

June 27, 2017

Notice

Our File Number: 17-107392-203

Errata – Natural and Non-Prescription Health Products Directorate’s (NNHPD) Drug Submission Performance Annual Report Fiscal Year 2016-2017

A revised version of the Natural and Non-Prescription Health Products Directorate’s (NNHPD) Drug Submission Performance Annual Report, Fiscal Year 2016-2017 is now available. The original version was dated June 23, 2017, and the revised version is dated June 27, 2017.

Revisions were made to the highlights section of the overview on page 9.

To obtain a full electronic copy of the NNHPD Annual Drug Submission Performance Report, please contact publications@hc-sc.gc.ca.



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Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Annual Report Fiscal Year 2016 – 2017

April 1 2016 – March 31 2017
(Revisions to page 9 – June 27, 2017)



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Table of Contents

TABLE OF CONTENTS	4
OVERVIEW (REVISED JUNE 27, 2017)	9
ACRONYMS	11
Submission Types	11
Documents	11
FEE CATEGORIES	12
PART 1: NON PRESCRIPTION DRUGS	13
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1	13
DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS	14
SUBMISSIONS RECEIVED	14
DINA: Received by Fee Category	14
WORKLOAD	15
DINA: Review Workload Showing the Percentage in Backlog	15
DINA: Review Workload by Fee Category	15
DINA: Screening Workload Showing the Percentage in Backlog	16
DINA: Screening Workload by Fee Category	16
DINA: Administrative Screening Workload Showing the Percentage in Backlog	17
DINA: Administrative-Screening Workload by Fee Category	17
DECISION DOCUMENTS	18
DINA: Decision Documents by Fee Category	18
PERFORMANCE	19
DINA: REVIEW Cycle Completions Showing Percentage within Target	19
DINA: SCREENING Cycle Completions Showing Percentage within Target	19
DINA: Administrative Screening Completions Showing Percentage within Target	20
DINF: CATEGORY FOUR DIN APPLICATIONS	21
SUBMISSIONS RECEIVED	21
DINF: Received by Fee Category	21
WORKLOAD	22

DINF: SCREENING Workload Showing Percentage in Backlog.....	22
DINF: Screening Workload by Fee Category.....	22
DECISION DOCUMENTS	23
DINF: Decision Documents by Fee Category	23
PERFORMANCE	23
DINF: Screening Cycle Completions	23
PDC: POST AUTHORIZATION DIVISION 1 CHANGES	24
SUBMISSIONS RECEIVED.....	24
PDC: Received by Fee Category	24
WORKLOAD	25
PDC: SCREENING Workload Showing Percentage in Backlog	25
PDC: Screening Workload by Fee Category	25
DECISION DOCUMENTS	26
PDC: Decision Documents by fee Category.....	26
PERFORMANCE	26
PDC: Screening Cycle Completions.....	26
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8	27
NDS: NEW DRUG SUBMISSIONS	28
SUBMISSIONS RECEIVED.....	28
NDS: Received by Fee Category	28
WORKLOAD	29
NDS: REVIEW Workload Showing Percentage in Backlog.....	29
NDS: Review Workload by Fee Category.....	29
NDS: SCREENING Workload / Backlog	30
NDS: Screening Workload by Fee Category	30
DECISION DOCUMENTS	31
NDS: Decision Documents by Fee Category	31
PERFORMANCE	32
NDS: REVIEW Cycle Completions Showing Percentage within Target.....	32
NDS: SCREENING Cycle Completions Showing Percentage within Target	32
SNDS: SUPPLEMENTAL NEW DRUG SUBMISSIONS	33
SUBMISSIONS RECEIVED.....	33

SNDS: Received by Fee Category	33
WORKLOAD	34
SNDS: REVIEW Workload Showing Percentage in Backlog.....	34
SNDS: Review Workload by Fee Category.....	34
SNDS: SCREENING Workload Showing Percentage in Backlog.....	35
SNDS: Screening Workload by Fee Category.....	35
DECISION DOCUMENTS.....	36
SNDS: Decision Documents by Fee Category	36
PERFORMANCE.....	37
SNDS: REVIEW Cycle Completions Showing Percentage within Target.....	37
SNDS: SCREENING Cycle Completions Showing Percentage within Target.....	37
NC: NOTIFIABLE CHANGES	38
SUBMISSIONS RECEIVED.....	38
NC: Received by Fee Category	38
WORKLOAD	39
NC: REVIEW Workload Showing Percentage in Backlog	39
NC: Review Workload by Fee Category	39
NC: SCREENING Workload Showing Percentage in Backlog.....	40
NC: Screening Workload by Fee Category.....	40
DECISION DOCUMENTS.....	40
NC: Decision Documents by Fee Category	40
PERFORMANCE.....	41
NC: REVIEW Cycle Completions Showing Percentage within Target.....	41
NC: SCREENING Cycle Completions Showing Percentage within Target.....	41
PART 2: DISINFECTANT DRUGS	43
DISINFECTANTS DRUGS FILED PURSUANT TO DIVISION 1	43
DIND: DIN APPLICATION – DISINFECTANT DRUG	44
SUBMISSIONS RECEIVED.....	44
DIND: Received by Fee Category	44
WORKLOAD	45
DIND: Review Workload Showing Percentage in Backlog	45
DIND: Screening Workload Showing Percentage in Backlog.....	45

DIND: Administrative Screening Workload Showing Percentage in Backlog.....	46
PERFORMANCE	47
DIND: Review Performance Showing Percentage within Target	47
DIND: Screening Performance Showing Percentage within Target.....	47
DIND: Administrative Screening Performance	48
DECISION DOCUMENTS	49
DIND: Decisions by Fee Category	49
PDC: POST AUTHORIZATION DIVISION 1 CHANGE	50
PDC: Received by Fee Category	50
PDC: Screening Workload Showing Percentage in Backlog.....	50
PDC: Screening Performance Showing Percentage within Target.....	51
PDC: Decisions by Fee Category	51
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8	52
NDS: NEW DRUG SUBMISSIONS	53
SUBMISSIONS RECEIVED.....	53
NDS- Disinfectant Drug: Received by Fee Category	53
WORKLOAD	53
NDS- Disinfectant Drug: Review Workload/Backlog at Fiscal Year End	53
NDS- Disinfectant Drug: Screening Workload/Backlog at Fiscal Year End.....	53
PERFORMANCE	54
NDS- Disinfectant Drug: Review Performance.....	54
NDS- Disinfectant Drug: Screening Performance.....	54
NDS- Disinfectant Drug: Administrative Screening Performance	54
DECISION DOCUMENTS	54
NDS- Disinfectant Drug: Decisions by Fee Category	54
NC: NOTIFIABLE CHANGES	55
SUBMISSIONS RECEIVED.....	55
NC- Disinfectant Drugs Received by Fee Category	55
WORKLOAD	55
NC- Disinfectant Drug: Review Workload / Backlog at Year End	55
NC- Disinfectant Drug: Screening Workload / Backlog at Year End	55
PERFORMANCE	56

NC- Disinfectant Drug: Review Performance	56
NC- Disinfectant Drug: Screening Performance	56
DECISION DOCUMENTS.....	56
NC- Disinfectant Drug: Decisions	56
MPNDS: PRE–NDS MEETING	56
MPNDS - Disinfectant Drug: Received by Fee Category	56

OVERVIEW (Revised June 27, 2017)

The NNHPD Annual Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over three consecutive fiscal years (April 1 to March 31) from 2014-2015 to 2016-2017. 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 2016-2017 report are:

The performance standard of greater than 90% review on time has been achieved for all the cost-recovered submissions. The overall workload has not significantly changed from the previous two fiscal years.

The number of DINA submissions received decreased to 149 in 2016-2017 from 196 in 2014-2015 or 223 in 2015-2016. The number of DINF received remained similar, from 195 in 2014-2015, 226 in 2015-2016 to 212 in 2016-2017.

The number of NDS submissions received increased 133% from 3 in 2015-2016 to 7 in 2016-2017. However, we received 12 submissions in 2014-2015. The number of SNDS submissions received increased 25% from 12 in 2015-2016 to 15 in 2016-2017 and 88% since 2014-2015 (only 8 submissions).

For disinfectants, the Directorate has seen a significant increase in PDC submissions, from 38 in 2015-2016 to 95 in 2016-2017. However, 90 submissions were received in 2014-2015. The number of NDS submissions received increased 400% from 1 in 2014-2015 and 2015-2016 to 5 in 2016-2017.

For the other submission types, the numbers remained similar over the three-year period.

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, which is the date the submission is considered administratively complete by Health Canada.

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

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

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

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

Office of Submissions and Intellectual Property, Therapeutic Products Directorate
Finance Building, A.L. # 0201A1
101 Tunney’s Pasture Driveway, Tunney’s Pasture
Ottawa, Ontario, K1A 0K9

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

Email: SIPDMAIL@hc-sc.gc.ca

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

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)* <i>This new NAS definition came into effect on April 1 2011</i>	Submissions 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 ingredient such as a salt, ester, enantiomer, solvate or polymorph.
Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.
Clinical or non-clinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.
Comparative studies	Submissions based on comparative studies (e.g. clinical or non-clinical data, bioavailability, pharmacokinetic and pharmacodynamic data) with or without chemistry and manufacturing data for a drug that does not include a new active substance.
Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.
Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.
Switch from prescription to nonprescription status	Submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the <i>Food and Drug Regulations</i> (i.e. identical claim for existing drug).
Labelling only	Submissions of labelling material (i.e. does not include supporting clinical or non-clinical data or chemistry and manufacturing data).
Administrative submission	Submissions in support of a manufacturer or product name change.
Disinfectants	Submissions and applications that include data in support of a disinfectant.
Drug identification number application - labelling standards	Applications attesting to compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

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

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

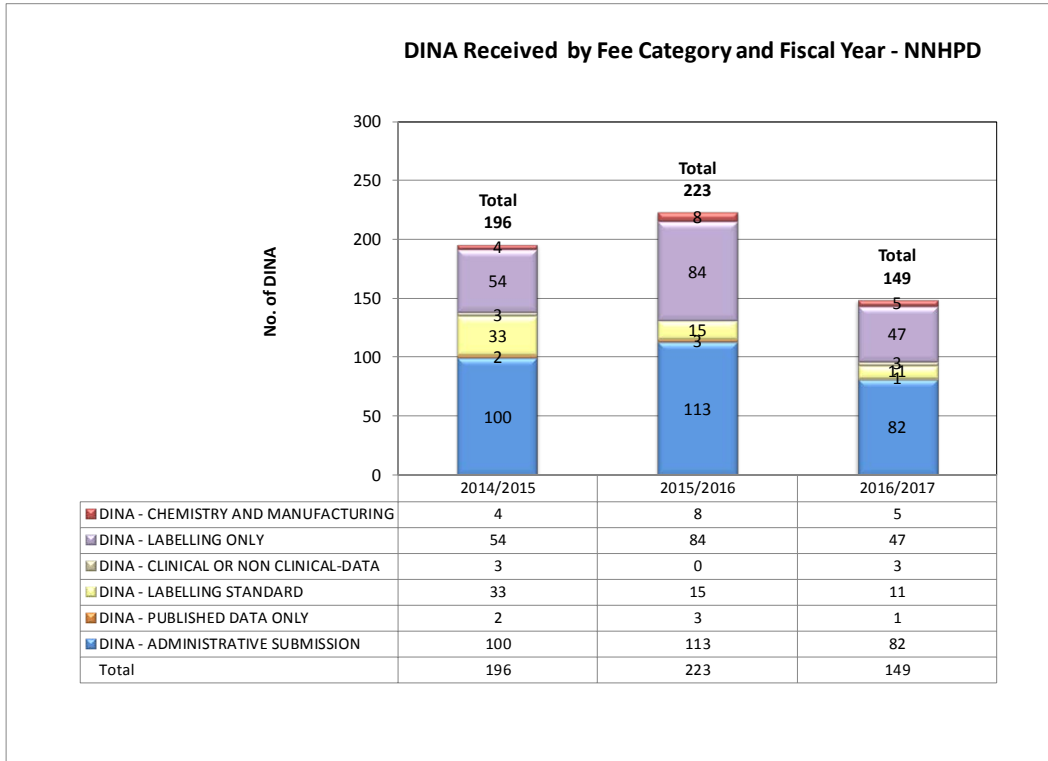
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS

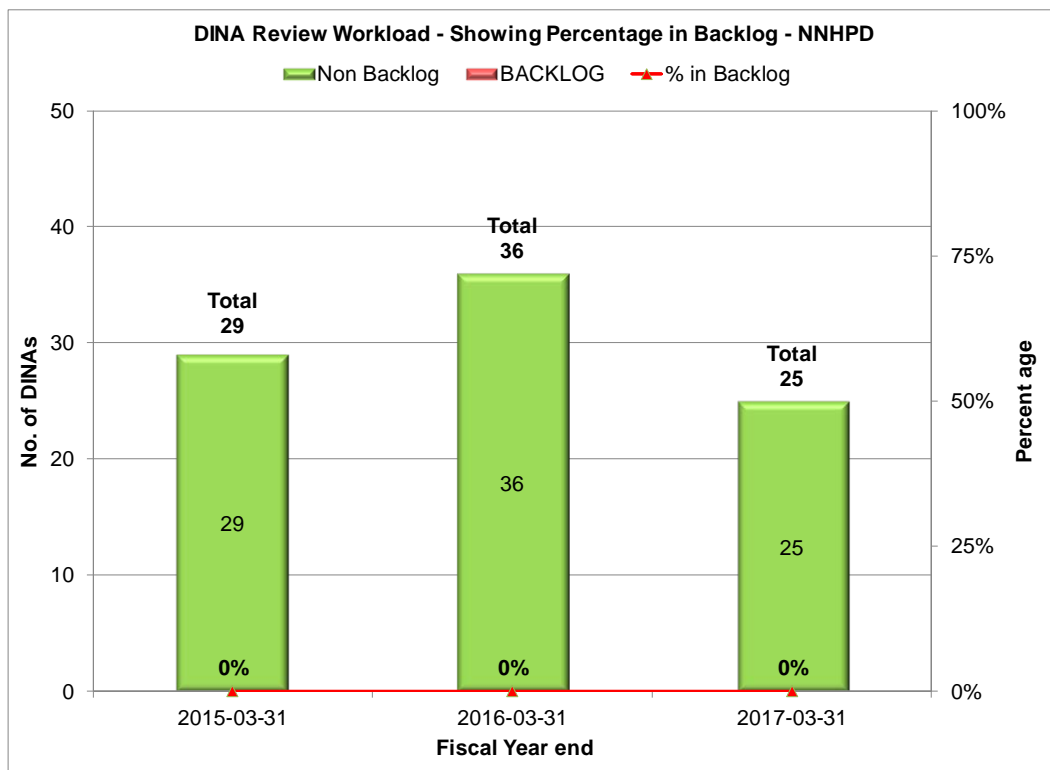
SUBMISSIONS RECEIVED

DINA: Received by Fee Category



WORKLOAD

DINA: Review Workload Showing the Percentage in Backlog

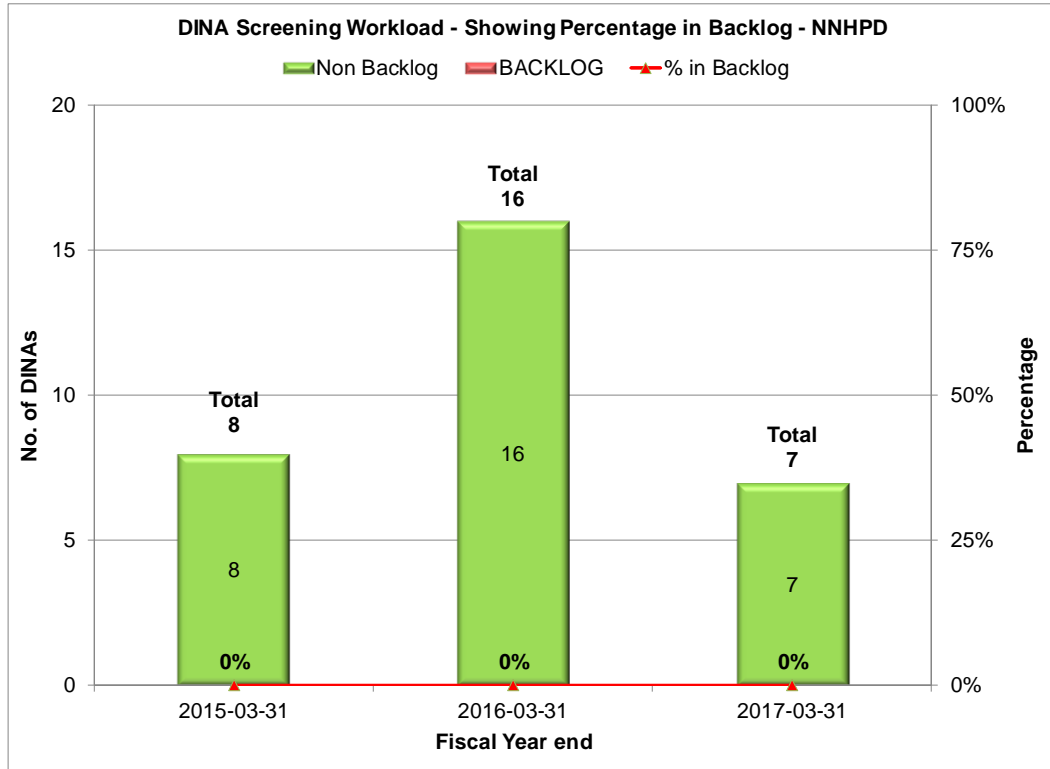


DINA: Review Workload by Fee Category

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

WORKLOAD

DINA: Screening Workload Showing the Percentage in Backlog

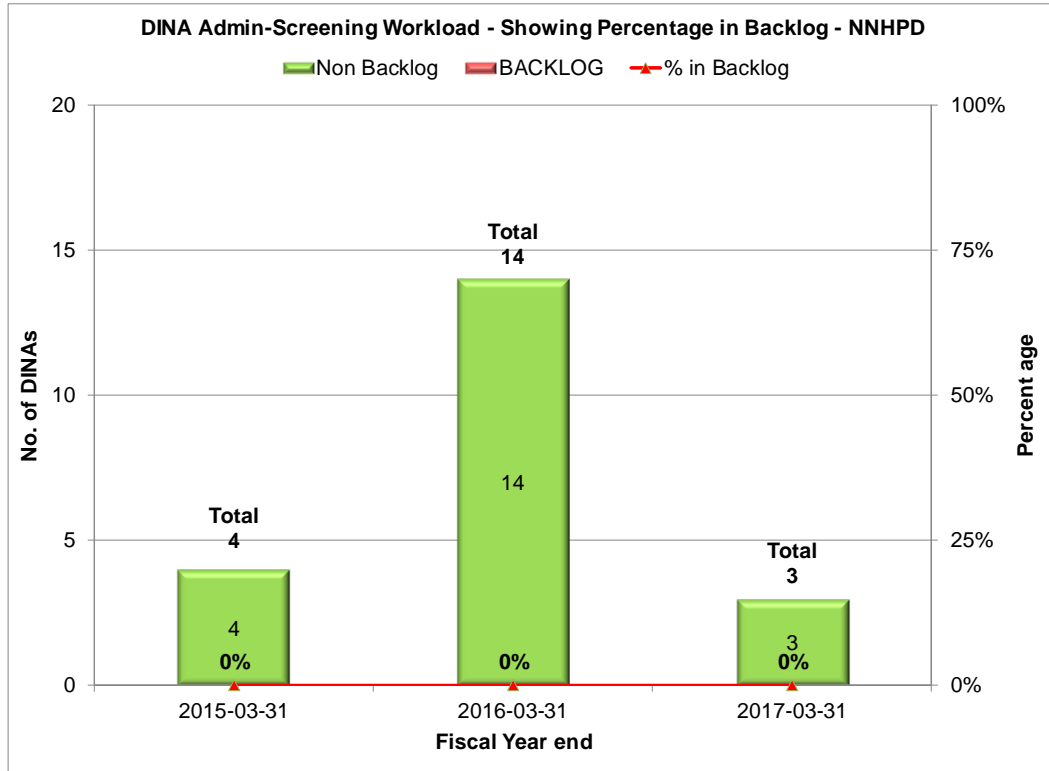


DINA: Screening Workload by Fee Category

DINA SCREENING WORKLOAD BY FEE CATEGORY - NNHPD			
	2015-03-31	2016-03-31	2017-03-31
Chemistry and Manufacturing	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clinical Data	0	0	2
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Only	6	14	4
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Published Data Only	0	0	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Standard	2	2	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	8	16	7
Non Backlog	8	16	7
BACKLOG	0	0	0
% in Backlog	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
Administrative	4	14	3
<i>Backlog</i>	0	0	0
Total	4	14	3
Non Backlog	4	14	3
BACKLOG	0	0	0
% in Backlog	0%	0%	0%

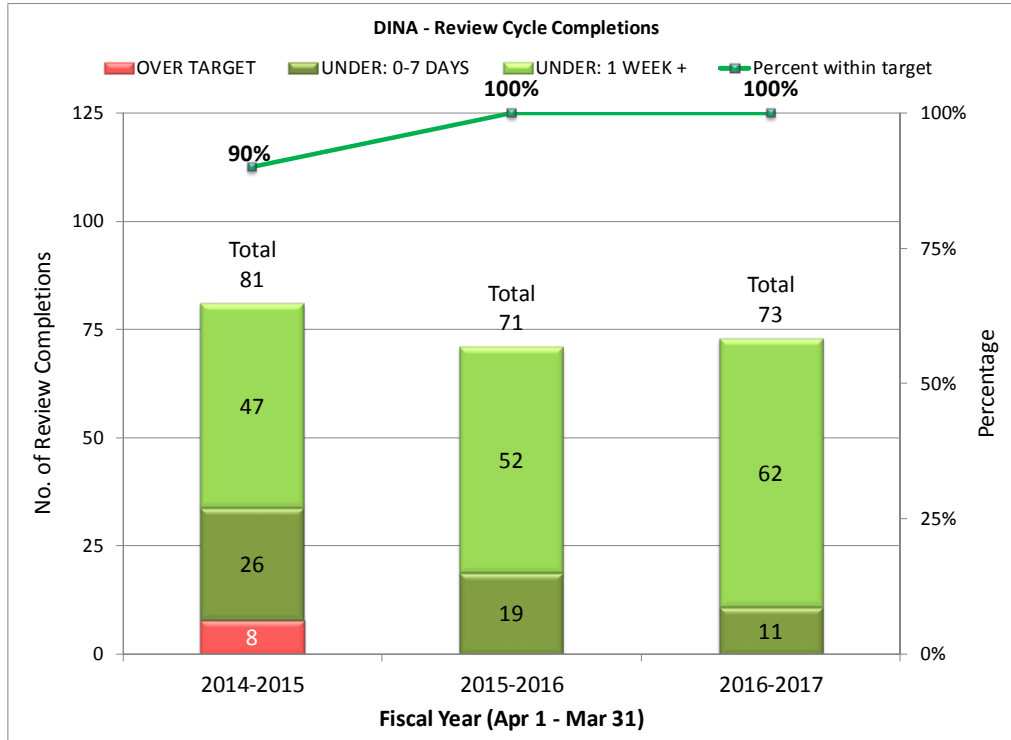
DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

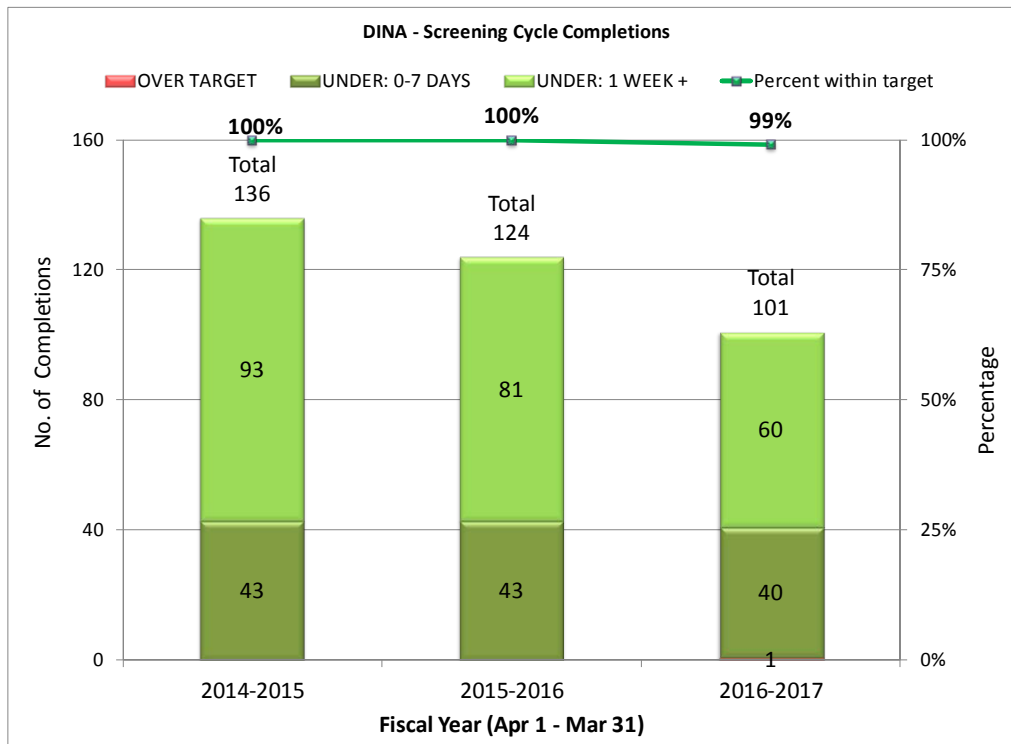
User Fee Category	Decision	2014/2015	2015/2016	2016/2017
ADMINISTRATIVE	CANCELLATION LETTER	6	5	3
	NOTIFICATION FORM DIN SUB	86	85	80
	REJECTION LETTER (SCR)	11	12	9
	SCREENING DEFICIENCY NOTICE	6	1	5
	NO OBJECTION LETTER			2
CHEMISTRY AND MANUFACTURING	NOTICE OF DEFICIENCY	1	0	0
	NOTICE OF NON-COMPLIANCE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

PERFORMANCE

DINA: REVIEW Cycle Completions Showing Percentage within Target

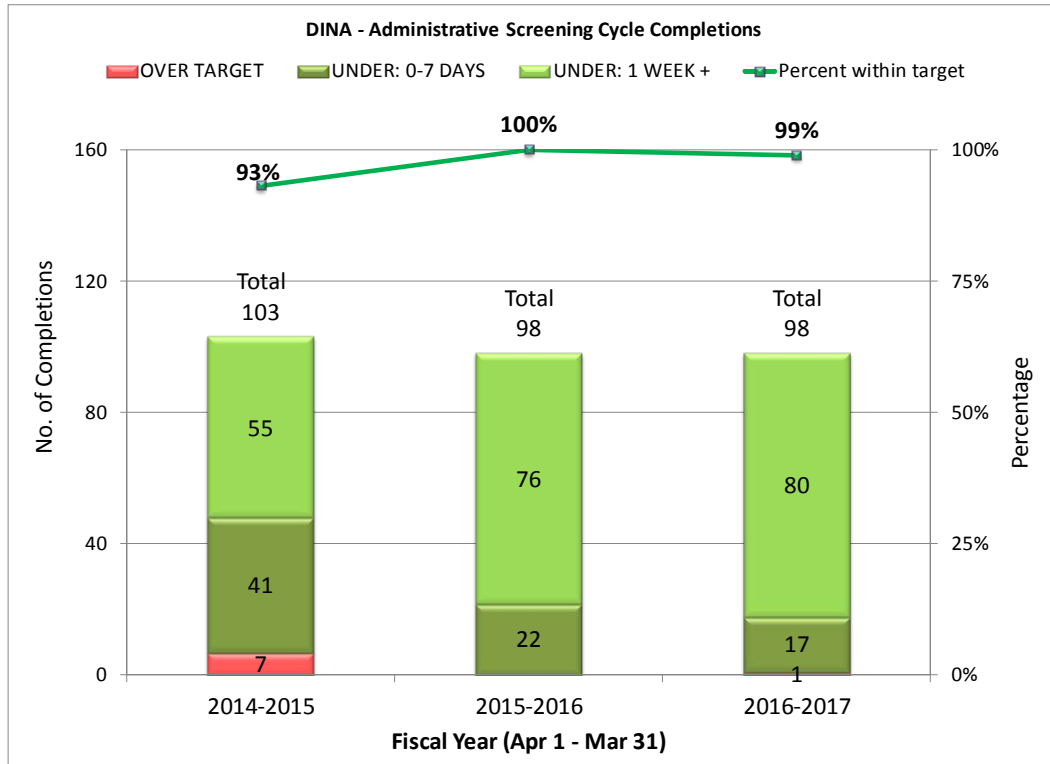


DINA: SCREENING Cycle Completions Showing Percentage within Target



PERFORMANCE

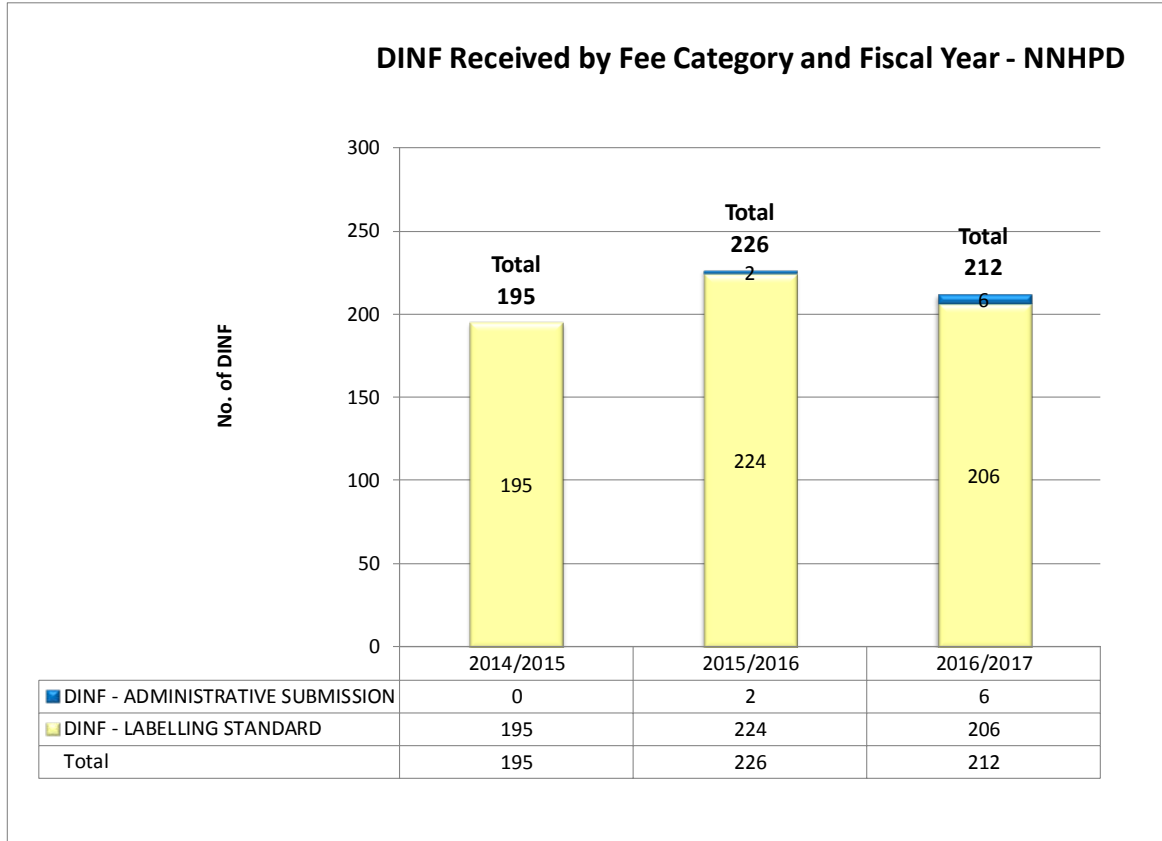
DINA: Administrative Screening Completions Showing Percentage within Target



DINF: CATEGORY FOUR DIN APPLICATIONS

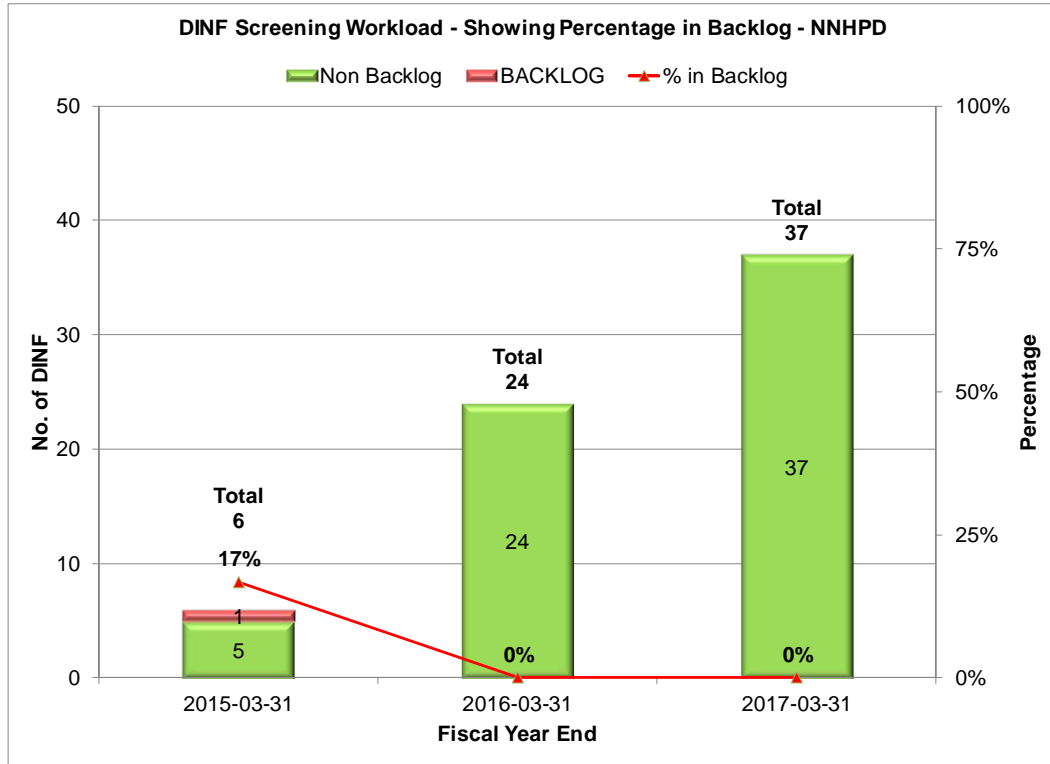
SUBMISSIONS RECEIVED

DINF: Received by Fee Category



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
Labelling Standard	6	24	35
<i>Backlog</i>	<i>1</i>	<i>0</i>	<i>0</i>
Administrative	0	0	2
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	6	24	37
Non Backlog	5	24	37
BACKLOG	1	0	0
% in Backlog	17%	0%	0%

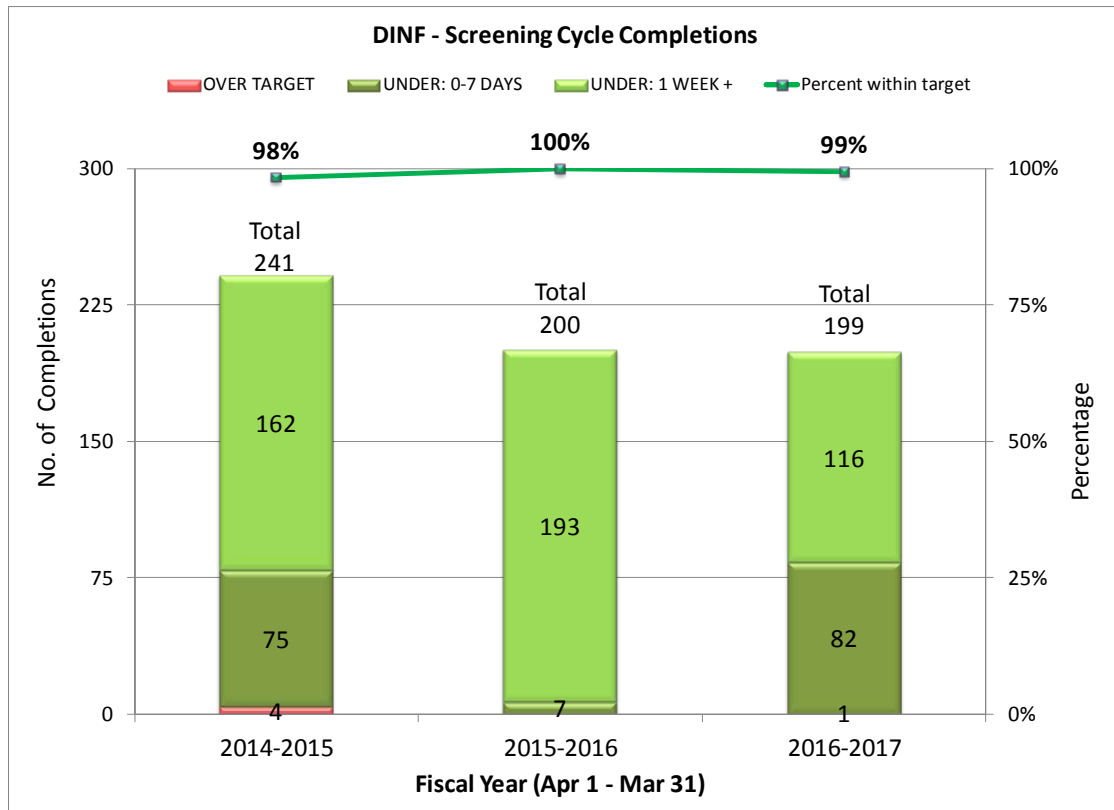
DECISION DOCUMENTS

DINF: Decision Documents by Fee Category

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

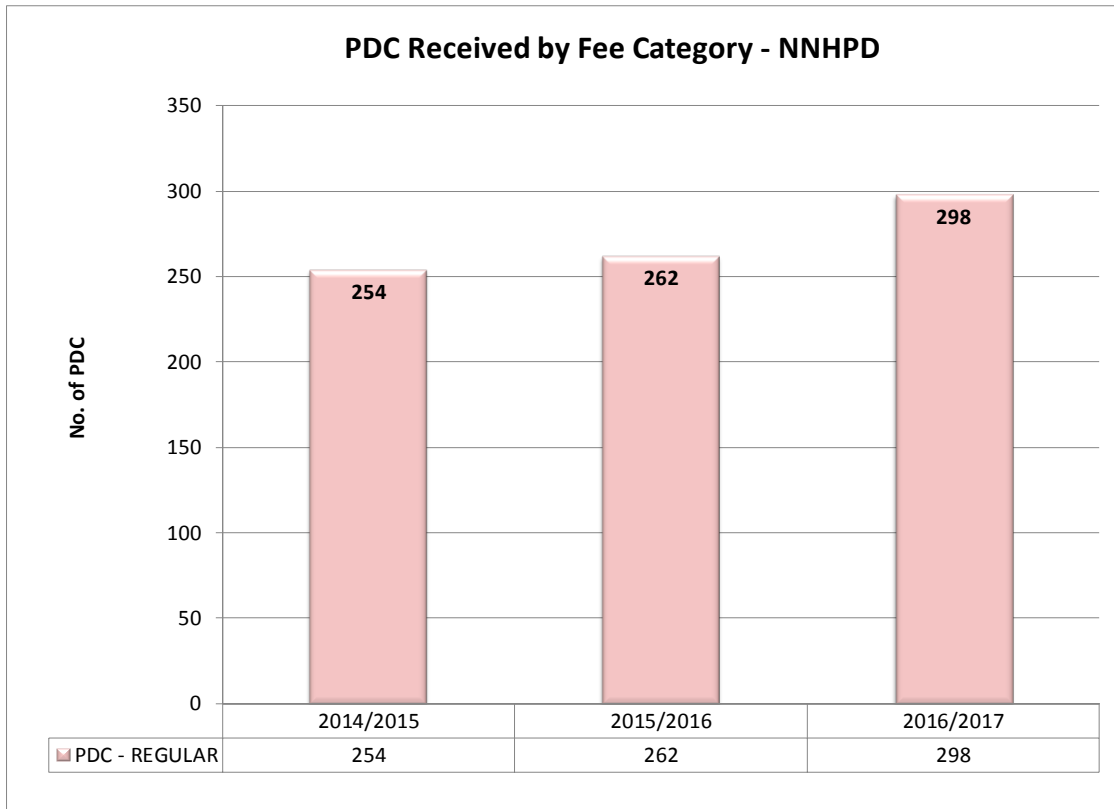
PERFORMANCE

DINF: Screening Cycle Completions



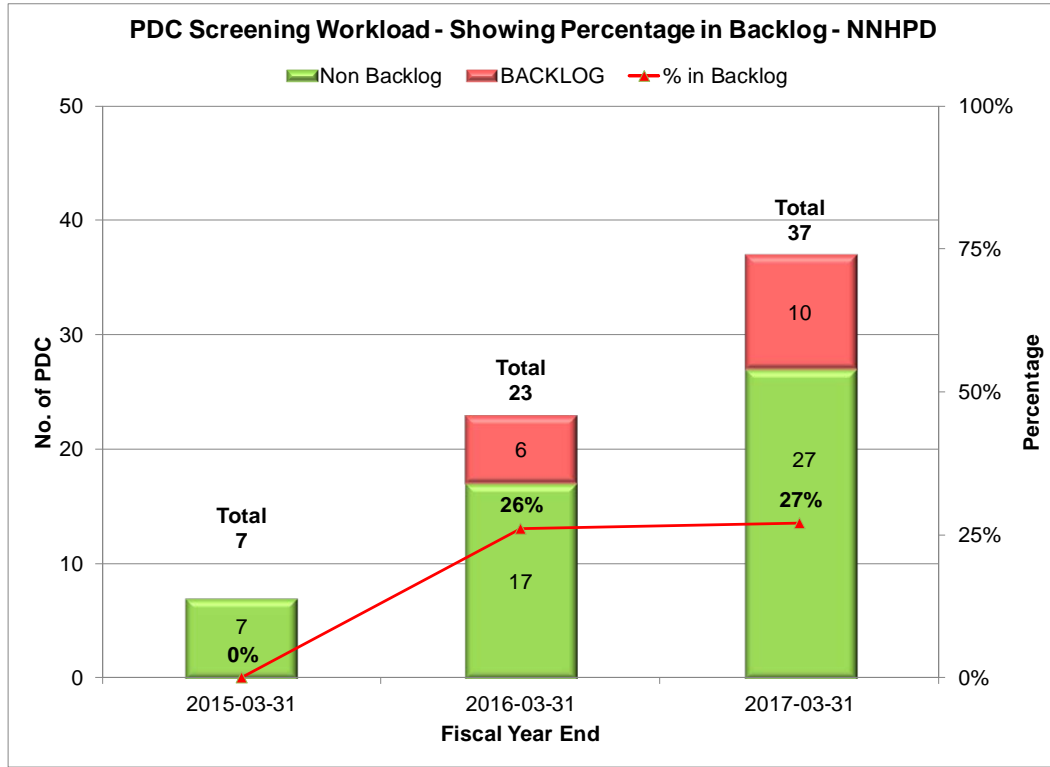
PDC: POST AUTHORIZATION DIVISION 1 CHANGES
SUBMISSIONS RECEIVED

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
Regular	7	23	37
<i>Backlog</i>	0	6	10
Total	7	23	37
Non Backlog	7	17	27
BACKLOG	0	6	10
% in Backlog	0%	26%	27%

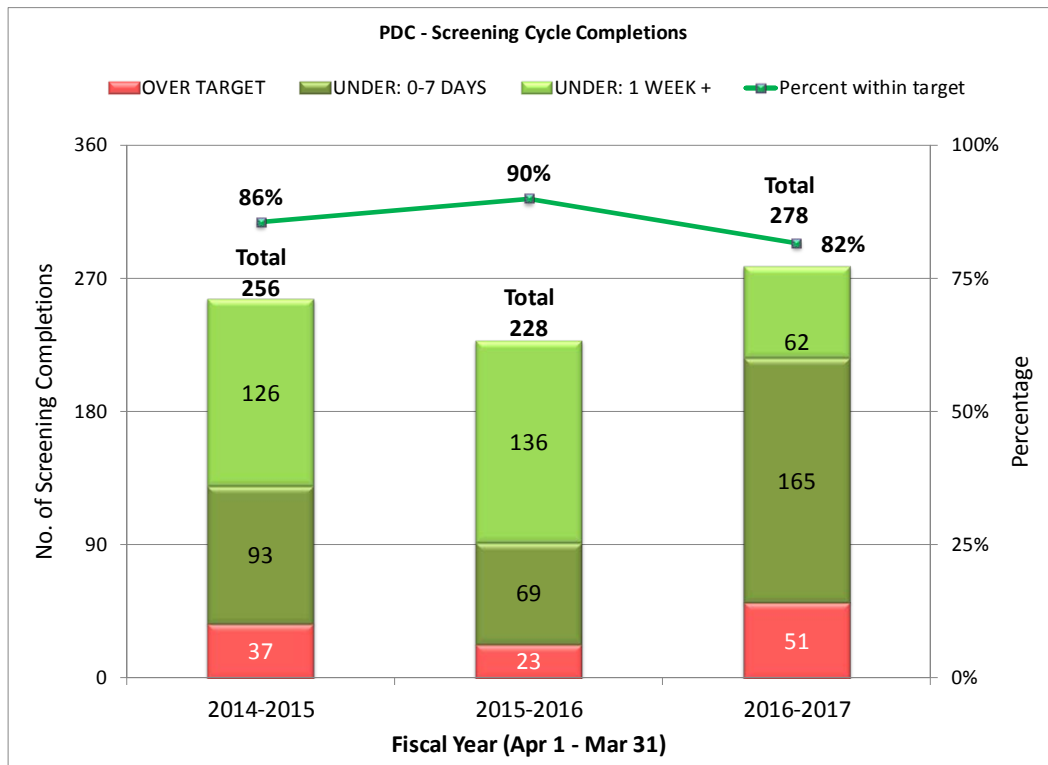
DECISION DOCUMENTS

PDC: Decision Documents by fee Category

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

PERFORMANCE

PDC: Screening Cycle Completions



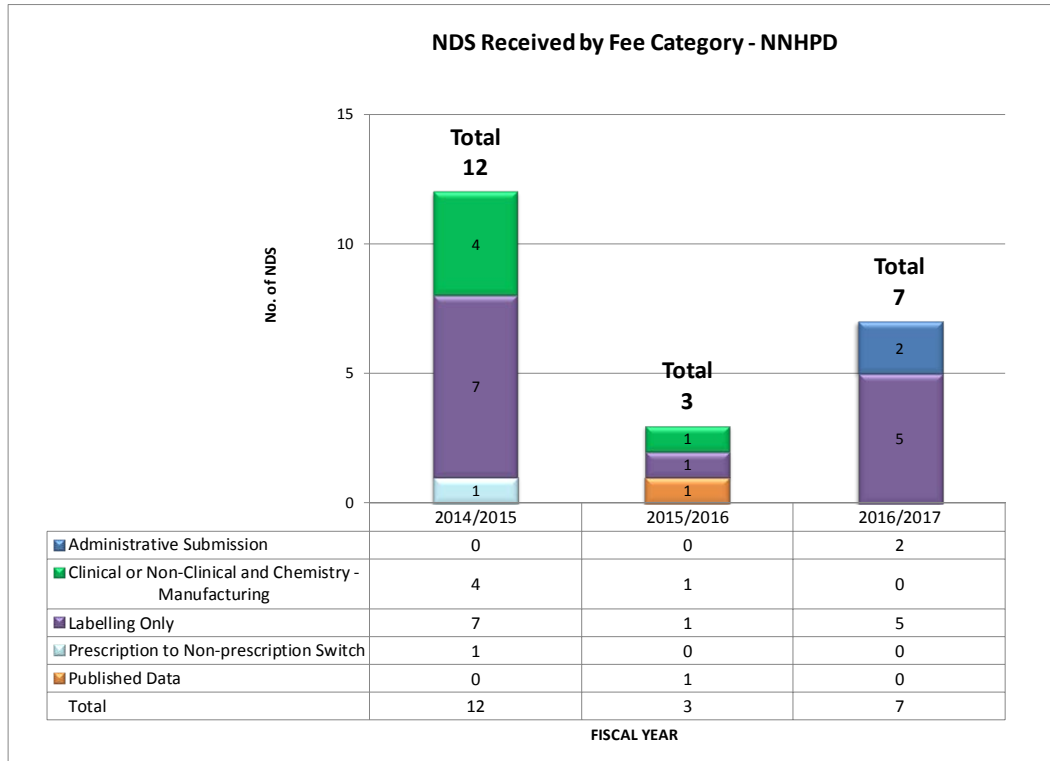
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8

in Part C of the *Food and Drug Regulations*

NDS: NEW DRUG SUBMISSIONS

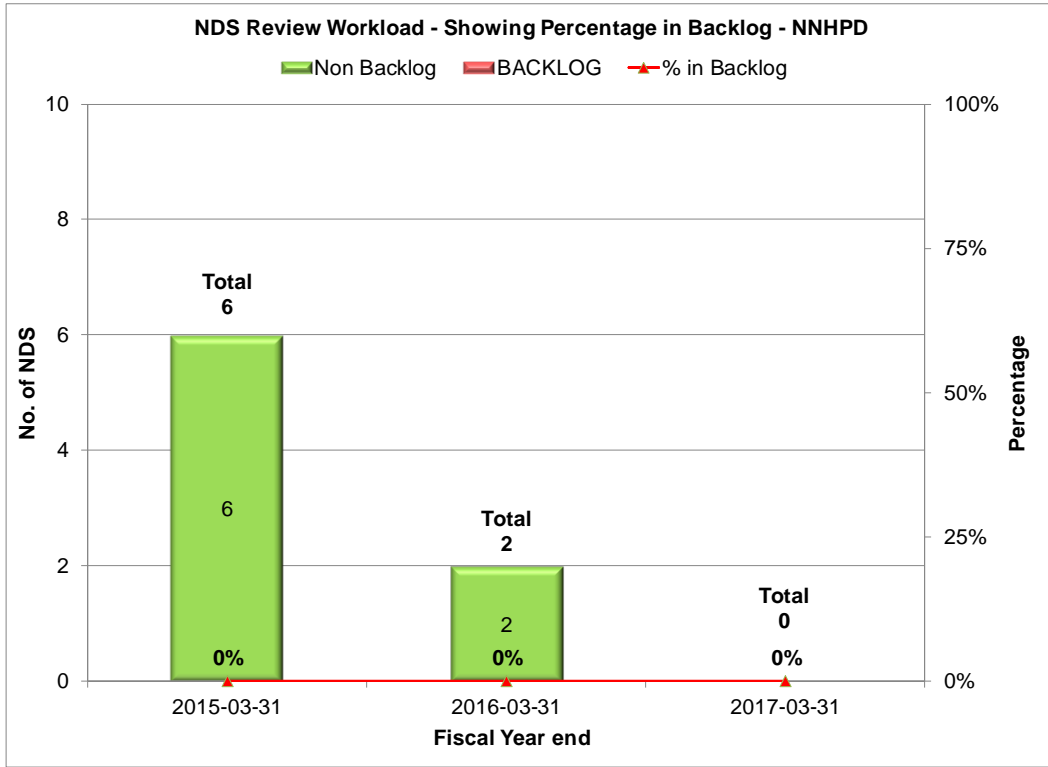
SUBMISSIONS RECEIVED

NDS: Received by Fee Category



WORKLOAD

NDS: REVIEW Workload Showing Percentage in Backlog

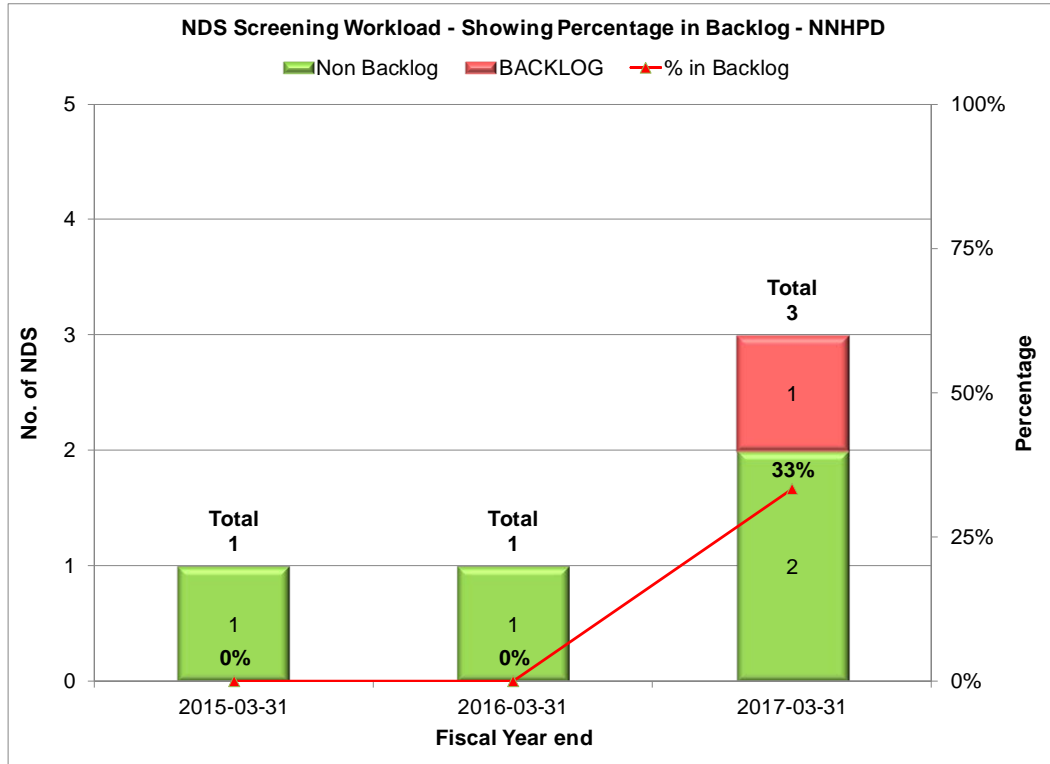


NDS: Review Workload by Fee Category

NDS REVIEW WORKLOAD BY FEE CATEGORY - NNHPD			
	2015-03-31	2016-03-31	2017-03-31
Clinical or Non-Clinical Data and Chemistry - Manufacturing	4	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Labelling Only	2	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	6	2	0
Non Backlog	6	2	0
BACKLOG	0	0	0
% in Backlog	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
Prescription to Non-Prescription Switch	1	0	0
<i>Backlog</i>	0	0	0
Published Data Only	0	1	0
<i>Backlog</i>	0	0	0
Labelling Only	0	0	3
<i>Backlog</i>	0	0	1
Total	1	1	3
Non Backlog	1	1	2
BACKLOG	0	0	1
% in Backlog	0%	0%	33%

DECISION DOCUMENTS

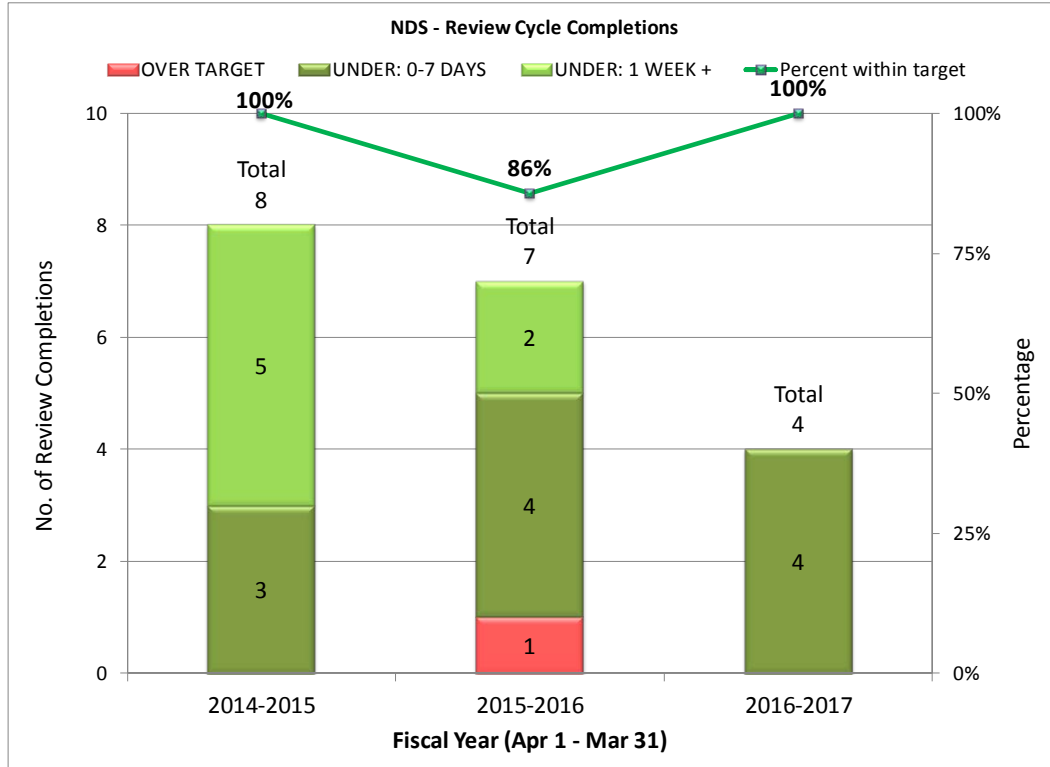
NDS: Decision Documents by Fee Category

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

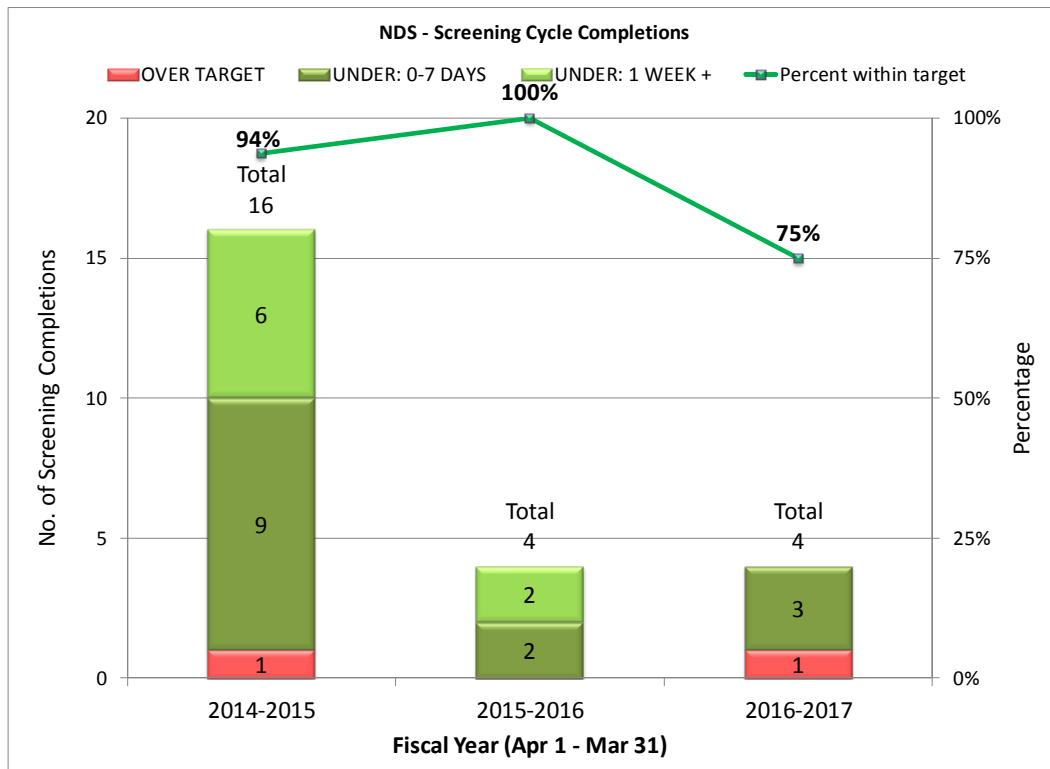
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: REVIEW Cycle Completions Showing Percentage within Target

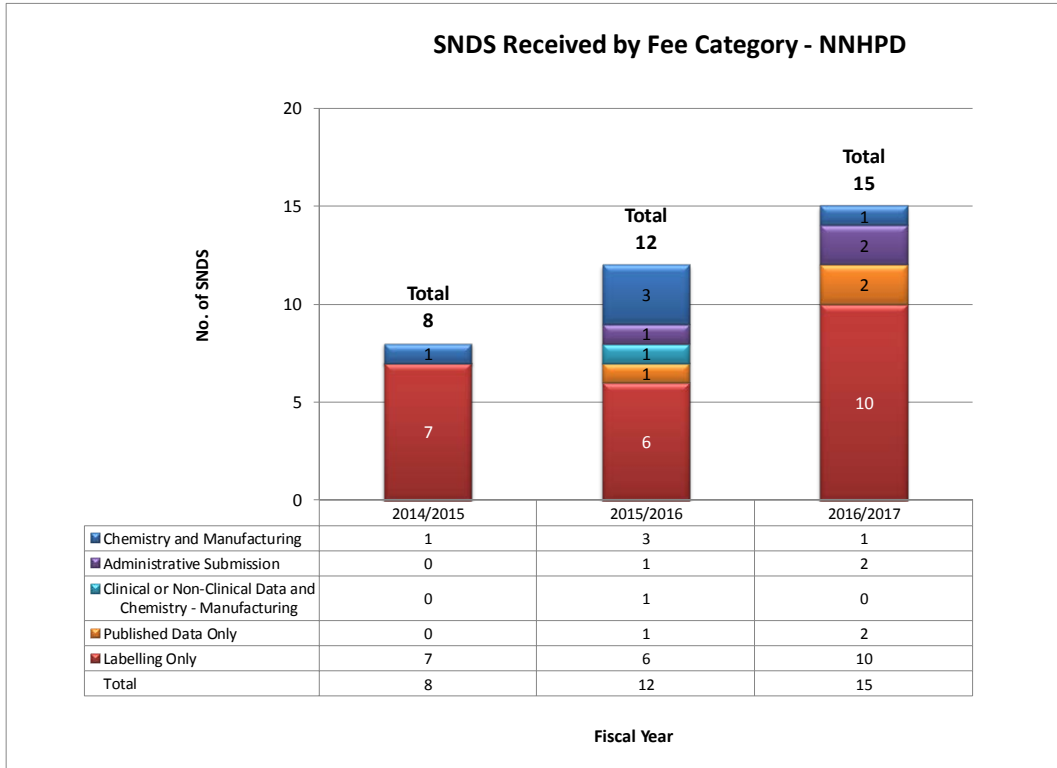


NDS: SCREENING Cycle Completions Showing Percentage within Target



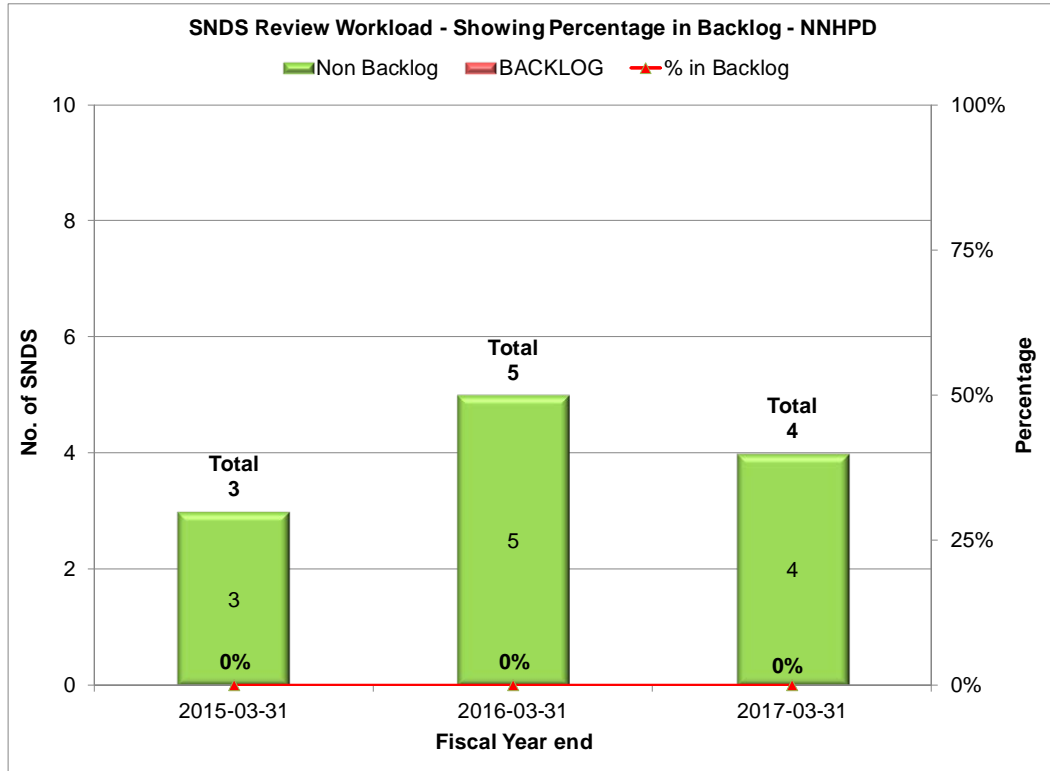
SNDS: SUPPLEMENTAL NEW DRUG SUBMISSIONS
SUBMISSIONS RECEIVED

SNDS: Received by Fee Category



WORKLOAD

SNDS: REVIEW Workload Showing Percentage in Backlog

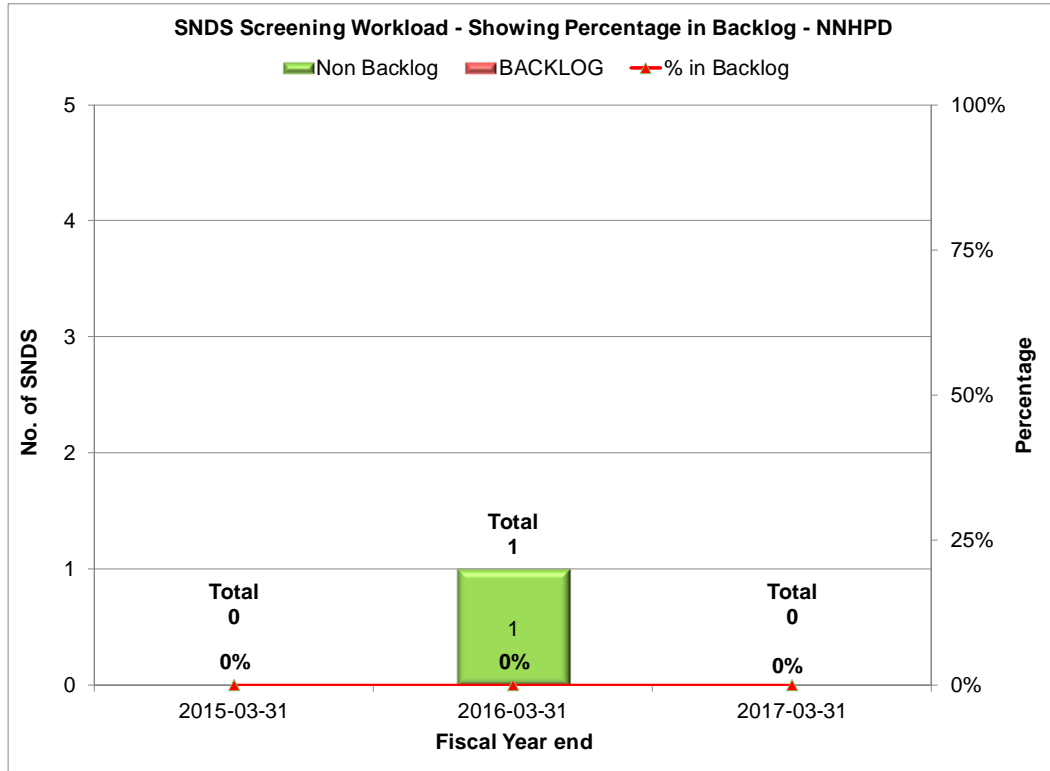


SNDS: Review Workload by Fee Category

SNDS REVIEW WORKLOAD BY FEE CATEGORY - NNHPD			
	2015-03-31	2016-03-31	2017-03-31
Labelling Only	2	1	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Published Data Only	0	1	2
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Chemistry and Manufacturing	1	2	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	3	5	4
Non Backlog	3	5	4
BACKLOG	0	0	0
% in Backlog	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
Chemistry and Manufacturing	0	1	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	1	0
Non Backlog	0	1	0
BACKLOG	0	0	0
% in Backlog	0%	0%	0%

DECISION DOCUMENTS

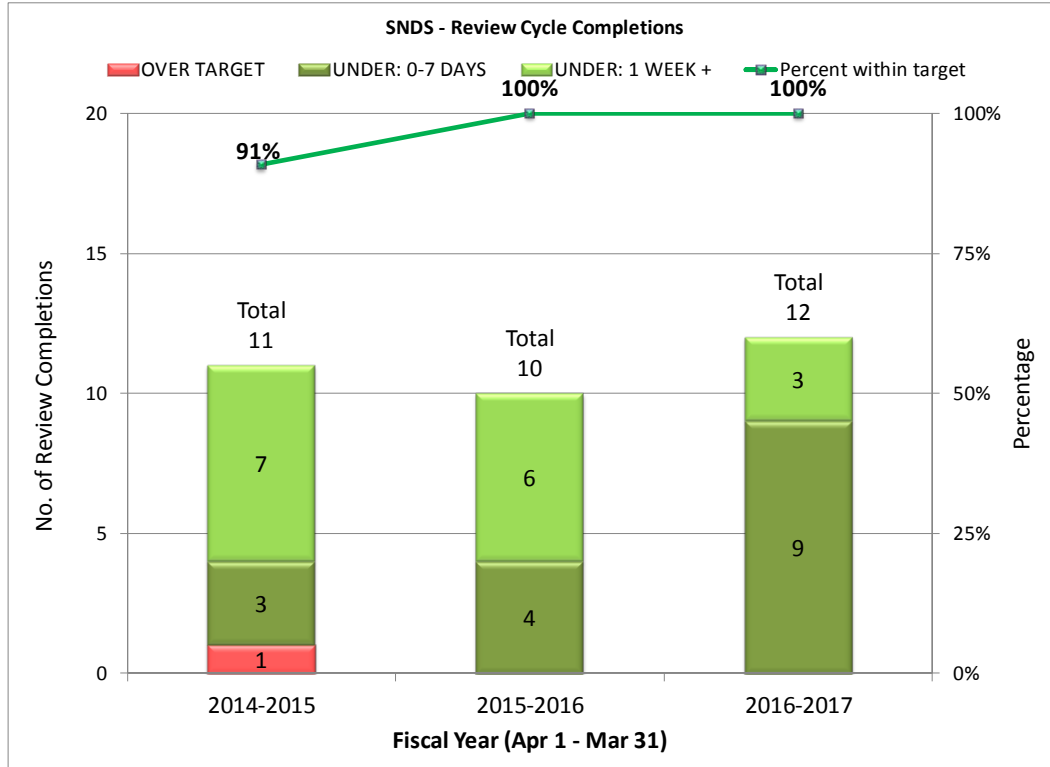
SNDS: Decision Documents by Fee Category

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

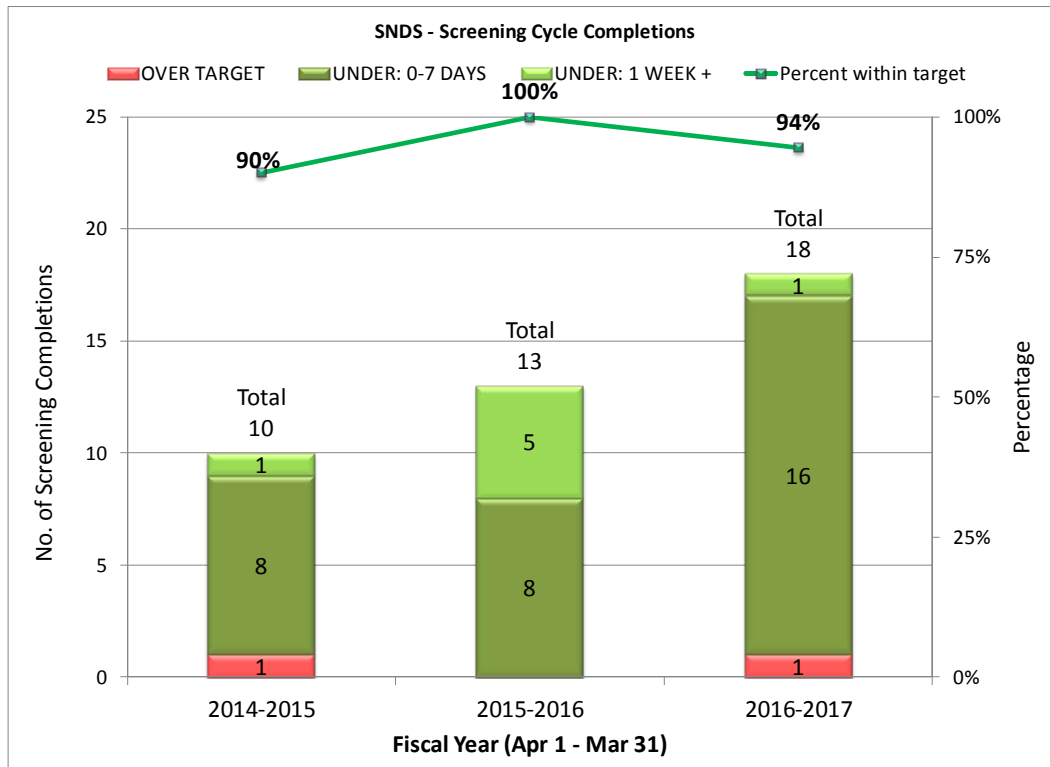
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: REVIEW Cycle Completions Showing Percentage within Target

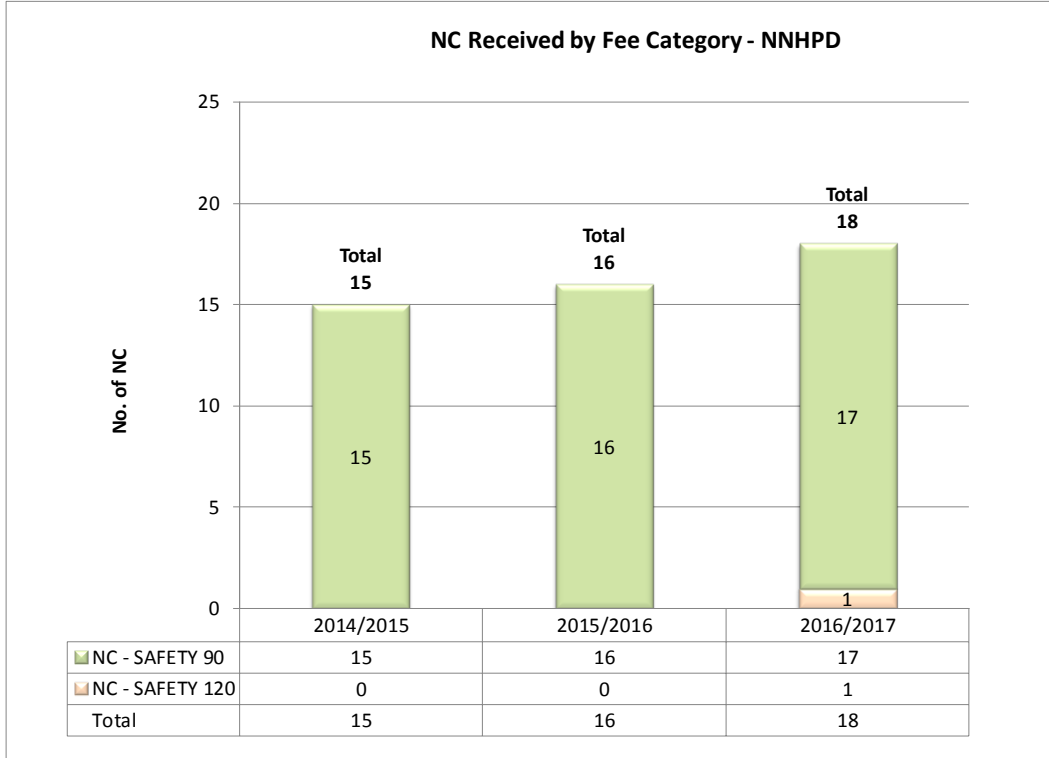


SNDS: SCREENING Cycle Completions Showing Percentage within Target



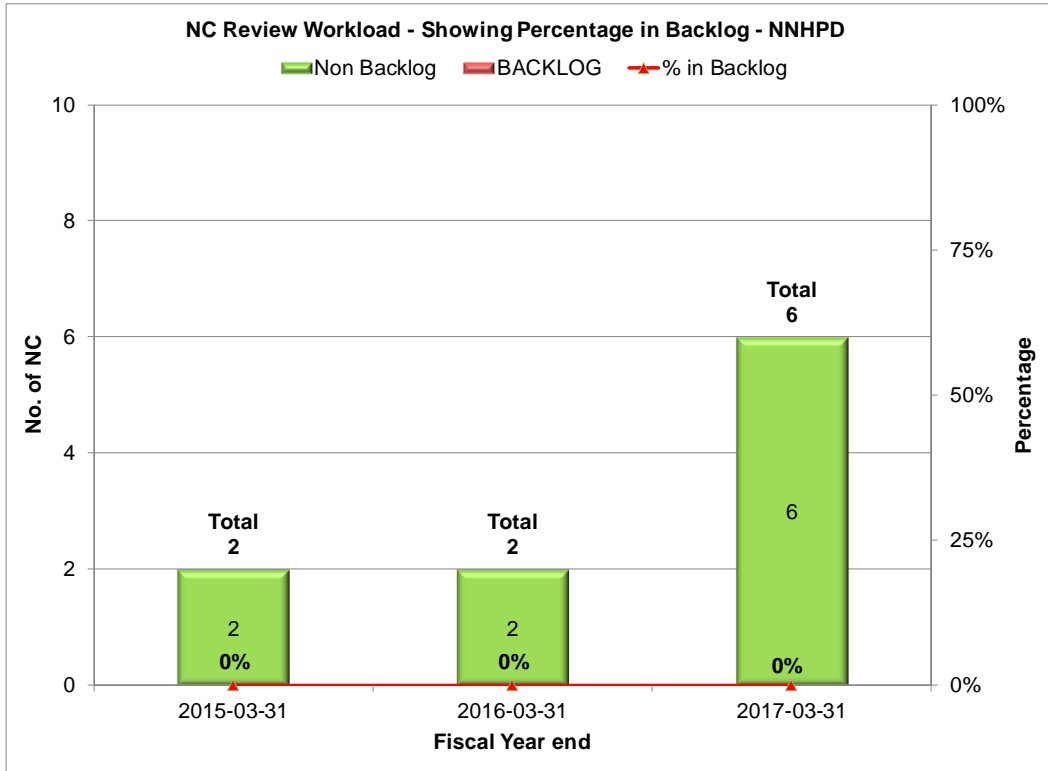
**NC: NOTIFIABLE CHANGES
SUBMISSIONS RECEIVED**

NC: Received by Fee Category



WORKLOAD

NC: REVIEW Workload Showing Percentage in Backlog

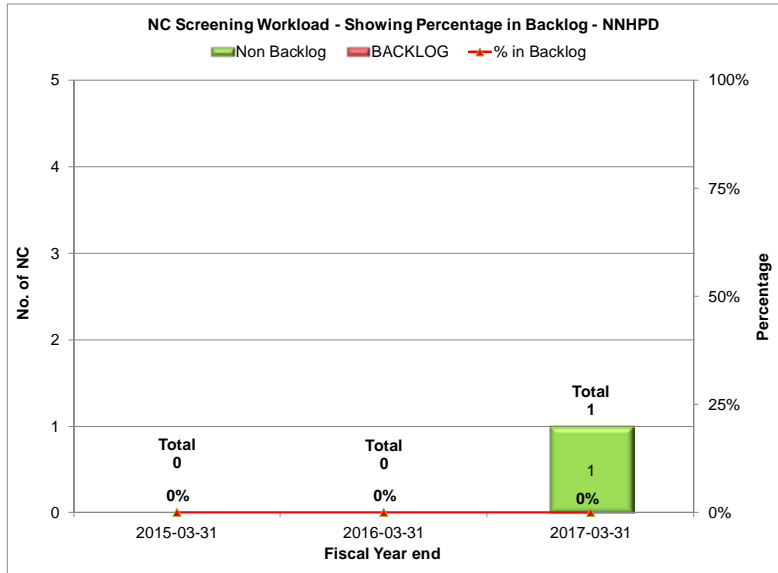


NC: Review Workload by Fee Category

NC REVIEW WORKLOAD BY FEE CATEGORY - NNHPD			
	2015-03-31	2016-03-31	2017-03-31
SAFETY 90	2	2	5
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
SAFETY 120	0	0	1
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	2	2	6
Non Backlog	2	2	6
BACKLOG	0	0	0
% in Backlog	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
SAFETY 90	0	0	1
<i>Backlog</i>	0	0	0
Total	0	0	1
Non Backlog	0	0	1
BACKLOG	0	0	0
% in Backlog	0%	0%	0%

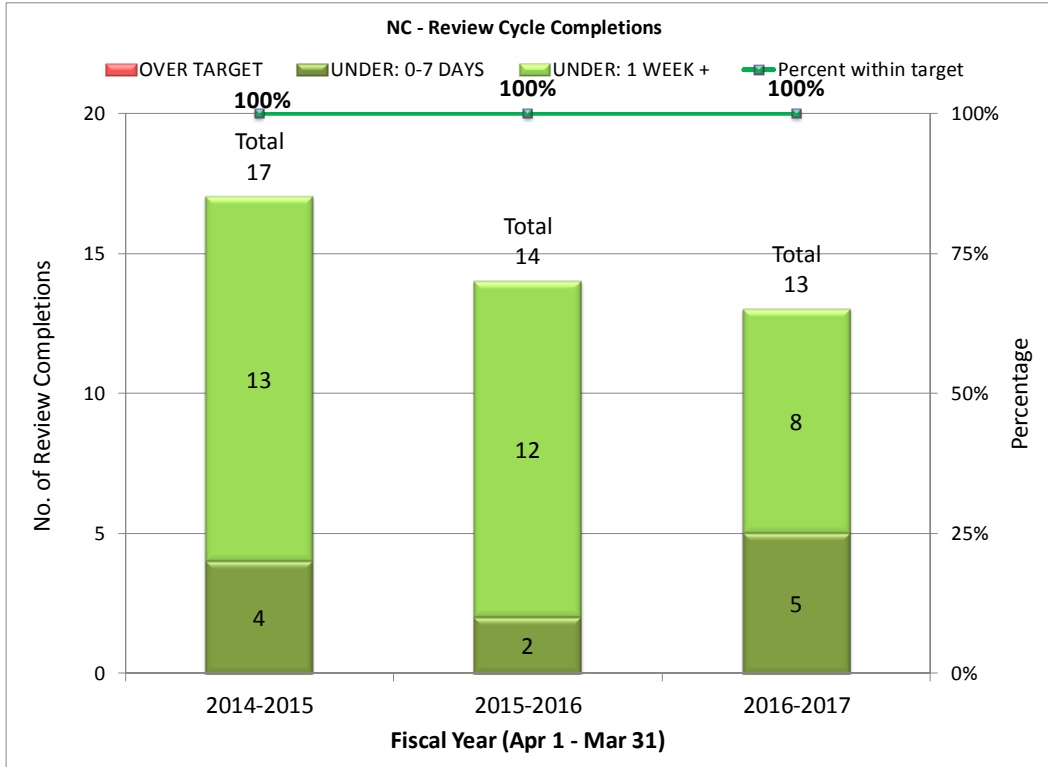
DECISION DOCUMENTS

NC: Decision Documents by Fee Category

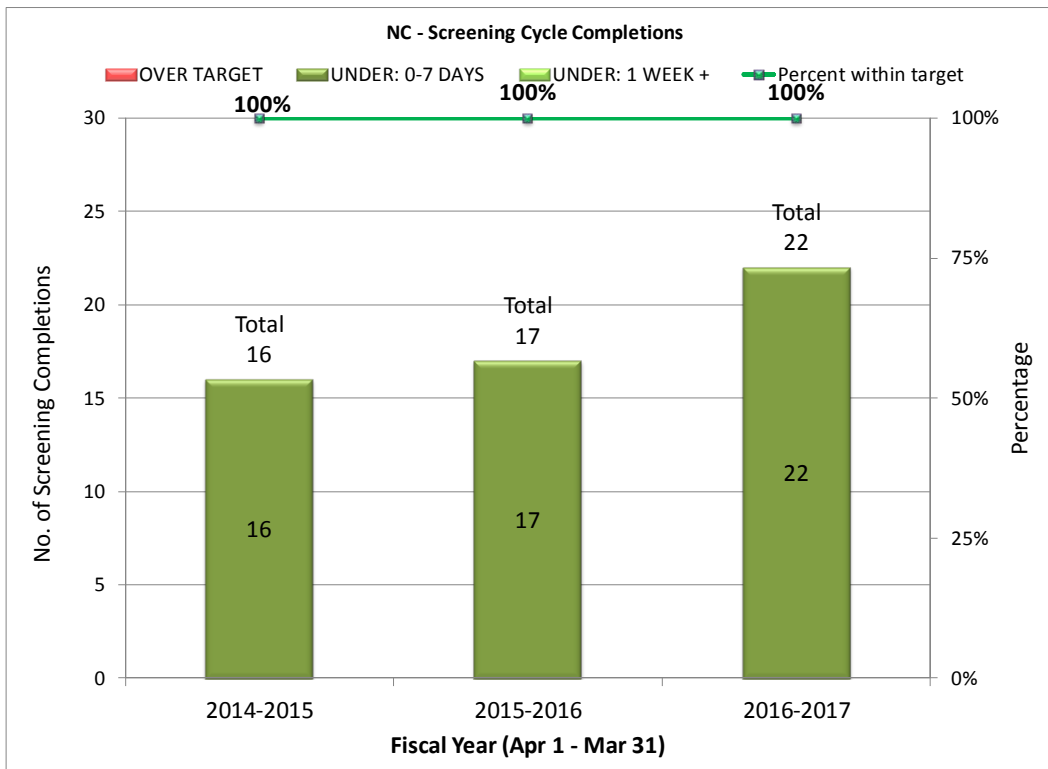
Class	Decision	2014/2015	2015/2016	2016/2017
SAFETY 90	NO OBJECTION LETTER	18	12	13
	CANCELLATION LETTER	0	0	1
	REJECTION LETTER (SCR)	0	0	1
	NOT SATISFACTORY NOTICE	0	1	0
	SCREENING DEFICIENCY NOTICE	0	3	4
	NC-HOLD (SWITCH)	1	1	0

PERFORMANCE

NC: REVIEW Cycle Completions Showing Percentage within Target



NC: SCREENING Cycle Completions Showing Percentage within Target



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PART 2: DISINFECTANT DRUGS

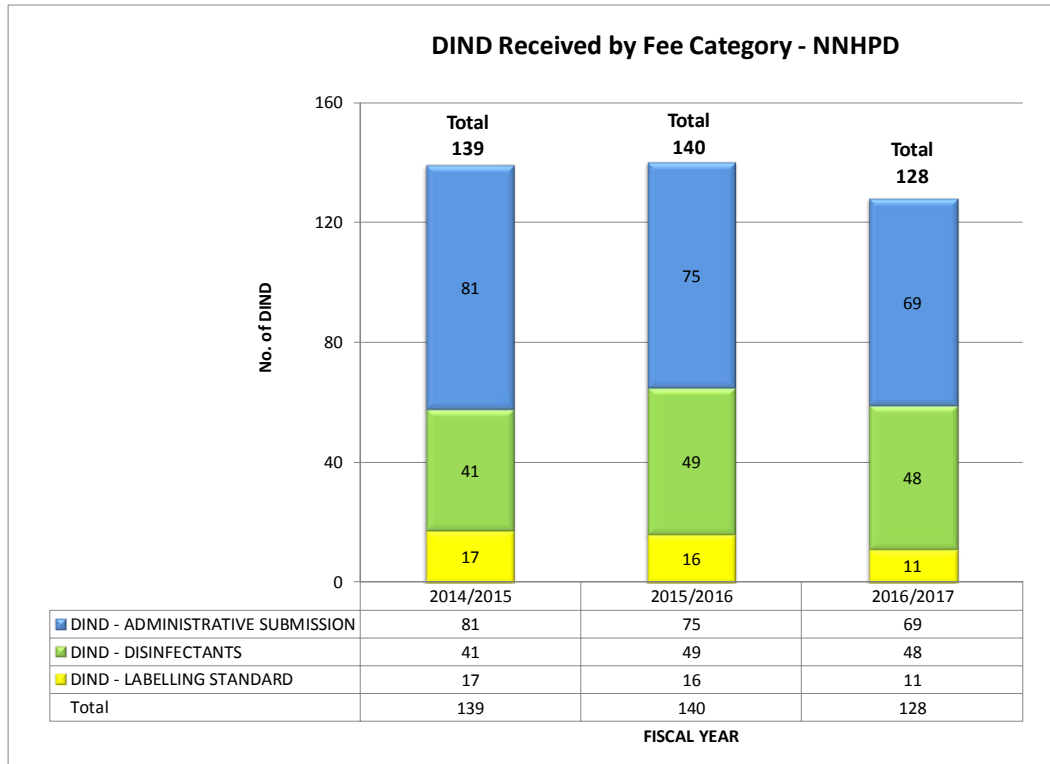
DISINFECTANTS DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: DIN APPLICATION – DISINFECTANT DRUG

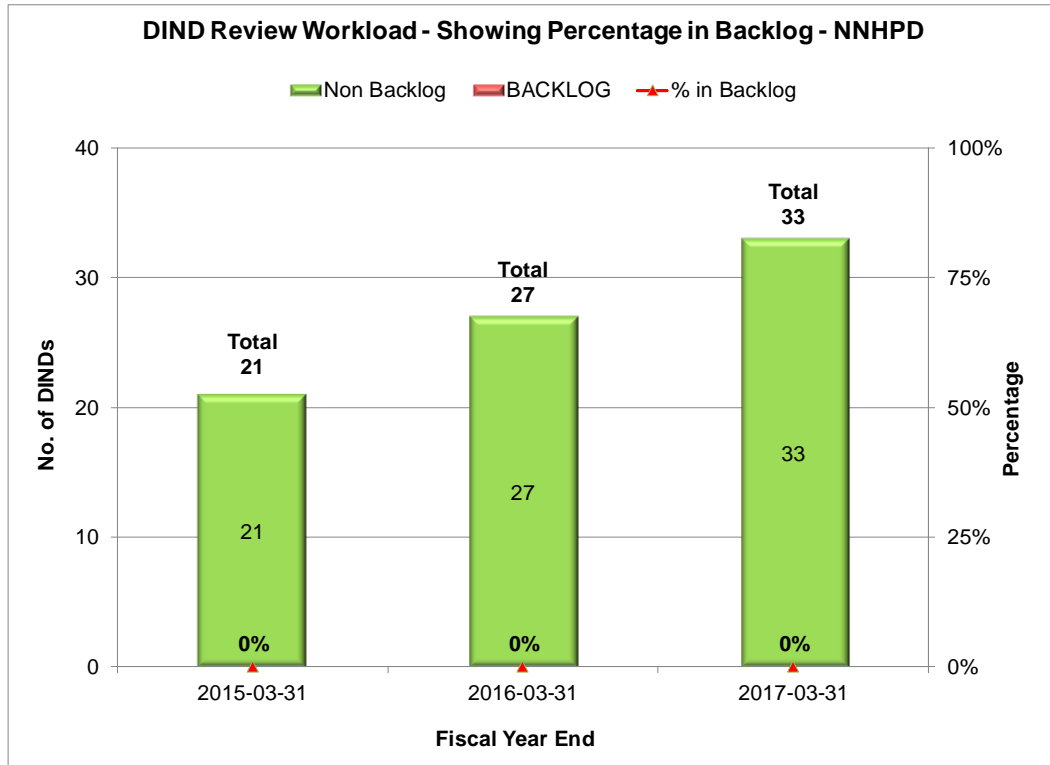
SUBMISSIONS RECEIVED

DIND: Received by Fee Category

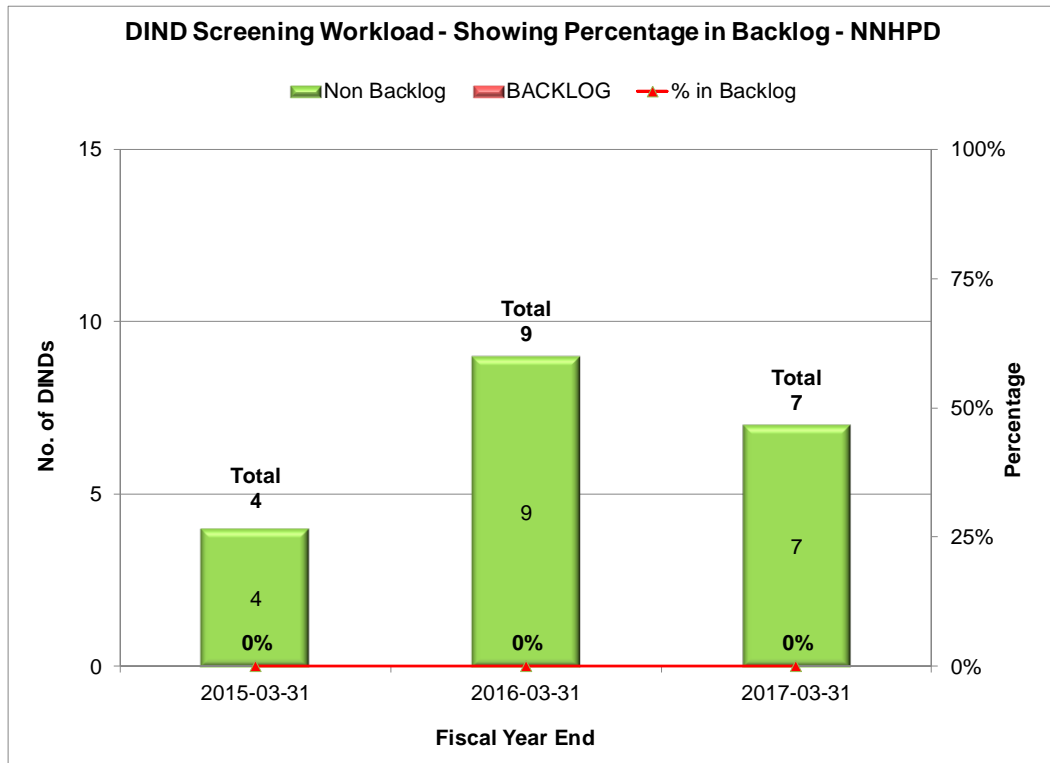


WORKLOAD

DIND: Review Workload Showing Percentage in Backlog

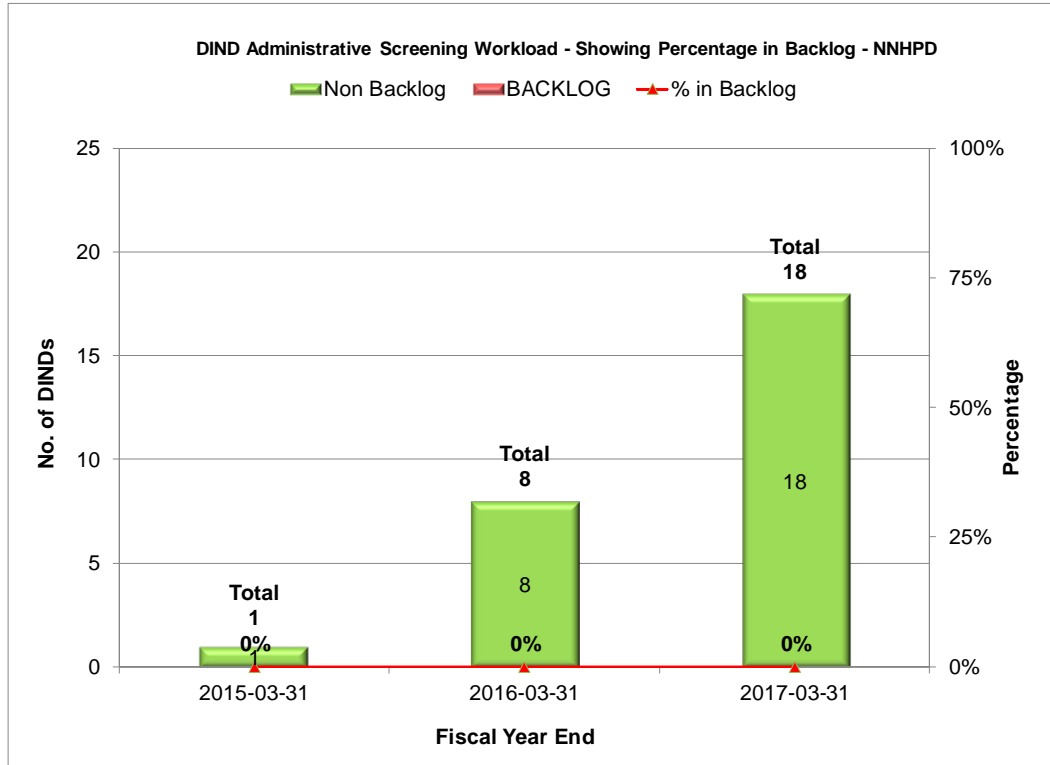


DIND: Screening Workload Showing Percentage in Backlog



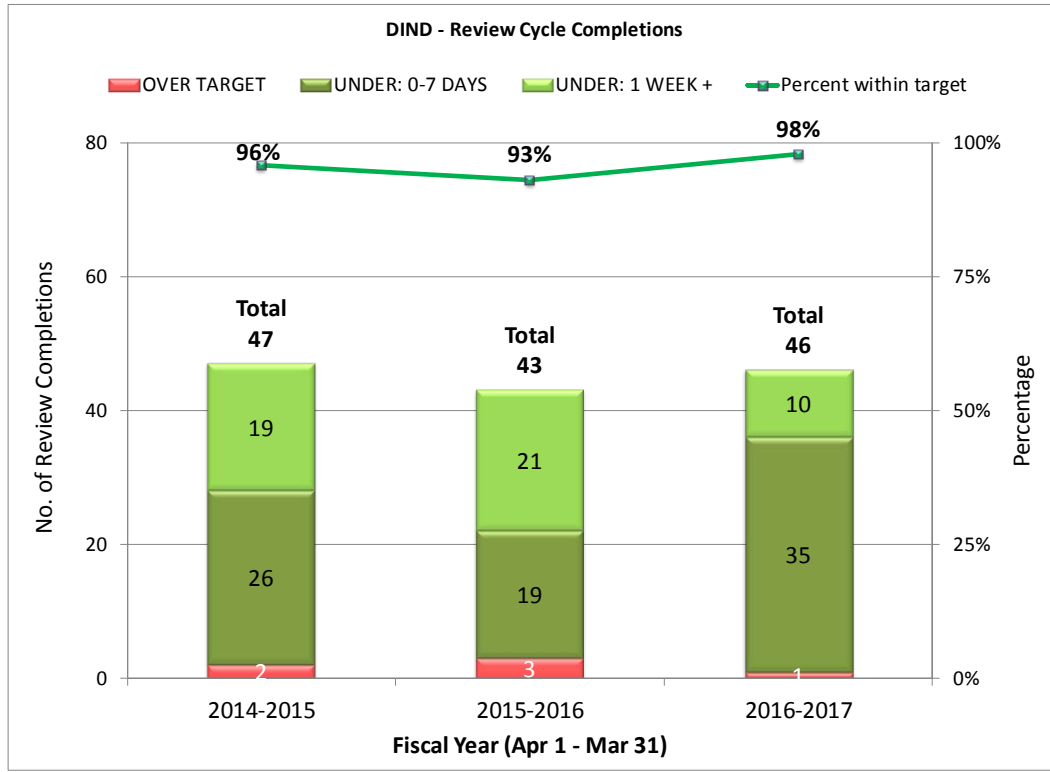
WORKLOAD

DIND: Administrative Screening Workload Showing Percentage in Backlog

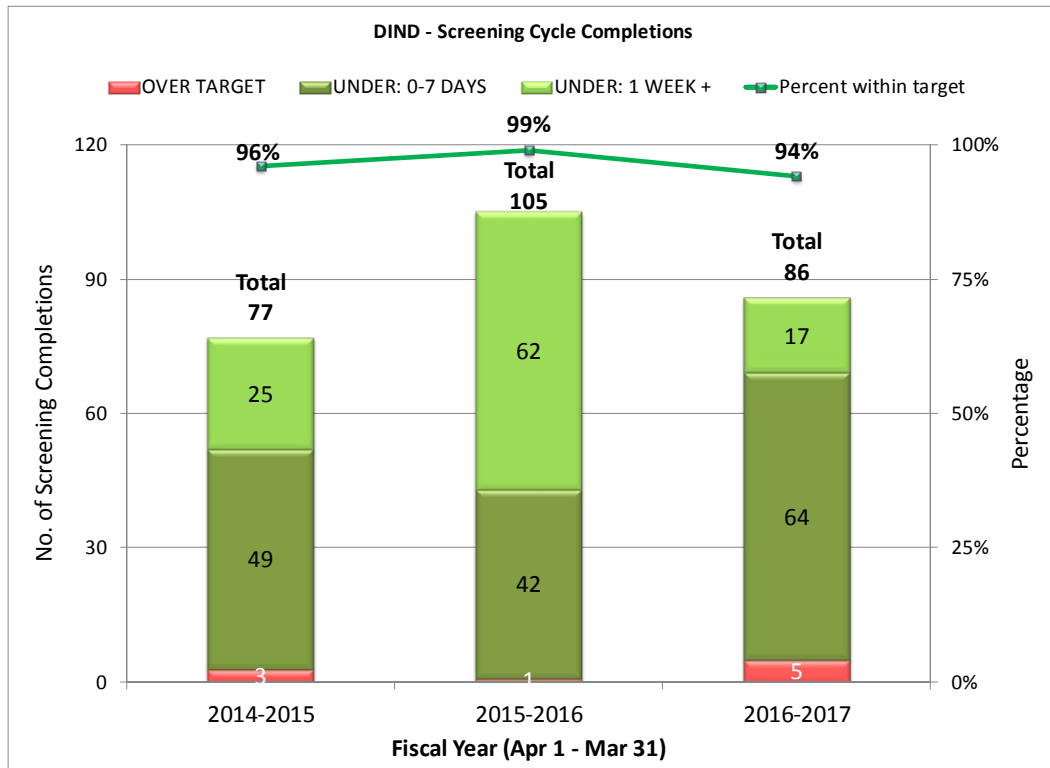


PERFORMANCE

DIND: Review Performance Showing Percentage within Target

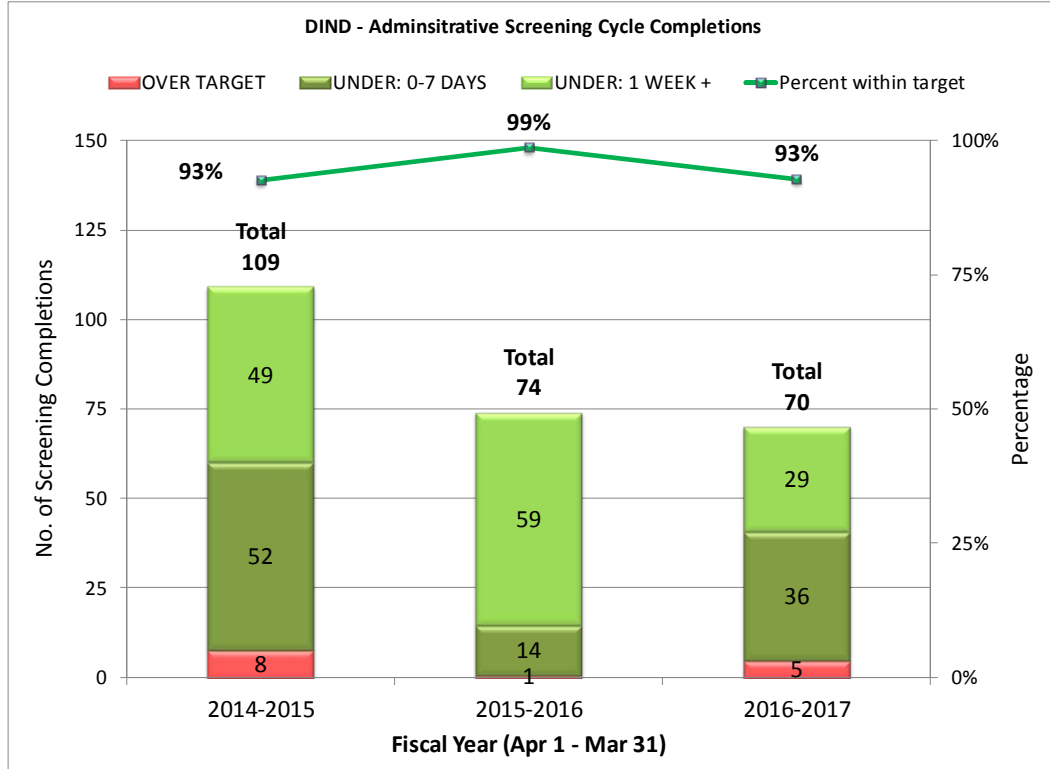


DIND: Screening Performance Showing Percentage within Target



PERFORMANCE

DIND: Administrative Screening Performance



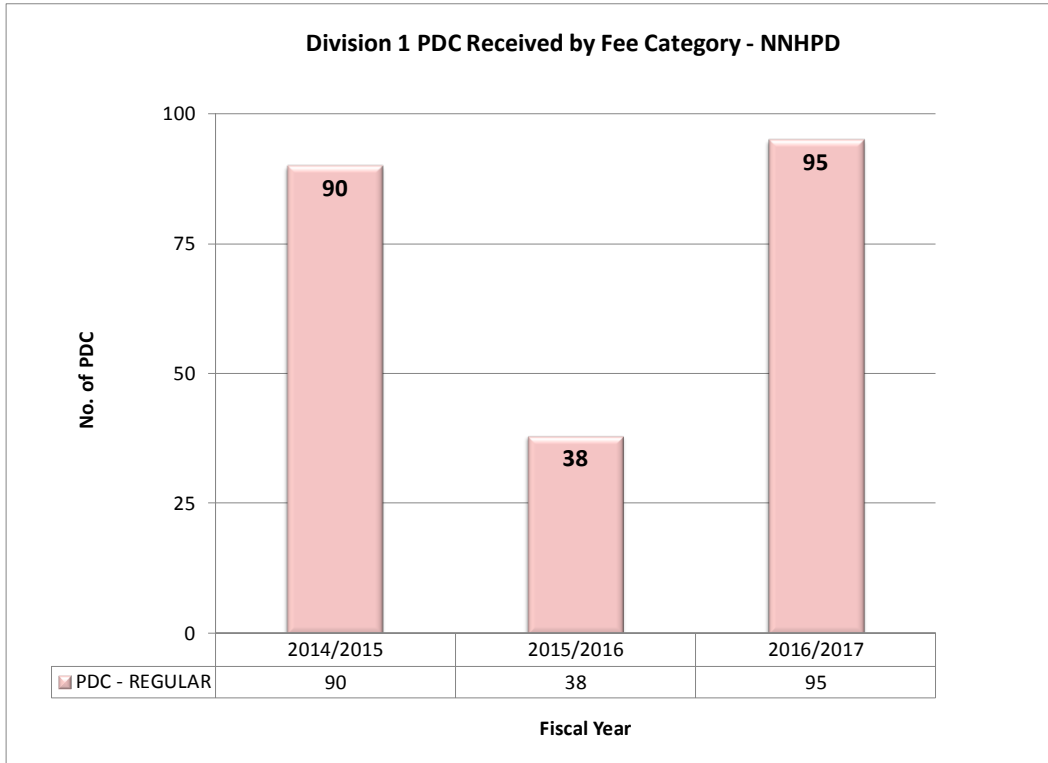
DECISION DOCUMENTS

DIND: Decisions by Fee Category

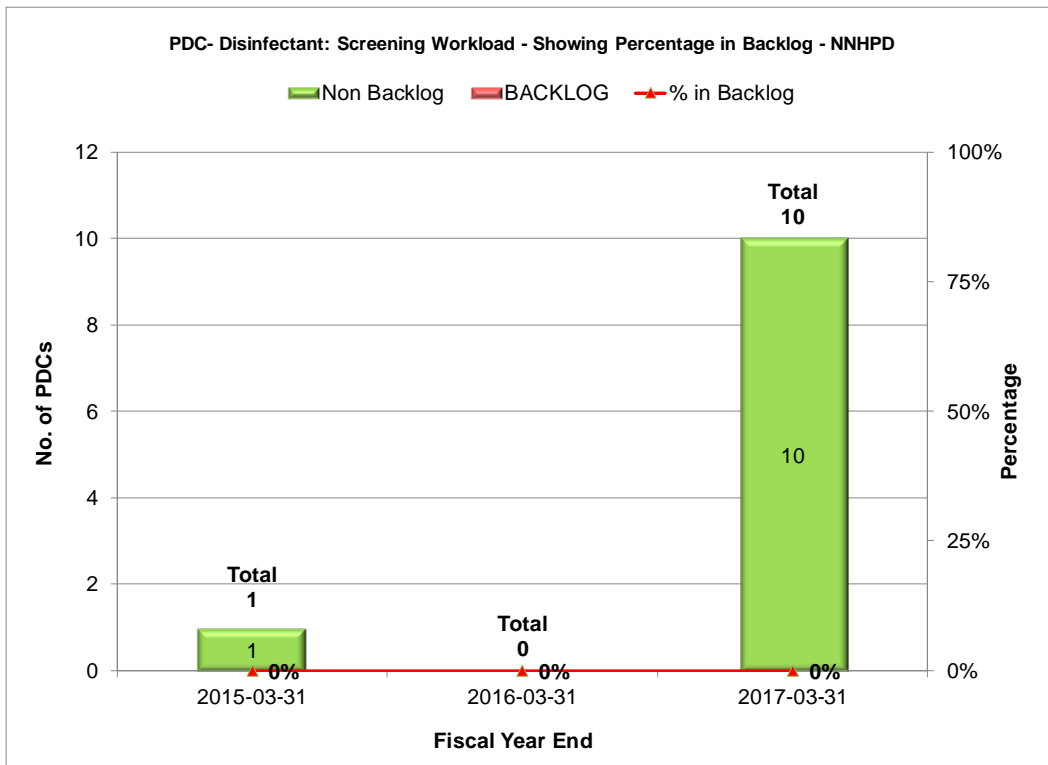
User Fee Category	Decision	2014/2015	2015/2016	2016/2017
ADMINISTRATIVE	CANCELLATION LETTER	2	3	1
	NO OBJECTION LETTER	1	0	3
	DIN INCORR SUBTYPE-CLASS	1	0	0
	NOTIFICATION FORM DIN SUB	90	54	43
	REJECTION LETTER (SCR)	3	9	9
	SCREENING DEFICIENCY NOTICE	14	11	18
DISINFECTANTS	DIN INCORR SUBTYPE-CLASS	2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

PDC: POST AUTHORIZATION DIVISION 1 CHANGE

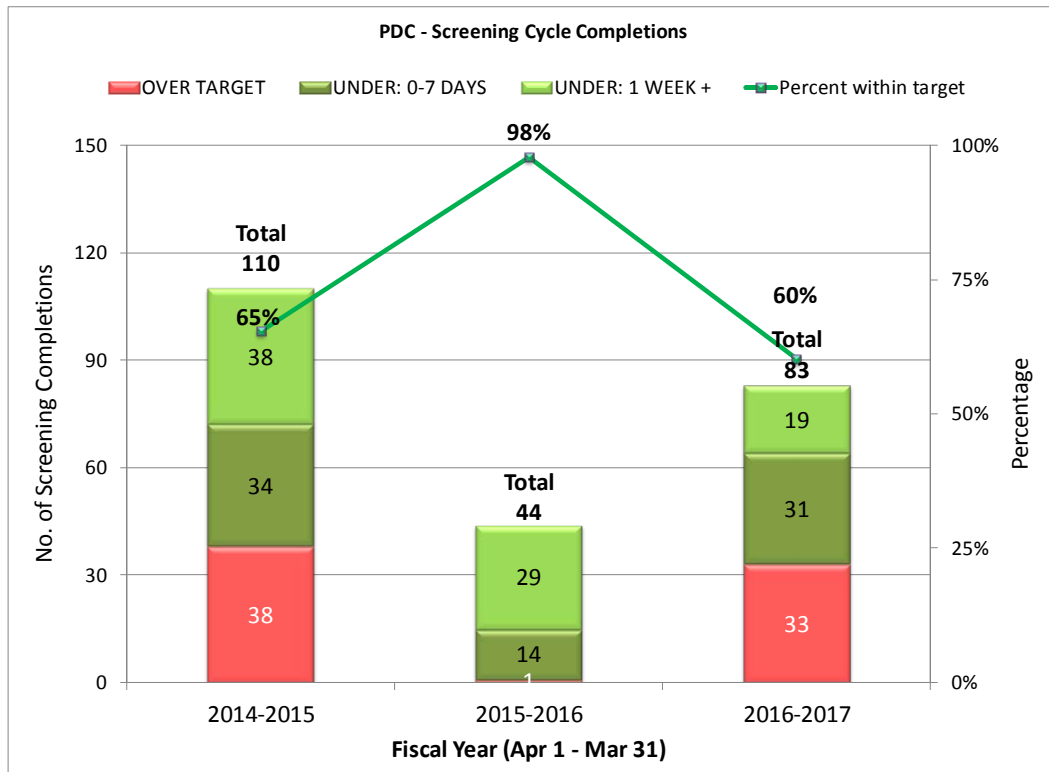
PDC: Received by Fee Category



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
REGULAR	CANCELLATION LETTER	2	1	1
	NO OBJECTION LETTER	83	37	41
	NOT SATISFACTORY NOTICE	24	3	38
	NOTIFICATION FORM DIN SUB	0	0	2
	REJECTION LETTER (SCR)	1	0	1

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
NDS-D: NEW DRUG SUBMISSION - DISINFECTANTS			
NDS-D DISINFECTANTS	1	1	4
NDS-D ADMINISTRATIVE SUBMISSION	0	0	1
<i>NDS-D Total</i>	<i>1</i>	<i>1</i>	<i>5</i>

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
NDS - Disinfectants	1	0	3
Backlog	0	0	0
Total Workload	1	0	3
Non Backlog	1	0	3
BACKLOG	0	0	0
% in Backlog	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
NDS - Disinfectants	0	0	2
Backlog	0	0	0
Total Workload	0	0	2
Non Backlog	0	0	2
BACKLOG	0	0	0
% in Backlog	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

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

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

DECISION DOCUMENTS

NDS- Disinfectant Drug: Decisions by Fee Category

User Fee Category	Decision	2014/2015	2015/2016	2016/2017
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	1
DISINFECTANTS	NOTICE OF NON-COMPLIANCE	3	0	0
	NOTICE OF COMPLIANCE*	3	1	0
	CANCELLATION LETTER	0	1	0
	SCREENING DEFICIENCY NOTICE	0	1	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 - USER FEE CATEGORY	2014/2015	2015/2016	2016/2017
NC: NOTIFIABLE CHANGE - NEW DRUG			
NC - SAFETY 90	4	0	0

WORKLOAD

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

REVIEW Workload Submission Type - Category	2015-03-31	2016-03-31	2017-03-31
NC - Safety-90	2	1	0
Backlog	0	0	0
Total Workload	2	1	0
Non Backlog	2	1	0
BACKLOG	0	0	0
% in Backlog	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
NC - Safety-90	3	0	0
Backlog	0	0	0
Total Workload	3	0	0
Non Backlog	3	0	0
BACKLOG	0	0	0
% in Backlog	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

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

DECISION DOCUMENTS

NC- Disinfectant Drug: Decisions

User Fee Category	Decision	2014/2015	2015/2016	2016/2017
SAFETY 90	NO OBJECTION LETTER	2	1	0
	CANCELLATION LETTER	1	0	0

MPNDS: PRE-NDS MEETING

MPNDS - Disinfectant Drug: Received by Fee Category

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

