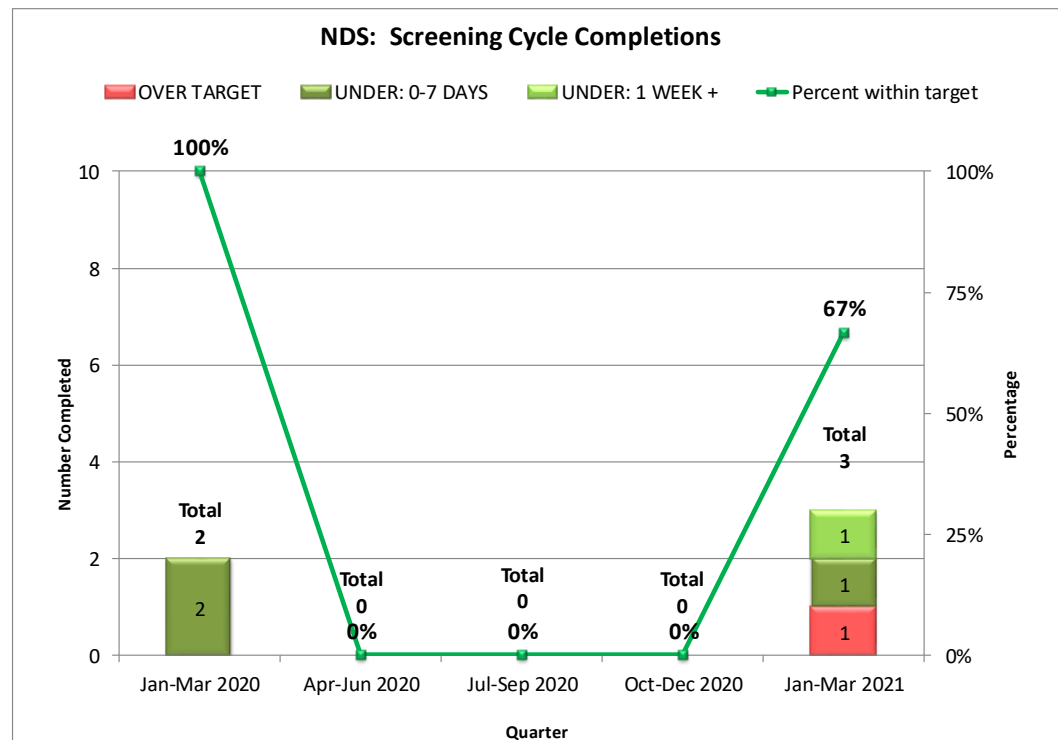
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions

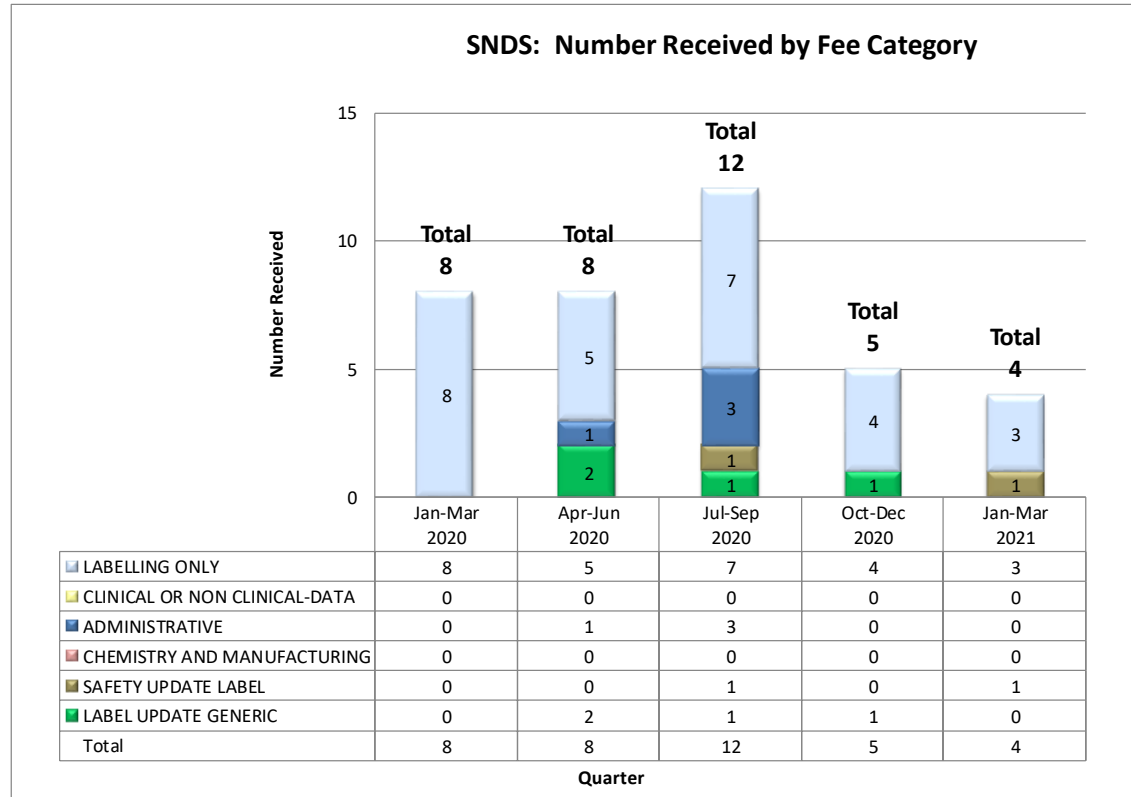


NDS: Screening Cycle Completions



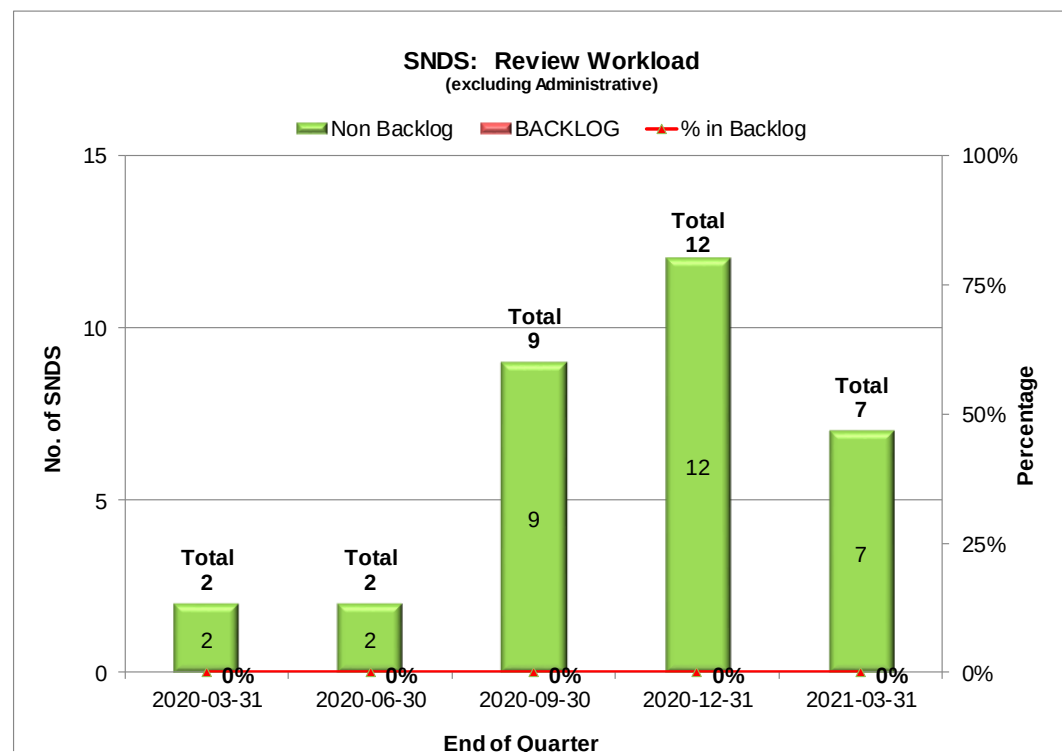
SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

SNDS: Number Received by Fee Category



WORKLOAD

SNDS: Review Workload

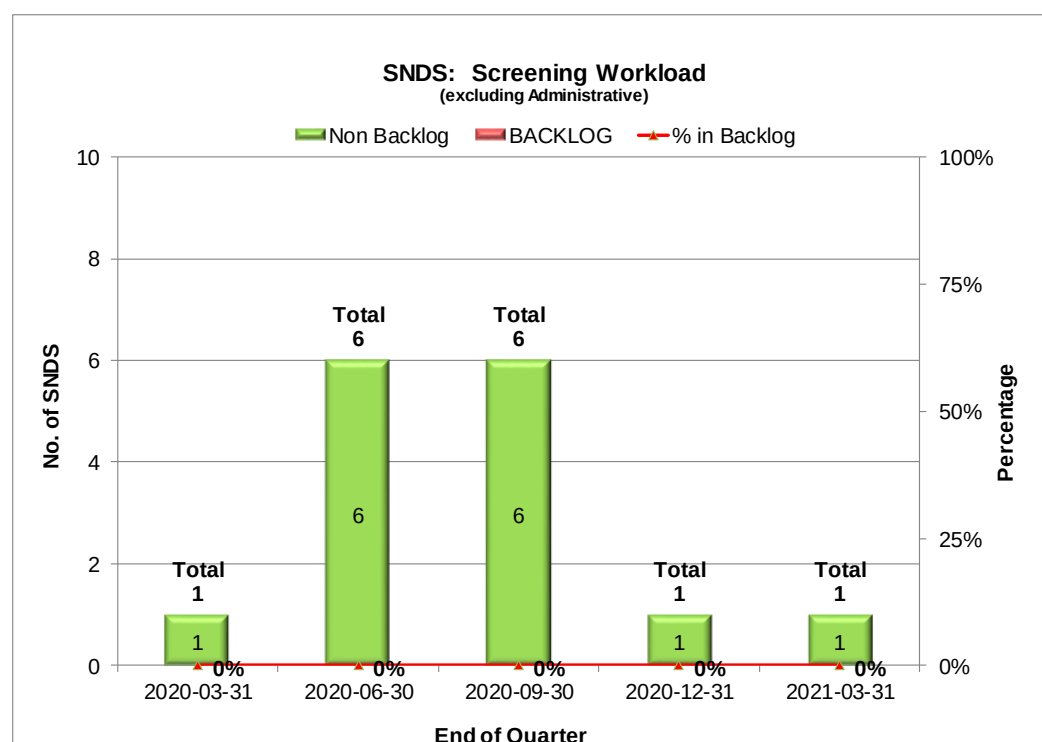


SNDS: Review Workload by Fee Category

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

DECISIONS

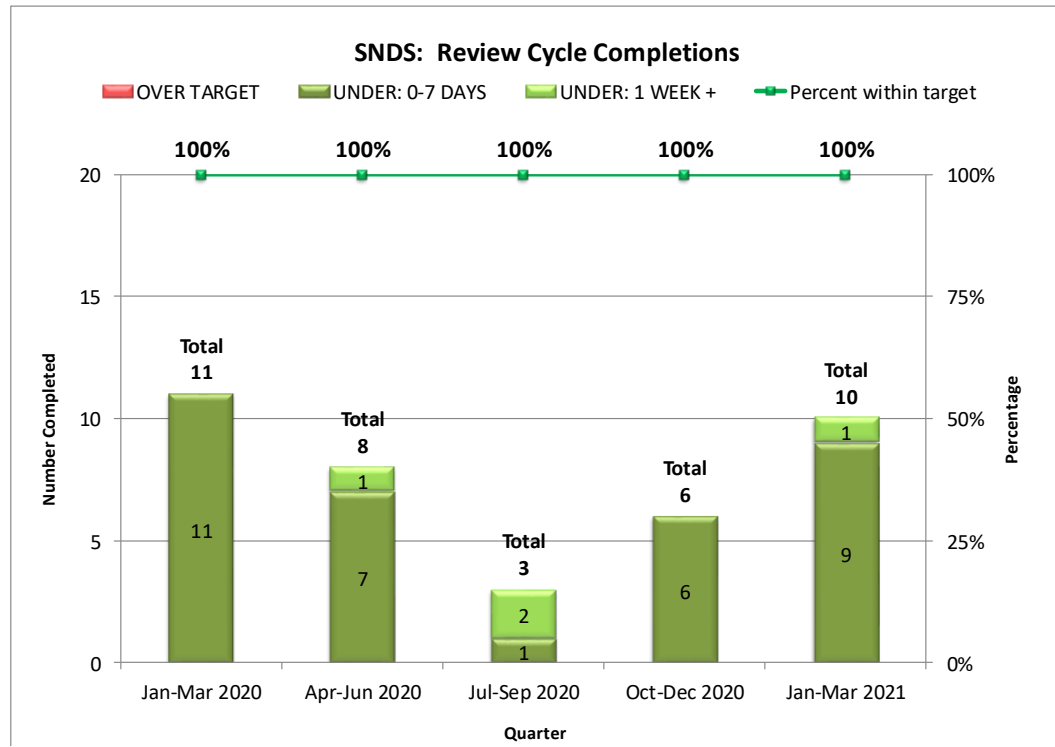
SNDS: Number of Decision by Fee Category

Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	1	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	0	1	0
	NOTICE OF NON-COMPLIANCE	1	0	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	7	6	1	5	8
	SCREENING DEFICIENCY NOTICE	5	0	1	0	0
	CANCELLATION LETTER	2	1	0	0	0
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	0	1	1	0
	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
SAFETY UPDATE LABEL	NOTICE OF COMPLIANCE*	0	0	0	0	1
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	1	0	0
	NOTICE OF COMPLIANCE*	0	0	2	2	0
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	2	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

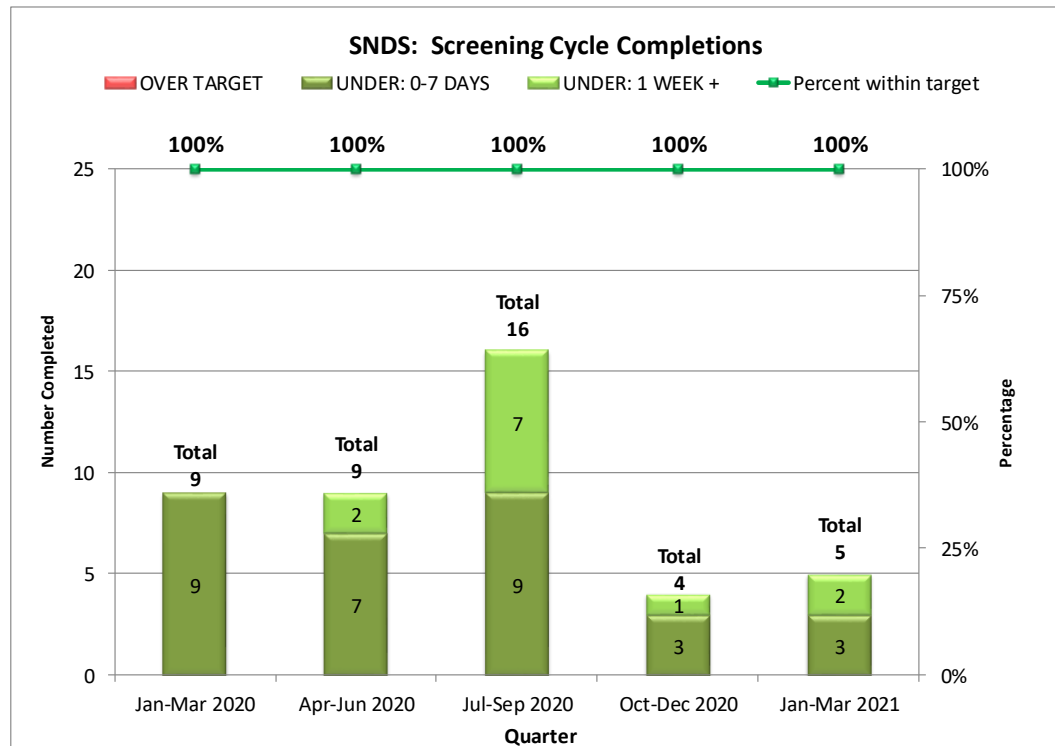
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: Review Cycle Completions



SNDS: Screening Cycle Completions



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

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

WORKLOAD**ANDS: Review Workload**

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

ANDS: Screening Workload

ANDS: SCREENING WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Comparative Studies with or without Chemistry - Manufacturing	1	0	0	1	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry and Manufacturing	0	0	1	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	1	0	1	1	1
Non Backlog	1	0	1	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					
	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Total	0	0	1	0	1
Non Backlog	0	0	1	0	1
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 2020	0	0	0	-	0
Apr-Jun 2020	1	1	0	50%	2
Jul-Sep 2020	0	3	0	100%	3
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0

ANDS: Screening Performance

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

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

Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
	CANCELLATION LETTER	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	1	1	0	0
	SCREENING DEFICIENCY NOTICE	1	1	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	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	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	6	0	7	6	2
CHEMISTRY AND MANUFACTURING	0	0	4	0	1
LABEL UPDATE GENERIC	0	1	4	3	2
LABELLING ONLY	8	7	7	10	5
Total	14	8	22	19	10

WORKLOAD**SANDS: Review Workload**

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	6	5	6	11	7
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	1	2	2	2
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	2	4	4
<i>Backlog</i>	0	0	0	0	0
Total	6	6	8	13	13
Non Backlog	6	6	8	13	13
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	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Labelling Only	2	3	5	6	4
<i>Backlog</i>	1	0	0	0	0
Chemistry and Manufacturing	0	0	2	0	0
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	0	2	1	0
<i>Backlog</i>	0	0	0	0	0
Total	2	3	9	7	4
Non Backlog	1	3	9	7	4
BACKLOG	1	0	0	0	0
% in Backlog	50%	0%	0%	0%	0%

SANDS: Administrative-Screening Workload

SANDS: ADMINISTRATIVE-SCREENING WORKLOAD by End of Quarter					
	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Total	5	0	3	2	2
Non Backlog	5	0	3	2	2
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 2020	0	1	0	100%	1
Apr-Jun 2020	0	8	0	100%	8
Jul-Sep 2020	0	4	5	100%	9
Oct-Dec 2020	0	2	0	100%	2
Jan-Mar 2021	0	10	0	100%	10

SANDS: Screening Performance

SANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jan-Mar 2020	1	9	0	90%	10
Apr-Jun 2020	1	3	5	89%	9
Jul-Sep 2020	0	6	13	100%	19
Oct-Dec 2020	0	7	3	100%	10
Jan-Mar 2021	1	10	3	93%	14

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

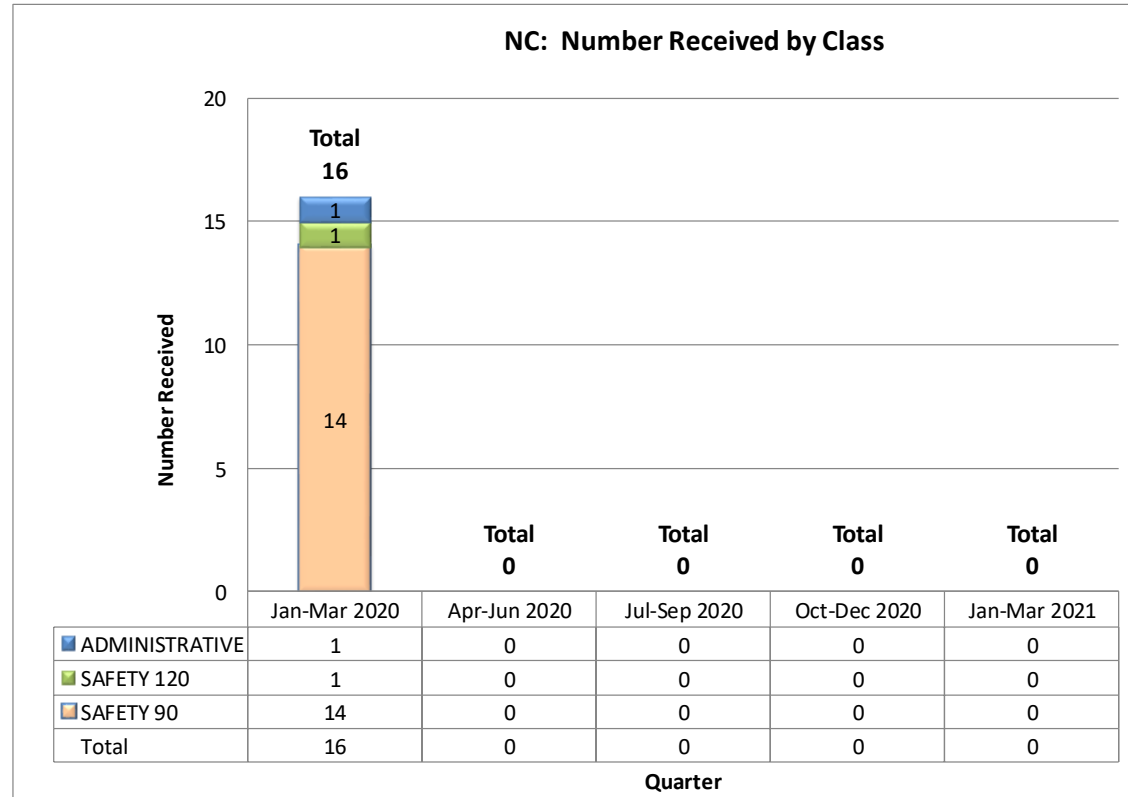
Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
LABELLING ONLY	NOTICE OF COMPLIANCE *	1	8	3	4	10
	SCREENING DEFICIENCY NOTICE	4	1	1	0	2
	CANCELLATION LETTER	0	0	1	0	1
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	2	5	3	6	3
	CANCELLATION LETTER	0	0	0	1	0
	SCREENING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

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

NC: NOTIFIABLE CHANGE

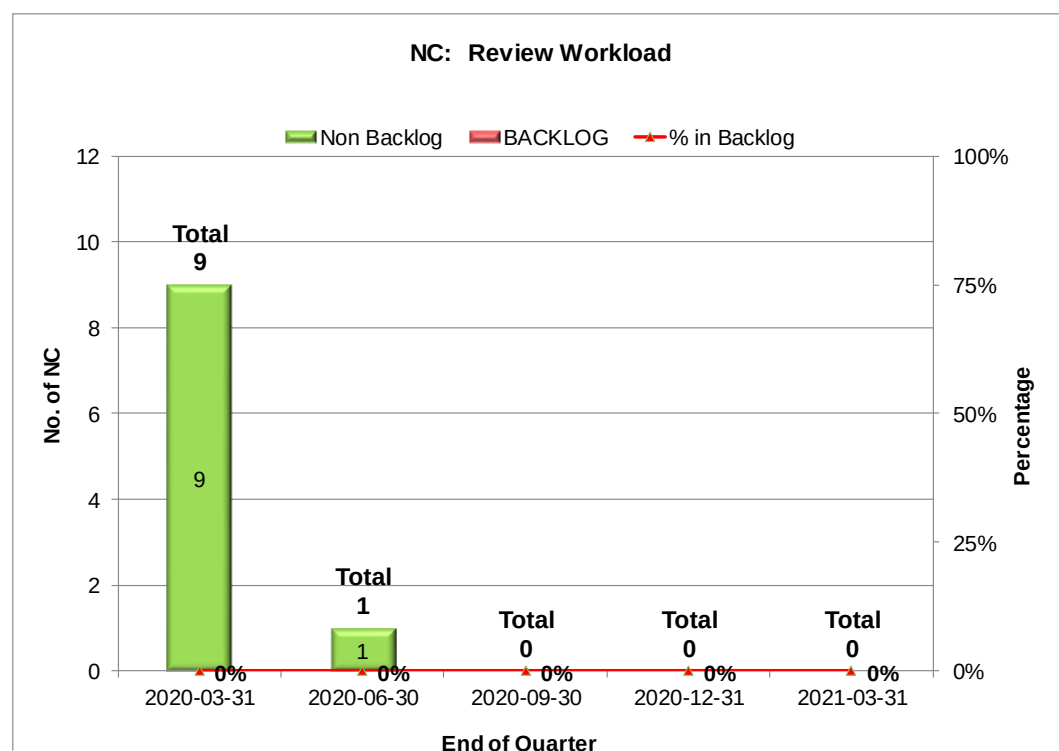
RECEIVED

NC: Number Received by Class



WORKLOAD

NC: Review Workload

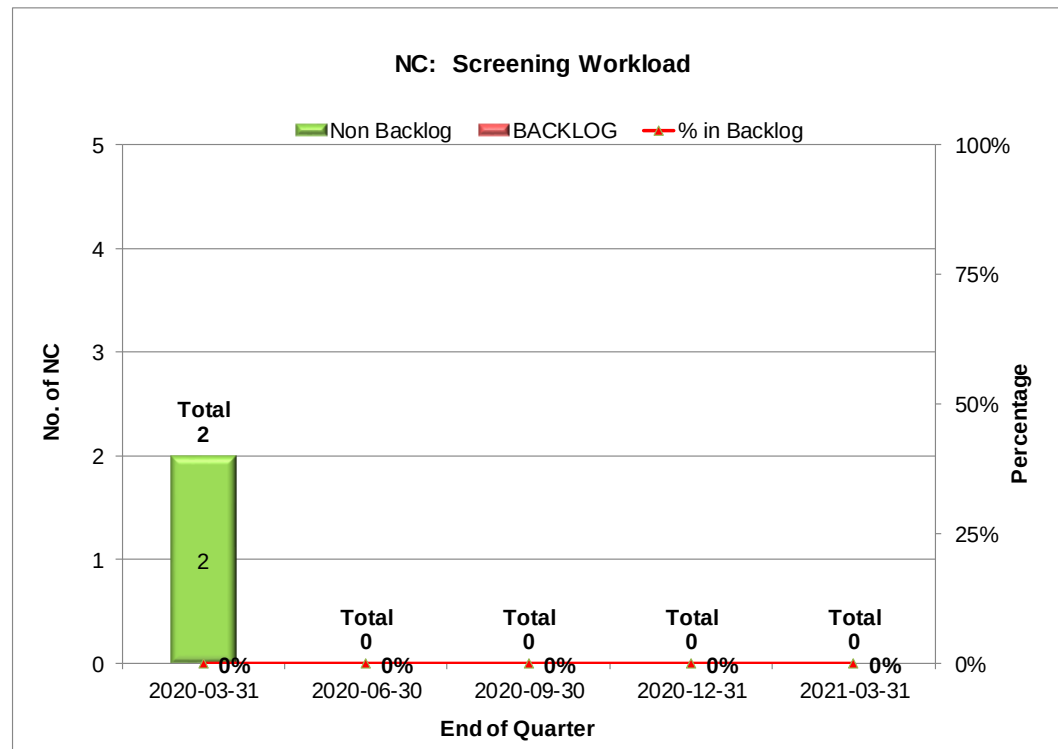


NC: Review Workload by class

NC: REVIEW WORKLOAD BY CLASS and End of Quarter					
Class	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Safety 90	8	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Safety 120	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	9	1	0	0	0
Non Backlog	9	1	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NC: Screening Workload



NC: Screening Workload by Class

NC: SCREENING WORKLOAD BY CLASS and End of Quarter					
Class	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Safety 90	2	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	2	0	0	0	0
Non Backlog	2	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC: Administrative Screening Workload

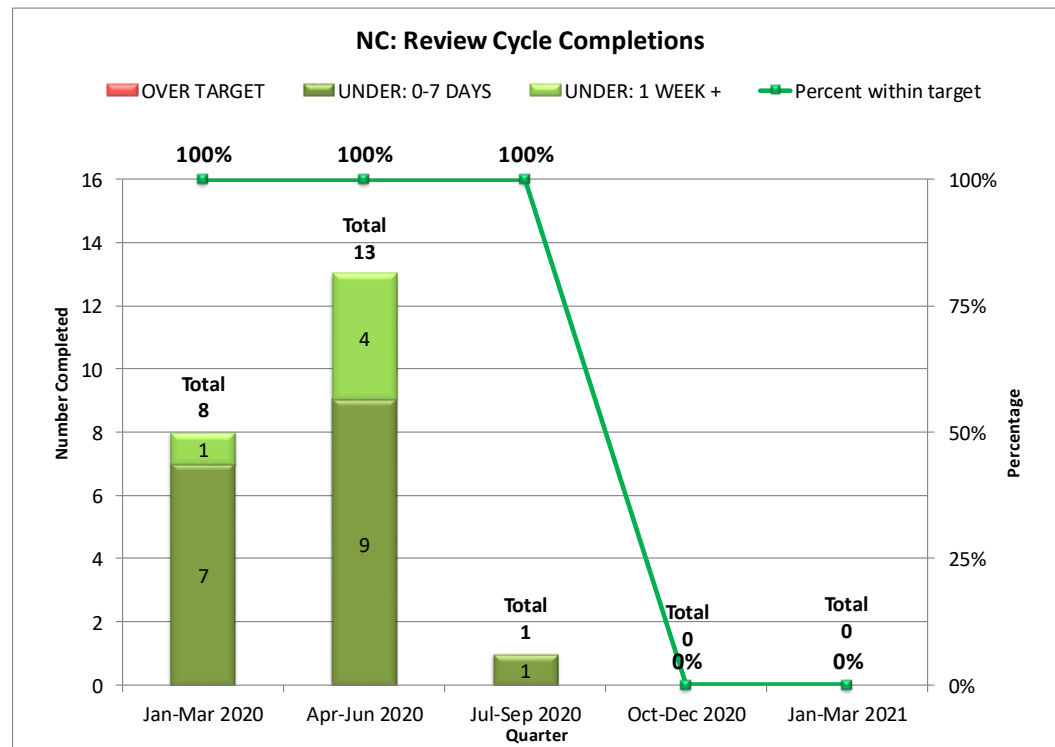
NC: ADMIN SCREENING WORKLOAD					
By End of Quarter					
Class	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
Administrative	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog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

DECISIONS**NC: Number of Decisions by Class**

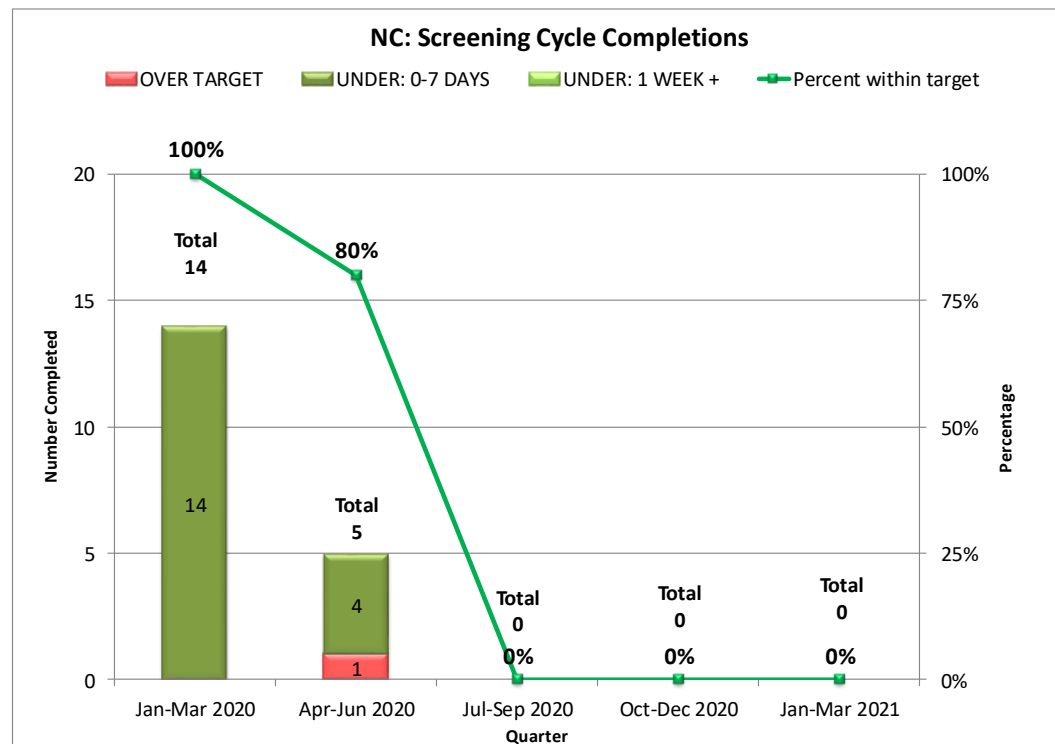
CLASS	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	NO OBJECTION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
SAFETY 90	NO OBJECTION LETTER	8	12	1	0	0
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	CANCELLATION LETTER	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	4	0	0	0	0
SAFETY 120	CANCELLATION LETTER	1	0	0	0	0
	NO OBJECTION LETTER	0	1	0	0	0

PERFORMANCE

NC: Review Cycle Completions



NC: Screening Cycle Completions



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

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

MPNDS: Number Received by Fee Category

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

MPSNDS: Number Received by Fee Category

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

PART 2: DISINFECTANT PRODUCTS

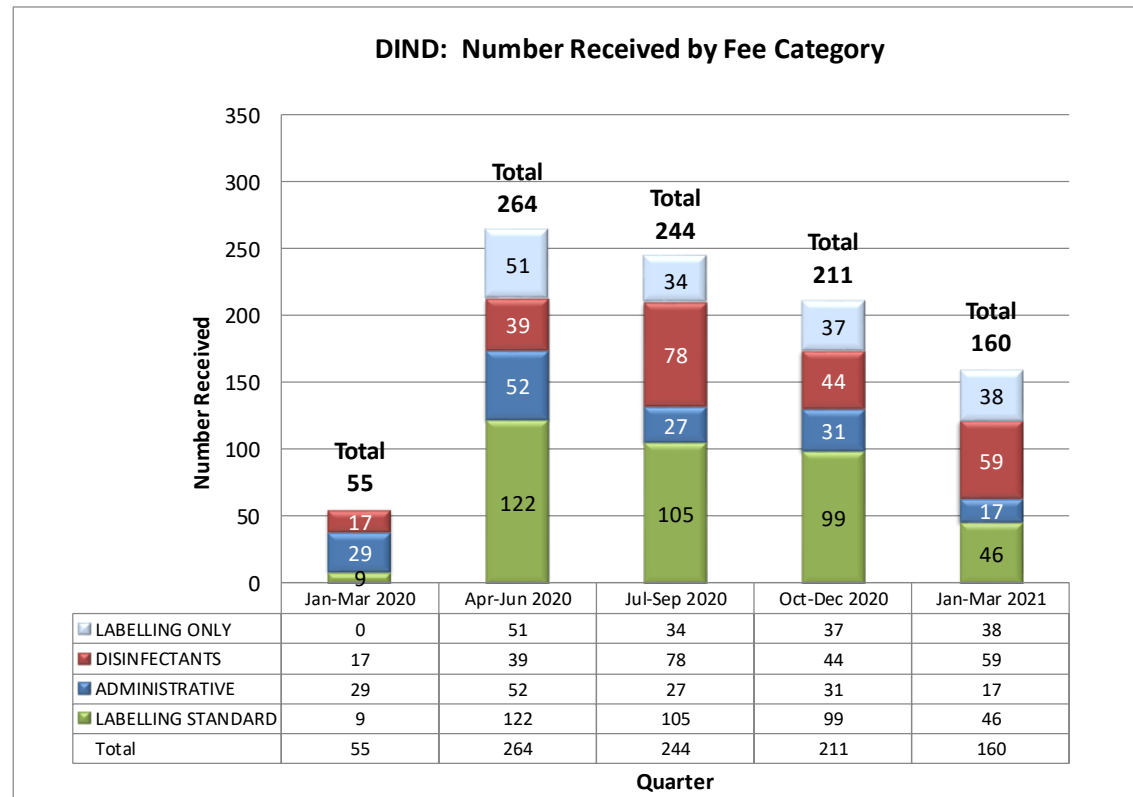
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

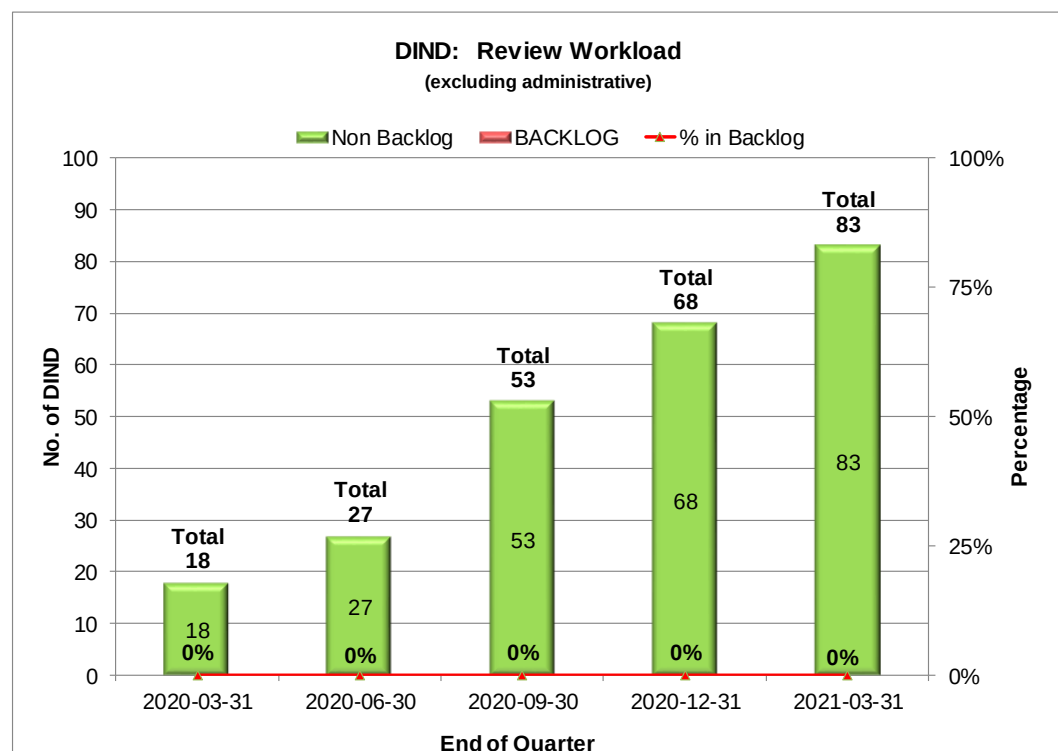
RECEIVED

DIND-Disinfectant Products: Number Received by Fee Category

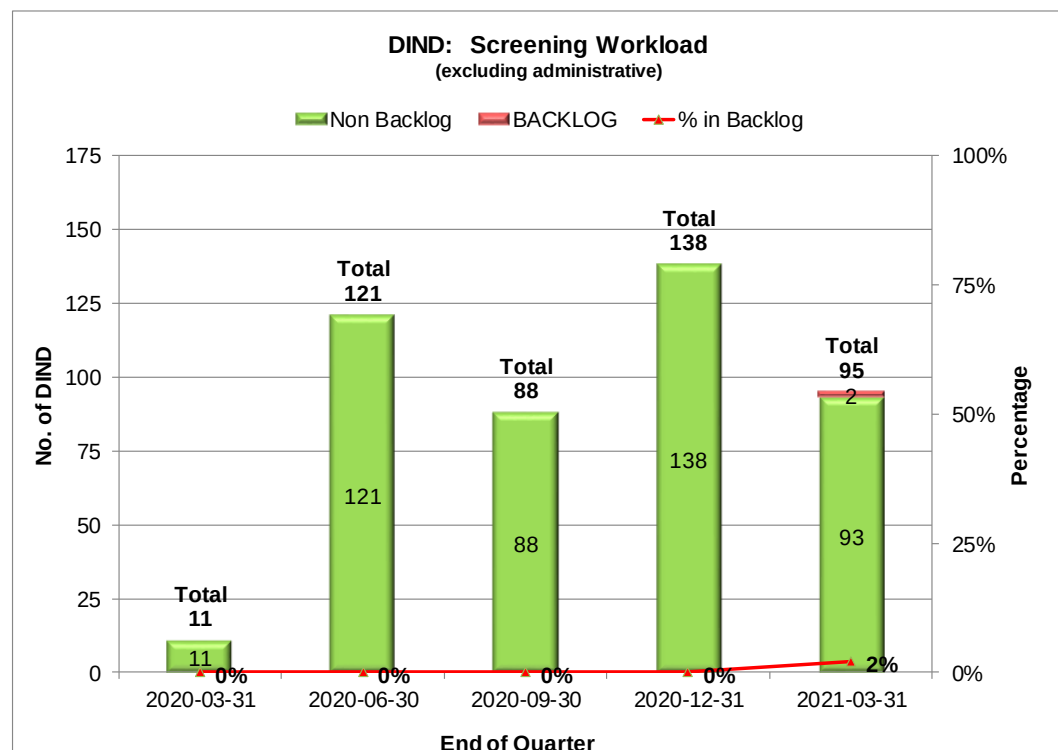


WORKLOAD

DIND-Disinfectant Products: Review Workload

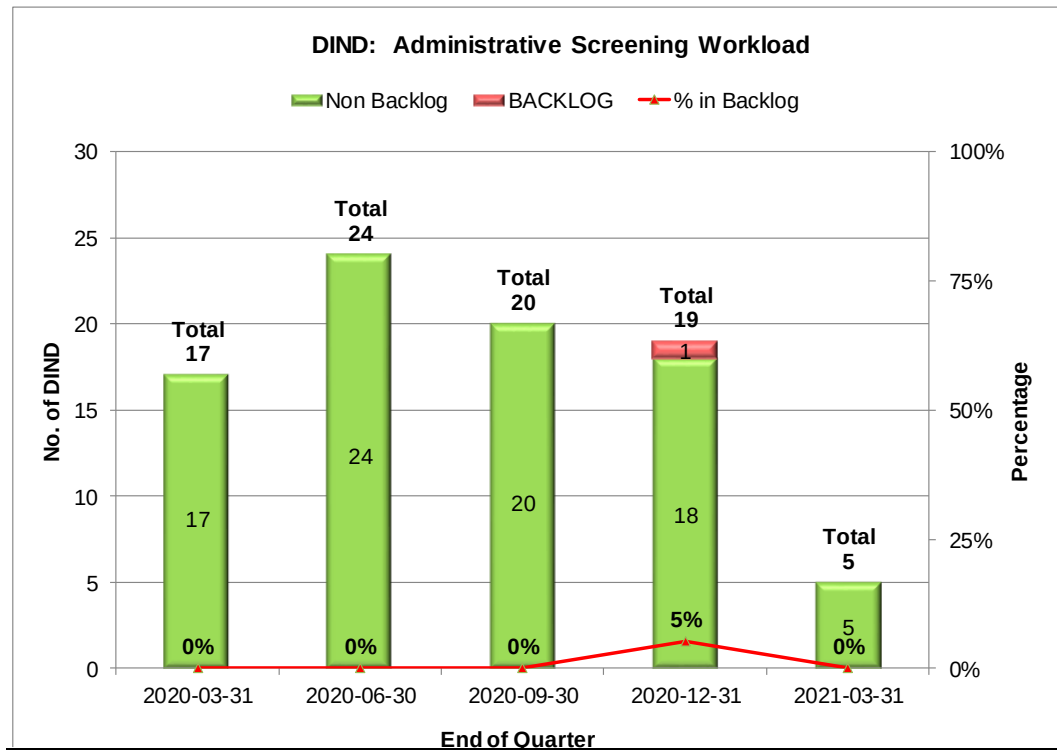


DIND-Disinfectant Products: Screening Workload



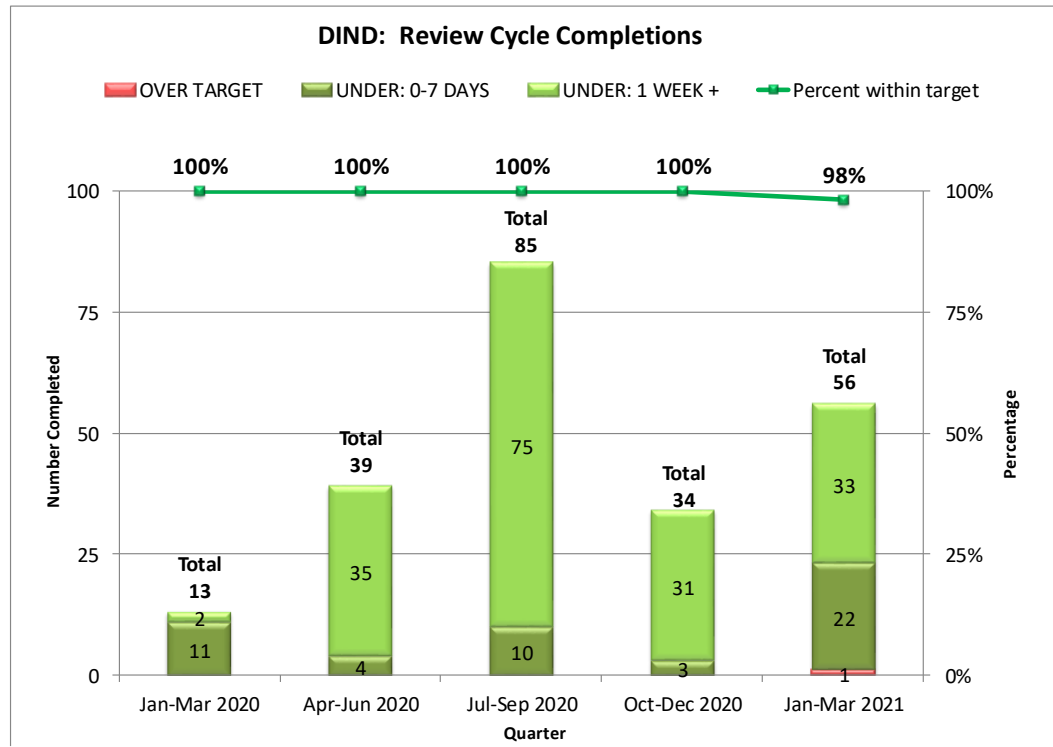
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

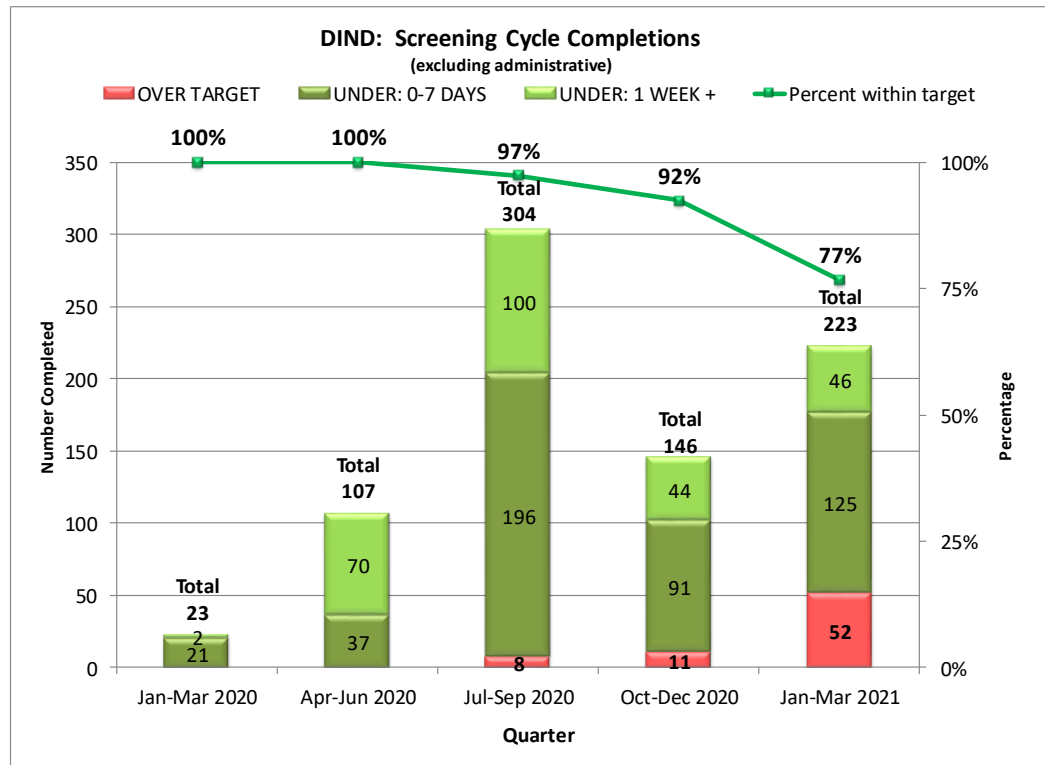


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

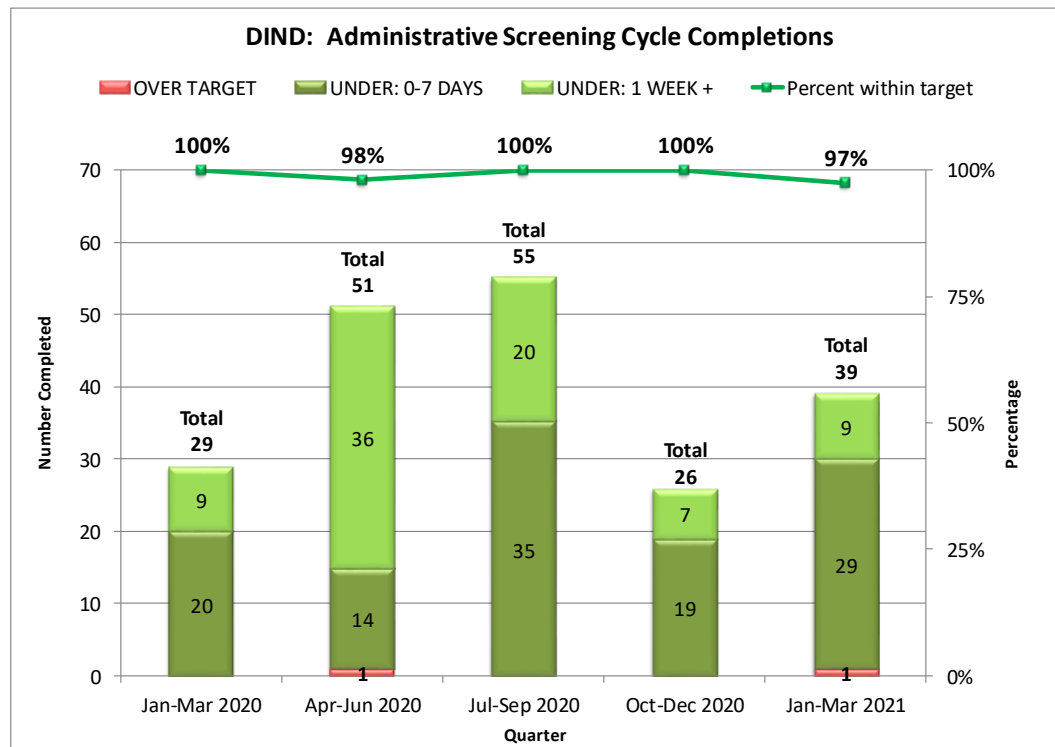


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



DECISIONS

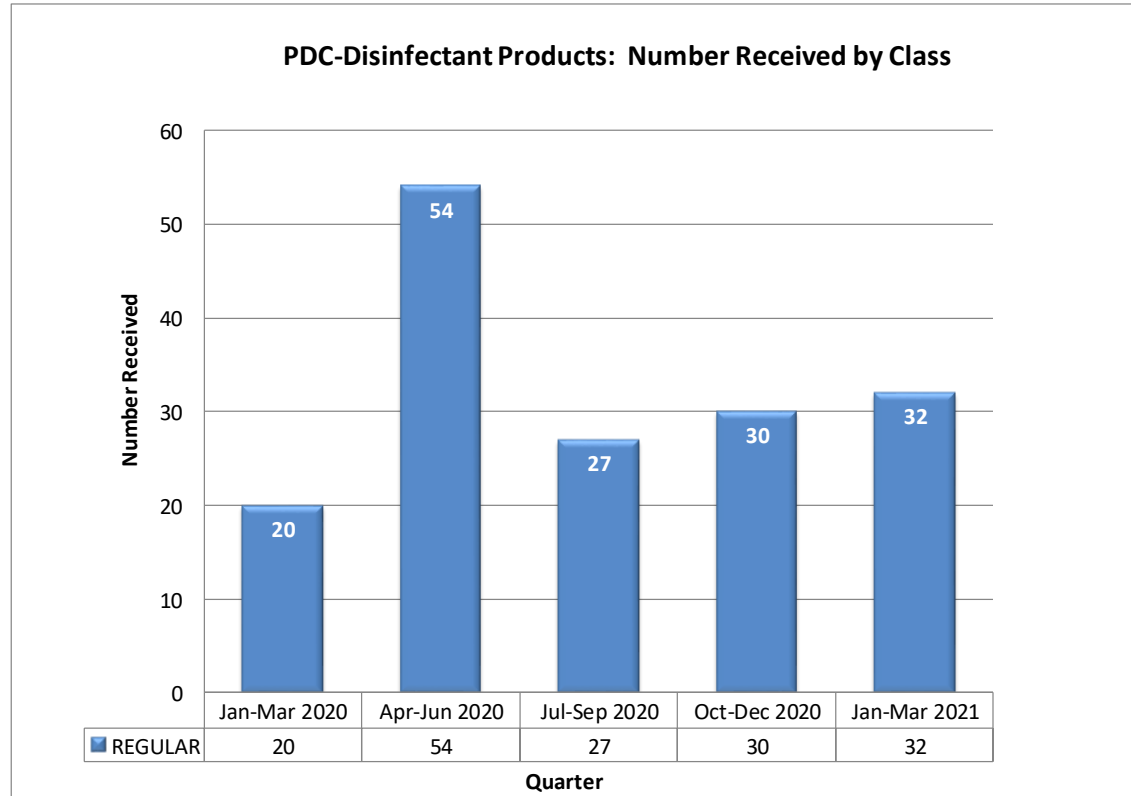
DIND-Disinfectant Products: Number of Decisions by Fee Category

Fee Category	Decision Document Type	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	5	8	4	8
	NO OBJECTION LETTER	0	4	9	0	0
	NOTIFICATION FORM DIN SUB	21	33	15	17	22
	REJECTION LETTER (SCR)	1	1	2	1	4
	SCREENING DEFICIENCY NOTICE	8	11	11	20	10
DISINFECTANTS	NO OBJECTION LETTER	2	11	28	22	12
	CANCELLATION LETTER	0	3	3	4	9
	NEW DRUG LETTER SCREEN	0	2	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	3	1
	NOTIFICATION FORM DIN SUB	11	8	11	5	12
	SCREENING DEFICIENCY NOTICE	0	6	12	12	11
	REJECTION LETTER (SCR)	1	0	4	8	1
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	10	27	104	59	79
	NO OBJECTION LETTER	0	0	1	0	2
	SCREENING DEFICIENCY NOTICE	5	11	22	40	22
	NEW DRUG LETTER SCREEN		1	0	0	0
	REJECTION LETTER (SCR)	0	0	7	3	7
	CANCELLATION LETTER	0	8	15	6	13
DISINFECTANT LABELLING ONLY	NOTIFICATION FORM DIN SUB	0	16	22	22	27
	NO OBJECTION LETTER	0	2	2	1	1
	CANCELLATION LETTER	0	3	4	2	10
	SCREEN. DEFICIENCY NOTICE	0	2	2	5	7
	NOTICE OF NON-COMPLIANCE	0	0	0	2	2
	REJECTION LETTER (SCR)	0	0	0	1	0

PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

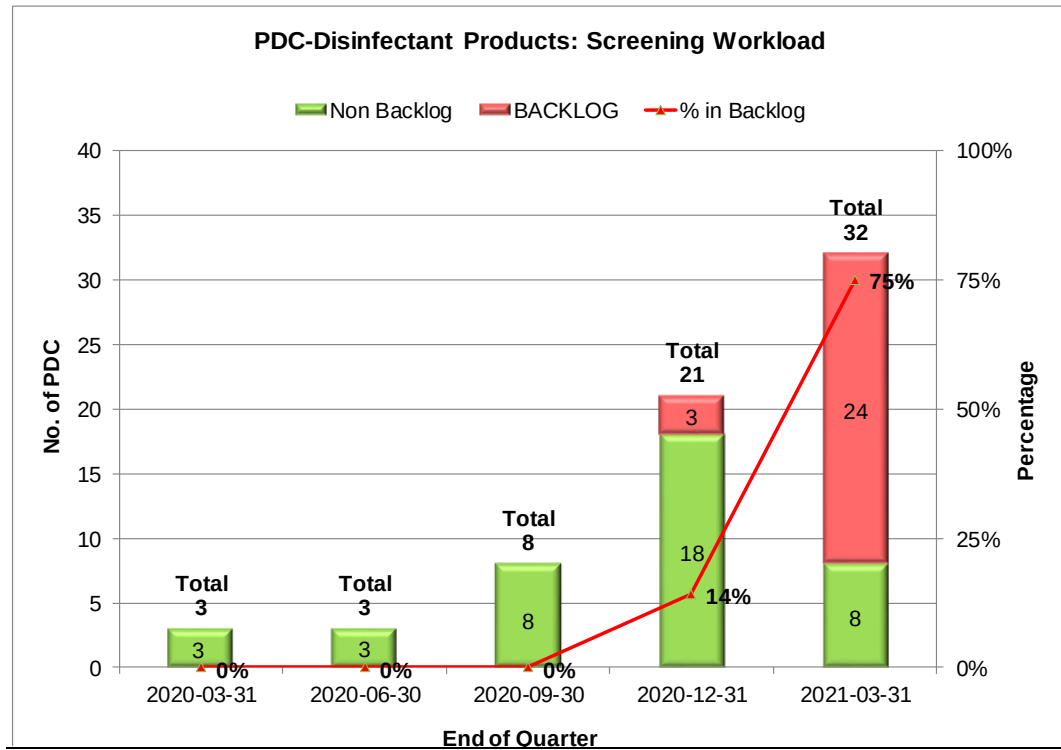
RECEIVED

PDC-Disinfectant Products: Received by Fee Class



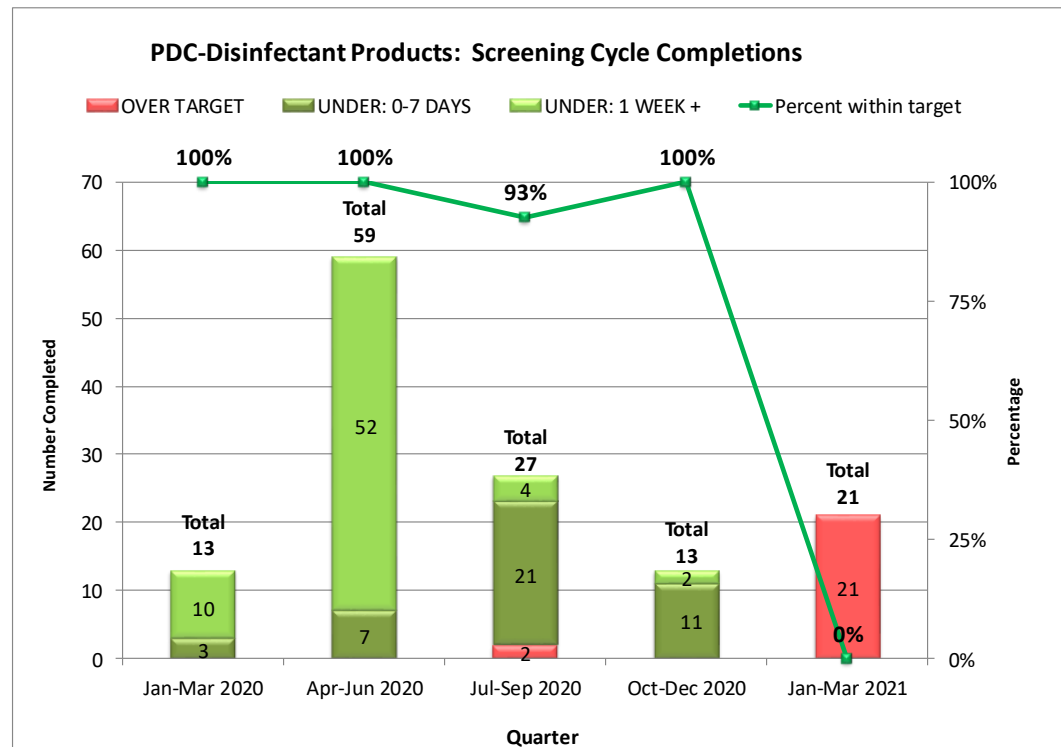
WORKLOAD

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 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
REGULAR	CANCELLATION LETTER	1	2	0	2	1
	NO OBJECTION LETTER	10	48	15	14	17
	NOT SATISFACTORY NOTICE	1	9	2	5	2
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	1
	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	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
ADMINISTRATIVE	0	0	0	0	0
DISINFECTANTS	0	2	1	1	1
<i>Total</i>	<i>0</i>	<i>2</i>	<i>1</i>	<i>1</i>	<i>1</i>

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

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

NDS-Disinfectant Products: Administrative-Screening Workload

NDS-D: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
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
Jan-Mar 2020	0	0	0	-	0
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	1	0	100%	1
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0

NDS-Disinfectant Products: Screening Performance

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

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 2020	0	0	0	-	0
Apr-Jun 2020	0	0	0	-	0
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	0	0	-	0
Jan-Mar 2021	0	0	0	-	0

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

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

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

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

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

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

NC-Disinfectant Products: REVIEW WORKLOAD (excluding Administrative) by End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
SAFETY 90	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%

NC-Disinfectant Products: Screening Workload

NC-Disinfectant Products: SCREENING WORKLOAD (excluding Administrative) by End of Quarter					
FEE CATEGORY	2020-03-31	2020-06-30	2020-09-30	2020-12-31	2021-03-31
SAFETY 90	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**NC-Disinfectant Products: Review Performance**

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

NC-Disinfectant Products: Screening Performance

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

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

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

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

PRE - DIN MEETING (MPDIN) DISINFECTANT PRODUCTS					
Fee Category	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1	3	0	1	1
CHEMISTRY AND MANUFACTURING	0	0	0	1	0
Total	1	4	0	2	1

MPNDS-Disinfectant Products: Received by Fee Category

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

MPSNDS-Disinfectant Products: Received by Fee Category

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