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Natural and Non-Prescription Health Products Directorate

Drug Submission Performance
Quarterly Report
October - December
2020



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Direction des produits de santé naturels et sans ordonnance - Rapport trimestriel du rendement des
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OVERVIEW

The NNHPD Quarterly Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive quarters from October - December 2019 to October - December 2020. 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 - December 2020 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), and a 96% increase when comparing Q3 2020-2021 (51) 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), and a 50% decrease when comparing Q3 2020-2021 (40) to Q2 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), and a 14% decrease when comparing Q3 2020-2021 (107) to Q2 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), and no change when comparing Q3 2020-2021 (0) to Q2 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), and a 58% decrease when comparing Q3 2020-2021 (5) to Q2 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), and no change when comparing Q3 2020-2021 (2) to Q2 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), and a 10% decrease when comparing Q3 2020-2021 (19) to Q2 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 and Q3 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), and decreased by 16% from Q2 2020-2021 to Q3 2020-2021 (224).

The decrease in overall submissions from Q2 2020-2021 to Q3 2020-2021 reflects a continued decrease in non-prescription drug hand sanitizer submissions. The complex submission streams (SNDS, ANDS, and SANDS) were either stable or decreased through Q3 2020-2021 when compared to Q2 2020-2021.

The numbers in Q1, Q2 and Q3 2020-2021 bring the total number of non-prescription drug submissions received to its highest to date per quarter. For Q1, Q2 and Q3 2020-2021 specifically, the increase in the number of submissions is mainly due to a high volume of submissions received for compliance with the plain language labelling requirements as well as the high demand for non-alcohol based antiseptic skin cleansers.

Of note, in the last 4 fiscal years (2016-2020), the numbers of non-prescription drug submissions received were 699, 658, 616 and 926. The number of submissions received in the first three quarters of the 2020-2021 FY is 767, representing 106% of the average number of submissions received in totality in each of the last four FYs. Assuming a similar trend for the last quarter of 2020-2021, upwards of 1000 submissions will be received, breaking yet another all-time high for the non-prescription drug submission workload.

Disinfectant Drug Submissions:

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

Overall, the total disinfectant drug submissions received decreased by 15% in Q2 2020-2021 (270) when compared to Q1 2020-2021 (319), and decreased by 9% from Q2 2020-2021 to Q3 2020-2021 (246). This maintains the total number of disinfectant drug submissions received to the highest it has ever been and is mainly attributed to the ongoing pandemic. For some submission types, such as DINDs and PDCs, the numbers received in each of the last three quarters are representative of the total numbers received for previous full FYs.

The number of PDCs spiked in Q1 2020-2021 then decreased by approximately half in Q2, which is explained by applications filed 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.

Similarly, the number of DIND submissions (Labelling Standard) spiked in Q2 2020-2021, and has remained very high over Q3 2020-2021 and Q4 2020-2021 (an average 100-fold increase compared to previous quarters). This is explained by applicants continuing to submit these types of submissions in high numbers to address the continued need for general disinfectants as part of the ongoing COVID-19 response.

The significant increase observed for DIND submissions (Full Reviews with efficacy data) in Q2 2020-2021 is explained by 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). This was followed by a significant increase of applications during Q2 2020-2021 when a test strain became available and laboratories were no longer in lock down. Overall, during Q3 2020-2021 a sustained increase in the volume of applications was observed compared to pre-COVID volumes maintained (a 366% increase for data submissions in Q3 2020-2021 compared to Q3 2019-2020). As a result, the active submission queue volume remains high, given that these DIND submissions have more complex review requirements, and therefore have longer performance standards often spanning multiple quarters.

Of note, in the last 4 fiscal years (2016-2020), the numbers of disinfectant drug submissions received were 179, 228, 218 and 234. 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. The total number of submissions received in Q1, Q2 and Q3 2020-2021 is 847, which represents more than three times the total number of submissions received in the totality of the 2016, 2017, 2018 and 2019 FYs. Assuming a similar trend for the last quarter of 2020-2021, upwards of 1000 submissions will be received, which is a never before seen surge for the disinfectant drug submission workload.

General Information

There are several steps involved in the drug submission review² and approval process:

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

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

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

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

For new drugs, **approvals** are Notice of Compliances (NOC) Issued or Issuable which are reported in the Decisions’ section. An NOC issuable is when a submission’s NOC is placed “on hold” awaiting authorization to market, due to changes from Prescription to Non-Prescription or due to Patented Medicines (NOC) Regulations.

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

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

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

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

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

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

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ACRONYMS

Submission Types

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

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to changes (Prescription to Non-Prescription)
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter
NOA	-	Notice of Authorization
NOA-TC	-	Notice of Authorization with Terms and Conditions

Fee Categories

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

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

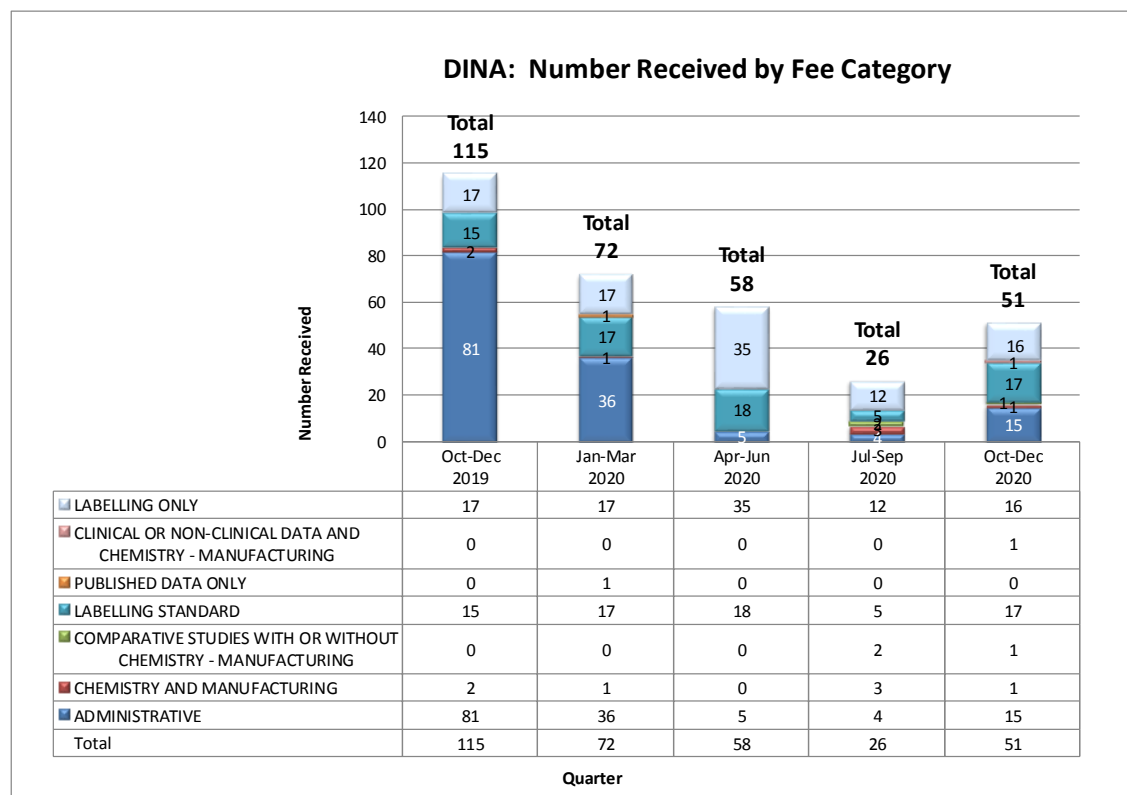
Over the counter (OTC) Drugs

NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

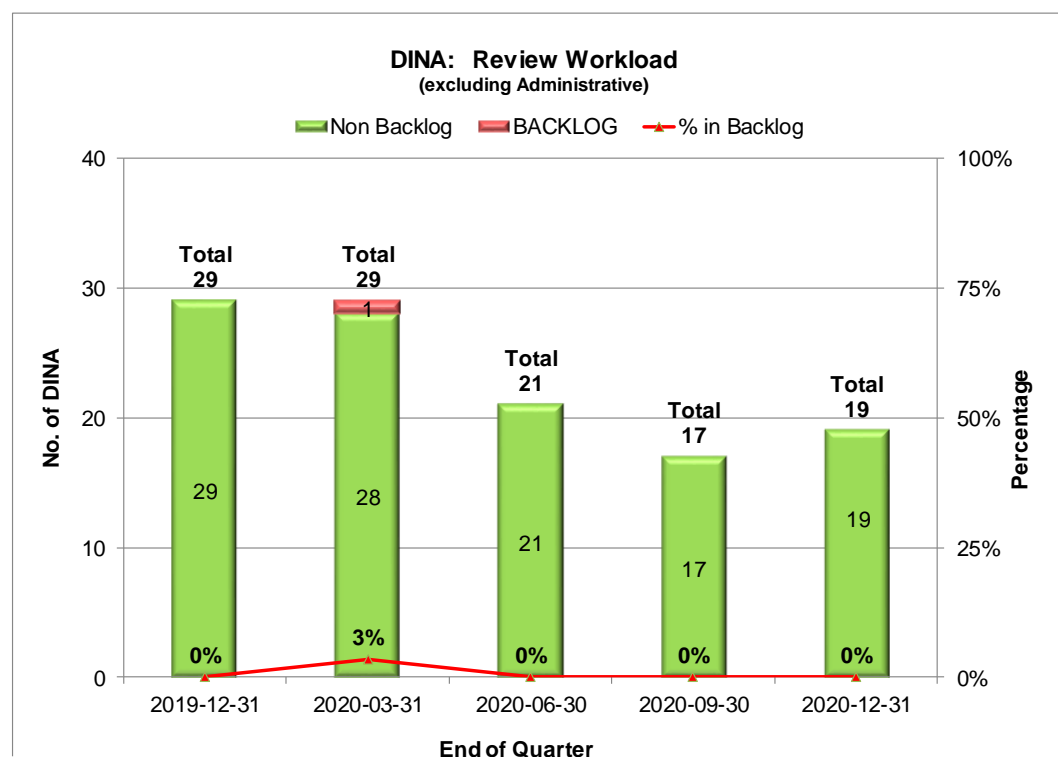
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

DINA: Number Received by Fee Category



WORKLOAD

DINA: Review Workload

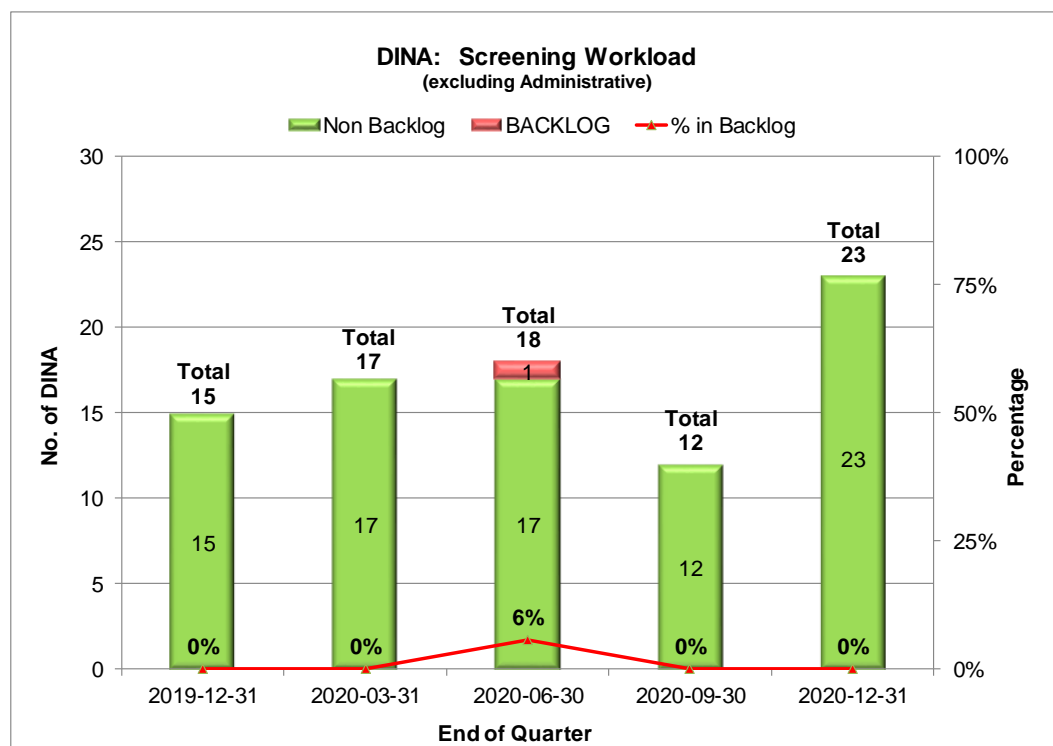


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Chemistry and Manufacturing	1	2	1	1	2
Backlog	0	1	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	0	0	1
Backlog	0	0	0	0	0
Labelling Only	28	27	19	14	14
Backlog	0	0	0	0	0
Published Data	0	0	1	1	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	1	2
Backlog	0	0	0	0	0
Total	29	29	21	17	19
Non Backlog	29	28	21	17	19
BACKLOG	0	1	0	0	0
% in Backlog	0%	3%	0%	0%	0%

WORKLOAD

DINA: Screening Workload

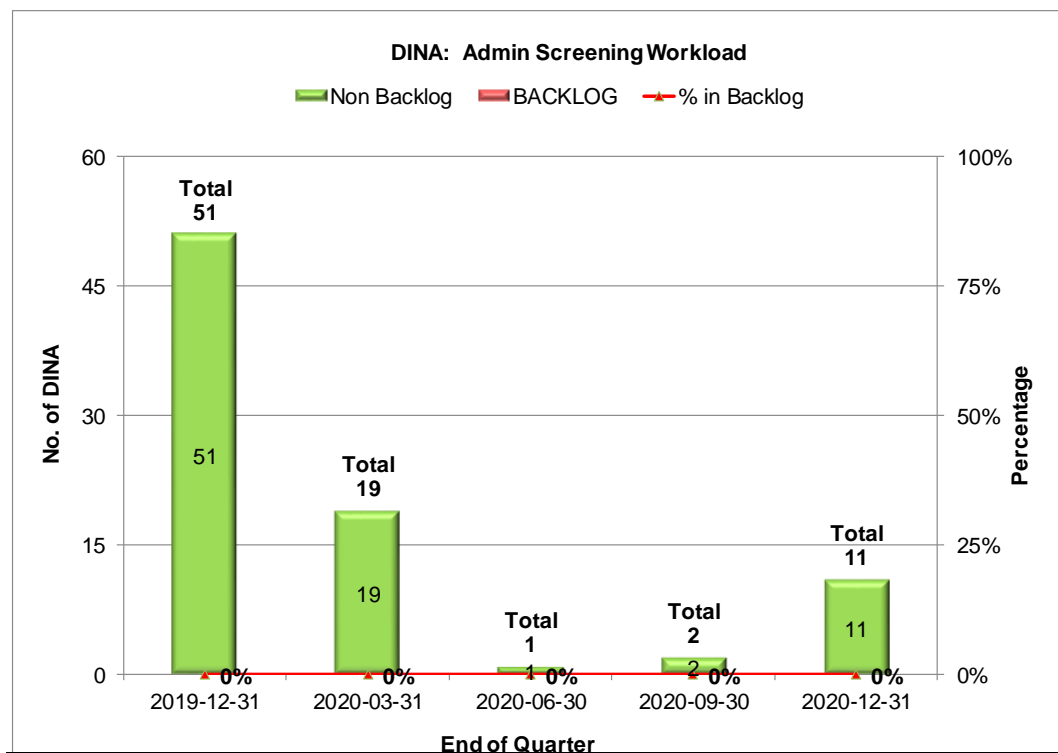


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Chemistry and Manufacturing	1	1	0	3	2
Backlog	0	0	0	0	0
Labelling Only	5	4	13	4	10
Backlog	0	0	1	0	0
Labelling Standard	9	11	5	5	11
Backlog	0	0	0	0	0
Published Data	0	1	0	0	0
Backlog	0	0	0	0	0
Total	15	17	18	12	23
Non Backlog	15	17	17	12	23
BACKLOG	0	0	1	0	0
% in Backlog	0%	0%	6%	0%	0%

WORKLOAD

DINA: Administrative-Screening Workload



DINA: Administrative-Screening Workload by Fee Category

DINA: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Administrative	51	19	1	2	11
Backlog	0	0	0	0	0
Total	51	19	1	2	11
Non Backlog	51	19	1	2	11
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

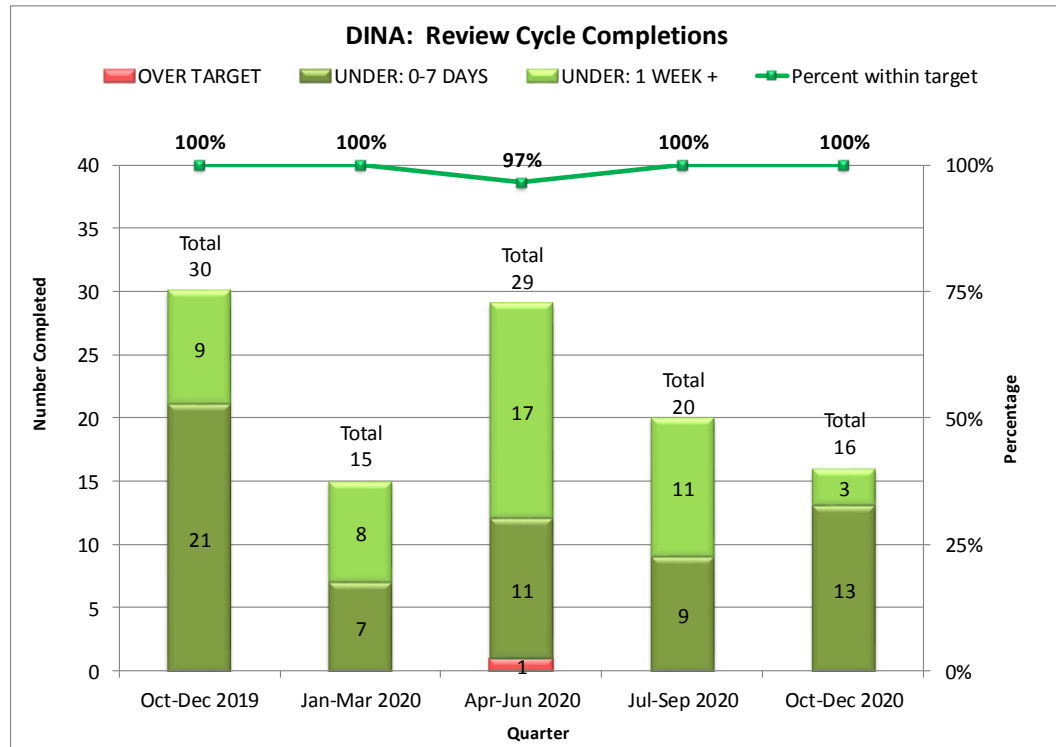
DECISIONS

DINA: Number of Decisions by Fee Category

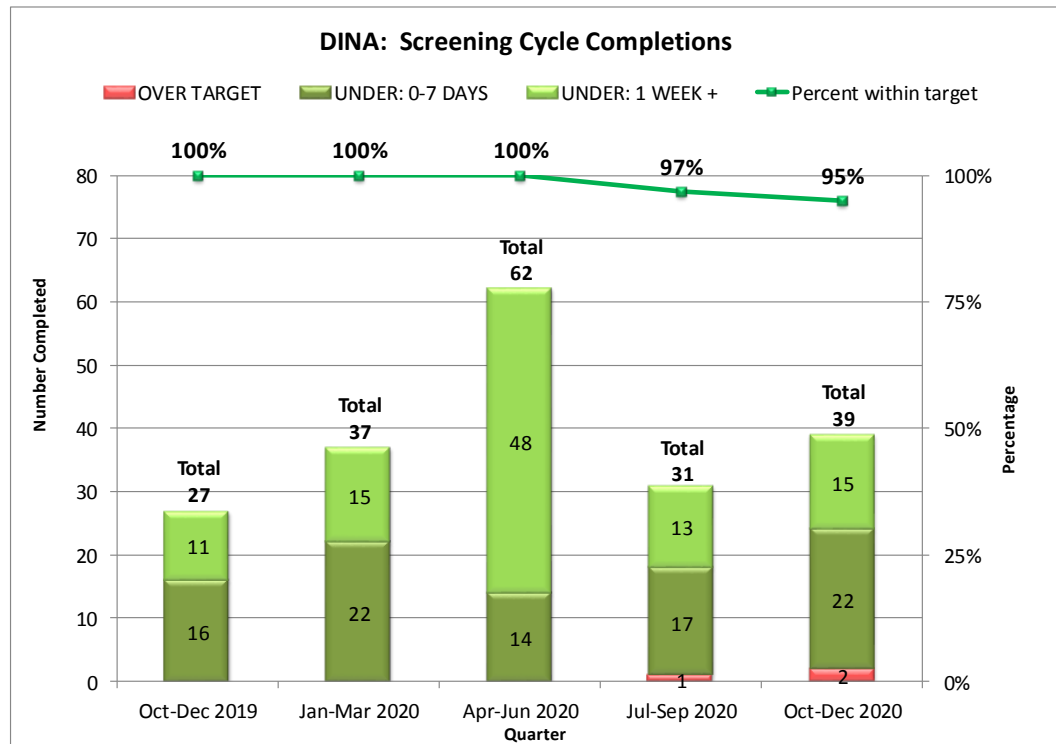
Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	CANCELLATION LETTER	3	0	1	1	0
	NOTIFICATION FORM DIN SUB	30	72	22	1	2
	REJECTION LETTER (SCR)	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	14	5	0	0	3
	NO OBJECTION LETTER	0	0	0	1	1
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	0	0	1	0	1
	CANCELLATION LETTER	1	0	1	0	0
	SCREENING DEFICIENCY NOTICE	1	1	0	0	3
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	1	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	0	2	0
LABELLING ONLY	CANCELLATION LETTER	4	2	9	3	2
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	4	5	3	1	1
	NOTICE OF NON-COMPLIANCE	0	0	1	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	24	11	23	19	13
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	3	2	2
LABELLING STANDARD	CANCELLATION LETTER	0	3	6	0	3
	NO OBJECTION LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	6	10	18	6	9
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	5	8	2	2
PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	1

PERFORMANCE

DINA: Review Cycle Completions

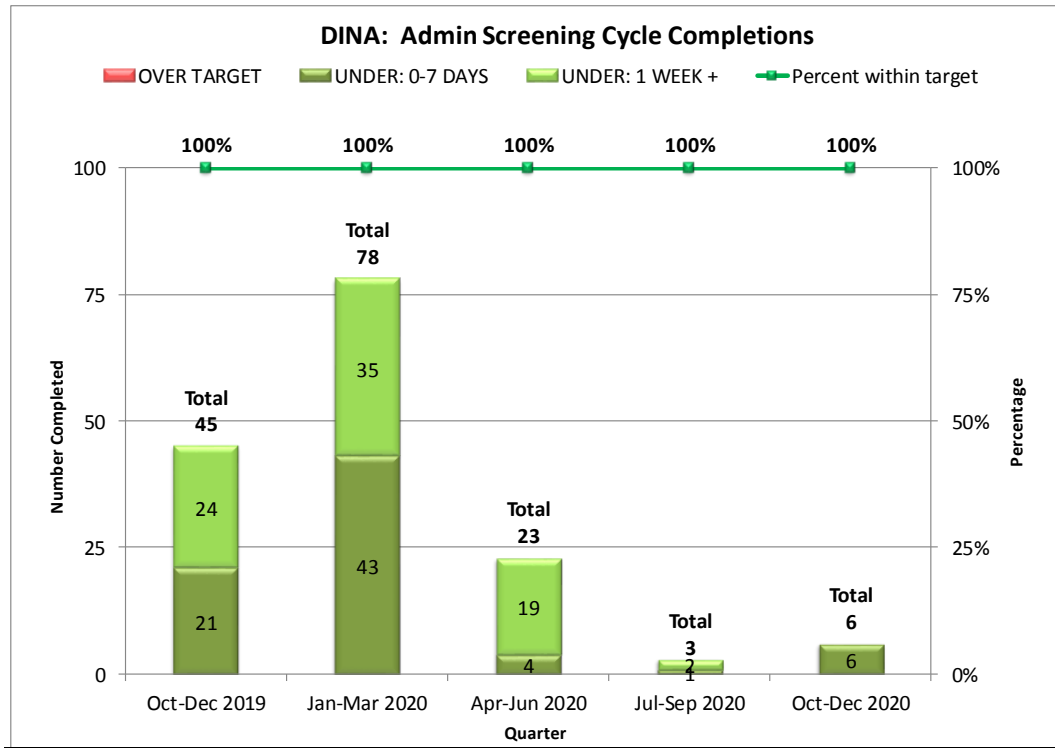


DINA: Screening Cycle Completions



PERFORMANCE

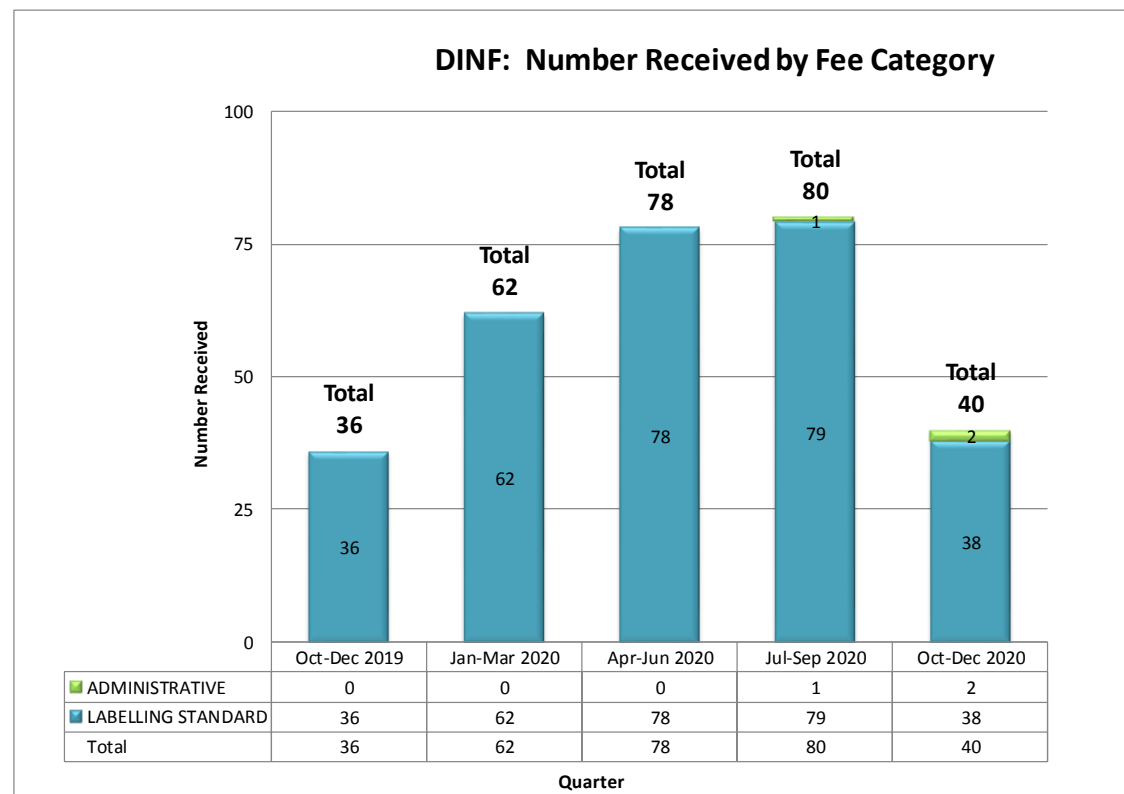
DINA: Administrative-Screening Cycle Completions



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

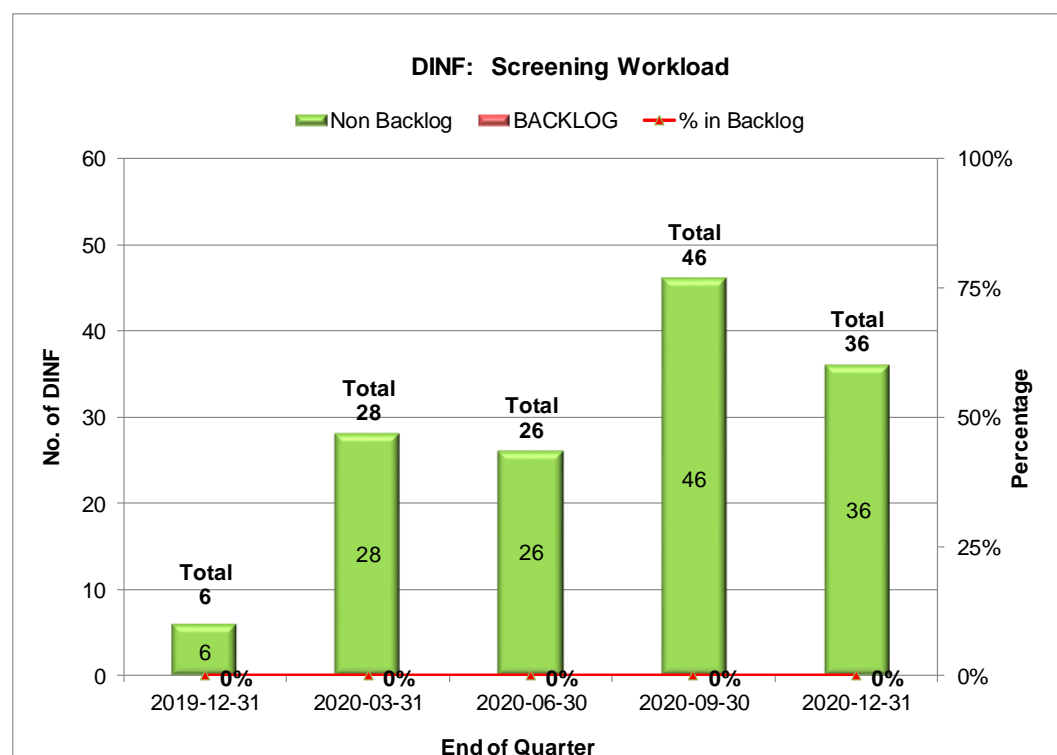
RECEIVED

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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Labelling Standard	6	28	26	45	36
Backlog	0	0	0	0	0
Administrative	0	0	0	1	0
Backlog	0	0	0	0	0
Total	6	28	26	46	36
Non Backlog	6	28	26	46	36
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

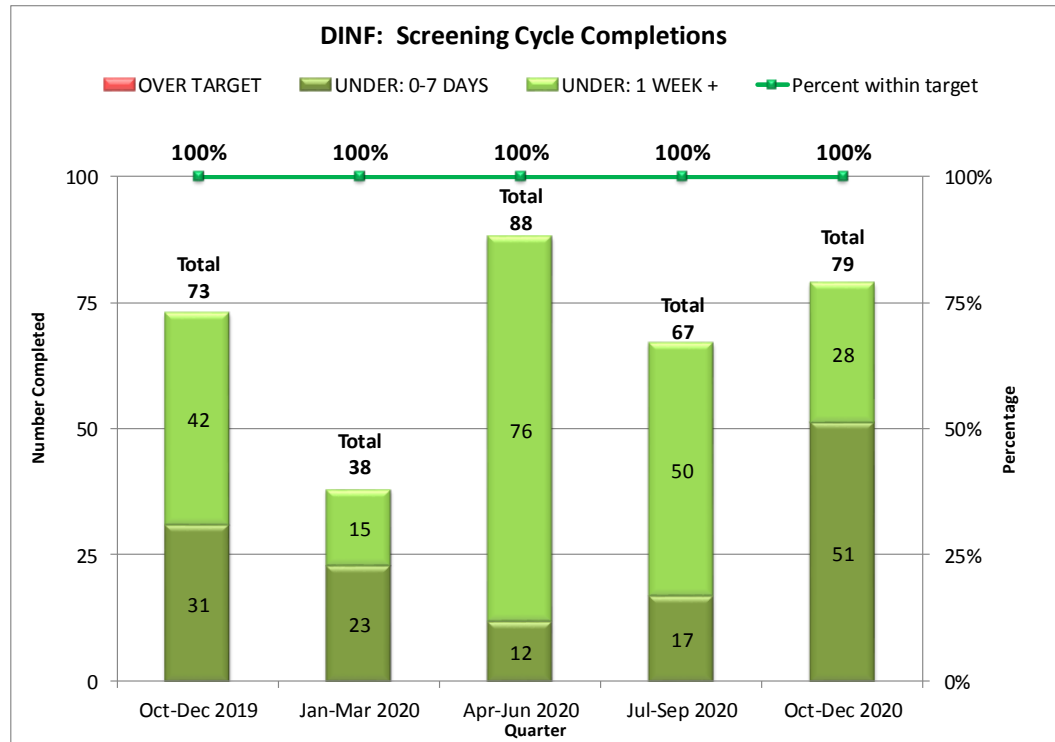
DECISIONS

DINF: Number of Decisions by Fee Category

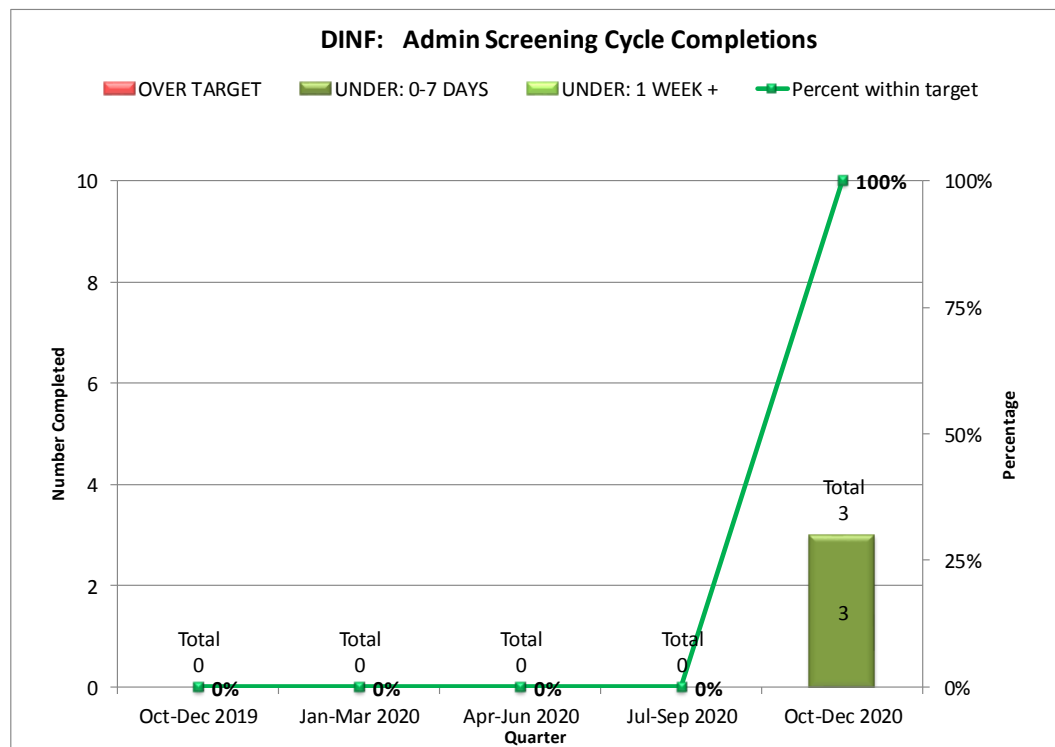
Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
LABELLING STANDARD	CANCELLATION LETTER	3	1	15	7	6
	NO OBJECTION LETTER	3	0	3	0	0
	NEW DRUG LETTER SCREEN	1	0	1	0	0
	NOTIFICATION FORM DIN SUB	57	32	56	52	52
	REJECTION LETTER (SCR)	2	1	0	0	1
	SCREENING DEFICIENCY NOTICE	8	4	18	8	21
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	3
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

PERFORMANCE

DINF: Screening Cycle Completions



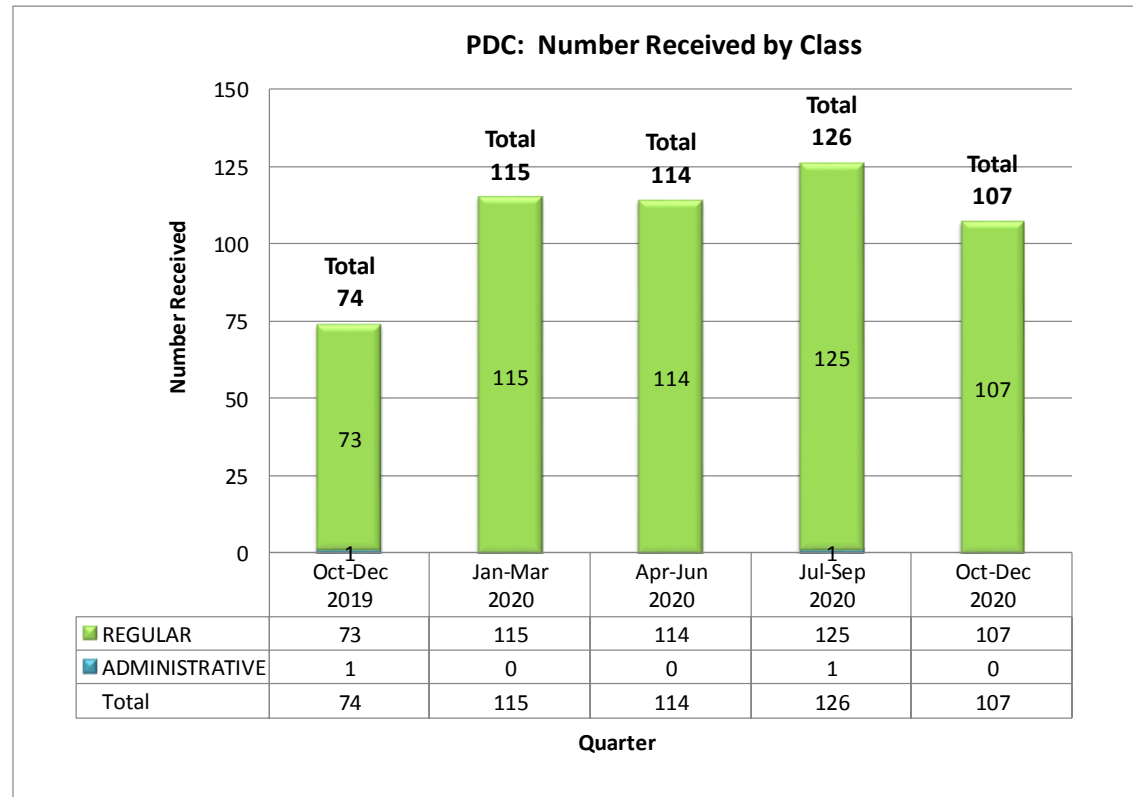
DINF: Admin-Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

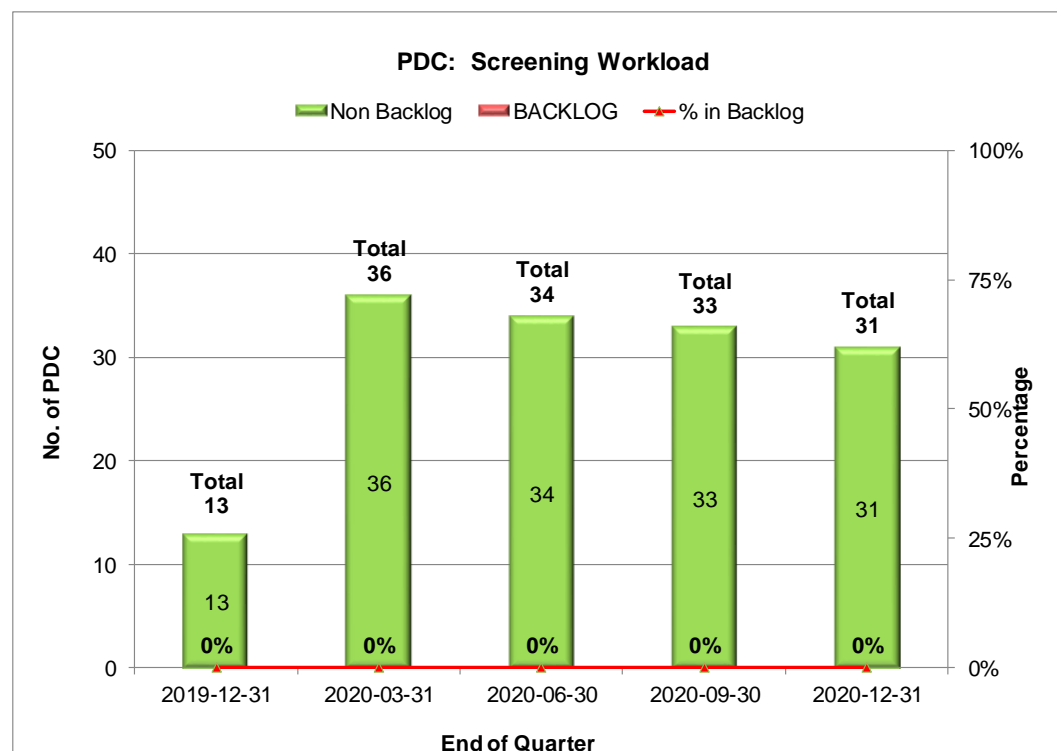
RECEIVED

PDC: Received by Class



WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS By End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Regular	12	36	34	33	31
Backlog	0	0	0	0	0
Administrative	1	0	0	0	0
Backlog	0	0	0	0	0
Total	13	36	34	33	31
Non Backlog	13	36	34	33	31
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

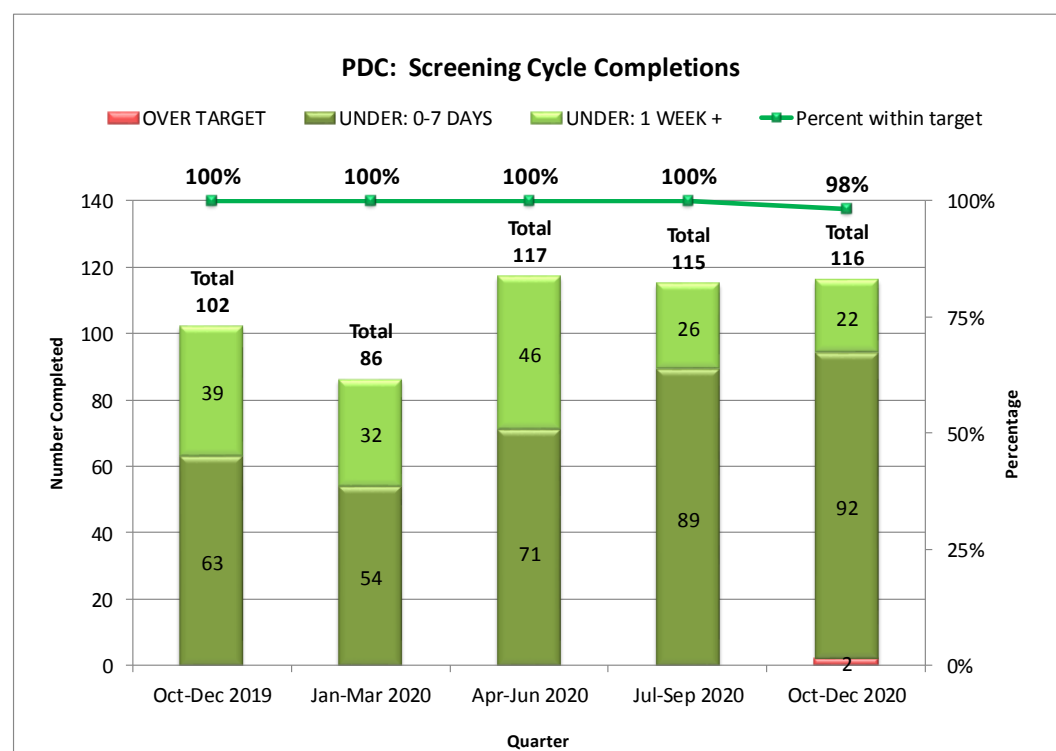
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
REGULAR	CANCELLATION LETTER	6	6	5	5	1
	NO OBJECTION LETTER	92	66	107	103	112
	NOT SATISFACTORY NOTICE	4	14	5	7	5
	REJECTION LETTER (SCR)	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING STANDARD	NO OBJECTION LETTER	0	0	0	0	1

PERFORMANCE

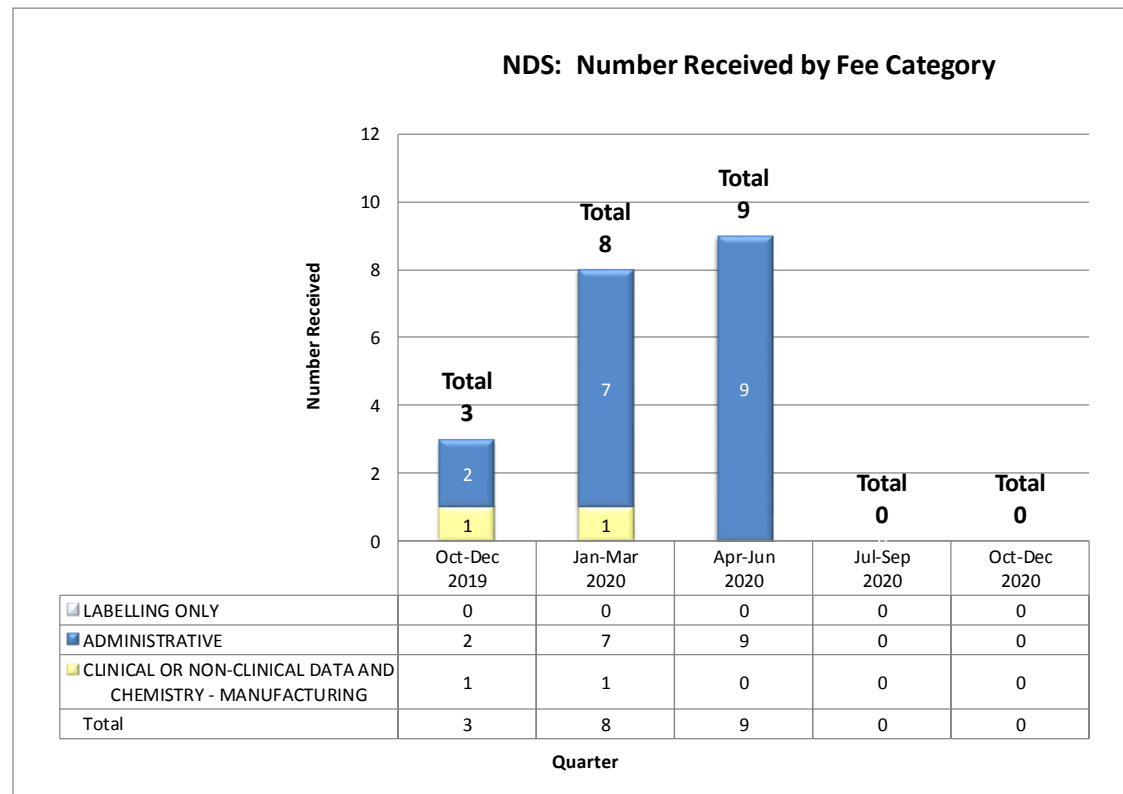
PDC: Screening Cycle Completions



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

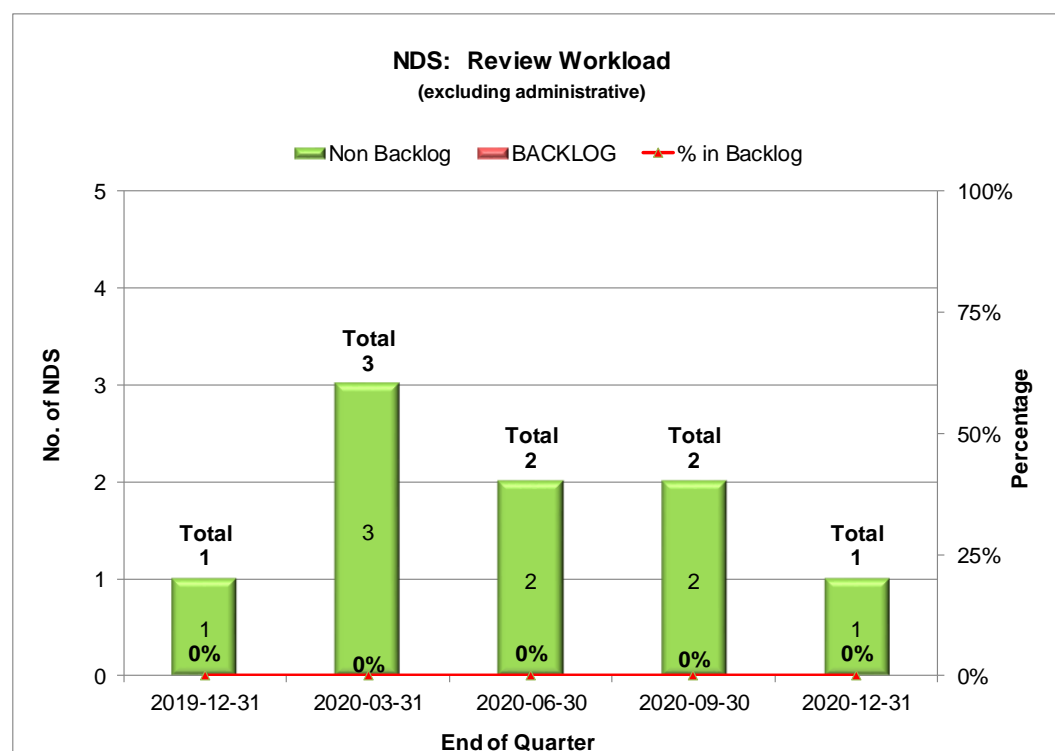
NDS: NEW DRUG SUBMISSION RECEIVED

NDS: Number Received by Fee Category



WORKLOAD

NDS: Review Workload

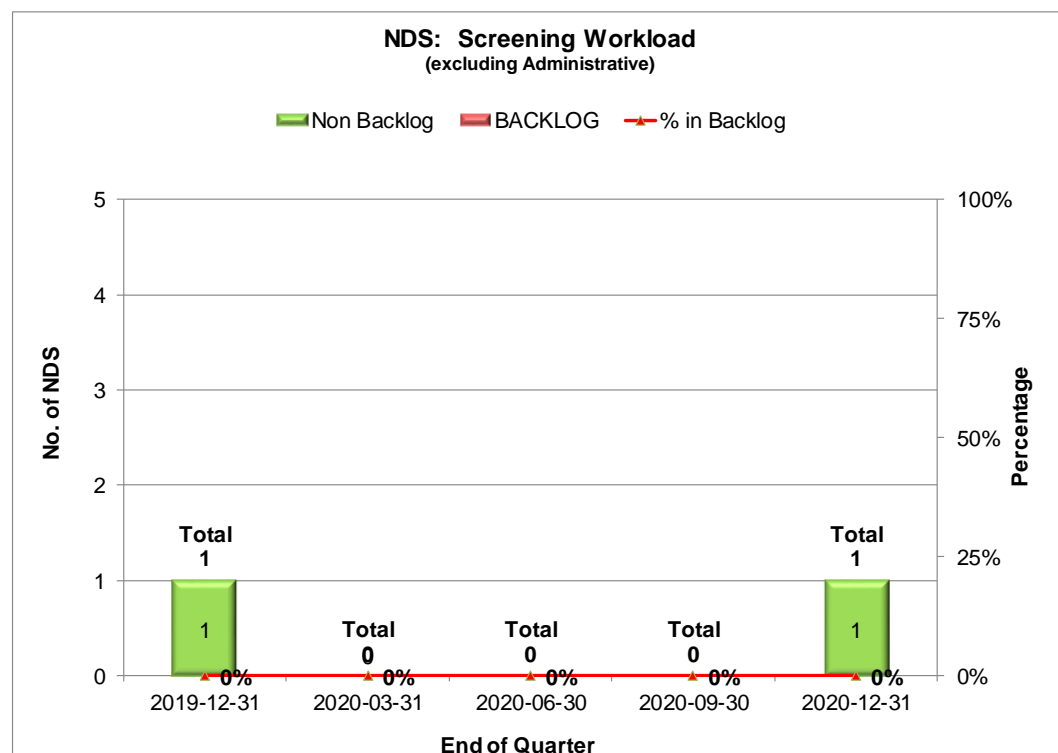


NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	3	2	2	1
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	1	3	2	2	1
Non Backlog	1	3	2	2	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NDS: Screening Workload



NDS: Screening Workload by Fee Category

NDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	0	0	0	1
Backlog	0	0	0	0	0
Labelling Only	0	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Total	1	0	0	0	1
Non Backlog	1	0	0	0	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

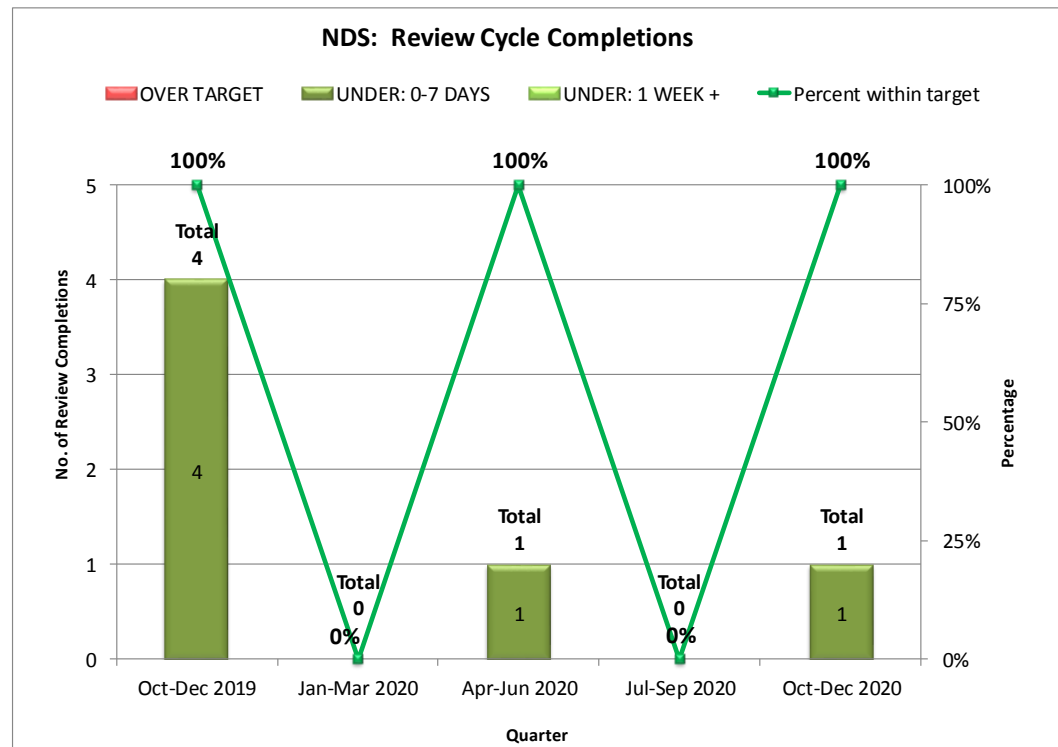
NDS: Number of Decisions by Fee Category

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	NOTICE OF COMPLIANCE*	2	1	11	5	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	1	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	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*	1	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*	2	0	0	0	0
	NOTICE OF NON-COMPLIANCE	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

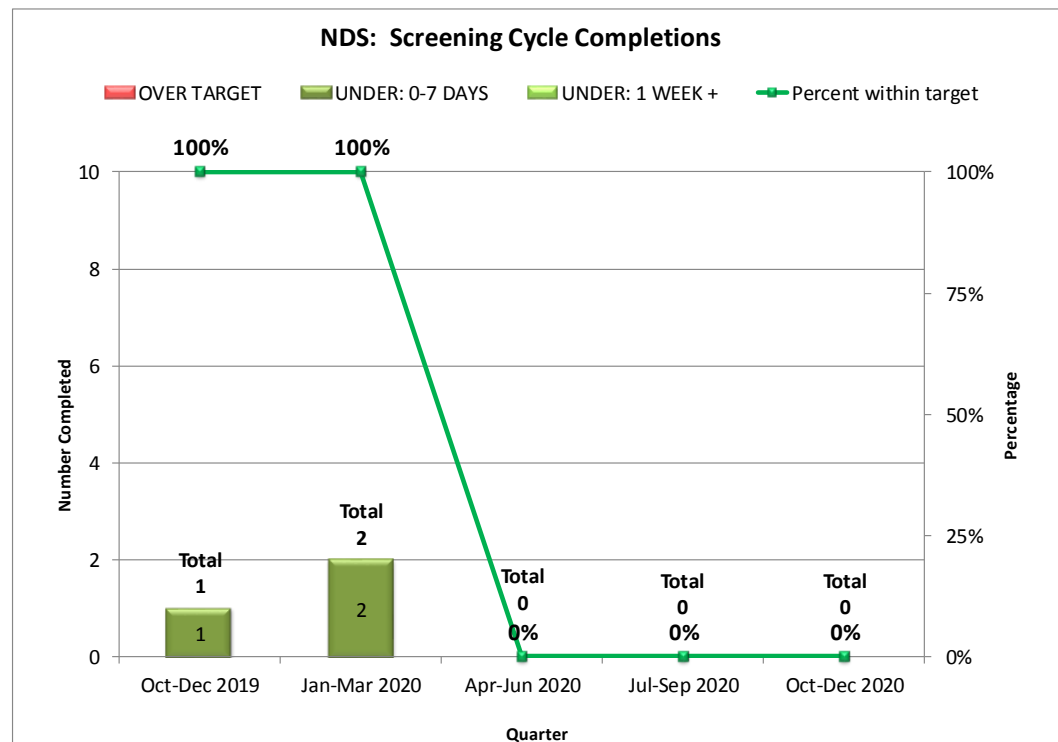
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions

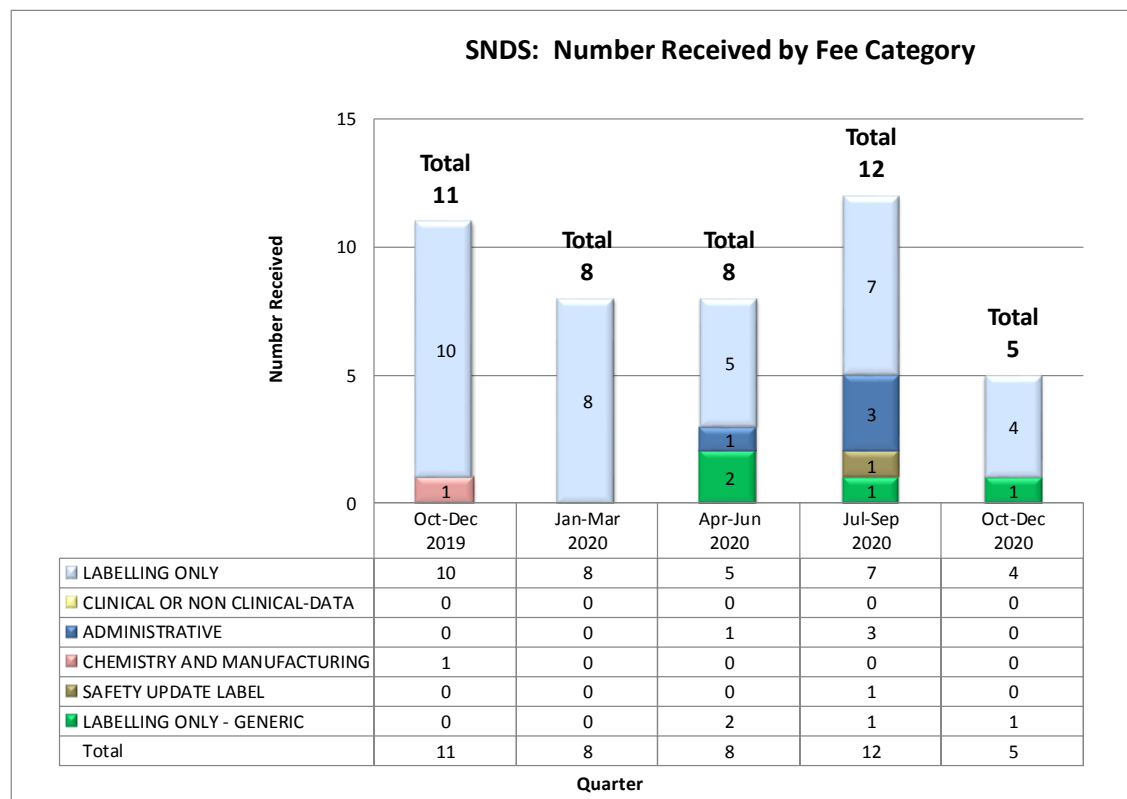


NDS: Screening Cycle Completions



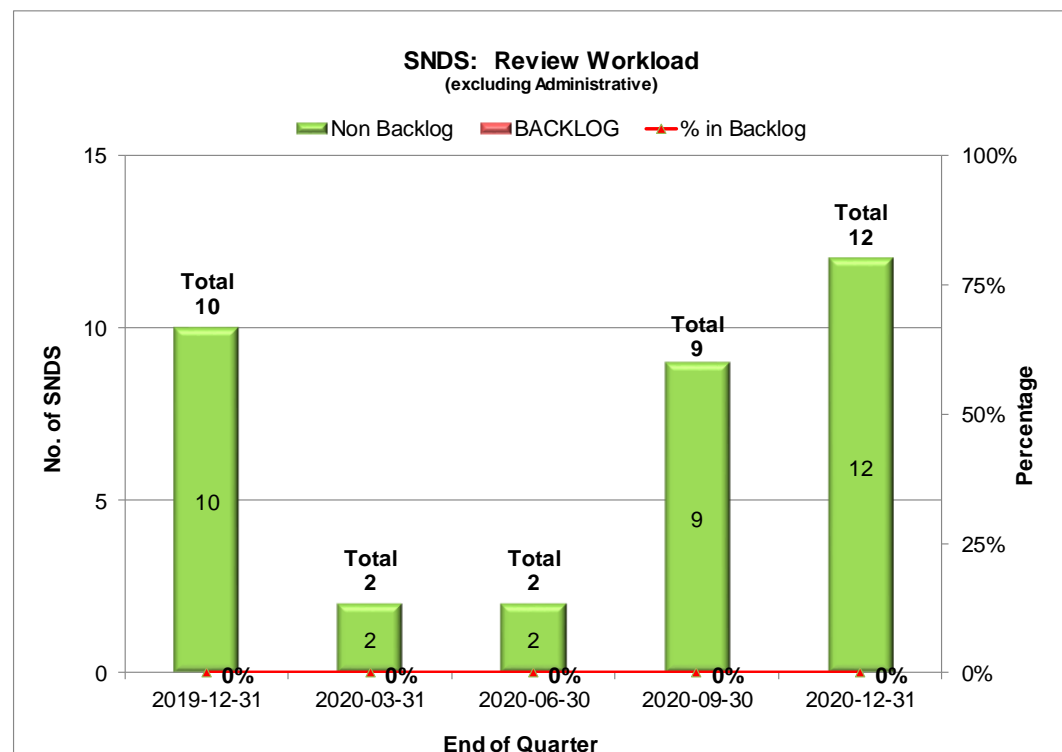
SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

SNDS: Number Received by Fee Category



WORKLOAD

SNDS: Review Workload

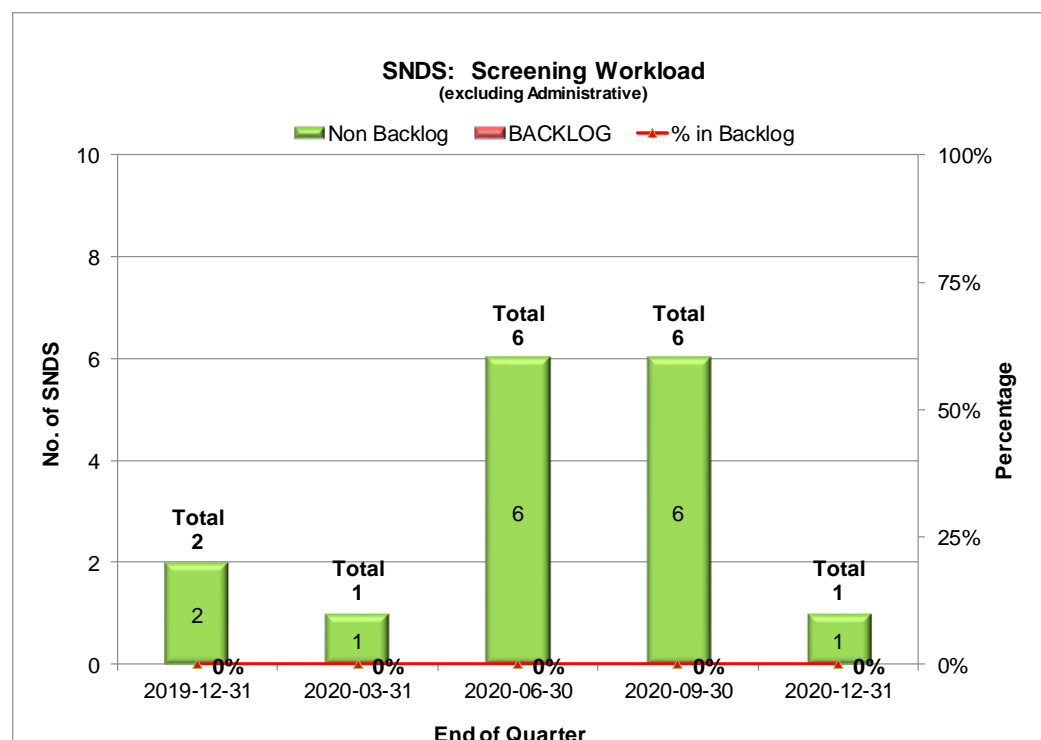


SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD					
BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Clinical or Non-Clinical Data	2	0	0	1	0
Backlog	0	0	0	0	0
Labelling Only	4	0	1	7	10
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	0	0	0	0
Backlog	0	0	0	0	0
Chemistry and Manufacturing	3	2	0	0	0
Backlog	0	0	0	0	0
Label Update Generic	0	0	1	1	1
Backlog	0	0	0	0	0
Safety Update Label	0	0	0	0	1
Backlog	0	0	0	0	0
Total	10	2	2	9	12
Non Backlog	10	2	2	9	12
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Chemistry and Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data	0	0	1	0	0
Backlog	0	0	0	0	0
Labelling Only	2	1	4	4	0
Backlog	0	0	0	0	0
Label Update Generic	0	0	1	1	1
Backlog	0	0	0	0	0
Safety Update Label	0	0	0	1	0
Backlog	0	0	0	0	0
Total	2	1	6	6	1
Non Backlog	2	1	6	6	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

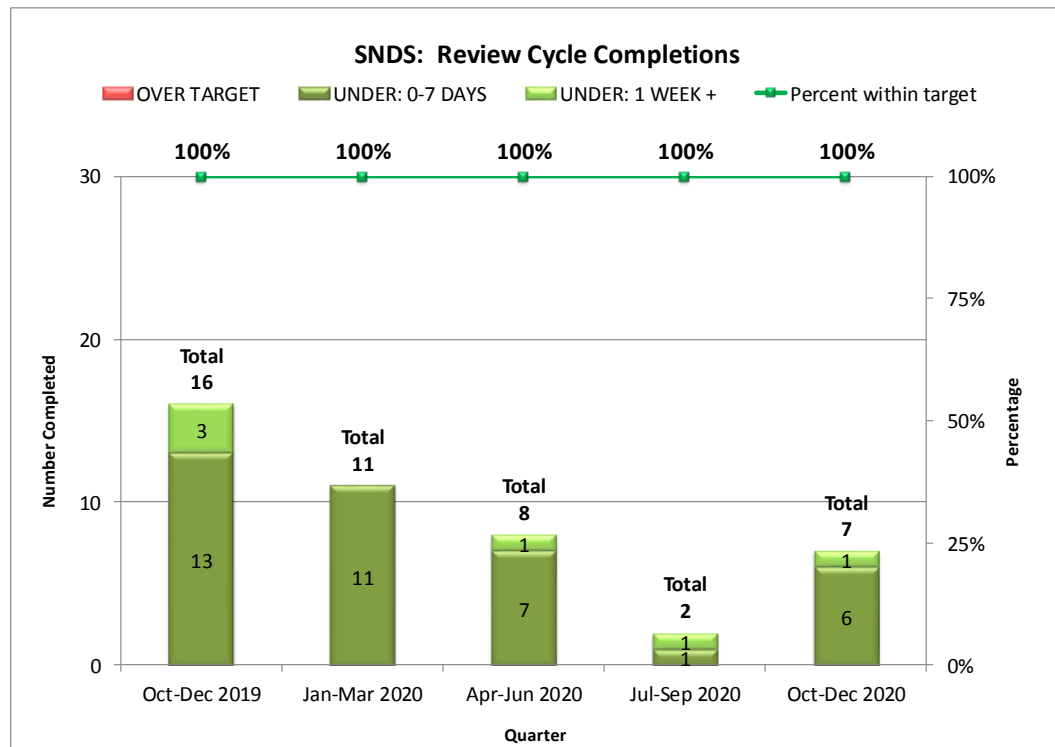
SNDS: Number of Decision by Fee Category

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	1	0	0	0
	NOTICE OF COMPLIANCE*	1	1	0	0	1
	NOTICE OF NON-COMPLIANCE	0	1	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*	15	7	6	1	5
	SCREENING DEFICIENCY NOTICE	3	5	0	1	0
	CANCELLATION LETTER	1	2	1	0	0
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	0	0	1	1
	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	1	0
	NOTICE OF COMPLIANCE*	0	0	0	2	2
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	2	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

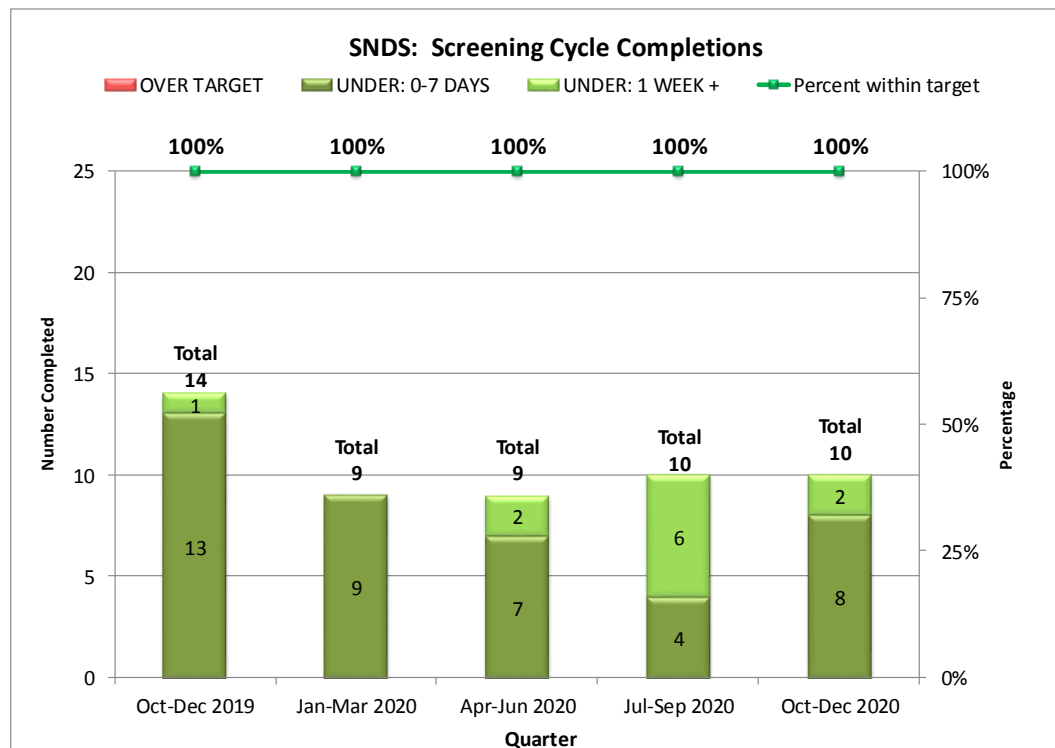
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

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	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
LABELLING ONLY	0	1	1	0	1
ADMINISTRATIVE	1	1	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	3	0	0	0	1
CHEMISTRY AND MANUFACTURING	0	0	0	1	0
Total	4	2	1	2	2

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Labelling Only	0	1	1	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	2	2	1	1
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	1	3	3	1	2
Non Backlog	1	3	3	1	2
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Comparative Studies with or without Chemistry - Manufacturing	1	1	0	0	1
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
Total	1	1	0	1	1
Non Backlog	1	1	0	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					
	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Total	1	0	0	1	0
Non Backlog	1	0	0	1	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE**ANDS: Review Performance**

ANDS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	1	0	100%	1
Jan-Mar 2020	0	0	0	-	0
Apr-Jun 2020	1	1	0	50%	2
Jul-Sep 2020	0	2	0	100%	2
Oct-Dec 2020	0	1	0	100%	1

ANDS: Screening Performance

ANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	2	0	100%	2
Jan-Mar 2020	0	4	0	100%	4
Apr-Jun 2020	0	1	2	100%	3
Jul-Sep 2020	0	0	0	-	0
Oct-Dec 2020	0	2	1	100%	3

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

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
LABELLING ONLY	NOTICE OF COMPLIANCE*	1	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	1	1	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	1

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

SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRUG SUBMISSION**RECEIVED****SANDS: Number Received by Fee Category**

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION (SANDS)					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	1	6	0	6	6
CHEMISTRY AND MANUFACTURING	0	0	0	4	0
LABELLING ONLY - GENERIC	0	0	1	4	3
LABELLING ONLY	5	8	7	7	10
<i>Total</i>	6	14	8	21	19

WORKLOAD**SANDS: Review Workload**

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Labelling Only	2	6	5	6	11
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	0	1	2	2
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	2	4
<i>Backlog</i>	0	0	0	0	0
Total	2	6	6	8	17
Non Backlog	2	6	6	8	17
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Labelling Only	2	2	3	5	6
<i>Backlog</i>	0	1	0	0	0
Chemistry and Manufacturing	0	0	0	2	0
<i>Backlog</i>	0	0	0	0	0
Label Update Generic	0	0	0	2	1
<i>Backlog</i>	0	0	0	0	0
Total	2	2	3	9	7
Non Backlog	2	1	3	9	7
BACKLOG	0	1	0	0	0
% in Backlog	0%	50%	0%	0%	0%

SANDS: Administrative-Screening Workload

SANDS: ADMINISTRATIVE-SCREENING WORKLOAD by End of Quarter					
	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Total	1	5	0	3	2
Non Backlog	1	5	0	3	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
Oct-Dec 2019	0	4	1	100%	5
Jan-Mar 2020	0	1	0	100%	1
Apr-Jun 2020	0	8	0	100%	8
Jul-Sep 2020	0	3	2	100%	5
Oct-Dec 2020	0	3	3	100%	6

SANDS: Screening Performance

SANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	11	0	100%	11
Jan-Mar 2020	1	9	0	90%	10
Apr-Jun 2020	1	3	5	89%	9
Jul-Sep 2020	0	4	6	100%	10
Oct-Dec 2020	0	9	10	100%	19

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

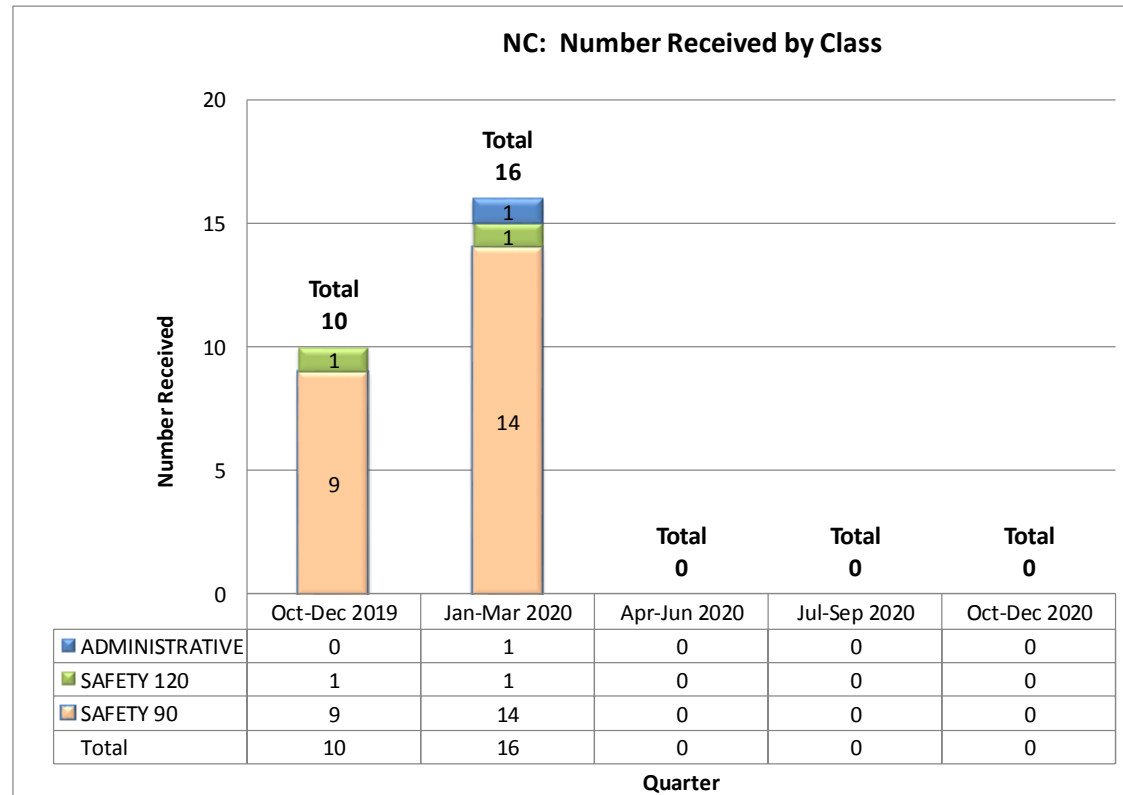
Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
LABELLING ONLY	NOTICE OF COMPLIANCE *	5	1	8	3	4
	SCREENING DEFICIENCY NOTICE	4	4	1	1	0
	CANCELLATION LETTER	1	0	0	1	0
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	0	2	5	3	6
	CANCELLATION LETTER	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
CHEMISTRY AND MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
LABEL UPDATE GENERIC	NOTICE OF COMPLIANCE*	0	0	0	1	2
	CANCELLATION LETTER	0	0	0	0	2
	SCREENING DEFICIENCY NOTICE	0	0	0	0	2

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

NC: NOTIFIABLE CHANGE

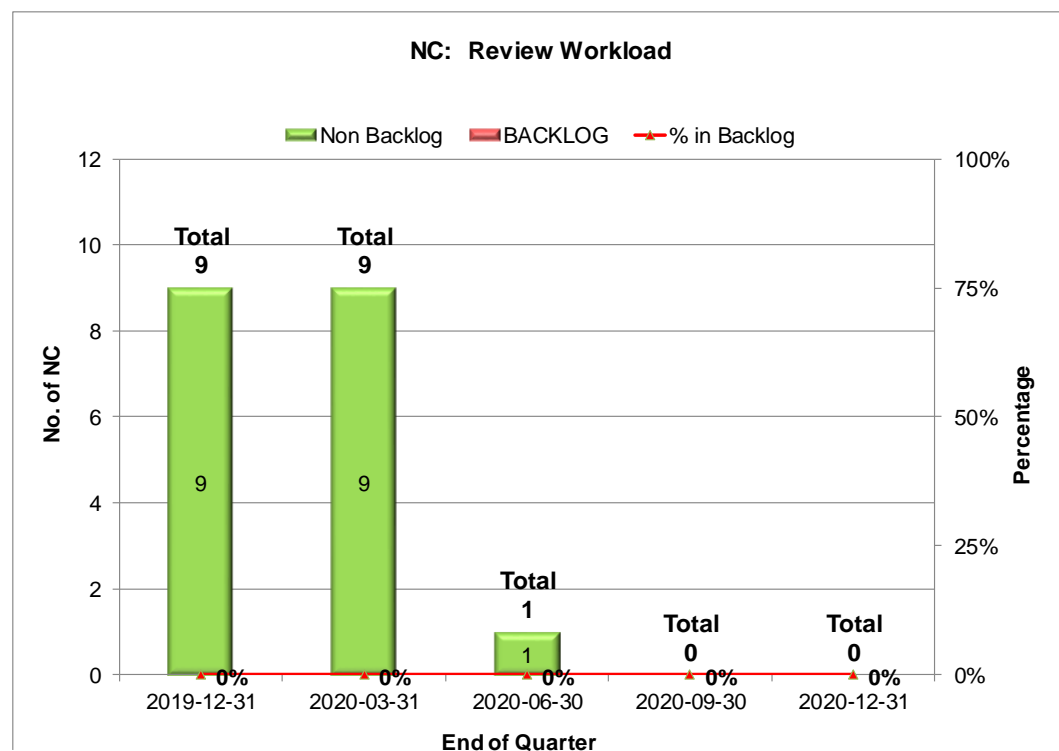
RECEIVED

NC: Number Received by Class



WORKLOAD

NC: Review Workload

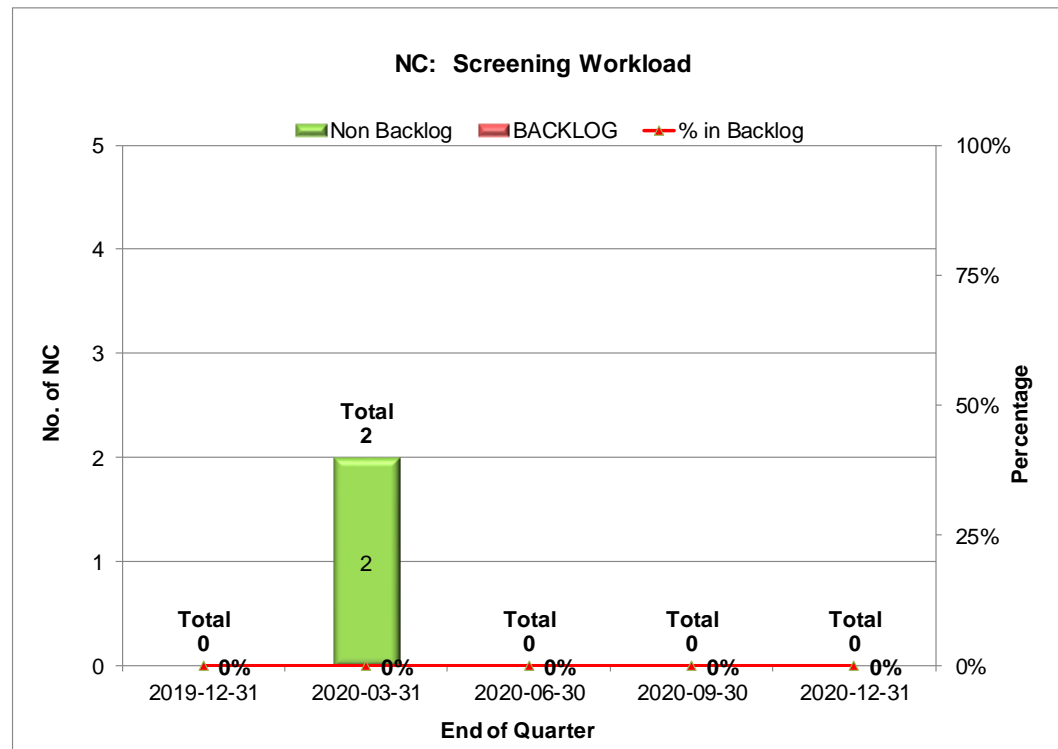


NC: Review Workload by class

NC: REVIEW WORKLOAD BY CLASS and End of Quarter					
Class	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Safety 90	8	8	1	0	0
<i>Backlog</i>	0	0	0	0	0
Safety 120	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	9	9	1	0	0
Non Backlog	9	9	1	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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Safety 90	0	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	2	0	0	0
Non Backlog	0	2	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC: Administrative Screening Workload

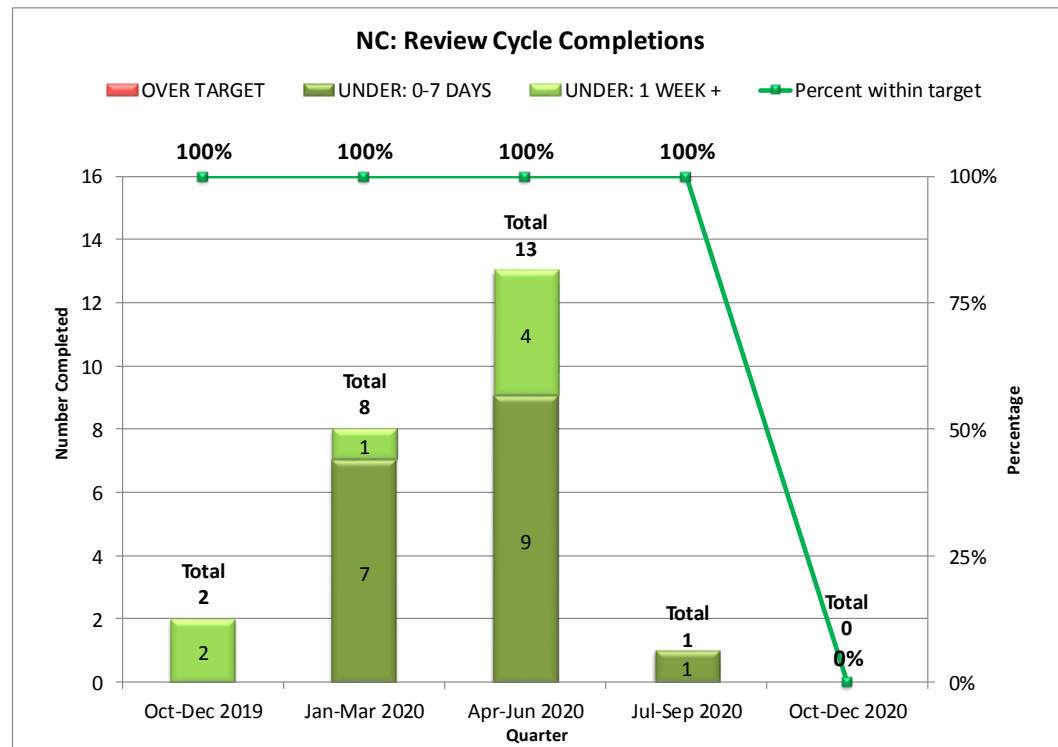
NC: ADMIN SCREENING WORKLOAD					
By End of Quarter					
Class	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Administrative	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

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

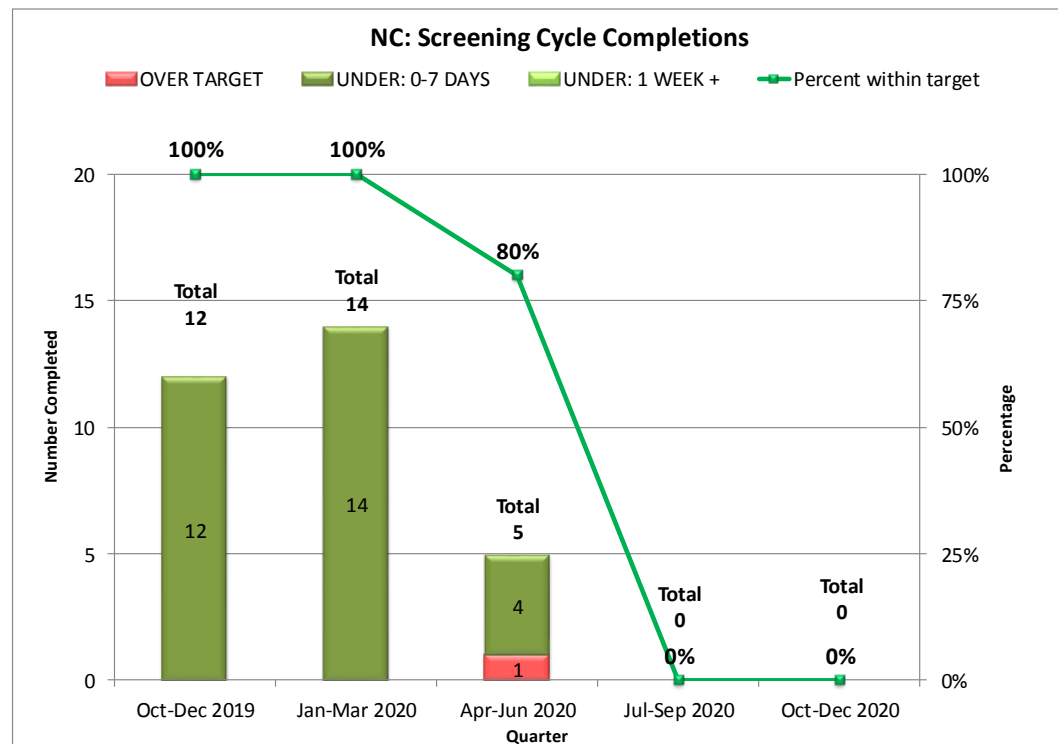
CLASS	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	NO OBJECTION LETTER	2	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
SAFETY 90	NO OBJECTION LETTER	1	8	12	1	0
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	CANCELLATION LETTER	1	1	0	0	0
	SCREENING DEFICIENCY NOTICE	1	4	0	0	0
SAFETY 120	CANCELLATION LETTER	0	1	0	0	0
	NO OBJECTION LETTER	0	0	1	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	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA	0	0	0	1	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	0	0	0	1	2
Total	0	0	0	2	2

MPNDS: Number Received by Fee Category

PRE - NDS MEETING (MPNDS)					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	1	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	1	0	0	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	0	0	1	0	0
Total	1	1	1	0	0

MPSNDS: Number Received by Fee Category

PRE - SNDS MEETING (MPSNDS)					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0
CHEMISTRY AND MANUFACTURING	0	0	0	0	1
Total	0	1	0	0	1

PART 2: DISINFECTANT PRODUCTS

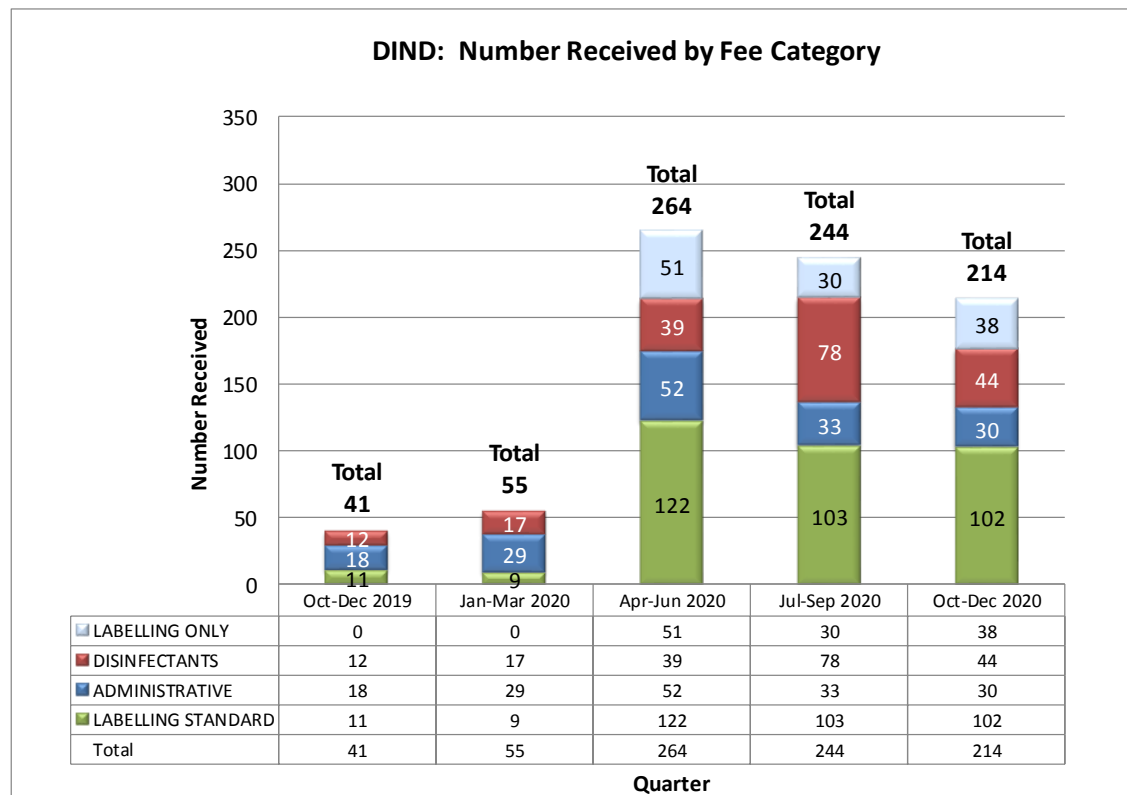
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

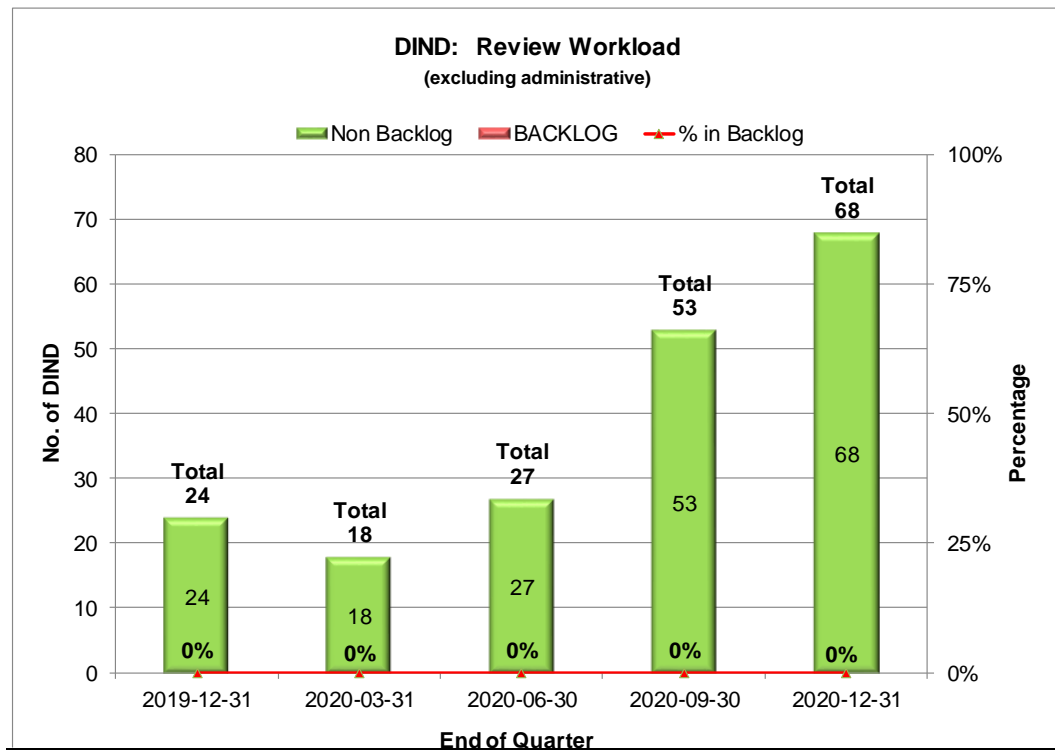
RECEIVED

DIND-Disinfectant Products: Number Received by Fee Category

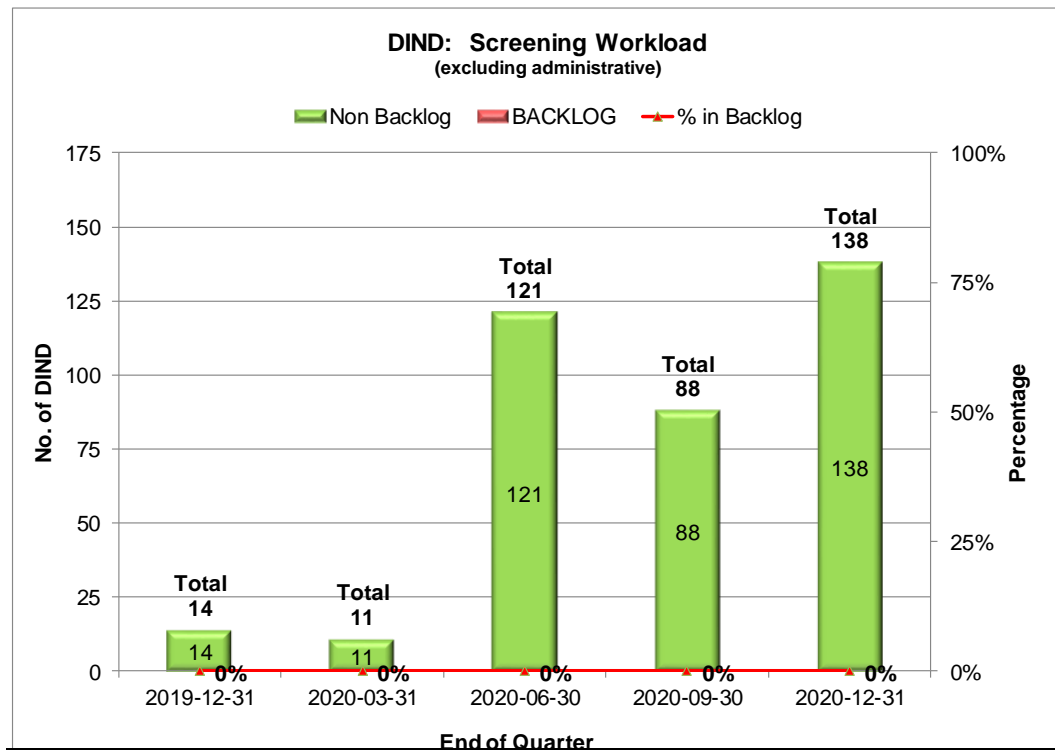


WORKLOAD

DIND-Disinfectant Products: Review Workload

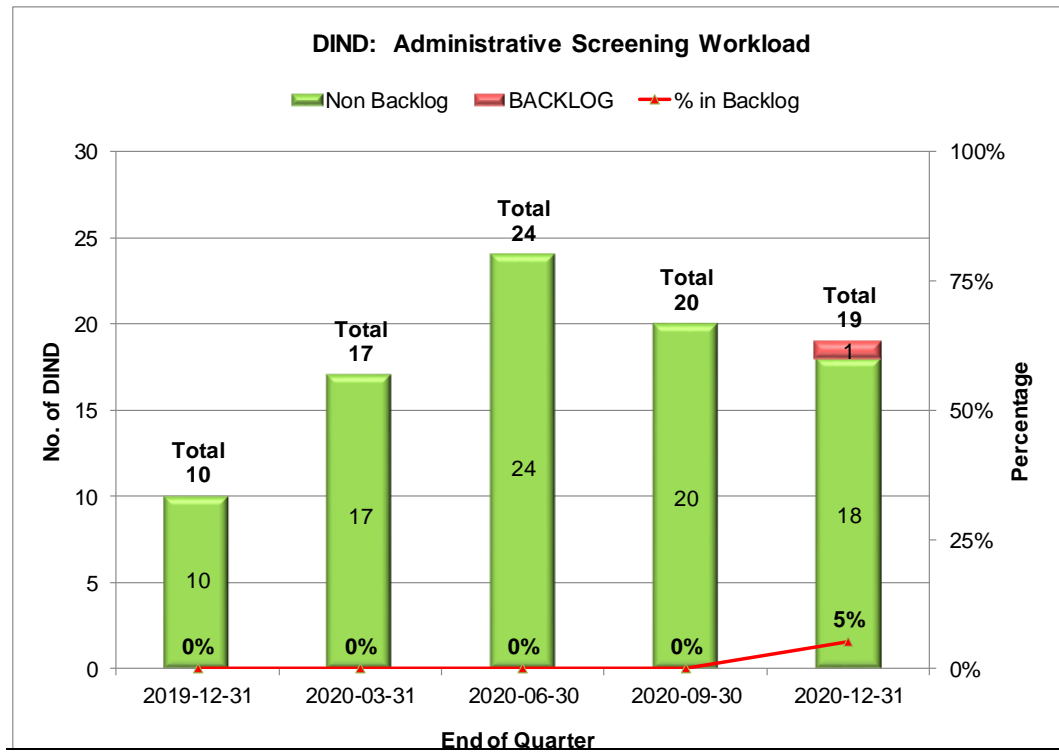


DIND-Disinfectant Products: Screening Workload



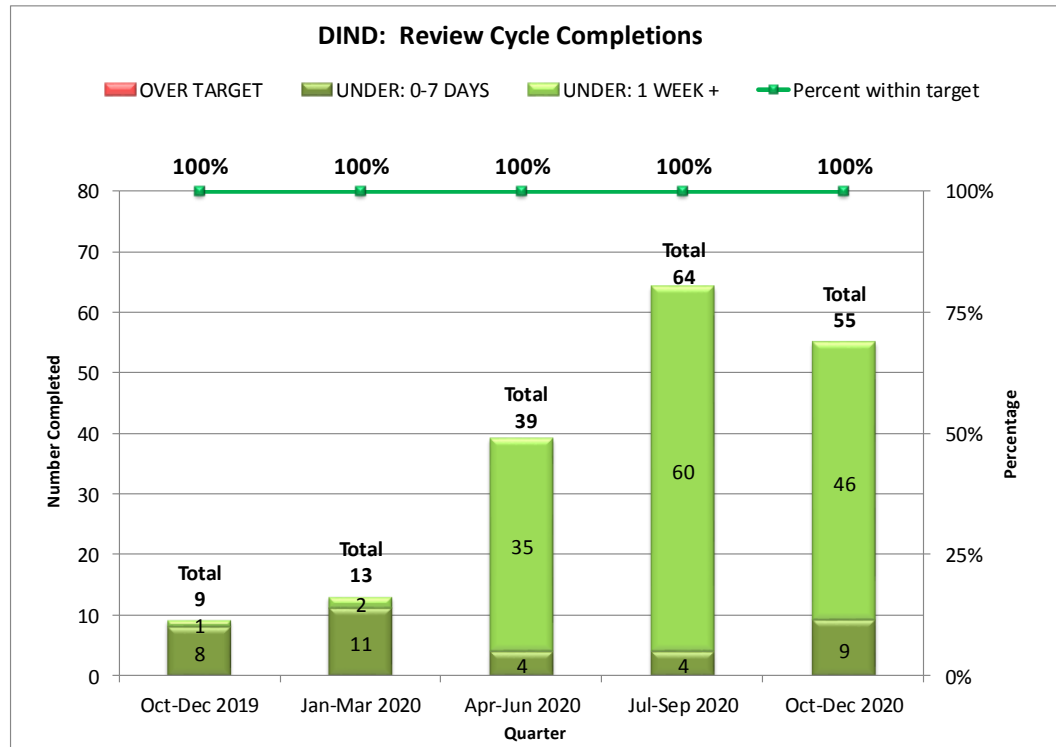
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

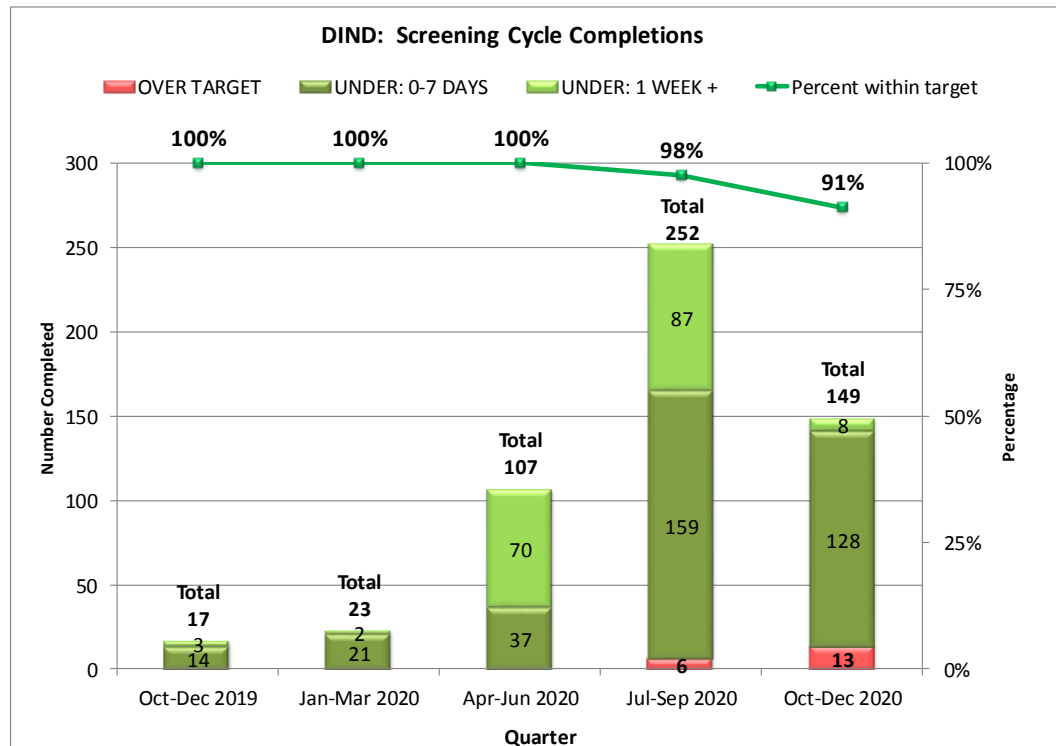


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

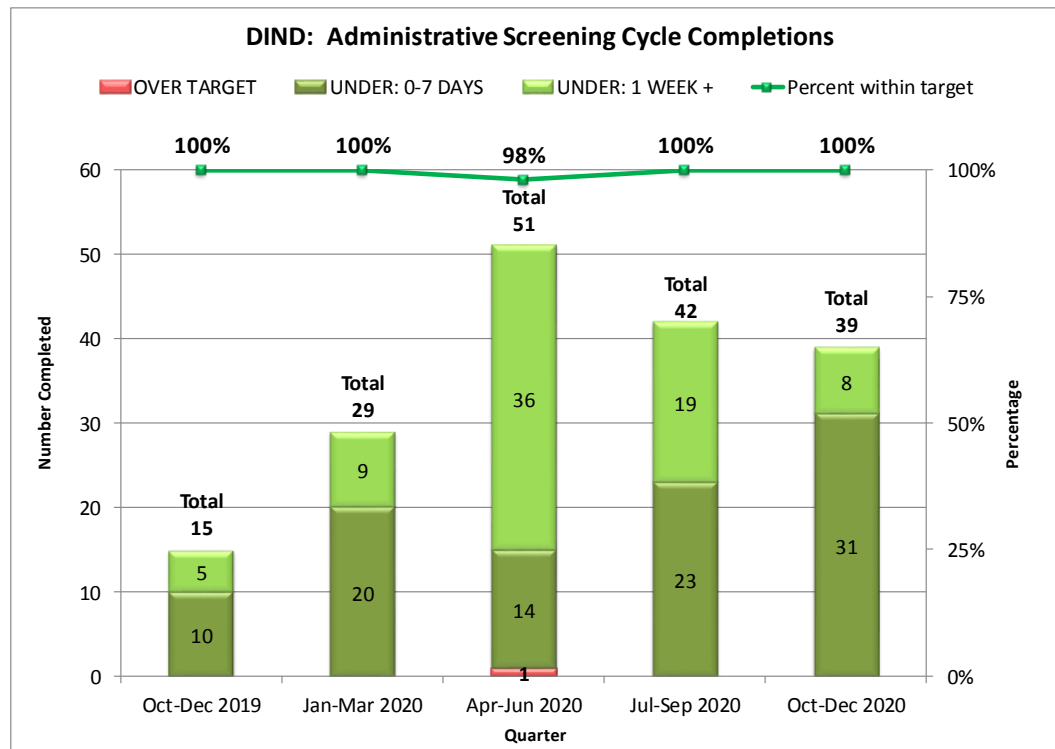


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



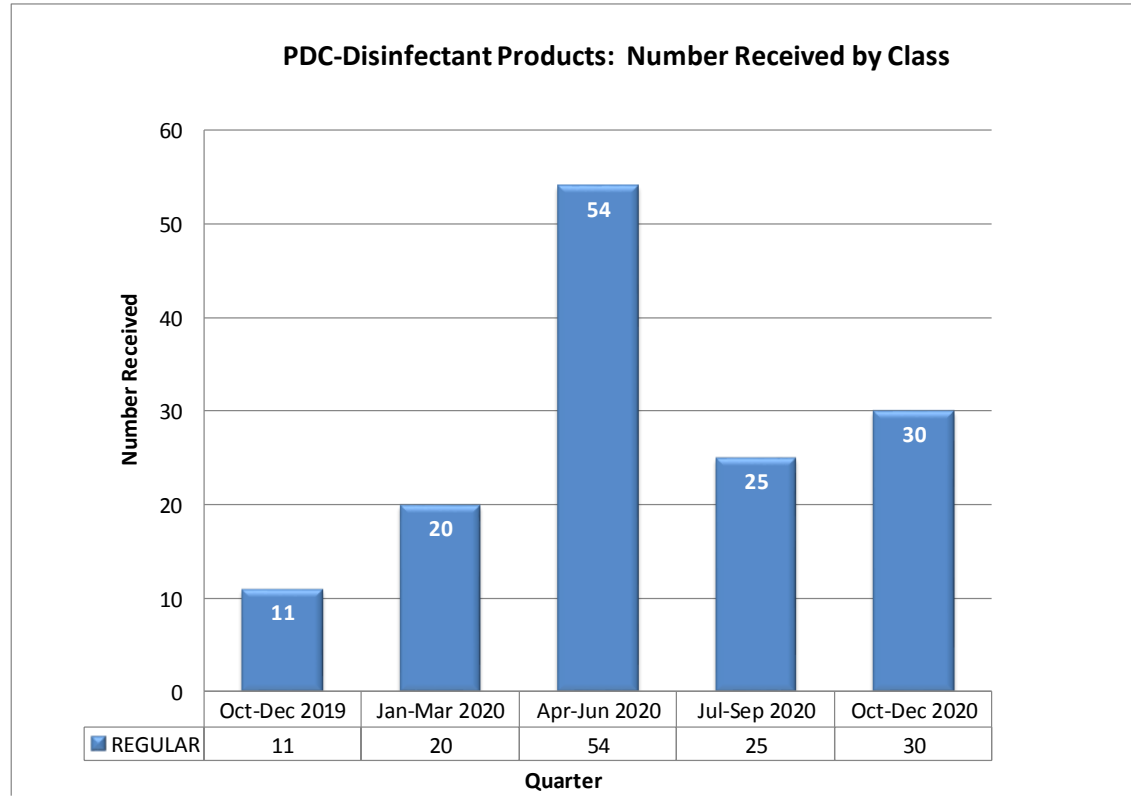
DECISIONS**DIND-Disinfectant Products: Number of Decisions by Fee Category**

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	5	8	4
	NO OBJECTION LETTER	0	0	4	9	0
	NOTIFICATION FORM DIN SUB	11	21	33	15	17
	REJECTION LETTER (SCR)	0	1	1	2	1
	SCREENING DEFICIENCY NOTICE	4	8	11	11	17
DISINFECTANTS	NO OBJECTION LETTER	3	2	11	28	22
	CANCELLATION LETTER	1	0	3	3	4
	NEW DRUG LETTER SCREEN	0	0	2	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	3
	NOTIFICATION FORM DIN SUB	6	11	8	11	5
	SCREENING DEFICIENCY NOTICE	0	0	0	4	12
	REJECTION LETTER (SCR)	0	1	6	11	8
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	5	10	27	104	59
	NO OBJECTION LETTER	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	2	5	11	23	39
	REJECTION LETTER (SCR)	0	0	0	7	3
	CANCELLATION LETTER	0	0	8	15	6
DISINFECTANT LABELLING ONLY	NOTIFICATION FORM DIN SUB	0	0	16	22	22
	NO OBJECTION LETTER	0	0	2	2	1
	CANCELLATION LETTER	0	0	3	4	2
	SCREEN. DEFICIENCY NOTICE	0	0	2	2	6
	NOTICE OF NON-COMPLIANCE	0	0	0	0	2
	REJECTION LETTER (SCR)	0	0	0	0	1

PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

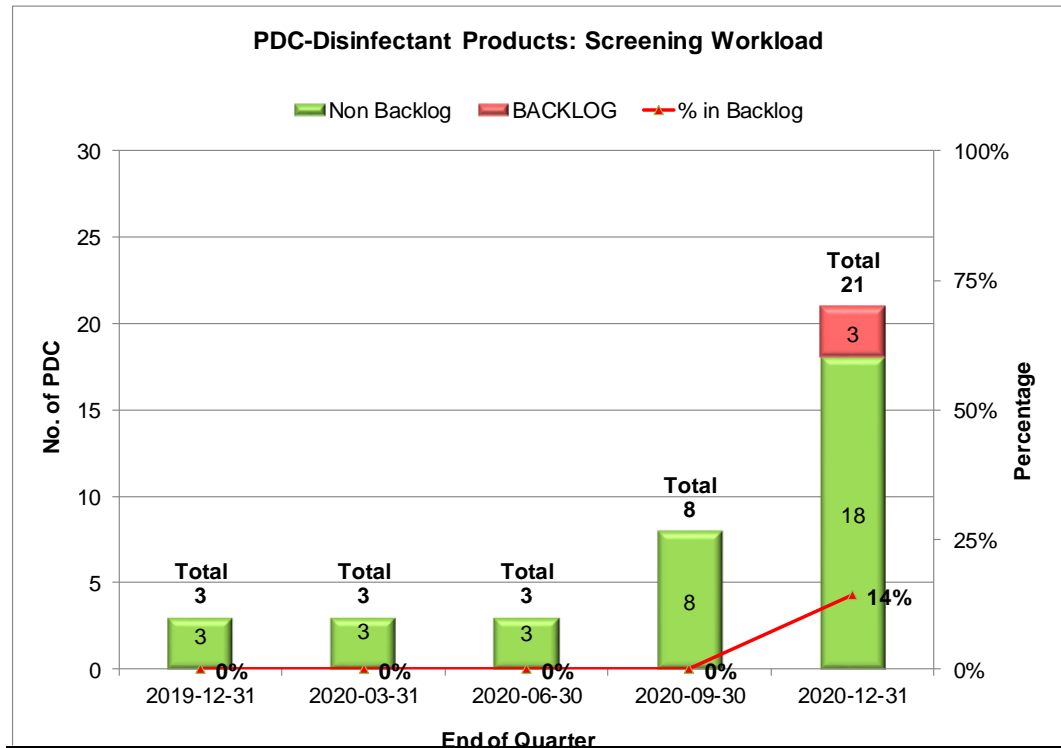
RECEIVED

PDC-Disinfectant Products: Received by Fee Class



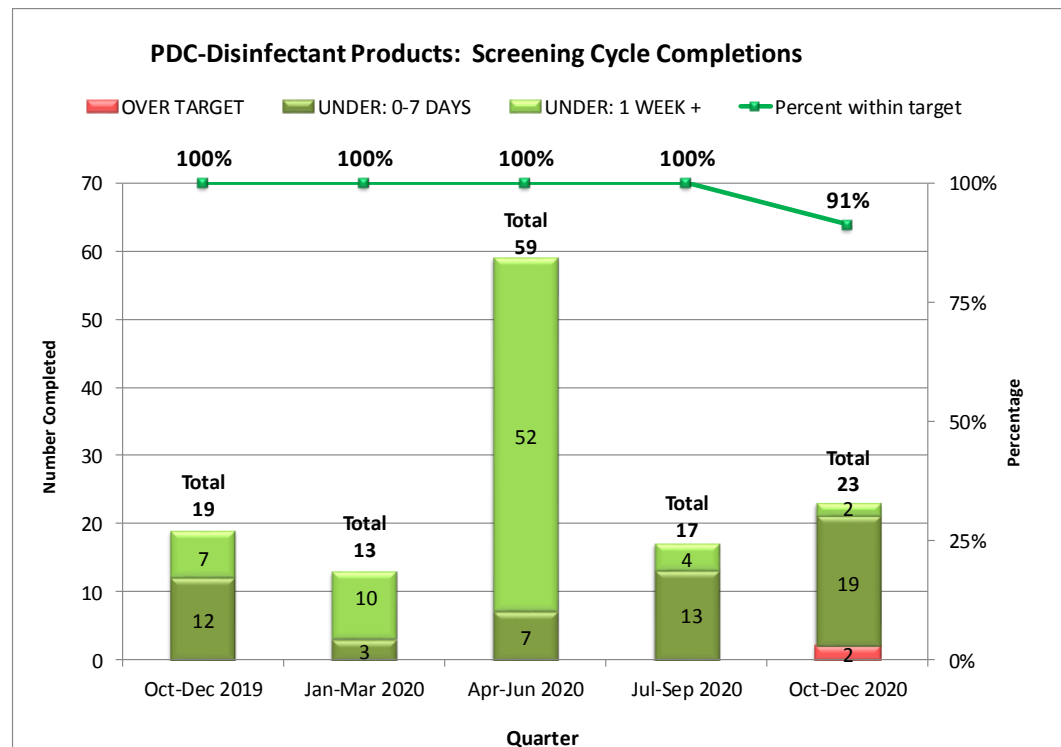
WORKLOAD

PDC-Disinfectant Products: Screening Workload



PERFORMANCE

PDC-Disinfectant Products: Screening Cycle Completions



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

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
REGULAR	CANCELLATION LETTER	0	1	2	0	2
	NO OBJECTION LETTER	16	10	48	15	13
	NOT SATISFACTORY NOTICE	2	1	9	2	5
	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 DISINFECTANT PRODUCTS					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
ADMINISTRATIVE	0	0	0	0	0
DISINFECTANTS	0	0	1	1	1
<i>Total</i>	<i>0</i>	<i>0</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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Disinfectants	0	1	1	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	1	1	0	0
Non Backlog	0	1	1	0	0
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Disinfectants	0	0	0	1	1
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	1	1
Non Backlog	0	0	0	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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
Administrative	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	0
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

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

NDS-D REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	1	0	100%	1
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

NDS-Disinfectant Products: Screening Performance

NDS-D SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Oct-Dec 2019	0	1	0	100%	1
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

NDS-Disinfectant Products: Administrative-Screening Performance

NDS-D ADMIN SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Oct-Dec 2019	0	0	0	-	0
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

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

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
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	1	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	0	1	0
	CANCELLATION LETTER	0	0	0	0	0
	REJECTION LETTER (SCR)	1	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	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	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
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	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
SAFETY 90	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%

NC-Disinfectant Products: Screening Workload

NC-Disinfectant Products: SCREENING WORKLOAD (excluding Administrative) by End of Quarter					
FEE CATEGORY	2019-12-31	2020-03-31	2020-06-30	2020-09-30	2020-12-31
SAFETY 90	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%

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

NC-DIS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	0	0	-	0
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

NC-Disinfectant Products: Screening Performance

NC-DIS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2019	0	0	0	-	0
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

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

Fee Category	Decision Document Type	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
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	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA	1	0	1	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	5	1	3	0	1
CHEMISTRY AND MANUFACTURING	0	0	0	0	1
Total	6	1	4	0	2

MPNDS-Disinfectant Products: Received by Fee Category

PRE - NDS MEETING (MPNDS) DISINFECTANT PRODUCTS					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	1
CHEMISTRY AND MANUFACTURING	0	0	0	0	1
Total	0	0	0	0	2

MPSNDS-Disinfectant Products: Received by Fee Category

PRE - SNDS MEETING (MPSNDS) DISINFECTANT PRODUCTS					
Fee Category	Oct-Dec 2019	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	0