



Health
Canada

Santé
Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance
Quarterly Report
October - December
2019



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.

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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 2018 to October - December 2019. 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.

Some of the highlights of the October - December 2019 report are:

Non-prescription Drug Submissions:

- There was a significant increase (174%) in the number of DINA submissions received: from 42 in July-September 2019 to 115 in this quarter (October-December 2019).
- There was a slight decrease (25%) in the number of DINF submissions received: from 48 in July-September 2019 to 36 in this quarter (October-December 2019).
- The number of PDC submissions received decreased (37%): from 115 in July-September 2019 to 73 in this quarter (October-December 2019).
- There was 3 NDS received in this quarter (October-December 2019), which is consistent with last quarter (July-September 2019).
- There was a slight decrease (27%) in the number of SNDS received: from 15 in July-September 2019 to 11 in this quarter (October-December 2019).
- There was 4 ANDS received in this quarter (October-December 2019), which is a 300% increase from last quarter (1 in July-September 2019).
- There was a slight increase (20%) in the number of SANDS received: from 5 in July-September 2019 to 6 in this quarter (October-December 2019).
- There was a significant increase (233%) in the number of NCs received: from 3 in July-September 2019 to 10 in this quarter (October-December 2019).

Overall, the total non-prescription drug submissions received increased by 11% in this quarter (258) when compared to the last quarter (232 in July-September 2019). This brings the total number of non-prescription drug submissions received to its highest in comparison to the past 4 quarters (232 in July-September 2019, 161 in April-June 2019, 185 in January-March 2019, and 161 in October-December 2018). This increase in the number of submissions is mainly due to a high volume of submissions received for compliance with the plain language labelling requirements.

Disinfectant Drug Submissions:

- The number of DIND submissions received increased slightly (24%): from 33 in July-September 2019 to 41 in this quarter (October-December 2019).
- The number of PDC submissions received decreased significantly (50%) from 22 in July-September 2019 to 11 in this quarter (October-December 2019).
- There were no NDS-D, SNDS-D or NCs received in this quarter (July-September 2019), which is in line with the numbers received in the last 3 quarters (July-September 2019, April-June 2019 and January-March 2019).

Overall, the total disinfectant drug submissions received remained constant, decreasing by 6% during this quarter (52 in October-December 2019) compared to last quarter (55 in July-September 2019).

General Information

There are several steps involved in the drug submission review¹ 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** is counted upon the conclusion of a scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set [performance standard](#)² which is based on the type of submission, class and cycle (status). Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

¹ For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

² Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the [Guidance for Industry: Management of Drug Submissions](#). This is not to be confused with the ‘UF Review 1 (iteration 1)’ performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the ‘Health Canada Departmental Performance Report (DPR)’.

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

Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
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 NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only³	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission	Submissions in support of a manufacturer or product name change.
Disinfectants⁴	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information, please refer to the [Guidance Document - Fees for the Review of Drug Submissions and Applications](#).

³ For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#).

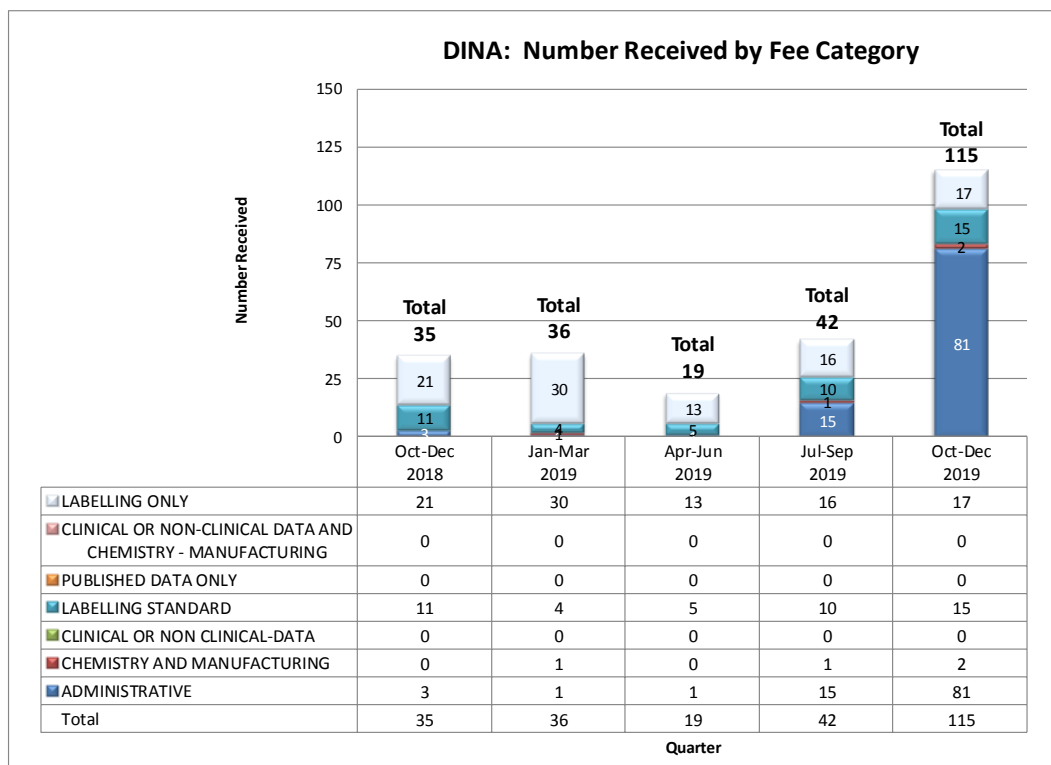
⁴ The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

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*

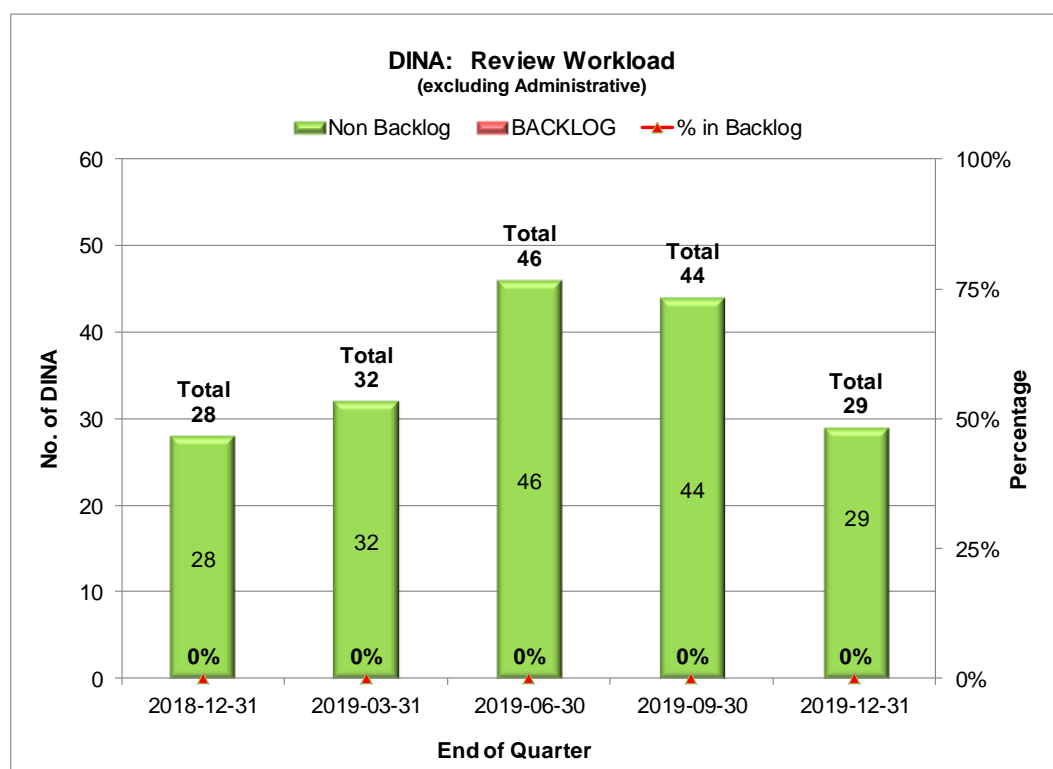
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER RECEIVED

DINA: Number Received by Fee Category



WORKLOAD

DINA: Review Workload

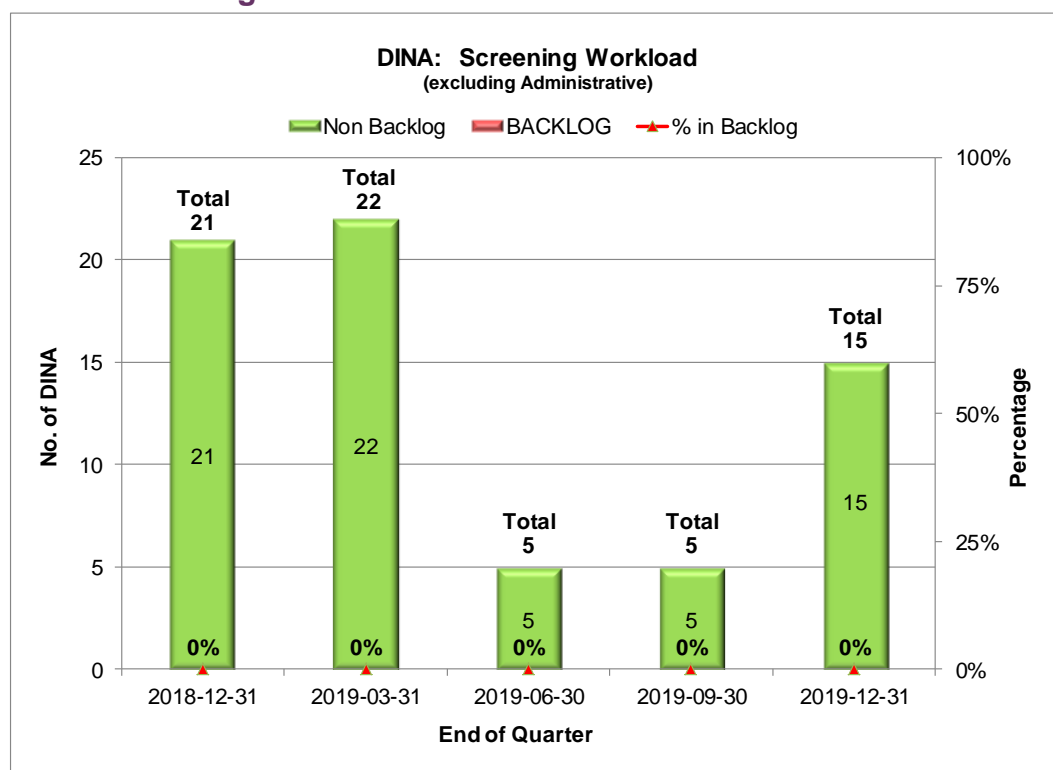


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Chemistry and Manufacturing	1	0	0	1	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clinical Data	1	0	1	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	0	1	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Only	24	32	44	42	28
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Published Data	1	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	28	32	46	44	29
Non Backlog	28	32	46	44	29
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Screening Workload

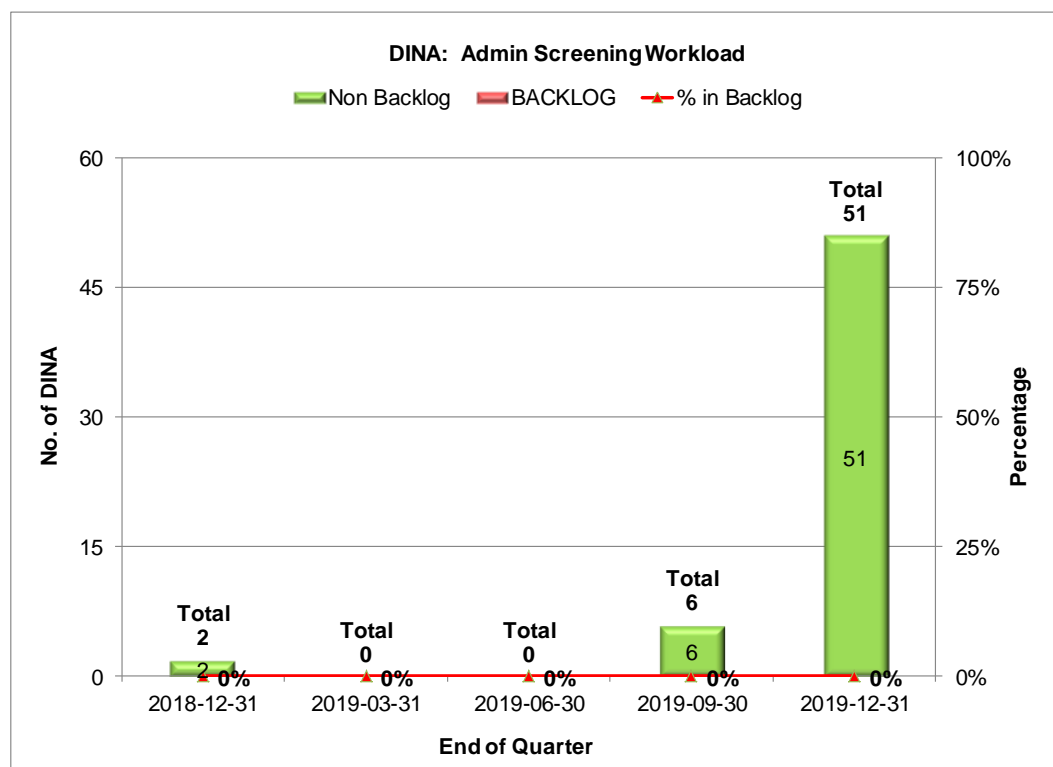


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Chemistry and Manufacturing	0	0	0	0	1
Backlog	0	0	0	0	0
Clinical or Non-Clinical	0	1	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	9	15	4	4	5
Backlog	0	0	0	0	0
Labelling Standard	12	6	1	1	9
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Total	21	22	5	5	15
Non Backlog	21	22	5	5	15
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Administrative-Screening Workload



DINA: Administrative-Screening Workload by Fee Category

DINA: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Administrative	2	0	0	6	51
<i>Backlog</i>	0	0	0	0	0
Total	2	0	0	6	51
Non Backlog	2	0	0	6	51
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

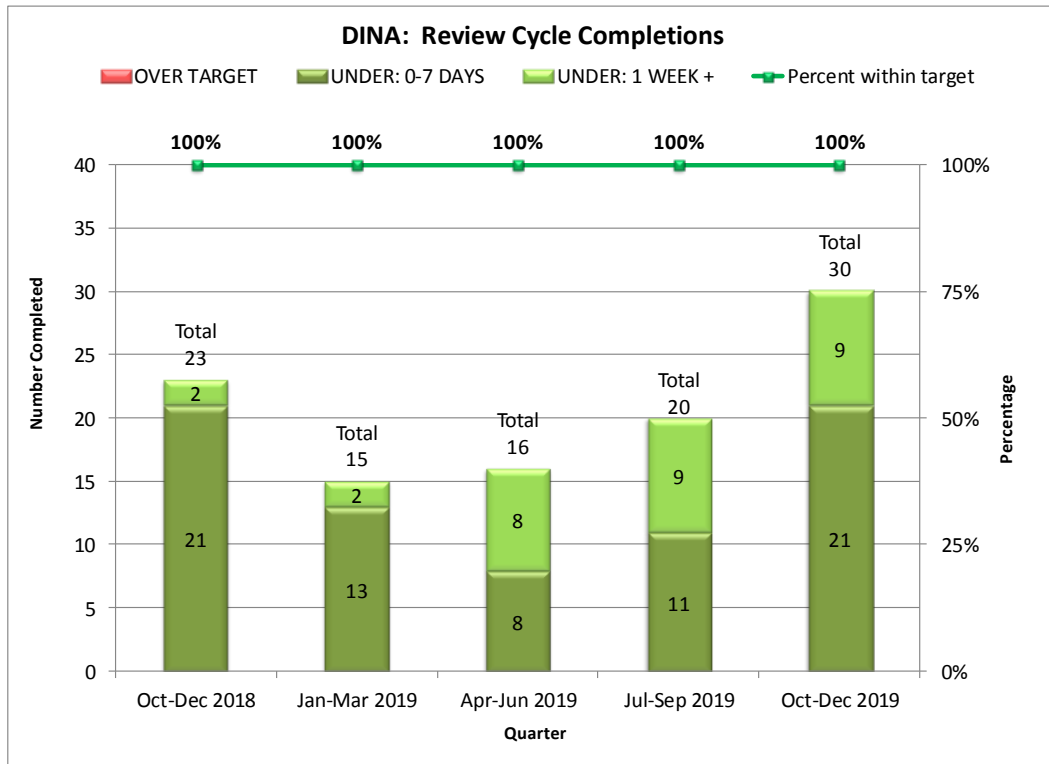
DECISIONS

DINA: Number of Decisions by Fee Category

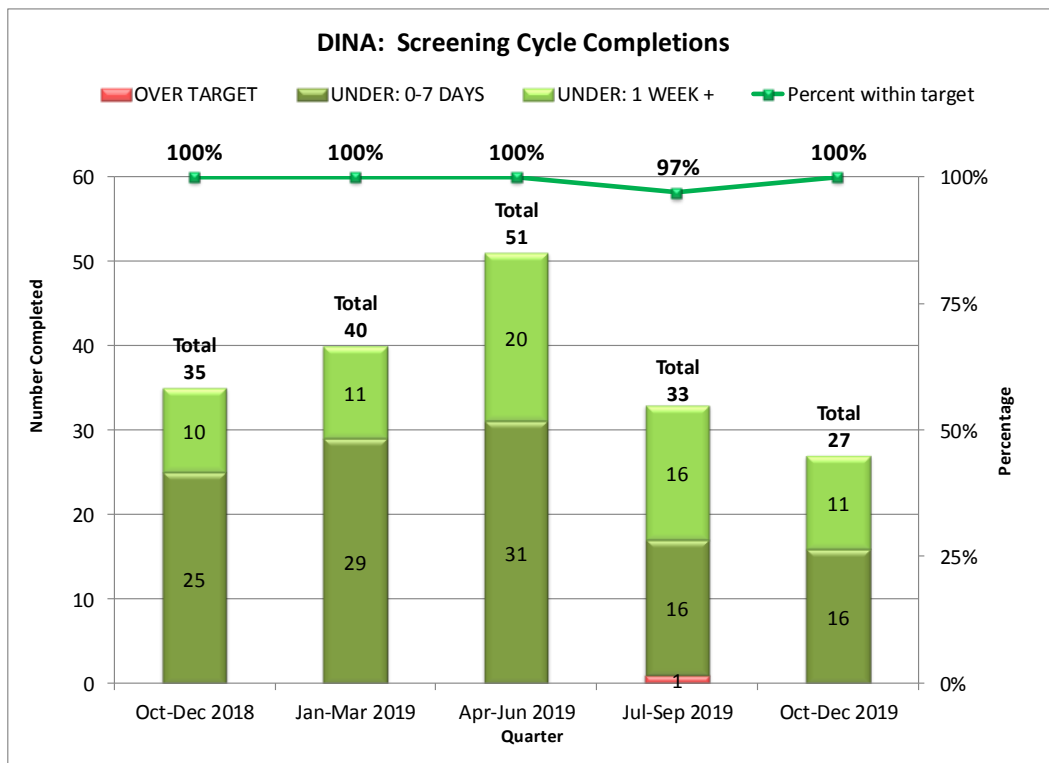
User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	CANCELLATION LETTER	1	3	1	3	3
	NOTIFICATION FORM DIN SUB	0	0	0	4	30
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	2	0	0	14
	NO OBJECTION LETTER	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	0	1	0	0	0
	CANCELLATION LETTER	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	1	0	0	1
	WITHDRAWAL NO RESP TO NON	0	0	0	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	0	0	1	0
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NO OBJECTION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	1	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
LABELLING ONLY	CANCELLATION LETTER	0	0	3	0	4
	NO OBJECTION LETTER	0	2	0	1	4
	NOTICE OF NON-COMPLIANCE	0	1	1	2	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	23	8	15	17	24
	REJECTION LETTER (SCR)	5	0	0	0	0
	SCREENING DEFICIENCY NOTICE	2	11	8	1	1
	WITHDRAWAL NO RESP TO NOD	0	0	0	0	0
	WITHDRAWAL NO RESP TO NON	0	0	1	0	0
LABELLING STANDARD	CANCELLATION LETTER	1	0	0	2	0
	NO OBJECTION LETTER	0	0	0	1	0
	NOTIFICATION FORM DIN SUB	7	6	9	9	6
	REJECTION LETTER (SCR)	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	5	4	3	1	1
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	1	0	0	0

PERFORMANCE

DINA: Review Cycle Completions

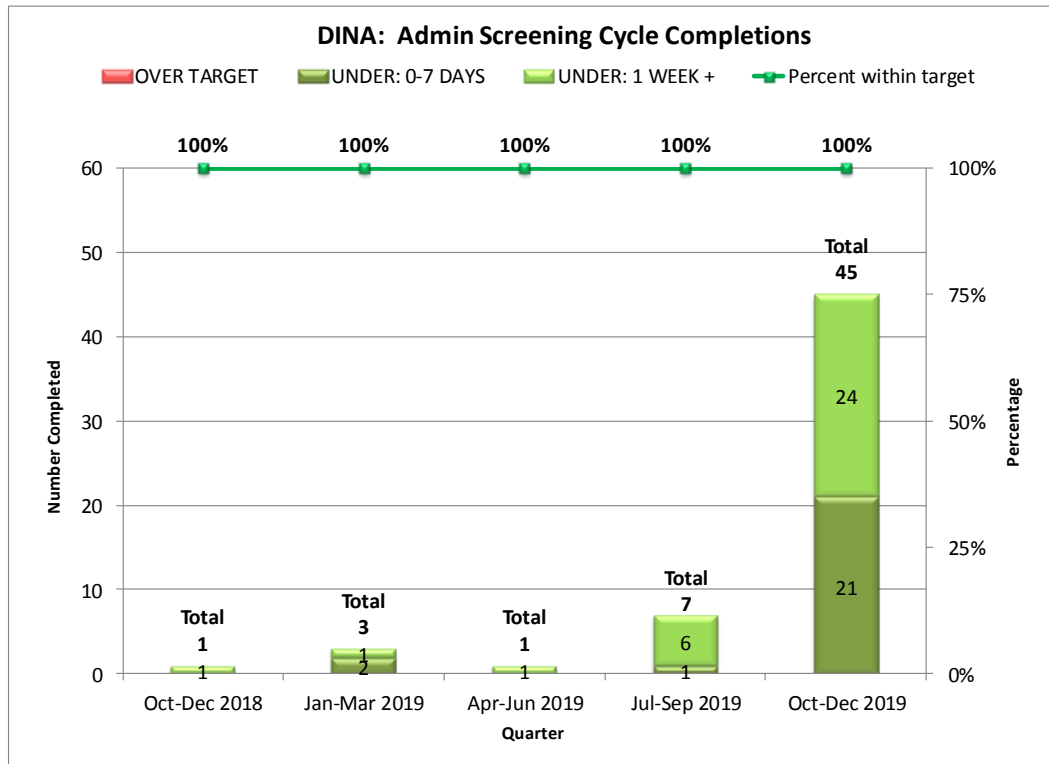


DINA: Screening Cycle Completions



PERFORMANCE

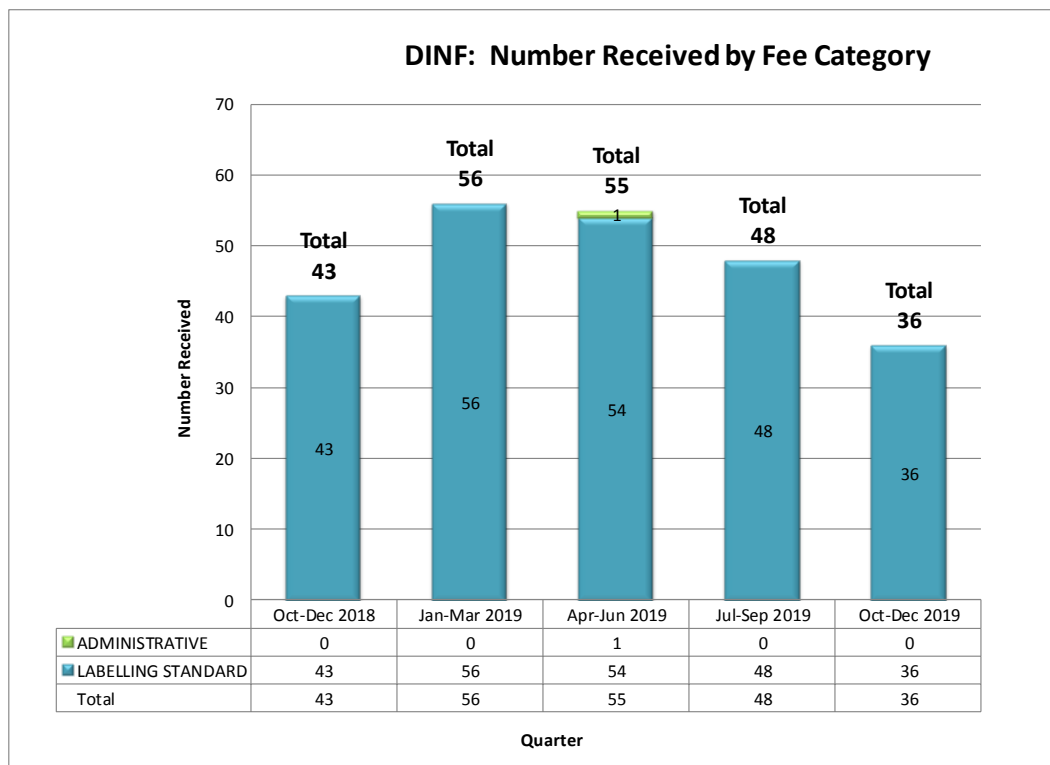
DINA: Administrative-Screening Cycle Completions



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

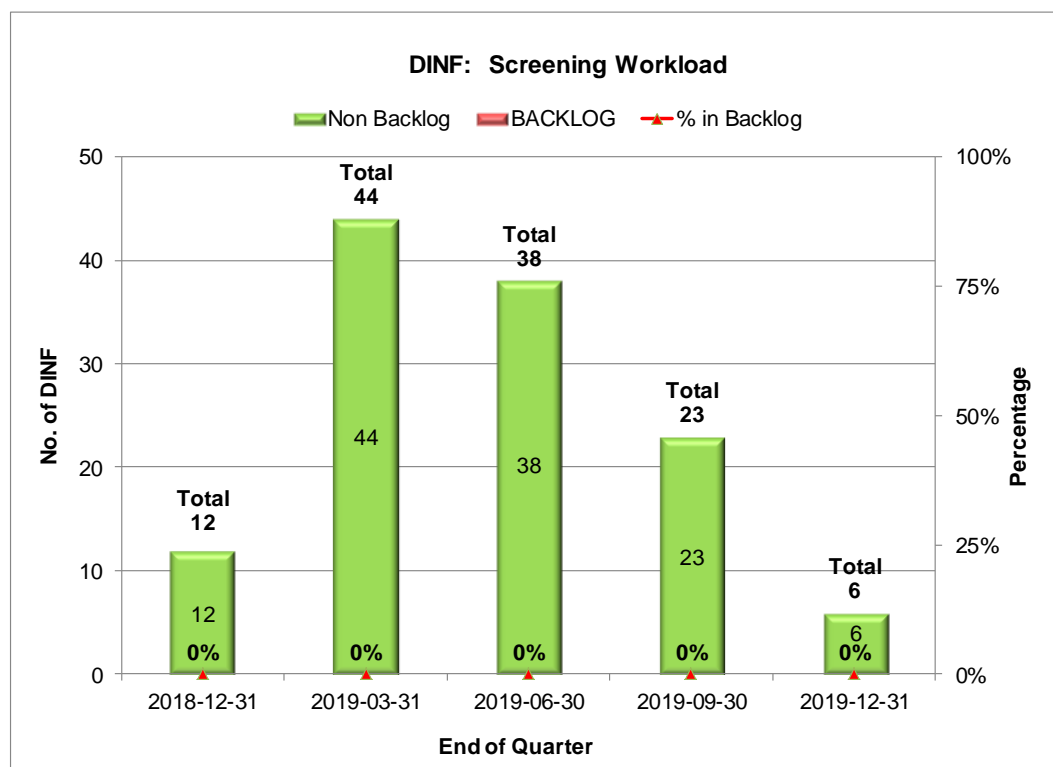
RECEIVED

DINF: Number Received by Fee Category



WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Labelling Standard	12	44	38	23	6
Backlog	0	0	0	0	0
Administrative	0	0	0	0	0
Backlog	0	0	0	0	0
Total	12	44	38	23	6
Non Backlog	12	44	38	23	6
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

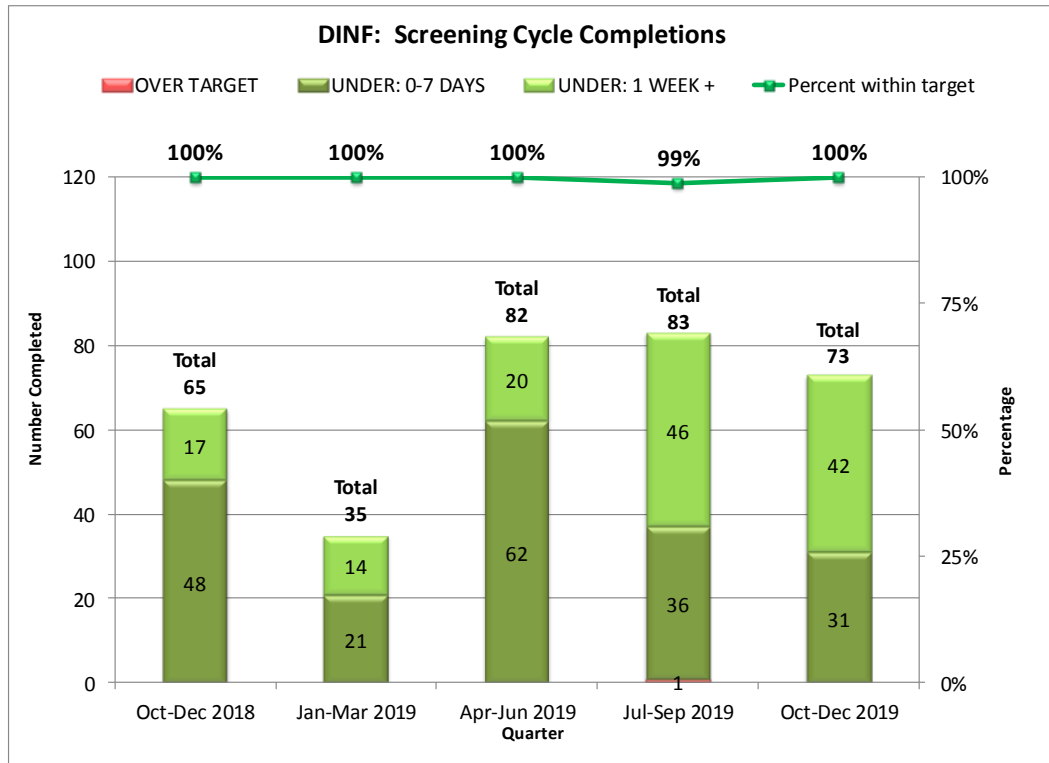
DECISIONS

DINF: Number of Decisions by Fee Category

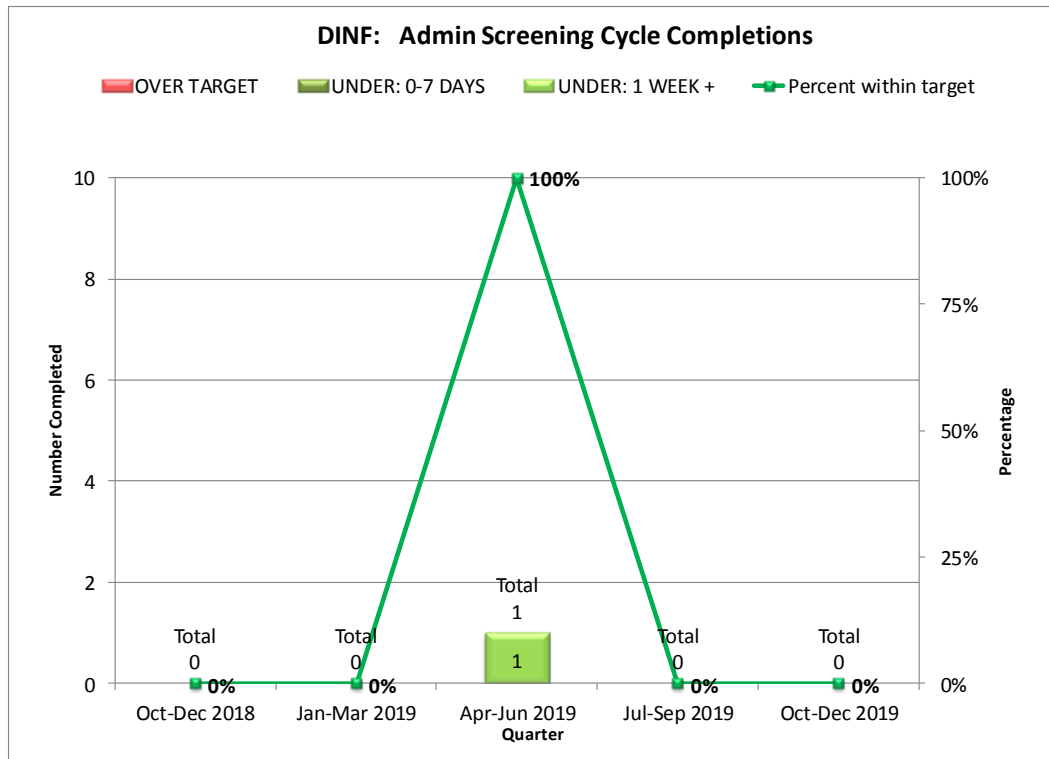
User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
LABELLING STANDARD	CANCELLATION LETTER	4	2	4	2	3
	NO OBJECTION LETTER	0	0	14	1	3
	NEW DRUG LETTER SCREEN	0	0	0	0	1
	NOTIFICATION FORM DIN SUB	29	22	52	52	57
	REJECTION LETTER (SCR)	4	1	1	2	2
	SCREENING DEFICIENCY NOTICE	34	12	14	30	8
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	0	1	0	0

PERFORMANCE

DINF: Screening Cycle Completions



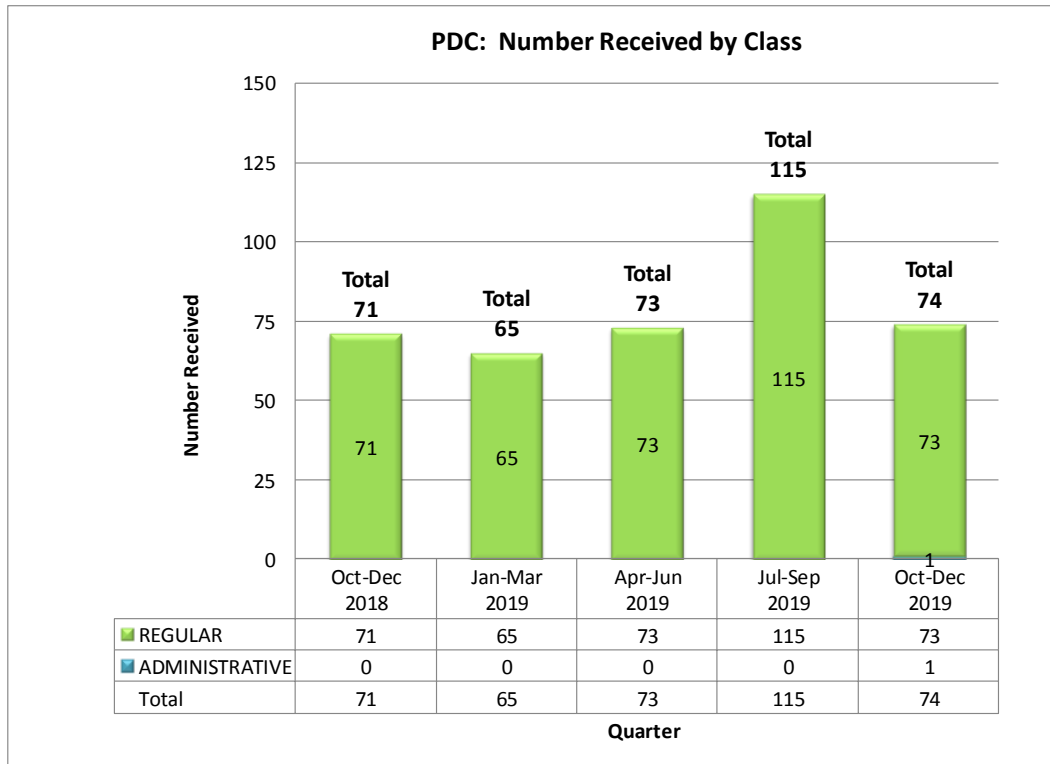
DINF: Admin-Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

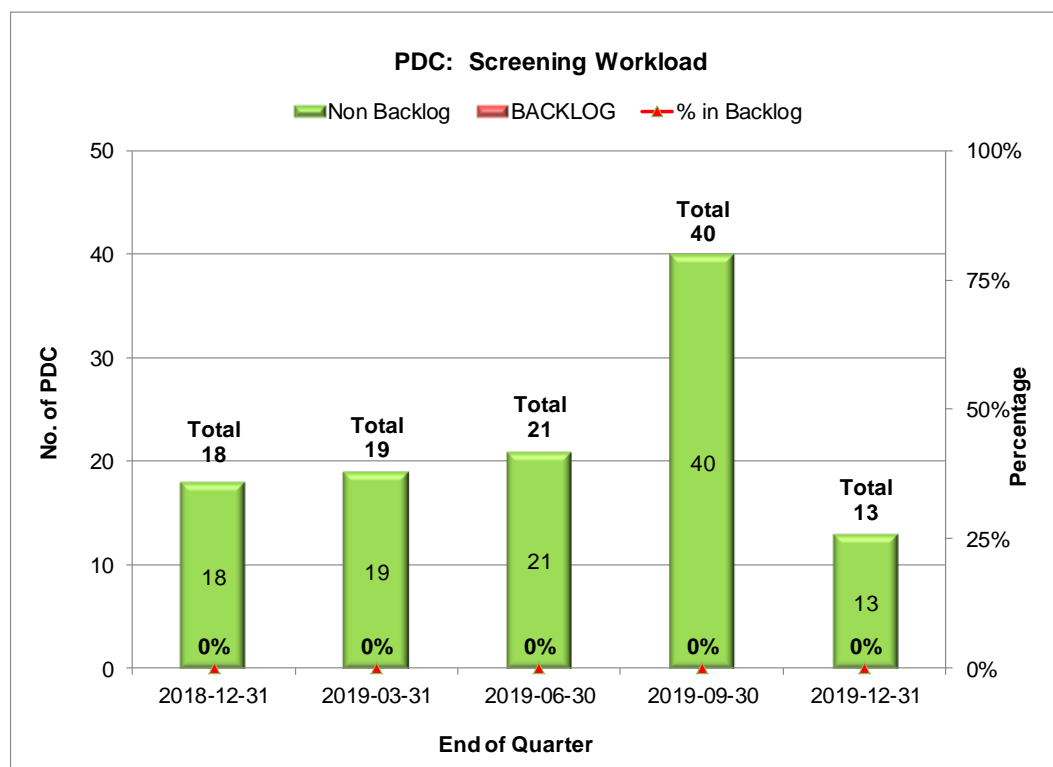
RECEIVED

PDC: Received by Class



WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS By End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Regular	18	19	21	40	12
Backlog	0	0	0	0	0
Administrative	0	0	0	0	1
Backlog	0	0	0	0	0
Total	18	19	21	40	13
Non Backlog	18	19	21	40	13
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

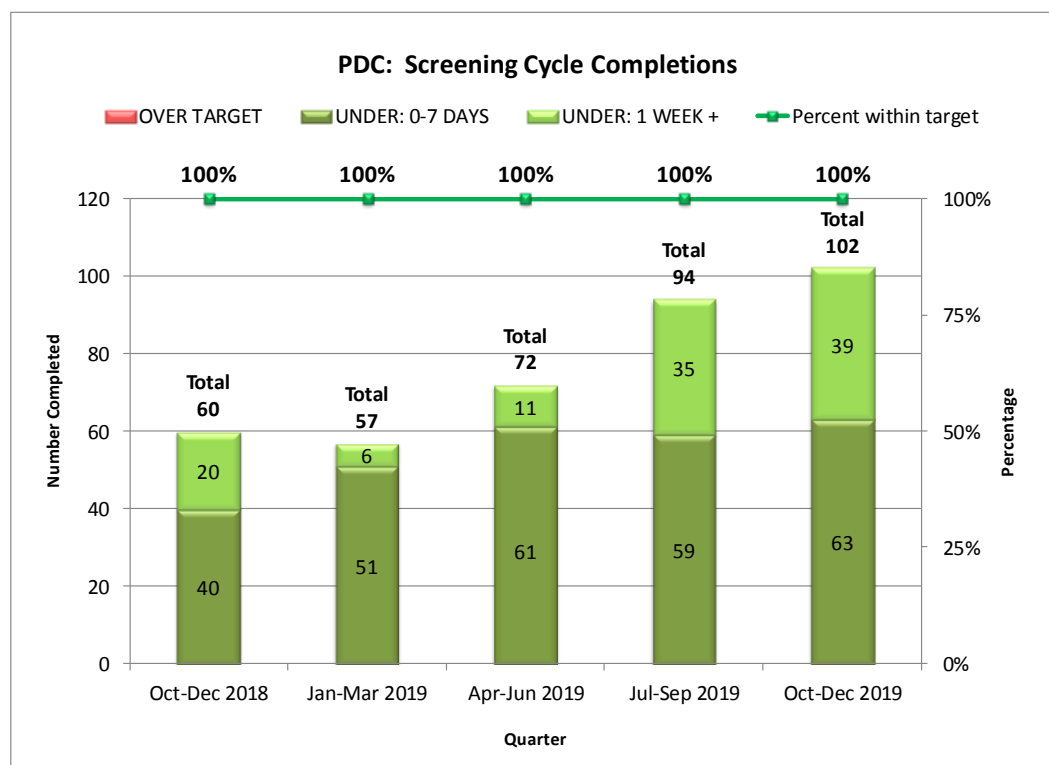
DECISIONS

PDC: Number of Decisions by Class

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
REGULAR	CANCELLATION LETTER	12	5	2	11	6
	NO OBJECTION LETTER	34	45	63	73	92
	NOT SATISFACTORY NOTICE	13	9	7	12	4
	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

PERFORMANCE

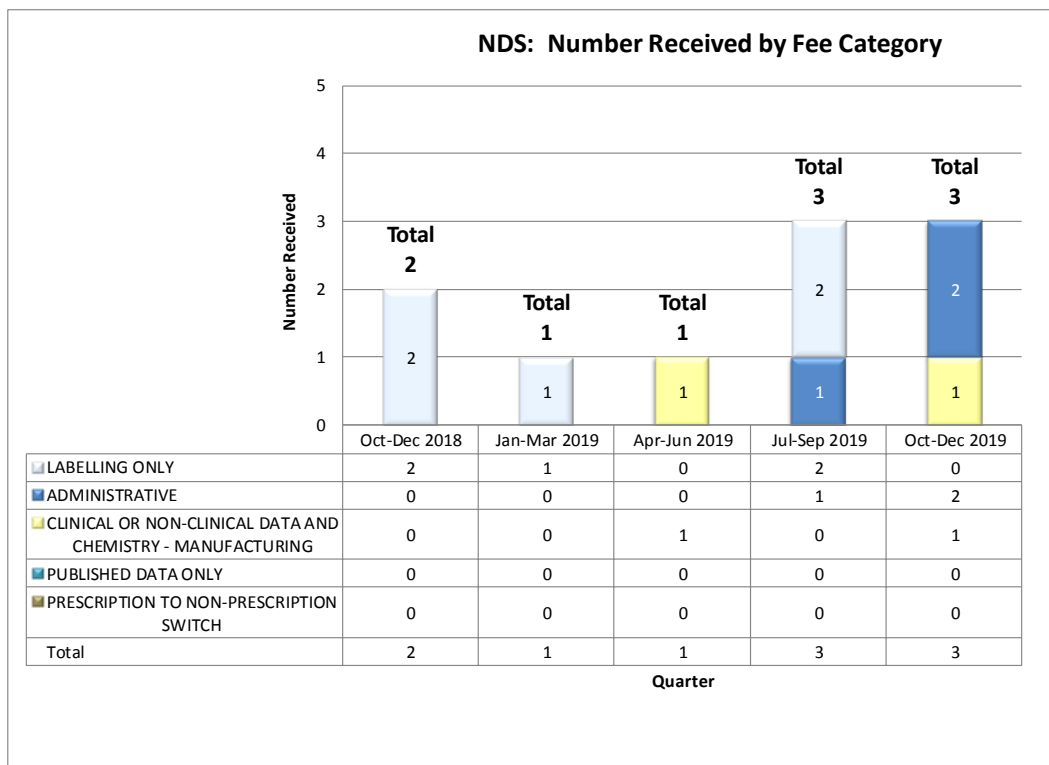
PDC: Screening Cycle Completions



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

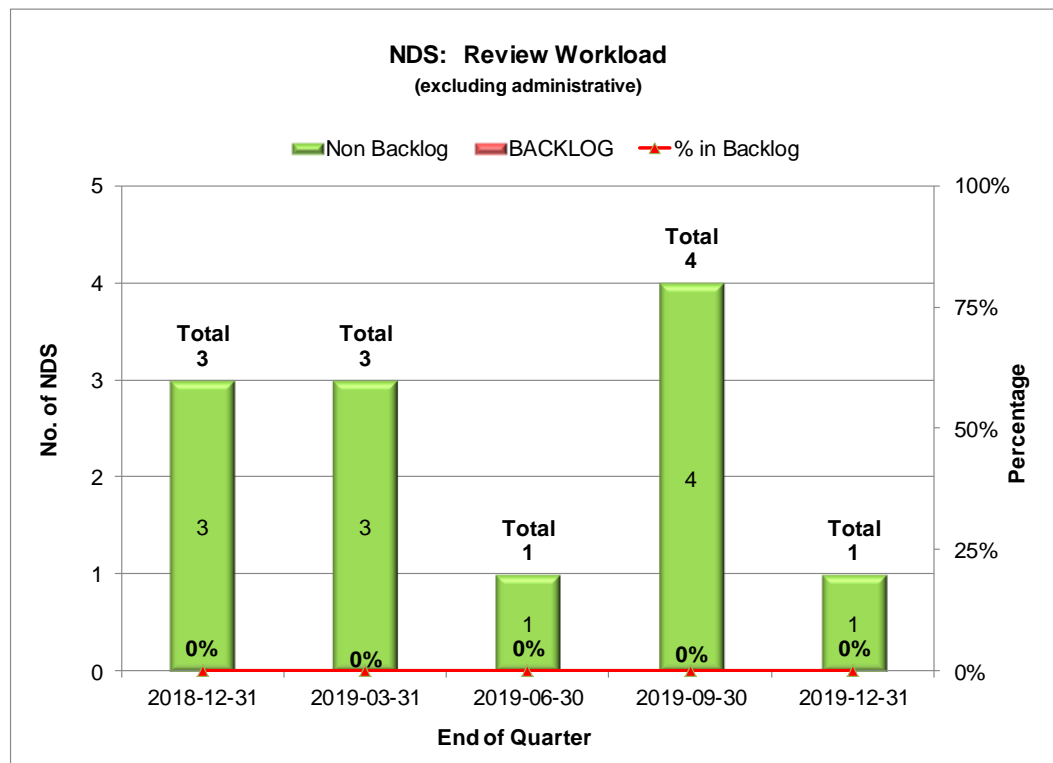
NDS: NEW DRUG SUBMISSION RECEIVED

NDS: Number Received by Fee Category



WORKLOAD

NDS: Review Workload

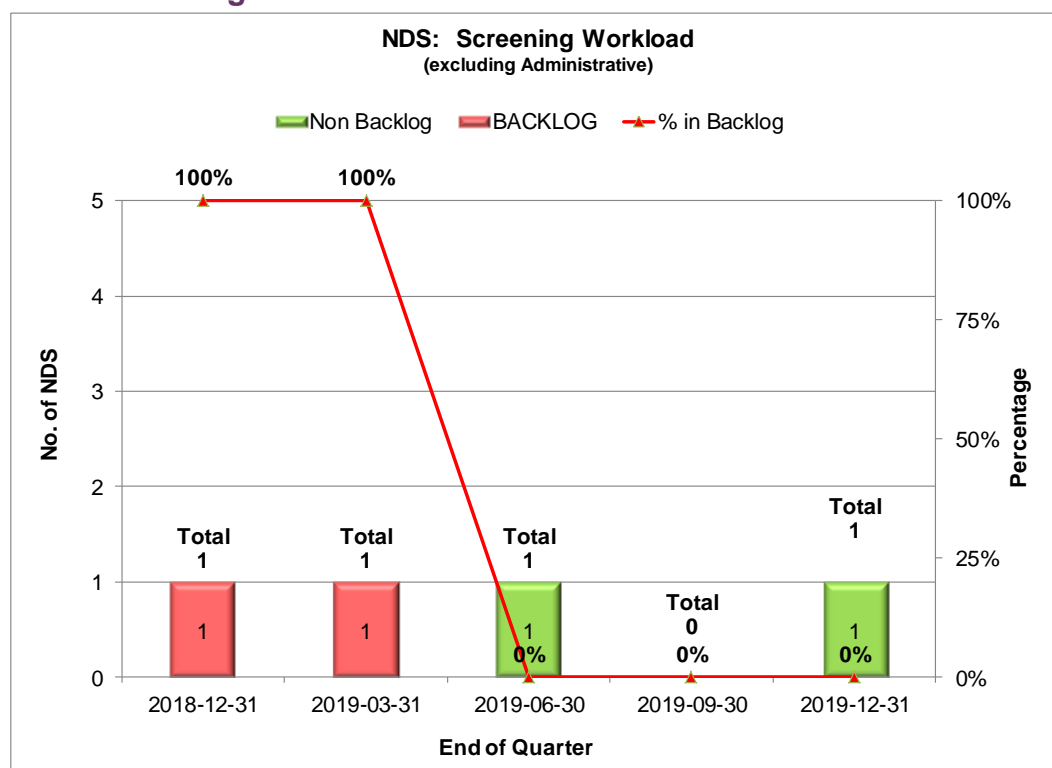


NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	1	0	1	1
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	0	1	1	0
Backlog	0	0	0	0	0
Labelling Only	1	2	0	2	0
Backlog	0	0	0	0	0
Total	3	3	1	4	1
Non Backlog	3	3	1	4	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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Prescription to Non-Prescription Switch	0	0	0	0	0
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	1	0	1
Backlog	0	0	0	0	0
Labelling Only	1	1	0	0	0
Backlog	1	1	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Total	1	1	1	0	1
Non Backlog	0	0	1	0	1
BACKLOG	1	1	0	0	0
% in Backlog	100%	100%	0%	0%	0%

(One administrative NDS was in screening on Dec 31 2019)

DECISIONS

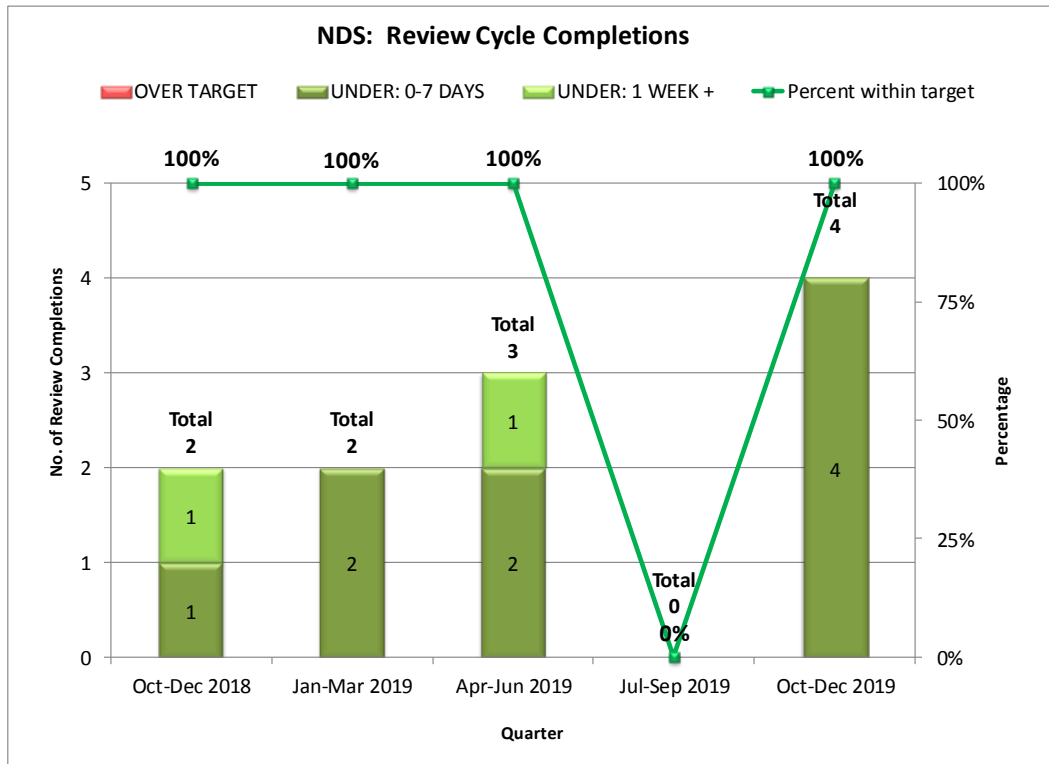
NDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	2
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	1	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	1
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	1	0	2	0	2
	NOTICE OF NON-COMPLIANCE	0	1	0	0	1
	SCREENING DEFICIENCY NOTICE	1	0	0	1	0
	CANCELLATION LETTER	0	0	1	0	0
PUBLISHED DATA ONLY	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	0	0	0

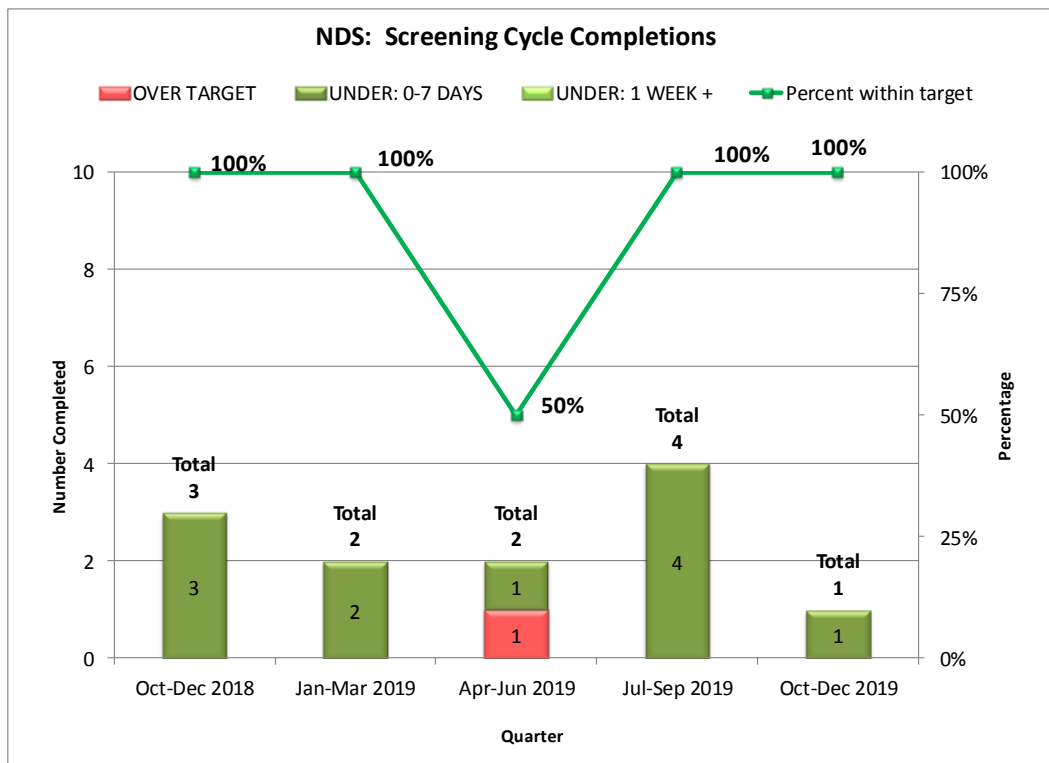
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions

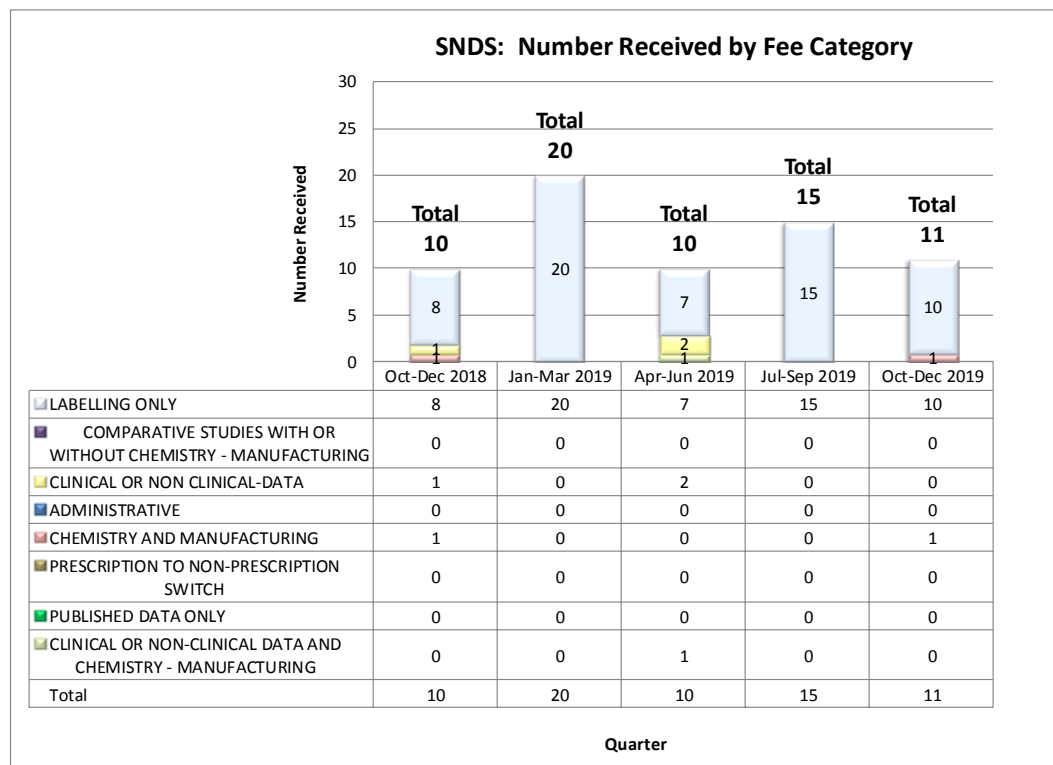


NDS: Screening Cycle Completions



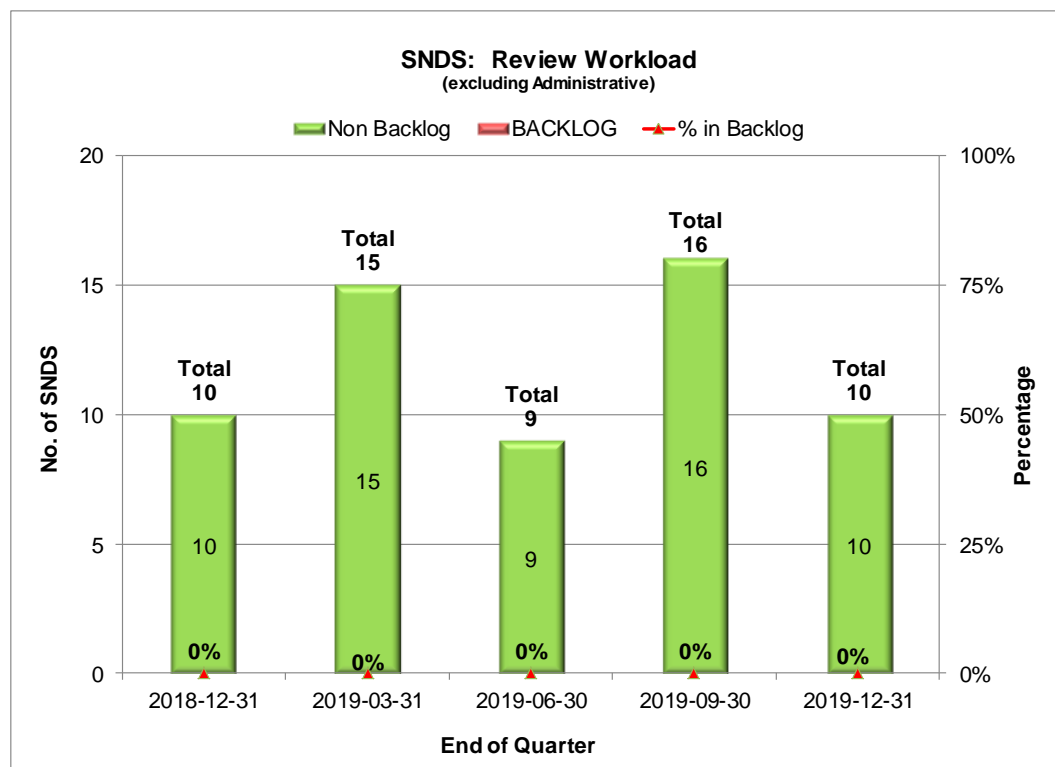
SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION RECEIVED

SNDS: Number Received by Fee Category



WORKLOAD

SNDS: Review Workload

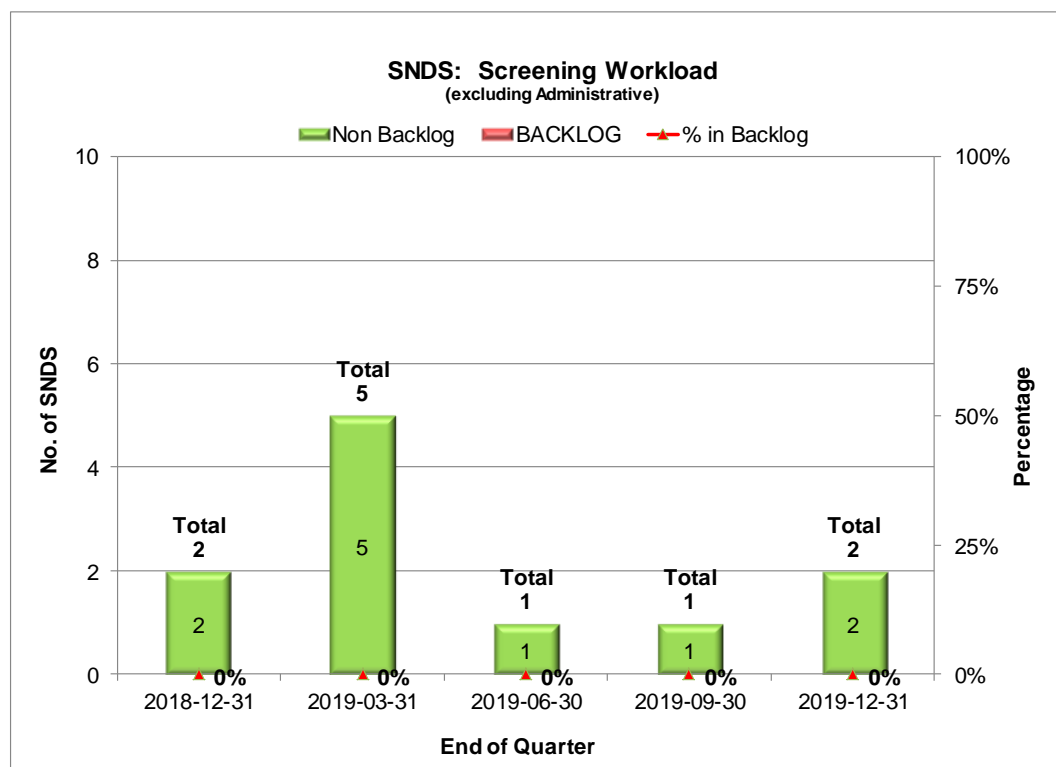


SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Clinical or Non-Clinical Data	1	1	3	3	2
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	6	12	5	12	4
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Prescription to Non-Prescription Switch	0	0	0	0	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	0	0	1	1
Backlog	0	0	0	0	0
Chemistry and Manufacturing	2	2	1	0	3
Backlog	0	0	0	0	0
Total	10	15	9	16	10
Non Backlog	10	15	9	16	10
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

SNDS: Screening Workload



SNDS: Screening Workload by Fee Category

SNDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Chemistry and Manufacturing	1	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	1	5	0	0	2
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	2	5	1	1	2
Non Backlog	2	5	1	1	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

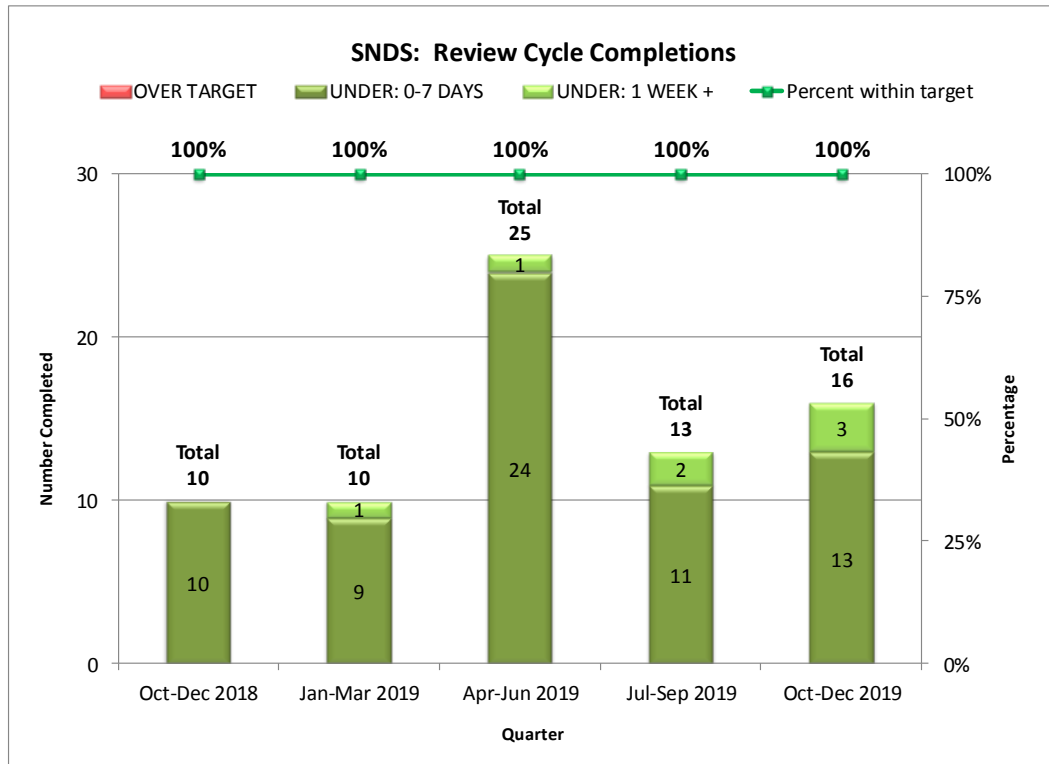
SNDS: Number of Decision by Fee Category

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	1
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	1	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	1	0	0	0	0
	NOTICE OF COMPLIANCE*	5	5	19	12	15
	SCREENING DEFICIENCY NOTICE	1	2	0	2	3
	CANCELLATION LETTER	1	2	1	0	1
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	2	3	5	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH) *	0	0	0	0	0
	CANCELLATION LETTER	0	1	0	0	0
PUBLISHED DATA ONLY	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	0	1	1	0
	NOTICE OF COMPLIANCE*	1	1	0	0	0
	SCREENING DEFICIENCY NOTICE	2	0	0	0	0

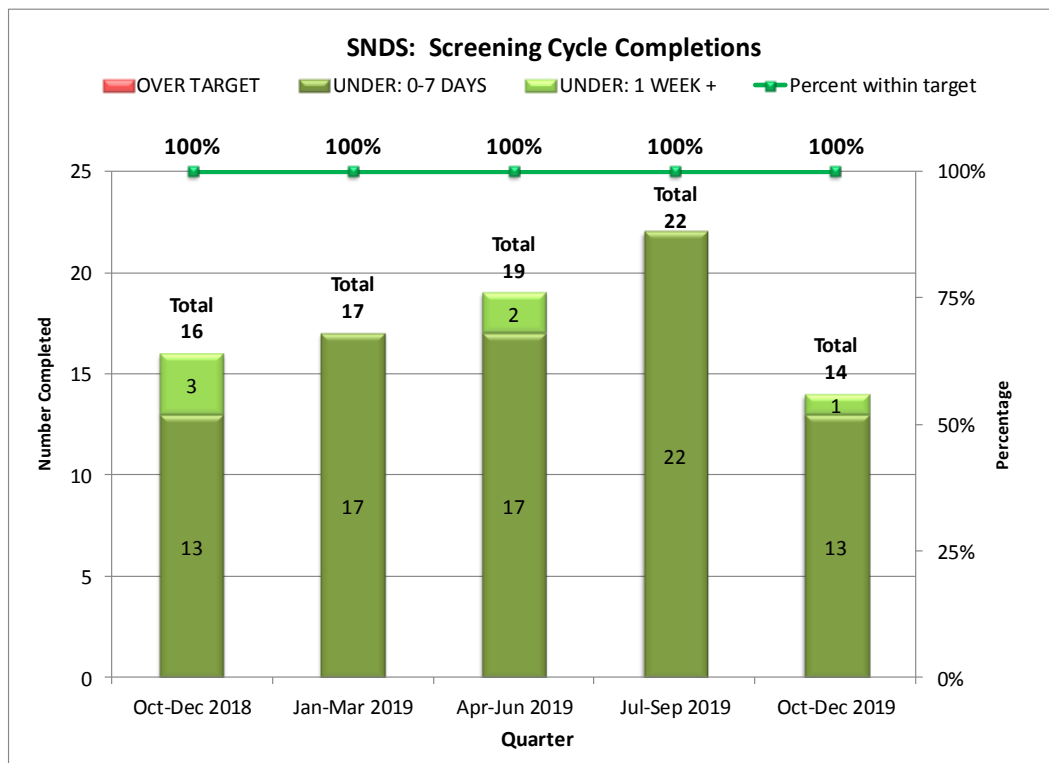
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

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)	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
LABELLING ONLY	0	0	0	1	0
ADMINISTRATIVE	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	0	0	3
Total	0	0	0	1	4

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Labelling Only	0	0	0	1	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	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%

ANDS: Screening Workload

ANDS: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	1
Non Backlog	0	0	0	0	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					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Administrative	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	1
Non Backlog	0	0	0	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
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	0	0	-	0
Oct-Dec 2019	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 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	1	0	100%	1
Oct-Dec 2019	0	2	0	100%	2

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

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	1

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

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

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION (SANDS)	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
ADMINISTRATIVE	0	0	0	0	1
LABELLING ONLY	0	0	0	5	5
Total	0	0	0	5	6

WORKLOAD

SANDS: Review Workload

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Labelling Only	0	0	0	1	2
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	1	2
Non Backlog	0	0	0	1	2
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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Labelling Only	0	0	0	0	2
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	2
Non Backlog	0	0	0	0	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Administrative-Screening Workload

SANDS: ADMINISTRATIVE-SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Administrative	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	1
Non Backlog	0	0	0	0	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

SANDS: Review Performance

SANDS REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	1	0	100%	1
Oct-Dec 2019	0	4	1	100%	5

SANDS: Screening Performance

SANDS SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	3	0	100%	3
Oct-Dec 2019	0	11	0	100%	11

DECISIONS

SANDS: Number of Decision by Fee Category

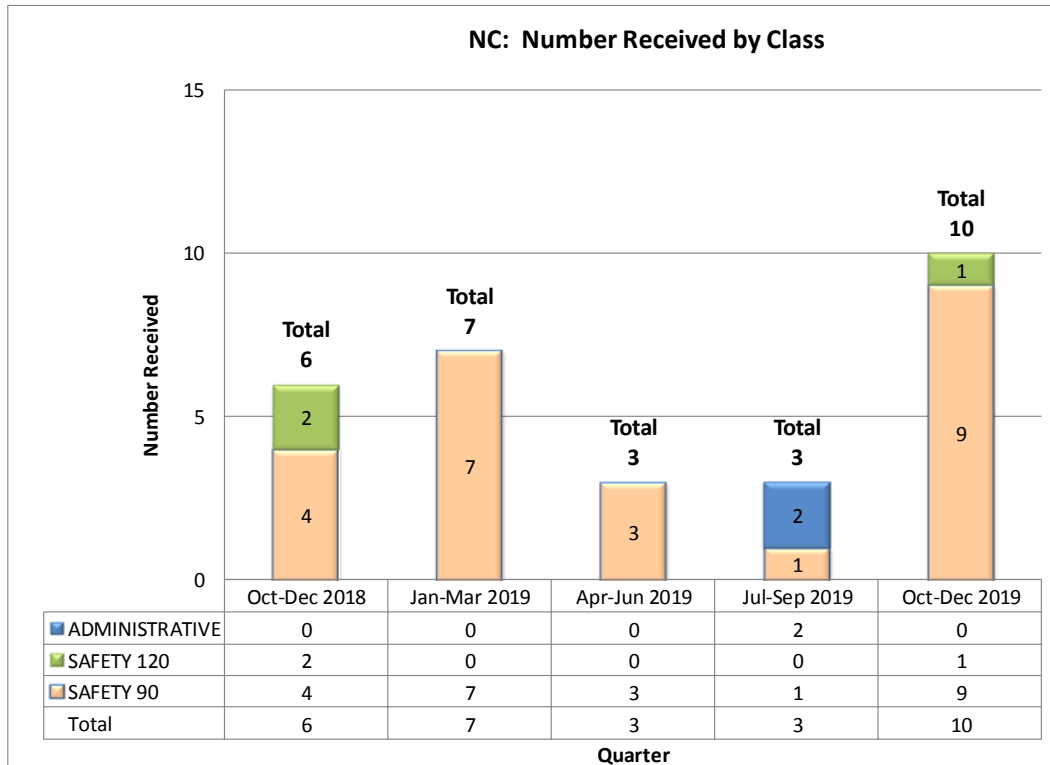
User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
LABELLING ONLY	NOTICE OF COMPLIANCE *	0	0	0	1	5
	SCREENING DEFICIENCY NOTICE	0	0	0	1	4
	CANCELLATION LETTER	0	0	0	0	1

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

NC: NOTIFIABLE CHANGE

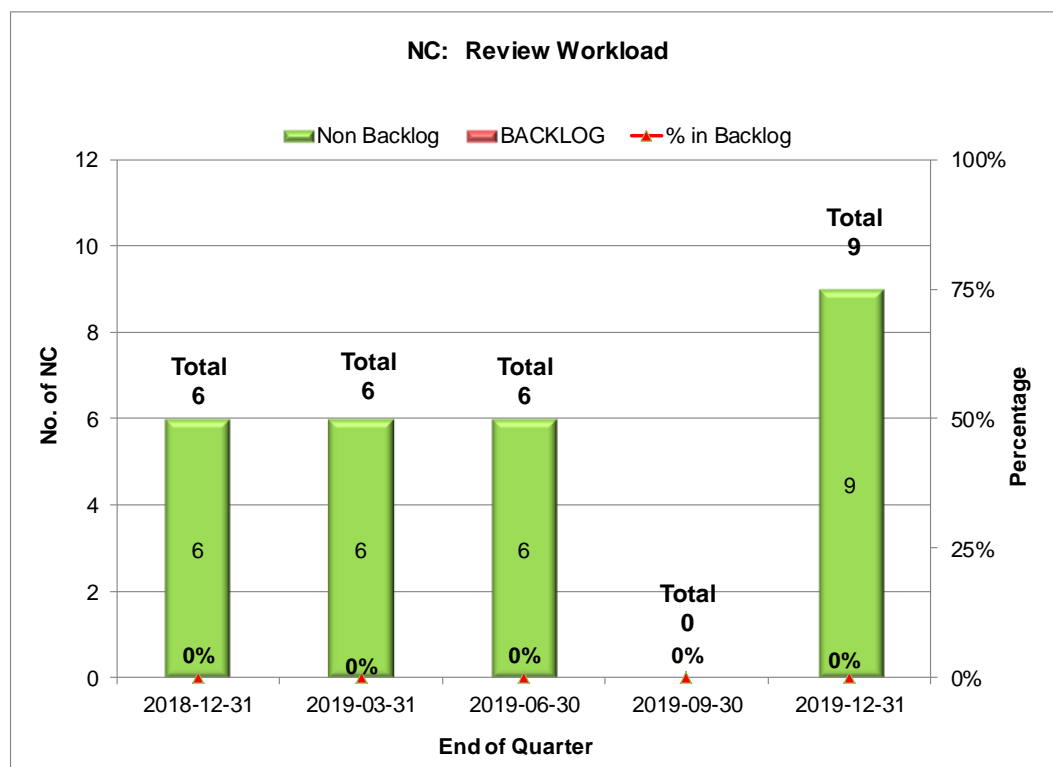
RECEIVED

NC: Number Received by Class



WORKLOAD

NC: Review Workload

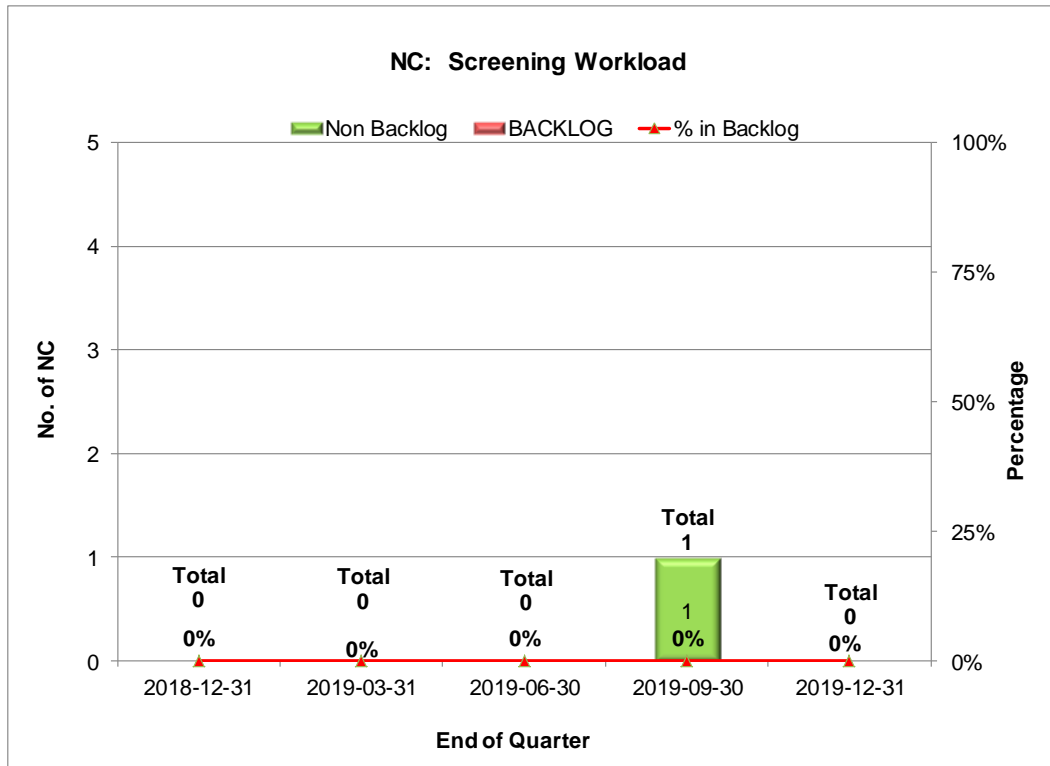


NC: Review Workload by class

NC: REVIEW WORKLOAD BY CLASS and End of Quarter					
Class	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Safety 90	4	4	6	0	8
<i>Backlog</i>	0	0	0	0	0
Safety 120	2	2	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	6	6	6	0	9
Non Backlog	6	6	6	0	9
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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Safety 90	0	0	0	1	0
<i>Backlog</i>	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%

NC: Administrative Screening Workload

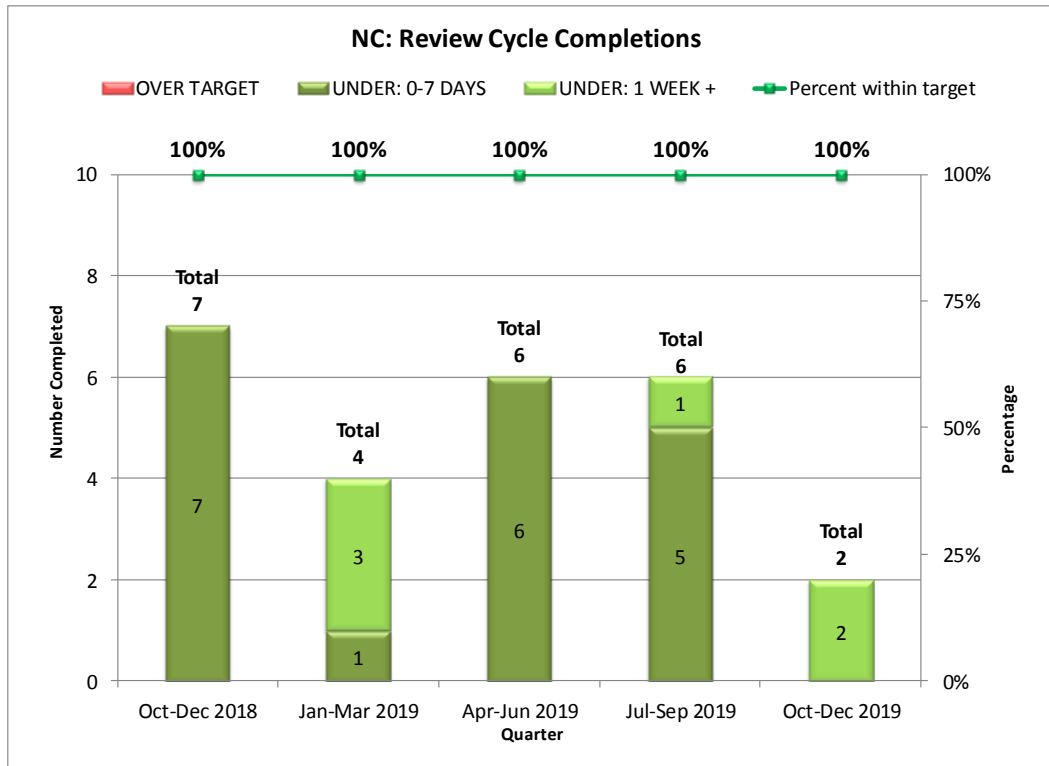
NC: ADMIN SCREENING WORKLOAD					
By End of Quarter					
Class	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Administrative	0	0	0	2	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	2	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>2</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

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

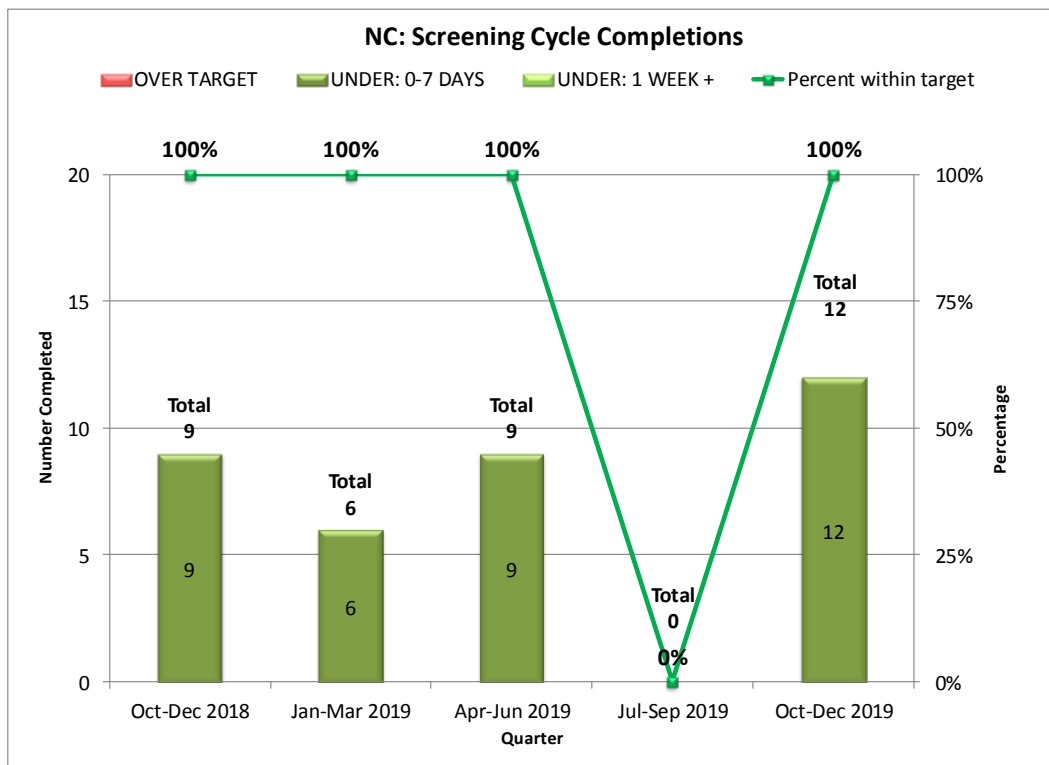
CLASS	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	NO OBJECTION LETTER	0	0	0	0	2
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
SAFETY 90	NO OBJECTION LETTER	7	1	4	6	1
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	CANCELLATION LETTER	3	0	0	0	1
	SCREENING DEFICIENCY NOTICE	2	3	0	0	1
SAFETY 120	CANCELLATION LETTER	0	0	0	0	0
	NO OBJECTION LETTER	0	0	2	0	0

PERFORMANCE

NC: Review Cycle Completions



NC: Screening Cycle Completions



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

PRE - DIN MEETING (MPDIN)	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	2	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1	2	0	0	0
Total	1	2	2	0	0

MPNDS: Number Received by Fee Category

PRE - NDS MEETING (MPNDS)	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1	0	1	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	0	0	0	1	1
Total	1	0	1	2	1

MPSNDS: Number Received by Fee Category

PRE - SNDS MEETING (MPSNDS)	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	0

PART 2: DISINFECTANT PRODUCTS

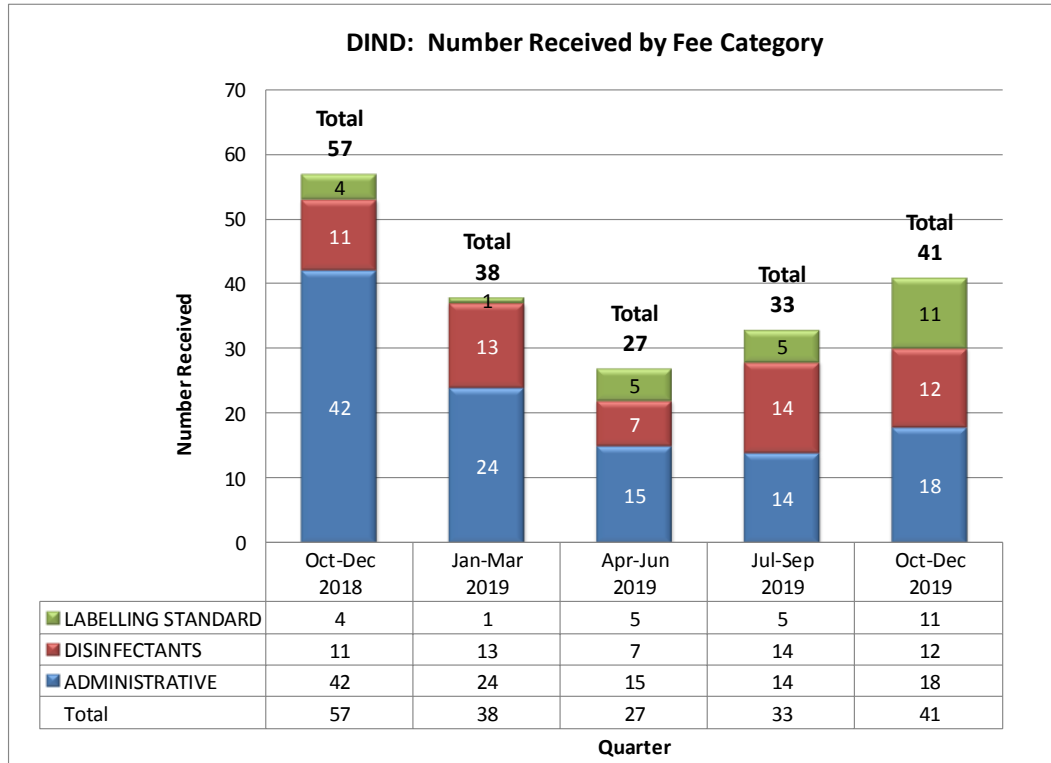
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS

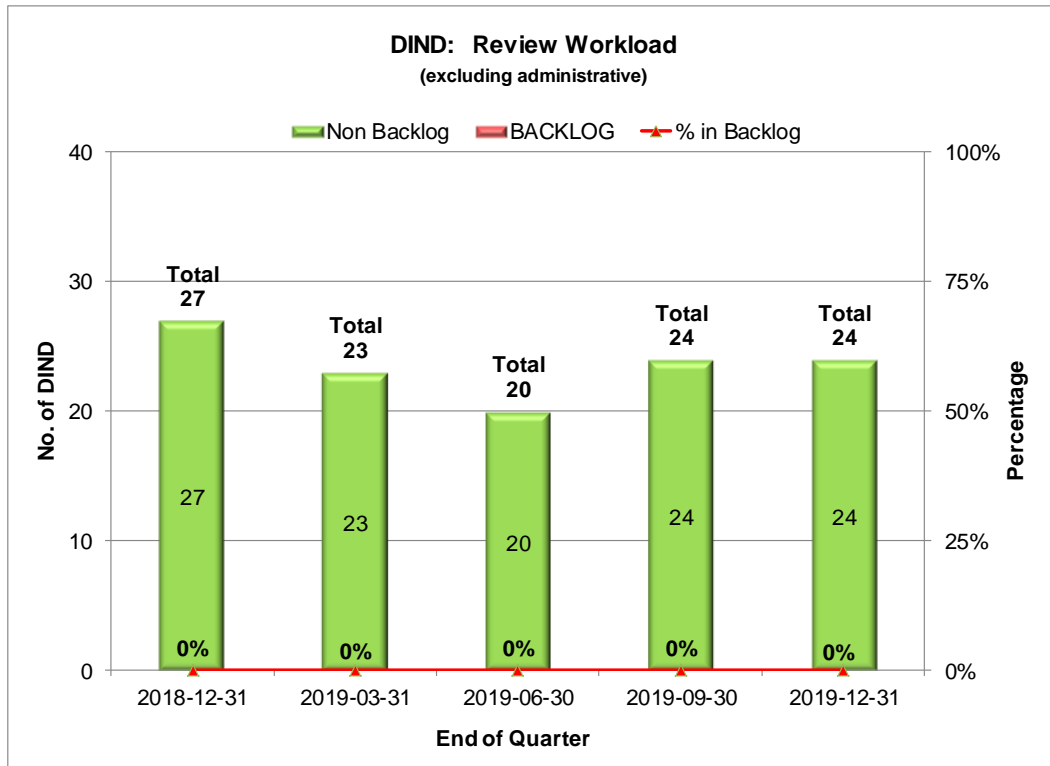
RECEIVED

DIND-Disinfectant Products: Number Received by Fee Category

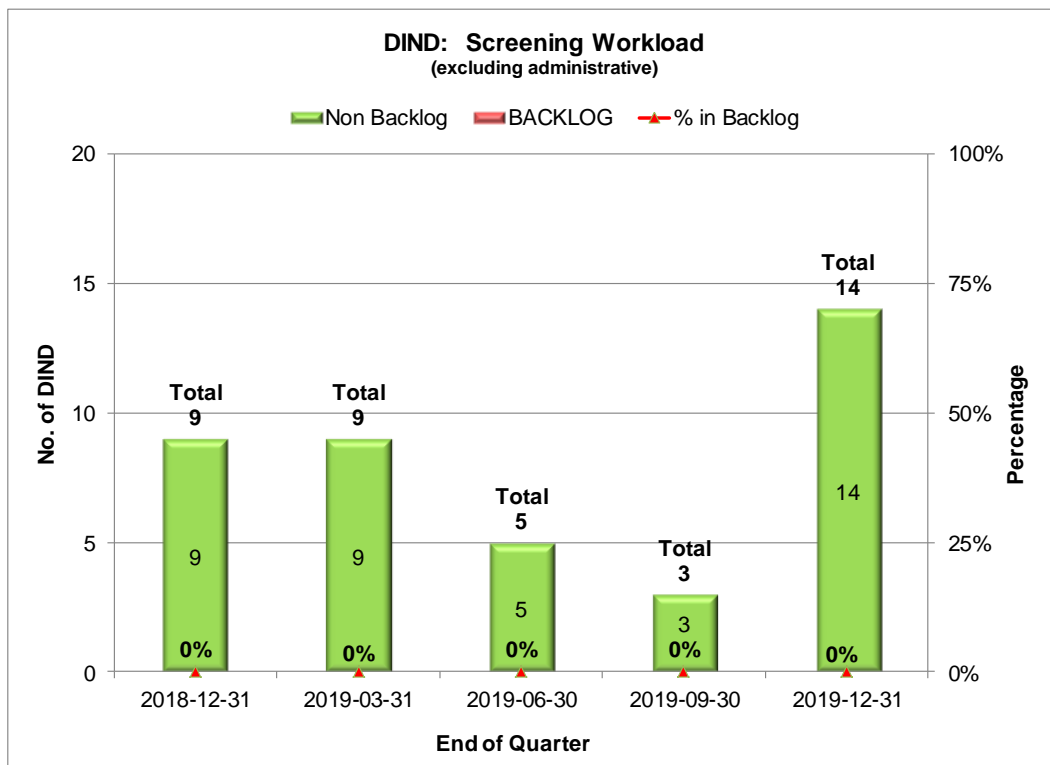


WORKLOAD

DIND-Disinfectant Products: Review Workload

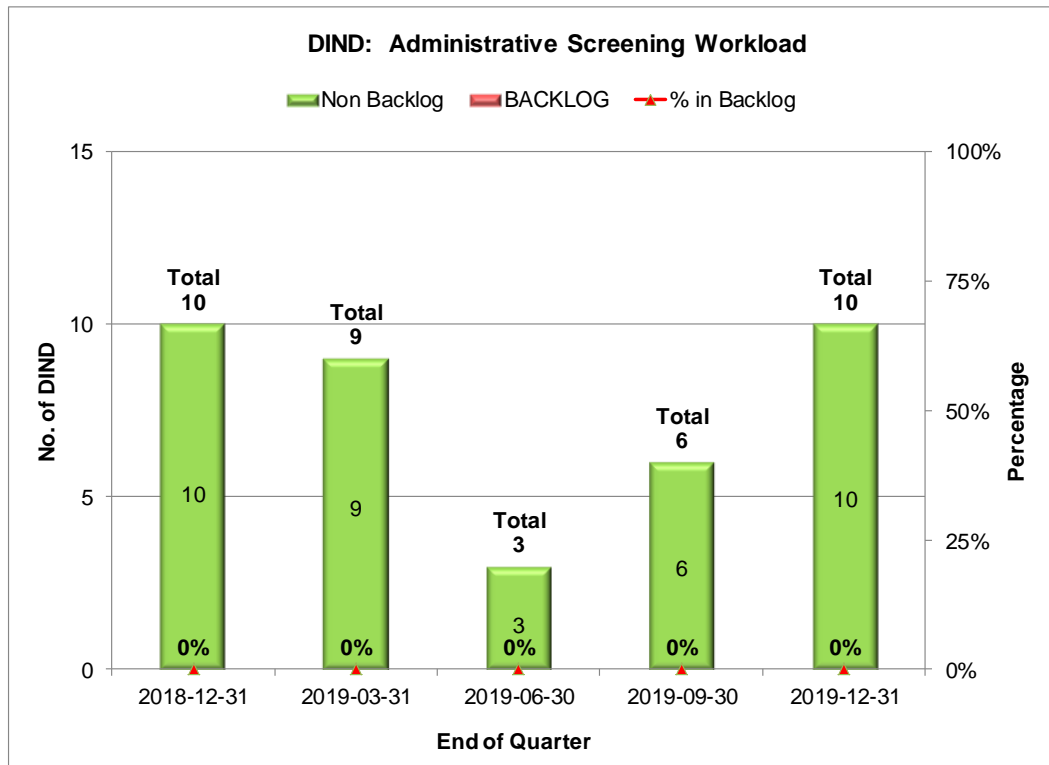


DIND-Disinfectant Products: Screening Workload



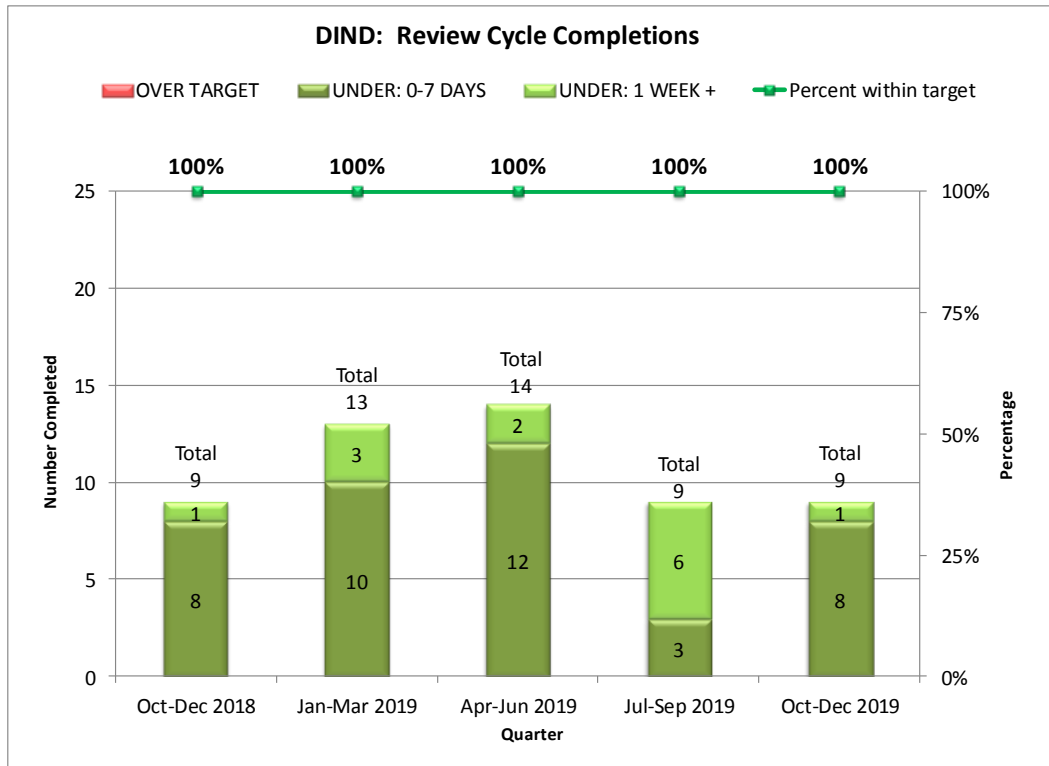
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

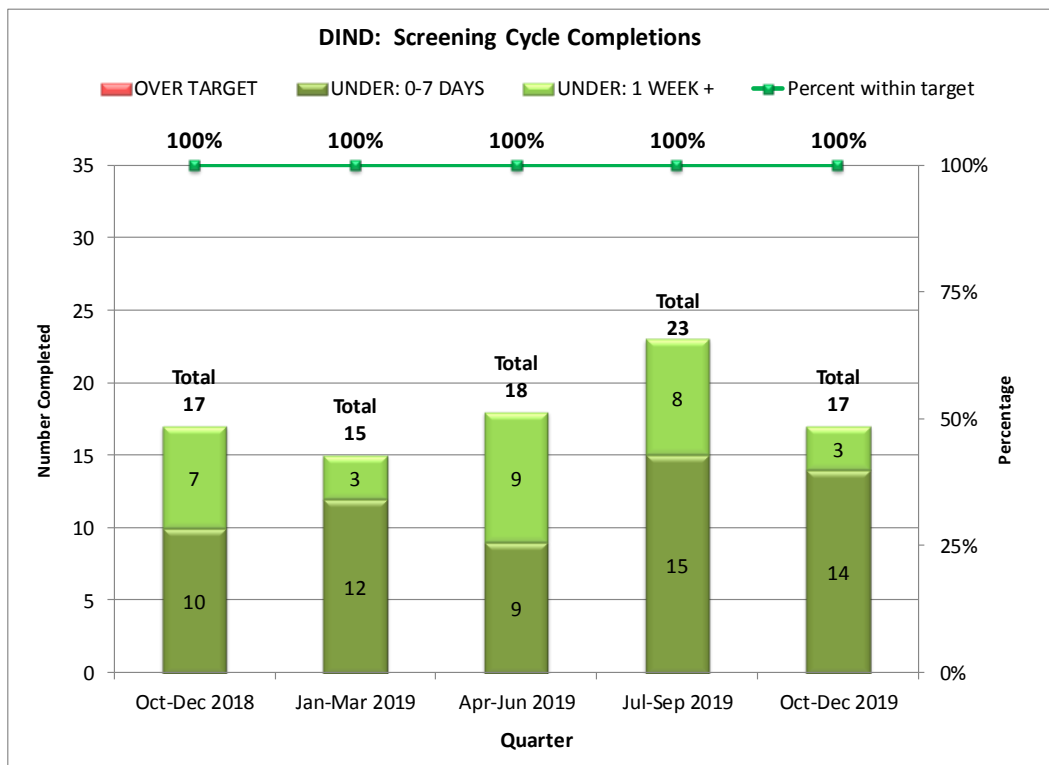


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

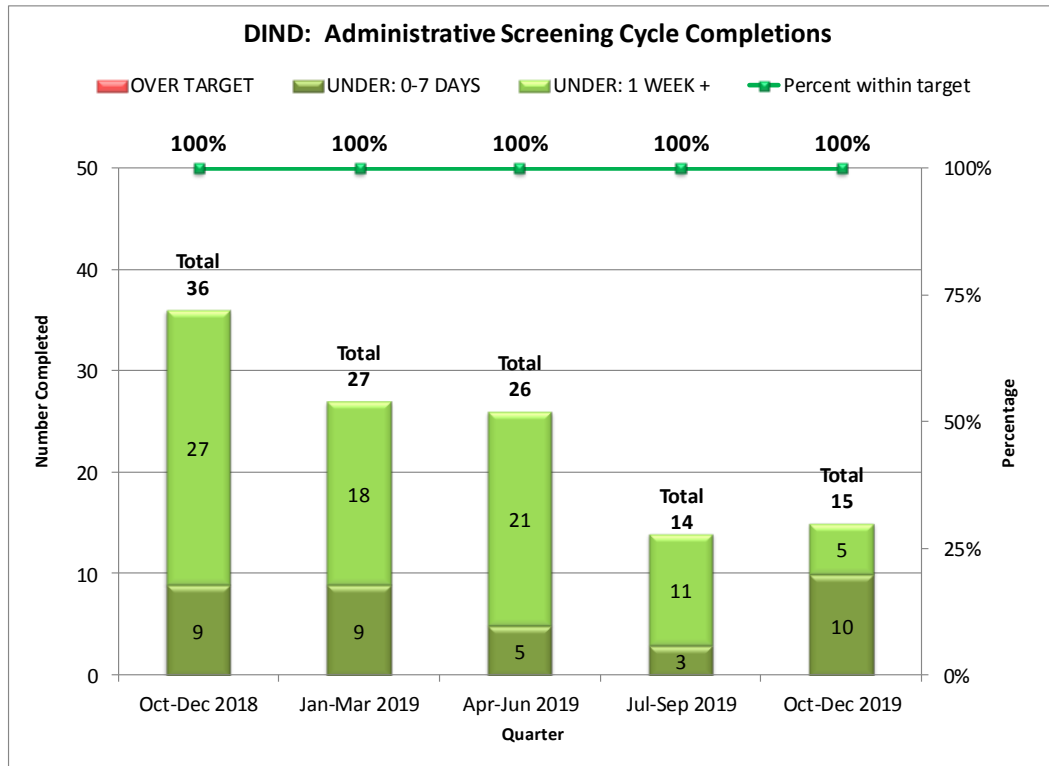


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



DECISIONS

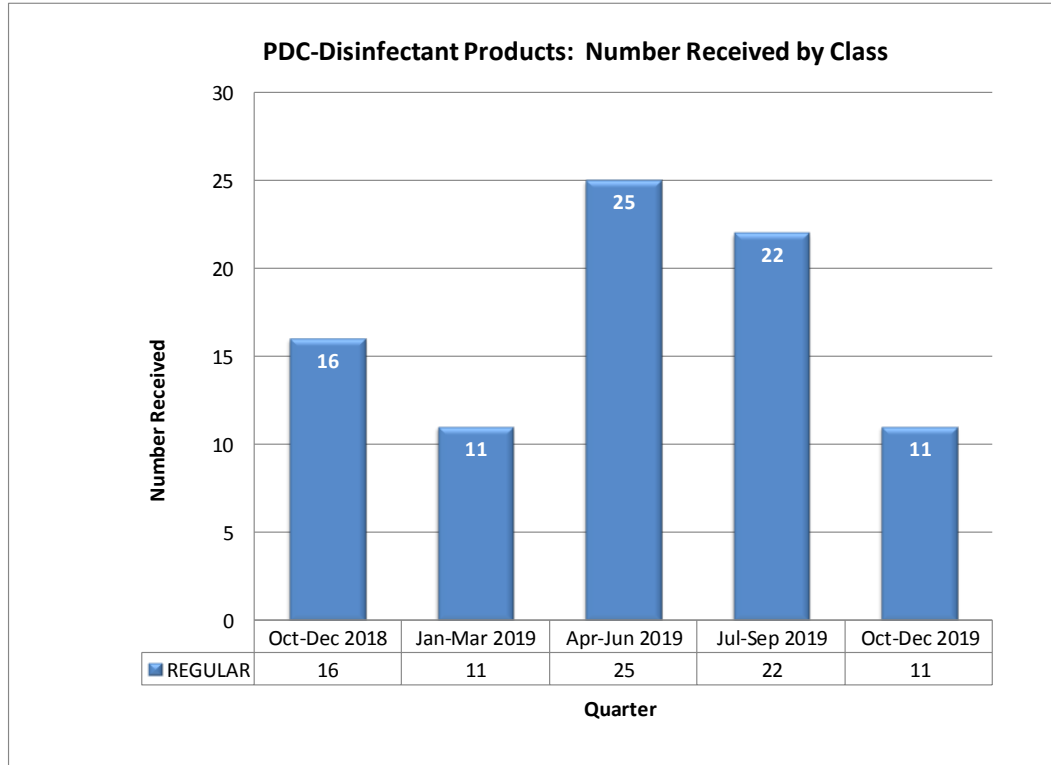
DIND-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	1	0	0	0
	NO OBJECTION LETTER	5	3	2	0	0
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	20	19	18	12	11
	REJECTION LETTER (SCR)	0	1	2	1	0
	SCREENING DEFICIENCY NOTICE	11	4	5	2	4
DISINFECTANTS	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	3	5	1	0	3
	CANCELLATION LETTER	1	2	0	0	1
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	6	8	13	9	6
	SCREENING DEFICIENCY NOTICE	2	2	3	2	0
	REJECTION LETTER (SCR)	0	0	0	2	0
	WITHDRAWAL NO RESP TO NON	0	0	0	0	0
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	1	3	4	4	5
	NO OBJECTION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	2	2
	REJECTION LETTER (SCR)	0	0	0	0	0

PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS

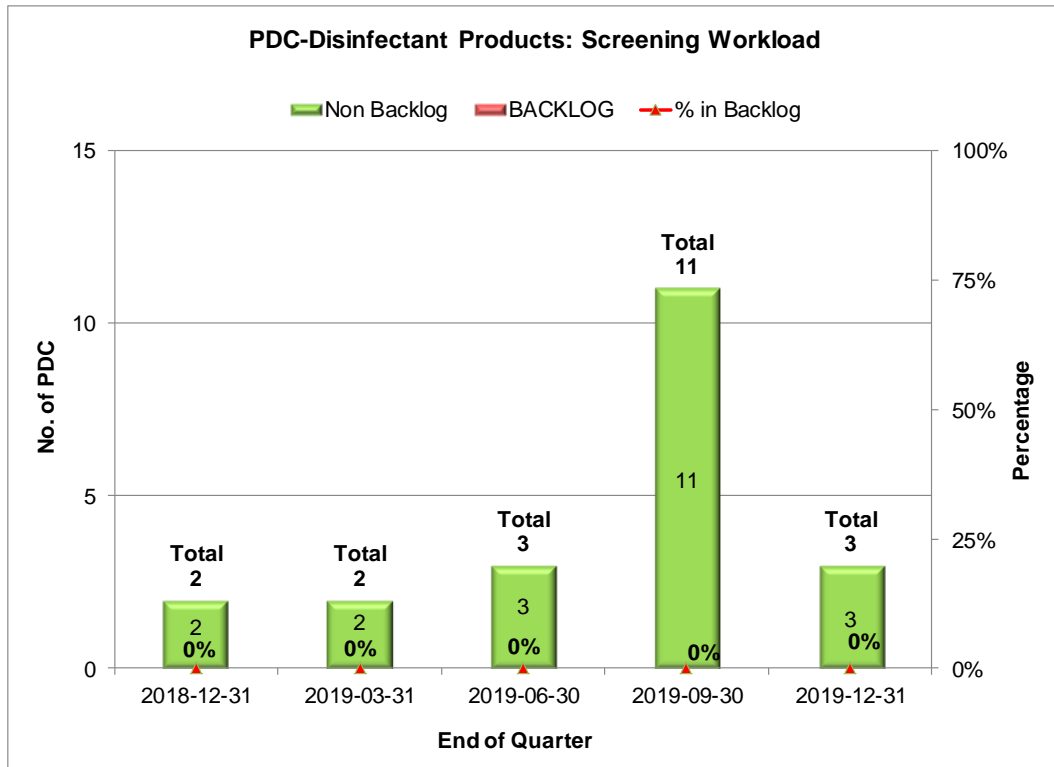
RECEIVED

PDC-Disinfectant Products: Received by Fee Class



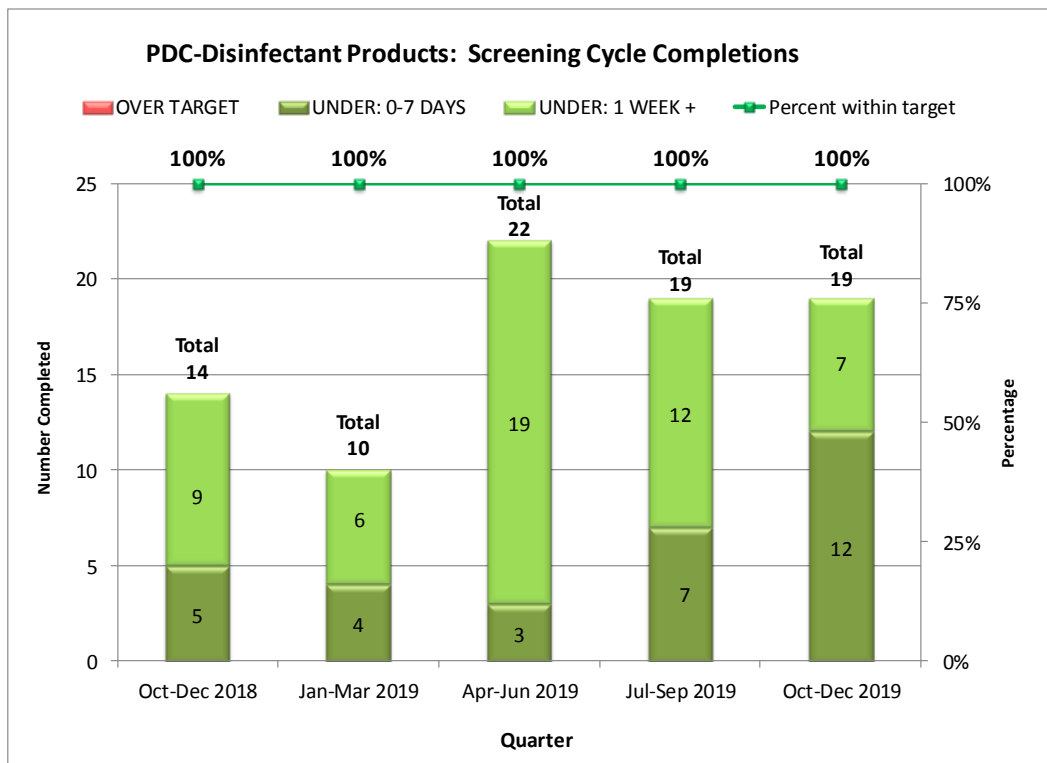
WORKLOAD

PDC-Disinfectant Products: Screening Workload



PERFORMANCE

PDC-Disinfectant Products: Screening Cycle Completions



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

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
REGULAR	CANCELLATION LETTER	0	0	1	1	0
	NO OBJECTION LETTER	13	7	18	18	16
	NOT SATISFACTORY NOTICE	0	3	3	0	2
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	1	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	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
ADMINISTRATIVE	0	0	0	0	0
DISINFECTANTS	1	0	0	0	0
Total	1	0	0	0	0

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

NDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Disinfectants	1	1	2	1	0
<i>Backlog</i>	0	0	0	0	0
Total	1	1	2	1	0
Non Backlog	1	1	2	1	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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
Disinfectants	0	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	1	0	0	0
Non Backlog	0	1	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Administrative-Screening Workload

NDS-D: ADMIN SCREENING WORKLOAD by End of Quarter					
FEE CATEGORY	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
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 2018	0	0	1	100%	1
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	0	1	100%	1
Oct-Dec 2019	0	1	0	100%	1

NDS-Disinfectant Products: Screening Performance

NDS-D SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Oct-Dec 2018	0	1	0	100%	1
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	1	0	100%	1
Jul-Sep 2019	0	0	0	-	0
Oct-Dec 2019	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 2018	0	1	0	100%	1
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	0	0	-	0
Oct-Dec 2019	0	0	0	-	0

DECISIONS

NDS-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	1	0	0	0	0
DISINFECTANTS	NOTICE OF NON-COMPLIANCE	1	0	0	0	1
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	1	0
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0

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

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

NOTIFIABLE CHANGE- DISINFECTANT PRODUCTS	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
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	2018-12-31	2019-03-31	2019-06-30	2019-09-30	2019-12-31
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
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	0	0	-	0
Oct-Dec 2019	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 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0
Apr-Jun 2019	0	0	0	-	0
Jul-Sep 2019	0	0	0	-	0
Oct-Dec 2019	0	0	0	-	0

DECISIONS

NC-Disinfectant Products: Number of Decisions by Class

User Fee Category	Decision Document Type	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
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	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	1
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	5
<i>Total</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>6</i>

MPNDS-Disinfectant Products: Received by Fee Category

PRE - NDS MEETING (MPNDS) DISINFECTANT PRODUCTS	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	0

MPSNDS-Disinfectant Products: Received by Fee Category

PRE - SNDS MEETING (MPSNDS) DISINFECTANT PRODUCTS	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019	Oct-Dec 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0