



Health
Canada

Santé
Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual
Report

Fiscal Year

2019-2020

April 1 2019 – March 31 2020



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

Également disponible en français sous le titre :
Direction des produits de santé naturels et sans ordonnance - Rapport annuel du rendement des présentations de drogue - Exercice financier 2019-2020

To obtain additional information, please contact:

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

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2020

Publication date: July 2020

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

Cat H166-3E-PDF
ISSN 2561-7680
Pub 200113

Table of Contents

TABLE OF CONTENTS	3
OVERVIEW	9
ACRONYMS	12
Submission Types.....	12
Documents.....	13
FEE CATEGORIES	14
PART 1: NON PRESCRIPTION DRUGS	15
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1	15
DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER	16
RECEIVED.....	16
DINA: Number Received by Fee Category.....	16
WORKLOAD	17
DINA: Review Workload.....	17
DINA: Review Workload by Fee Category.....	17
DINA: Screening Workload.....	18
DINA: Screening Workload by Fee Category.....	18
DINA: Administrative-Screening Workload.....	19
DINA: Administrative-Screening Workload by Fee Category.....	19
DECISIONS.....	20
DINA: Number of Decisions by Fee Category.....	20
PERFORMANCE	22
DINA: Review Cycle Completions.....	22
DINA: Screening Cycle Completions.....	22
DINA: Administrative-Screening Cycle Completions.....	23
DINF: APPLICATION FOR A DIN FOR A CATEGORY IV MONOGRAPH PRODUCT	24
RECEIVED.....	24
DINF: Number Received by Fee Category.....	24

WORKLOAD	25
DINF: Screening Workload	25
DINF: Screening Workload by Fee Category	25
DECISIONS	26
DINF: Number of Decisions by Fee Category	26
PERFORMANCE.....	27
DINF: Screening Cycle Completions	27
PDC: POST AUTHORIZATION DIVISION 1 CHANGE	28
RECEIVED.....	28
PDC: Number Received by Class	28
WORKLOAD	29
PDC: Screening Workload.....	29
PDC: Screening Workload by Class	29
DECISIONS	30
PDC: Number of Decisions by Class	30
PERFORMANCE.....	30
PDC: Screening Cycle Completions	30
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8	31
NDS: NEW DRUG SUBMISSION	32
RECEIVED.....	32
NDS: Number Received by Fee Category	32
WORKLOAD	33
NDS: Review Workload	33
NDS: Review Workload by Fee Category	33
NDS: Screening Workload	34
NDS: Screening Workload by Fee Category	34
DECISIONS	35
NDS: Number of Decisions by Fee Category	35
PERFORMANCE.....	36
NDS: Review Cycle Completions	36
NDS: Screening Cycle Completions.....	36
SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION	37

RECEIVED	37
SNDS: Number Received by Fee Category.....	37
WORKLOAD	38
SNDS: Review Workload.....	38
SNDS: Review Workload by Fee Category	38
SNDS: Screening Workload.....	39
SNDS: Screening Workload by Fee Category.....	39
DECISIONS	40
SNDS: Number of Decisions by Fee Category	40
PERFORMANCE	41
SNDS: Review Cycle Completions	41
SNDS: Screening Cycle Completions	41
ANDS: ABBREVIATED NEW DRUG SUBMISSION	42
RECEIVED	42
ANDS: Number Received by Fee Category	42
WORKLOAD	43
ANDS: Review Workload.....	43
ANDS: Screening Workload	43
ANDS: Administrative-Screening Workload	43
PERFORMANCE	44
ANDS: Review Performance.....	44
ANDS: Screening Performance.....	44
ANDS: Administrative Screening Performance	44
DECISIONS	45
ANDS: Number of Decisions by Fee Category.....	45
SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRUG SUBMISSION	46
RECEIVED	46
SANDS: Number Received by Fee Category.....	46
WORKLOAD	47
SANDS: Review Workload.....	47
SANDS: Screening Workload	47
SANDS: Administrative-Screening Workload	47
PERFORMANCE	48
SANDS: Review Performance	48

SANDS: Screening Performance	48
SANDS: Administrative Screening Performance	48
DECISIONS	49
SANDS: Number of Decisions by Fee Category	49
NC: NOTIFIABLE CHANGE	50
RECEIVED	50
NC: Number Received by Class	50
WORKLOAD	51
NC: Review Workload.....	51
NC: Review Workload by Class	51
NC: Screening Workload.....	52
NC: Screening Workload by Class	52
DECISIONS	53
NC: Number of Decisions by Class	53
PERFORMANCE.....	54
NC: Review Cycle Completions	54
NC: Screening Cycle Completions	54
PRE-MEETINGS	55
MPDIN: Number Received by Fee Category	55
MPNDS: Number Received by Fee Category	55
MPSNDS: Number Received by Fee Category	55
PART 2: DISINFECTANT PRODUCTS	56
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1	56
DIND: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - DISINFECTANT PRODUCTS	57
RECEIVED	57
DIND-Disinfectant Products: Number Received by Fee Category	57
WORKLOAD	58
DIND-Disinfectant Products: Review Workload	58
DIND-Disinfectant Products: Screening Workload.....	58
DIND-Disinfectant Products: Administrative-Screening Workload.....	59
PERFORMANCE.....	60
DIND-Disinfectant Products: Review Cycle Completions.....	60

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

NC-Disinfectant Products: Review Workload	69
NC-Disinfectant Products: Screening Workload	69
PERFORMANCE.....	70
NC-Disinfectant Products: Review Performance	70
NC-Disinfectant Products: Screening Performance	70
DECISIONS	70
NC-Disinfectant Products: Number of Decisions by Class	70
PRE-MEETINGS - DISINFECTANT PRODUCTS	71
MPNDS-Disinfectant Products: Received by Fee Category	71
MPSNDS-Disinfectant Products: Received by Fee Category.....	71

OVERVIEW

The NNHPD Annual Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive fiscal years (April 1 to March 31) from 2015-2016 to 2019-2020. 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.

Some of the highlights of the 2019-2020 report are:

The performance standard of 90% review on time has been achieved for all the cost-recovered and non-cost-recovered non-prescription drug (Over the Counter and Disinfectant) submissions evaluated by the Natural and Non-prescription Health Products Directorate (NNHPD).

Non-Prescription (Over the Counter - OTC) Drugs:

- The number of DINA submissions received increased significantly (104%) from the previous year: 245 in 2019-2020 compared to 120 in 2018-2019. Administrative DINA submissions account for the majority of this increase: 135 received in 2019-2020 and only 8 received in 2018-2019.
- An increase of 24% was observed in the number of DINF submissions received (209 for 2019-2020) from the previous year following a steady decrease seen in the 4 preceding years: 226 in 2015-2016, 212 in 2016-2017, 185 in 2017-2018, to 169 in 2018-2019.
- The number of PDC submission received increased 51% from the previous year: 380 in 2019-2020 compared to 252 in 2018-2019. Submissions filed to be in compliance with the plain language labelling (PLL) requirements contributed to this increase.
- The number of NDS submissions received increased 5-fold from the previous year: 15 in 2019-2020 compared to 3 in 2018-2019. Administrative NDS submissions account for the majority of this increase: 10 received in 2019-2020 while none were received in 2018-2019. The number of SNDS submissions received also increased but to a lesser degree (13%): 45 in 2019-2020 compared to 40 in 2018-2019.
- NNHPD took over the responsibility for ANDS and SANDS submissions from the Therapeutic Products Directorate beginning September 2019. For the 2019-2020 fiscal year, 7 ANDS submissions were received and 24 SANDS submissions were received. The majority of the SANDS submissions were filed in the Labelling Only category (16) – to be compliant with the PLL requirements.
- The number of NC submissions received is consistent with the previous year: 32 in both 2019-2010 and 2018-2019.

Overall, the total non-prescription drug submissions received increased by 50% during 2019-2020 (926) compared to 2018-2019 (616). This increase follows a slight decreasing trend observed in the total number of non-prescription drug submissions received in the previous 4 fiscal years (742 in 2015-2016; 699 in 2016-2017; 658 in 2017-2018; and 616 in 2018-2019). In addition to the increased volume of submissions received, the Plain Language Labelling (PLL) requirements came into force for non-prescription drugs on June 13, 2017, significantly changing the label review process for these drugs and further increasing the time/effort required to review individual submissions over the past 3 fiscal years.

Disinfectant Drugs:

- The number of DIND submissions received decreased slightly (7%) from the previous year; 154 in 2019-2020 compared to 165 in 2018-2019. However, the number of DIND submissions received remain high as compared to earlier fiscal years: 140 in 2015-2016 and 128 in 2016-2017.
- A significant (72%) increase was observed for disinfectant PDC submissions, from 46 in 2018-2019 to 79 in 2019-2020. This increase brings the number closer to the 95 received in 2016-2017, than to the numbers received in 2015-2016 (38) and 2018-2019 (46).
- The number of disinfectant NDS submissions remained low; 1 in 2019-2020 compared to 2 received in 2018-2019.

Overall, the total disinfectant drug submissions received increased by 10% during 2019-2020 (234) compared to 2018-2019 (213). The total volume of disinfectant drug submission received has not fluctuated greatly in the last 5 years (+/- 15%) with the exception of 2017-2018 where a total of 297 submissions were received. This year's total is more consistent with those received in the 2015-2016 (179), 2016-2017 (228), and 2018-2019 (213) fiscal years.

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.

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

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.

Approvals are Notice of Compliances (NOC) Issued or Issuable. 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**² 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 is compared to a set [performance standard](#)³ which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude “refiled”⁴ submissions.

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

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

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

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

² 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.

³ 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).

⁴ For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#)

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
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 biological 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 Only⁵	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission⁶	Submissions in support of a manufacturer or product name change.
Disinfectants⁷	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](#)

⁵ For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

⁶ For additional information, please consult the ["Changes in Manufacturer and/or Product Name Policy" \(2015\)](#)

⁷ 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.

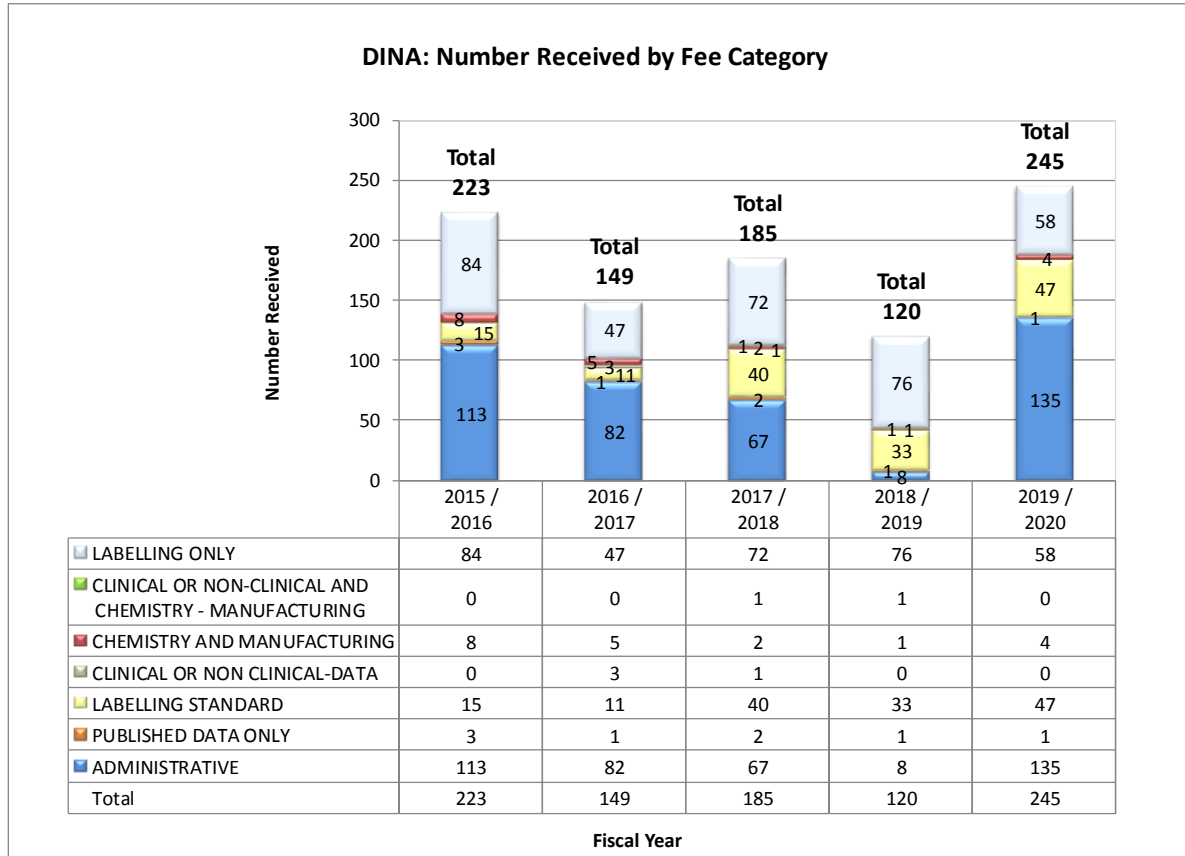
PART 1: NON PRESCRIPTION DRUGS ***Over the Counter (OTC) Drugs***

NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

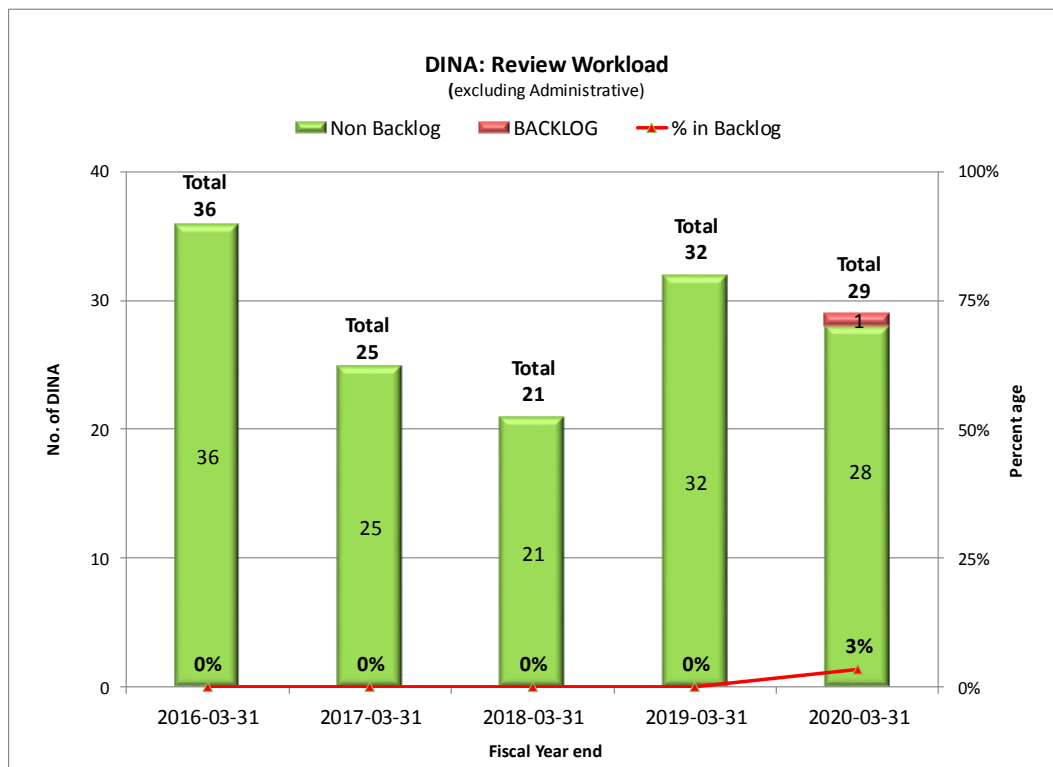
**DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER
RECEIVED**

DINA: Number Received by Fee Category



WORKLOAD

DINA: Review Workload

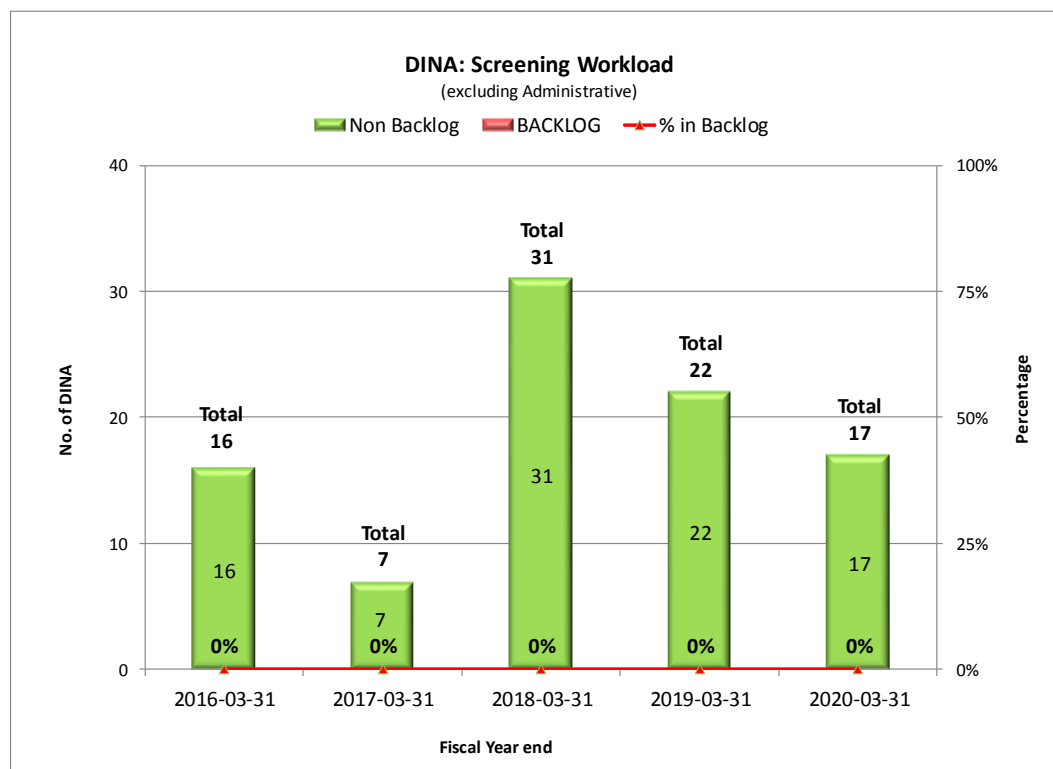


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Only	30	18	19	32	27
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	4	5	1	0	2
<i>Backlog</i>	0	0	0	0	1
Clinical or Non-Clinical Data	1	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Published Data Only	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical /C&M	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Total	36	25	21	32	29
Non Backlog	36	25	21	32	28
BACKLOG	0	0	0	0	1
% in Backlog	0%	0%	0%	0%	3%

WORKLOAD

DINA: Screening Workload

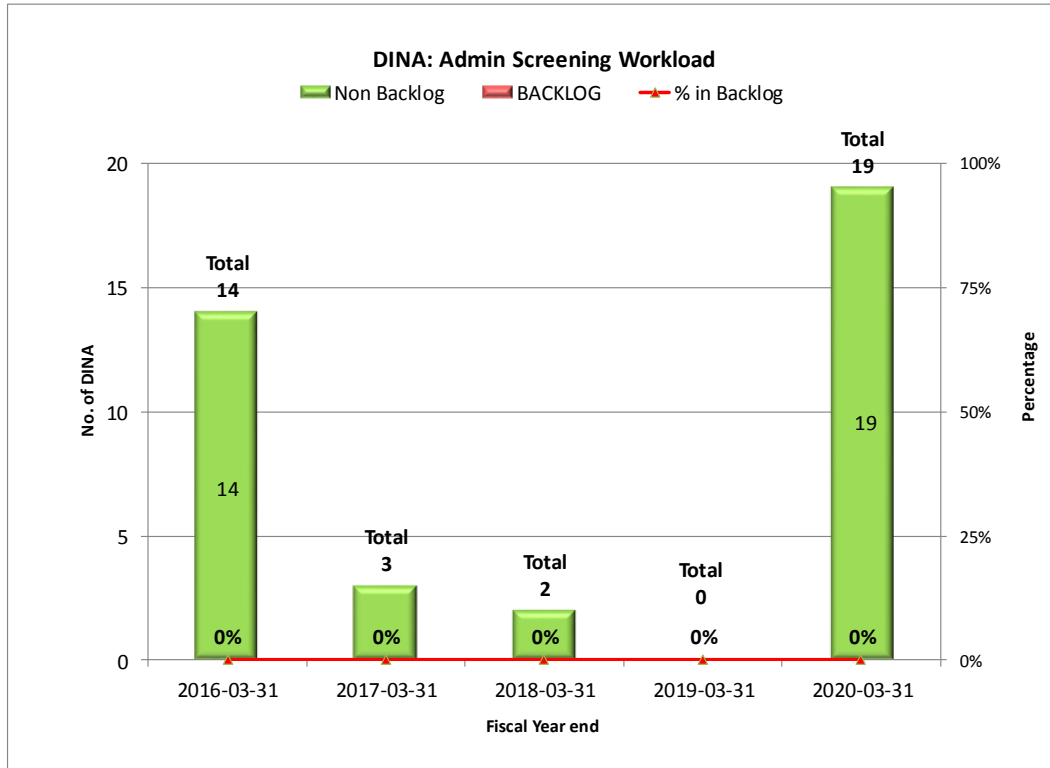


DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Only	14	4	21	15	3
<i>Backlog</i>	0	0	0	0	0
Labelling Standard	2	0	10	6	12
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	2	0	1	0
<i>Backlog</i>	0	0	0	0	0
Published Data Only	0	1	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	16	7	31	22	17
Non Backlog	16	7	31	22	17
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 Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Administrative	14	3	2	0	19
<i>Backlog</i>	0	0	0	0	0
Total	14	3	2	0	19
Non Backlog	14	3	2	0	19
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

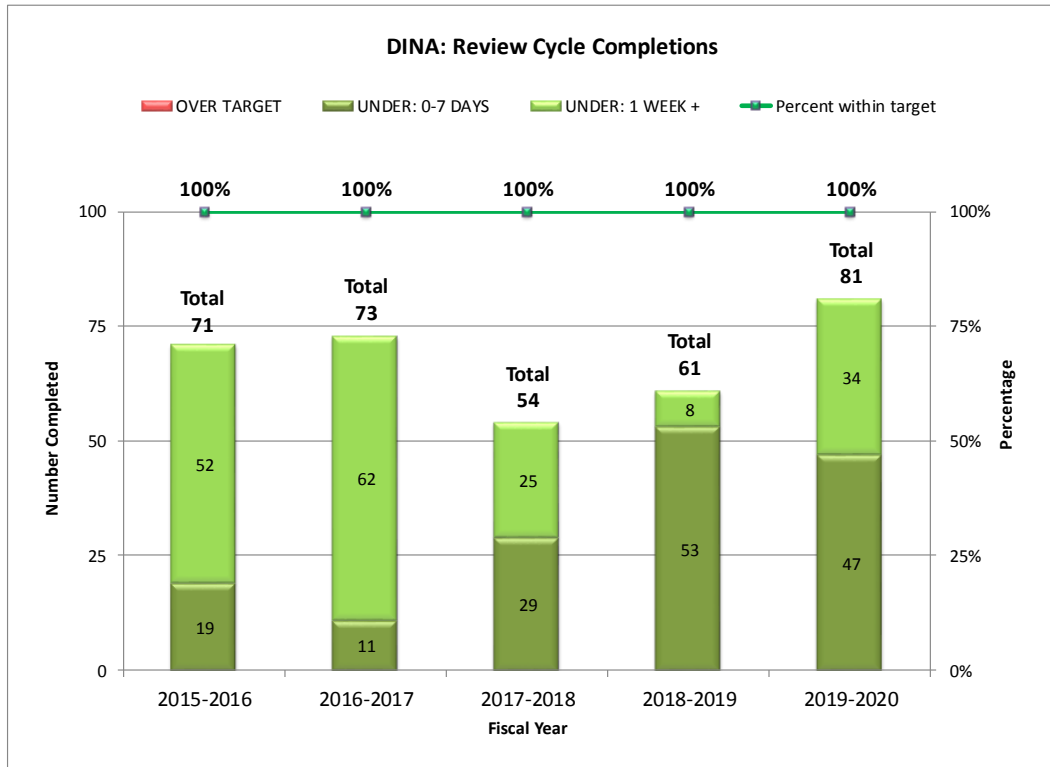
DINA: Number of Decisions by Fee Category

DIN APPLICATION (DIN-A): Decisions by Fee Category						
User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	85	80	32	0	106
	NO OBJECTION LETTER	0	2	0	0	0
	REJECTION LETTER (SCR)	12	9	2	0	1
	SCREENING DEFICIENCY NOTICE	1	5	4	2	19
	CANCELLATION LETTER	5	3	36	10	7
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	2	1	3	0	0
	NO OBJECTION LETTER	0	0	0	3	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	4	4	0	0
	CANCELLATION LETTER	1	2	4	0	1
	SCREENING DEFICIENCY NOTICE	6	3	0	1	2
CLINICAL OR NON-CLINICAL DATA	WITHDRAWAL NO RESP TO NON	0	1	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	2	0	1
	NO OBJECTION LETTER	1	0	1	0	0
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	2	1	0
	SCREENING DEFICIENCY NOTICE	0	1	1	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	CANCELLATION LETTER	0	0	0	1	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	1	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
	NOTIFICATION FORM DIN SUB	0	0	0	1	0
LABELLING ONLY	NOTIFICATION FORM DIN SUB	48	39	36	45	66
	NO OBJECTION LETTER	6	22	2	3	10
	NOTICE OF NON-COMPLIANCE	9	2	0	6	3
	CANCELLATION LETTER	9	7	15	4	9
	DIN INCORR SUBTYPE-CLASS	3	0	0	0	0
	REJECTION LETTER (SCR)	4	5	1	7	0

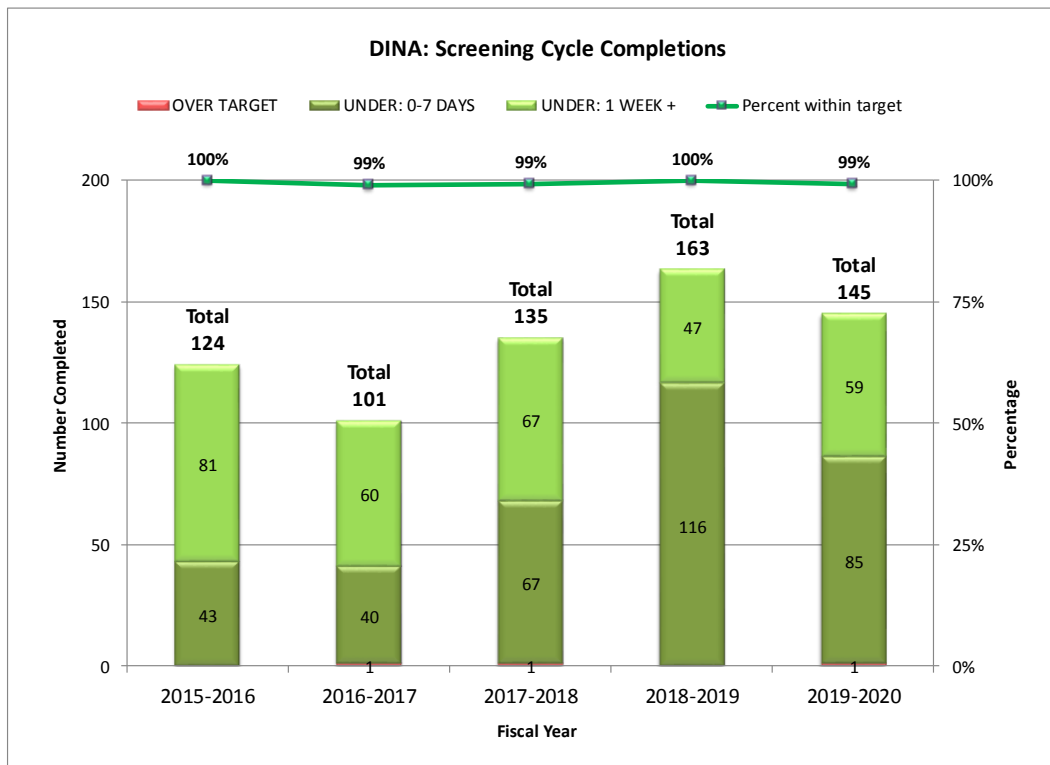
DIN APPLICATION (DIN-A): Decisions by Fee Category						
User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
	SCREENING DEFICIENCY NOTICE	20	15	30	24	8
	NOTICE OF DEFICIENCY	1	0	1	2	0
	WITHDRAWAL NO RESP TO NOD	1	0	0	1	0
	WITHDRAWAL NO RESP TO NON	0	0	0	1	1
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	12	13	29	30	34
	NO OBJECTION LETTER	0	1	0	0	1
	CANCELLATION LETTER	1	1	0	5	5
	REJECTION LETTER (SCR)	2	0	0	1	1
	SCREENING DEFICIENCY NOTICE	3	1	14	25	9
PUBLISHED DATA	NOTIFICATION FORM DIN SUB	2	2	1	1	0
	SCREENING DEFICIENCY NOTICE	1	0	2	0	0
	NOTICE OF NON-COMPLIANCE	1	0	0	0	0
	NON WITHDRAWAL LETTER	0	1	0	0	0
	CANCELLATION LETTER	1	0	0	1	0

PERFORMANCE

DINA: Review Cycle Completions

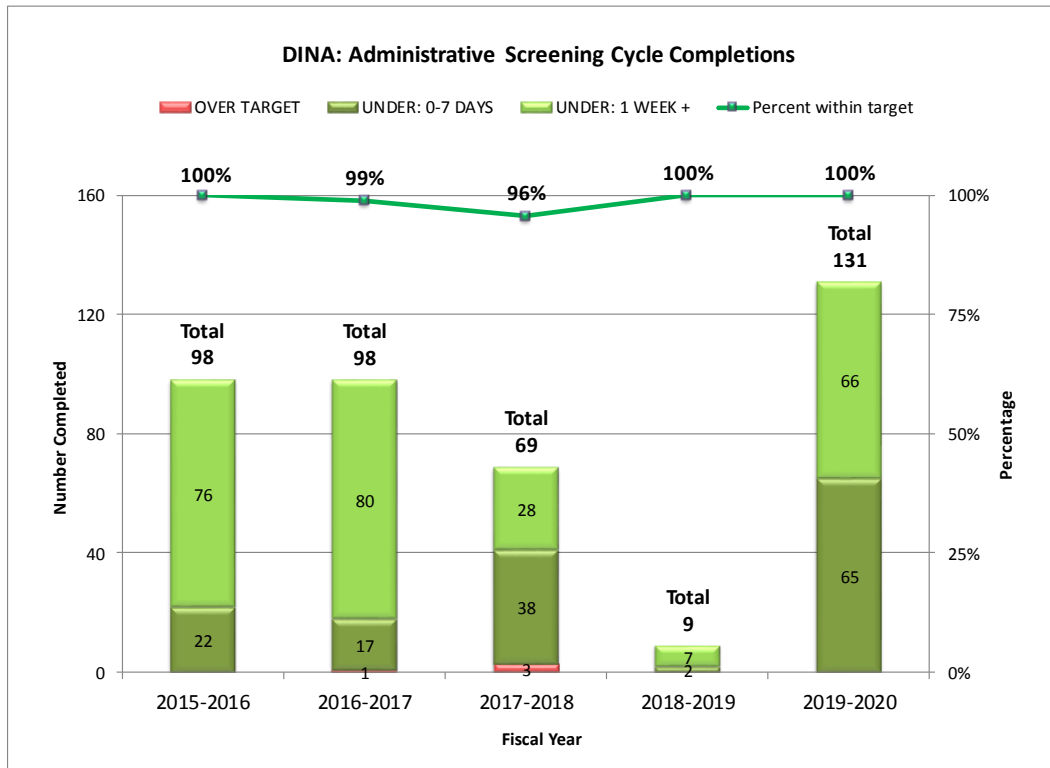


DINA: Screening Cycle Completions



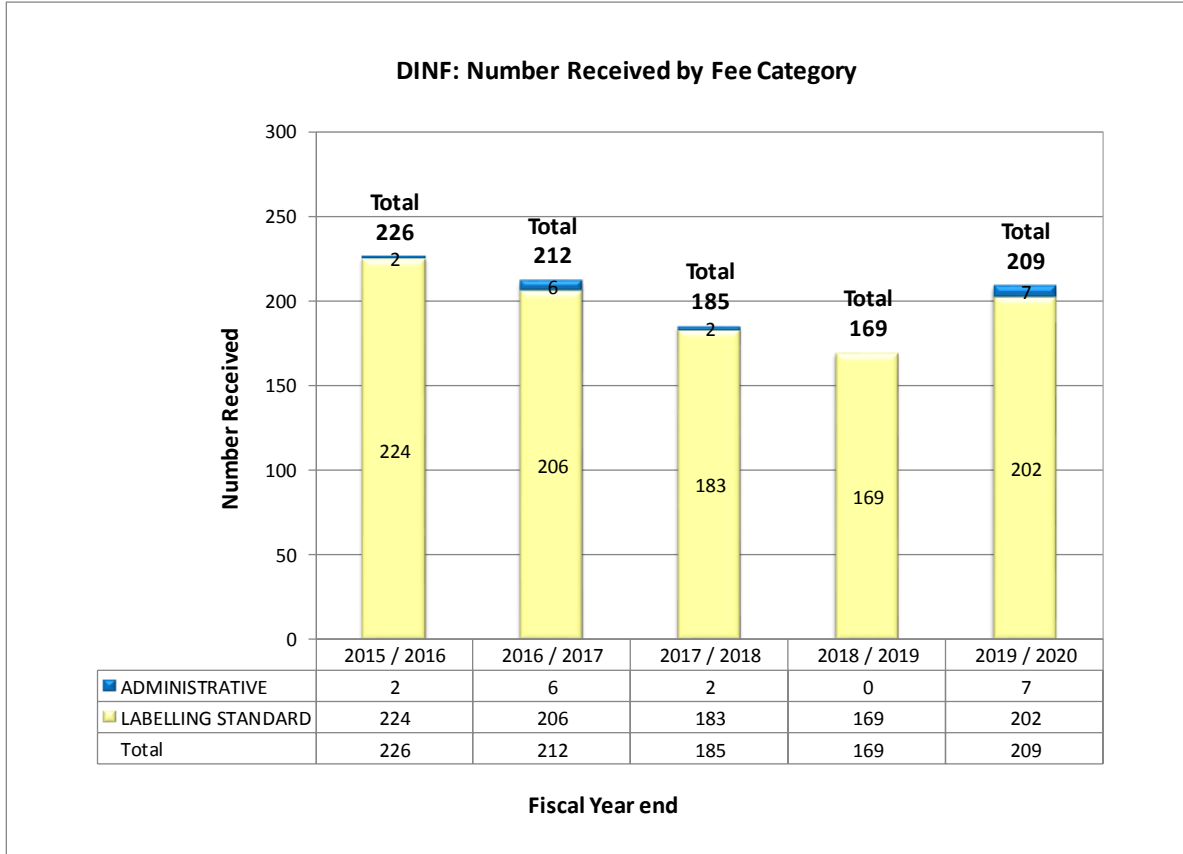
PERFORMANCE

DINA: Administrative-Screening Cycle Completions



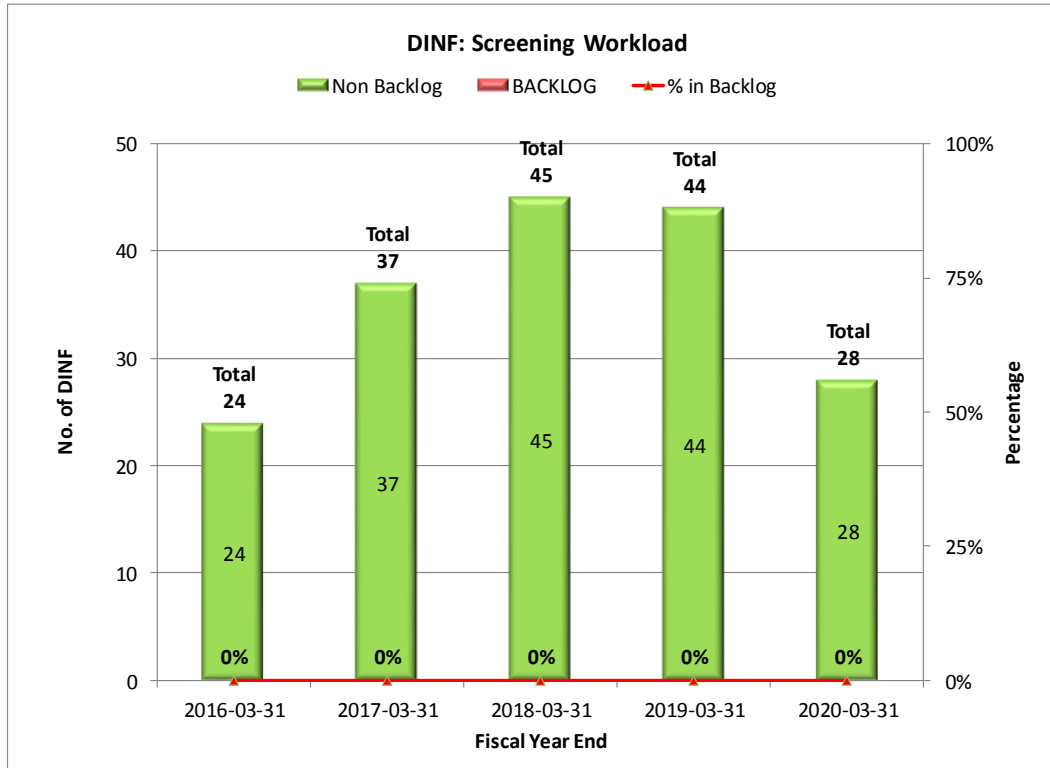
**DINF: APPLICATION FOR A DIN FOR A CATEGORY IV MONOGRAPH PRODUCT
RECEIVED**

DINF: Number Received by Fee Category



WORKLOAD

DINF: Screening Workload



DINF: Screening Workload by Fee Category

DINF: SCREENING WORKLOAD BY FEE CATEGORY and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Standard	24	35	45	44	28
<i>Backlog</i>	0	0	0	0	0
Administrative	0	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	24	37	45	44	28
Non Backlog	24	37	45	44	28
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

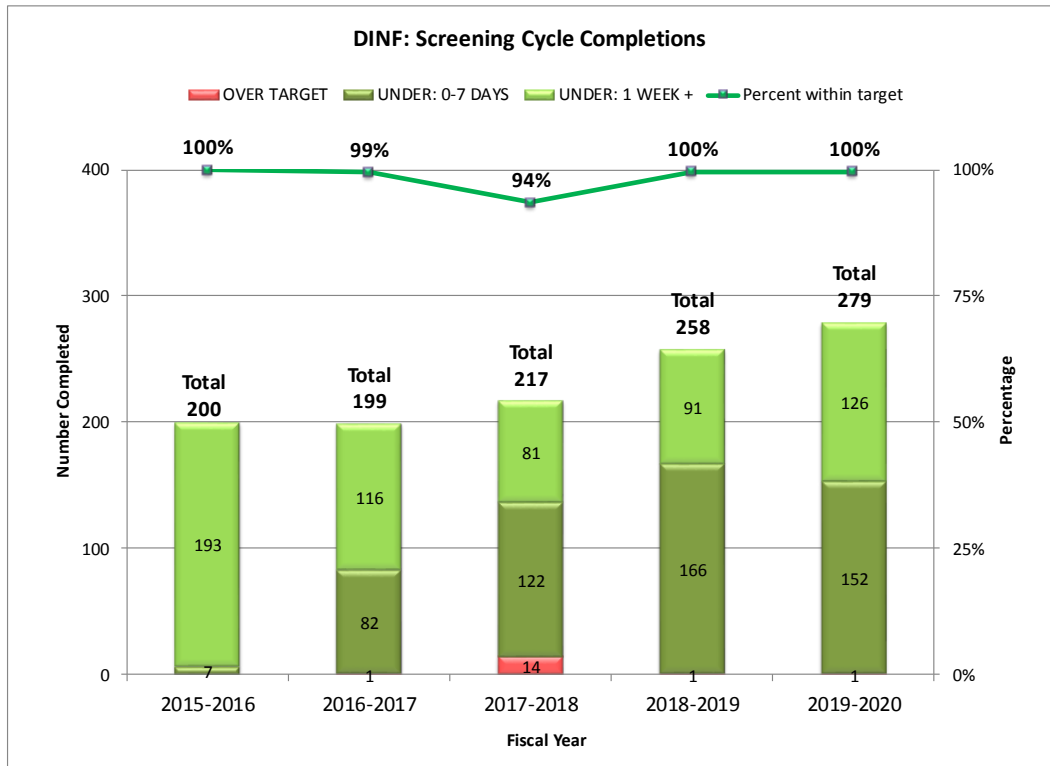
DECISIONS

DINF: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	199	152	134	143	193
	NO OBJECTION LETTER	0	1	1	2	18
	NEW DRUG LETTER SCREEN	1	0	1	0	1
	CANCELLATION LETTER	2	15	6	13	10
	REJECTION LETTER (SCR)	0	8	4	13	6
	SCREENING DEFICIENCY NOTICE	1	30	75	105	59
ADMINISTRATIVE	CANCELLATION LETTER	1	0	2	0	1
	NOTIFICATION FORM DIN SUB	0	2	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	REJECTION LETTER (SCR)	1	1	0	0	0

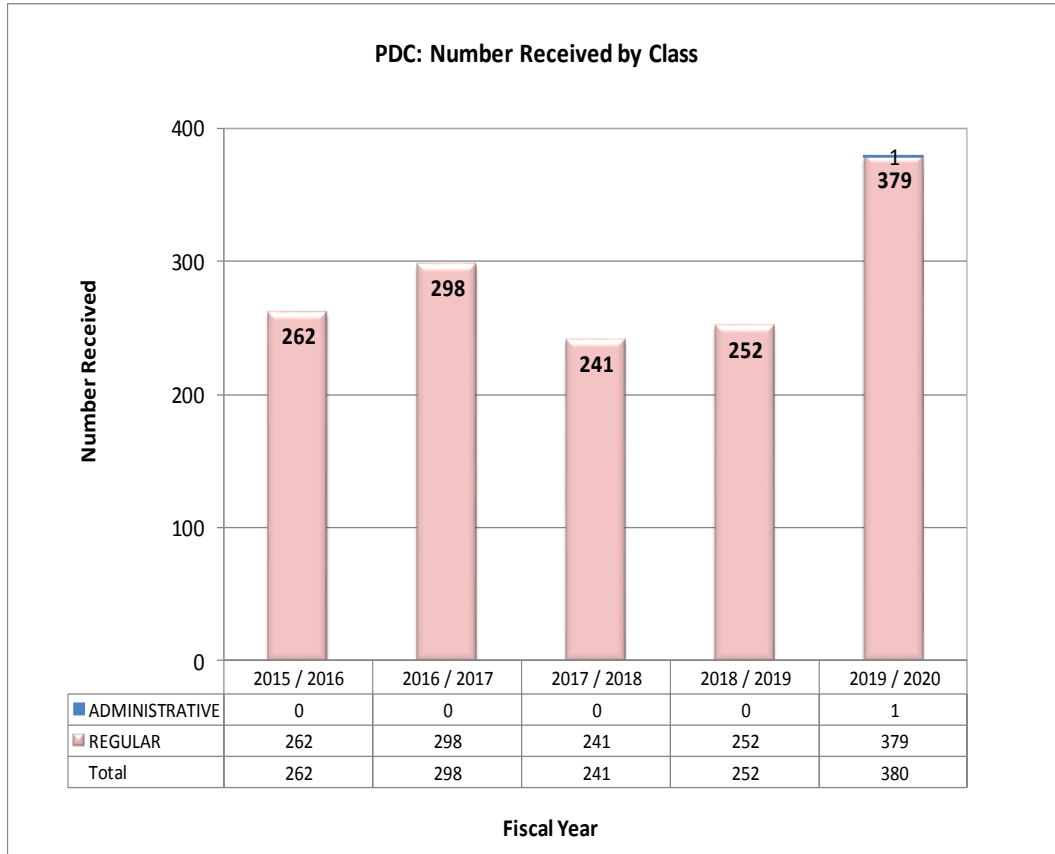
PERFORMANCE

DINF: Screening Cycle Completions



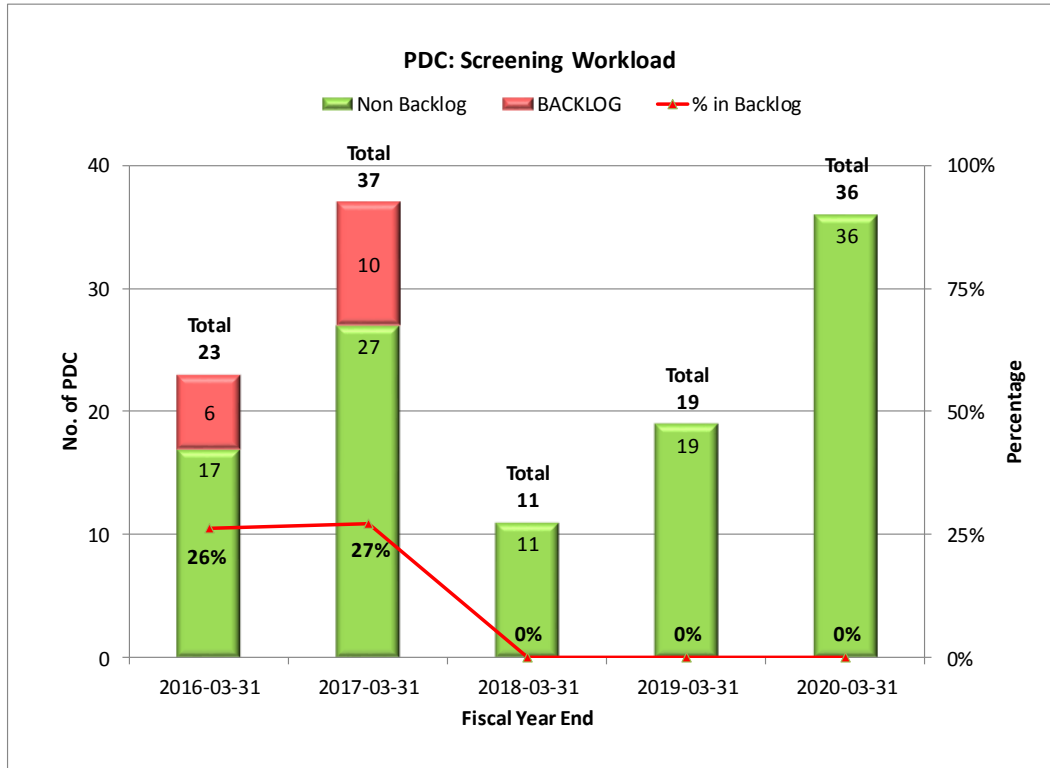
**PDC: POST AUTHORIZATION DIVISION 1 CHANGE
RECEIVED**

PDC: Number Received by Class



WORKLOAD

PDC: Screening Workload



PDC: Screening Workload by Class

PDC: SCREENING WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Regular	23	37	11	19	36
<i>Backlog</i>	<i>6</i>	<i>10</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	23	37	11	19	36
Non Backlog	17	27	11	19	36
BACKLOG	6	10	0	0	0
% in Backlog	26%	27%	0%	0%	0%

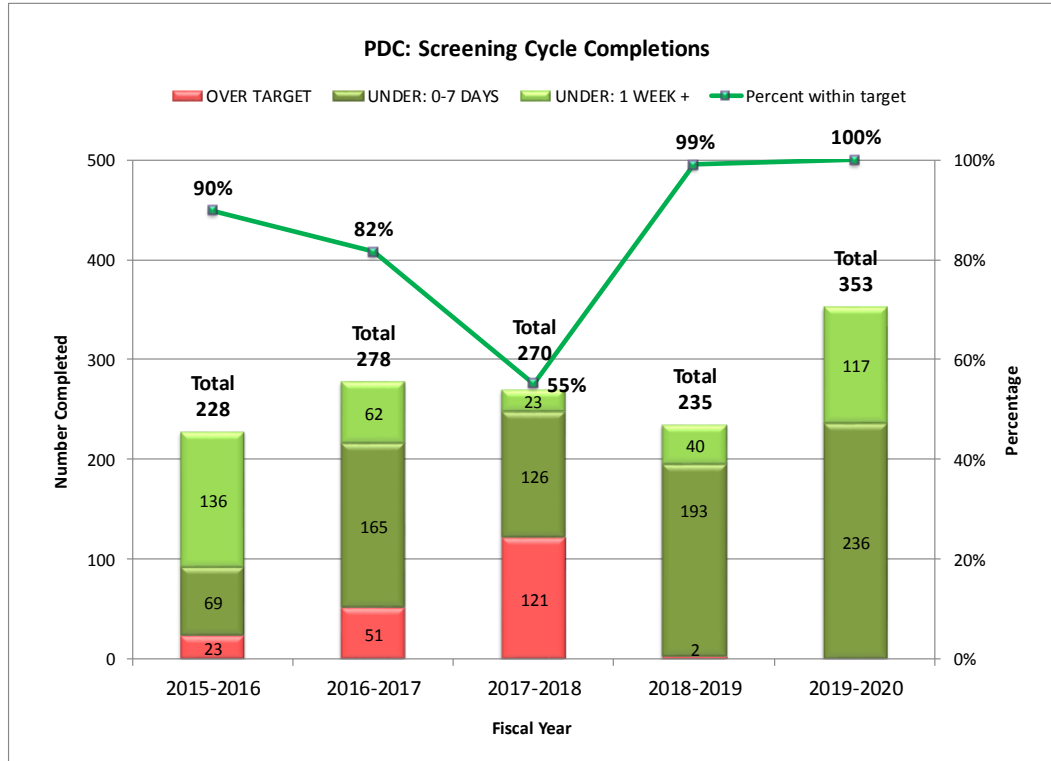
DECISIONS

PDC: Number of Decisions by Class

Class	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
REGULAR	NO OBJECTION LETTER	212	268	256	175	294
	NOT SATISFACTORY NOTICE	12	9	9	35	37
	NOTIFICATION FORM DIN SUB	1	0	0	0	0
	CANCELLATION LETTER	14	3	5	26	25
	REJECTION LETTER (SCR)	0	0	0	1	1
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
ADMINISTRATIVE	NO OBJECTION LETTER	0	0	0	0	1

PERFORMANCE

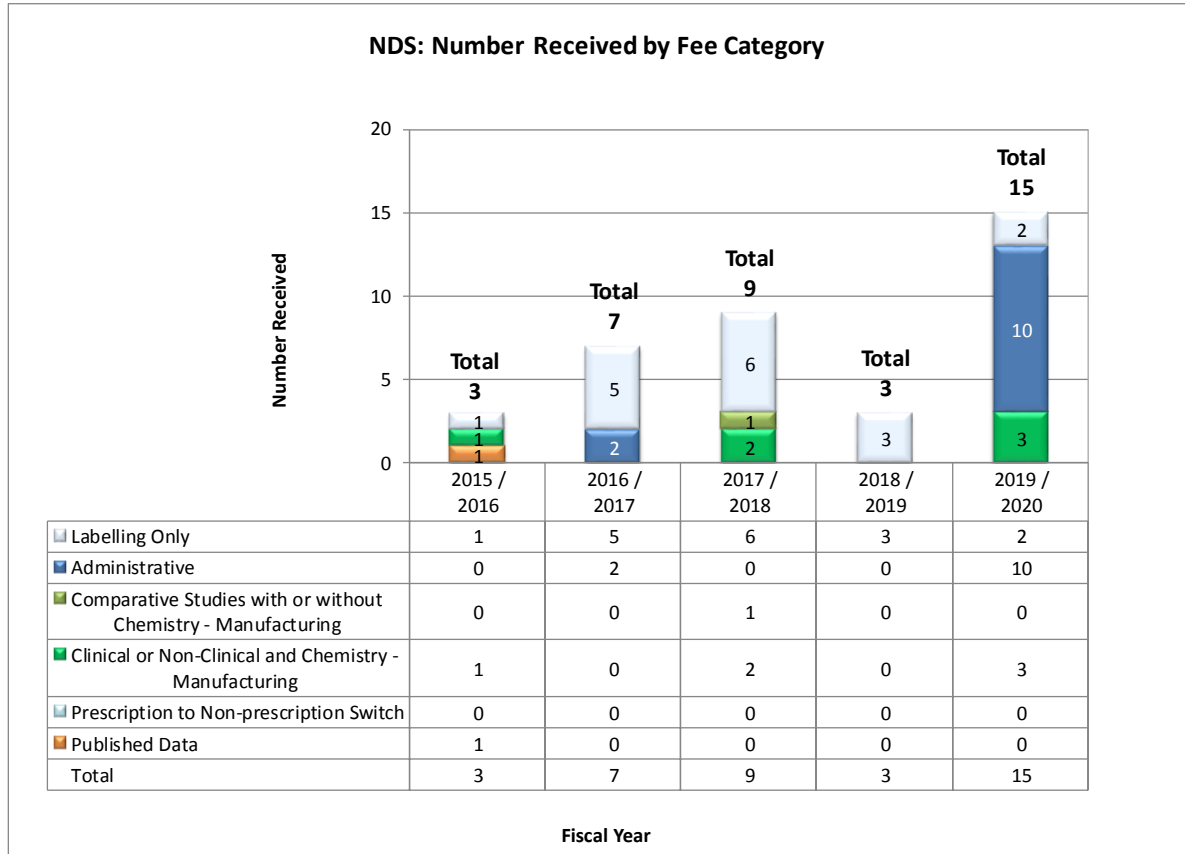
PDC: Screening Cycle Completions



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

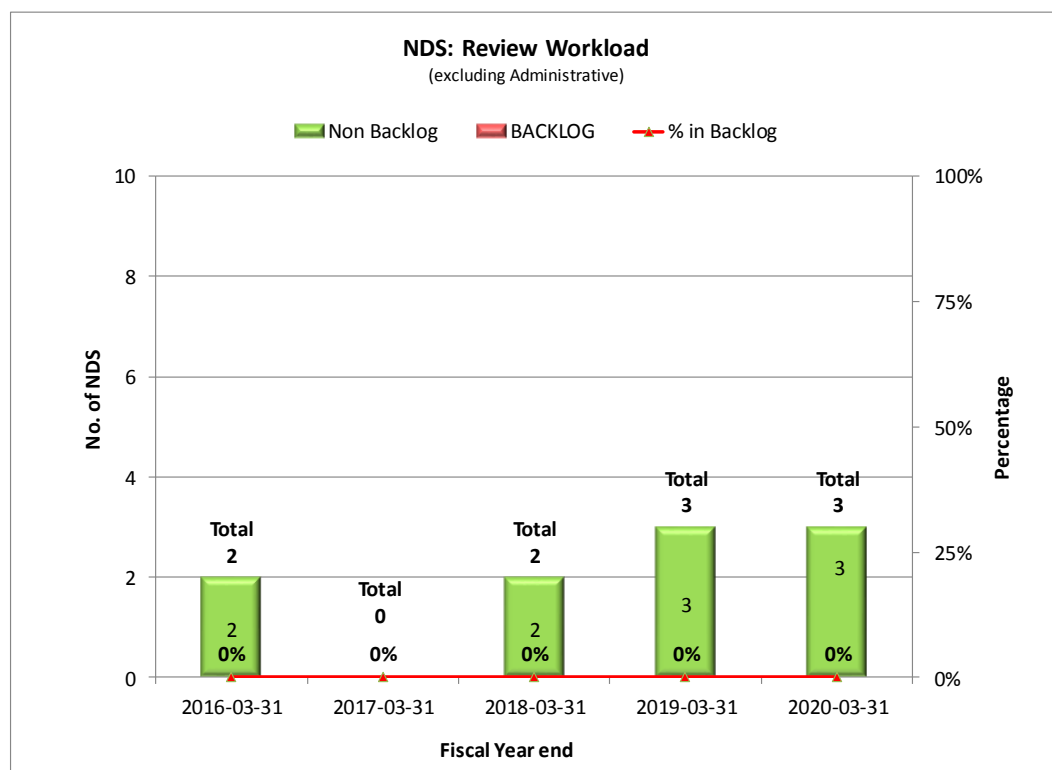
**NDS: NEW DRUG SUBMISSION
RECEIVED**

NDS: Number Received by Fee Category



WORKLOAD

NDS: Review Workload

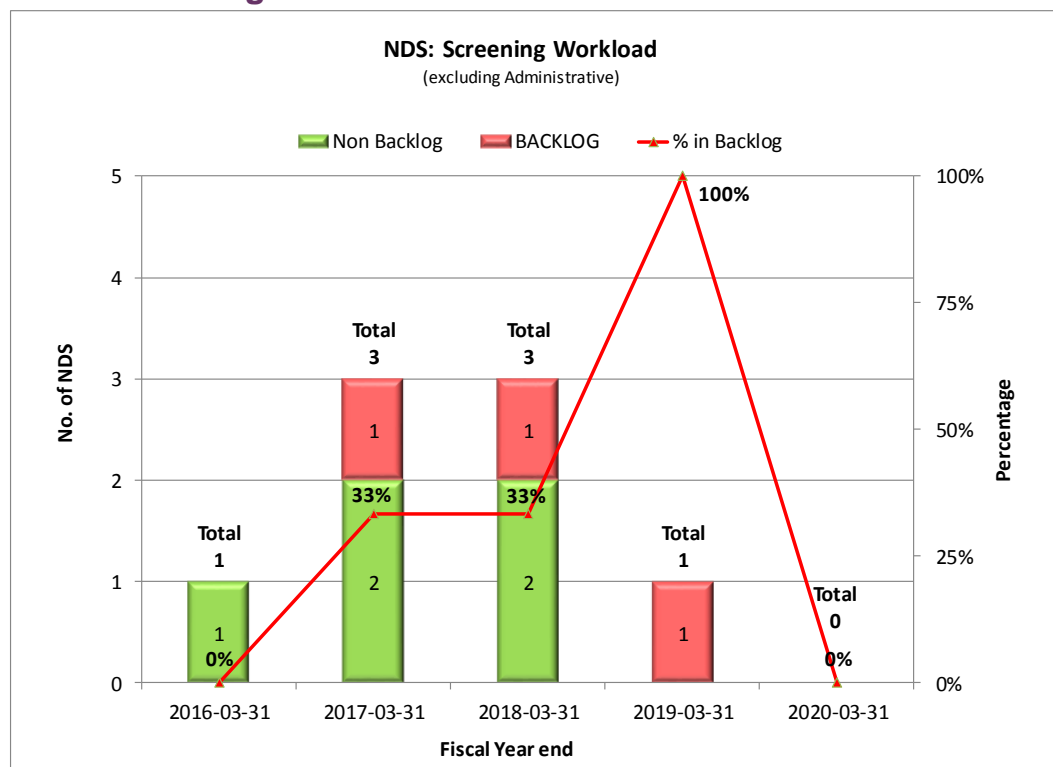


NDS: Review Workload by Fee Category

NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	0	1	1	3
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without C&M	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	1	0	1	2	0
<i>Backlog</i>	0	0	0	0	0
Total	2	0	2	3	3
Non Backlog	2	0	2	3	3
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 Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Published Data Only	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	3	1	1	0
<i>Backlog</i>	0	1	1	1	0
Clinical or Non-Clinical /C&M	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without C&M	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Total	1	3	3	1	0
Non Backlog	1	2	2	0	0
BACKLOG	0	1	1	1	0
% in Backlog	0%	33%	33%	100%	0%

DECISIONS

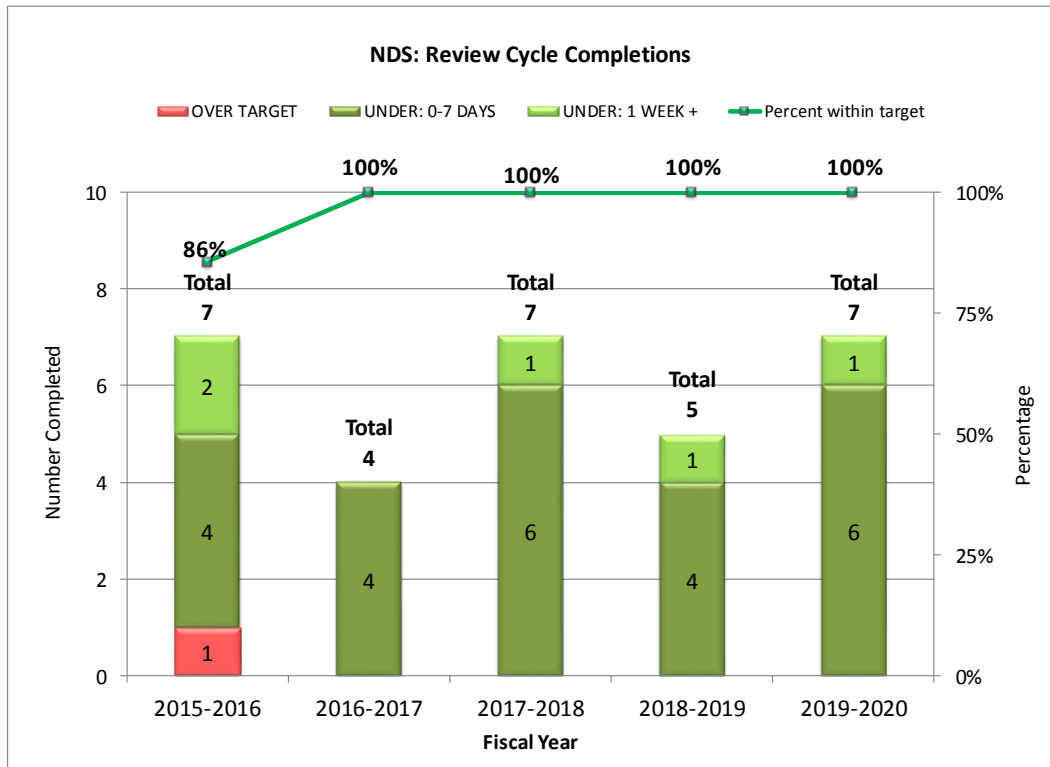
NDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	2	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	3
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	0	1	1	0
	NOC ON HOLD (SWITCH)*	2	0	0	0	0
	NOD WITHDRAWAL LETTER	1	0	0	0	0
	NOTICE OF COMPLIANCE*	1	1	0	1	1
	NOTICE OF DEFICIENCY	1	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
	NOTICE OF COMPLIANCE*	0	0	0	0	1
LABELLING ONLY	NOTICE OF COMPLIANCE*	2	3	6	2	4
	CANCELLATION LETTER	0	0	1	0	1
	SCREENING DEFICIENCY NOTICE	0	2	3	1	1
	NOTICE OF NON-COMPLIANCE	0	0	0	1	1
PRESCRIPTION TO NON- PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	1	0	0	0	0

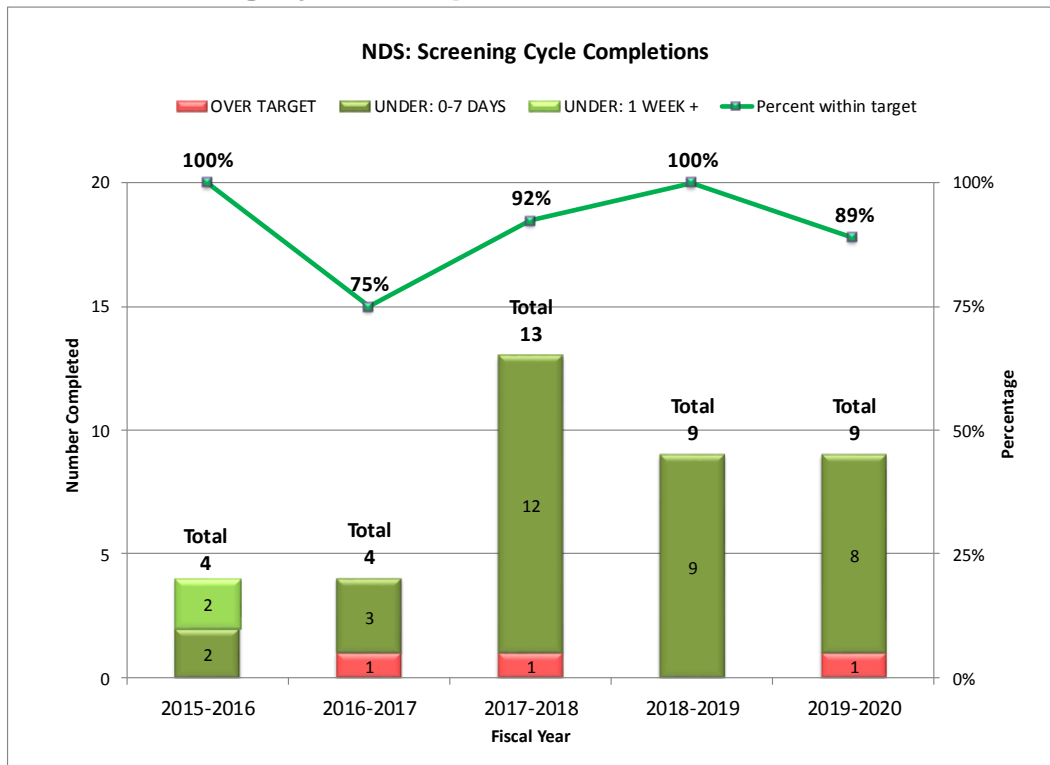
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions

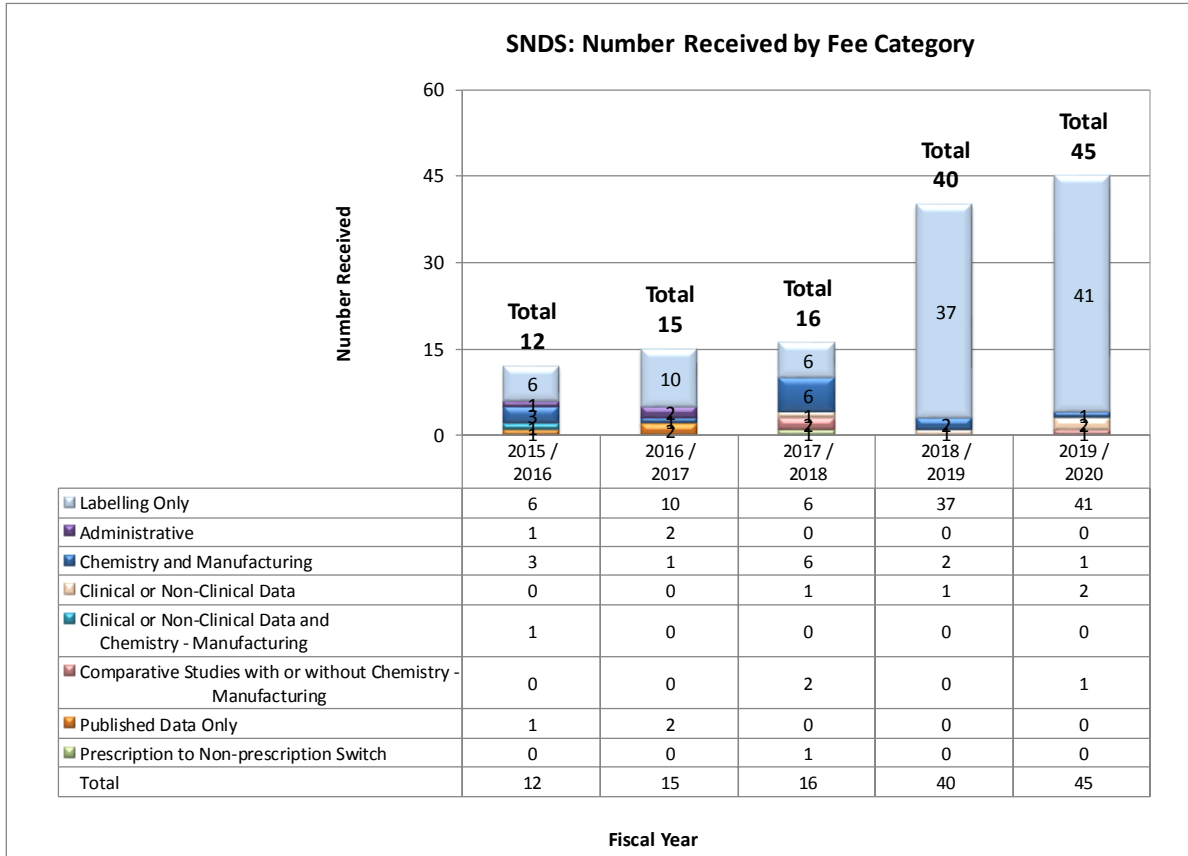


NDS: Screening Cycle Completions



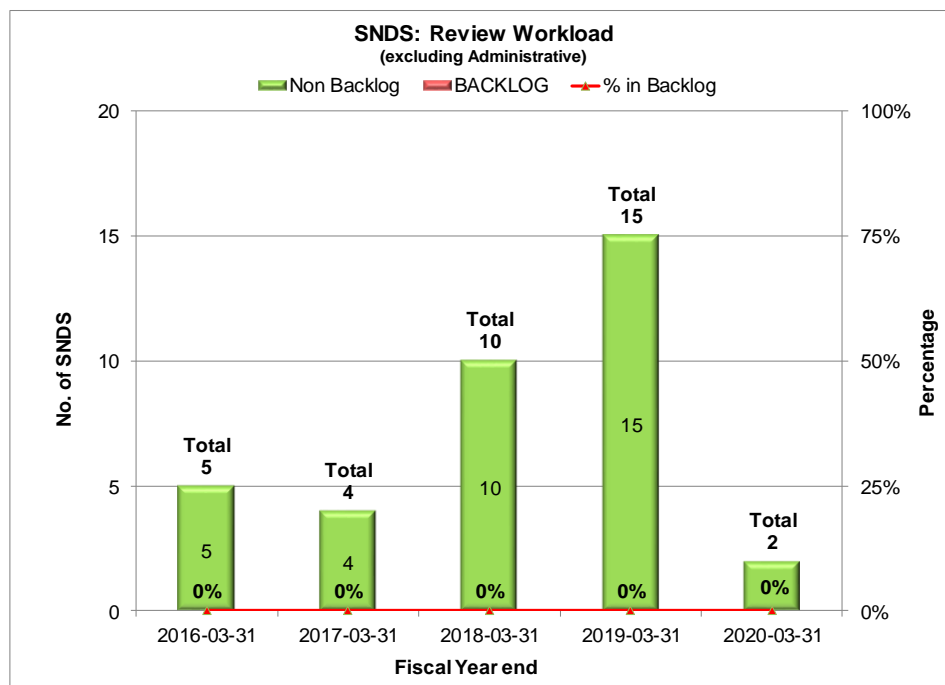
**SNDS: SUPPLEMENT TO A NEW DRUG SUBMISSION
RECEIVED**

SNDS: Number Received by Fee Category



WORKLOAD

SNDS: Review Workload

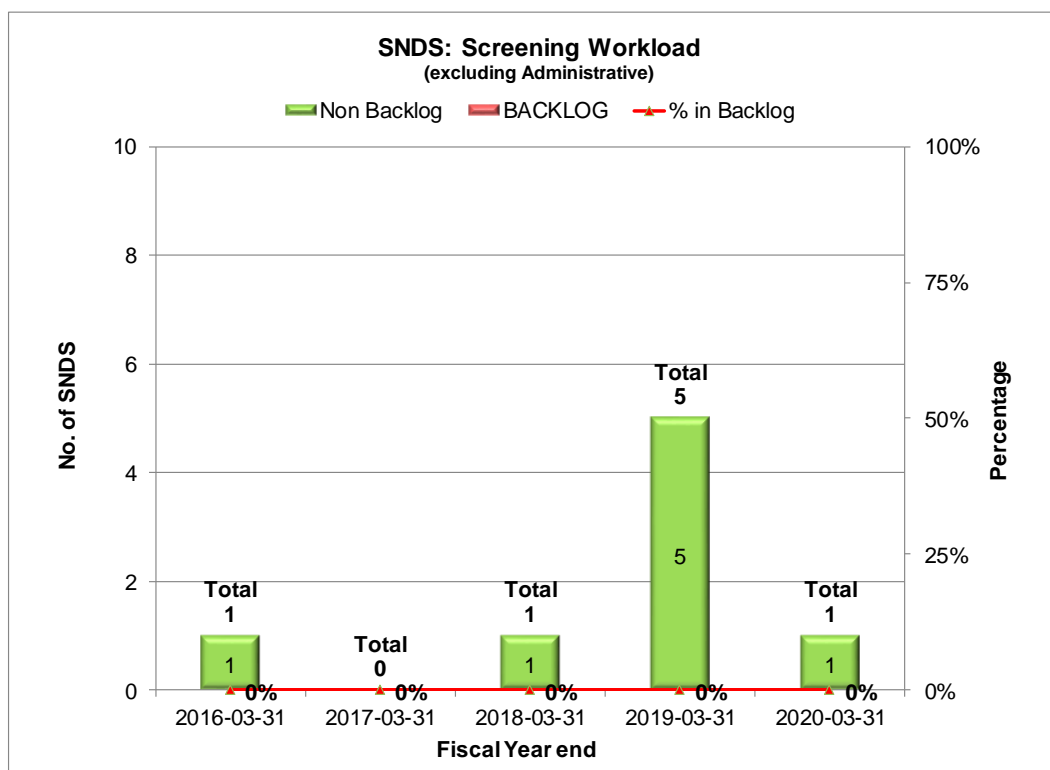


SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Labelling Only	1	1	2	12	0
<i>Backlog</i>	0	0	0	0	0
Published Data Only	1	2	0	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	2	1	4	2	2
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data and C&M	1	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without C&M	0	0	2	0	0
<i>Backlog</i>	0	0	0	0	0
Prescription to Non-Prescription Switch	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Total	5	4	10	15	2
Non Backlog	5	4	10	15	2
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 Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Chemistry and Manufacturing	1	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	0	5	1
<i>Backlog</i>	0	0	0	0	0
Total	1	0	1	5	1
Non Backlog	1	0	1	5	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISIONS

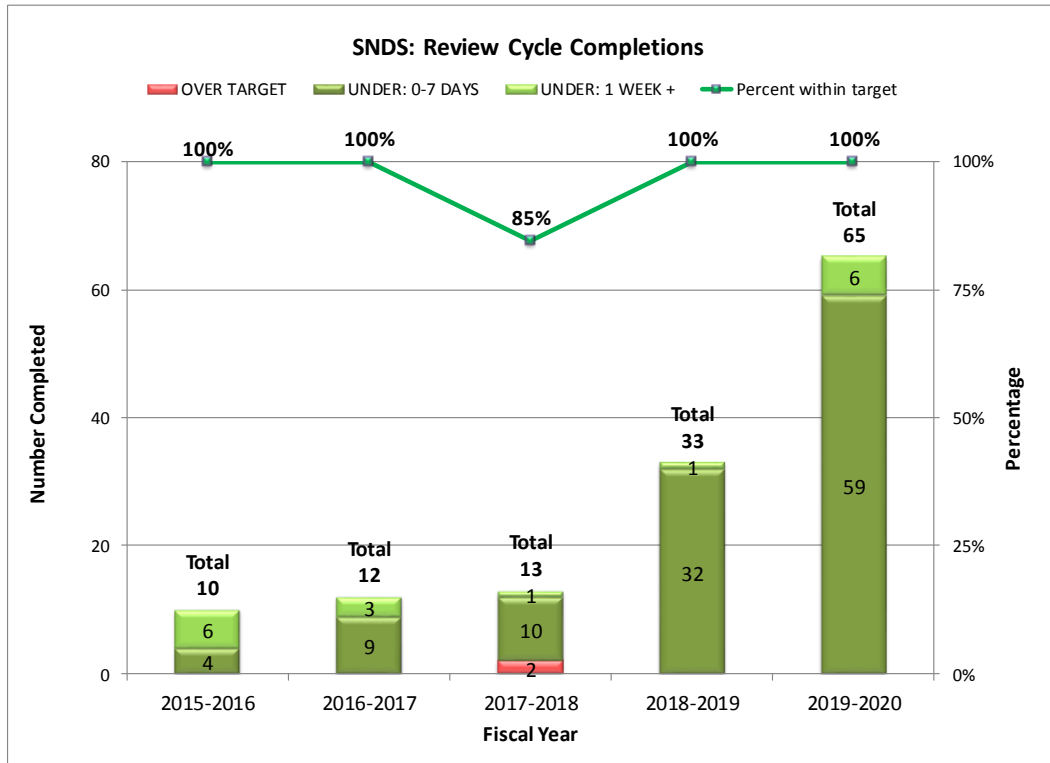
SNDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	1
	NOTICE OF COMPLIANCE*	0	0	0	1	2
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	1	0	0	0
	NOTICE OF COMPLIANCE*	1	2	3	5	1
CHEMISTRY AND MANUFACTURING	NOTICE OF COMPLIANCE*	1	2	3	5	1
	NOTICE OF NON-COMPLIANCE	1	1	0	1	2
	SCREENING DEFICIENCY NOTICE	1	1	5	2	0
	NOTICE OF COMPLIANCE*	0	0	0	2	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF DEFICIENCY	0	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	1	1
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	CANCELLATION LETTER	1	2	0	0	0
ADMINISTRATIVE	SCREENING DEFICIENCY NOTICE	0	2	0	0	0
	NOC ON HOLD (SWITCH)*	1	0	0	1	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	6	5	6	13	53
	SCREENING DEFICIENCY NOTICE	0	3	3	5	11
	CANCELLATION LETTER	0	4	0	3	4
	NOTICE OF DEFICIENCY	0	1	0	1	0
	NOTICE OF NON-COMPLIANCE	1	0	1	7	5
	NOC ON HOLD (SWITCH)*	0	0	0	1	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	CANCELLATION LETTER	0	0	0	1	0
	CANCELLATION LETTER	0	0	0	0	0
PUBLISHED DATA ONLY	NOTICE OF COMPLIANCE*	0	1	2	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0

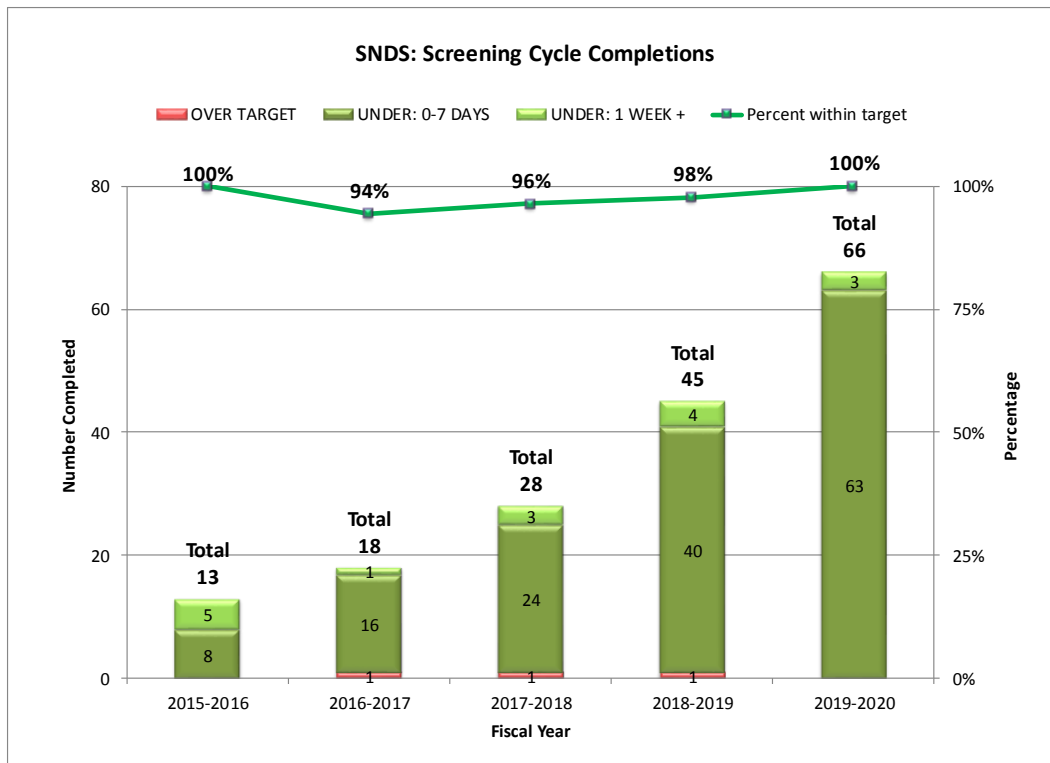
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

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)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
Administrative	0	0	0	0	2
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	3
Labelling Only	0	0	0	0	2
Total	0	0	0	0	7

WORKLOAD

ANDS: Review Workload

ANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies with or without C&M	0	0	0	0	2
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry & Manufacturing	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Only	0	0	0	0	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	3
Non Backlog	0	0	0	0	3
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

ANDS: Screening Workload

ANDS: SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies with or without C&M	0	0	0	0	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry & Manufacturing	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Only	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	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 USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Administrative	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

ANDS: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	1	0	100%	1

ANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	7	0	100%	7

ANDS: Administrative Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	1	0	100%	1

DECISIONS

ANDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1

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

SANDS: SUPPLEMENT TO AN ABBREVIATED NEW DRUG SUBMISSION

RECEIVED

SANDS: Number Received by Fee Category

SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSION (SANDS)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
Administrative	0	0	0	0	7
Chemistry and Manufacturing	0	0	0	0	1
Labelling Only	0	0	0	0	16
Total	0	0	0	0	24

WORKLOAD

SANDS: Review Workload

SANDS: REVIEW WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies with or without C&M	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	0	0	6
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	6
Non Backlog	0	0	0	0	6
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SANDS: Screening Workload

SANDS: SCREENING WORKLOAD BY USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Comparative Studies with or without C&M	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	0	0	1
<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 USER FEE CATEGORY and Fiscal Year End					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
ADMINISTRATIVE	0	0	0	0	5
<i>Backlog</i>	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

SANDS: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	6	1	100%	7

SANDS: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	1	21	0	95%	22

SANDS: Administrative Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	0	0	-	0
2018-2019	0	0	0	-	0
2019-2020	0	2	0	100%	2

DECISIONS

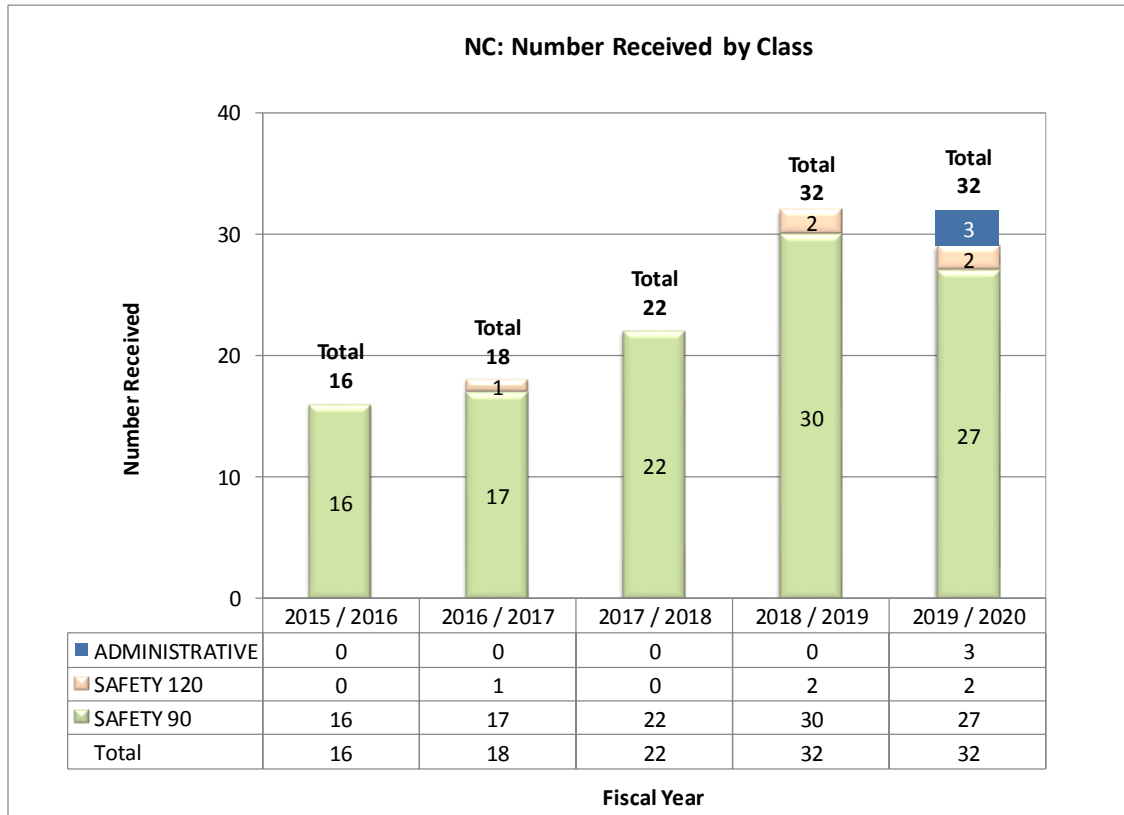
SANDS: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	NOTICE OF COMPLIANCE*	0	0	0	0	2
LABELLING ONLY	CANCELLATION LETTER	0	0	0	0	1
	NOTICE OF COMPLIANCE*	0	0	0	0	7
	SCREENING DEFICIENCY NOTICE	0	0	0	0	8

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

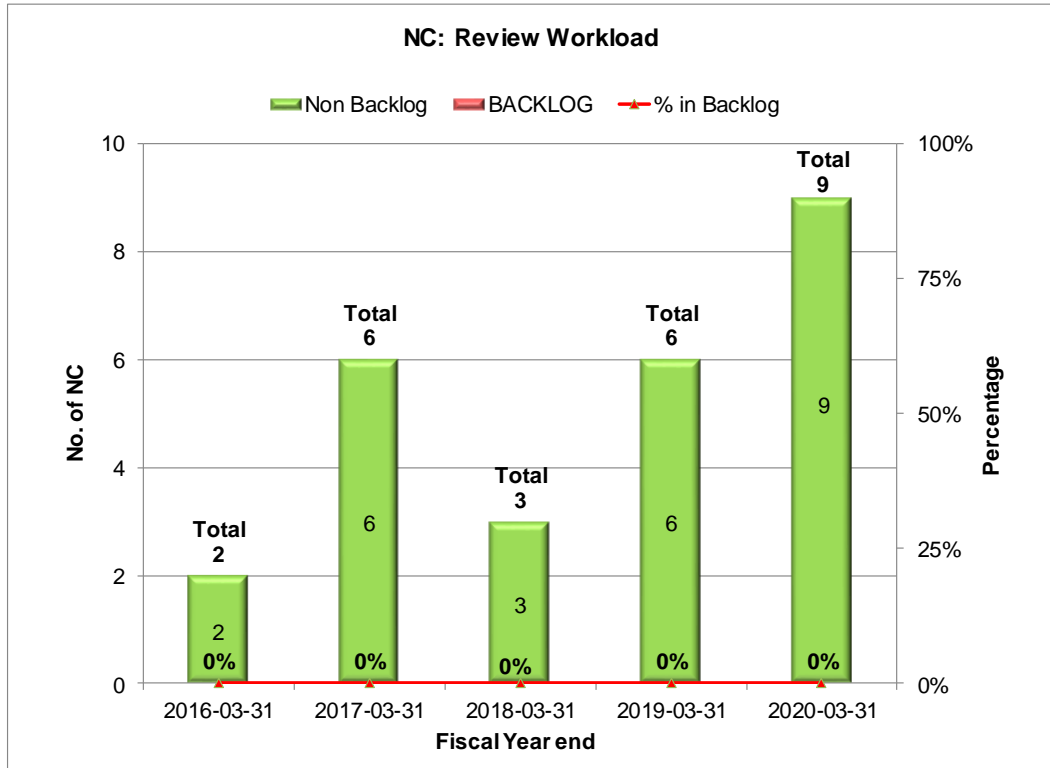
**NC: NOTIFIABLE CHANGE
RECEIVED**

NC: Number Received by Class



WORKLOAD

NC: Review Workload

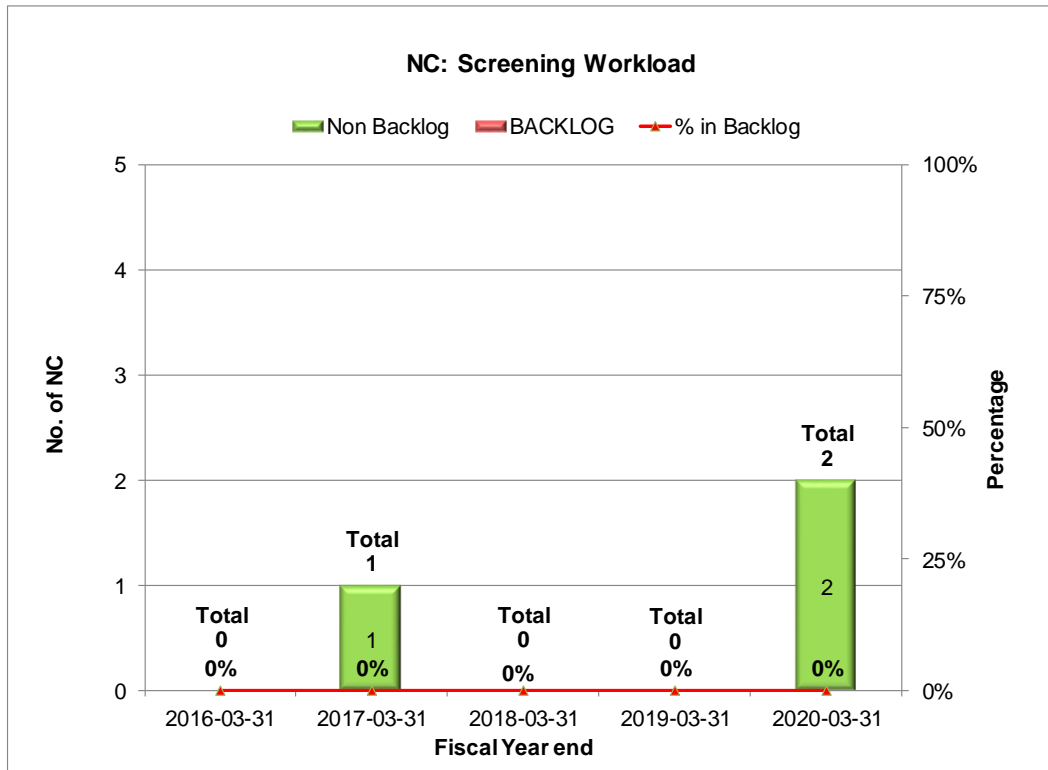


NC: Review Workload by Class

NC: REVIEW WORKLOAD BY CLASS and Fiscal Year end					
CLASS	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
SAFETY 90	2	5	3	4	8
<i>Backlog</i>	0	0	0	0	0
SAFETY 120	0	1	0	2	1
<i>Backlog</i>	0	0	0	0	0
Total	2	6	3	6	9
Non Backlog	2	6	3	6	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 Fiscal Year end					
CLASS	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
SAFETY 90	0	1	0	0	2
<i>Backlog</i>	0	0	0	0	0
Total	0	1	0	0	2
Non Backlog	0	1	0	0	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

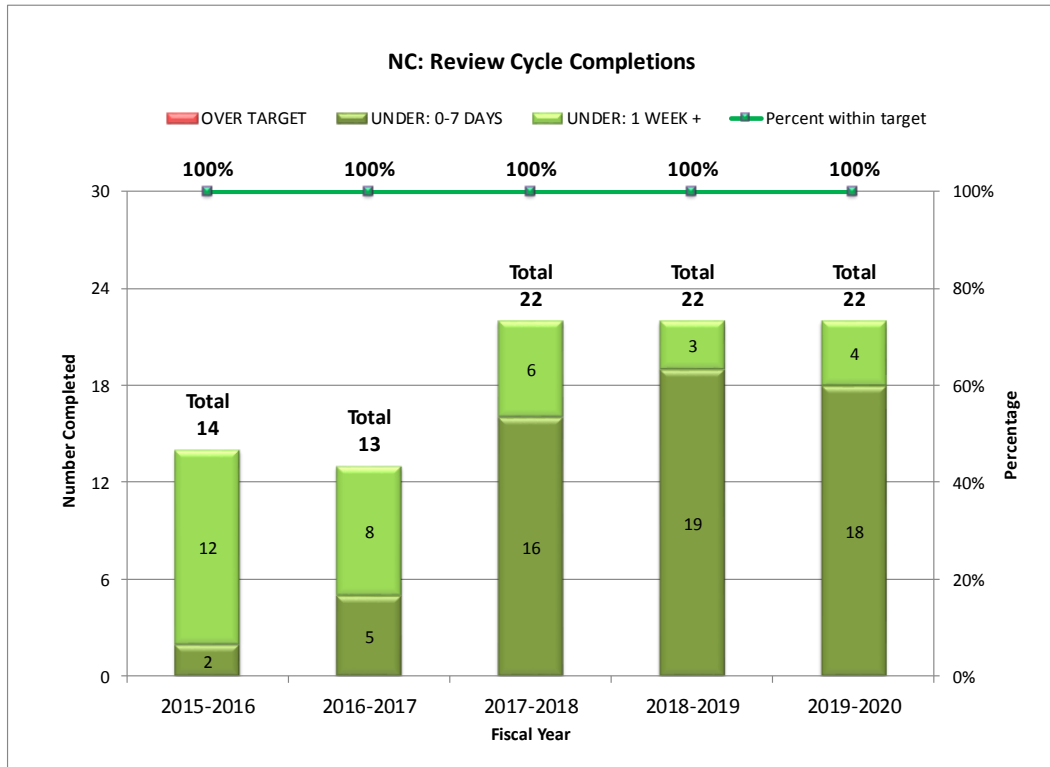
DECISIONS

NC: Number of Decisions by Class

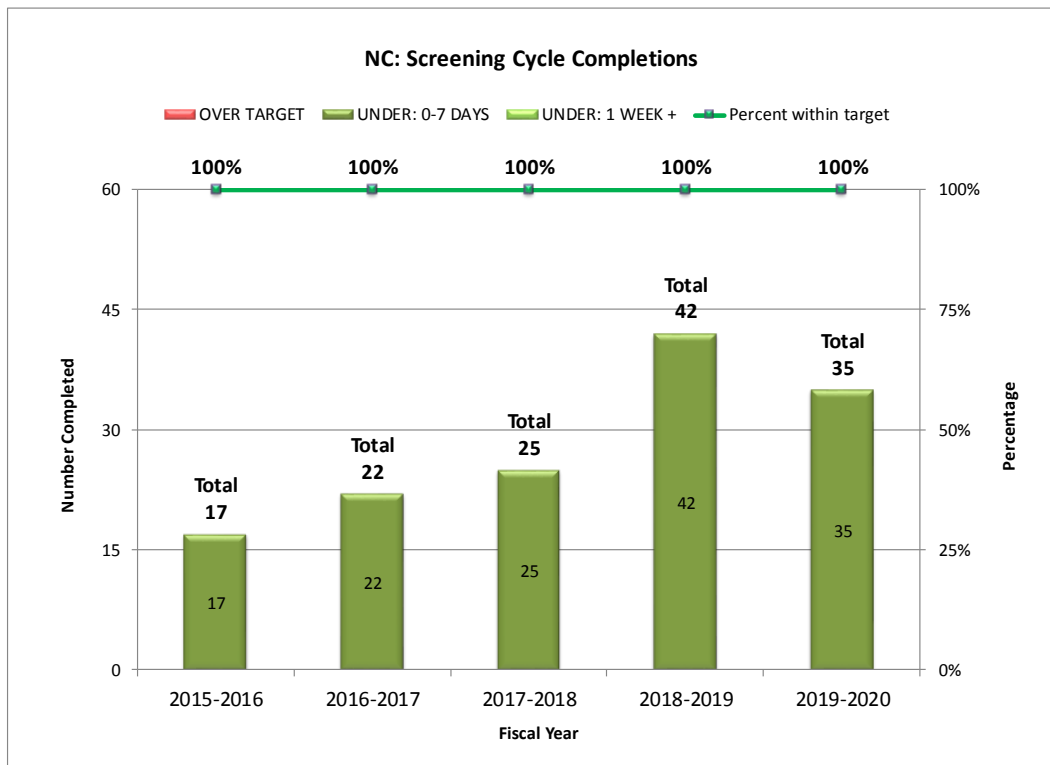
Class	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	1
	NO OBJECTION LETTER	0	0	0	0	2
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
SAFETY 90	NO OBJECTION LETTER	12	13	20	19	19
	CANCELLATION LETTER	0	1	2	8	2
	REJECTION LETTER (SCR)	0	1	1	1	0
	NOT SATISFACTORY NOTICE	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	3	4	5	16	8
	NC-HOLD (SWITCH)	1	0	0	0	0
SAFETY 120	CANCELLATION LETTER	0	0	1	0	1
	NO OBJECTION LETTER	0	0	0	0	2

PERFORMANCE

NC: Review Cycle Completions



NC: Screening Cycle Completions



PRE-MEETINGS

MPDIN: Number Received by Fee Category

PRE - DIN MEETING (MPDIN)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
Clinical or Non-Clinical Data	0	0	0	0	2
Total	0	0	0	0	2

MPNDS: Number Received by Fee Category

PRE - NDS MEETING (MPNDS)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
Clinical or Non-Clinical and Chemistry - Manufacturing	0	0	0	0	4
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	2
Total	0	0	0	0	6

MPSNDS: Number Received by Fee Category

PRE - SNDS MEETING (MPSNDS)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
Clinical or Non-Clinical Data	0	0	0	0	1
Total	0	0	0	0	1

PART 2: DISINFECTANT PRODUCTS

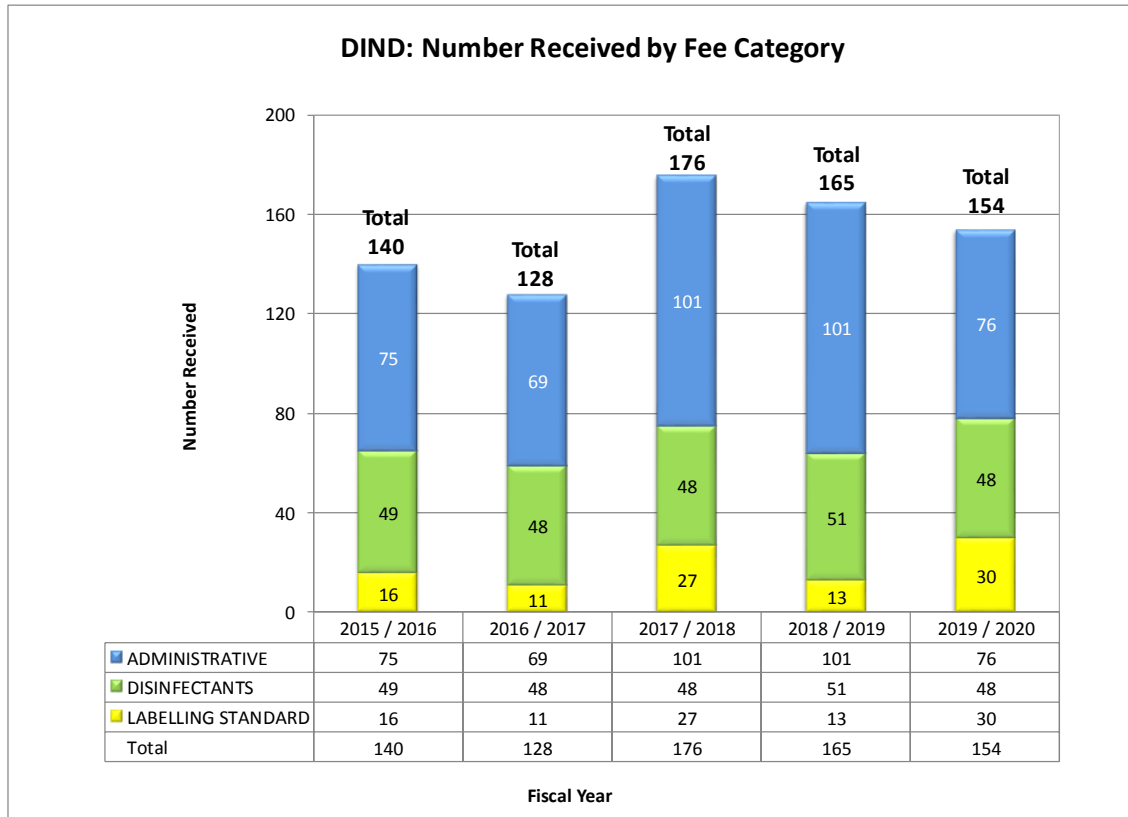
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

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

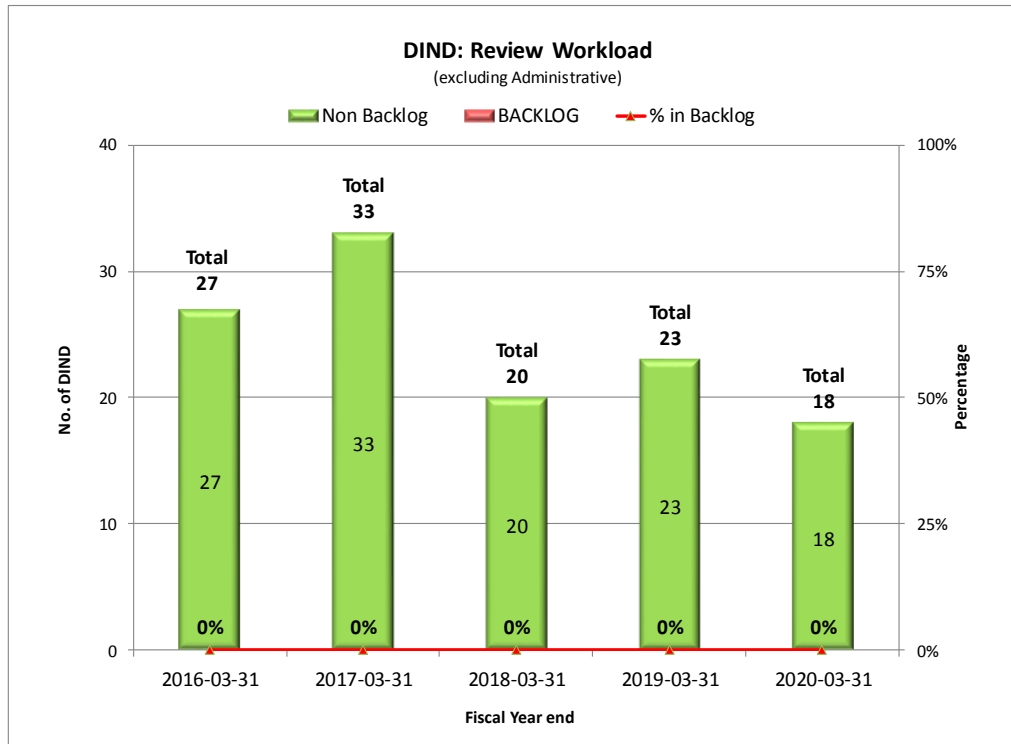
RECEIVED

DIND-Disinfectant Products: Number Received by Fee Category

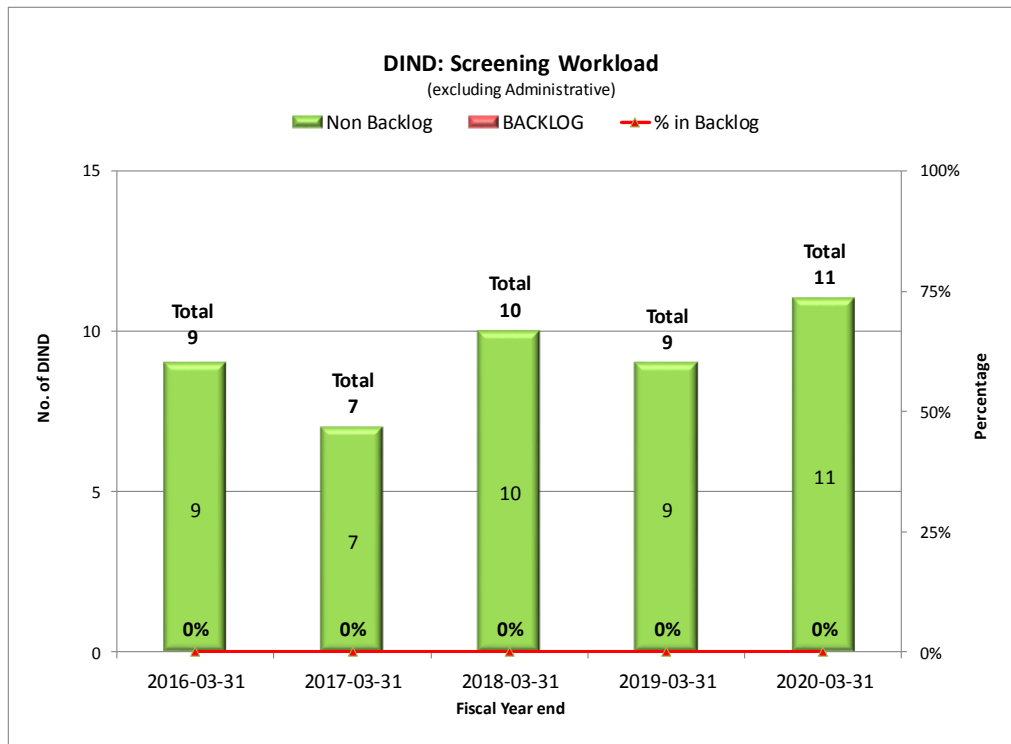


WORKLOAD

DIND-Disinfectant Products: Review Workload

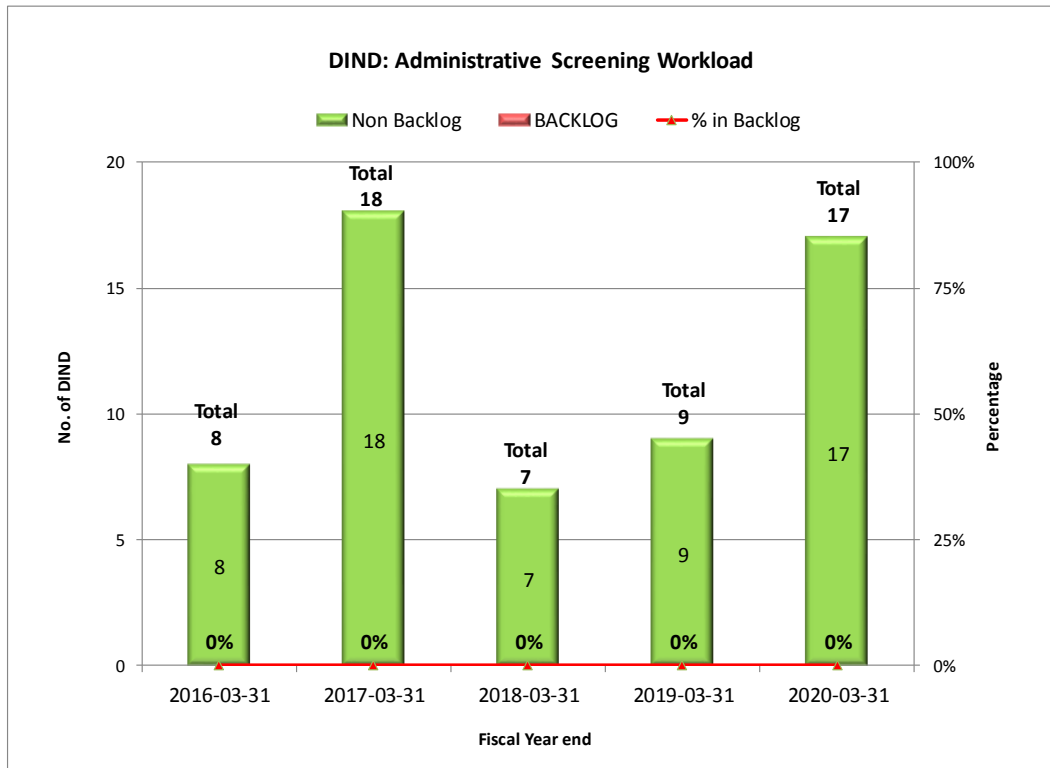


DIND-Disinfectant Products: Screening Workload



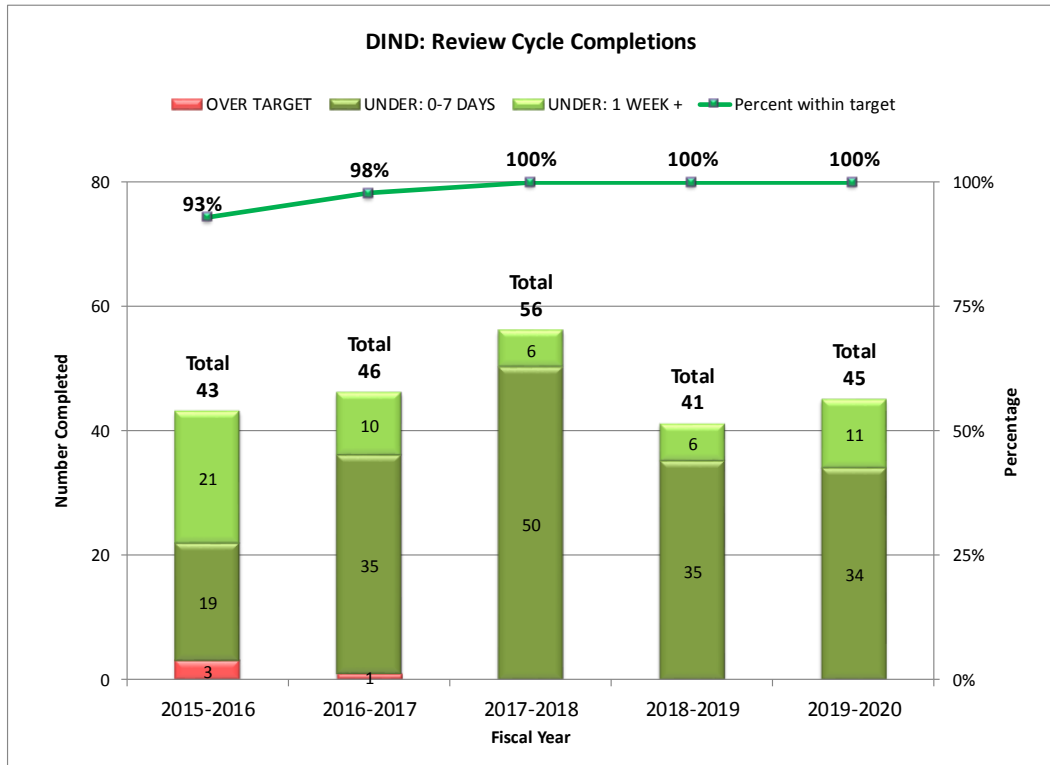
WORKLOAD

DIND-Disinfectant Products: Administrative-Screening Workload

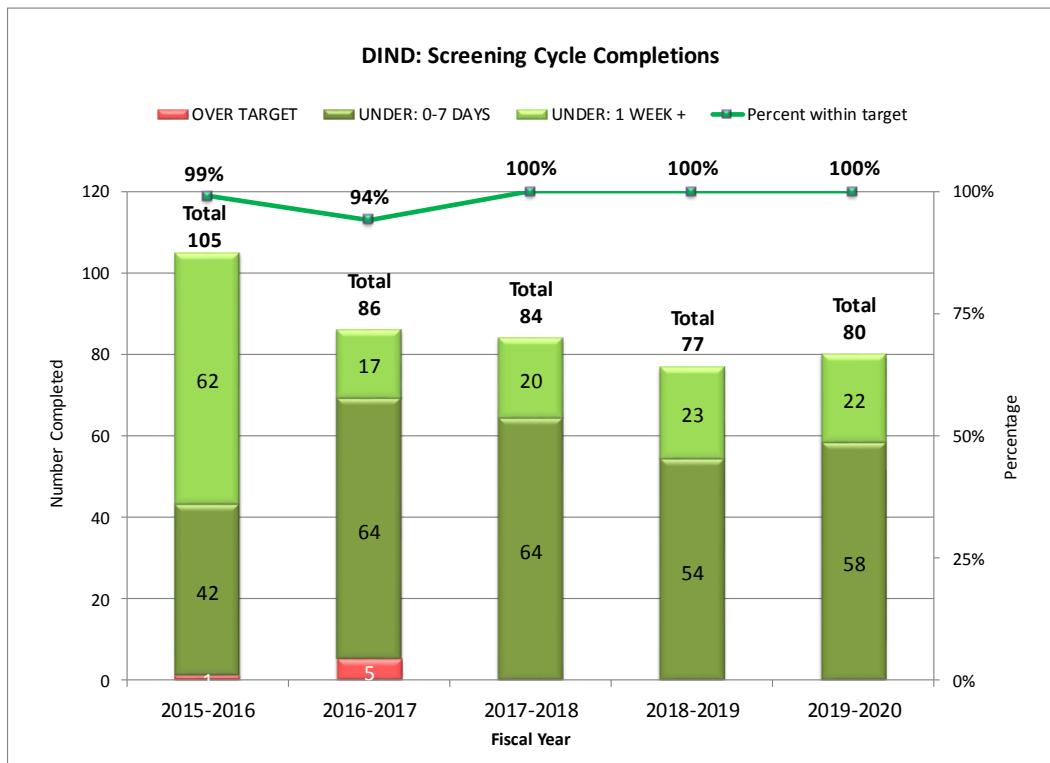


PERFORMANCE

DIND-Disinfectant Products: Review Cycle Completions

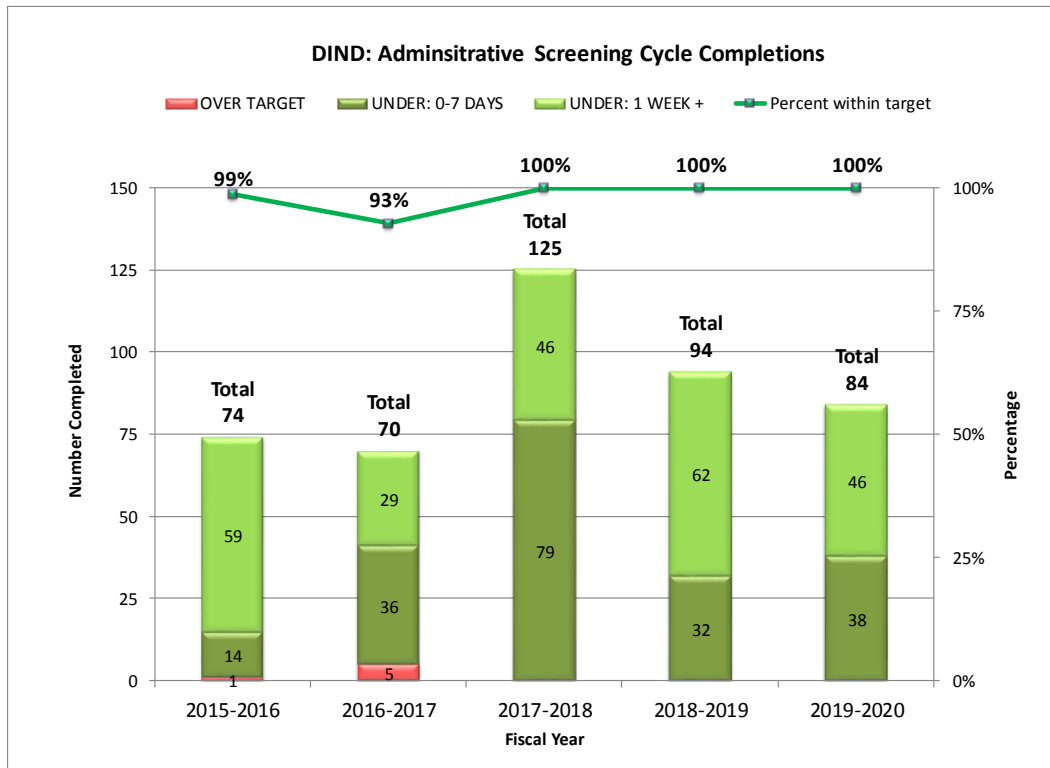


DIND-Disinfectant Products: Screening Cycle Completions



PERFORMANCE

DIND-Disinfectant Products: Administrative-Screening Cycle Completions



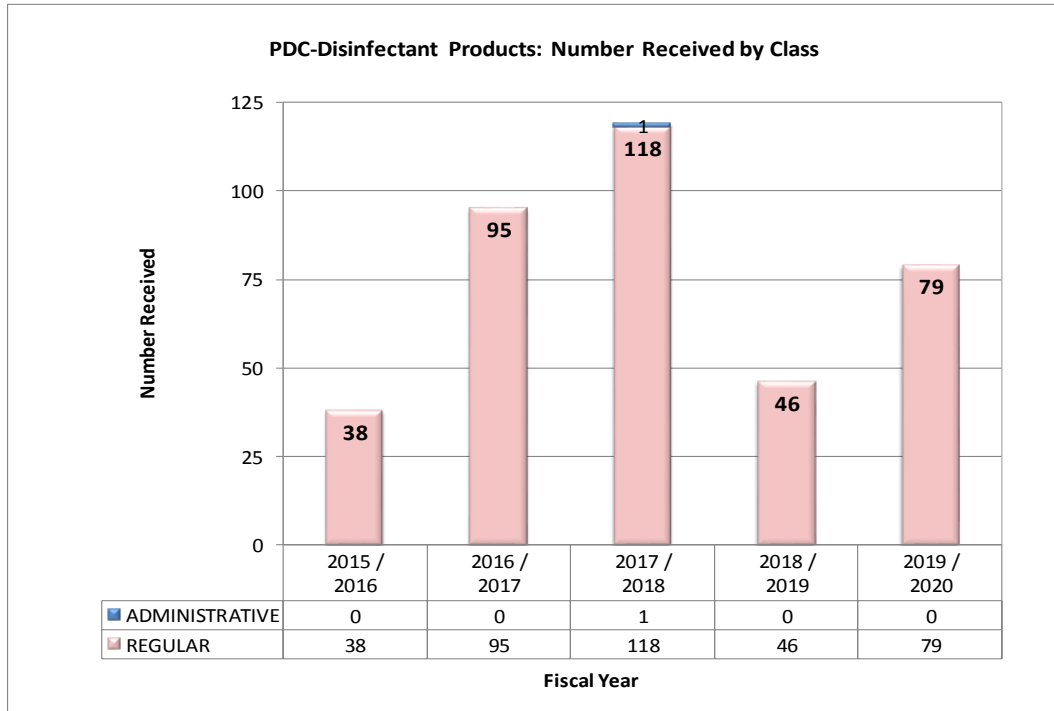
DECISIONS

DIND-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	54	43	94	62	62	
	NO OBJECTION LETTER	0	3	0	9	2	
	CANCELLATION LETTER	3	1	2	8	0	
	REJECTION LETTER (SCR)	9	9	15	1	4	
	SCREENING DEFICIENCY NOTICE	11	18	20	22	19	
DISINFECTANTS	NOTIFICATION FORM DIN SUB	20	27	37	33	39	
	NO OBJECTION LETTER	10	9	17	8	6	
	CANCELLATION LETTER	2	1	3	4	1	
	NEW DRUG LETTER SCREEN	3	0	0	0	0	
	NOD WITHDRAWAL LETTER	1	0	0	0	0	
	NON WITHDRAWAL LETTER	1	0	0	0	0	
	NOTICE OF DEFICIENCY	0	1	0	0	0	
	NOTICE OF NON-COMPLIANCE	13	9	1	0	0	
	SCREENING DEFICIENCY NOTICE	30	20	5	8	5	
	REJECTION LETTER (SCR)	3	6	1	0	2	
	WITHDRAWAL NO RESP TO NON	1	0	0	0	0	
	LABELLING STANDARD	NOTIFICATION FORM DIN SUB	13	8	20	14	23
		NO OBJECTION LETTER	0	0	1	0	0
SCREENING DEFICIENCY NOTICE		6	4	10	5	9	
REJECTION LETTER (SCR)		1	1	3	4	0	

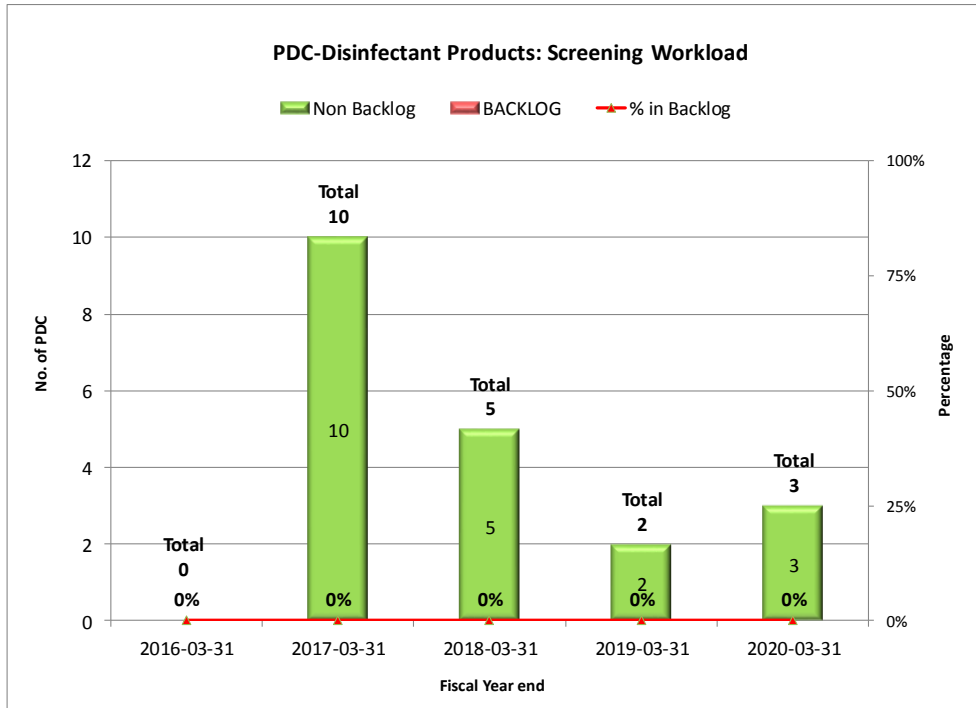
PDC: POST AUTHORIZATION DIVISION 1 CHANGES - DISINFECTANT PRODUCTS RECEIVED

PDC-Disinfectant Products: Received by Class



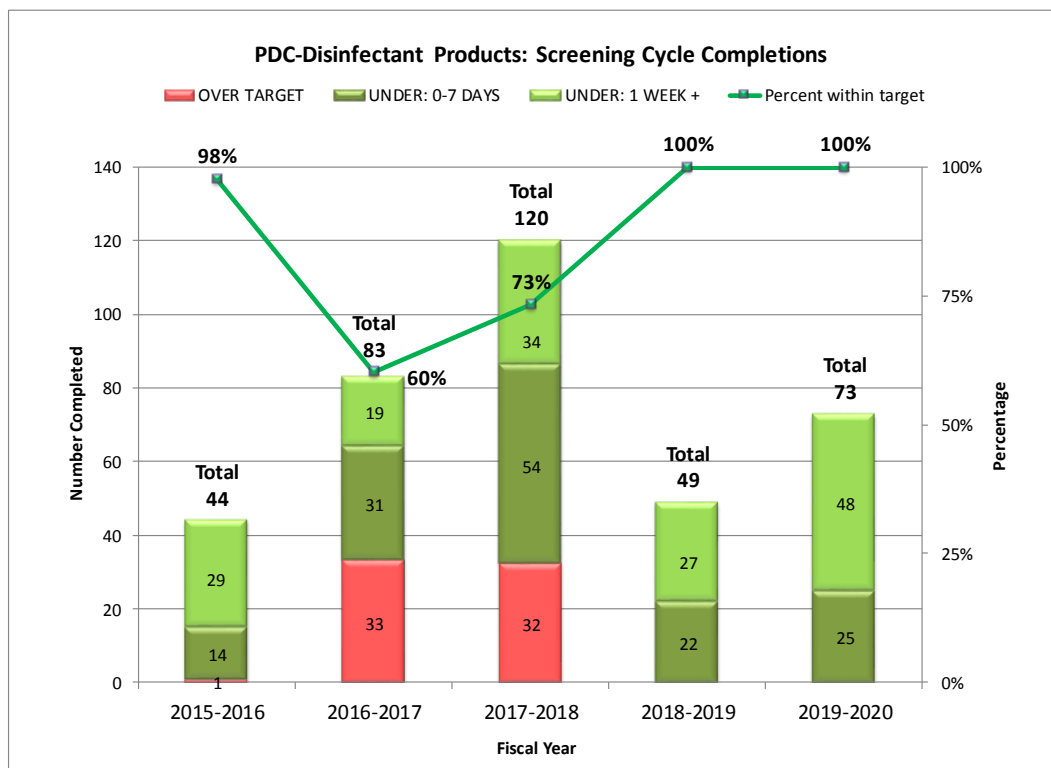
WORKLOAD

PDC-Disinfectant Products: Screening Workload



PERFORMANCE

PDC-Disinfectant Products: Screening Cycle Completions



DECISIONS

PDC-Disinfectant Products: Number of Decisions by Class

Class	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1	0	0
REGULAR	NO OBJECTION LETTER	37	41	78	39	62
	NOT SATISFACTORY NOTICE	3	38	35	9	6
	CANCELLATION LETTER	1	1	0	0	3
	NOTIFICATION FORM DIN SUB	0	2	4	0	0
	REJECTION LETTER (SCR)	0	1	4	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0

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

NDS-D: NEW DRUG SUBMISSION - DISINFECTANT PRODUCTS

RECEIVED

NDS-Disinfectant Products: Number Received by Fee Category

NEW DRUG SUBMISSION DISINFECTANT PRODUCTS (NDS-D)					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
DISINFECTANTS	1	4	2	1	1
ADMINISTRATIVE	0	1	0	1	0
Total	1	5	2	2	1

WORKLOAD

NDS-Disinfectant Products: Review Workload

NDS-D Disinfectant Products: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Dinsinfectants	0	3	2	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Screening Workload

NDS-D Disinfectant Products: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Dinsinfectants	0	2	0	1	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-Disinfectant Products: Administrative-Screening Workload

NDS-D Disinfectant Products: ADMIN SCREENING WORKLOAD by Fiscal Year end					
FEE CATEGORY	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
Administrative	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NDS-Disinfectant Products: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	1	0	100%	1
2016-2017	0	0	0	-	0
2017-2018	0	3	0	100%	3
2018-2019	0	1	1	100%	2
2019-2020	0	1	1	100%	2

NDS-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	1	100%	1
2016-2017	0	0	6	100%	6
2017-2018	0	9	0	100%	9
2018-2019	0	1	0	100%	1
2019-2020	0	4	0	100%	4

NDS-Disinfectant Products: Administrative-Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	1	0	0	0%	1
2017-2018	0	0	0	-	0
2018-2019	0	2	0	100%	2
2019-2020	0	0	0	-	0

DECISIONS

NDS-Disinfectant Products: Number of Decisions by Fee Category

User Fee Category	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
ADMINISTRATIVE	CANCELLATION LETTER	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	1	0	1	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
DISINFECTANTS	NOTICE OF COMPLIANCE*	1	0	1	1	0
	NOTICE OF NON-COMPLIANCE	0	0	0	1	1
	NOTICE OF DEFICIENCY	0	0	3	0	0
	NOD WITHDRAWAL LETTER	0	0	1	0	0
	REJECTION LETTER (SCR)	0	0	2	0	1
	CANCELLATION LETTER	1	0	0	0	1
	SCREENING DEFICIENCY NOTICE	1	3	3	0	1

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

NC: NOTIFIABLE CHANGE - DISINFECTANT PRODUCTS

RECEIVED

NC-Disinfectant Products: Received by Class

NOTIFIABLE CHANGE- DISINFECTANT PRODUCTS					
Class	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
SAFETY 90	0	0	1	0	0

WORKLOAD

NC-Disinfectant Products: Review Workload

NC-Disinfectant Products: REVIEW WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
SAFETY-90	1	0	0	0	0
Backlog	0	0	0	0	0
Total	1	0	0	0	0
Non Backlog	1	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-Disinfectant Products: Screening Workload

NC-Disinfectant Products: SCREENING WORKLOAD BY CLASS (excluding Administrative) and Fiscal Year end					
CLASS	2016-03-31	2017-03-31	2018-03-31	2019-03-31	2020-03-31
SAFETY-90	0	0	0	0	0
Backlog	0	0	0	0	0
Total	0	0	0	0	0
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NC-Disinfectant Products: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	1	100%	1
2016-2017	0	0	0	-	0
2017-2018	0	0	1	100%	1
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0

NC-Disinfectant Products: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2015-2016	0	0	0	-	0
2016-2017	0	0	0	-	0
2017-2018	0	1	0	100%	1
2018-2019	0	0	0	-	0
2019-2020	0	0	0	-	0

DECISIONS

NC-Disinfectant Products: Number of Decisions by Class

Class	Decision Document Type	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
SAFETY 90	NO OBJECTION LETTER	1	0	1	0	0

PRE-MEETINGS - DISINFECTANT PRODUCTS

MPNDS-Disinfectant Products: Received by Fee Category

PRE-NDS MEETING (MPNDS) DISINFECTANT PRODUCTS					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
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					
User Fee Category	2015 / 2016	2016 / 2017	2017 / 2018	2018 / 2019	2019 / 2020
CLINICAL OR NON-CLINICAL DATA	0	0	0	1	0

