Health Canada Santé Canada

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual Report

Fiscal Year

2017-2018

April 1 2017 – March 31 2018

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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 2017-2018

To obtain additional information, please contact:

Health Canada
Address Locator 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9
Tel.: 613-941-7281
Fax: 613-941-0825
E-mail: hc.tpd.web.publications.sc@canada.ca

Publication date: May 2018

Cat H166-3E-PDF
ISSN 2561-7680
Pub 180081

Table of Contents

OVERVIEW

The NNHPD Annual Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over four consecutive fiscal years (April 1 to March 31) from 2014-2015 to 2017-2018. 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 2017-2018 report are:

The performance standard of greater than 90% review on time has been achieved for all the cost-recovered submissions.

The overall number of submissions for the non-prescription drugs has not significantly changed from the previous two fiscal years. However, Plain language labelling (PLL) requirements came into force for the non-prescription drugs on June 13 2017, significantly changing the label review process as bilingual label mock-ups are now being reviewed at the time of filing.

Non-Prescription Drugs:

The number of DINA submissions received increased from the previous year; 185 in 2017-2018 compared to 149 in 2016-2017. A small decrease was observed in the number of DINF received, from 226 in 2015-2016, 212 in 2016-2017 to 185 in 2017-2018.

The number of NDS submissions received increased 29% from 7 in 2016-2017 to 9 in 2017-2018. The number of SNDS submissions received (n=16) remained similar to that for the previous year (n=15), however the number of SNDS- Chemistry and Manufacturing had increased by 500% from 1 in 2016-2017 to 6 in 2017-2018. Also, the NC submissions increased by 22% from 18 in 2016-17 to 22 in 2017-18.

By third quarter, backlog for PDC submissions (non-cost recovered) was cleared, and all PDC submissions were subsequently cleared within the set performance standard.

Disinfectant Drugs:

For disinfectants, the Directorate has seen a 38% increase in DIND submissions, from 128 in 2016-2017 to 176 in 2017-2018. This increase is also high compared to 139 in 2014-2015 and 140 in 2015-2016, representing a 28% increase compared to those fiscal years.

Additionally for disinfectants, a 24% increase was seen for PDC submissions, from 95 in 2016-2017 to 118 in 2017-2018. This is a significant increase (311%) compared to the 38 received in 2015-2016.

The number of disinfectant NDS submissions received stabilized to previously typical numbers in 2017-2018 (i.e., 2 in 2017-2018, and 1 in both of 2014-2015 and 2015-2016) compared to the 5 received in 2016-2017.

General Information

There are several steps involved in the drug submission review[1] 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.

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.

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

[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).

"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, Therapeutic Products 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

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

This page is left blank intentionally.

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
DIND	-	Application for a Drug Identification Number – Disinfectant Product
DINF	-	Application for a Drug Identification Number - Category IV Product – (Labelling Standard)
NDS	-	New Drug Submission
NC	-	Notifiable Change – New Drug
PDC	-	Post-DIN Changes
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SANDS	-	Supplemental Abbreviated New Drug Submission
SNDS	-	Supplemental New Drug Submission
SNDS-C	-	Supplemental New Drug Submission – CONFIRMATORY

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 Only[5]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[6]	Submissions in support of a manufacturer or product name change.
Disinfectants[7]	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

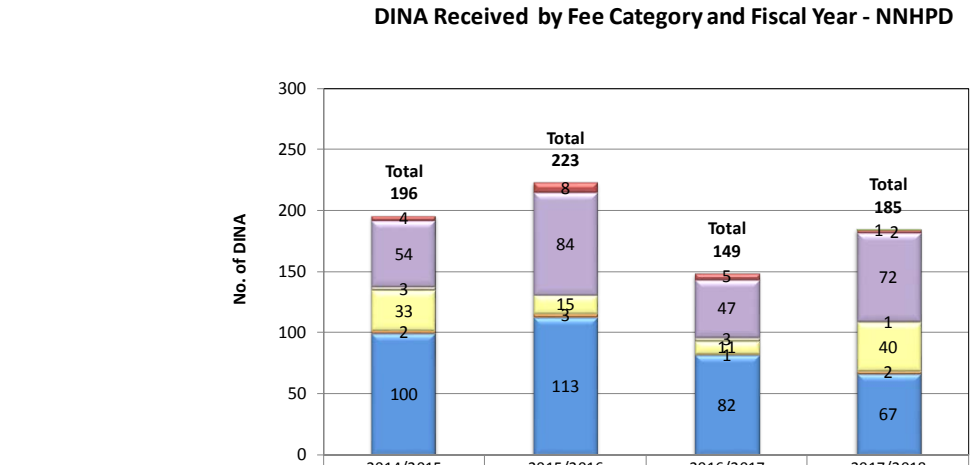
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS

SUBMISSIONS RECEIVED

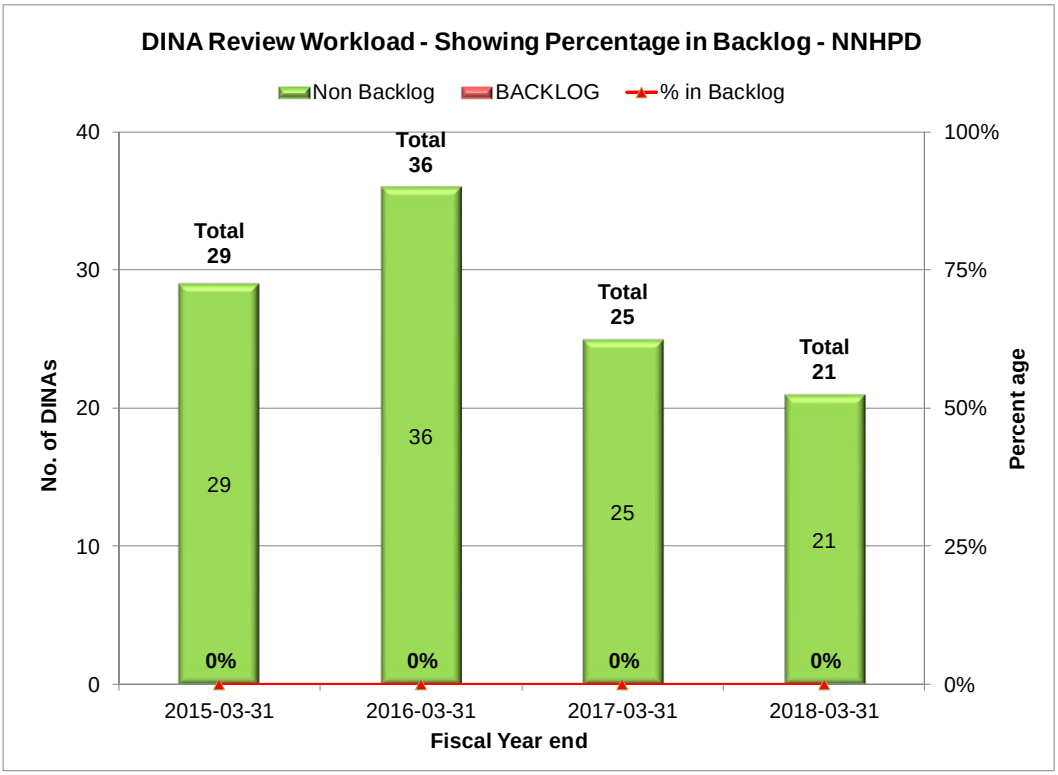
DINA: Received by Fee Category



	2014/2015	2015/2016	2016/2017	2017/2018
DINA - CLINICAL OR NON-CLINICAL AND CHEMISTRY - MANUFACTURING	0	0	0	1
DINA - CHEMISTRY AND MANUFACTURING	4	8	5	2
DINA - LABELLING ONLY	54	84	47	72
DINA - CLINICAL OR NON CLINICAL-DATA	3	0	3	1
DINA - LABELLING STANDARD	33	15	11	40
DINA - PUBLISHED DATA ONLY	2	3	1	2
DINA - ADMINISTRATIVE	100	113	82	67
Total	196	223	149	185

WORKLOAD

DINA: Review Workload Showing the Percentage in Backlog

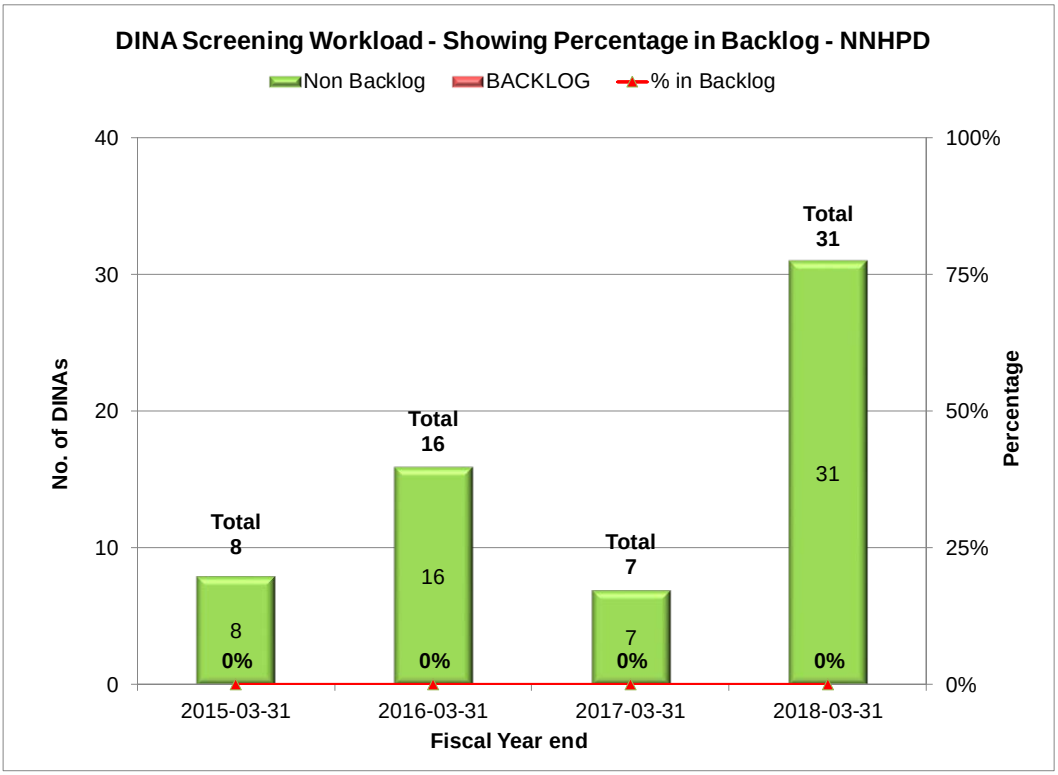


DINA: Review Workload by Fee Category

DINA REVIEW WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**24**	**30**	**18**	**19**
Backlog	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	**1**	**4**	**5**	**1**
Backlog	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	**2**	**1**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*
Published Data Only	**2**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*
Clinical or Non-Clinical /C&M	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*
Total	**29**	**36**	**25**	**21**
Non Backlog	**29**	**36**	**25**	**21**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

WORKLOAD

DINA: Screening Workload Showing the Percentage in Backlog

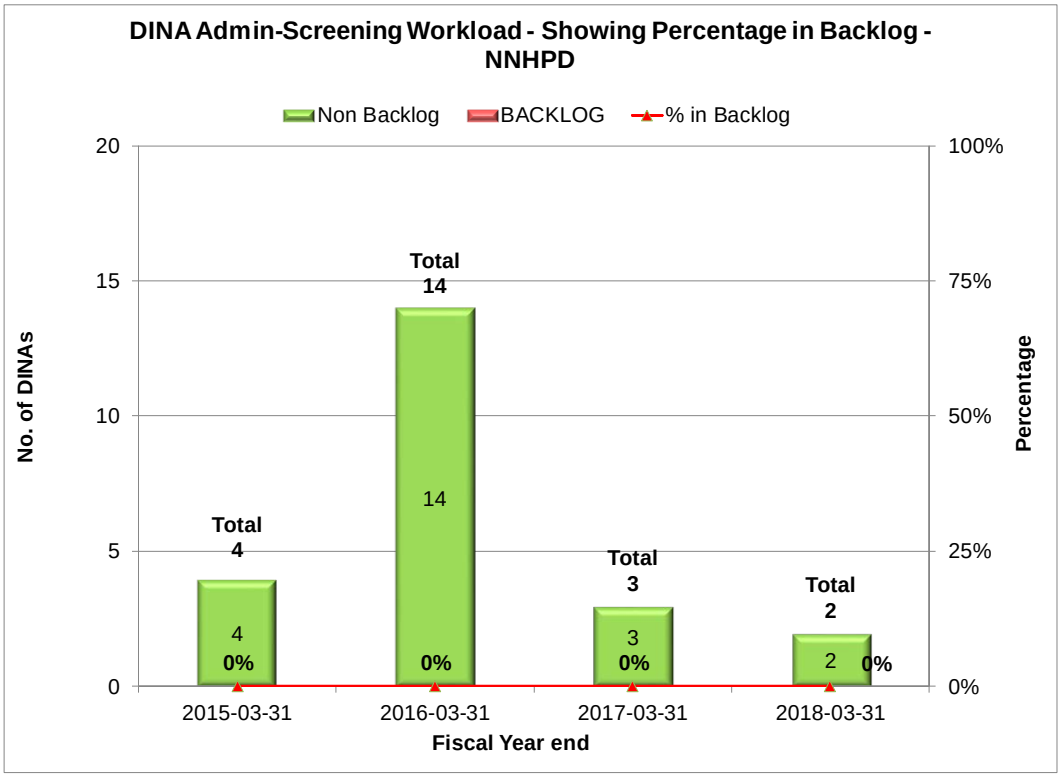


DINA: Screening Workload by Fee Category

DINA SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**6**	**14**	**4**	**21**
Backlog	*0*	*0*	*0*	*0*
Labelling Standard	**2**	**2**	**0**	**10**
Backlog	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*
Published Data Only	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*
Total	**8**	**16**	**7**	**31**
Non Backlog	**8**	**16**	**7**	**31**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

WORKLOAD

DINA: Administrative Screening Workload Showing the Percentage in Backlog



DINA: Administrative-Screening Workload by Fee Category

DINA ADMIN-SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Administrative	**4**	**14**	**3**	**2**
Backlog	*0*	*0*	*0*	*0*
Total	**4**	**14**	**3**	**2**
Non Backlog	**4**	**14**	**3**	**2**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

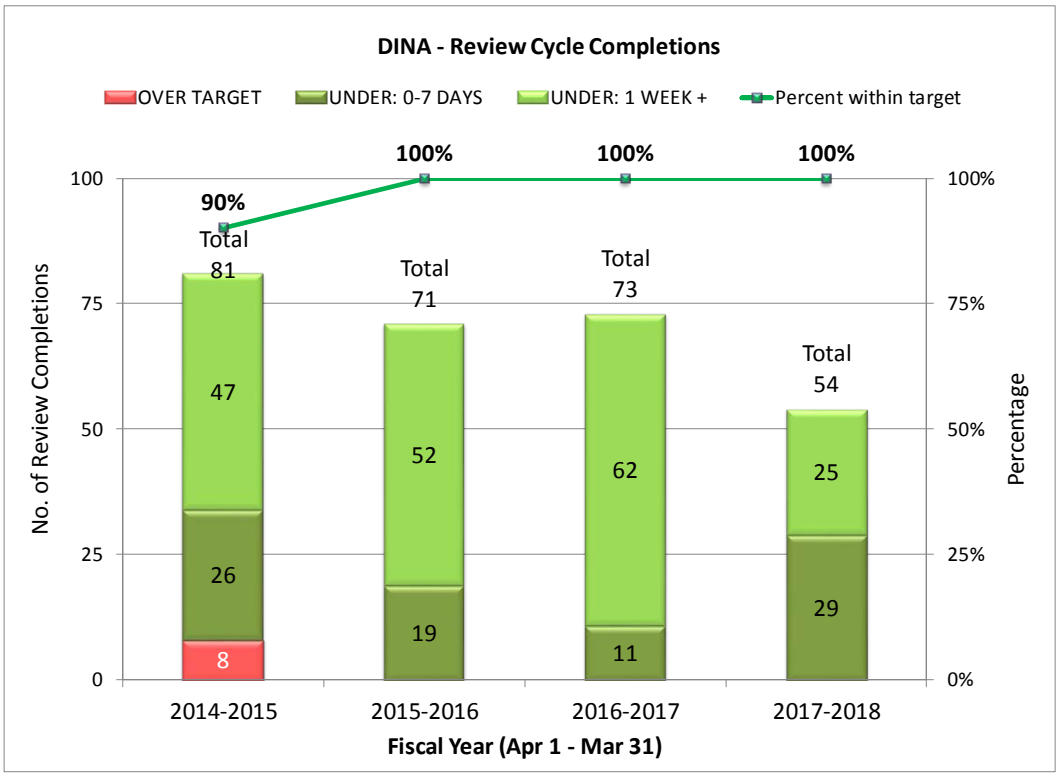
DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

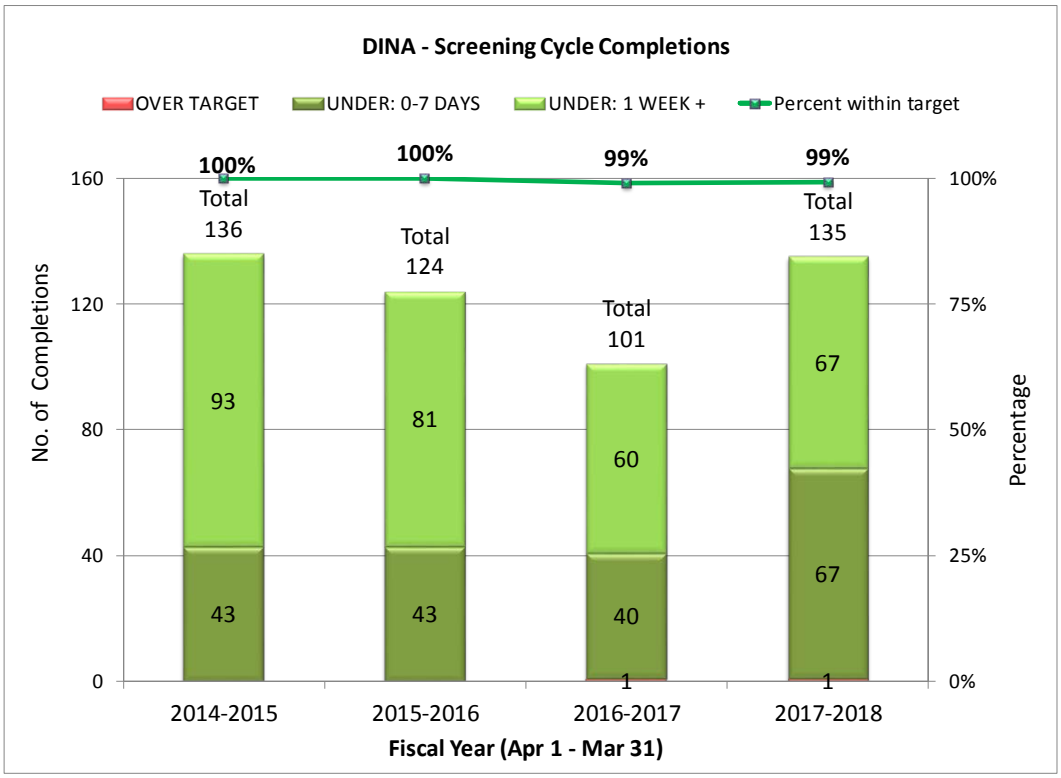
User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	86	85	80	32
	NO OBJECTION LETTER	0	0	2	0
	REJECTION LETTER (SCR)	11	12	9	2
	SCREENING DEFICIENCY NOTICE	6	1	5	4
	CANCELLATION LETTER	6	5	3	36
CHEMISTRY AND MANUFACTURING	NOTIFICATION FORM DIN SUB	5	2	1	3
	NO OBJECTION LETTER	1	0	0	0
	NOTICE OF DEFICIENCY	1	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	4	4
	CANCELLATION LETTER	0	1	2	4
	SCREENING DEFICIENCY NOTICE	0	6	3	0
	WITHDRAWAL NO RESP TO NON	0	0	1	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	2	0	0	2
	NO OBJECTION LETTER	0	1	0	1
	NOTICE OF DEFICIENCY	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	0	1	2
	SCREENING DEFICIENCY NOTICE	1	0	1	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	1	0	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	1
LABELLING ONLY	NOTIFICATION FORM DIN SUB	63	48	39	36
	NO OBJECTION LETTER	2	6	22	2
	NOTICE OF NON-COMPLIANCE	3	9	2	0
	CANCELLATION LETTER	5	9	7	15
	DIN INCORR SUBTYPE-CLASS	11	3	0	0
	REJECTION LETTER (SCR)	1	4	5	1
	SCREENING DEFICIENCY NOTICE	11	20	15	30
	NOTICE OF DEFICIENCY	0	1	0	1
	WITHDRAWAL NO RESP TO NOD	0	1	0	0
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	25	12	13	29
	NO OBJECTION LETTER	0	0	1	0
	CANCELLATION LETTER	2	1	1	0
	REJECTION LETTER (SCR)	2	2	0	0
	SCREENING DEFICIENCY NOTICE	9	3	1	14
PUBLISHED DATA	NOTIFICATION FORM DIN SUB	0	2	2	1
	SCREENING DEFICIENCY NOTICE	1	1	0	2
	NOTICE OF NON-COMPLIANCE	0	1	0	0
	NON WITHDRAWAL LETTER	0	0	1	0
	CANCELLATION LETTER	0	1	0	0

PERFORMANCE

DINA: REVIEW Cycle Completions Showing Percentage within Target

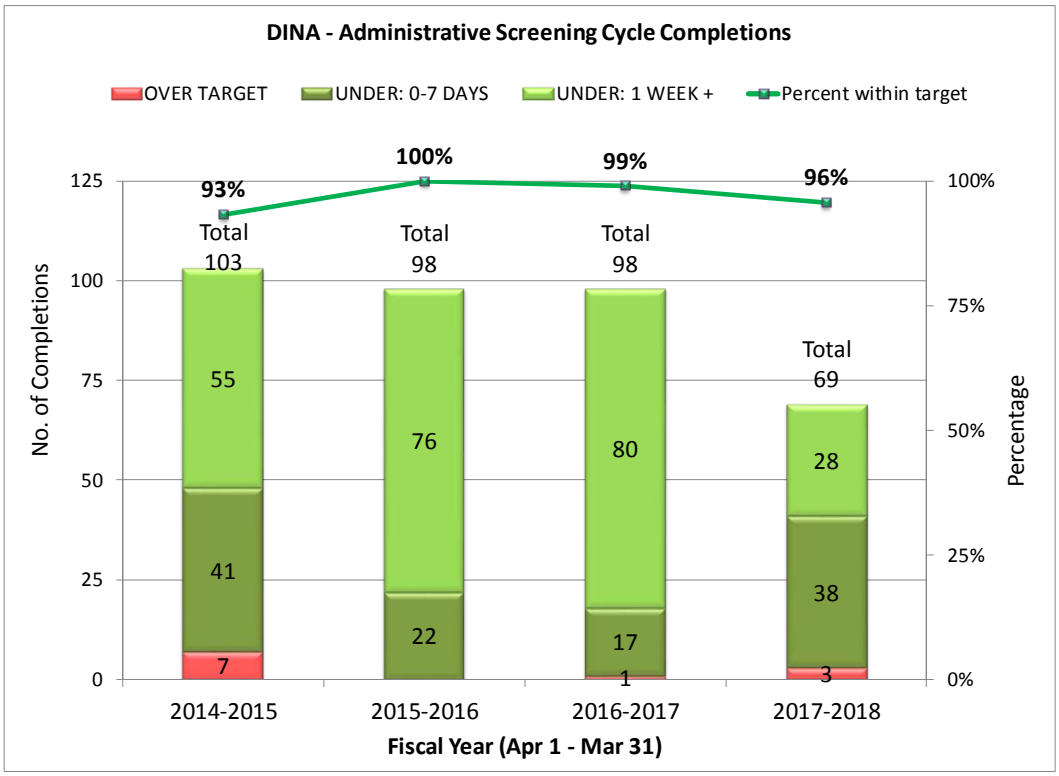


DINA: SCREENING Cycle Completions Showing Percentage within Target



PERFORMANCE

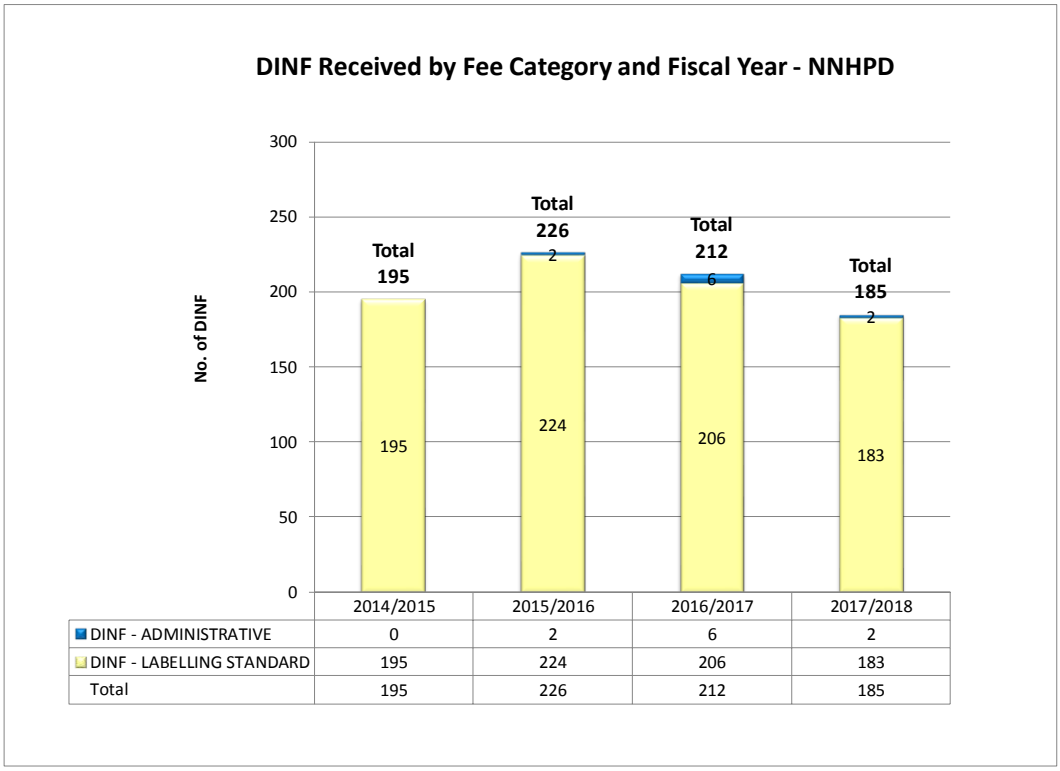
DINA: Administrative Screening Completions Showing Percentage within Target



DINF: CATEGORY FOUR DIN APPLICATIONS

SUBMISSIONS RECEIVED

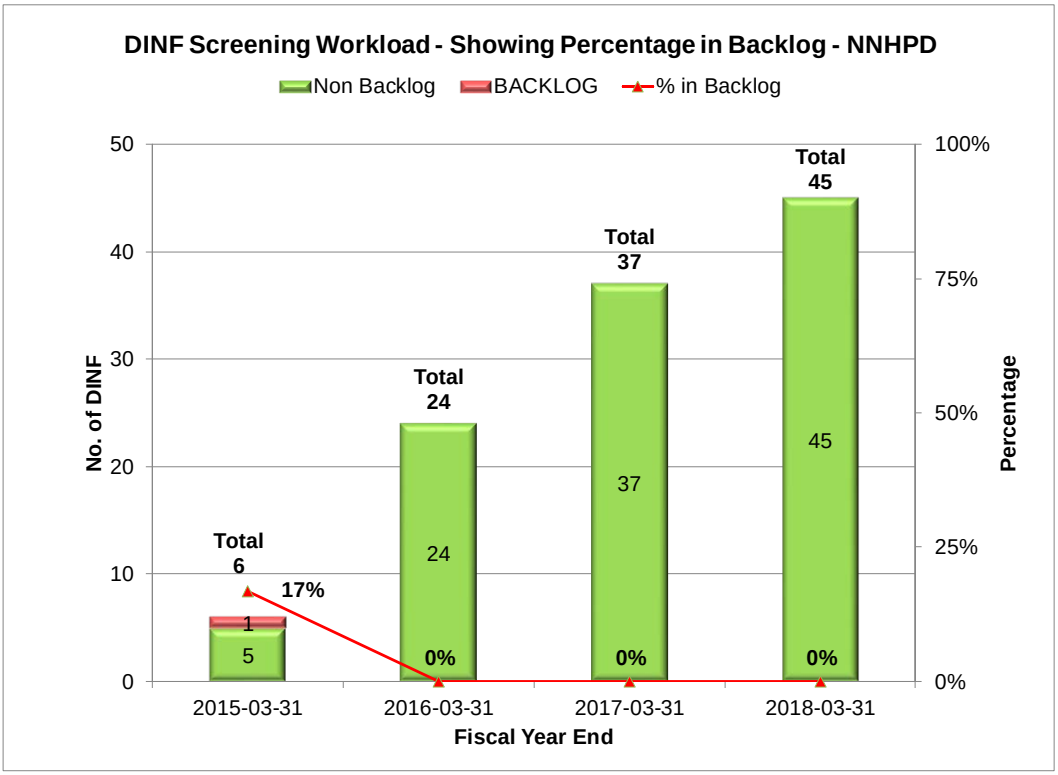
DINF: Received by Fee Category



	2014/2015	2015/2016	2016/2017	2017/2018
DINF - ADMINISTRATIVE	0	2	6	2
DINF - LABELLING STANDARD	195	224	206	183
Total	195	226	212	185

WORKLOAD

DINF: SCREENING Workload Showing Percentage in Backlog



DINF: Screening Workload by Fee Category

DINF SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Standard	**6**	**24**	**35**	**45**
Backlog	*1*	*0*	*0*	*0*
Administrative	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*
Total	**6**	**24**	**37**	**45**
Non Backlog	**5**	**24**	**37**	**45**
BACKLOG	**1**	**0**	**0**	**0**
% in Backlog	**17%**	**0%**	**0%**	**0%**

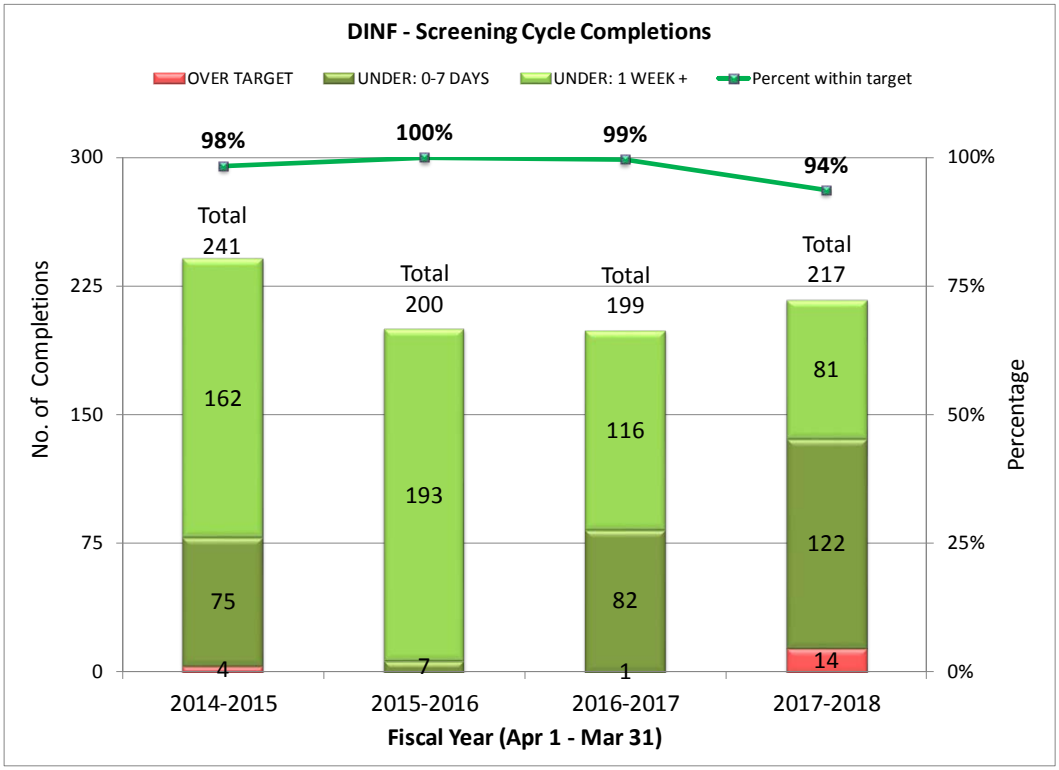
DECISION DOCUMENTS

DINF: Decision Documents by Fee Category

User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	218	199	152	134
	NO OBJECTION LETTER	0	0	1	1
	DIN INCORR SUBTYPE-CLASS	4	0	0	0
	NEW DRUG LETTER SCREEN	4	1	0	1
	CANCELLATION LETTER	6	2	15	6
	REJECTION LETTER (SCR)	3	0	8	4
	SCREENING DEFICIENCY NOTICE	11	1	30	75
ADMINISTRATIVE	CANCELLATION LETTER	0	1	0	2
	NOTIFICATION FORM DIN SUB	0	0	2	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0
	REJECTION LETTER (SCR)	0	1	1	0

PERFORMANCE

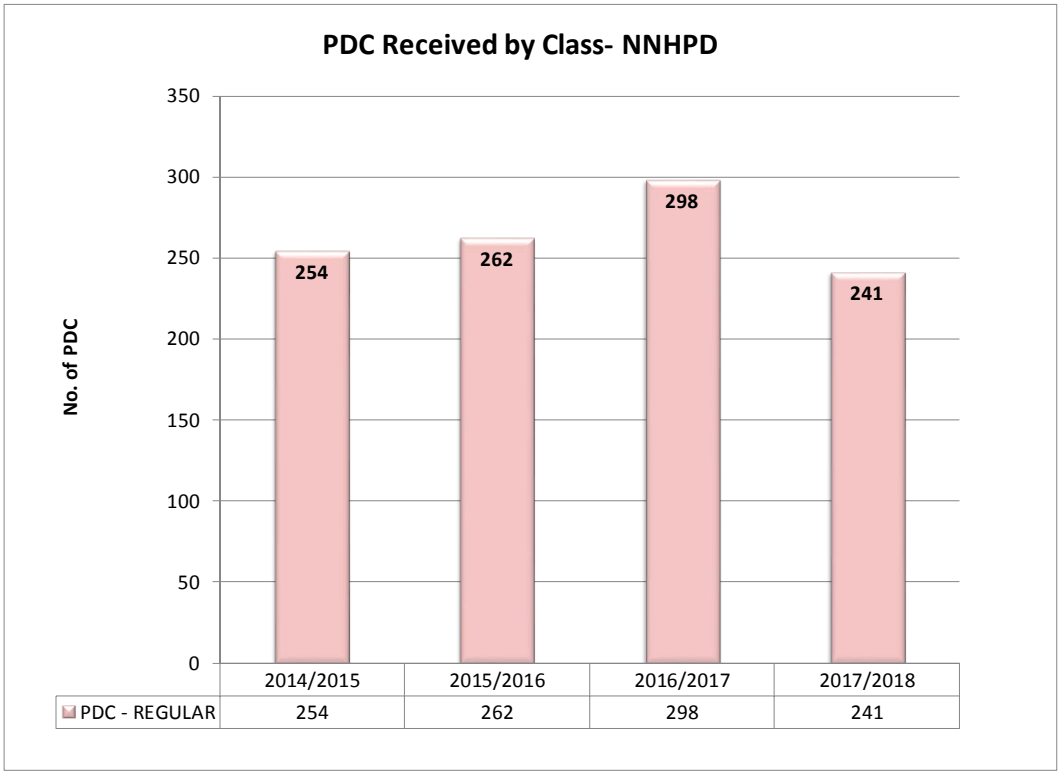
DINF: Screening Cycle Completions



PDC: POST AUTHORIZATION DIVISION 1 CHANGES

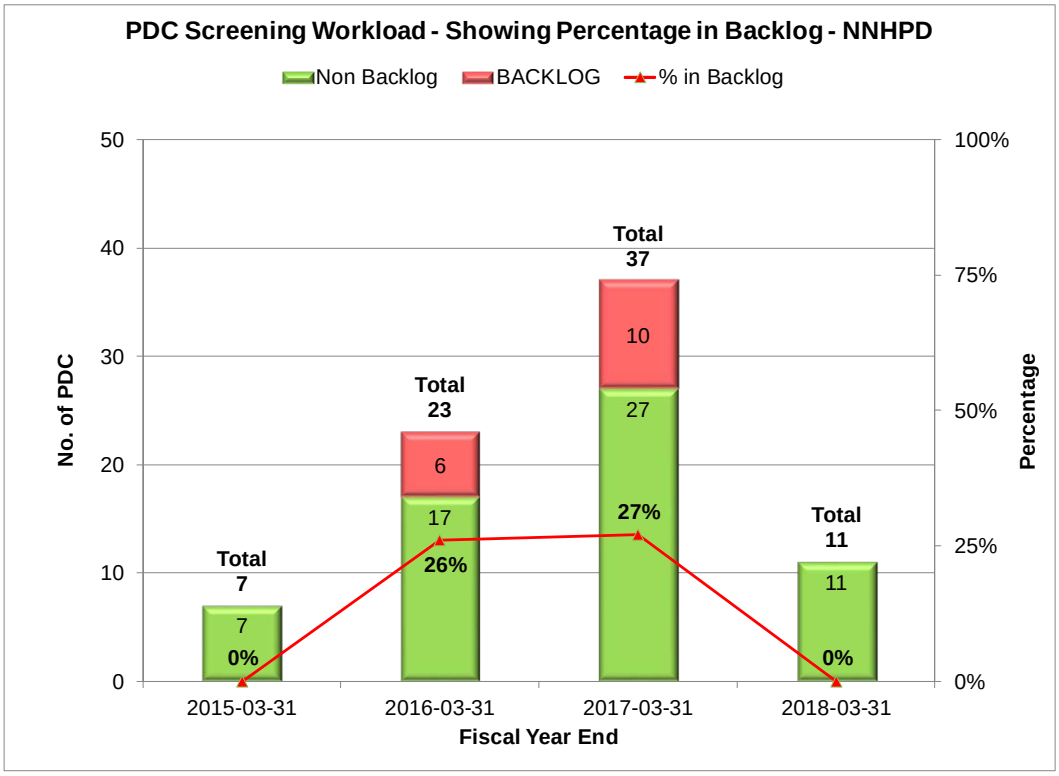
SUBMISSIONS RECEIVED

PDC: Received by Fee Category



WORKLOAD

PDC: SCREENING Workload Showing Percentage in Backlog



PDC: Screening Workload by Fee Category

PDC SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Regular	**7**	**23**	**37**	**11**
Backlog	*0*	*6*	*10*	*0*
Total	**7**	**23**	**37**	**11**
Non Backlog	**7**	**17**	**27**	**11**
BACKLOG	**0**	**6**	**10**	**0**
% in Backlog	**0%**	**26%**	**27%**	**0%**

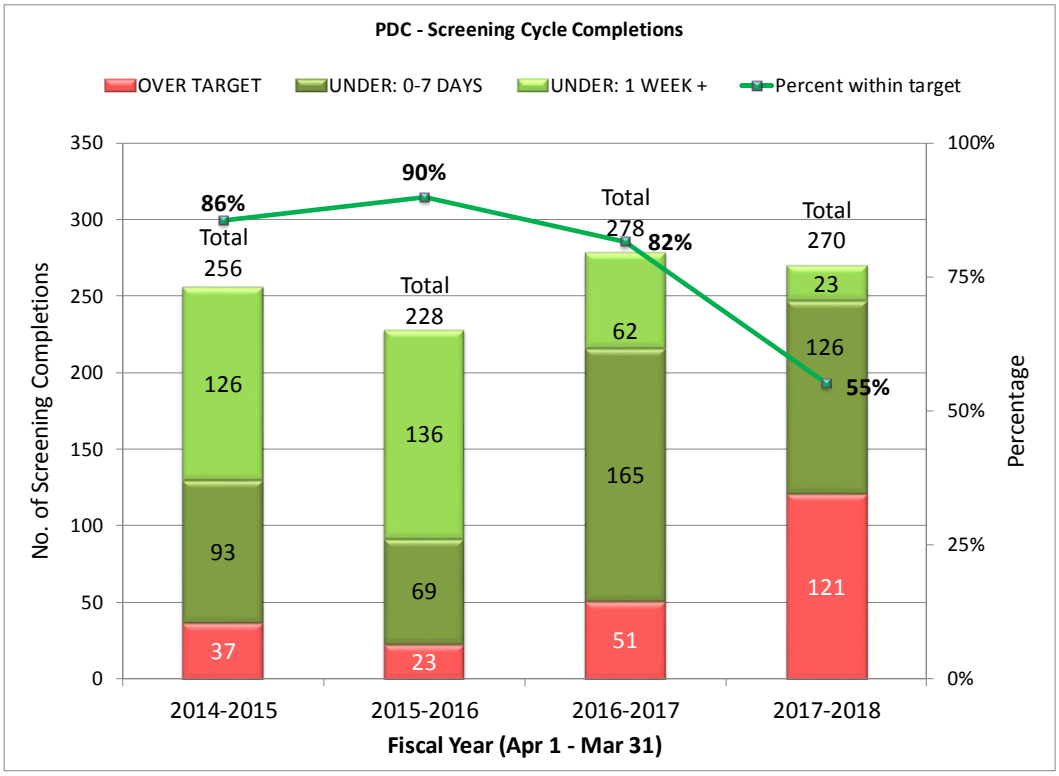
DECISION DOCUMENTS

PDC: Decision Documents by fee Category

Class	Decision	2014/2015	2015/2016	2016/2017	2017/2018
REGULAR	NO OBJECTION LETTER	241	212	268	256
	NOT SATISFACTORY NOTICE	7	12	9	9
	NOTIFICATION FORM DIN SUB	1	1	0	0
	CANCELLATION LETTER	8	14	3	5

PERFORMANCE

PDC: Screening Cycle Completions



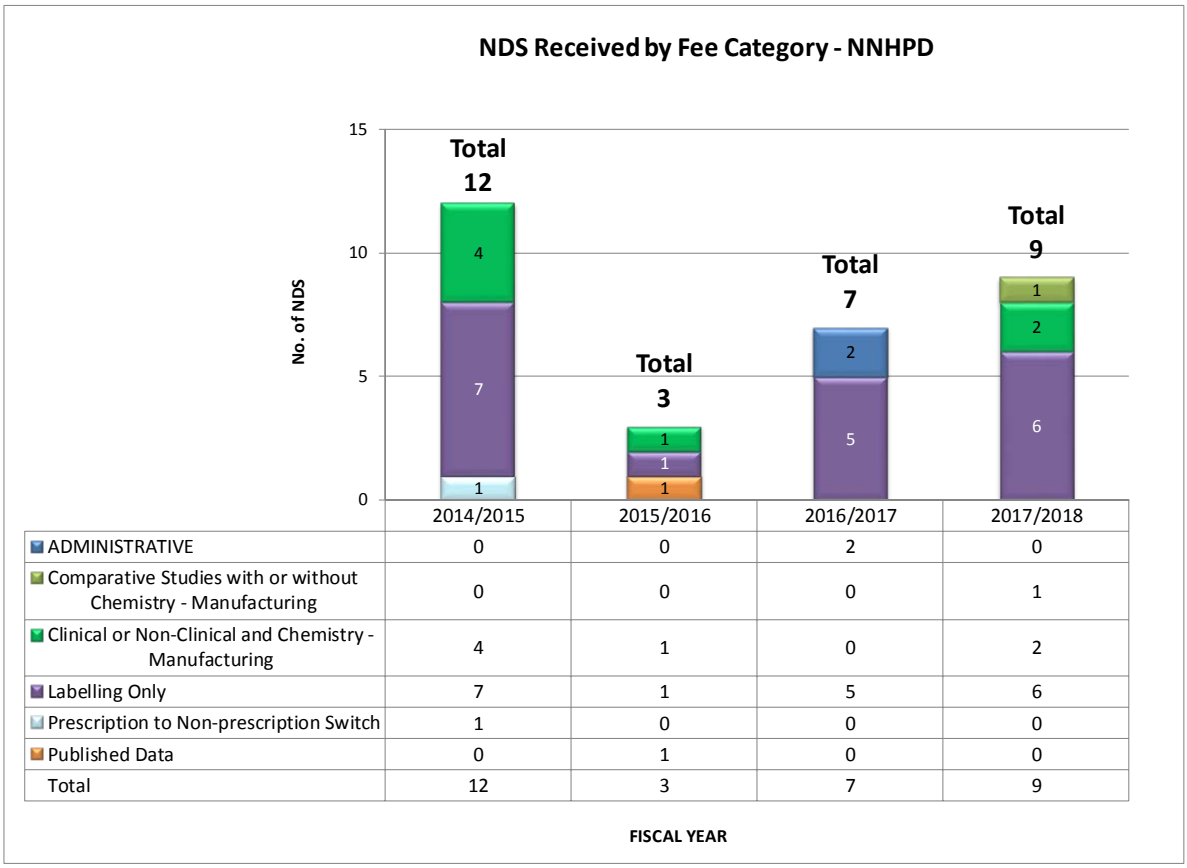
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS: NEW DRUG SUBMISSIONS

SUBMISSIONS RECEIVED

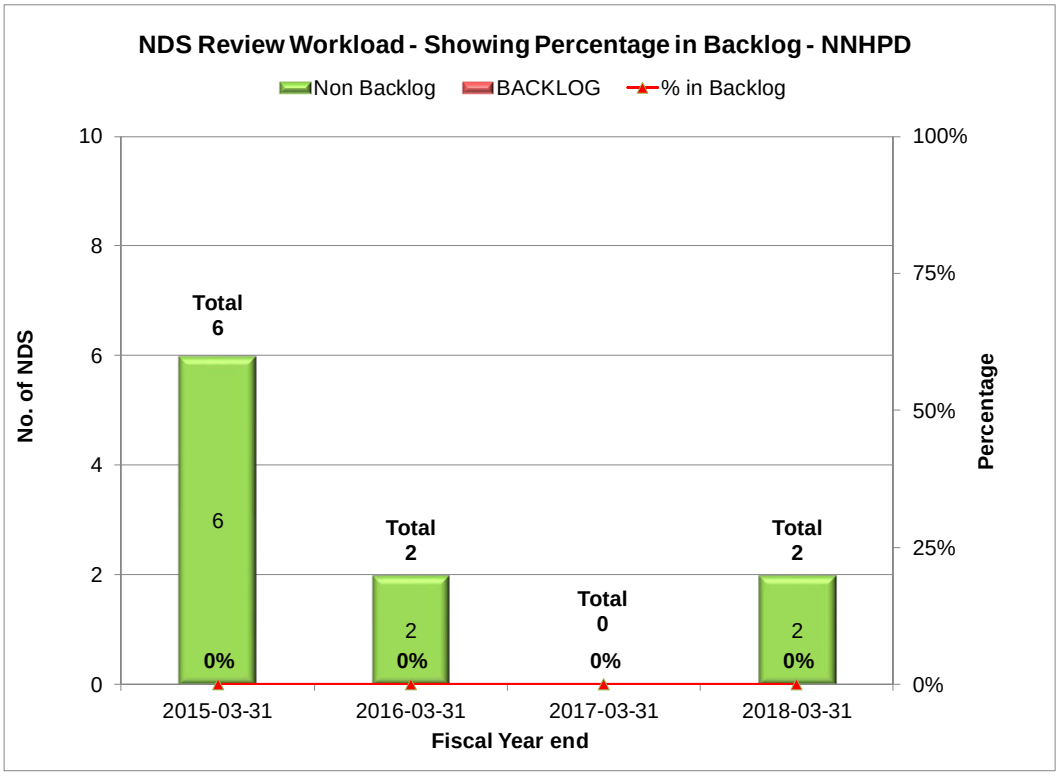
NDS: Received by Fee Category



	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	0	0	2	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	1
Clinical or Non-Clinical and Chemistry - Manufacturing	4	1	0	2
Labelling Only	7	1	5	6
Prescription to Non-prescription Switch	1	0	0	0
Published Data	0	1	0	0
Total	12	3	7	9

WORKLOAD

NDS: REVIEW Workload Showing Percentage in Backlog

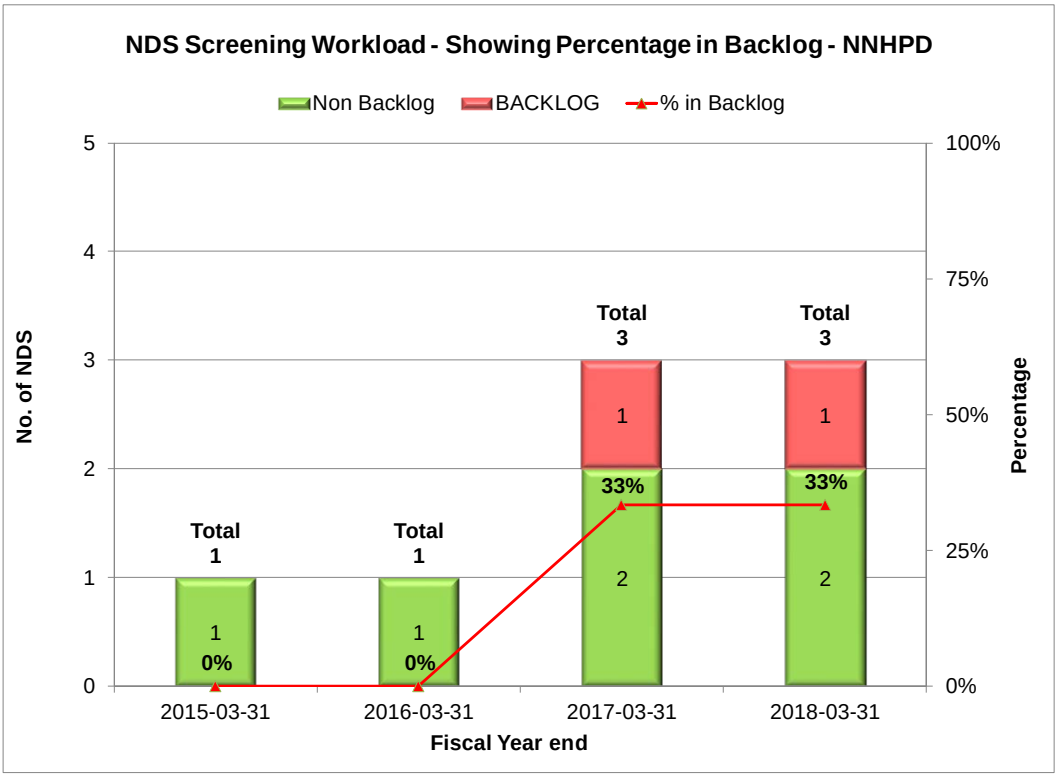


NDS: Review Workload by Fee Category

NDS REVIEW WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	**4**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*
Labelling Only	**2**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*
Total	**6**	**2**	**0**	**2**
Non Backlog	**6**	**2**	**0**	**2**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

WORKLOAD

NDS: SCREENING Workload / Backlog



NDS: Screening Workload by Fee Category

NDS SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Prescription to Non-Prescription Switch	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*
Published Data Only	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*
Labelling Only	0	0	3	1
Backlog	**0**	**0**	**1**	**1**
Clinical or Non-Clinical /C&M	0	0	0	1
Backlog	**0**	**0**	**0**	**0**
Comparative Studies with or without C&M	0	0	0	1
Backlog	**0**	**0**	**0**	**0**
Total	**1**	**1**	**3**	**3**
Non Backlog	**1**	**1**	**2**	**2**
BACKLOG	**0**	**0**	**1**	**1**
% in Backlog	**0%**	**0%**	**33%**	**33%**

DECISION DOCUMENTS

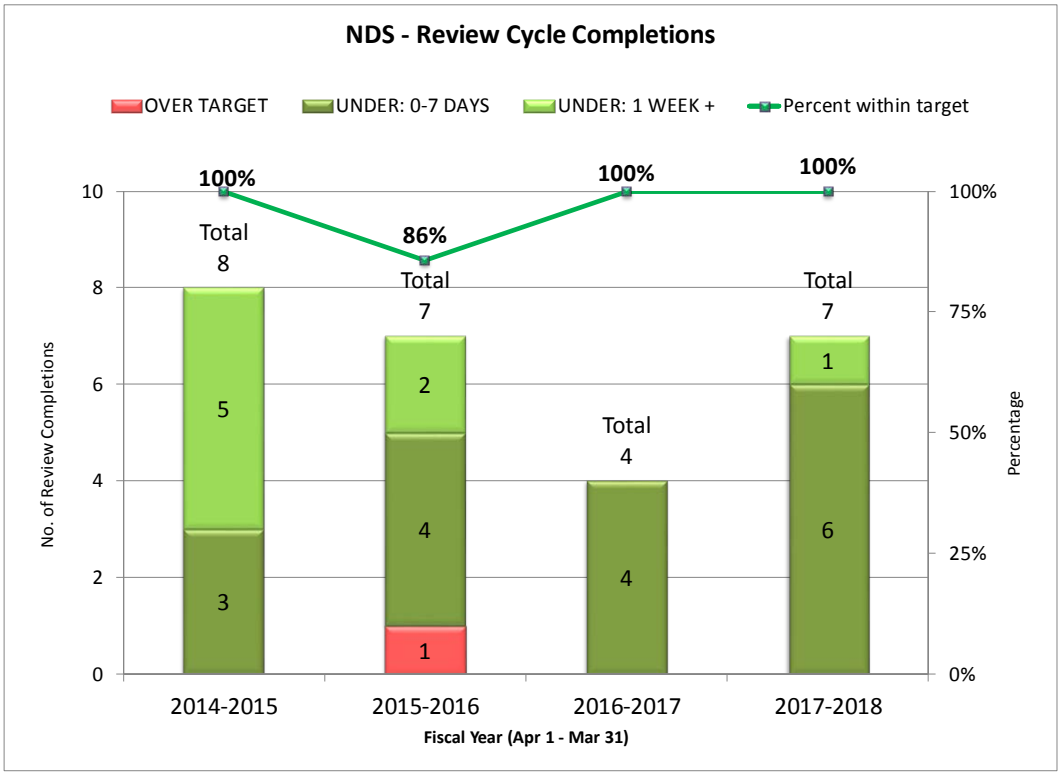
NDS: Decision Documents by Fee Category

User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	CANCELLATION LETTER	0	0	2	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	3	1	0	1
	NOC ON HOLD (SWITCH)*	0	2	0	0
	NOD WITHDRAWAL LETTER	0	1	0	0
	NOTICE OF COMPLIANCE*	0	1	1	0
	NOTICE OF DEFICIENCY	0	1	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	2	0	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	5	2	3	6
	CANCELLATION LETTER	0	0	0	1
	SCREENING DEFICIENCY NOTICE	1	0	2	3
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	1	1	0	0

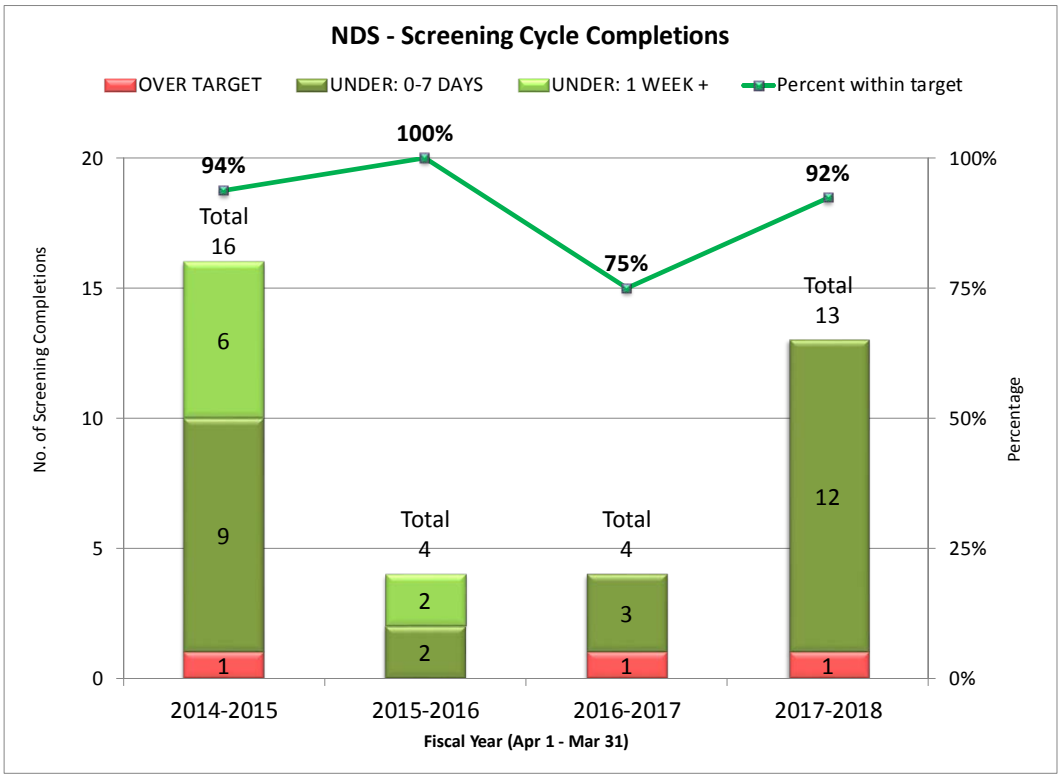
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: REVIEW Cycle Completions Showing Percentage within Target



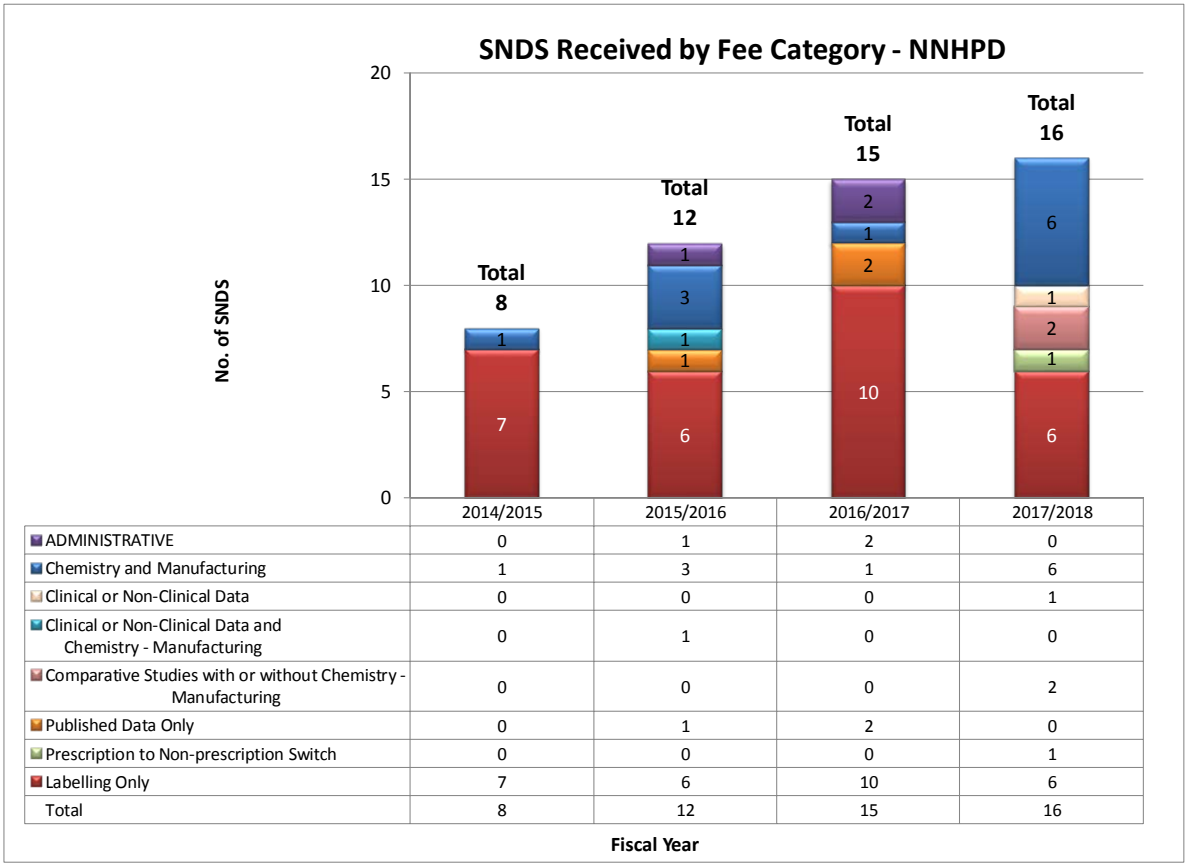
NDS: SCREENING Cycle Completions Showing Percentage within Target



SNDS: SUPPLEMENTAL NEW DRUG SUBMISSIONS

SUBMISSIONS RECEIVED

SNDS: Received by Fee Category

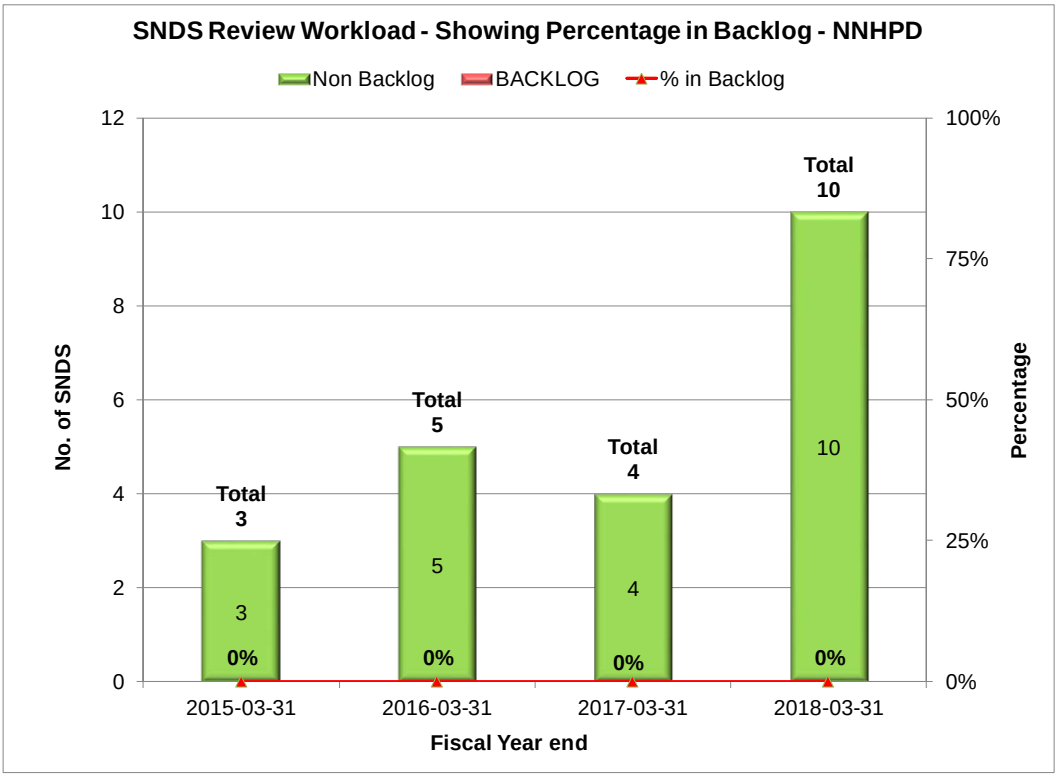


	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	0	1	2	0
Chemistry and Manufacturing	1	3	1	6
Clinical or Non-Clinical Data	0	0	0	1
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	1	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	2
Published Data Only	0	1	2	0
Prescription to Non-prescription Switch	0	0	0	1
Labelling Only	7	6	10	6
Total	8	12	15	16

Fiscal Year

WORKLOAD

SNDS: REVIEW Workload Showing Percentage in Backlog

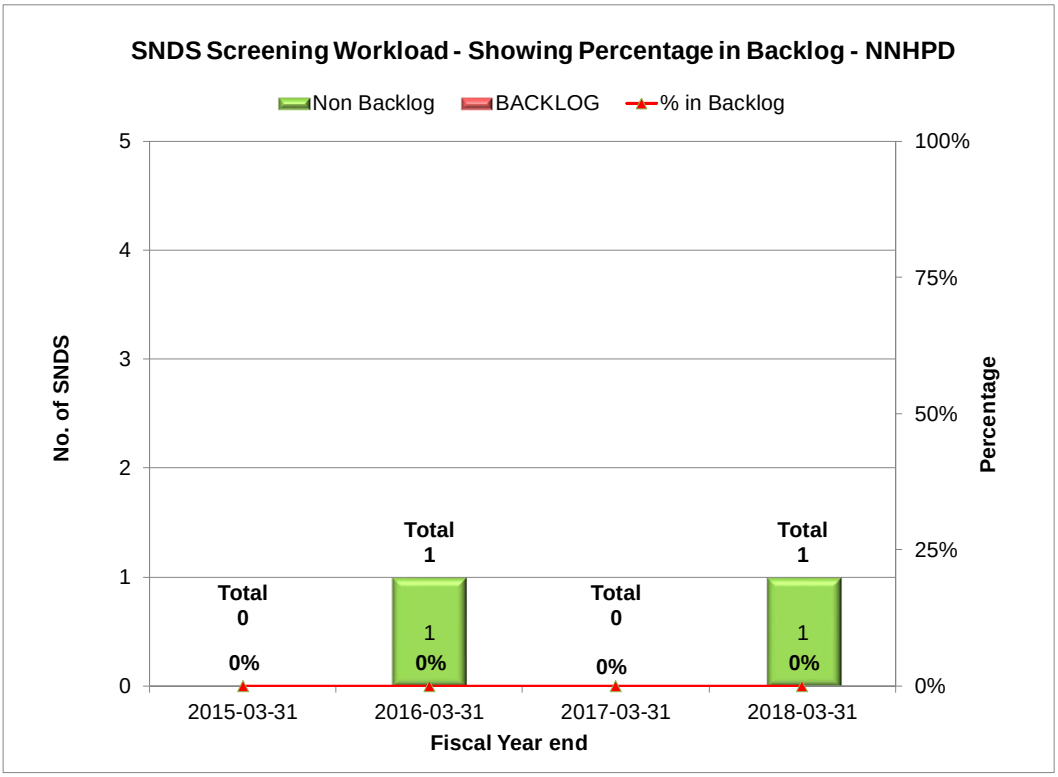


SNDS: Review Workload by Fee Category

SNDS REVIEW WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Labelling Only	**2**	**1**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*
Published Data Only	**0**	**1**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*
Chemistry and Manufacturing	**1**	**2**	**1**	**4**
Backlog	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data and C&M	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*
Clinical or Non-Clinical Data	***0***	***0***	***0***	***1***
Backlog	*0*	*0*	*0*	*0*
Comparative Studies with or without C&M	***0***	***0***	***0***	***2***
Backlog	*0*	*0*	*0*	*0*
Prescription to Non-Prescription Switch	***0***	***0***	***0***	***1***
Backlog	*0*	*0*	*0*	*0*
Total	**3**	**5**	**4**	**10**
Non Backlog	**3**	**5**	**4**	**10**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

WORKLOAD

SNDS: SCREENING Workload Showing Percentage in Backlog



SNDS: Screening Workload by Fee Category

SNDS SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
Chemistry and Manufacturing	**0**	**1**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*
Total	**0**	**1**	**0**	**1**
Non Backlog	**0**	**1**	**0**	**1**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

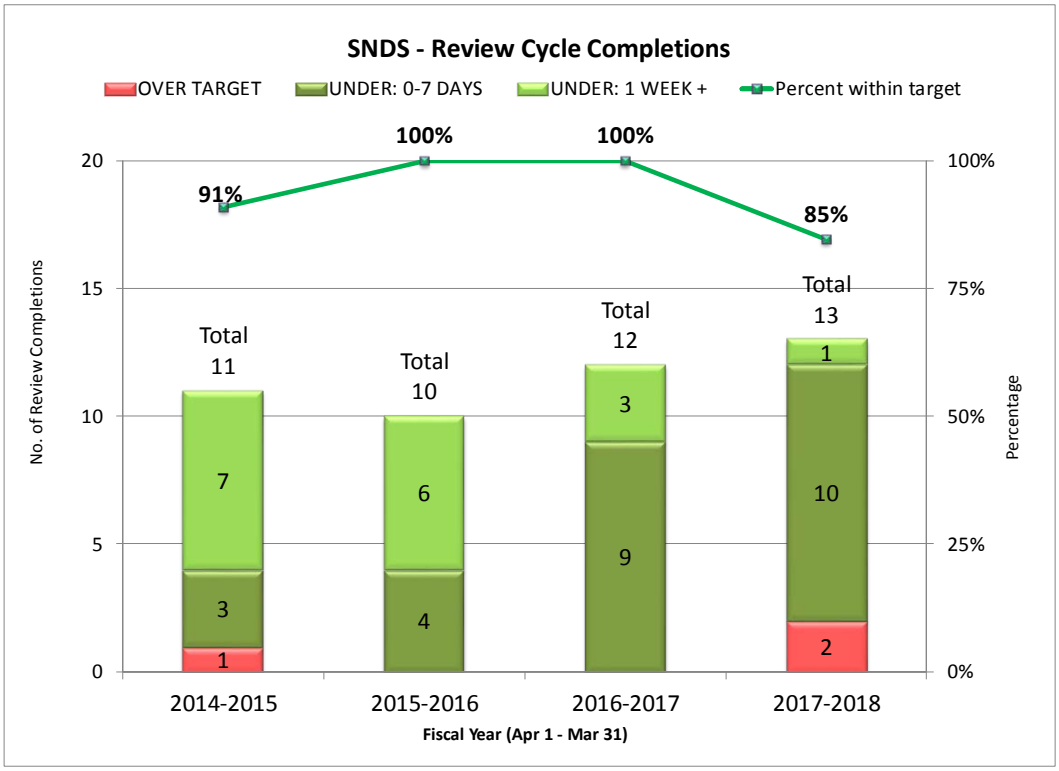
SNDS: Decision Documents by Fee Category

User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	1	0	0	0
	NOTICE OF COMPLIANCE*	2	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	1	0
CHEMISTRY AND MANUFACTURING	NOTICE OF COMPLIANCE*	0	1	2	3
	NOTICE OF NON-COMPLIANCE	0	1	1	0
	SCREENING DEFICIENCY NOTICE	0	1	1	5
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	2	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	1
ADMINISTRATIVE	CANCELLATION LETTER	0	1	2	0
	SCREENING DEFICIENCY NOTICE	0	0	2	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	1	1	0	0
	NOTICE OF COMPLIANCE*	4	6	5	6
	SCREENING DEFICIENCY NOTICE	1	0	3	3
	CANCELLATION LETTER	1	0	4	0
	NOTICE OF DEFICIENCY	0	0	1	0
	NOTICE OF NON-COMPLIANCE	0	1	0	1
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	0	0
PUBLISHED DATA ONLY	CANCELLATION LETTER	1	0	0	0
	NOTICE OF COMPLIANCE*	0	0	1	2
	SCREENING DEFICIENCY NOTICE	0	0	1	0

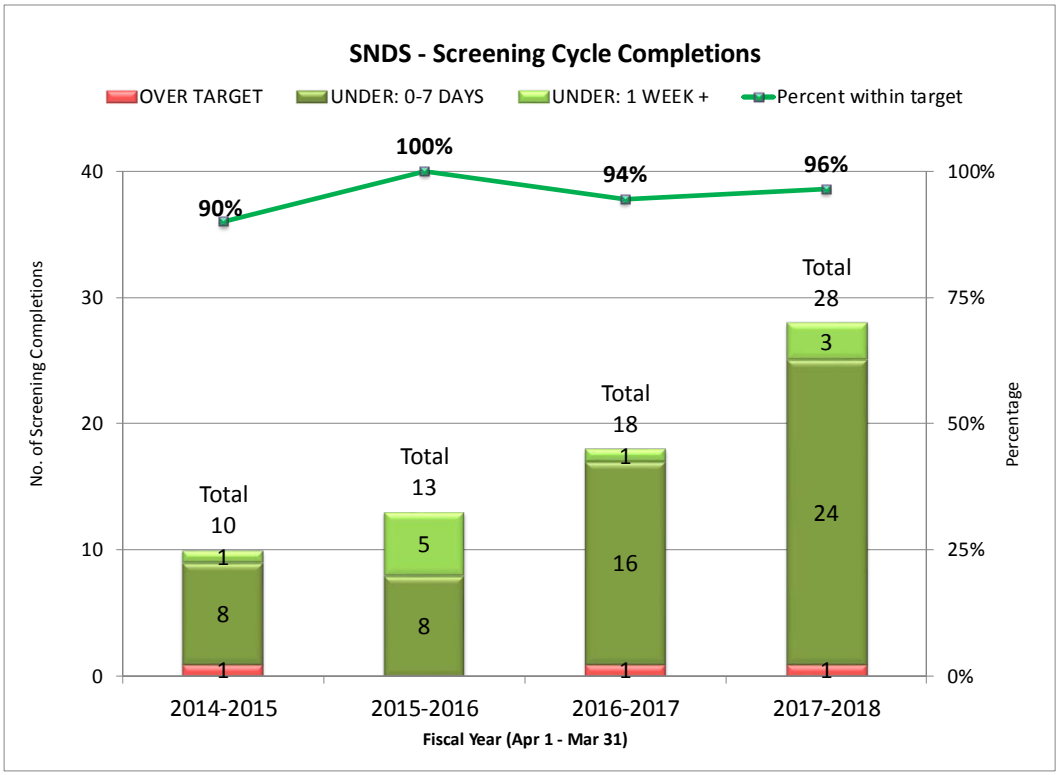
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: REVIEW Cycle Completions Showing Percentage within Target



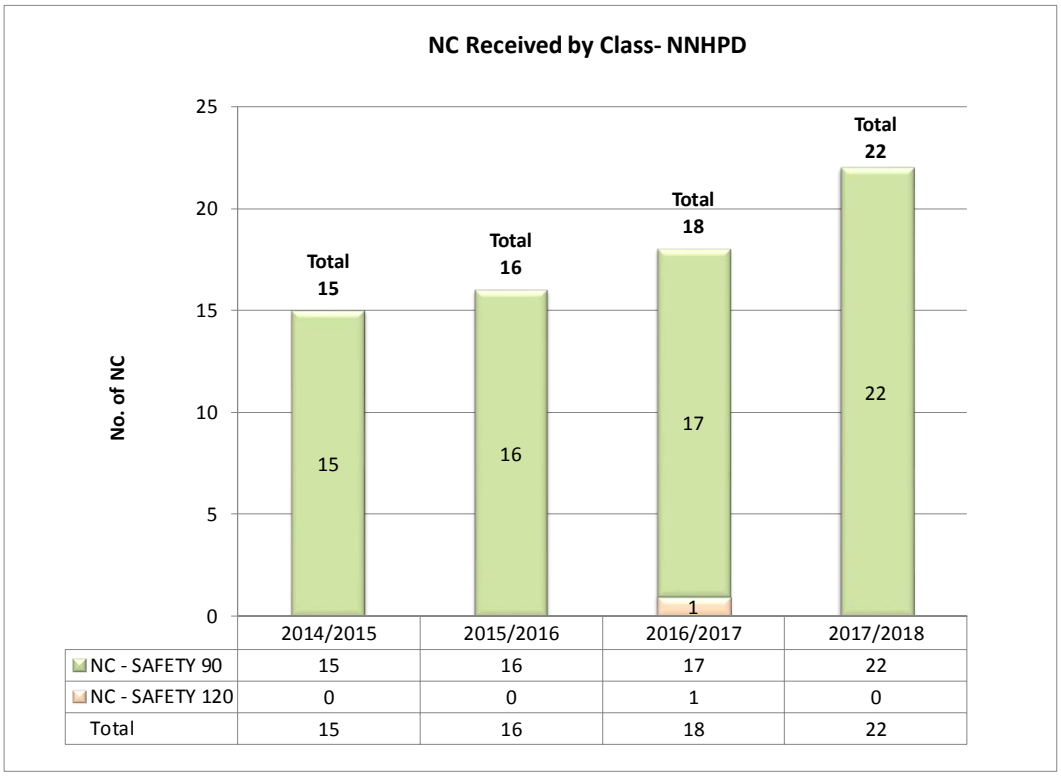
SNDS: SCREENING Cycle Completions Showing Percentage within Target



NC: NOTIFIABLE CHANGES

SUBMISSIONS RECEIVED

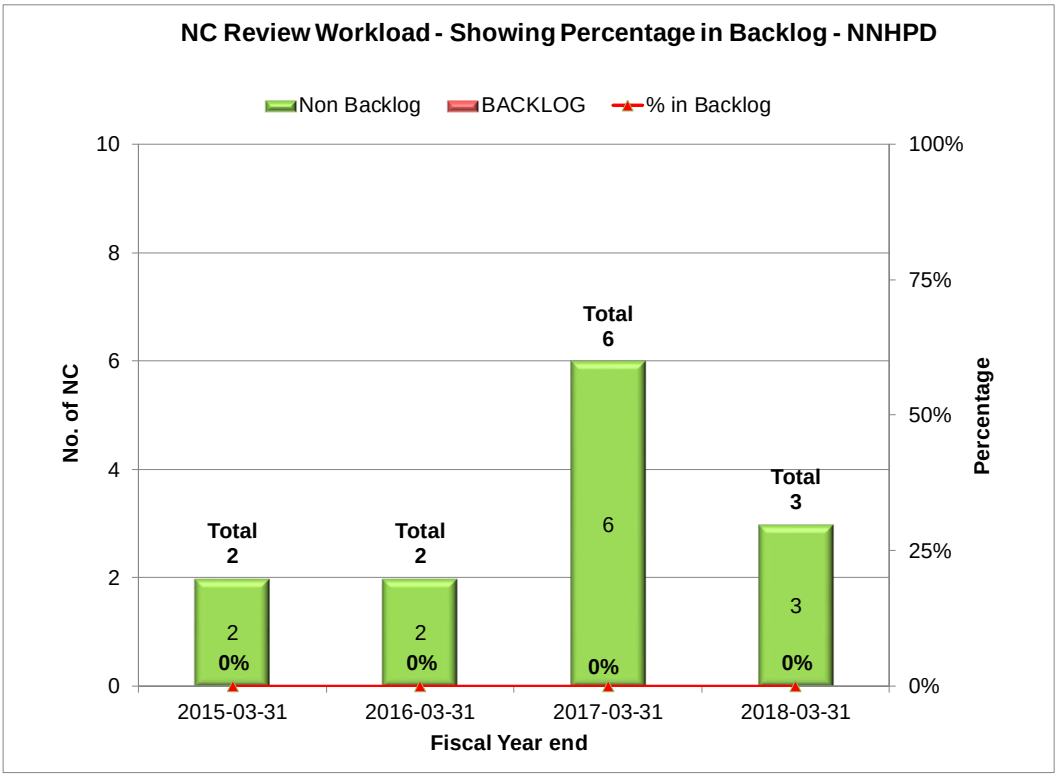
NC: Received by Fee Category



	2014/2015	2015/2016	2016/2017	2017/2018
NC - SAFETY 90	15	16	17	22
NC - SAFETY 120	0	0	1	0
Total	15	16	18	22

WORKLOAD

NC: REVIEW Workload Showing Percentage in Backlog

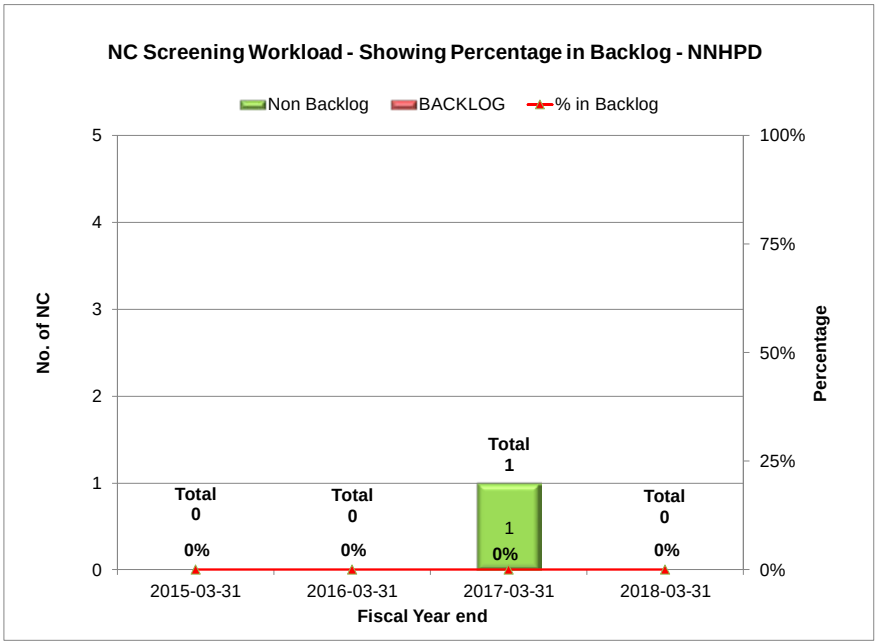


NC: Review Workload by Fee Category

NC REVIEW WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
SAFETY 90	**2**	**2**	**5**	**3**
Backlog	*0*	*0*	*0*	*0*
SAFETY 120	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*
Total	**2**	**2**	**6**	**3**
Non Backlog	**2**	**2**	**6**	**3**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

WORKLOAD

NC: SCREENING Workload Showing Percentage in Backlog



NC: Screening Workload by Fee Category

NC SCREENING WORKLOAD BY FEE CATEGORY - NNHPD				
	2015-03-31	2016-03-31	2017-03-31	2018-03-31
SAFETY 90	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*
Total	**0**	**0**	**1**	**0**
Non Backlog	**0**	**0**	**1**	**0**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

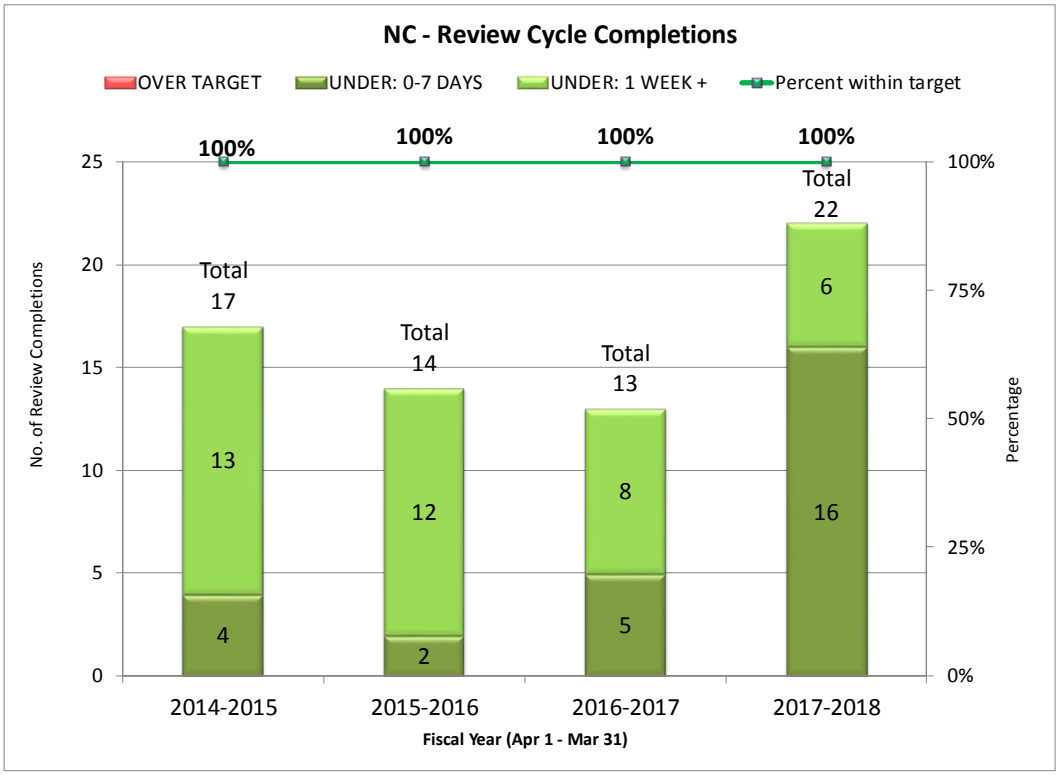
DECISION DOCUMENTS

NC: Decision Documents by Fee Category

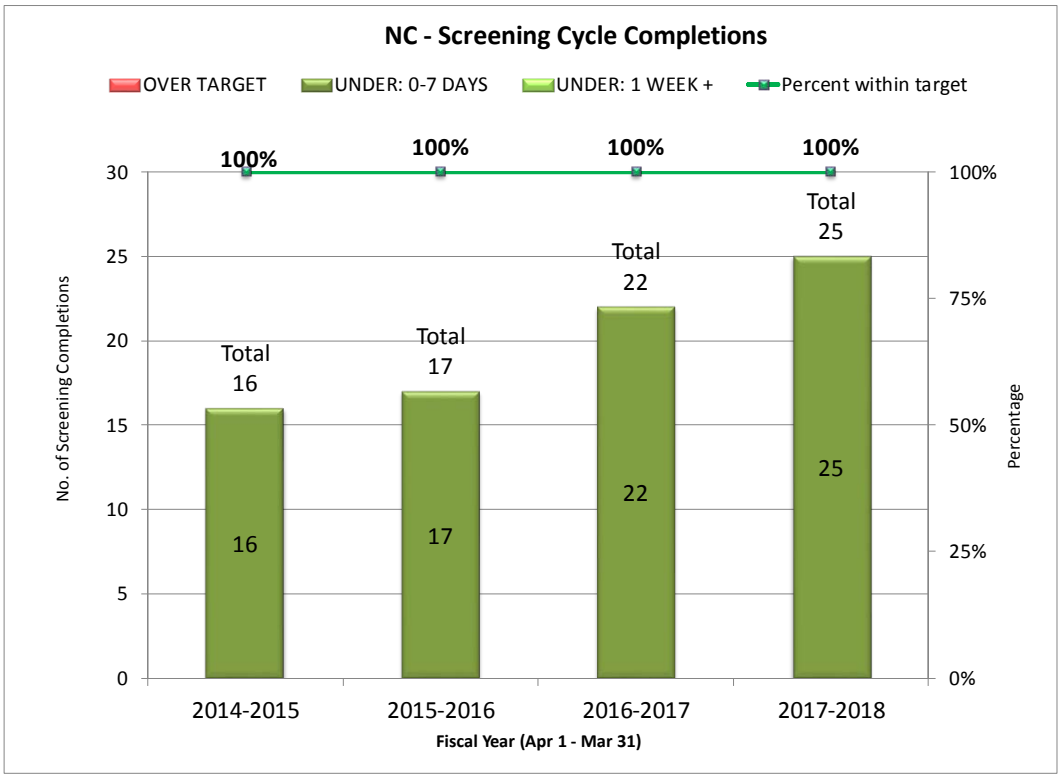
User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
SAFETY 90	NO OBJECTION LETTER	18	12	13	20
	CANCELLATION LETTER	0	0	1	2
	REJECTION LETTER (SCR)	0	0	1	1
	NOT SATISFACTORY NOTICE	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	3	4	5
	NC-HOLD (SWITCH)	1	1	0	0
SAFETY 120	CANCELLATION LETTER	0	0	0	1

PERFORMANCE

NC: REVIEW Cycle Completions Showing Percentage within Target



NC: SCREENING Cycle Completions Showing Percentage within Target



This page is left blank intentionally.

PART 2: DISINFECTANT DRUGS

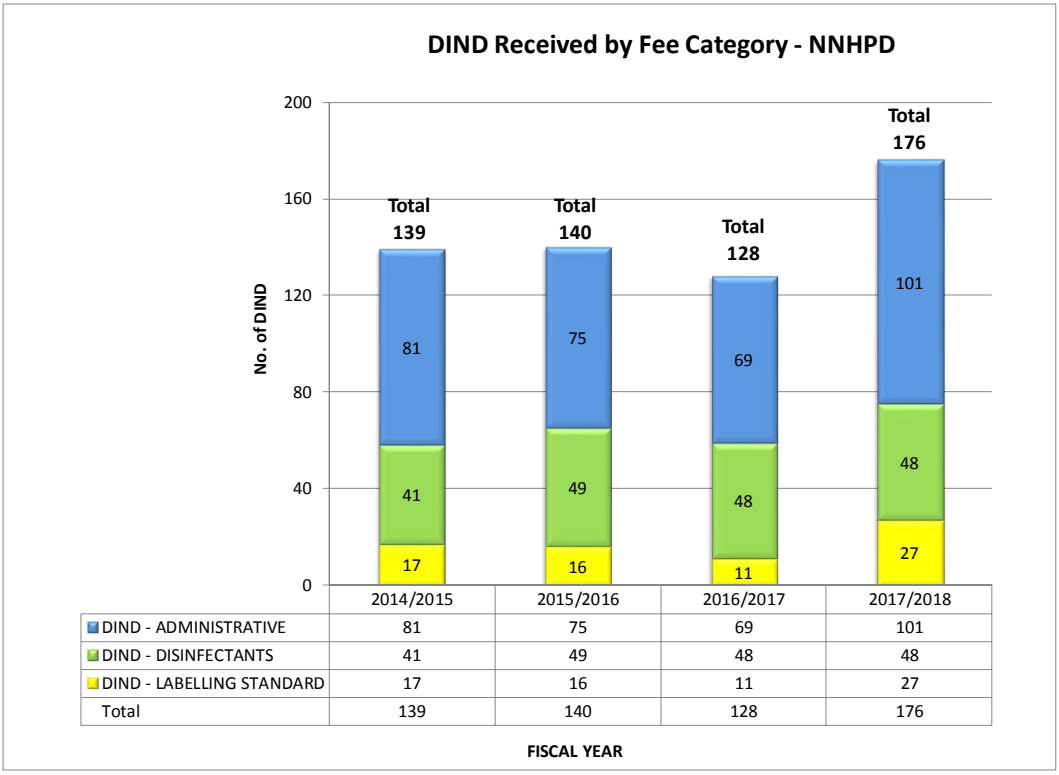
DISINFECTANTS DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: DIN APPLICATION – DISINFECTANT DRUG

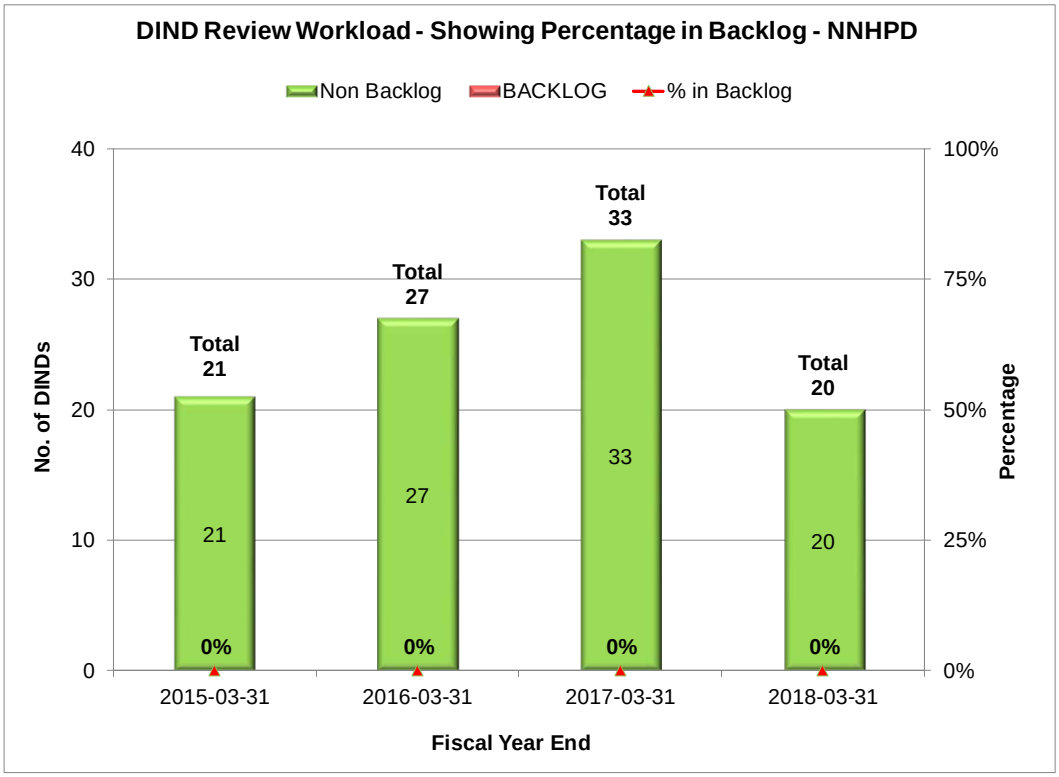
SUBMISSIONS RECEIVED

DIND: Received by Fee Category

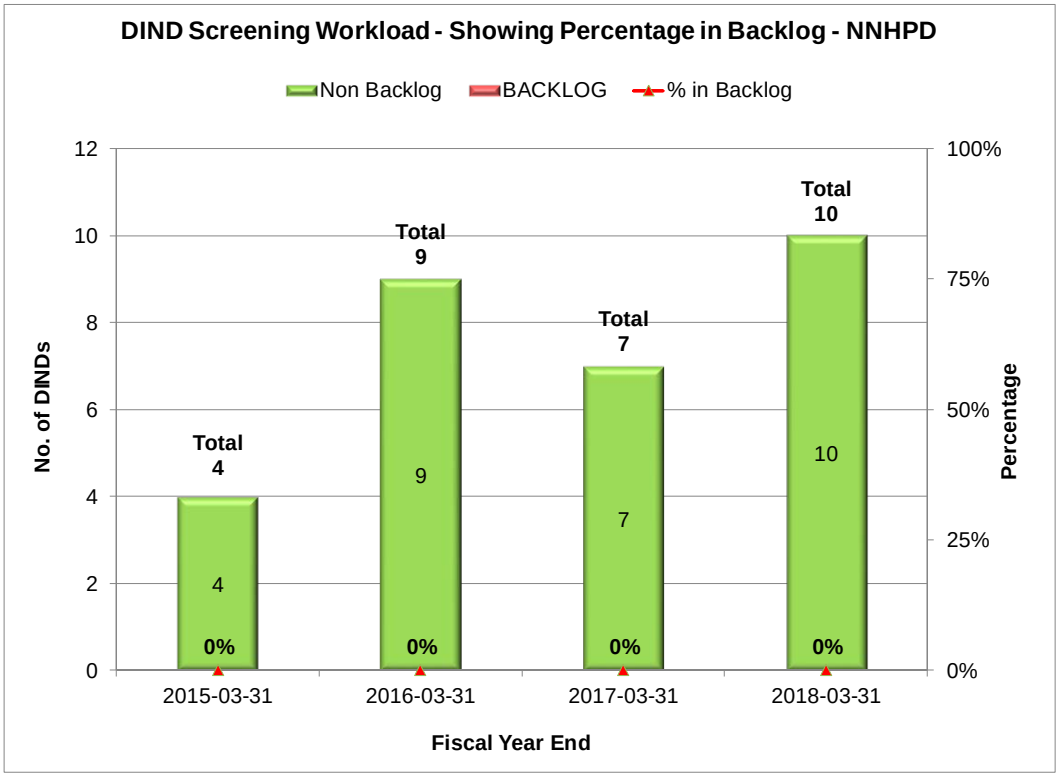


WORKLOAD

DIND: Review Workload Showing Percentage in Backlog

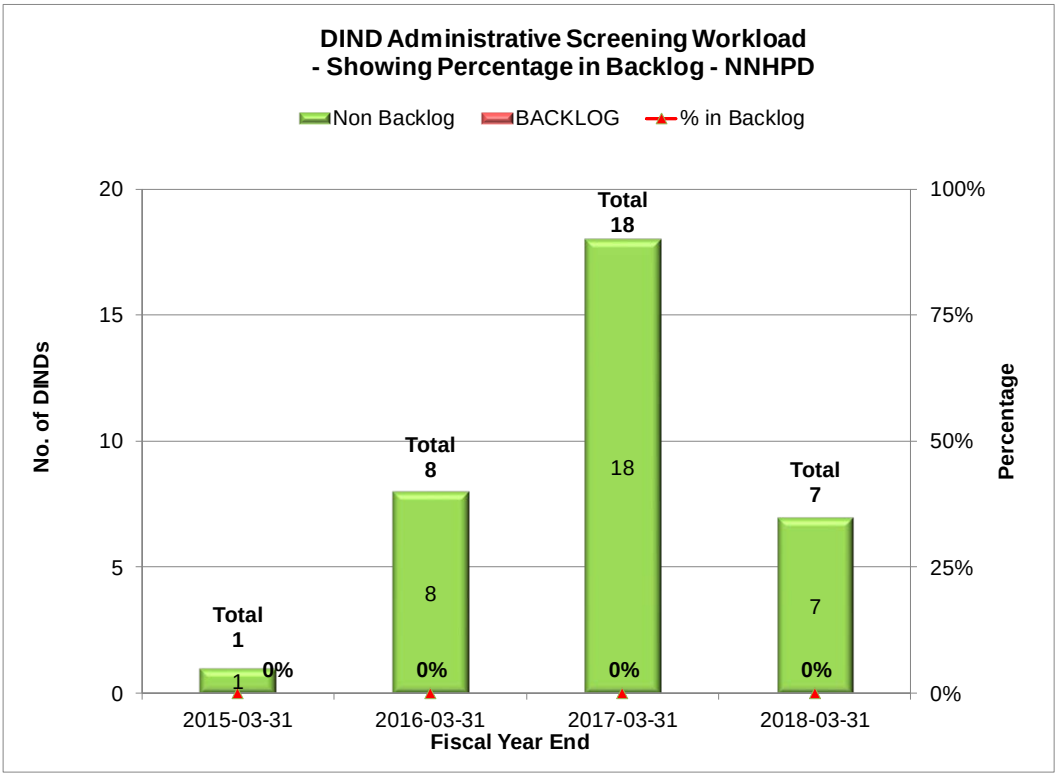


DIND: Screening Workload Showing Percentage in Backlog



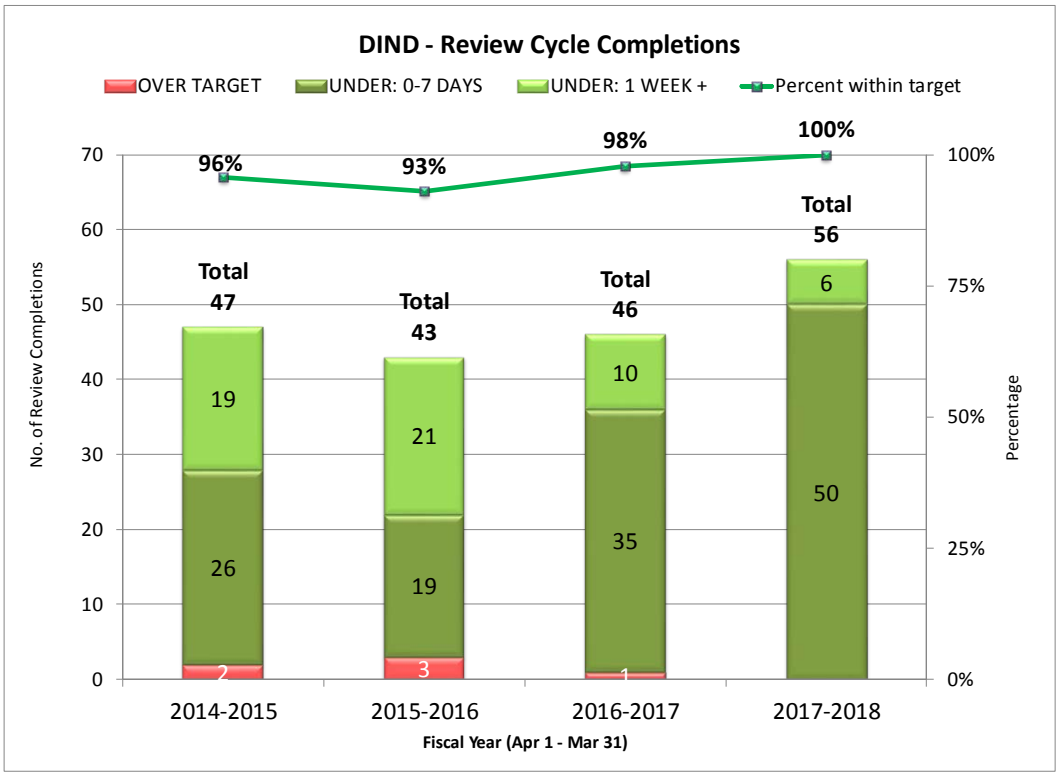
WORKLOAD

DIND: Administrative Screening Workload Showing Percentage in Backlog

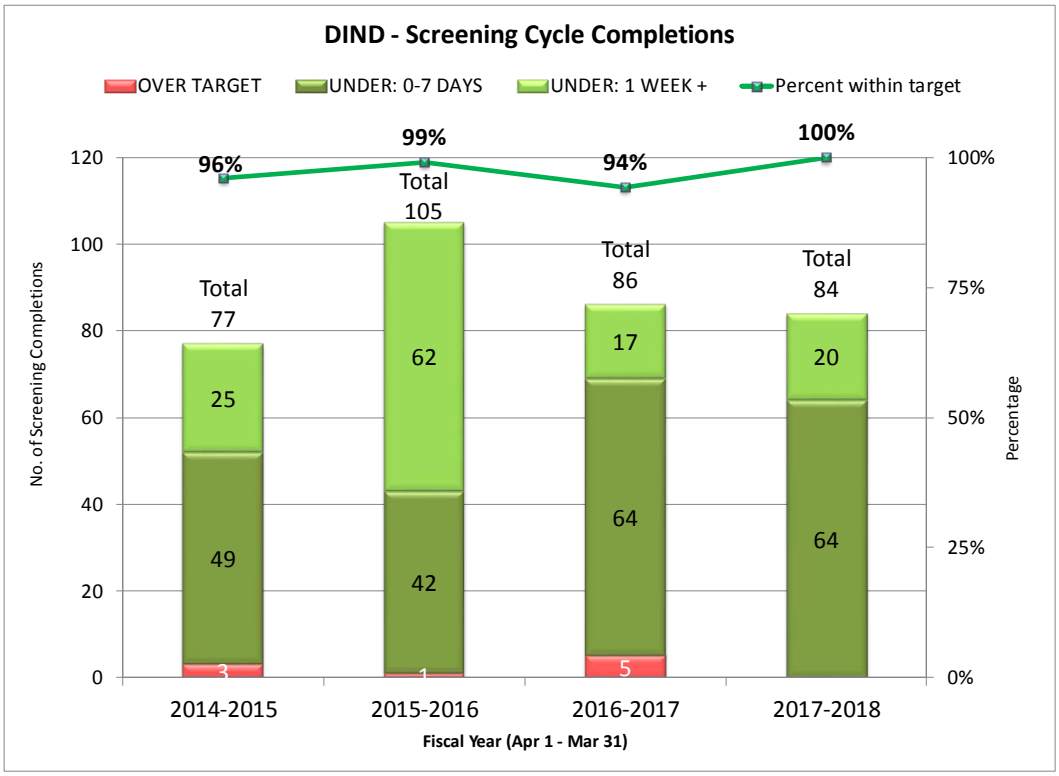


PERFORMANCE

DIND: Review Performance Showing Percentage within Target

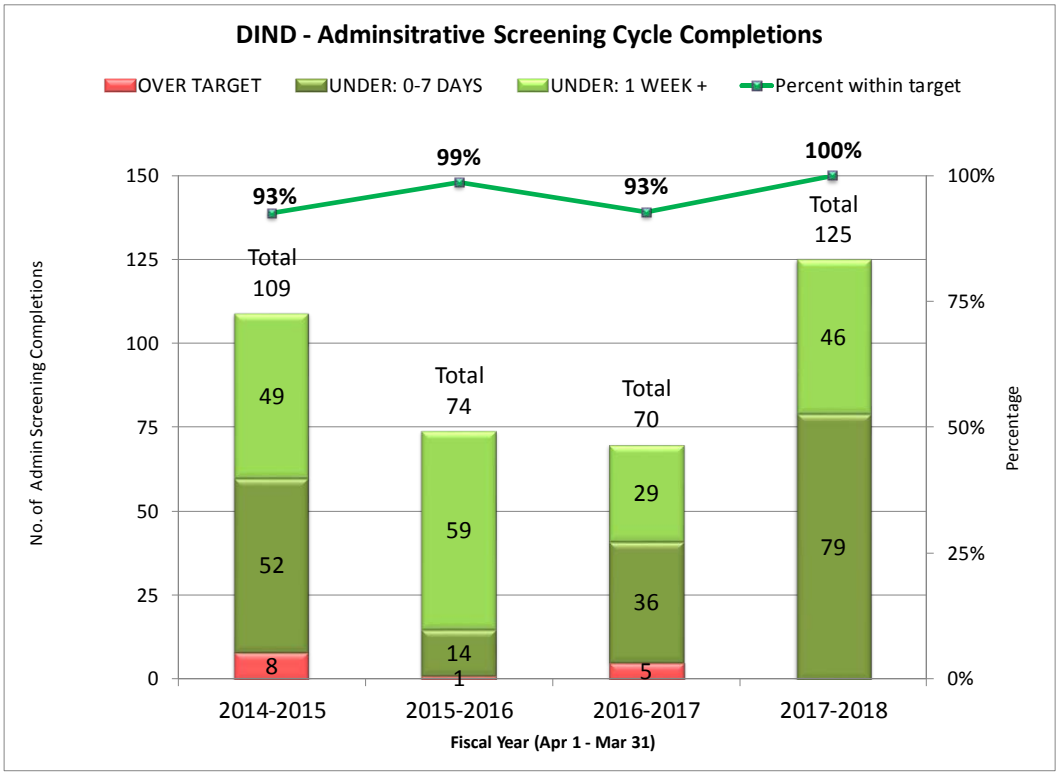


DIND: Screening Performance Showing Percentage within Target



PERFORMANCE

DIND: Administrative Screening Performance



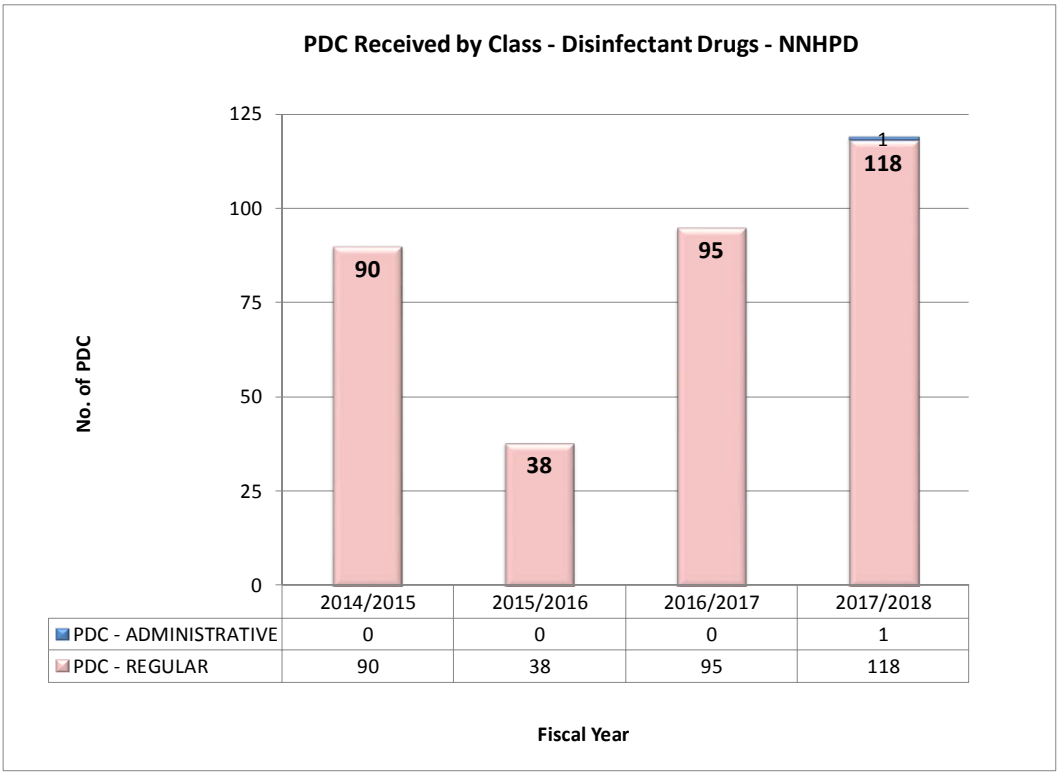
DECISION DOCUMENTS

DIND: Decisions by Fee Category

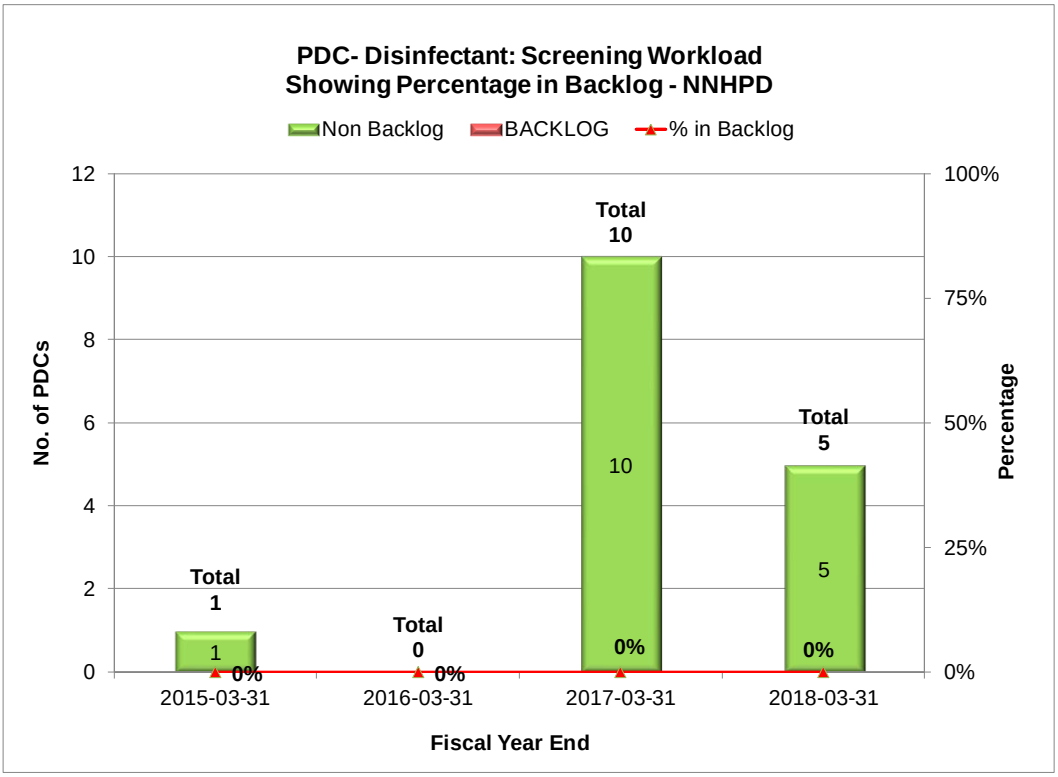
User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	NOTIFICATION FORM DIN SUB	90	54	43	94
	NO OBJECTION LETTER	1	0	3	0
	DIN INCORR SUBTYPE-CLASS	1	0	0	0
	CANCELLATION LETTER	2	3	1	2
	REJECTION LETTER (SCR)	3	9	9	15
	SCREENING DEFICIENCY NOTICE	14	11	18	20
DISINFECTANTS	NOTIFICATION FORM DIN SUB	25	20	27	37
	NO OBJECTION LETTER	14	10	9	17
	CANCELLATION LETTER	2	2	1	3
	NEW DRUG LETTER SCREEN	0	3	0	0
	NOD WITHDRAWAL LETTER	0	1	0	0
	NON WITHDRAWAL LETTER	1	1	0	0
	NOTICE OF DEFICIENCY	0	0	1	0
	NOTICE OF NON-COMPLIANCE	8	13	9	1
	DIN INCORR SUBTYPE-CLASS	2	0	0	0
	SCREENING DEFICIENCY NOTICE	3	30	20	5
	REJECTION LETTER (SCR)	1	3	6	1
	WITHDRAWAL NO RESP TO NON	0	1	0	0
	WITH.UNACCEPT.RESP.NON SC	1	0	0	0
LABELLING STANDARD	NOTIFICATION FORM DIN SUB	18	13	8	20
	NO OBJECTION LETTER	0	0	0	1
	SCREENING DEFICIENCY NOTICE	8	6	4	10
	REJECTION LETTER (SCR)	1	1	1	3

PDC: POST AUTHORIZATION DIVISION 1 CHANGE

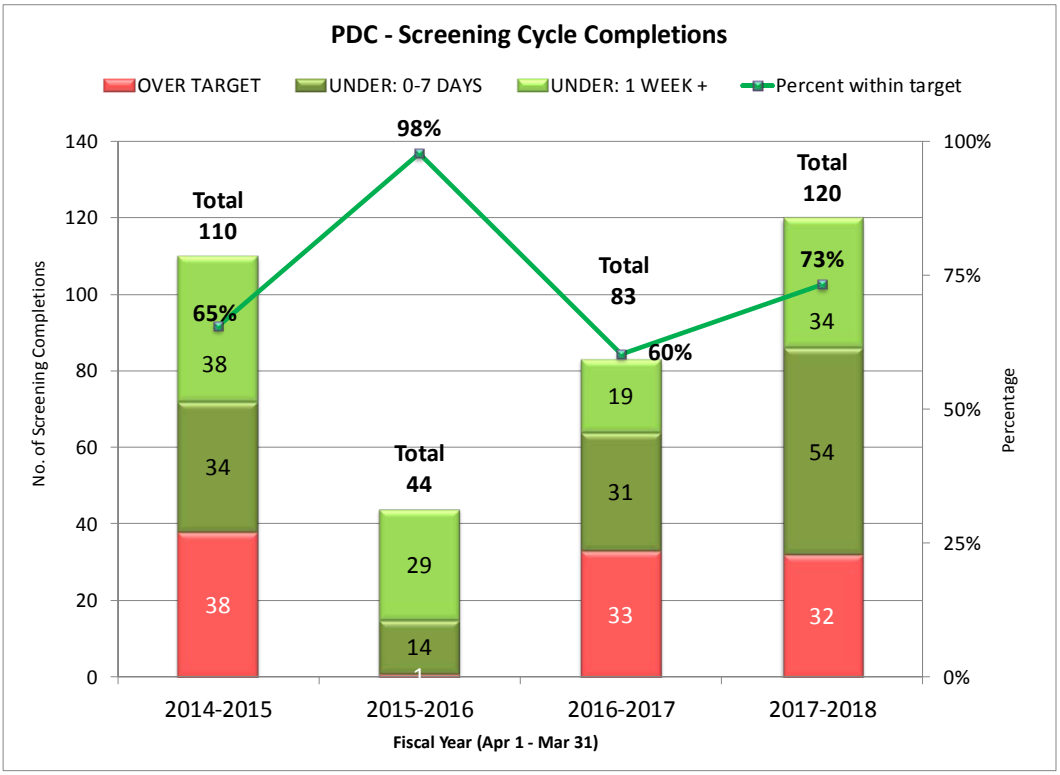
PDC: Received by Fee Category



PDC: Screening Workload Showing Percentage in Backlog



PDC: Screening Performance Showing Percentage within Target



PDC: Decisions by Fee Category

Class	Decision	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	1
REGULAR	NO OBJECTION LETTER	83	37	41	78
	NOT SATISFACTORY NOTICE	24	3	38	35
	CANCELLATION LETTER	2	1	1	0
	NOTIFICATION FORM DIN SUB	0	0	2	4
	REJECTION LETTER (SCR)	1	0	1	4

DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS: NEW DRUG SUBMISSIONS

SUBMISSIONS RECEIVED

NDS- Disinfectant Drug: Received by Fee Category

SUBMISSION TYPE - USER FEE CATEGORY	2014/2015	2015/2016	2016/2017	2017/2018
NDS-D: NEW DRUG SUBMISSION - DISINFECTANTS				
NDS-D DISINFECTANTS	1	1	4	2
NDS-D ADMINISTRATIVE	0	0	1	0
NDS-D Total	***1***	***1***	***5***	***2***

WORKLOAD

NDS- Disinfectant Drug: Review Workload/Backlog at Fiscal Year End

REVIEW Workload Submission Type - Category	2015-03-31	2016-03-31	2017-03-31	2018-03-31
NDS - Disinfectants	1	0	3	2
Backlog	0	0	0	0
Total Workload	**1**	**0**	**3**	**2**
Non Backlog	**1**	**0**	**3**	**2**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

NDS- Disinfectant Drug: Screening Workload/Backlog at Fiscal Year End

SCREENING Workload Submission Type - Category	2015-03-31	2016-03-31	2017-03-31	2018-03-31
NDS - Disinfectants	0	0	2	0
Backlog	0	0	0	0
Total Workload	**0**	**0**	**2**	**0**
Non Backlog	**0**	**0**	**2**	**0**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

PERFORMANCE

NDS- Disinfectant Drug: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2014-2015	0	0	6	100%	**6**
2015-2016	0	1	0	100%	**1**
2016-2017	0	0	0	0%	**0**
2017-2018	0	3	0	100%	**3**

NDS- Disinfectant Drug: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2014-2015	0	0	4	100%	**4**
2015-2016	0	0	1	100%	**1**
2016-2017	0	0	6	100%	**6**
2017-2018	0	9	0	100%	**9**

NDS- Disinfectant Drug: Administrative Screening Performance

ADMIN SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2014-2015	0	0	0	0%	**0**
2015-2016	0	0	0	0%	**0**
2016-2017	1	0	0	0%	**1**
2017-2018	0	0	0	0%	**0**

DECISION DOCUMENTS

NDS- Disinfectant Drug: Decisions by Fee Category

User Fee Category	Decision	2014/2015	2015/2016	2016/2017	2017/2018
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0
DISINFECTANTS	NOTICE OF COMPLIANCE*	3	1	0	1
	NOTICE OF NON-COMPLIANCE	3	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	3
	NOD WITHDRAWAL LETTER	0	0	0	1
	REJECTION LETTER SCREENING	0	0	0	2
	CANCELLATION LETTER	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	1	3	3

*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 CHANGES

SUBMISSIONS RECEIVED

NC- Disinfectant Drugs Received by Fee Category

SUBMISSION TYPE - CLASS	2014/2015	2015/2016	2016/2017	2017/2018
NC: NOTIFIABLE CHANGE - NEW DRUG				
NC - SAFETY 90	4	0	0	1

WORKLOAD

NC- Disinfectant Drug: Review Workload / Backlog at Year End

REVIEW Workload Submission Type - Category	2015-03-31	2016-03-31	2017-03-31	2018-03-31
NC - Safety-90	2	1	0	0
Backlog	0	0	0	0
Total Workload	**2**	**1**	**0**	**0**
Non Backlog	**2**	**1**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

NC- Disinfectant Drug: Screening Workload / Backlog at Year End

SCREENING Workload Submission Type - Category	2015-03-31	2016-03-31	2017-03-31	2018-03-31
NC - Safety-90	3	0	0	0
Backlog	0	0	0	0
Total Workload	**3**	**0**	**0**	**0**
Non Backlog	**3**	**0**	**0**	**0**
BACKLOG	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**

PERFORMANCE

NC- Disinfectant Drug: Review Performance

REVIEW Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2014-2015	0	0	2	100%	**2**
2015-2016	0	0	1	100%	**1**
2016-2017	0	0	0	0%	**0**
2017-2018	0	0	1	100%	**1**

NC- Disinfectant Drug: Screening Performance

SCREENING Fiscal Year	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within target	Total
2014-2015	0	0	3	100%	**3**
2015-2016	0	0	0	0%	**0**
2016-2017	0	0	0	0%	**0**
2017-2018	0	1	0	100%	**1**

DECISION DOCUMENTS

NC- Disinfectant Drug: Decisions

Class	Decision	2014/2015	2015/2016	2016/2017	2017/2018
SAFETY 90	NO OBJECTION LETTER	2	1	0	1
	CANCELLATION LETTER	1	0	0	0

MPNDS: PRE–NDS MEETING

MPNDS - Disinfectant Drug: Received by Fee Category

SUBMISSION TYPE - CLASS	2014/2015	2015/2016	2016/2017	2017/2018
MPNDS: PRE - NDS MEETING				
MPNDS - CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	1	0	0	0